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The AMWA Journal expresses the interests, concerns, and expertise of members. Its purpose is to inspire, motivate, inform, and educate them. The Journal furthers dialog among all members and communicates the purposes, goals, advantages, and benefits of the American Medical Writers Association as a professional organization.

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Ghostwriting Prevalence Among AMWA and EMWA Members (2005 to 2014)

By Cindy W. Hamilton, PharmD, ELS,a and Adam Jacobs, PhDb
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ABSTRACT
Introduction: Ghostwriting, defined as undisclosed substantial contributions by medical writers, is considered to be unethical by the American Medical Writers Association (AMWA), the European Medical Writers Association (EMWA), and other professional associations.

Methods: To determine the prevalence of ghostwriting among medical writers coincident with educational campaigns, we initiated a Web-based, self-administered, confidential survey of AMWA and EMWA members in 2005 and repeated it in 2008, 2011, and 2014. We focused on manuscripts to which survey participants had made substantial contributions and now report final findings from all surveys.

Results: The number of participants with valid data was 843 in 2005, 773 in 2008, 620 in 2011, and 410 in 2014. The mean weighted percentage of manuscripts with undisclosed contributions was 61.8% (95% confidence interval [CI], 59.0% to 64.6%) in 2005, 41.7% (95% CI, 38.6% to 44.7%) in 2008, 33.0% (95% CI, 29.7% to 36.3%) in 2011, and 34.4% (95% CI, 30.2% to 38.5%) in 2014. In univariate analyses, participants familiar with more authorship guidelines were less likely to have undisclosed contributions; regression coefficients ranged from -6.6% (95% CI, -8.5% to -4.8%) in 2005 to -10.6% in 2014 (95% CI, -13.1% to -8.0%; all P values <.001).

Conclusions: The 44% decrease in the rate of manuscripts with undisclosed contributions between 2005 and 2014 is encouraging, but the 34% rate of ghostwriting among medical writers remains unacceptable. While these findings should not be generalized to the overall prevalence of ghostwriting in the literature (because survey participation was restricted to AMWA and EMWA members who made substantial contributions to manuscripts), our findings suggest the need for further collaborative efforts to promote transparency and to conduct research about how to achieve best practices in medical publication.

“A lack of transparency results in distrust and a deep sense of insecurity.”
—Dalai Lama

Ghostwriting, defined as undisclosed substantial contributions by medical writers to manuscripts published in medical journals, has long been recognized as unethical. Without transparency, readers are denied the opportunity to judge the potential influence by groups with special interests and other conflicts. Allegations of bias and other transgressions have a domino-like effect and tarnish not only the reputations of medical communicators but also the entire profession of medical communication as well as their sponsors.

During the last 10 to 15 years, professional and trade organizations representing medical writers, journal editors, and the pharmaceutical industry have attempted to clarify and expand authorship guidelines, including how to distinguish the legitimate role of professional medical writers from that of ghostwriters. For example, the American Medical Writers Association (AMWA) adopted a position statement on the contributions of medical writers to scientific publications in 2002, and the European Medical Writers Association (EMWA) published more detailed guidelines in 2005. In 2005, the International Society of Medical Publication Professionals (ISMPP) was founded to enhance medical publication integrity and transparency and to improve standards and best practices. Recently, ISMPP supported the development and publication of the third version of the Good Publication Practice (GPP3) for communicating industry-sponsored research. The International Committee of Medical Journal Editors (ICMJE) increased the number of authorship criteria and made them more specific. The Pharmaceutical Research and Manufacturers of America (PhRMA) also

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updated their guidelines. These professional organizations now agree that medical writing assistance is acceptable provided that both substantial contributions to manuscripts and any potential conflicts of interest are disclosed.

Coincident with efforts to clarify guidelines, medical writing organizations launched campaigns to educate stakeholders about transparency and other best practices. For example, AMWA appointed a task force in 2001,14 which recommended a stepwise process beginning with publications and presentations to educate the medical community about the contributions of medical writers to scientific communications.15 To further improve awareness among members, AMWA subsequently developed new ethics workshops and, in 2010, began requiring an ethics workshop for completion of each AMWA certificate. EMWA and ISMPP also undertook educational campaigns.

Ghostwriting is presumed to be widespread, but a recent systematic review has shown that estimates have often been based on anecdotal evidence, statements taken out of context, and confusion about authorship criteria.16 Furthermore, the prevalence was unknown among medical writers in the early 2000s. To determine the prevalence of ghostwritten manuscripts among AMWA and EMWA members before, during, and after implementation of educational initiatives, we initiated a series of surveys in 2005. Our secondary objective was to determine the prevalence of medical writers’ requests for acknowledgment and variables associated with acknowledgment. The preliminary results from each survey have been previously presented, usually as conference posters or presentations.17-20 The purpose of this article is to report complete and final findings from all 4 surveys.

METHODS
The methods have been reported previously18 and are reproduced with modifications as needed to accommodate more recent surveys. A series of surveys was conducted over 3-week periods in October or November of 2005, 2008, 2011, and 2014, using an Internet survey tool (SurveyMonkey; www.surveymonkey.com). Survey methods were identical, apart from the addition of a single question from 2008 onward as described in the next paragraph. All AMWA and EMWA members were invited by email to participate in the survey; one or two email reminders were sent. No incentives were offered. To encourage participation, we promised that responses would be anonymous and the survey would take only 5 minutes to complete.

We developed the survey instrument by using repeated rounds of pilot testing among groups of medical writers. The 2005 survey instrument comprised 13 multiple-choice questions and 1 open-ended question about the practices and experiences of medical writers who make substantial contributions to manuscripts intended for submission to medical journals. (See the Appendix on page 11 for the survey questions.) Subsequent surveys were identical to the 2005 survey except for the addition of a question about the type of manuscript to which participants had made substantial contributions (question 11). Some questions allowed for internal validation of responses. For example, participants were considered to have invalid data if they indicated that 90% or 100% of manuscripts did not disclose their substantial contributions (question 3), that they always or usually requested acknowledgment when they made substantial contributions (question 7), and that this request was always or usually granted (question 8). In other words, contradictory responses to question 3 compared with questions 7 and 8 were considered to be invalid. Participants with invalid data were excluded from the analyses. If participants answered any parts of question 5 about familiarity with relevant guidelines but did not answer whether or not they were familiar with that guideline, then we assumed that they were not familiar with that guideline. Otherwise, missing data were ignored without attempt at imputation.

All statistical analyses were done using Stata version 8.2 or later (StataCorp, College Station, Texas). The primary analysis was calculation of mean percentage of manuscripts containing undisclosed contributions in the last year (question 3) weighted in proportion to the number of manuscripts to which participants had made substantial contributions and that were intended for submission to medical journals during an average year (question 2). The response category >20 manuscripts/year was assumed to be 25 manuscripts/year. The 95% confidence interval (95% CI) was calculated assuming that responses were normally distributed. An unweighted mean and 95% CI were also calculated similarly. The assumption behind the calculation of 95% CIs was checked by calculating bootstrap confidence intervals as a sensitivity analysis. Because there was good agreement between the normal distribution CIs and the bootstrap CIs, the bootstrap CIs are not presented here.
Secondary analyses were done to test the null hypothesis that familiarity with relevant guidelines (question 5) was not associated with frequency of undisclosed contributions. Linear regression analysis was used to test whether the percentage of undisclosed contributions was associated with the number of guidelines with which the participant was familiar (maximum 5, minimum 0).

Further exploratory analyses investigated the potential association between undisclosed contributions and other variables (i.e., number of manuscripts to which participants had made substantial contributions during an average year, familiarity with each of the 5 guidelines specifically, type or place of employment, number of years of experience in medical communication, and membership in professional organizations). These associations were investigated in an exploratory sense in both univariate and stepwise multivariate analyses, with thresholds of $P > .1$ for removing variables and $P < .05$ for re-entry.

Results were analyzed in an identical manner for all surveys, except that the proportion of review papers was included in the multivariate analyses as an extra independent variable in the 2008, 2011, and 2014 data. No formal statistical comparisons were made between surveys because this was not a pre-specified objective when the 2005 survey was planned.

RESULTS
The survey participation rate ranged from 28% (1537 participants/5463 email invitations) in 2005 to 8% (464/5664) in 2014, which suggests that both the percentage and number of survey participants decreased over time (Table 1). Participants represented a wide variety of types of employment, years of experience, and numbers of manuscripts—with no obvious changes over time (Table 2). In each survey year, the largest single employment category was freelance. Consistent with the relative sizes of the organizations, more participants were members of AMWA than EMWA. In 2014, 52 participants reported that they were not members of either organization and were excluded from further analysis.

<table>
<thead>
<tr>
<th>Participants</th>
<th>Number (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Invitations sent by email</td>
<td>N=5463</td>
</tr>
<tr>
<td>All participants</td>
<td>1537 (28)</td>
</tr>
<tr>
<td>Contributing participants</td>
<td>943 (17)</td>
</tr>
<tr>
<td>Participants with valid data</td>
<td>843 (15)</td>
</tr>
<tr>
<td>Member of AMWA or EMWA$^a$</td>
<td>843 (15)</td>
</tr>
</tbody>
</table>

$^a$Participants could be a member of both AMWA and EMWA.

The mean, weighted percentages of manuscripts with undisclosed contributions were 61.8% (95% CI, 59.0% to 64.6%) in 744 participants in 2005 and 34.4% (95% CI, 30.2% to 38.5%) in 354 participants in 2014, for an overall decrease of 44.3% (Figure 1). The mean, unweighted percentages of manuscripts with undisclosed contributions were 58.8% (95% CI, 55.8% to 61.8%) in 750 participants in 2005 and 26.4% (22.4% to 30.4%) in 355 participants in 2014.

Survey participants’ experience of and practice in requesting acknowledgment were generally consistent with trends in the percentages of manuscripts with undisclosed contributions (Table 3). For example, the percentage of participants who reported a decreased prevalence of ghostwriting was 39% (270/688) in 2005 and 64% (217/339) in 2014. The percentage of participants who requested disclosure of their contributions was 50% (370/747) in 2005 and 79% (282/357) in 2014. The percentage whose requests for disclosure were granted was 83% (304/365) in 2005 and remained high in 2014 (95% [267/281]). The percentage of participants who encouraged authors and other contributors to follow ICMJE guidelines was 55% (332/609) in 2005 and 81% (276/341) in 2014.

Reported familiarity with guidelines appeared to increase over time (Figure 2). For example, the percentage of participants who were familiar with ICMJE guidelines was 54% (399/735) in 2005 and 85% (304/356) in 2014.

In univariate analyses of data from each survey year, participants who were familiar with more guidelines were less likely to have undisclosed contributions. Specifically, the regression coefficients for the change in percentage of undisclosed contributions for familiarity with each additional guideline was -6.6% (95% CI, -8.5% to -4.8%) in 2005, -7.7% (95% CI, -9.6% to 5.8%) in 2008, -7.7% (95% CI, -9.5% to 5.8%) in 2011, and -10.6% in 2014 (95% CI, -13.1% to 8.0%; all $P$ values <.001; data not shown in tables). This means that writers made, on average, 10.6% fewer undisclosed contributions for each guideline with which they were familiar in 2014, and the interpretation of the regression coefficients is similar in other years.

In the stepwise multivariate analyses, ghostwriting or disclosures were associated with 8 variables in at least 2 survey years (Table 4). Ghostwriting was associated with making substantial contributions to more than 10 papers per year (relative to only 1 to 2 papers per year; $P < .05$ in 2005, 2011, and 2014) and to review-type articles (relative to original-research articles; $P < .05$ in 2008 and 2011). Similarly, ghostwriting was associated with being a freelance writer (relative to being...
Table 2. Characteristics of Participants With Valid Data Across Survey Years

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Number of Responses (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Employment</td>
<td>N=746</td>
</tr>
<tr>
<td>Self-employed or freelance</td>
<td>289 (39)</td>
</tr>
<tr>
<td>Pharmaceutical, biotech, or medical device company</td>
<td>208 (28)</td>
</tr>
<tr>
<td>Medical communication, medical education, or PR</td>
<td>112 (15)</td>
</tr>
<tr>
<td>Hospital, university, or medical school</td>
<td>77 (10)</td>
</tr>
<tr>
<td>Contract research organization</td>
<td>32 (4)</td>
</tr>
<tr>
<td>Other</td>
<td>28 (4)</td>
</tr>
<tr>
<td>Years of experience</td>
<td>N=737</td>
</tr>
<tr>
<td>0–2</td>
<td>85 (12)</td>
</tr>
<tr>
<td>3–5</td>
<td>158 (21)</td>
</tr>
<tr>
<td>6–10</td>
<td>208 (28)</td>
</tr>
<tr>
<td>11–15</td>
<td>106 (14)</td>
</tr>
<tr>
<td>16–20</td>
<td>71 (10)</td>
</tr>
<tr>
<td>&gt;20</td>
<td>109 (15)</td>
</tr>
<tr>
<td>Number of manuscripts in an average year</td>
<td>N=776</td>
</tr>
<tr>
<td>1–2</td>
<td>169 (22)</td>
</tr>
<tr>
<td>3–5</td>
<td>275 (35)</td>
</tr>
<tr>
<td>6–10</td>
<td>184 (24)</td>
</tr>
<tr>
<td>&gt;10</td>
<td>148 (19)</td>
</tr>
<tr>
<td>Membership</td>
<td>N=736</td>
</tr>
<tr>
<td>AMWA</td>
<td>631 (86)</td>
</tr>
<tr>
<td>EMWA</td>
<td>127 (17)</td>
</tr>
</tbody>
</table>

PR, public relations.

Figure 1. Prevalence of ghostwriting across survey years. Error bars represent 95% CIs.

Figure 2. Increased familiarity with guidelines across survey years. "Survey question: “Are you familiar with the content of the following guidelines? Check all that apply.”
GPP, Good Publication Practice; ICMJE, International Committee of Medical Journal Editors.
<table>
<thead>
<tr>
<th>Type of experience or practice</th>
<th>2005</th>
<th>2008</th>
<th>2011</th>
<th>2014</th>
</tr>
</thead>
<tbody>
<tr>
<td>Perceived change in prevalence of ghostwriting in last 5 years</td>
<td>N=688</td>
<td>N=651</td>
<td>N=526</td>
<td>N=339</td>
</tr>
<tr>
<td>Decreased to none</td>
<td>20 (3)</td>
<td>72 (11)</td>
<td>95 (18)</td>
<td>51 (15)</td>
</tr>
<tr>
<td>Decreased but still occurs</td>
<td>250 (36)</td>
<td>340 (52)</td>
<td>275 (52)</td>
<td>166 (49)</td>
</tr>
<tr>
<td>No change</td>
<td>360 (52)</td>
<td>198 (30)</td>
<td>137 (26)</td>
<td>107 (32)</td>
</tr>
<tr>
<td>Increased</td>
<td>58 (8)</td>
<td>41 (6)</td>
<td>19 (4)</td>
<td>15 (4)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Request acknowledgment</th>
<th>N = 747</th>
<th>N = 665</th>
<th>N = 533</th>
<th>N = 357</th>
</tr>
</thead>
<tbody>
<tr>
<td>Always</td>
<td>187 (25)</td>
<td>288 (43)</td>
<td>309 (58)</td>
<td>205 (57)</td>
</tr>
<tr>
<td>Usually</td>
<td>183 (24)</td>
<td>168 (25)</td>
<td>118 (22)</td>
<td>77 (22)</td>
</tr>
<tr>
<td>Rarely or never, but I am not opposed</td>
<td>354 (47)</td>
<td>194 (29)</td>
<td>99 (19)</td>
<td>73 (20)</td>
</tr>
<tr>
<td>Rarely or never because I am opposed</td>
<td>23 (3)</td>
<td>15 (2)</td>
<td>7 (1)</td>
<td>2 (1)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Requests for acknowledgment granted</th>
<th>N = 365</th>
<th>N = 466</th>
<th>N = 424</th>
<th>N = 281</th>
</tr>
</thead>
<tbody>
<tr>
<td>Always</td>
<td>127 (35)</td>
<td>224 (48)</td>
<td>257 (61)</td>
<td>173 (62)</td>
</tr>
<tr>
<td>Usually</td>
<td>177 (48)</td>
<td>185 (40)</td>
<td>142 (34)</td>
<td>94 (33)</td>
</tr>
<tr>
<td>Rarely or never</td>
<td>61 (17)</td>
<td>57 (12)</td>
<td>25 (6)</td>
<td>14 (5)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Encourage others to follow ICMJE guidelines</th>
<th>N = 609</th>
<th>N = 598</th>
<th>N = 495</th>
<th>N = 341</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes</td>
<td>332 (55)</td>
<td>426 (71)</td>
<td>401 (81)</td>
<td>276 (81)</td>
</tr>
<tr>
<td>No</td>
<td>277 (45)</td>
<td>172 (29)</td>
<td>94 (19)</td>
<td>65 (19)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>&gt;10 papers/year</td>
<td>11.4 (2.2 to 20.5)</td>
<td>9.6 (-0.6 to 19.7)</td>
<td>26.2 (16.4 to 36.1)</td>
<td>23.9 (10.5 to 37.2)</td>
</tr>
<tr>
<td>Mostly reviews</td>
<td>Not included</td>
<td>14.1 (5.0 to 23.1)</td>
<td>12.0 (2.2 to 21.8)</td>
<td>Not included</td>
</tr>
<tr>
<td>Freelance</td>
<td>27.8 (17.6 to 38.0)</td>
<td>14.9 (3.2 to 26.6)</td>
<td>5.3 (-4.3 to 15.0)</td>
<td>10.0 (-1.7 to 21.7)</td>
</tr>
<tr>
<td>Familiarity with the following guideline</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>AMWA</td>
<td>Not included</td>
<td>NA</td>
<td>-8.8 (-16.0 to -1.6)</td>
<td>-8.7 (-16.9 to -0.5)</td>
</tr>
<tr>
<td>EMWA</td>
<td>-8.2 (-15.0 to -1.4)</td>
<td>-6.5 (-13.4 to 0.4)</td>
<td>-7.5 (-13.6 to -1.5)</td>
<td>Not included</td>
</tr>
<tr>
<td>GPP</td>
<td>Not included</td>
<td>NA</td>
<td>-14.0 (-21.6 to -6.4)</td>
<td>-18.4 (-27.2 to -9.6)</td>
</tr>
<tr>
<td>ICMJE</td>
<td>-14.0 (-20.4 to -7.6)</td>
<td>-17.1 (-24.7 to -9.5)</td>
<td>-15.7 (-23.6 to -7.9)</td>
<td>-20.5 (-31.5 to -9.4)</td>
</tr>
<tr>
<td>PhRMA</td>
<td>-7.3 (-14.4 to -0.1)</td>
<td>Not included</td>
<td>-15.4 (-21.8 to -9.0)</td>
<td>Not included</td>
</tr>
</tbody>
</table>

NA, not applicable; PE, probability estimate (expressed as percentages), where positive values indicate the variable is associated with ghostwriting and negative values indicate the variable is associated with disclosure.

Table 3. Experience of and Practice in Requesting Acknowledgment

Table 4. Stepwise Multivariate Linear Regression Analysis

NA, not applicable; PE, probability estimate (expressed as percentages), where positive values indicate the variable is associated with ghostwriting and negative values indicate the variable is associated with disclosure.

aP<.05 in at least 2 surveys.

bRelative to 1 to 2 papers/year.

cRelative to contributions to manuscripts conveying original data; this question was not included in the 2005 survey.

dNot included in multivariate analysis usually because not significant (P>.1) in univariate analysis (see footnote c).

eEmployment type with hospital, university, or medical school as the reference value.
employing a hospital, university, or medical school; \( P \leq .01 \) in 2005 and 2008). Disclosure was associated with familiarity with guidelines from AMWA, EMWA, GPP, ICMJE, and PhRMA. Of these, ICMJE was significant in all 4 survey years (\( P < .001 \)), with probability estimates ranging from -14.0% (95% CI, -20.4% to -7.6%) in 2005 to -20.5% (95% CI, -31.5% to -9.4%) in 2014.

**DISCUSSION**

Our survey findings provide unique insights into the prevalence of ghostwriting among medical writers during the last decade. The mean, weighted percentage of manuscripts with undisclosed contributions was 62% in 2005, fell sequentially in the next 2 surveys to a low of 33% in 2011, and persisted at 34% in 2014. While the rate remained unacceptably high in 2014 and failed to sustain the improvement seen in the first 3 surveys, the overall decrease was 44% between the first and last surveys. This drop is noteworthy, particularly when combined with the results of regression analyses. There were strong correlations between disclosures and familiarity with guidelines in both univariate and stepwise multivariate analyses, some of which persisted throughout the 4 surveys. For example, disclosure was associated with familiarity with ICMJE guidelines, with regression coefficients suggesting that participants familiar with ICMJE guidelines had 14% to 21% fewer undisclosed contributions compared with those who were not familiar with these guidelines. Decreases in the rates of undisclosed contributions between 2005 and 2008 and again between 2008 and 2011 coincided with international efforts to clarify publication guidelines\(^5,6,8-11,15,21\) and increase awareness of them.\(^14,15,22\)

The high level of guideline awareness in our 2014 survey is consistent with that in other recently reported surveys.\(^23,24\) For example, the Medical Publishing Insights and Practices Initiative (MPIP) evaluated familiarity with and reliance on authorship guidelines among 4 stakeholder groups.\(^23\) Nearly 500 people, with good representation in each group, participated in the online survey. Most medical writers (88%), publication professionals (97%), and journal editors (89%) were aware of ICMJE authorship criteria; however, only 49% of clinical investigators were familiar with these guidelines. Also, medical writers (51%), publication professionals (70%), and journal editors (59%) were more likely to rely on these guidelines than clinical investigators (28%).\(^23\) Like MPIP, the Global Publication Survey studied current practices and implementation of publication guidelines among nearly 500 stakeholders,\(^24\) especially employees at medical communication agencies (51%) and at pharmaceutical or device companies (30%). Again, the majority of both agency and industry participants routinely referred to ICMJE for guidance on ethical practice (93%).\(^24\) In 2014, 85% of our survey participants were familiar with ICMJE guidelines. Also in our 2014 survey, 79% of participants requested disclosure of their contributions and 95% reported that their requests for disclosure were granted.

It is intriguing that writers who contributed to larger numbers of manuscripts were more likely to have undisclosed contributions than less prolific writers. This explains why the weighted proportion of undisclosed contributions was slightly higher than the unweighted proportion, as participants’ responses were weighted in proportion to the number of manuscripts. It is possible that some contributions made by prolific writers were not substantial and, for example, were limited to copy editing. As such, those contributions may have been less deserving of acknowledgement than more substantial contributions and perhaps may not have met the traditional definition of ghostwriting. Substantial contribution, however, is undefined in most guidelines, so interpretation can often be a gray area. Alternatively, contributing to larger numbers of manuscripts may indeed be correlated with ghostwriting.

While our survey findings do not prove cause and effect, the evidence can be used to generate hypotheses that merit further evaluation and that might have practical implications. For example, a recent survey\(^25\) indicates that the Certified Medical Publication Professional (CMPP) credential is a surrogate marker for broader and more current knowledge of medical publication guidelines. This is not surprising because medical writers would be expected to be aware of guidelines if they had invested in the certification examination, achieved a passing score, and maintained the credential. If future research confirms that certification and other variables are associated with transparency and other types of ethical behavior, then employers, contractors, and authors could use these findings to enhance their criteria for selecting medical writers. In addition, these findings may inspire companies to encourage or even require their writers to take advantage of educational opportunities and to audit freelance writers for awareness of and compliance with best practices.\(^26\)
Our findings have additional implications for different stakeholders. Professional organizations should escalate their efforts to educate members about the dangers of ghostwriting and other unethical practices that can damage the entire profession and can embroil authors and funders in controversy and potential legal action. Members should commit to lifelong learning practices as guidelines are likely to continue evolving. Medical writers who refuse to ghostwrite can take heart in knowing that their requests for acknowledgment are likely to be granted.

Our findings should not be generalized to the overall prevalence of ghostwriting in the medical literature because survey participation was restricted to AMWA and EMWA members who had made substantial contributions to manuscripts. Although the proportion of this subset to the overall prevalence is unknown, we can make an estimate based on another survey in which medical writing assistance was declared in 6% of publications in 1000 high-ranking journals. If we assume that medical writers do not disclose one-third of their contributions and that the ratio of undisclosed to disclosed contributions is therefore 1:2, then the combined findings from our survey and the previous survey suggest an overall ghostwriting prevalence of approximately 3% (9% – 6%). This estimate, however, should be interpreted with caution because it is based on data from different sources. On the other hand, this estimate is closer to that reported in previous, well-designed, serial surveys in different fields. The prevalence was 1.4% in 1996 and 0.16% in 2008.

Our survey has additional limitations. The most important limitation is the potential for selection bias of both participants (eg, self-selection) and their survey responses. Although respectable for an email survey without incentives, our response rate was low enough that participants might not be representative of all AMWA and EMWA members, who in turn might not be representative of all medical writers. The low response rate is partly attributable to the previously mentioned restriction to a subset of AMWA and EMWA members. The proportion of AMWA and EMWA members who make substantial contributions to manuscripts is unknown; however, 26.8% (108/403) of AMWA members reported that their primary area of work was scientific publications in a recent survey (data on file). If this proportion is generalizable to EMWA and is extrapolated to the entire sample, then 1518 medical communicators (5664 × 26.8%) were eligible for our survey in 2014. This estimate suggests a participation rate of 28.8% (437/1518 × 100%), which is better than the rate derived from the entire membership of AMWA and EMWA (see Table 1). The large decrease between 2005 and 2008 is probably due to clarification of the survey invitation to better define target participants. We cannot explain further decreases in response rates in 2011 and 2014. The number of participants probably would have been higher if ISMPP members had been invited, but our first survey preceded that organization. To maintain consistency and allow for comparison across survey years, we did not invite ISMPP to participate in subsequent surveys. As the survey was anonymous, we do not know how many respondents in more recent surveys had also participated in previous surveys. Therefore, it is not possible to know whether the observed decrease in ghostwriting represents individual writers changing their practices, a new cohort of writers who are less likely to make undisclosed contributions than writers working in earlier years, or a combination of both.

Another limitation is that data were self-reported and based on recall. As such, participants familiar with ethical guidelines may have been tempted to answer survey questions in ways suggesting ethical practices, or participants may have forgotten times when they did not observe ethical practices. It is possible that AMWA and EMWA members are more likely to follow guidelines than medical writers who are not members of these organizations and that those who devote time to survey participation are also more likely to devote time to learning ethical guidelines and complying with them. These hypotheses suggest that our results might underestimate the prevalence of ghostwriting.

Another limitation is the deliberate avoidance of the word “ghostwriting,” which was excluded from the survey invitation to prevent entrapment by email security filters. Another reason for avoiding this word was an attempt to prevent confusion because the term is frequently misunderstood and potentially ambiguous. Unfortunately, these efforts necessitated the use of lengthy, often awkward wording, which might have led to unintended answers to survey questions about the prevalence of ghostwriting. At the same time, our survey included questions designed to identify inconsistent responses; fewer than 2% of participants were eliminated because of invalid responses.

CONCLUSIONS
Our survey findings are bittersweet. The 44% decrease in the rate of manuscripts with undisclosed contributions between 2005 and 2014 is encouraging, but the 34% rate of ghostwriting remains unacceptably high. Furthermore, the failure to sustain the improvement seen in the first 3 surveys is not only disappointing but also perplexing. Clearly, there is no room for complacency. We challenge our medical writer colleagues and professional organizations to intensify collaborative efforts to promote transparency and to conduct research about how to achieve best practices in medical publication.
AUTHORS’ COMMENTARY

These survey findings suggest that the prevalence of ghostwriting remains unacceptable despite extensive efforts by AMWA, EMWA, and other organizations to educate medical authors about ethical practices. We challenge you to view these survey findings as a call to action. The strong correlations between guideline awareness and ethical practices suggest the need for renewed and expanded educational campaigns. Become an advocate of integrity by educating others about best practices in medical publication. Do it for the health care community and your profession. Do it for yourself. Do it today.

—Cindy W. Hamilton and Adam Jacobs

Author declarations and disclosures: Both authors declare that we: 1) have provided or do provide ethical medical writing services to academic, biotechnology, or pharmaceutical clients; 2) have no financial relationships that may be relevant to the submitted work; and 3) are active in national and international not-for-profit associations that encourage ethical medical writing practices. No external sponsors were involved in the preparation of this manuscript, and no external funding was used.

Author contact: cindy@hamiltonhouse.va.com

References
20. Hamilton C, Peña T, Platt M, Gertel A. Transforming perceptions of medical writers from coal to diamonds—if Superman can do it, so can we! (open session 24). American Medical Writers Association Annual Conference. San Antonio, TX; 2015.
Appendix. Survey Instrument

1. Do you contribute substantially to the writing or editing of manuscripts prepared on behalf of authors and intended for submission to medical journals?
   - yes
   - no

2. During an average year, to how many manuscripts intended for submission to medical journals do you make substantial contributions? ____ (1, 2, 3 0. 0. >20)

3. In the last year, what percentage of manuscripts submitted for publication did not contain disclosure of your substantial contribution as a medical writer or editor, either in a byline, as an author, or in an acknowledgment? ____% (0% – 100%, increments of 10)

4. In your experience, how has the frequency of undisclosed substantial contributions changed during the last 5 years?
   - decreased to none
   - decreased but still occurs
   - no change
   - increased

5. Are you familiar with the content of the following guidelines?
   - yes
   - no

   American Medical Writers Association’s (AMWA’s) Position Statement (www.amwa.org)
   - yes
   - no

   European Medical Writers Association’s (EMWA’s) Guidelines (www.emwa.org/Mum/EMWAguidelines.pdf)
   - yes
   - no

   Good Publication Practice (GPP) for Pharmaceutical Companies (http://www.gpp-guidelines.org/)
   - yes
   - no

   ICMJE Uniform Requirements (www.icmje.org)
   - yes
   - no

   - yes
   - no

6. Do you encourage authors and other contributors to follow these guidelines?
   - AMWA’s Position Statement
     - yes
     - no

   - EMWA’s Guidelines
     - yes
     - no

   - GPP for Pharmaceutical Companies
     - yes
     - no

   - ICMJE’s Uniform Requirements
     - yes
     - no

   - PhRMA’s Guidelines
     - yes
     - no

7. Do you request acknowledgment when you make substantial contributions to manuscripts submitted to medical journals?
   - always
   - usually
   - rarely or never, but I am not opposed to the practice
   - rarely or never, because I am opposed to the practice

8. How often is your request granted for acknowledgment of your substantial contributions to manuscripts submitted to medical journals?
   - always
   - usually
   - rarely or never

9. Do you disclose your pertinent professional or financial relationships (eg, receipt of funding from a manufacturer or other organization associated with the product mentioned in the manuscript) when you are acknowledged for substantial contributions to manuscripts submitted to medical journals?
   - always
   - usually
   - rarely or never

10. How often is your request granted for disclosure of your professional or financial relationships?
    - always
    - usually
    - rarely or never

11. During an average year, how many of your manuscripts convey original data?
    - Most manuscripts convey original data.
    - Most manuscripts are review-like articles.
    - Manuscripts are approximately evenly divided between original data and review-like articles.

12. By what kind of organization are you employed? (Select only one.)
    - medical communication, medical education, or public relations company
    - contract research organization (CRO)
    - hospital, university, or medical school
    - journal office or publisher
    - pharmaceutical, biotech, or medical device company
    - professional society or association
    - self-employed or freelance
    - other ______________________

13. How many years have you been employed in medical communication? (Insert the number of years as a whole numeric value, not as a fraction or decimal.) ____ years

14. To which organizations do you belong? (Check all that apply.)
    - American Medical Writers Association (AMWA)
    - Board of Editors in the Life Sciences (BELS)
    - Council of Science Editors (CSE)
    - Drug Information Association (DIA)
    - European Medical Writers Association (EMWA)
    - International Society for Medical Publication Professionals (ISMPP)
    - National Association of Science Writers (NASW)
    - Other (please specify) ______________________

15. Please use the space below to add comments and to elaborate on any of your answers to this questionnaire.

   *Question 11 was added in 2008 (ie, not included in the 2005 survey).*
The term “meta-analysis” was first coined by Gene Glass in 1976. While admitting the term was “a bit grand,” Glass emphasized its precision and appropriateness. He defined meta-analysis as a “statistical analysis of a large collection of analytic results from individual studies for the purpose of integrating the findings.”

With the increasing number of studies in all scientific fields, the need to synthesize results has assumed growing importance. Accordingly, the number of meta-analyses has risen at a phenomenal rate. A PubMed search for the word meta-analysis in the title or abstract yielded 1 article for 1977, 952 for 2000, and 12,965 for 2014. The results of meta-analyses play an important role in modern-day health care. They are used by providers to aid decision-making for individual patients, organizations to direct health care policies, and researchers to identify areas requiring future study.

As with all publications, the usefulness of meta-analyses depends largely on the manner in which they are conducted. Minimizing bias when selecting the studies to include and performing appropriate statistical analyses are key ways to enhance the validity of meta-analyses. Equally important is the manner in which the methods and results of meta-analyses are reported, as only by accurate, clear, and transparent reporting can one properly assess the validity of the methodology, results, and conclusions.

To improve the quality of reporting meta-analyses, the Preferred Reporting Items for Systematic Reviews and Meta-analyses (PRISMA) statement was published in 2009. This internationally accepted statement includes a list of 27 items considered necessary for accurate and transparent reporting, plus a recommended flow diagram outlining the process of selecting the included studies. These guidelines address many of the potential limitations of meta-analyses. Although the PRISMA statement is internationally accepted, not all journal editors require meta-analysis authors to follow its guidelines. A review of 60 journals from 6 major medical specialties conducted in November 2014 found that only 57% of journals required or recommended following the guidelines. Likewise, recent meta-analyses do not fully follow the PRISMA guidelines. In a review of 44 meta-analyses published in November 2014, a median of 57.7% of PRISMA checklist items were reported adequately and 29.6% were reported, but inadequately. A PRISMA-like flow diagram was present in 93.2% of meta-analyses. The median percentage of PRISMA items reported adequately was higher for meta-analyses published in journals that required or recommended following the guidelines (63.0%) than for meta-analyses published in journals that did not (55.6%) (P < .02). It was also higher for meta-analyses in which the authors indicated following the guidelines (59.3%) than for meta-analyses in which the authors did not state this (55.6%) (P < .05). Further efforts are required to promote more widespread use of the PRISMA guidelines and adequate reporting of all checklist items.

This article discusses the characteristics, merits, and limitations of meta-analyses, as well as the origin and content of the PRISMA statement. It explains how the statement addresses many limitations of meta-analyses and presents...
original data showing whether or not medical journals currently require authors to follow the PRISMA guidelines, as well as the extent to which recent meta-analyses follow these guidelines. It is imperative that biomedical writers who write or edit meta-analyses understand the role of the PRISMA guidelines in improving the quality of reporting in these articles. It is likewise important that all biomedical writers appreciate the function of the guidelines in helping to evaluate whether a published meta-analysis is a valid information source.

**META-ANALYSIS DEFINED**

On the basis of Glass’ original definition,1 meta-analyses are most simply defined as statistical analyses of the combined results of more than 1 study. Of note, this definition does not specify the characteristics of the studies; they can be of any form (eg, randomized controlled trials [RCTs], observational cohort studies), size, quality, number, or publication status. It also does not specify the method of study selection. Thus, a meta-analysis could involve combining data from any 2 studies.

Most commonly, a meta-analysis involves the analysis of data obtained from studies contained within a systematic review. The Cochrane Collaboration, an international network of researchers who collect and summarize health research evidence, defines meta-analysis as “the use of statistical techniques in a systematic review to integrate the results of included studies.” It defines a systematic review as “a review of a clearly formulated question that uses systematic and explicit methods to identify, select, and critically appraise relevant research, and to collect and analyze data from the studies that are included in the review.”

In general usage, the term meta-analysis often refers to more than just a set of statistical techniques. It is frequently used to indicate a specific type of publication that encompasses these techniques. In this article, meta-analysis is used in this more general sense to refer to a systematic review that includes a meta-analysis of data.

**MERITS OF META-ANALYSES**

Meta-analyses reduce large quantities of information to a manageable size and allow conclusions to be generated when single trials have insufficient power because of their small size.5 Meta-analyses are considerably less expensive and faster to perform than RCTs. They are particularly useful when an RCT would be difficult or impossible, such as when an RCT would be unethical or when a condition is so uncommon that it would be difficult to recruit a sufficient number of participants.

By accumulating the results of a number of studies in a single location, meta-analyses allow one to observe the overall consistency of results across different studies. Meta-analyses typically provide a table showing the results of individual studies, including estimates of the size of the observed effect and confidence intervals for each estimate. Generally, this is combined with a visual representation of the results known as a forest plot. The degree of consistency of the results from various studies is generally quantified by such tests as the $I^2$, Tau, or Cochran’s Q tests, which generate a single value. In general, as the consistency decreases, the validity of the meta-analysis results decreases. If substantial inconsistency (also known as statistical heterogeneity) is detected, the results of individual studies should be reviewed to look for patterns that may explain the differences. If, for example, a specific group(s) appears to exhibit different results, then subgroup analysis may be performed to confirm this.

**LIMITATIONS OF META-ANALYSES**

Unlike RCTs, meta-analyses cannot provide direct evidence of causality. Instead, meta-analyses are observational studies, and the specific studies included in a meta-analysis and the methods used to combine and analyze their data have a major impact on the final results. As such, meta-analyses are most appropriately used to support the findings of other studies, generate hypotheses, and/or help design future RCTs.

Bias can be introduced in various ways when selecting studies. In general, the more limited the selection process, the higher the likelihood of bias, as potentially relevant articles may not be retrieved. For example, limiting the studies to those written in certain language(s) is convenient but may overlook important studies. Including only English-language articles is common, the impact of which likely varies from topic to topic.9 A study of 18 meta-analyses reported that the effect size when only English-language studies were analyzed was only 2% higher than when studies in other languages were included.10 By contrast, using a single database (eg, MEDLINE) or search portal (eg, PubMed) can have a major impact on the results of a meta-analysis, as the articles retrieved through different databases and search portals vary considerably. This is in large part because of differences in the journals queried in the searches: for example, approximately one-third of journals indexed in MEDLINE are not indexed in EMBASE, and vice versa.11 Including only studies published in peer-reviewed journals is likewise problematic. Studies with positive results tend to be preferentially published in medical journals, thereby introducing the possibility of publication bias.4 The possibility of this type of bias is often estimated by constructing a funnel plot, which is a scatterplot of the effect sizes reported in the studies included in the meta-analysis. The impact of publication bias may be reduced, albeit not eliminated, by including additional sources of data, such as unpublished studies, conference abstracts, and other forms of “gray literature.”9 The meta-analysis funding source may also introduce bias.
Bias within the included studies is another potential limitation of meta-analyses. The quality of studies, including the degree of potential bias, has a major influence on the validity of meta-analysis results. No matter how well a meta-analysis is otherwise conducted, the adage "garbage in, garbage out" applies. Meta-analyses generally use such methods as the Jadad scoring system or Cochrane Collaboration’s domain-based tool to assess the risk of within-study bias. Eliminating poor quality studies or performing separate analyses for high- and low-quality studies can improve the validity of the meta-analysis results.

Furthermore, the size of the included studies can influence meta-analysis results, as large trials may exert an excessive effect when combining data from various studies. Inspecting a forest plot facilitates detection of this possibility, as the plot depicts the size as well as the results of the studies. Sensitivity analyses can confirm whether a large trial has an undue influence on the results by determining whether the results differ when re-analyzed after the large trial is excluded.

Another potential limitation of meta-analyses involves the process of deciding which studies exhibit enough similarity to justify pooling their results for a combined statistical analysis. This decision is somewhat subjective, is frequently difficult, and requires a solid understanding of the topic as well as research methodology. Differences in study populations or methods are often referred to as clinical or methodological heterogeneity, respectively, to distinguish them from the statistical heterogeneity of study results discussed above. Some clinical heterogeneity between studies is desirable, as it allows the results to be more generalizable than those of individual studies, which often use strict inclusion and exclusion criteria to evaluate homogeneous populations. A large degree of heterogeneity precludes combining all studies into a single analysis but can facilitate subgroup analysis.

**ORIGIN OF THE PRISMA STATEMENT**

As meta-analyses and systematic reviews began to appear in the medical literature, deficiencies in reporting became apparent. Information was frequently lacking regarding such aspects as use of a protocol, methods for identifying and selecting studies, assessments of the quality of included studies, and funding sources. An important step towards improving the quality of reporting meta-analyses appeared in 1999 with publication of the Quality of Reporting of Meta-analyses (QUOROM) statement. This statement provided a checklist of 18 items considered important for clear, accurate, and transparent reporting of meta-analyses of clinical trials, plus a recommended flow diagram outlining the process of selecting trials for the meta-analysis.

Ten years later, the QUOROM statement was replaced by the PRISMA statement, which not only extended its applicability to systematic reviews, but also expanded the checklist to reflect progress that had been made in the science of systematic reviews. The 27 PRISMA checklist items are categorized in sections found in a typical research paper (Title, Abstract, Introduction, Methods, Results, and Discussion), plus an additional section regarding funding. (Table S1, online supplemental materials) The statement also includes an updated flow diagram of the study selection process. A modified PRISMA flow diagram is shown in Figure 1.

**Figure 1.** Flow diagram outlining the process for selecting the included meta-analyses. This is modified from the PRISMA statement flow diagram. The 27 PRISMA checklist items are categorized in sections found in a typical research paper (Title, Abstract, Introduction, Methods, Results, and Discussion), plus an additional section regarding funding. (Table S1, online supplemental materials) The statement also includes an updated flow diagram of the study selection process. A modified PRISMA flow diagram is shown in Figure 1.

<table>
<thead>
<tr>
<th>Article Identification</th>
<th>881 records retrieved from PubMed search</th>
</tr>
</thead>
<tbody>
<tr>
<td>First 60 records selected</td>
<td></td>
</tr>
<tr>
<td>60 records screened</td>
<td></td>
</tr>
<tr>
<td>47 full-text articles assessed for eligibility</td>
<td></td>
</tr>
<tr>
<td>44 meta-analyses included</td>
<td></td>
</tr>
<tr>
<td>13 records excluded</td>
<td></td>
</tr>
<tr>
<td>5 non-systematic review, no meta-analysis</td>
<td></td>
</tr>
<tr>
<td>3 meta-analysis plus other study type</td>
<td></td>
</tr>
<tr>
<td>2 systematic review, no meta-analysis</td>
<td></td>
</tr>
<tr>
<td>2 meta-analysis, studies not from systematic review</td>
<td></td>
</tr>
<tr>
<td>1 original research study, no meta-analysis</td>
<td></td>
</tr>
<tr>
<td>3 articles excluded</td>
<td></td>
</tr>
<tr>
<td>2 meta-analysis plus other study type</td>
<td></td>
</tr>
<tr>
<td>1 original research study, no meta-analysis</td>
<td></td>
</tr>
</tbody>
</table>

1. *meta-analysis plus another study type: 2 animal studies, 1 case series.*
2. *meta-analysis plus another study type: 1 non-systematic review, 1 case series.*
PRISMA AND META-ANALYSIS LIMITATIONS

The PRISMA statement addresses many potential limitations of meta-analyses, as the checklist and flow diagram provide information in a clear and transparent manner regarding a number of these issues. This allows the reader to understand the extent to which the limitations may be present. Furthermore, the PRISMA statement may even help diminish the impact of potential limitations, as researchers who anticipate following the guidelines when reporting their results are likely to consider the relevant issues when designing their meta-analysis. Table S1 in the online supplemental materials indicates how meta-analysis limitations are addressed by specific checklist items.

RESEARCH QUESTION 1: DO JOURNALS REQUIRE THE USE OF PRISMA GUIDELINES?

Methods

To examine whether journals require meta-analysis authors to follow the guidelines, the current instructions for authors of 60 journals from 6 major medical specialties (10 from each specialty) were reviewed on November 30, 2014. The specialties were selected from categories in the 2013 Journal Citation Reports list of impact factors. The journals were those with the 10 highest impact factors in each category. Impact factors were used to select journals as a convenient way to identify commonly cited journals in the specialties; their use is not meant to imply that these are the highest quality journals.

Results

Almost one-half (47%) of the journals stated that authors were required to follow PRISMA guidelines, and another 10% simply recommended their use. (Table 1) Obstetrics and gynecology and general and internal medicine journals most frequently required or recommended use of the guidelines. Methods to ensure following the guidelines, such as requiring submission of a PRISMA checklist or flow diagram, were used by fewer journals (27% required a checklist and 20% required a diagram).

RESEARCH QUESTION 2: DO META-ANALYSES FOLLOW THE PRISMA GUIDELINES?

Methods

The extent to which biomedical meta-analyses follow PRISMA guidelines has not been established. To obtain current data regarding this issue, the completeness of reporting in accordance with the PRISMA guidelines was recorded for 44 meta-analyses published online between November 3, 2014 and November 18, 2014. (Appendix 1, online supplemental materials) These meta-analyses were obtained through a PubMed search performed on November 19, 2014, using the search term meta-analysis and these filters: English language and November 1, 2014, to present publication date. Of the 881 retrieved records, the first 60 were selected with the goal of obtaining the most recent articles. Titles and abstracts of these 60 records were screened to determine whether they met the inclusion criteria: English language article, meta-analysis of studies contained within a systematic review, and absence of another type of study (except a systematic review) combined with the meta-analysis. After excluding 13 records that clearly did not meet these criteria, the full-text versions of the remaining articles were retrieved. Upon assessment of these versions, 3 additional articles were excluded. Figure 1 depicts a PRISMA-like flow diagram outlining the process for selecting the included meta-analyses plus reasons for excluding articles at the title and abstract screening and full-text assessment phases.

Data extracted from the 44 final meta-analyses included whether the journal recommended or required following PRISMA guidelines, whether the authors indicated that they

Table 1. Requirements of 10 High-Impact Factor Journals From 6 Major Medical Specialties Regarding the Use of PRISMA Guidelines

<table>
<thead>
<tr>
<th>Medical Specialty</th>
<th>Following PRISMA Guidelines Recommended a  n (%)</th>
<th>Following PRISMA Guidelines Required b  n (%)</th>
<th>PRISMA Checklist Required  n (%)</th>
<th>PRISMA Flow Diagram Required  n (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Obstetrics and Gynecology d</td>
<td>2 (20)</td>
<td>7 (70)</td>
<td>1 (10)</td>
<td>1 (10)</td>
</tr>
<tr>
<td>Medicine: General and Internal</td>
<td>2 (20)</td>
<td>6 (60)</td>
<td>3 (30)</td>
<td>4 (40)</td>
</tr>
<tr>
<td>Anesthesiology</td>
<td>1 (10)</td>
<td>5 (50)</td>
<td>5 (50)</td>
<td>1 (10)</td>
</tr>
<tr>
<td>Pediatrics</td>
<td>1 (10)</td>
<td>3 (30)</td>
<td>3 (30)</td>
<td>2 (20)</td>
</tr>
<tr>
<td>Surgery</td>
<td>0</td>
<td>4 (40)</td>
<td>2 (20)</td>
<td>2 (20)</td>
</tr>
<tr>
<td>Critical Care Medicine</td>
<td>0</td>
<td>3 (30)</td>
<td>2 (20)</td>
<td>2 (20)</td>
</tr>
<tr>
<td>Total e</td>
<td>6 (10)</td>
<td>28 (47)</td>
<td>16 (27)</td>
<td>12 (20)</td>
</tr>
</tbody>
</table>

a journals are those with the highest impact factors in each category, as indicated in the 2013 Journal Citation Reports list of impact factors. If a journal did not publish meta-analyses, it was excluded, and the journal with the next highest impact factor was selected.

b includes statements that authors were “encouraged” or “recommended” to follow guidelines or that guidelines are “valuable to help” write a meta-analysis.

c includes statements that authors “should,” “must,” or “are requested to” follow guidelines or statements to “follow” or “please follow” the guidelines.

d medical specialty percentages represent the percentage of the 10 journals in the designated specialty.

e total percentages represent the percentage of all 60 journals.
followed these guidelines, the completeness of reporting each PRISMA checklist item, and the presence of a PRISMA-like flow diagram. The completeness of reporting was rated as “adequate,” “inadequate,” “not reported,” or “not applicable” based on criteria established for a previous study ([Appendix 2, online supplemental materials]). The rating was performed by the author (MDD).

The Mann-Whitney Rank-Sum test was used to compare the completeness of reporting PRISMA items according to whether or not the journals required or recommended following the PRISMA guidelines and whether or not the authors stated that they followed the guidelines. P values <.05 were considered statistically significant.

Results

Of the meta-analyses evaluated, none reported all PRISMA checklist items adequately. Ge et al previously noted the same finding: none of their 312 systematic reviews and meta-analyses reported all items adequately. The median number of checklist items reported adequately in the current study was 16 (range, 4 to 25), which represents a median percentage of 57.7% (range, 16% to 92.6%) of applicable items. Previous studies have reported mean percentages of adequately reported PRISMA items ranging from 64% to 81%. The lower percentage in the current study may reflect the use of more strict criteria, as the percentage rose to 87.3% when items rated as adequate or inadequate were combined. The median percentages of items rated as inadequate alone and not reported were 29.6% and 14.8%, respectively.

Checklist items 1, 3, 14, 17, 21, and 23 were most commonly reported adequately (in 90.9% to 100% of meta-analyses) (Table 2, Figure 2). The high percentage for item 1 (title signify-

<table>
<thead>
<tr>
<th>PRISMA Checklist Item</th>
<th>Adequate n (%)</th>
<th>Inadequate n (%)</th>
<th>Not reported n (%)</th>
<th>Not applicable n (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>TITLE</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1. Title</td>
<td>41 (93.2)</td>
<td>0</td>
<td>3 (6.8)</td>
<td>0</td>
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<td>ABSTRACT</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2. Structured summary</td>
<td>1 (2.3)</td>
<td>37 (84.1)</td>
<td>6 (13.6)</td>
<td>0</td>
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<tr>
<td>INTRODUCTION</td>
<td></td>
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<tr>
<td>3. Rationale</td>
<td>44 (100)</td>
<td>0</td>
<td>0</td>
<td>0</td>
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<tr>
<td>4. Objectives</td>
<td>8 (18.2)</td>
<td>36 (81.8)</td>
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<td>0</td>
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<td>METHODS</td>
<td></td>
<td></td>
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<td></td>
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<tr>
<td>5. Protocol and registration</td>
<td>3 (6.8)</td>
<td>2 (4.6)</td>
<td>39 (88.6)</td>
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</tr>
<tr>
<td>6. Eligibility criteria</td>
<td>12 (27.3)</td>
<td>32 (72.7)</td>
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<td>0</td>
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<td>7. Information sources</td>
<td>7 (15.9)</td>
<td>37 (84.1)</td>
<td>0</td>
<td>0</td>
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<td>8. Search</td>
<td>23 (52.3)</td>
<td>0</td>
<td>21 (47.7)</td>
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<td>9. Study selection</td>
<td>17 (38.6)</td>
<td>9 (20.5)</td>
<td>18 (40.9)</td>
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<td>10. Data collection process</td>
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<td>18 (40.9)</td>
<td>9 (20.5)</td>
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<td>11. Data items</td>
<td>32 (72.7)</td>
<td>7 (15.9)</td>
<td>5 (11.4)</td>
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<td>12. Risk of bias in individual studies</td>
<td>8 (18.2)</td>
<td>28 (63.6)</td>
<td>8 (18.2)</td>
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<td>13. Summary measures</td>
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<td>2 (4.5)</td>
<td>4 (9.1)</td>
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<td>14. Synthesis of results</td>
<td>40 (90.9)</td>
<td>3 (6.8)</td>
<td>1 (2.3)</td>
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<td>15. Risk of bias across studies</td>
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<td>1 (2.3)</td>
<td>15 (34.1)</td>
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<td>16. Additional analyses</td>
<td>16 (36.4)</td>
<td>16 (36.4)</td>
<td>6 (13.6)</td>
<td>6 (13.6)</td>
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<td>RESULTS</td>
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<td></td>
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<td>19. Risk of bias within studies</td>
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<td>20. Results of individual studies</td>
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<td>21 (47.7)</td>
<td>5 (11.4)</td>
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<td>2 (4.5)</td>
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<td>1 (2.3)</td>
<td>14 (31.8)</td>
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<td>23. Additional analyses</td>
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<td>6 (13.6)</td>
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<td>11 (25.0)</td>
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<td>0</td>
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<td>26. Conclusions</td>
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<td>FUNDING</td>
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<td>27. Funding</td>
<td>16 (36.4)</td>
<td>14 (31.8)</td>
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</tbody>
</table>

*All n values represent the number of meta-analyses in which the item received the corresponding rating. *

*These percentages represent the percentage of all 44 meta-analyses. As items 16 and 23 were “not applicable” for 6 meta-analyses, the percentages of meta-analyses for which they were applicable and reported adequately were 42.1% and 97.4%, respectively.*
ing the article as a meta-analysis) likely reflects the ease of reporting this. The high percentage for item #3 (study rationale explained in the Introduction) is consistent with standard practice for all scientific papers. The high percentages for items 14, 21, and 23 reflect generally appropriate reporting of the methods and results of meta-analytic statistical techniques. The high percentage for item 17 (numbers and reasons for excluding articles during the study selection process) likely reflects the ease of reporting these data, especially if a flow diagram is used. Although a flow diagram was not required to achieve an adequate rating for this item, 41 of the 44 meta-analyses (93.2%) included a PRISMA-like flow diagram.

Items 2, 4, and 7 were most commonly rated as inadequately reported (in 81.8% to 84.1% of meta-analyses). For item 2, a structured summary was usually present, but not all elements were included. Journal-specific word limits and content requirements may have contributed to this. For item 4 (explicit statement regarding objectives in the Introduction), most meta-analyses reported some, but not all, of the “participants, interventions, comparisons, outcomes, study design” (PICOS) elements. Most commonly, the study design was missing. The high percentage of inadequate reporting for item 7 (information sources, including last search date) was due to the frequent absence of a last search date.

Item 5 was most commonly not reported (in 88.6% of the meta-analyses). To warrant this rating, a meta-analysis neither mentioned whether a protocol existed nor gave a registration number. Like other forms of research, meta-analyses require a prespecified protocol to avoid the potential for selective analysis and reporting based on interim study results.7 Furthermore, registration of the protocol in a registry such as the PROSPERO register for systematic reviews (www.crd.york.ac.uk/PROSPERO/) is recommended to encourage authors to follow their protocol. Nevertheless, even registration may be insufficient. In a study of 288 Cochrane Library systematic reviews (whose protocols are all registered with Cochrane), the primary outcome measure differed from that listed in the protocol in 48 (17%) reviews, and the study results were more likely to be positive in those reviews with an outcome change than in those with no change.22

As shown in Table 3, the median percentage of PRISMA items reported adequately was higher for meta-analyses published in journals that required or recommended following the PRISMA guidelines (63.0%) than for meta-analyses published in journals that did not (55.6%). The percentage was also higher for meta-analyses in which the authors indicated that they followed the PRISMA guidelines (59.3%) than for meta-analyses in which the authors did not state this (55.6%). Although the differences reached statistical significance for both factors, neither had a dramatic impact on improving the completeness of reporting. The 59.3% for meta-analyses in which authors stated they followed the guidelines was considerably lower than anticipated. This may partially reflect journal-specific word limits and content requirements, but it
is possible that authors did not appreciate the importance of adequately reporting each item. It is likewise conceivable that they did not understand how to follow the guidelines, despite the clear and explicit descriptions contained in the PRISMA checklist and the availability of an accompanying comprehensive “explanation and elaboration” article4 published concurrently with the PRISMA statement.

LIMITATIONS
The methodology used to address the question of whether meta-analyses follow the PRISMA guidelines introduces limitations that should be considered when interpreting the results. For example, rating the completeness of reporting individual items was somewhat subjective, especially for items 6, 12, 19, 21, 24, and 25. As no standardized definitions have been published, the criteria used to define these ratings were established de novo by the author and a colleague for use in another study,17 based on descriptions in the PRISMA statement3 and “explanation and elaboration” article.4 This rating system has not been validated. Furthermore, only 1 person determined the ratings in the current investigation; it would have been preferable to rate the items by consensus of more than 1 investigator. Another limitation relates to the process of selecting the meta-analyses, as the included articles were publications indexed in a single database (PubMed) over a mere 16-day period. It is unclear whether these are truly representative examples of recent meta-analyses.

CONCLUSION
As meta-analyses play an increasingly prominent role in health care decision-making, their merits and limitations should be recognized and assessed. The PRISMA statement facilitates this process by promoting accurate, clear, and transparent reporting. Many medical journals (57% of those evaluated in this article) recognize the importance of the PRISMA guidelines by recommending or requiring their use by meta-analysis authors, although only approximately one-fourth of journals employ specific measures to ensure their use. Likewise, recent meta-analyses do not fully follow the guidelines, as a median of only 57.7% of PRISMA checklist items were reported adequately. Further efforts are required to promote more widespread use of the PRISMA guidelines and encourage adequate reporting of all checklist items.

Acknowledgment
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Author disclosure: The author notes that she has no commercial associations that may pose a conflict of interest in relation to this article.

Author contact: mddaleymd@gmail.com

References
4. Liberati A, Altman DG, Tetzlaff J, et al. The PRISMA statement for reporting systematic reviews and meta-analyses of studies that evaluate

### Table 3. Median Percentage of PRISMA Checklist Items Reported Adequately According to Whether the Journal Required Use of the PRISMA Guidelines and Whether the Authors Indicated Following the Guidelines

<table>
<thead>
<tr>
<th>Meta-analyses</th>
<th>Median Percentage of Items Reported Adequately (range)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total (N=44)</td>
<td>57.7 (16.0–92.6)</td>
</tr>
<tr>
<td>Journal statement recommending or requiring that the PRISMA guidelines be followed</td>
<td></td>
</tr>
</tbody>
</table>
| Yes (n=18)                                             | 63.0 (40.0–92.6)
| No (n=26)                                              | 55.6 (16.0–70.4)                                       |
| Author statement that PRISMA guidelines were followed   |                                                        |
| Yes (n=21)                                             | 59.3 (44.0–92.6)
| No (n=23)                                              | 55.6 (16.0–70.4)

*aP<.02 versus No group (Mann–Whitney Rank-Sum test).
*bP<.05 versus No group (Mann–Whitney Rank-Sum test).
17. Daley MD, Moher D, Martin LA. Anesthesiology systematic reviews and meta-analyses: completeness of reporting in accordance with the PRISMA guidelines (meeting abstract). Anesthesiology. 2015;A2993.

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Introduction
Any type of medical writing that reports data needs to undergo some type of quality control (QC) to ensure that documents or other materials are not riddled with errors. Quality control may involve a number of tasks, including consistency checks, editing, and content verification. For individuals who possess the necessary skills, starting as a QC reviewer is one way for those interested in medical writing to get a foot in the door. Starting a medical writing career as a dedicated QC reviewer allows for gaining familiarity with clinical documents, style guides, and conventions.1

Definition and Scope of Quality Control
According to the International Conference on Harmonisation’s Guideline for Good Clinical Practice, QC consists of “the operational techniques and activities undertaken as part of the quality assurance system to verify that the requirements for the quality of trial-related activities have been fulfilled.”2 It should be applied to each stage of data handling to ensure that all data are reliable. This includes the collection, storage, processing, and reporting of the data.

For medical writing purposes, QC generally means verifying that the deliverable (including but not limited to a clinical study report, marketing application, protocol, or manuscript) is accurate compared to the source documentation (including tables, figures, and listings and the protocol) and conforms to the style guide and template (if provided). The QC process is important to ensure that accurate and high-quality data are presented.

The Importance of Quality Control
Quality control provides a level of assurance that the data on which decisions are made and any materials associated with a product are complete and accurate and that patient safety is being protected. Regulators may not believe a company’s claim that a product is safe and effective and has gone through the necessary rigorous steps of drug development if the marketing application is riddled with errors. In fact, the Food and Drug Administration has indicated that errors in datasets, such as transcription or transposition mistakes, can reduce confidence in the overall accuracy of the data and may lend support for a “refusal to file” decision, which means the application for the product in question would not be reviewed until such problems are fixed.3

In addition, errors in labeling have led to the recall of drugs from the market. In 2014, Sagent Pharmaceuticals initiated a voluntary recall of ketorolac tromethamine injection because it was labeled with an expiration date that was longer than the known stability of the product.4 Likewise, in 2014, Baxter International Inc voluntarily recalled a highly concentrated potassium chloride injection because of mislabeling of the overpouch with a higher concentration, which could have led to serious and life-threatening consequences in a high-risk patient population if they received a lower than intended dose.5

Skills Needed to Perform Quality Control
An effective QC reviewer should have the following skills:
• Attention to detail
• Analytical ability
• Problem-solving capabilities, such as the ability to identify the correct source document when not clearly indicated
• Organizational skills
• Interpersonal skills and ability to communicate clearly
• Editorial and proofreading ability
• Knowledge of medical writing processes, including how team members influence the content of the document
• Strong computer skills and expertise with common applications, such as Microsoft Word

Ensuring an Effective Quality Control Process
By Lima Chutkan, PhD, RAC/ Medical Writer and Consultant, Whitsell Innovations Inc, Chapel Hill, NC
Developing these skills not only improves your ability to perform QC but also makes you a better medical writer. As a medical writer, you may be asked to perform QC, either directly by a client or for a colleague before a document goes to a client. Possessing these skills as a medical writer allows you to put forward a high-quality document from the beginning of the process.

**How to Perform Effective Quality Control**

Deliverables can be varied and complex, and the style and conventions may differ widely depending on the type of document. Regardless of the type of document, the process outlined in Figure 1 provides best practices to ensure an effective QC.

1. **Establish expectations with the author.** You should be aware of the type of QC requested, how thorough you need to be, what to do if you have questions, how and when the author would like to be contacted, and how QC findings should be documented (for example, by tracking changes in a document, inserting comments, or listing the issues on a spreadsheet). Some documents might not have source documentation (such as a protocol that has evolved past the initial concept sheet or synopsis) or may have already gone through QC by functional area experts. In these cases, you may only need to copyedit and not perform content verification. Establishing communication preferences is a key part of establishing expectations. For example, establish whether you should contact the author as you go if you have questions (for example, regarding unverifiable data) or send a consolidated list at the end.

2. **Identify any special circumstances.** For example, you may be a part of a team providing QC of several related documents, such as modules of a marketing application, and you may have to contact other members of the team to verify cross-references to different documents. It may be helpful to schedule time with the author to review any special circumstances.

3. **Identify any standard operating procedures (SOPs) that apply to the process.** Clients may have different processes regarding QC, including SOPs, checklists, and verification forms. If the client SOP includes tasks that conflict with the SOPs of your company, confirm with your author which SOP should be followed.

4. **Confirm the timelines.** Clarify whether the due date indicates that your involvement in the process is over or if you should expect follow-up questions from the author.

5. **Confirm the type and location of document and source documents.** If you are familiar with the type of document for QC, you are likely to be aware of the typical source documents. If you are unfamiliar with the type of document, you may have to confirm that all the necessary source documents have been provided. You should also confirm the location of the documents. In some cases, the document and sources may be sent to you via email, but if there are concerns regarding security or if the client has specific guidelines, you may be asked to retrieve the documents from a shared folder on the Web or document management system. Confirm that you have received links to all the necessary documents and that you have access and the correct permissions to download them at the beginning of the project to prevent delays.

6. **Perform a “gap analysis” to verify that you have all the materials that you need.** An SOP or checklist may guide you in determining what you need if you do not have expertise with the type of document.

7. **Perform QC and document findings.** Second, identify any special circumstances. For example, you may be a part of a team providing QC of several related documents, such as modules of a marketing application, and you may have to contact other members of the team to verify cross-references to different documents. It may be helpful to schedule time with the author to review any special circumstances.

Third, identify any standard operating procedures (SOPs) that apply to the process. Clients may have different processes regarding QC, including SOPs, checklists, and verification forms. If the client SOP includes tasks that conflict with the SOPs of your company, confirm with your author which SOP should be followed.

Fourth, confirm the timelines. Clarify whether the due date indicates that your involvement in the process is over or if you should expect follow-up questions from the author.

Fifth, confirm the type of document for QC and the source documents. If you are familiar with the type of document for QC, you are likely to be aware of the typical source documents. If you are unfamiliar with the type of document, you may have to confirm that all the necessary source documents have been provided. You should also confirm the location of the documents. In some cases, the document and sources may be sent to you via email, but if there are concerns regarding security or if the client has specific guidelines, you may be asked to retrieve the documents from a shared folder on the Web or document management system. Confirm that you have received links to all the necessary documents and that you have access and the correct permissions to download them at the beginning of the project to prevent delays.

Sixth, perform a gap analysis to verify that you have all the materials that you need. An SOP or checklist may guide you in determining what you need if you do not have expertise with the type of document.

Seventh, once you have what you need and know what is expected from you, perform QC. A thorough QC includes consistency checks, editing, and content verification. Examples of common tasks performed during QC are provided (see Box). As a note, QC typically occurs at the end of the process, after the document has gone through multiple rounds of review by numerous reviewers. Therefore, these documents may include text that was written by several authors. Unless the text is inaccurate or grammatically incorrect, follow the style guide and refrain from injecting personal preferences on word placement, style, and flow. If a style guide is not provided, it is important to ensure consistency within the document, including word choice (for example, subject versus patient) and formatting of document elements, such as headers and footers. While a good QC reviewer can improve a document, the primary job is ensuring accuracy and consistency, not...
rewriting or restructuring a document according to personal preferences.

Finally, once QC is complete, ensure that it is documented according to the applicable SOPs. This may include completing a checklist or signing a review form.

Effective QC requires complex multitasking. When performing QC for the first few times, it may be easier, although more time consuming, to perform content verification first before reading the document for spelling, grammar, and punctuation, and then again for flow and consistency. The ability to perform all of these tasks during one readthrough develops over time. Regardless of expertise, checklists are a good way of breaking down a complex process into manageable pieces, and they help ensure that even small and easily overlooked steps are performed. Checklists may be provided by the client as part of the SOPs, but QC reviewers can also develop their own checklists, which can be general or document specific, and they may use multiple checklists on the same document. Document-specific checklists can cover the types of source documents needed, which aids in performing the gap analysis and provides the conventions used throughout the document (for example, using past tense in the methods section of a clinical study report versus future tense in a protocol).

The process outlined in Figure 1 presents best practices to ensure an effective QC process regardless of the type of document. Quality control is an important part of the medical writing process, and developing the skills needed for effective QC as a medical writer can lead to higher-quality documents earlier in the process and greater client satisfaction.

Author disclosure: The author notes that she has no commercial associations that may pose a conflict of interest in relation to this article.

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References
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In the United States, agencies that determine health care access and reimbursement include national health authorities, formulary decision-makers, and commercial insurers. A central goal of these agencies is to provide patient access to the most effective health care while also weighing the impact of costs of drugs, devices, medical procedures, diagnostic tests, and treatment strategies. When making access or reimbursement decisions, agencies may conduct a health technology assessment (HTA), which is a policy-research process that informs agencies as to which health care products will provide the greatest value. As part of the HTA process, an agency may ask a manufacturer for clinical and economic data that describe the overall value of a health care product in terms of its efficacy, safety, and cost compared with the standard of care and other existing therapies.

The Academy of Managed Care Pharmacy (AMCP) is a national society of managed-care pharmacists and other health care professionals in the United States. In 2000, this society developed a format for preparing dossiers on health care product information. This format is called the AMCP Format for Formulary Submission (ie, AMCP dossier). Since 2000, the AMCP dossier format has undergone several updates and has become a nationally recognized guideline for organizing health care information in a consistent and structured manner that enables cross-product evaluations.

In this article, we provide a high-level overview of health care access and reimbursement in the United States, general information on the uses, content, and preparation of AMCP dossiers, and perspectives on how medical writing professionals can contribute to AMCP dossiers. Although writing and editing regulatory documents and publications are established roles for medical writers in the pharmaceutical industry, preparation of AMCP dossiers and other payer-related documents offers a new opportunity in medical communications.

The US System for Health Care Access and Reimbursement is Complex

Challenges facing health care providers and patients for gaining access to health care products include rising health care costs, budgetary concerns, and insurance reimbursement restrictions. In the United States, access of health care providers and patients to a medical product is often determined by pharmacy and therapeutics (P&T) committees or other similar medical-technology review committees housed within a payer agency or health care institution. P&T committees decide which health care products to place on the formularies of hospitals, insurance companies, acute- and long-term care facilities, the Centers for Medicare and Medicaid Services (CMS), and managed care organizations. These P&T committees are usually composed of physicians, pharmacists, nurses, administrators, and other health care professionals who manage the formulary list by using an evidence-based process to help ensure the safe and appropriate use of health care products and procedures within a budget limit. Health care products and tools considered for inclusion on a formulary so they can be used for patient care often include medications, medication-associated products or devices, medication-use policies, decision-support tools, and guidelines.

Health care reimbursement is managed by federal programs such as CMS and the Veterans Health Administration.
and by private insurance companies such as Aetna, Cigna, Kaiser Permanente, United Healthcare, and Anthem. In addition, pharmaceutical benefits for those with drug coverage are often managed through a pharmacy benefits manager such as Express Scripts or CVS Caremark. Pharmacy benefit managers typically work for employers and health plans to negotiate favorable prices with drug companies and drugstores.

Health Technology Assessments
One of the tools used by a P&T committee to help decide what to include on a formulary is an HTA. An HTA is defined as policy research that investigates the consequences that result from applying a health care technology. Data taken into consideration during the HTA process include efficacy, safety, real-world effectiveness (such as findings from observational studies or clinical practice as gathered from observational chart reviews), cost-effectiveness, cost, patient-reported outcomes, as well as social, legal, ethical, and political impacts. HTAs are used to inform coverage and payment decisions and to advise clinicians and patients about the appropriate use of a technology. The importance of informed decision making to the access and reimbursement environment in the United States is underscored by a provision included in the Patient Protection and Affordable Care Act to create a Patient-Centered Outcomes Research Institute (PCORI) to investigate how payers can use data from the “real world” to make coverage decisions. Countries outside the United States also have well-established HTA processes (often performed by government-run advisory or reimbursement agencies) and may ask US-based manufacturers for information about health care products to help make informed access and reimbursement decisions.

HTAs are commonly performed by governmental agencies, nonprofit groups, and private insurance companies (including pharmacy benefit managers) to inform coverage and payment decisions. US reimbursement agencies may conduct HTAs themselves or may ask outside organizations to perform HTA activities. For example, CMS issues national coverage determinations for those health technologies that may have a major impact on Medicare coverage. To inform a national coverage determination, CMS may request an HTA by the Agency for Healthcare Research and Quality (AHRQ) or advice from the Medicare Evidence Development & Coverage Advisory Committee (MEDCAC). The AHRQ and MEDCAC recommendations are advisory, with CMS retaining the authority for reimbursement decisions. (Note that the Food and Drug Administration [FDA] does not perform HTAs).

What is an AMCP Dossier?
As part of an HTA, access/reimbursement agencies may request information on a health care product from manufacturers. In the United States, manufacturers will often provide requested information in the format of an AMCP dossier, which is submitted to managed care organizations and other formulary decision makers such as national and regional health insurers, pharmacy benefit managers, hospital systems, and state Medicaid agencies. Access/reimbursement agencies may request other types of payer-related dossiers, but these documents often contain information similar to that in an AMCP dossier. These documents are then evaluated by a P&T committee or medical-technology review committee for making access and reimbursement decisions.

The AMCP-dossier format was developed by the AMCP to provide a systematic and structured way of obtaining the appropriate clinical and economic information from manufacturers that is needed to support effective coverage and reimbursement decisions. The current version of the AMCP format can be found on the AMCP website. The table provides a summary of dossier characteristics. Some agencies conducting an HTA may customize the AMCP format for their own needs. Manufacturers are permitted to supply data in an AMCP dossier that are not included in the FDA-approved label for a health care product as long as the request for information is unsolicited (not prompted by the manufacturer). It is important that the request be unsolicited because the US federal government prohibits commercial promotion of any off-label uses of FDA-approved health care products.

Key information in an AMCP dossier includes clinical, real-world outcome, quality-of-life, and cost data. Clinical data, such as efficacy and safety information, are often obtained from clinical trial results. A dossier may also include effectiveness information based on real-world data from observational trials/medical databases as well as health-related quality-of-life information based on patient-reported outcomes. The dossier section titled “Economic Value and Modeling Report” contains information on the health outcomes and costs associated with the health care technology under consideration. Several types of economic models may be described. For example, a cost-effectiveness model can compare the costs (derived from health care systems, US private payers, or Medicare) and consequences (health outcomes) between 2 products. A budget-impact model analyzes how adding a product to the formulary of a payer agency will affect the budget. To derive the projected per-member per-month costs, a budget impact model will estimate the drug costs, health care cost offsets (eg, increased cost might be offset by increased effectiveness), adverse event costs, and the expected use of the product in the population covered by the health care system. Budget impact models may be provided by a manufacturer as a spreadsheet, so that P&T committees can perform analyses using their own internal data.
How is an AMCP Dossier developed by a Manufacturer?

Manufacturers in the United States have traditionally focused heavily on strategies for obtaining FDA approval to market their products. However, a product’s commercial success is now becoming increasingly dependent on demonstrating that an FDA-approved product has value compared with already available technology, and, therefore, should be made available in the medical community and be reimbursed. Thus, providing clinical, safety, and economic information in an AMCP dossier that can be supplied to agencies in response to an unsolicited request is becoming increasingly important for the success of a new product.

Medical writers who have experience with developing scientific publications or regulatory documents within a company may have the appropriate background to prepare payer-related documents such as AMCP dossiers (see Box). Some companies may even have staff (including medical writers) dedicated to developing payer-related deliverables. The development of an ACMP dossier usually requires cross-functional input from various teams and content experts such as medical-team leaders, health economists, and regulatory-team leaders. The high-level writing and organizational services that medical writers provide can be valuable to the team effort of developing a high-quality, evidence-based AMCP dossier. From a company’s perspective, key steps involved in developing an AMCP dossier often include:

1. Strategic planning: Determine the value proposition of the health technology, the existing evidence base, and any information or data gaps (eg, need for a literature review); define clear roles and responsibilities; and establish clear processes and timelines. A medical writer could assist with developing timelines, identifying key sources needed for developing the dossier, and working with team members to clearly articulate the value of the health technology being described.

2. Content development: Several drafts are often developed that are reviewed by team members and senior management. Though AMCP dossiers are tailored to the needs of a requesting agency, material can sometimes be leveraged from other documents previously developed within a company. The main body of evidence in the AMCP dossier must be organized in a succinct manner with detailed information reserved for appendices. A medical writer could assist with performing the literature review, identifying key evidence to include in the main body, drafting and revising the dossier, and addressing comments from reviewers.

3. Final review and approval: The final document is reviewed by senior-level executives. A medical writer could address final comments from approvers. Once approved, the dossier can then be used to fulfill unsolicited requests from payer agencies.

Conclusions

The importance of AMCP dossiers and other payer-related documents is expected to grow as access/reimbursement agencies in the United States and worldwide tackle the increasingly challenging task of how to provide access to effective new medical technologies while also managing costs. In addition, the access and reimbursement environment in the United States will continue to evolve because of factors such as the political and economic landscape, the Patient Protection and Affordable Care Act, and fairness and ethical issues. The development of expensive, specialized drugs tailored to smaller populations (with such drugs often requiring special handling and...
administration) and the development of personalized medicine based on genetic testing may pose particular challenges for future access/reimbursement decision making.

As payer-related documents become increasingly crucial to access and reimbursement decisions, medical writers may have increased opportunities to work on such documents. The skills developed when working on scientific publications or regulatory documents make medical writers well-poised to transition to working on payer-related deliverables. Gaining experience with preparing AMCP dossiers can provide a fundamental background in preparing other types of payer-related documents (eg, other dossier types requested as part of an HTA) because the information requested is often similar to that found in an AMCP dossier. More information on payer-related documents and access/reimbursement topics can be found in the references listed in the bibliography and by visiting the AMCP website (www.amcp.org).

Author declaration and disclosures: The views expressed in this article are those of the authors and are not necessarily those of the companies with which the authors are affiliated. Linda L. Rice is an employee of Amgen Inc and owns Amgen Inc stock. Jessie Wolfe Galson is a contract writer for Amgen Inc and owns Amgen Inc and Vanda Pharmaceutical stock.

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References

Box 1. How does writing a scientific publication or regulatory document compare with writing a payer document?

Perspective from a scientific publication writer:
• Experience writing clinical manuscripts or health economic manuscripts provides a strong background for working on payer-related documents, especially in terms of understanding and writing about clinical data, quality-of-life data, and outcomes data.
• The payer-document work plan often is more fluid and rapidly changing than a publication plan. A payer-document work plan is often influenced by the socioeconomic environment and policies in a country (particularly true for HTA dossiers requested by foreign countries).
• There is no author byline on a payer-related document. Only company staff develop these documents (thus, the company is the author of the payer-related document).

Perspective from a regulatory writer:
• The skills for writing regulatory documents (eg, clinical study reports) are similar to those required for writing payer-related documents in terms of creation of document content based on analysis and synthesis of complex clinical data, management of the document review and approval process, extensive collaboration with other team members, and knowledge of the drug development process.
• Timelines for the submission of regulatory documents to regulatory agencies are usually set far in advance and involve the simultaneous preparation of multiple documents. An AMCP dossier is more stand-alone with a less predictable timeline because it is submitted in response to an unsolicited request. (Note that timelines for other types of payer documents that support HTAs are often set in advance).
• Regulatory documents for clinical submissions are primarily based on efficacy and safety data from clinical trials and provide information for package inserts. Regulatory documents do not discuss costs. A payer-document has broader content including real-world effectiveness data, cost data, cost-effectiveness data, and more extensive descriptions of patient-reported outcomes. Internal sources are primarily used to write regulatory documents (for example, clinical trial tables and listings, protocols, and clinical study reports), whereas payer-documents often rely more on scientific publications.
In clinical research we face the fundamental problem of generalization. We want to improve patients’ lives by developing new drugs and treatments. However, in the course of the development of a new drug, we can only test it in a fraction of patients who have the disease. At best we can test our new treatment in a few thousand study participants. We then need to generalize from what we find in our studies to the potentially millions of patients ‘out there.’

Before we generalize, we must be sure that we cover our bases. To obtain trustworthy results in a study, we must apply all the principles of good clinical practice. We pre-specify our main hypothesis and the primary endpoint we will be evaluating, we use a random sample of representative patients, we conduct the study in a double-blind way, and we accurately analyze our samples. After the study we calculate the results and we know precisely how well our drug works in the study participants. However, we want to also know how effective our drug is in the overall population of patients. Unfortunately there is no way to materially know the effectiveness in the overall population. We will never be able to conduct a study that includes all patients with the disease, even if we knew who they were.

In situations like this, when we want to extrapolate from a (small) sample to an overall population, we can use confidence intervals, commonly abbreviated as CI. Based on the results from our study we can construct a range of values that will, with a defined likelihood, comprise the true—but unknown—value in the overall population. In this sense, any result that we obtain in a study population is an estimate of the true effect in the overall population. Confidence intervals, more precisely their width, give us an indication of how ‘good’ our estimate is.

Let’s look at an example. Suppose we tested a new anti-diabetic drug in 100 patients with type 2 diabetes. Let’s assume that we were measuring effectiveness by looking at the proportion of responders, which we defined in our study as patients whose HbA1C (glycosylated hemoglobin) level in the blood was below 7.0% at the end of the study. We found that 33 people (33%) reached this target (and 67% did not). Using the appropriate formula (in this case the adjusted Wald method\(^1\)), we can calculate that the 95% CI is from 25% to 43%. Thus, in regard to the overall population, we have a point estimate of 33% (the value we found in our sample) and a lower confidence limit of 25% and an upper confidence limit of 43%. If we were to repeat this study many times (in other groups of patients) and always calculated the 95% CI, we expect that the calculated CIs would include the true population value in 95% of samples but would not include it in 5% of samples. It is also acceptable to say that there is a 95% chance that the 95% CI contains the population value.

Confidence intervals can be computed for any level of confidence. It has become a tradition to calculate the 95% CIs but confidence levels of 90% and 99% are also used. When we use a 90% CI we accept that we have only a 90% chance that our CI includes the population value and a 10% chance that it does not. If we want to be more confident that the CI contains the population value we may want to calculate the 99% CI, then there we accept only a 1% chance that it does not contain the population value. Compared with a 95% CI, a 90% CI is narrower and a 99% CI is wider (Figure 1).

The width of a confidence intervals depends on:

- a) The confidence level (also called confidence coefficient) chosen, ie, 95%, or other value
- b) The variability of the data; more variability will make CIs wider.
- c) The sample size. The smaller the sample, the wider the confidence interval; the larger the sample, the smaller the CI. If you want to halve the CI, you need to increase your sample fourfold (inverse square root relationship).

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\(^1\) The calculation of a confidence interval for a proportion is simple but beyond the scope of this paper. Please see Motulsky 2014 for more detail.
As seen above, CIs add a sense of precision to our estimates (ie, the study results). This feature helps us to judge their clinical relevance. In the example, we know that the true rate of response to the drug in the overall population could be as low as 25% but also as high as 43%. While we might have some doubts whether it is much of an achievement to have just 25% of responders, we might more readily view it as a big step forward if 43% were classified as responders. In such cases, when the lower and upper confidence limits denote two very different clinical outcomes, we would need to conclude that the sample was just too small and the CI therefore too wide to allow a final judgment on the effectiveness of the drug. Hence we have to repeat the study with a larger sample size.

Another feature of CIs that supports the clinical interpretation is that CIs are expressed in the unit of the variable that is being investigated; in our example, the unit is percent of responders. If we had looked at cholesterol concentrations, our point estimate would have the unit of mg/dL and so would the CI.

So far we have only looked at the descriptive use of CIs. However, CIs can also help us to come to conclusions (inferential use). In this regard, CIs are even more useful than p-values.

Let’s expand our example a bit. Let’s assume we have repeated the study with 1,000 patients. In the new study we had measured HbA1C values at the start of the study and at the end of the study. Now we want to know whether our new drug also had an effect on the mean HbA1C concentrations. At study start, we measure a mean HbA1C concentration of 8.6% with a 95% CI of 8.4% to 8.8%; at study end we measure a mean concentration of 7.8% with a 95% CI from 7.6% to 8.0%. We notice immediately that the two 95% CIs do not overlap (Figure 2). If this is the case, we can be sure that the difference between the 2 mean values is statistically significant at the 0.05 level.

Conversely, if the 2 CIs overlap, we can conclude that the differences in mean values would not be statistically significant.

### Issues of Notation

When reporting confidence intervals, some conventions should be followed to prevent confusion with measures of dispersion such as standard deviation or standard error of the mean. We should report the point estimate along with the unit and the lower and upper confidence limit. Therefore 8.6% (95% CI, 8.4% to 8.8%) is recommended and 8.6%, (95% CI ±0.2%) is not. If we provide the lower and upper confidence limits, the reader does not need to calculate the lower and upper values. This helps the reader interpret the clinical relevance of the data.

### Assumptions

The generalization from a (small) sample to a (large) overall population is only valid if certain assumptions are met.

1. Random sample. A confidence interval is only valid if the sample that we are analyzing has been drawn by a random process from the larger population we want to investigate.
2. Independent observations. A confidence interval is only valid if patients have been included independently from each other. This would not be the case if many patients brought siblings into the study.
3. Data were calculated and tabulated correctly. This means that we have not made any systematic mistake that could introduce bias in the analysis of the data.

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**Figure 1.** Responder rate of 33% (point estimate) with 95% confidence interval from 25% to 43% from a sample of 100 participants. For comparison the 99% CI and the 90% CI for the same data are shown. To be more confident that our CI contains the population value, we need to include a greater range therefore the 99% CI is wider than the 95% CI and the 90%. If we accept a 10% chance that our CI does not contain the population value, we can use the 90% CI which then needs to cover a smaller range and can thus be narrower than the 95% CI. (©Thomas M. Schindler)

**Figure 2.** Mean HbA1C concentrations in a study of 1000 patients. HbA1C was measured at study start and at study end, mean values with the 95% CIs indicated by connected triangles are shown. As the 95% CIs do not overlap, the difference between the two means is statistically significant at the 0.05 level.

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**Resources**


According to data from the Pew Research Center, 65% of adults and 76% of Internet users in the United States use at least one social media site. The result is a huge number of comments and conversations taking place online. By one estimate, people post approximately 500 million messages per day on Twitter alone.

Tapping into these conversations can provide insight into hot topics and industry trends and lead you to people and key opinion leaders with experience in the topics and issues you want to know more about or that you are writing about. With people sharing millions of insights every day, however, it can be difficult to find exactly what and whom you are looking for.

Most social media sites enable you to search for people by name to locate an individual’s personal account. Both Twitter and Facebook allow you to search without logging in. In contrast, you must be logged into your LinkedIn account to use that site’s search tool. Once logged in, you can search to find posts by LinkedIn members or people who have been designated by LinkedIn as “influencers.” However, with Twitter and Facebook in particular, if the users you are searching for have common names or they don’t use their real names on their accounts, the search results will not be very relevant. Keep in mind that search results always depend on the users’ privacy settings for the sites they use. Strict privacy settings will limit what is available to the public, regardless of the search tool you use.

To more efficiently search multiple social media platforms and achieve more relevant results, here are some search engines and tips to consider.

**Google**

Google is the go-to tool for most online keyword searches. But did you know that Google enables you to search individual social media sites without logging into each site, or even without having a personal account? The trick is to use Google advanced search commands.

To search a particular site, start your search string with **site: followed by the particular site you want to search, followed by the term or terms you are searching for.** If you are searching for those terms only in the Web page addresses (referred to as URLs), then add the command **inurl:** to the search string.

Let’s take a look at some examples. To search YouTube for videos that have something to do with Pfizer, we would use the following search string in Google:

```
site: www.YouTube.com Pfizer
```

The results yield multiple YouTube channels associated with Pfizer.

To search a different site or to use a different search term, simply replace **www.YouTube.com** with the URL for the particular site you want to search and replace Pfizer with the term you are searching. If you are looking for an exact multiple-word phrase match, be sure to put the search term in quotation marks.

To search for YouTube videos about medical writing, we would use the following search string in Google:

```
site: www.YouTube.com “medical writing”
```

For a search of people on Facebook commenting about medical writing, the search string would be:

```
site: www.facebook.com “medical writing”
```

With Google advanced search options, you don’t have to limit your searches to one particular site. To search all sites ending in .com that include medicalwriting in the URL, the search string would be:

```
site:.com inurl:medicalwriting
```

To search all sites ending in .com that have content that includes the phrase medical writing, the search string would be:

```
site:.com “medical writing”
```

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Tips for Searching Social Media

By Cynthia L. Kryder, MS, CCC-Sp / Medical Communications Consultant, Phoenixville, PA
Notice the absence of spaces after the colons in all of these examples. If you insert a space after the colons, the search results will no longer be limited by site or URL.

For any of these Google searches, you could also restrict results to a specific period of time. Perhaps you are interested in whether anyone recently created or updated a blog post about the Zika virus. Type the following in the Google search box:

```
zilla inurl:blog
```

Then click Search Tools and select Past 24 hours or Past hour from the time options.

**Social Searcher**

Social Searcher began as a search engine for Facebook content but now also offers real-time searches of multiple social networks, including Twitter, YouTube, Vimeo, Google+, Facebook, Instagram, Tumblr, Reddit, Flickr, and Dailymotion. You need not be logged into any of these sites to search. Social Searcher also provides analytics so you can monitor how many mentions a search term receives by week, day, and hour and by network. It also provides a list of the most popular hashtags for the search term.

The free service allows you to perform 100 real-time searches daily and set up 2 email alerts for key words. The premium package ranges from 3.49 to 19.49 Euros per month depending on the bells and whistles you want. To search, enter the search term or terms you want in the Exact Keywords box on the left sidebar.

**Social Mention**

Social Mention is another search engine that enables you to search multiple social networks simultaneously. Unlike Social Searcher, Social Mention also searches blogs, microblogs, comments, bookmarks, and videos. You also can set up Social Mention to receive daily email alerts for searches of particular keywords.

To search, enter the search term in the search box. If you are searching a phrase, such as *medical writing*, put quotation marks around it.

**UVRX Social Search**

UVRX social search uses Google's custom search technology to enable you to essentially build your own search engine. You specify the sites you want to search and UVRX does the rest. Choose from Facebook, Twitter, Myspace, Plaxo, Bebo, Tumblr, Livejournal, Flickr, Google+, and LinkedIn. That's right. With UVRX you can search LinkedIn without logging into the site or without having your own profile. When I searched UVRX for *medical writing*, 29 of the first 30 results were from LinkedIn, and some of these were for LinkedIn content I didn't find through other searches. To search, choose the sites and then enter your search term in the search box, using quotation marks if searching for a phrase.

Any of these tools can save you time when sifting through the plethora of content published on social media. Search results can help you to:

- Learn what people are saying about a particular subject
- Identify trends and topics to write about so you can better focus your content
- Discover the type of content that already exists for a particular subject
- Find experts and key opinion leaders
- Use more relevant hashtags to better market your content

**Author disclosure:** The author notes she has no commercial associations that may pose a conflict of interest to this article.

**Author contact:** clkwriter@comcast.net

**References**


**Social Media Searching Links**

Twitter advanced search
https://twitter.com/search-advanced

Facebook people search
www.facebook.com/people-search.php

LinkedIn search help
https://help.linkedin.com/app/answers/detail/a_id/46415~/searching-for-member-posts

Social Searcher
www.social-searcher.com

Social Mention
www.socialmention.com

UVRX Social Search
http://UVRX.com.social/html
At last year’s conference, we announced our new conference branding—AMWA’s Medical Writing & Communication Conference. This year, we move forward under our new cohesive identity, which brings focus to our goal of the conference being the premier event for medical communicators. This is the event that medical writers and editors must attend to stay ahead in the field.

The overarching brand of “AMWA’s Medical Writing & Communication Conference” will continue from year to year while the specific theme for each conference changes. This year’s theme is “Trends and Opportunities for Medical Communicators.” Here are some highlights of what is in store at this year’s conference in Denver, October 5 to October 8.

NEW CONFERENCE SCHEDULE
How often have you wished you could take this open session but it conflicts with that workshop that you have been planning to take since the last conference? This year, we have arranged the offerings so that you don’t have to choose between workshops and other activities. Programming will begin earlier in the week than in past years. Workshops will be offered all day Wednesday, Thursday morning, and Saturday afternoon. During the remaining conference time, attendees will be able to take advantage of other activities, including open sessions, roundtables, and networking opportunities.
AWARD LECTURES

While conference planning continues, we are pleased to announce our 2016 AMWA Alvarez and McGovern Award recipients, who will be featured speakers in Denver.

The 2016 Walter C. Alvarez Award recipient is Roxanne Khamsi, chief news editor of the international biomedical journal Nature Medicine. The Alvarez Award is presented to a member or nonmember of AMWA to honor excellence in communicating health care developments and concepts to the public.

As chief news editor, Khamsi has expanded long-form coverage of science and championed stories about studies that challenge the scientific status quo. Her longtime focus on health research in underreported regions of the world has earned praise, including an Excellence in Media Award from the Global Health Council, a membership organization supporting and connecting global health advocates. Other awards she has received for her writing include a first-place award from the Association of Health Care Journalists in the trade-publication category for her coverage of insurance issues plaguing medical foods and Mental Health America’s Media Award for Coverage of Mental Health Research. Khamsi’s medical reporting has appeared in a wide range of publications including The Economist, Scientific American, Slate, Popular Science, New York magazine, and The New York Times. She has many years of science reporting experience, including working for The New Scientist and Nature and serving as deputy editor of The Baltic Times.

The Alvarez Award presentation and address are scheduled for the afternoon of October 6.

The 2016 McGovern Award recipient is Kevin Pho, MD, a board-certified internal medicine physician and founder of KevinMD.com, which Forbes called a “must-read health blog.” The McGovern Award is presented to a member or nonmember of AMWA to recognize a preeminent contribution to any of the various modes of medical communication.

The social media analytics company Klout named Pho the Web’s top social media influencer in health care and medicine, and, in 2009, CNN named @KevinMD one of its 5 recommended Twitter health feeds. His dual perspectives as a practicing physician and a health care social media leader highlight his unique social media journal. Pho is co-author of the book Establishing, Managing, and Protecting Your Online Reputation: A Social Media Guide for Physicians and Medical Practice, and his opinion columns regularly appear in USA Today, where he is a member of their Board of Contributors. He has also written for CNN.com and The New York Times’ Room for Debate section. His opinion pieces highlight the challenges doctors face, ranging from the primary care shortage to the epidemic of physician burnout. Transforming his social media presence into a mainstream media voice, he continues to share his story with audiences nationwide on TV and at national conferences and meetings.

The McGovern Award presentation and address are scheduled for the morning of October 8.

ANNUAL CONFERENCE COMMITTEE

A lot of planning activities go on behind the scenes to organize the annual conference. The team of dedicated AMWA volunteers that make up the AMWA Annual Conference Committee continue to work hard to bring you offerings that are in line with what members have requested. Although the deadline for conference proposals has passed, we always welcome suggestions. Please send your emails to ymikyas@kapconsult.com and stay tuned for more conference-related information coming your way.
During the past several months, much of the AMWA leadership’s focus and energy has gone into the Strategic Planning Initiative (SPI). This project, under the direction of President-Elect Lori Alexander (affectionately nicknamed “the SPI Master”), is intended to determine what priorities AMWA should set in order to best serve both its members and its mission “to promote excellence in medical communication and to provide educational resources in support of that goal.” In the previous issue of the Journal, 2014–2015 AMWA President Karen Klein described the process by which SPI has gathered information from an ever-widening circle of stakeholders, from the Executive Committee and Board of Directors to many other medical communicators both inside and outside of AMWA.

One of the most recent efforts in this process was a survey sent to medical communicators in many different fields. The 446 responses received are being used to inform the next steps of SPI—and, ultimately, the direction AMWA will take in the coming years.

Who Took the Survey?
Respondents were 81% members, 14% former members, and 5% nonmembers. Most were between 30 and 59 years old (30 to 39 [23%], 40 to 49 [27%], or 50 to 59 [26%]); only 5% were under 30. Nearly half (49%) had worked in medical communication for 10 years or more. When asked about their primary work setting, 40% described themselves as self-employed or freelance; the next most common settings were pharmaceutical/biotechnology company (14%), medical writing/communication agency (9%), and university or medical school (7%). The majority of respondents described their chief role at work as writer (29%), editor (13%), or writer and editor (33%). With regard to respondents’ primary area of interest at work, the most common choices were scientific publications (27%), regulatory writing (20%), medical research (12%), and continuing education (9%).

What Did We Learn?
When asked about their reasons for joining AMWA, respondents’ answers focused on 3 benefits: education, professional development, and networking opportunities (Table 1). Likewise, when asked what about AMWA they have valued the most, 51% of respondents chose “professional development or educational program offerings,” and 27% selected “opportunities to network with other professionals in the field.” Regarding what they thought was AMWA’s most important accomplishment, respondents most frequently chose “delivering high-quality education, either in person or through self-study” (38%). The second and third most popular choices were “advocating for best practices in medical communication through the development of the code of ethics and position statement on the contributions of medical writers to scientific publications” (20%) and “providing opportunities for medical communicators to network with other professionals in the field” (20%).

What Do They Want to Learn, and How?
Because education is central to AMWA’s mission, the survey included questions about which topics respondents would most like to see covered in an AMWA education course. Of the 23 possible answers, “advanced medical writing skills” was the most common first choice (11%) and second choice (12%). (Other common first, second, and third choices included “freelance business methods and issues” and “professional development, eg, career growth, coaching/mentoring, negotiating salary.”) Also, when respondents were asked what they saw as the greatest opportunity for AMWA to provide value to the medical communication profession over the next 5 years, the most popular by far of the 5 answer choices was “high-quality education for advanced medical writing” (44%).

Another question regarding education asked what delivery method respondents preferred. The most popular choice was “e-learning (online, on-demand, at your own pace)” (39%),
followed by “blended (combination of face-to-face and online)” (32%) and “face-to-face conference or training course” (20%).

What Do They Want From AMWA in the Future?
Two items asked respondents to choose an area that, if AMWA improved or expanded upon it, would make them more likely to join AMWA or to renew their membership. The most popular first choice was “access to online professional development or educational activities” (31%), followed by “resources to connect members with potential clients or employers” (18%) and “access to templates and samples to help me do my job” (17%). These 3 items were common second choices, as well (20%, 21%, and 15%, respectively).

Table 1. Respondents’ Primary and Secondary Reasons for Joining AMWA

<table>
<thead>
<tr>
<th>Answer Option</th>
<th>Primary</th>
<th>Secondary</th>
</tr>
</thead>
<tbody>
<tr>
<td>Access to member discounts</td>
<td>7 (1.7%)</td>
<td>8 (1.9%)</td>
</tr>
<tr>
<td>Access to AMWA products/services</td>
<td>4 (1.0%)</td>
<td>19 (4.6%)</td>
</tr>
<tr>
<td>Career development/resumé</td>
<td>55 (13.2%)</td>
<td>37 (8.9%)</td>
</tr>
<tr>
<td>AMWA certificate program</td>
<td>36 (8.7%)</td>
<td>48 (11.6%)</td>
</tr>
<tr>
<td>Educational opportunities</td>
<td>64 (15.4%)</td>
<td>58 (14.0%)</td>
</tr>
<tr>
<td>Employer encouraged or required</td>
<td>16 (3.8%)</td>
<td>9 (2.2%)</td>
</tr>
<tr>
<td>Employment opportunities</td>
<td>18 (4.3%)</td>
<td>18 (4.3%)</td>
</tr>
<tr>
<td>Freelance/contract opportunities</td>
<td>31 (7.5%)</td>
<td>38 (9.2%)</td>
</tr>
<tr>
<td>Networking opportunities</td>
<td>36 (8.7%)</td>
<td>85 (20.5%)</td>
</tr>
<tr>
<td>Professional development</td>
<td>134 (32.2%)</td>
<td>69 (16.6%)</td>
</tr>
<tr>
<td>To keep up with the industry</td>
<td>9 (2.2%)</td>
<td>20 (4.8%)</td>
</tr>
<tr>
<td>Other (please specify)</td>
<td>6 (1.4%)</td>
<td>6 (1.4%)</td>
</tr>
</tbody>
</table>

The 3 most popular answers to each question are in bold.

What Is AMWA Doing About It?
In response to these findings (as well as those of earlier phases of SPI, and other forms of member feedback), AMWA has begun several initiatives, including the following:

- The preference for e-learning has spurred AMWA to put substantial emphasis on developing offerings for Online Learning (www.amwa.org/online_learning). We are also examining ways to put more of our existing educational material into a user-friendly online format.
- To increase all members’ opportunities for networking, AMWA is launching its Engage platform, which will provide listserv-like connectivity among all members. Members will also be able to upload documents (eg, templates and samples) that they want to share with others.
- Because of respondents’ interest in advanced medical writing skills, AMWA’s Education Department has created an Advanced Topics Working Group to find out what sort of advanced skills AMWA’s mid-career and advanced-level members are interested in learning.

These efforts are just the first steps in a larger process of aligning AMWA’s activities with the needs of its members and of the medical writing profession. Exciting times are ahead!

AMWA’s First Class of Certified Medical Writers

AMWA’s Medical Writing Certification program has been years in the making, involving careful planning, development of policies and procedures, and the creation of a certification examination. At long last, in January, AMWA announced its first group of individuals to be granted the Medical Writer Certified (MWC) designation.

Medical writers who hold the MWC credential have demonstrated that they possess medical writing-related skills such as gathering, evaluating, organizing, interpreting and presenting information on health and medicine and familiarity with best practices and ethical standards. The first Medical Writing Certification examination took place on September 30, 2015, in San Antonio, Texas, before the opening of AMWA’s annual conference.

The following medical writers have earned the credential of Medical Writer Certified (MWC):


Upcoming Medical Writing Certification examination opportunities include:

- **April 15, 2016**, before the AMWA Delaware Valley Chapter 20th Annual Princeton Conference, Princeton, New Jersey
- **October 6, 2016**, before AMWA’s Medical Writing and Communication Conference, Denver, Colorado.

Information about applying for the certification exam and study materials are available at www.amwa.org/certification.
It is with great sadness that we report the death of Guy Whitehead, PhD, editor emeritus at the Mayo Clinic. Those of us who are long-time members of AMWA knew him well and benefited from his teaching, his generosity, his gentle and humble personality, and his friendship.

Because Guy became a member of AMWA in 1973, many others knew him much longer than I did. However, Guy and I had a special bond: At the time we met, I was living in Lexington, Kentucky, and had taught at the University of Kentucky for several years; Guy had earned his bachelor’s degree at Eastern Kentucky University in Richmond, just a few miles down I-75 from Lexington, and, after earning his PhD at Vanderbilt, had also taught at UK for many years. We had many enjoyable conversations about our Kentucky experiences.

Guy taught 39 credit workshops for AMWA between 1976 and 2000. I first met him when I took his workshop Sentence Structure and Patterns at the annual conference in Atlanta in 1993. One of the most valuable things I learned from this workshop is the importance of writing from the reader’s viewpoint, a fact that, as an English major, I probably should have learned previously but had not. That one technique has changed my own writing style and has become one of my favorite teaching topics. On the next page you can read many tributes to Guy from AMWA members who knew him and participated in his workshops. All of us remember Guy’s passion for his subject matter, his courteous but compelling presentation style, and his gracious and approachable demeanor. Guy received the Golden Apple Award for outstanding workshop leadership in 1989; his co-recipient that year was Edie Schwager. What a magnificent duo!

In 1983, Guy was named a Fellow of AMWA. In 1986, he received the President’s Award; this award is bestowed each year by AMWA’s president and recognizes a member who has made outstanding contributions to AMWA but has never served on the Executive Committee. In 2004, Guy received AMWA’s highest honor, the Swanberg Award. His award address was titled “How I Learned to Edit Medical Manuscripts.” You can read this address in the collection of past issues of the journal on AMWA’s website (www.amwa.org; AMWA J. 2004;19[4]:162–166). I highly recommend it as great reading.

In 2000, Guy decided that it was time to step down from his position as a workshop leader. I was deeply honored when he asked me to take over the leadership of Sentence Structure and Patterns and gave me his original handwritten materials. I still have them, and I cherish them because I cherished Guy and his friendship. Several others have also led this workshop, and the success that any of us may have achieved with it is due to Guy and his example.

Guy passed away on January 14, 2016, surrounded by his family. However, his memory lives on in those of us who knew him, spent time with him, and enjoyed his thoughtfulness and humor. He was, in the very best sense of the word, a gentleman, and I am grateful to have known him, to have learned from him, and to have been asked to write this tribute to him. He will be greatly missed.

—Flo Witte
Past President of AMWA (2003–2004)
Past Presidents of AMWA

Remember Guy Whitehead

In one of my former lives, I was a post-doc at the Mayo Clinic. That year the Clinic offered a writing class led by Guy Whitehead and Bernie Forscher. It was my first formal training in medical writing. How fortunate I was to have that introduction to a lifelong passion. From that time and on through my AMWA experience, Guy was a teacher, mentor, role model, friend, and all-around classy gentleman. I am grateful that he was a part of my professional life.

—Martha Tacker, 1984–1985

Guy was a wonderful person and a real gentleman. I took his workshop early in my career and learned so much.


By the time I got to know him, Guy’s image was as one of those distinguished “elder statesmen” of AMWA. That veneer would occasionally slip, and I found him to be a lively, good-humored colleague—willing to commiserate on any number of topics. He was a model teacher and his AMWA legacy will endure.


Guy was a magnificent human being in every respect. At the risk of sounding trite, I would have to call him a gentleman and a scholar. Modest, humble, and unpretentious, he was an inspirational force in AMWA. His workshop on sentence structure blew me away. The excellent content as well as his careful, insightful, and encouraging comments on the homework made his workshop one of AMWA’s finest educational offerings. His generosity in sharing his workshop materials helped many future workshop leaders, as others have mentioned. We have all lost a wonderful friend and colleague.

—Lynn Alperin, 2000–2001

At one point, I was asked to teach an additional section of Sentence Structure and Patterns. To prepare for this role, I first attended Guy’s class, and the positive responses he provided on the homework would have motivated any student to do his or her best. Guy then provided me with his materials and helped me to understand exactly what he had been thinking when he developed the workshop. He was a consummate teacher and a delightful mentor.

—Helen Hodgson, 2001–2002

Edie Stern introduced me to Guy Whitehead and his lovely wife. His course helped me to understand not only sentence structure, but how to form outlines and tables. He probably didn’t intend to include the latter, but it followed quite naturally. At a reception after the class, I must have gushed my appreciation. Guy sent a note saying that he apologized for basking so unabashedly in my admiration. Years later, Guy was selected as the Swanberg Award recipient, and I was honored to sit at his table. What wonderful memories!

—Susan Siefert, 2005–2006

Guy taught the first workshop I took at an AMWA conference and is part of what made me want to join the organization. If members as intelligent and experienced as Guy were willing to share their knowledge, I knew this was the place I could learn how to be a medical writer!

—Barbara Snyder, 2011–2012
As I enter my second year as education administrator, I am excited by the changes that have already occurred and are continuing in AMWA’s education program. It is evolving to continue meeting the needs of medical communicators, who are now more connected than ever.

Through our recent acquisition of a learning management system (LMS), we are now delivering on-demand and interactive learning activities to your mobile devices and computer. AMWA Online Learning comprises interactive learning activities, live and on-demand webinars, and resource documents. Our interactive learning activities combine the knowledge of AMWA’s subject matter experts with online learning tools to bring AMWA’s education to you. “Ten Characteristics of Effective Tables and Graphs” was the first activity we deployed, and “Harness the Power of Endnote: Manage Your Library’s Data” was released in January 2016. Be sure to check AMWA Online Learning throughout the year because we have a variety of activities in development.

Our webinar series is entering its third year. Some webinars are free as an AMWA member benefit; other webinars are accessible to AMWA members and nonmembers for a fee, with AMWA members receiving discounted rates. Don’t worry if you missed the live program. One of the features of AMWA Online Learning is that we are now able to archive all of our live webinars for viewing at a time that is convenient to you. For those who need continuing education (CE) credits, including those individuals who recently received AMWA’s new MWC credential, AMWA Online Learning allows learners to more easily see those activities that can be applied toward their CE credits and also provides ongoing access to their educational records to track their progress.

A documents portal in AMWA Online Learning provides access to 12 Pocket Trainings, which are mini tutorials on specific topics created by AMWA members for AMWA members. Recent additions to the Pocket Trainings include How to Find the Best Journal for Your Scientific Manuscript by Agnella Izzo Matic, PhD, and Writing for Medical, Regulatory, and Legal Review by Sarah Zimov, PhD. While most of the Pocket Trainings are PDFs, we do have a podcast by Julie Munden on Who’s Who and What’s What at MedComms.

Our Self-Study Modules continue to be valuable, enduring resources and provide the opportunity to earn an Essential Skills Certificate without attending in-person workshops. For convenience and affordability, the ES Express Package allows learners to purchase the 7 individual modules and includes enrollment in the certificate program.

Finally, the hallmark of AMWA’s Education Program has been and continues to be the in-person workshops. These are 3-hour intensive experiences enabling learners to actively engage with AMWA’s workshop leaders and other participants and are offered at chapter conferences as well as the annual conference. Planning has already begun for the AMWA 2016 Medical Writing & Communication Conference in Denver, Colorado, and I am excited to announce that our workshops will now take place before and after the conference programming. Thus, attendees will no longer have to choose between attending an open session or a workshop. For those enrolled in our certificate program, you could take up to 4 workshops in Denver—earning half of your credits toward a certificate.

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As a new benefit for AMWA members, Medical Communication News officially launched in November 2015. Twice monthly, industry news is emailed to AMWA members. Archived issues are available at www.amwa.org/medcommnews.
The Malaria Project: The U.S. Government’s Secret Mission to Find a Miracle Cure
Karen M. Masterson


From the seaports of the American South in the 18th and 19th centuries to the Panama Canal’s excavation in the early 20th century, malaria has long been a force to reckon with—never more so than in the African and Asian battlefields of World War II. The Malaria Project: The U.S. Government’s Secret Mission to Find a Miracle Cure by Karen M. Masterson provides new details about the relentless race against malaria in the 1940s.

Masterson, a former political reporter who turned to medical writing and spent 3 months at the Centers for Disease Control and Prevention learning the science of malaria, has produced a page-turning account of a pivotal time in world history. What is new about this story—and helps make the narrative so gripping—is her incorporation of information from previously classified files at the US National Archives. Letters, reports from scientific meetings, and government memoranda document how antimalarial drugs were created and tested at a breakneck pace. By 1942, American soldiers were so incapacitated by malaria that one-for-one substitutions of entire divisions were standard in military planning. The US government responded by organizing what the author terms a “Manhattan Project–style” program to combat malaria.

In perhaps the most compelling sections, Masterson describes how candidate compounds were tested in men incarcerated in several US prisons and in syphilis patients with brain damage from untreated or end-stage disease. While such practices are shocking to current-day sensibilities and are in violation of today’s research protocol requirements, the author presents the context in which these experiments occurred to help readers better understand why the experiments were done.

Time was of the essence, readers quickly learn, as the author describes the frustrations of multiple dead-ends and promising compounds gone awry. For example, one compound, quinacrine (Atabrine), was effective against malaria, albeit with nasty side effects, like turning the skin bright yellow. But servicemen refused to take the drug because it was rumored to cause impotence. Eventually, General George C. Marshall wrote a furious memo requiring all US officers in Northern Africa and Asia to monitor firsthand every soldier taking—and actually swallowing—the daily dose.

Masterson also deftly handles many subthemes throughout the book including: how a dawning appreciation for medical ethics eventually eliminated malaria experiments in humans, how the infrastructure created to fight malaria eventually became the National Institutes of Health, how pharmaceutical companies were involved in the search for antimalarial agents, and how current malaria-control programs in endemic countries work (or don’t—even today, two African children die from malaria per minute).

The Malaria Project shows Masterson’s impressive grasp of parasitology, tropical medicine, and infectious diseases. The book is well-indexed and clear without being condescending. Readers also will meet many larger-than-life colorful individuals; their stories provide zip and human interest throughout. For military history buffs, nonfiction enthusiasts, or those seeking a good explanation of the vector-host relationship, this book will reward your interest with great satisfaction.

—Karen Potvin Klein, MA, ELS

Karen (immediate past president of AMWA) wrote her master’s thesis on Walter Reed and yellow fever and remains intrigued by the intersection of history and tropical disease.
Cancer—the ubiquitous enemy of clinicians worldwide—touches innumerable people through diagnoses in self, family, friends, neighbors, and colleagues. After You Hear It’s Cancer: A Guide to Navigating the Difficult Journey Ahead is a new addition to the literature available for this readership, but for many may miss the mark. The book was written by John Leifer, a retired health administrations business executive, with insights from his radiology oncologist wife, Lori Lindstrom Leifer; the book developed as a result of the couple’s own brush with cancer.

They present their story amidst other US adult cancer survivors’ experiences to share an inside viewpoint of essential patient knowledge from a unique patient-clinician perspective. The authors also hope to ease other people’s entry into and pathway through the complex health care oncology system with real-life examples. But their approach lacks the meaningfulness I was hoping to find.

The book reveals quickly that Lori was diagnosed with early-stage breast cancer that did not require chemotherapy, radiation, or mastectomy. After the short prologue, the book’s remaining narrative is separated into 3 broad sections: part I discusses the diagnosis and treatment planning stages; part II, active treatment; and part III, considerations after initial therapy ends. Each section contains 5 to 7 clearly titled chapters that address important aspects of living with a cancer diagnosis. For example, the active treatment chapters individually highlight pain control, treatment costs, nutritional needs, and more. The distinctions between chapters and sections are logical and walk readers through various cancer journeys, from early patient experiences, through treatment and into recurrence or hospice stages. The book closes with end notes for each chapter and topical resources.

The first 2 sections incorporate useful advice about details of early cancer care; many passages describe patient resources that are freely available from the National Cancer Institute or the American Society of Clinical Oncology. The third portion—on post-treatment challenges, including recurrence, late treatment options, hospice, and financial drain—is shorter and vaguer. Lori and her caregiver husband have not (yet) experienced costly treatments (or financial assistance programs) or late complications. Although the authors feature other patients with these issues, the shift from Lori as patient to Lori as clinician was jarring. For a more balanced memoir approach, the authors could have shared their own fears about future concerns; conversely, they could have condensed their personal story more poignantly as an extended prologue and featured other patients more significantly.

The authors clearly had good intentions—to fill a knowledge and compassion gap in cancer literature—but they perhaps overshot. From the first chapter, Lori and her husband are unrelatable—and likely so for many others as well. For example, Lori diagnoses herself and calls her doctor (at home) for a same-day biopsy result, with no mention of insurance coverage.

As a daughter of 2 parents with cancer diagnoses in the past 2 years, and formerly a practicing clinician (pharmacist), I do not feel that everyday patient experiences mimic Lori’s carefully presented story of her diagnosis and treatment. In fact, my mother’s experience with the same type and stage of cancer differed dramatically: diagnosis took many weeks to confirm, and the numerous appointments, exams, and visits to specialists only confused and worried her. Surgery was months later; afterward, insurance issues extended the burden. Although the cancer experience for these authors must have been scary, the lack of emotional connection in the book was palpable to me, and I was not even a cancer patient.

The authors aim for a conversational approach that generally uses lay language; however, end-of-chapter bulleted summaries, or patient to-do checklists, would be a wonderful touch to make this book truly useful. Overall, I
I first picked up Richard MacManus’s *Health Trackers: How Technology Is Helping Us Monitor and Improve Our Health*, driven by a curiosity to find ways to monitor my own health and those of my loved ones. Today’s market is flooded with health-tracking technologies that enable monitoring steps, heart rate, sleep quality, and more. While some of these devices have become household names, the fast pace of new products to choose from can be overwhelming. In addition, society at large may not be aware of the diversity of health-tracking technologies available and the philosophies driving the way many people now want to manage their health.

MacManus’s book caters to readers interested in health tracking by providing an overview of tools, such as step counters (Fitbit), digital body weight monitors (Withings scale, Weight Watchers programs), nutrition and calorie monitors (MyFitnessPlan), health dashboards (TicTrac), microbiome analyzer (uBiome), personal genomics (23andMe), and brain scans (Neuroprofile; technology in development). The book captures the early shaky steps of health-tracking entrepreneurs who sought to give palpable forms to mere concepts. From narrations of the development history to personal-user stories, each chapter brings to life the applicability of self-tracking devices and apps.

*Health Trackers* explains that self-tracking has the potential to change health care from a reactive to a proactive process. An individual who monitors various aspects of his or her health may better manage existing conditions and even prevent the onset of certain diseases. Patients can now give their physicians fairly accurate data on their health, which can be correlated with other health metrics. As MacManus illustrates, for some physicians who have been early proponents of self-tracking by patients, “the modern doctor-patient relationship….is more of a collaboration than a consultation. The doctor is still the medical expert, but she is relying on the patient to take more responsibility for [his or her] healthcare.”

Alongside the bright promises of health-tracking technologies, there exist current challenges that demand mention. Self-tracking tools merely allow the capture of health data; MacManus highlights that a critical step is the translation of data into actionable medical information. The medical knowledge of physicians is indispensable when it comes to data interpretation. Moreover, some fields, such as personal genomics and microbiome analysis, ultimately depend on the advancement of biomedical research to uncover the usefulness of health data. How far medical society will integrate self-tracking technologies into routine practice, therefore, remains to be seen.

Two key factors that self-tracking technologies rely on are the self-motivation of the person doing the tracking and smooth user experience. The book touches upon some creative ways today’s entrepreneurs are envisioning improvements.

*Health Trackers* is a timely and insightful read that demonstrates how technology can increase our awareness of our bodies. The book also sends a clear message to the medical society on the benefits of self-tracking for health care management. MacManus’ own journey through diabetes and self-tracking has spiked my interest to learn more about the value of these technologies in clinical practice.

—Ananya De, BPharm, PhD

Ananya is a medical writer in Winchester, Massachusetts.
Do you specialize in freelance medical writing in any particular way, such as by therapeutic area, industry, or types of projects?

There are good reasons to specialize in certain types of projects and/or therapeutic areas—and good reasons not to specialize. In general, if you’re a new freelance, you should focus more broadly to attract more clients. As you gain experience, you can narrow your focus, which is what I did.

I’ve always focused on medical marketing communications, but that’s a broad area of medical writing rather than a specialty. Early on, I worked on many types of writing (condition/disease descriptions for books and health websites, newsletter and magazine stories, Web content, annual reports, and other reports) for different audiences (consumers and patients, physicians, and others) and clients (health websites, publishers, hospitals, medical communication agencies, foundations, and associations). As I gained more experience and found that I loved writing for consumers and patients, I began to target my marketing to hospitals and associations that focus on particular diseases. While I still do other types of medical marketing communications, more of my work these days is magazine, newsletter, and Web content for consumers and patients, with hospitals and associations as my clients. I’ve always written about many therapeutic areas.

Benefits of specialization include:
- Deep knowledge of your specialty
- Ability to predict trends and speak intelligently about them when pitching new clients
- Great contacts
- Frequent recommendations from colleagues and clients who know about your specialization

Disadvantages of specialization include:
- Difficulty expanding beyond your current specialty
- Fewer opportunities for diversification, which is very important in freelancing
- Being perceived by colleagues and clients as doing one thing
- Lots of competition for limited projects
- Steep learning curve for new therapeutic areas or types of medical writing

—Lori De Milto

During my long freelance medical writing career, I specialized in working directly with many pharmaceutical companies or with their agencies. Most of my work was in the areas of continuing education for physicians, nurses, and pharmacists and in the preparation of home-study modules for pharmaceutical sales training, both domestic and international.

Specialization in these areas enabled me to keep abreast of the many changes in rules and regulations issued by the Food and Drug Administration (FDA) and other governing bodies. When working with new product managers, I helped them navigate the criteria needed for many different pharmaceutical products under their management. By specializing, I provided extra value and expertise to my clients and became an integral part of the group of talented folks brought together for each project.

Although specialization had many positives in my career, it also had a few drawbacks. The many mergers and acquisitions within the pharmaceutical industry from the 1980s on often meant that the folks with whom you worked were either out of the loop after the merger or let go during the reorganization. Sometimes, following a merger of 2 strong pharmaceutical companies, my involvement was curtailed and the work I had been doing was awarded to those employed by the acquiring company. “Win some/lose some” became the common buzzword among freelance pharmaceutical writers.

Luckily, in one instance, I was able to follow one very good client during his career with 5 different pharmaceutical companies, all the result of mergers and acquisitions beyond his control.

In today’s world, I am not sure that a new freelance writer could prosper and grow following my career path and those of many others. While I totally support specialization, freelance writers today must clearly look at their own strengths, abilities, and interests plus the demands in the marketplace to determine their career directions. Active membership in AMWA and taking part in the many educational opportunities will expose freelance writers to the many pathways for success.

—Elizabeth L. Smith
Because of extensive experience as an employee in the pharmaceutical/biotech industry, I opted to specialize by industry rather than by therapeutic area or project type when I started my own business. Of course, this has turned out to be a very broad category, since it includes medical communications, sales training, continuing medical education, regulatory affairs, marketing communications, patient education, public relations, and more—essentially, any kind of writing and communication that takes place in the industry. It also includes nearly all media and a multitude of therapeutic areas. So I have not focused on a single medical specialty, target audience, or medium.

There are definite advantages to specializing by industry. The chief advantage, of course, is the acquisition of an in-depth understanding of your industry, whether it is pharma/biotech, publishing, managed care, nonprofit associations, or other sectors. In the pharmaceutical/biotech industry, this understanding includes:

- Familiarity with the process of drug discovery and development, from the bench to the clinic, then on to marketing, promotion, and sales
- Knowledge of the myriad regulations guiding the industry, both in the United States and worldwide
- Understanding clinical study design and implementation from Phases 1 through 4, as well as the regulations for reporting and submitting results to the FDA
- Understanding the functional relationship between regulatory affairs, clinical research, medical affairs, and marketing/sales (which means you know where to find resources others may overlook)

Specializing by an industry as broad and comprehensive as pharma/biotech brings constant challenges and continual learning about new medical and therapeutic areas, various target audiences, and new media. However, while such versatility is extremely useful during a difficult economy, one disadvantage is the risk of becoming too general, a jack-of-all-trades but master-of-none. As well, too much learning curve on too many topics can, at times, become a bit taxing on the brain.

Clearly, broader experience expands your prospective client base. In recent years (since the 2008 economic slump), my projects have included writing grant applications; rewriting or editing personal statements for physicians applying for residency; reviewing, critiquing or editing graduate school theses; writing hospital website content, developing and writing policies and procedures for managed care and nonprofits; editing medical textbooks; and consulting in the development of nonprofit organizations. Yet in spite of this fabulous flexibility, I suspect that a more focused specialization streamlines the marketing process and may be very satisfying as well. Were I starting out again today, I might specialize and become an expert in 1 or 2 diseases, or perhaps focus on a single medium. Well . . . maybe.

—Cathryn D. Evans

Is it easier to find business if you are a freelance medical editor or a freelance medical writer?

I am not sure if it’s easier to find work as an editor than as a writer, but I have had no difficulties keeping a full load since I started my medical editing business in 1997, with the exception of August 2008 when the economic downturn began to hit the entire country. Otherwise, I have had plenty of work.

I find business mostly through word of mouth, by recommendations from work colleagues, and from my thorough LinkedIn profile (www.linkedin.com/in/melissabogen). Although I do not have my own website, my LinkedIn profile provides a substantial Web presence. LinkedIn has provided me an opportunity to showcase my portfolio and some of my talents; for example, I have posted files on LinkedIn that people can review and download.

Active membership in AMWA and other professional organizations such as BELS (www.BELS.org) and The Editorial Freelancers Association (www.the-efa.org) have been essential to broadening my client base. Not only have I gained competence by taking classes, but I have also gained confidence and networking no longer unnerves me. Volunteering—particularly in AMWA—is a great way to meet people and stay abreast of trends in medical publishing. And if clients want a writer, I can refer them to AMWA members with whom I have worked.

—Melissa L. Bogen

Although I am not a medical editor, I believe I am qualified to answer this question because my freelance company does a lot of editing work that I subcontract to medical editors. All of the clients with whom we work—medical education companies, medical communications companies, and medical advertising
agencies—rely on the important skills and talents of professional medical editors. Therefore, in my experience, there are just as many opportunities for freelance medical editors as there are for freelance medical writers—not necessarily more, but certainly not less!

With this in mind, it is also just as important for freelance medical editors as freelance medical writers to have strong marketing muscles. Promise what you’re going to deliver and deliver on what you promise. Always deliver on time, on target, and on budget. Promote your freelance business through a website, social media, and the AMWA Freelance Directory. And elevate your visibility as a leader by presenting an open session at the annual conference or a chapter conference, developing a workshop or a webinar for AMWA Online Learning, and engaging with AMWA as a volunteer at the chapter or national level. All these things will build your freelance brand and help make you successful.

—Brian Bass

What tips to do you have for a new freelance trying to build a portfolio of samples?

Prospective clients expect to see writing samples before they hire you. But don’t despair if you don’t have samples or don’t think you have enough samples. There are several ways to showcase your writing ability and develop great samples. Your LinkedIn profile, when done right, is a great writing sample, as is your website.

If you don’t have any (or enough) samples from paid work that you can post or link to, develop some unpaid samples. Ways to do this include writing for the AMWA Journal or your chapter’s newsletter, writing LinkedIn Pulse blog posts, and writing for other groups you belong to or other blogs. Choose a topic that’s relevant to your work and target clients. You can use assignments from some AMWA workshops as writing samples too.

Develop “spec” samples to show that you can do work you haven’t done before. A spec sample is modeled after a type of writing you want to do, such as a journal article, CME program, or a hospital Web page. Review good existing samples and then develop a similar sample for a pretend client. If the project is big, develop a sample for part of it. Clearly label this as a spec sample.

Also, you may already have writing samples that you don’t think of as such. Many scientific medical writers are surprised to learn that the journal articles they wrote as bench scientists or graduate students are writing samples. Think about what you’ve already written that you can use as a writing sample or revise into a spec sample.

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—Lori De Milto

In medical communications as in other types of businesses, it's hard to get a job without experience and hard to get experience without a job. If you’re new to freelancing, you probably already have plenty of work experience as a medical communicator to help fill out your portfolio. If you’re new to both freelancing and medical communications, you have a much tougher road ahead. In either case, I have a few tips to offer to help you build your portfolio of samples.

Tip 1: DIY. If you want to show clients you’re capable even though you don’t have the experience to prove it, do it yourself. For example, if you want to show that you can write manuscripts, pick a topic in a therapeutic area in which you’re comfortable, conduct the literature searches, procure and review the references, and write a review manuscript. There’s nothing stopping you from applying this same strategy to writing a promotional brochure, a product monograph, a PowerPoint presentation, a video script, website content, or a consumer brochure or article.

Tip 2: Don’t DIY. If you do Tip 1, I also suggest you invest in a professional medical editor to make sure that whatever document or piece you produce is suitable for presentation to prospective clients. This is one thing you don’t want to do yourself, especially if you’re also an editor. You’ll invariably miss details an objective reviewer will spot and not hesitate to bring to your attention.

Tip 3: Keep it confidential. Many professional medical communicators lack hefty portfolios of samples not because they lack work experience, but because it would be unethical to show them. Confidentiality and strict ethical practices are vital in our business, and actions speak louder than words, so market your ethical principles! If a potential client asks you to show a sample of work that is protected by a confidentiality agreement or otherwise sound ethical principle, respond that as much as you want to prove you can do the work, your ethical commitment prevents you from showing relevant samples that could jeopardize your clients’ businesses, and point out that your work for them would be protected by the same commitment to high ethical standards. Then, offer to put the person in touch with one of your clients (someone who has already agreed to give you a recommendation, and what
happy client wouldn’t want to help you?) who can speak for your relevant experience, expertise, and ability. In my experience this works every time!

**Tip 4: Throw a client a bone.** I never recommend working for free, but one can never say never. If you’re between a rock and a hard place, or if you really, really want an opportunity to break into a new kind of writing and pick up a sample for your portfolio along the way, ask one of your clients or a prospective client to give you an opportunity to show them what you can do by offering your services at a one-time-only reduced rate.

**Tip 5: Ask a client for a bone.** I’ve found that the best way to branch out comes from clients who already trust you. When a need arises that isn’t obviously in your skill set, clients are still more likely to give the project to a writer they know and trust than to someone untried and unproven, particularly when the stakes are high. Now, you can wait for an opportunity to arise to build your portfolio, or you can ask for it. Ask a client whether they have a different kind of project than those you’ve done in the past, but perhaps in the same therapeutic area so you have some familiar ground.

—Brian Bass

It is important to keep a portfolio of samples to show potential clients. A portfolio can contain a variety of samples, including blog contributions, articles for local and national AMWA newsletters and journals; journal articles; medical conference posters; newspaper articles; newsletter articles; and items posted on LinkedIn Pulse.

Most of the samples above will be from unpaid volunteer work, but they are worth the time investment since they serve as effective writing samples. Sometimes a client will want a sample that is protected by confidentiality agreements. It is not possible to provide those without the appropriate permissions. In those cases, I have asked some of my older and trusted clients if I can use some of the work as samples of my writing. In some cases if the work was done several years ago they usually agree. Any work that is published on the Web or in print is especially easy to provide as samples.

—Ruwaida Vakil

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Do you have a question for the Freelance Forum? Send it to JournalEditor@amwa.org

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What Does Therefore Mean?

By Laurie Endicott Thomas, MA, ELS

Recently, I wrote something that was copyedited by a poorly trained editor. She caught a few typos, for which I was grateful. Unfortunately, she introduced more errors than she fixed. The most infuriating thing that she did was to add the word *therefore* inappropriately in numerous places. Wherever I had 3 or more consecutive statements of fact about something, she added *therefore* at the beginning of the last statement, just as you would put the word *and* before the last item in a list that you’ve written out in a sentence. I asked her why she kept adding *therefore*. She said it was “for flow.” I started to explain why the added *therefores* made no sense, but then I realized that logical arguments are probably not going to impress someone who does not understand what *therefore* means.

*Therefore* means “for that reason, because of that, on that ground, or to that end.” In other words, it suggests that a sentence or clause is the conclusion of an argument. In logic, an argument is a set of statements (premises) given to support a conclusion. Consider the following example of the classic syllogism, which is a type of logical argument. Notice that both of the premises and the conclusion are complete sentences:

- Major premise: All men are mortal.
- Minor premise: Socrates is a man.
- Conclusion: Socrates is mortal.

A logic textbook might present an argument with the premises and conclusion all neatly labeled and on separate lines. In ordinary text, however, you are more likely to see it written like this:

• All men are mortal, and Socrates is a man; *therefore*, Socrates is mortal.

Notice that the premises have become clauses within a larger sentence. Note also that the word *therefore* serves as a conjunctive adverb that ties the conclusion to the premises. In this sentence, *therefore* thus serves as a *conclusion indicator*. It clarifies the logical relationship between the first 2 independent clauses and the final independent clause of the sentence. It means that the writer feels that we should accept the truth of the last clause of the sentence because we accept the truth of the first 2 clauses.

You might also see the same syllogism written out as follows:

- **Because** all men are mortal and Socrates is a man, Socrates is mortal.
- Socrates is mortal **because** all men are mortal and Socrates is a man.

In those examples, the word *because* serves as a premise indicator. The Box provides a list of some common premise indicators and conclusion indicators. They alert you to the possibility that the author is making an argument, and they help you identify the premises and conclusion of the argument. Once you have identified the premises and conclusion of an argument, you can go on to ask important questions. Are the premises true? Do they support the conclusion?

**Box 1. Premise Indicators and Conclusion Indicators**

**Premise Indicators**
as shown by
as/as indicated by
assuming that
because
considering that
follows from
for the reason that
for/for one thing
given that
inasmuch as
on account of the fact that
owing to
seeing that
since

**Conclusion Indicators**
as a result
consequently
demonstrates that
*ergo*
hence
here are some reasons why
it follows that
must be the case that
necessarily
so
therefore
thus
we can conclude that
which entails that
which implies that
which means that
which proves that
As you analyze an argument, you may find that one or more of the required premises are missing. The Greek philosopher Aristotle pointed out that people often leave some of the premises of an argument unstated, usually because those premises would be obvious to an intelligent person. Aristotle called this kind of incomplete argument an enthymeme. The following is a second-order enthymeme because it leaves out the minor premise:

- Socrates is mortal because all men are mortal.

A first-order enthymeme leaves out the major premise, and a third-order enthymeme leaves out the conclusion.

*Because* and *since* are often used as premise indicators. However, not everything preceded by *because* or *since* is a premise of an argument. Sometimes, *because* is used to express cause and effect, rather than to give you reasons for accepting a particular conclusion.

- His car skidded *because* the road was icy on the bridge.

That statement explains *why the car skidded* but doesn’t give you a reason to believe *that the car skidded*. In that sentence, because does not indicate a premise.

The word *since* can serve as a premise indicator, but it can also be used to express timing. *The American Medical Association Manual of Style* says that *since* should be avoided if it can be construed to mean “from the time of” or “from the time that.” In other words, premise indicators and conclusion indicators alert you to the possibility that someone is making a logical argument but they don’t necessarily prove that an argument is being made.

In ancient Greece, educated people understood that one must learn some basic lessons in grammar before one can begin to study logic and that one must study logic before one can begin to study rhetoric, which is the art of persuasive speech. The Romans considered grammar, logic, and rhetoric to be liberal arts. The word *liberal* literally meant appropriate for freeborn men (*liberi*). In contrast, slaves (*servi*) were taught the servile arts, to make them better servants.¹ The purpose of the liberal arts is to teach one to think rationally and express oneself persuasively. Thus, the liberal arts are also appropriate for medical doctors and medical communicators. In 2005, the American Medical Association Press published *Evidence-Based Practice: Logic and Critical Thinking in Medicine* to urge everyone involved in medicine or medical communication to study logic.² Yet before you can begin to study logic, you must brush up on your grammar.

Laurie Endicott Thomas is a medical editor certified by the Board of Editors in the Life Sciences. She is also the author of 3 books, *including Not Trivial: How Studying the Traditional Liberal Arts Can Set You Free* (www.nottrivialbook.com).

**Author contact:** laurie@gorillaprotein.com.

**References**

Calendar of Meetings

American Copy Editors Society
March 31–April 2, 2016
Portland, OR
www.copydesk.org/
national-conference/

Association of Health Care
Journalists
April 7–10, 2016
Cleveland, OH
http://healthjournalism.org/index.php

International Society for
Medical Publication
Professionals (ISMPP)
April 11–13, 2016
National Harbor, MD
www.ismpp.org/annual-meeting

European Medical Writers
Association
May 10–14, 2016
Munich, Germany
www.emwa.org

Society for Technical
Communication
May 15–18, 2016
Anaheim, CA
http://summit.stc.org

Council of Science Editors
May 14–17, 2016
Denver, CO
www.councilscienceeditors.org

National Organization of
Research Development
Professionals
May 23–25, 2016
Orlando, FL
www.nordp.org/annual-conference

Society for Scholarly
Publishing
June 1–3, 2016
Vancouver, BC, Canada
www.sspnet.org

Canadian Science Writers’
Association
June 2–5, 2016
Guelph, Ontario
http://sciencewriters.ca/

American Society for Indexing
June 16–18, 2016
Chicago, IL
www.asindexing.org/

DIA
June 26–30, 2016
Philadelphia, PA
www.diaglobal.org

International Society of Managing
and Technical Editors
August 11–12, 2016
Philadelphia, PA
www.ismte.org

Health Literacy Annual Research
Conference
October 17–18, 2016
Bethesda, MD
www.bumc.bu.edu/
healthliteracyconference/

National Association of Science
Writers
October 28–November 1, 2016
San Antonio, TX
http://nasw.org

Medical Writing &
Communication
Conference
OCTOBER 5-8 | DENVER, CO
Trends and Opportunities for Medical Communicators

AMWA CHAPTER
CONFERENCES
www.amwa.org/chpt_conferences2

The Delaware Valley Chapter
April 16, 2016
Princeton, NJ

Northern California Chapter
April 16, 2016
San Francisco, CA

Carolinas Chapter
May 6, 2016
Chapel Hill, NC

Michigan Chapter
May 14, 2016
Ann Arbor, MI

Indiana Chapter
June 10–11, 2016
Indianapolis, IN

American Public Health
Association
October 29–November 2, 2016
Denver, CO
www.apha.org/annualmeeting

Eighth International Congress
on Peer Review and Biomedical
Publication
September 10–12, 2017
Chicago, IL
www.peerreviewcongress.org
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- Harness the Power of EndNote
- Discover Ten Characteristics of Effective Tables and Graphs
- Watch On-Demand Recordings of AMWA Live Webinars
- Find Resources, Digital Publications, and More
**Meta-analyses: Merits, Limitations, and Application of the PRISMA Statement**

**APPENDIX 1**

Information regarding the 44 meta-analyses included in the analysis assessing the completeness of reporting in accordance with the PRISMA guidelines. The meta-analyses are listed in the order retrieved listed in the PubMed search results. The meta-analyses were published in a total of 38 journals. The median number of meta-analyses per journal was 1 (range 1-4).

<table>
<thead>
<tr>
<th>First Author</th>
<th>Title</th>
<th>Journal</th>
<th>Online Publication Date</th>
<th>Doi Number</th>
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</thead>
<tbody>
<tr>
<td>Deng SB</td>
<td>Adjunctive manual thrombus aspiration during ST-segment elevation myocardial infarction: a meta-analysis of randomized controlled trials</td>
<td>PloS One</td>
<td>November 18, 2014</td>
<td>10.1371/journal.pone.0113481</td>
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<tr>
<td>Cuspidi C</td>
<td>White-coat hypertension, as defined by ambulatory blood pressure monitoring, and subclinical cardiac organ damage: a meta-analysis</td>
<td>J Hypertension</td>
<td>November 17, 2014</td>
<td>10.1097/HJH.0000000000000416</td>
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<tr>
<td>Lampit A</td>
<td>Computerized cognitive training in cognitively healthy older adults: a systematic review and meta-analysis of effect modifiers</td>
<td>PloS One</td>
<td>November 18, 2014</td>
<td>10.1371/journal.pmed.1001756</td>
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<tr>
<td>Lee MS</td>
<td>Meta-analyses of developing brain function in high-risk and emerged bipolar disorder</td>
<td>Front Psychiatry</td>
<td>November 3, 2014</td>
<td>10.3389/fpsyt.2014.00141</td>
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<tr>
<td>Wu W</td>
<td>Effects of Tai Chi on exercise capacity and health-related quality of life in patients with chronic obstructive pulmonary disease: a systematic review and meta-analysis</td>
<td>Int J Chron Obstruct Pulm Dis</td>
<td>November 7, 2014</td>
<td><a href="http://dx.doi.org/10.2147%2FCOPD.970862">http://dx.doi.org/10.2147%2FCOPD.970862</a></td>
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<th>Journal</th>
<th>Online Publication Date</th>
<th>Doi Number</th>
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<tr>
<td>Zhang SY</td>
<td>Meta-analysis of association between ALDH2 rs671 polymorphism and essential hypertension in Asian populations</td>
<td>Herz</td>
<td>November 19, 2014</td>
<td>10.1007/s00059-014-4166-2</td>
</tr>
<tr>
<td>Church PC</td>
<td>Systematic review with meta-analysis: magnetic resonance enterography signs for the detection of inflammation and intestinal damage in Crohn's disease</td>
<td>Aliment Pharmacol Ther</td>
<td>November 18, 2014</td>
<td>10.1111/apt.13024</td>
</tr>
<tr>
<td>Aly AR</td>
<td>Ultrasound-guided shoulder girdle injections are more accurate and more effective than landmark-guided injections: a systematic review and meta-analysis</td>
<td>Br J Sports Med</td>
<td>November 17, 2014</td>
<td>10.1136/bjsports-2014-093573</td>
</tr>
<tr>
<td>Patel HC</td>
<td>Magnitude of blood pressure reduction in the placebo arms of modern hypertension trials: implications for trials of renal denervation</td>
<td>Hypertension</td>
<td>November 17, 2014</td>
<td>10.1161/HYPERTENSINAH.114.04640</td>
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<tr>
<td>Louie KS</td>
<td>Do prostate cancer risk models improve the predictive accuracy of PSA screening? A meta-analysis</td>
<td>Ann Oncol</td>
<td>November 17, 2014</td>
<td>not available</td>
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<td>Peixoto HM</td>
<td>Serological diagnosis of canine visceral leishmaniasis in Brazil: systematic review and meta-analysis</td>
<td>Trop Med Int Health</td>
<td>November 18, 2014</td>
<td>10.1111/tmi.12429</td>
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<td>Gourlan M</td>
<td>Efficacy of theory-based interventions to promote physical activity. A meta-analysis of randomised controlled trials</td>
<td>Health Psychol Rev</td>
<td>November 17, 2014</td>
<td>10.1080/17437199.2014.981777</td>
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<tr>
<td>Zhu TY</td>
<td>Preoperative risk factors for residual tricuspid regurgitation after isolated left-sided valve surgery: a systematic review and meta-analysis</td>
<td>Cardiology</td>
<td>November 14, 2014</td>
<td>10.1159/000367589</td>
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<tr>
<td>Tu B</td>
<td>Coronary revascularization in diabetic patients: a systematic review and Bayesian network meta-analysis</td>
<td>Ann Intern Med</td>
<td>November 18, 2014</td>
<td>10.7326/M14-0808</td>
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<thead>
<tr>
<th>First Author</th>
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<th>Journal</th>
<th>Online Publication Date</th>
<th>Doi Number</th>
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<tbody>
<tr>
<td>Chen J</td>
<td>Cytoplasmic and/or nuclear expression of β-catenin correlate with poor prognosis and unfavorable clinicopathological factors in hepatocellular carcinoma: a meta-analysis</td>
<td>PloS One</td>
<td>November 17, 2014</td>
<td>10.1371/journal.pone.0111885</td>
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<tr>
<td>Cai G</td>
<td>Associations between ERAP1 polymorphisms and ankylosing spondylitis susceptibility: an updated meta-analysis</td>
<td>Mod Rheumatol</td>
<td>November 17, 2014</td>
<td>10.3109/14397595.2014.973658</td>
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<tr>
<td>Ashraf I</td>
<td>Hyoscine for polyp detection during colonoscopy: A meta-analysis and systematic review.</td>
<td>World J Gastrointest Endoscop</td>
<td>November 16, 2014</td>
<td>10.4253/wjge.v6.i11.549</td>
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<tr>
<td>Li J</td>
<td>Interleukin-17 SNPs and serum levels increase ulcerative colitis risk: A meta-analysis</td>
<td>World J Gastroenterol</td>
<td>November 14, 2014</td>
<td>10.3748/wjg.v20.i42.15899</td>
</tr>
<tr>
<td>Banglawala SM</td>
<td>Olfactory outcomes in chronic rhinosinusitis with nasal polyposis after medical treatments: a systematic review and meta-analysis</td>
<td>Int Forum Allergy Rhinol</td>
<td>November 14, 2014</td>
<td>10.1002/alr.21373</td>
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<tr>
<td>Pandey A</td>
<td>Exercise training in patients with heart failure and preserved ejection fraction: a meta-analysis of randomized control trials</td>
<td>Circ Heart Fail</td>
<td>November 16, 2014</td>
<td>10.1161/CIRCHEARTFAILURE.114.001615</td>
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<tr>
<td>Yin W</td>
<td>The efficacy and safety of non-steroidal anti-inflammatory drugs in preventing the recurrence of colorectal adenoma: a meta-analysis and systematic review of randomized trials</td>
<td>Colorectal Dis</td>
<td>November 14, 2014</td>
<td>10.1111/codi.12838</td>
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</table>
Meta-analyses: Merits, Limitations, and Application of the PRISMA Statement

APPENDIX 2
Data extraction form used to obtain information regarding study characteristics and completeness of reporting PRISMA items for the 44 evaluated meta-analyses. A separate form was completed for each study. For the PRISMA checklist items, the rating was indicated by highlighting the appropriate cell. For items designated as “inadequate,” the specific criteria responsible for the rating were indicated by additional highlighting.

First author ____________________________
Title ____________________________
Journal ____________________________
Journal requires or recommends use of PRISMA guidelines □ Yes □ No
Earliest publication date ____________________________
Statement that PRISMA guidelines were followed □ Yes □ No
Presence of PRISMA-like flow diagram □ Yes □ No

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<thead>
<tr>
<th>PRISMA Item/Description</th>
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<th>Not Reported</th>
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<tr>
<td><strong>TITLE</strong></td>
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</tr>
<tr>
<td>1: Title</td>
<td>Yes</td>
<td>Stated, but not correct</td>
<td>No</td>
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<tr>
<td>Identify the report as a systematic review (SR), meta-analysis (MA), or both.</td>
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<tr>
<td><strong>ABSTRACT</strong></td>
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<tr>
<td>2. Structured summary</td>
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<tr>
<td>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; SR registration number.</td>
<td>Structured summary with all applicable elements (registration # required only if stated in paper)</td>
<td>Structured summary, but no background; objectives; data sources; study eligibility criteria, participants, and interventions; study appraisal and synthesis methods; results; limitations; conclusions and implications of key findings; or SR registration #</td>
<td>No structured summary</td>
<td></td>
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<tr>
<td><strong>INTRODUCTION</strong></td>
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<tr>
<td>3. Rationale</td>
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<tr>
<td>Describe the rationale for the review in the context of what is already known.</td>
<td>Rationale stated and related to the current knowledge</td>
<td>Rationale stated but no indication of its relationship to current knowledge</td>
<td>No rationale stated</td>
<td></td>
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<tr>
<td><strong>4. Objectives</strong></td>
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<tr>
<td>Provide an explicit statement of questions being addressed with reference to participants, interventions, comparisons, outcomes, and study design (PICOS).</td>
<td>Clear statement of objective(s), including all PICOS elements (S refers to the design of the included studies)</td>
<td>Objective(s) not clearly stated or only some PICOS elements included. Elements included:</td>
<td>No objectives stated</td>
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<tr>
<td><strong>METHODS</strong></td>
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</tr>
<tr>
<td>5. Protocol and registration</td>
<td>Indicates whether SR protocol exists, where the protocol can be accessed, and the SR registration information (including #)</td>
<td>Indicates whether a protocol exists but does not state where to access it (if applicable) or does not provide any information about registration</td>
<td>Does not state whether a protocol exists and does not give registration information</td>
<td></td>
</tr>
<tr>
<td>6. Eligibility criteria</td>
<td>States both study-related and SR-related inclusion criteria and provides rationale for at least one of the criteria</td>
<td>Does not state study-related criteria or does not state report-related criteria or stated both types of criteria but the listing is obviously incomplete or no rationale is provided for any criteria</td>
<td>Eligibility criteria not stated</td>
<td></td>
</tr>
<tr>
<td>7. Information sources</td>
<td>States all information sources and date when search(es) were last performed</td>
<td>Does not state last search date or not all information sources stated</td>
<td>No information sources stated</td>
<td></td>
</tr>
<tr>
<td>8. Search</td>
<td>At least 1 full search (with limits if applicable) is provided</td>
<td>Full search provided but no limits indicated</td>
<td>No full electronic search strategy</td>
<td></td>
</tr>
<tr>
<td>9. Study selection</td>
<td>States who and how (eg, blinded, duplicate) studies were selected for the SR and MA. Includes statement about disagreement resolution, if duplicate</td>
<td>Does not state who selected the studies or does not state how the studies were selected for the SR or does not state the process for selecting the MA studies or does not state the process for disagreement resolution</td>
<td>No statement regarding the process of selecting studies</td>
<td></td>
</tr>
<tr>
<td>10. Data collection process</td>
<td>States who and how (eg, use of form, duplicate, contact authors for raw data) data were extracted. Includes statement about disagreement resolution if duplicate</td>
<td>Does not state who extracted data or does not state how data were extracted or does not state process for disagreement resolution</td>
<td>No statement regarding the process of data extraction</td>
<td></td>
</tr>
<tr>
<td>11. Data items</td>
<td>Lists and defines all variables and states assumptions/simplifications if applicable</td>
<td>Does not list all variables or does not define all variables that require definitions or does not state assumptions/simplifications (if applicable)</td>
<td>No variables stated</td>
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<tr>
<td><strong>METHODS (continued)</strong></td>
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</tr>
<tr>
<td>12. Risk of bias in individual studies</td>
<td>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 information will be used in any data synthesis.</td>
<td>Clearly inadequate description of methods used to assess risk of bias or does not specify whether risk of bias assessment was done at study or outcome level or does not state how information will be used in the data synthesis</td>
<td>No description of methods for assessing risk of bias for studies</td>
<td></td>
</tr>
<tr>
<td>13. Summary measures</td>
<td>State the principal summary measures (eg, risk ratio, difference in means).</td>
<td>Primary summary measures stated (eg, risk ratios, odds ratios, risk differences, difference in means, hazard ratios)</td>
<td>Summary measures stated but they were not the primary measures used</td>
<td>No summary measures stated</td>
</tr>
<tr>
<td>14. Synthesis of results</td>
<td>Describe the methods of handling data and combining results of studies, if done, including measures of consistency (eg, I²) for each meta-analysis.</td>
<td>Describes data handling (eg, combining groups, only subset(s) used, transforming data), if performed; rationale for not combining studies, if decide not to do MA; methods of combining results; method to assess heterogeneity or inconsistency; effects approach (eg, fixed or random)</td>
<td>Not all data handling described or rationale for not combining results into a MA not stated or heterogeneity / inconsistency not stated or effects approach not stated</td>
<td>No methods for handling data or synthesis of results stated</td>
</tr>
<tr>
<td>15. Risk of bias across studies</td>
<td>Specify any assessment of risk of bias that may affect the cumulative evidence (eg, publication bias, selective reporting within studies).</td>
<td>Indicates method(s) of assessment of risk of bias (eg, funnel plot, within-study selective reporting)</td>
<td>Indicates some, but not all, methods of assessment performed (as per the Results) for the risk of bias</td>
<td>No method indicated for assessing the risk of bias across studies</td>
</tr>
<tr>
<td>16. Additional analyses</td>
<td>Describe methods of additional analyses (eg, sensitivity or subgroup analyses, meta-regression), if done, indicating which were pre-specified.</td>
<td>Methods of additional analyses described, if performed</td>
<td>Methods stated but not indicated whether pre-specified or does not state the methods for all additional analyses reported in the Results</td>
<td>No description of methods although additional analyses were done</td>
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<th>PRISMA Item/Description</th>
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<td><strong>RESULTS</strong></td>
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<tr>
<td>17. Study selection</td>
<td>Specifies number of studies present at each stage (screened, assessed, and included) and reasons for exclusion of studies at each stage. Flow diagram not necessary.</td>
<td>Number of studies present at all stages not specified or reasons for studies excluded at each stage not specified</td>
<td>No statement about the number of studies present at any stage (except at final included stage)</td>
<td></td>
</tr>
<tr>
<td>18. Study</td>
<td>Specifies study characteristics collected for each study and gives citation for each study</td>
<td>Does not specify all study characteristics collected for each study or provides characteristics/citations for only some studies or does not provide citations for all study</td>
<td>No specification of characteristics collected for each study</td>
<td></td>
</tr>
<tr>
<td>19. Risk of bias within studies</td>
<td>Presents risk of bias measures for each study (eg. blinding assessments for patients, healthcare providers, data collectors, outcome assessors)</td>
<td>Presents results of risk of bias assessments for only some studies or presents only summary statistics for risk of bias assessments</td>
<td>No results presented for risk of bias within studies assessments</td>
<td></td>
</tr>
<tr>
<td>20. Results of individual studies</td>
<td>Specifies outcome summary data for each intervention group (actual numbers, not just percentages) and effect size estimates with CI (in a table or forest plot), for each included study</td>
<td>For the main outcomes, summary data for each intervention group not presented for every study or effect-size estimates plus CIs for each intervention group not presented for every study</td>
<td>No outcome summary data or effect-size estimates given for any individual study</td>
<td></td>
</tr>
<tr>
<td>21. Synthesis of results</td>
<td>Presents the main results; presents the results of each MA, with CIs and measures of consistency</td>
<td>Does not present all main results (as determined by objectives/methods) or does not present CIs and measures of consistency for all MAs performed</td>
<td>No main results reported</td>
<td></td>
</tr>
<tr>
<td>22. Risk of bias across studies</td>
<td>Presents results of risk of bias across studies assessments (eg, funnel plot)</td>
<td>Does not present results of all planned risk of bias assessments (as per Methods section)</td>
<td>No results of risk of bias across studies assessments</td>
<td></td>
</tr>
<tr>
<td>23. Additional analyses</td>
<td>Presents results of all additional analyses, including all that were planned</td>
<td>Does not report results of all planned additional analyses (as per Methods section)</td>
<td>No results of additional analyses presented (although planned, as per Methods)</td>
<td>No additional analyses planned or performed</td>
</tr>
</tbody>
</table>

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<table>
<thead>
<tr>
<th>PRISMA Item/Description</th>
<th>Adequate</th>
<th>Inadequate</th>
<th>Not Reported</th>
<th>Not Applicable</th>
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</thead>
<tbody>
<tr>
<td><strong>DISCUSSION</strong></td>
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<tr>
<td>24. Summary of evidence</td>
<td>Summarizes main findings, discusses strength of evidence for main findings, and discusses relevance of results.</td>
<td>Fails to summarize some of main findings or does not discuss strength of evidence for main findings or does not discuss relevance of results.</td>
<td>Provides no summary of main findings</td>
<td></td>
</tr>
<tr>
<td>25. Limitations</td>
<td>Discusses study/outcome level (eg, risk of bias), and at review level (eg, incomplete retrieval of identified research, reporting bias).</td>
<td>Discusses limitations only at study/outcome or discusses limitations only at review level or obvious important limitations (at any level) not discussed</td>
<td>No discussion of any limitations</td>
<td></td>
</tr>
<tr>
<td>26. Conclusions</td>
<td>Discusses interpretation of results in context of other evidence and notes implications for further research</td>
<td>No interpretation of results in context of other evidence or no implications for further research</td>
<td>No interpretation of results in context of other evidence and no implications for future research</td>
<td></td>
</tr>
<tr>
<td><strong>FUNDING</strong></td>
<td></td>
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<td>27. Funding</td>
<td>Indicates whether funding and/or other support was received for the study and describes the sources, if applicable. Indicates whether the funding agency had any additional role(s) in the MA and describes that role, if applicable</td>
<td>Does not indicate whether funding/other support received or does not describe sources of funding/other support, if applicable, or does not specify whether funding agency had additional role(s) or does not describe additional role(s), if applicable</td>
<td>Does not mention whether MA was funded or supported</td>
<td></td>
</tr>
</tbody>
</table>