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AMWA JOURNAL MISSION STATEMENT

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.
ABSTRACT
Objective: To describe the tasks and responsibilities involved in creating 4 summary documents associated with a drug application filed in Common Technical Document (CTD) format: Summary of Clinical Efficacy (SCE), Summary of Clinical Safety (SCS), Integrated Summary of Effectiveness (ISE), and Integrated Summary of Safety (ISS).

Methods and Materials: A 45-question survey was administered via SurveyMonkey to 188 invited participants believed to have written at least 1 of the 4 summary documents.

Results: The response rate was 46.8% (88/188); 77.3% (68/88) were qualified respondents (lead writers or substantive contributors to 1 or more of the documents) and had 5 or more years of experience writing regulatory documents (73.5%, 50/68). The majority (79.4%, 54/68) resided in the US. Respondents submitted CTD-based drug applications worldwide: US: 95.6% (65/68); European Union (EU): 82.4% (56/68); Japan: 27.9% (19/68); rest of world: 33.8% (23/68). The majority had been lead writers or substantive contributors to an SCE (79.4%) and SCS (83.8%). The most commonly used method of text creation was a mix of de novo and repurposed content. Almost half participated in decisions regarding the analysis of efficacy data (SCE, 46.3%) and the overall safety evaluation plan (SCS, 54.4%). Many multitasked (writing an ISE/SCE and ISS/SCS simultaneously) or developed a plan with their counterpart to align the companion documents. Summary documents were most often written before the Clinical Study Reports (CSRs) had been finalized. Respondents identified errors in final tables and listings that could have compromised the integrity of the drug application.

Conclusions: The results suggest that writers make substantive contributions to clinical summary documents as well as strategic contributions to the drug submission process. Writers create de novo text and/or intelligently repurpose content for critical sections of each document (introductory sections, sections that present and summarize data, and discussion and conclusions sections). Such activities invalidate the notion that a summary document is the result of a simplistic “copy and paste” process. By identifying errors in the final tables and listings, writers contribute to the scientific accuracy of the data and the integrity of the drug application.

BACKGROUND AND RATIONALE
Sponsors seeking approval of a drug in 1 of the 3 International Council for Harmonisation (ICH) regions—the European Union (EU), Japan, and the United States of America (US)—have agreed to assemble all quality, safety, and efficacy information in a common format known as the Common Technical Document (CTD). This harmonized approach has eliminated the need to reformat submission information for different ICH regulatory authorities. The CTD consists of 5 modules: Module 1 (region specific), Module 2 (summaries of data in Modules 3, 4, and 5), Module 3 (quality data), Module 4 (nonclinical data), and Module 5 (clinical data).1

Module 2 contains 2 clinical summary documents, the Summary of Clinical Efficacy (SCE, Section 2.7.3) and the Summary of Clinical Safety (SCS, Section 2.7.4).2 Both documents play a crucial role in a CTD-based drug application because they identify, organize, and condense efficacy and safety data from across the development program and provide conclusions regarding those data, thus providing a highly condensed version of the case for drug approval. In addition, drug applications submitted to the US Food and Drug Administration (FDA) must contain 2 clinical summary documents not required in other ICH regions: Integrated Summary of Effectiveness (ISE)3 and the Integrated Summary of Safety (ISS),4 both placed in Section 5.3.5.3 of Module 5.5

Nancy R. Katz, PhD, MWC™ and Linda Fossati Wood, RN, MPH
This article reports the conduct and results of a pilot survey called The Scope of Summary Documents. The goal of the survey was to describe the tasks involved in creating 4 summary documents associated with a CTD-based drug application: the SCE, SCS, ISE, and ISS. We sought to determine what role the writer played in development of these summaries, what challenges existed, and what methods the writers of these documents used to overcome these challenges. This pilot survey is intended to inform future studies describing the profession of medical writing.

METHODS AND MATERIALS
We administered a 45-item questionnaire via SurveyMonkey from February 11 to March 1, 2015. One question qualified respondents, and 44 questions defined respondent characteristics and elicited information about tasks involved in creating the SCE, SCS, ISE, and ISS. Participation was by invitation only, with questionnaires sent to 188 writers in our personal network whom we believed had written at least 1 of the summary documents within the last 2 years. Data were collected in Excel and analyzed using descriptive statistics (mean [standard deviation], median, minimum, and maximum) for the total population of respondents (ie, not broken down by region or other subgroup).

RESULTS
Response Rate and Respondent Characteristics
The qualifying question was “Within the last 2 years, have you been the lead medical writer or made substantive writing contributions to at least 1 of the 4 summary documents?” A lead writer had determined the regulatory content of a summary document and had written at least 50% of that document. A substantive contributor had written at least 30% of a summary document in conjunction with the lead writer.

The response rate was 46.8% (88/188) (Table 1). Of the 88 respondents, 77.3% (68/88) were qualified; that is, they had served as lead writers or substantive contributors for at least 1 of the summary documents. The remaining 23.9% (20/88) were unqualified respondents who answered the qualifying question only.

Of the 68 qualified respondents, 73.5% (50/68) had 5 or more years’ experience writing clinical summary documents, 67.6% (46/68) worked as full- or part-time employees in the pharmaceutical or biotechnology industry, and 79.4% (54/68) resided in the US (Table 2). Respondents submitted drug applications worldwide: 95.6% (65/68) in the US, 82.4% (56/68) in the EU, 27.9% (19/68) in Japan, and 33.8% (23/68) in other world regions.

<table>
<thead>
<tr>
<th>Respondents</th>
<th>N (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of invitations issued</td>
<td>188</td>
</tr>
<tr>
<td>Respondents</td>
<td>88 (46.8)</td>
</tr>
<tr>
<td>Qualified respondents</td>
<td>68 (77.3)</td>
</tr>
<tr>
<td>Unqualified respondents who answered the qualifying question only</td>
<td>20 (22.7)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Qualified Respondents (N=68)</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Lead writer or substantive contributor to SCE</td>
<td>54 (79.4)</td>
</tr>
<tr>
<td>Lead writer or substantive contributor to SCS</td>
<td>57 (83.8)</td>
</tr>
<tr>
<td>Lead writer or substantive contributor to ISE</td>
<td>32 (47.1)</td>
</tr>
<tr>
<td>Lead writer or substantive contributor to ISS</td>
<td>42 (61.8)</td>
</tr>
</tbody>
</table>

Notes: A “qualified” respondent had been a lead writer or substantive contributor to at least 1 summary document (SCE, SCS, ISE, ISS) within the last 2 years. A lead writer had determined the regulatory content of a summary document and written at least 50% of that document. A substantive contributor had written at least 30% of a summary document in conjunction with the lead writer. Not all qualified respondents (N=68) completed every survey question, nor were they expected to, as the qualifying question required that a respondent had been a lead writer or substantive contributor to only 1 of the 4 summary documents. Thus, a respondent who had been a lead writer for the SCE but not for the other 3 documents (SCS, ISE, or ISS) did not answer questions about those documents. Also, respondents who had never submitted a drug application to the US FDA, which requires an ISE and ISS (not required in the EU), did not answer questions about an ISE or an ISS.

CTD, Common Technical Document; ISE, Integrated Summary of Effectiveness; ISS, Integrated Summary of Safety; SCE, Summary of Clinical Efficacy (Section 2.7.3 of the CTD); SCS, Summary of Clinical Safety (Section 2.7.4 of the CTD).

Methods of Content Creation
Respondents used 4 methods to create content for the summary documents: (1) they created content de novo (ie, writing new text or developing in-text tables to communicate new or previously nonexistent information); (2) they repurposed content (identifying and modifying content from an outside source and then integrating that content into the summary document); (3) they used a mix of de novo and repurposed content; and (4) they received content from another team member or an outside source. In addition, respondents actively participated actively in the process of managing documents and made strategic contributions to document planning, including decisions for pooling of data. Finally, respondents overcame specific challenges related to the source materials upon which the summary documents were based.
SCE Development

Fifty-four of the 68 qualified respondents (79.4%) had been lead writers or substantive contributors to an SCE (Table 3). For Section 2.7.3.1, Background and Overview, 94.4% (51/54) of respondents used a mix of de novo and repurposed text (Tables 3 and 4).

Section 2.7.3.2, Summary of Results of Individual Studies, requires provision of narrative descriptions of the studies in the clinical development program. A narrative description is a textual summary of an individual clinical study. Many studies in a typical drug development program investigate both efficacy and safety outcomes; however, some studies focus primarily on safety. When writing narratives for studies that investigated both efficacy and safety, 57.4% of respondents (31/54) described the study methods and provided summary of efficacy results only. In contrast, 22.2% (12/54) described the study methods and provided a summary of both the efficacy and the safety results. In the case of a study whose primary focus was safety, 18.5% (10/54) described the safety methods and included a summary of the safety results in this section of the SCE (Table 3).

Methods of content creation for Section 2.7.3.3, Comparison and Results Across Studies, varied based on whether or not efficacy data were pooled. All studies can be summarized but not all can be integrated. Disparate study designs precluded pooling of data for many drug development programs. (Unlike the ISE and ISS, data integration across studies is not required for the Module 2 summaries). When efficacy data were pooled, approximately one-half of the respondents (46.3%, 25/54) participated in decisions regarding analysis of that data (Table 3). Any text based on pooled efficacy tables must be written de novo, and the assumption was that lead writers or substantive contributors to an SCE performed this task. When data were not pooled (and, consequently, no analyses were performed to integrate data), 64.8% (35/54) of respondents repurposed efficacy data from individual source documents such as CSRs, while 31.5% (17/54) received efficacy data from another team member.

Section 2.7.3.4, Analysis of Clinical Information Relevant to Dosing Recommendations, and Section 2.7.3.5, Persistence of Efficacy and/or Tolerance of Effects, must be written de novo because the information required for these sections does not exist in the source documents (for the most part, the CSRs). For Section 2.7.3.4, 53.7% (29/54) of respondents were primarily responsible for writing this section, and 37.0% (20/54) received text from another team member. For Section 2.7.3.5, 57.4% (31/54) were primarily responsible for writing this section, and 35.2% (19/54) received text from another team member.

When respondents incorporated references to the published literature into the SCE (an optional section), 27.8% (15/54) conducted the literature search and wrote a de novo summary of the publications. The same percentage (27.8%, 15/54) received the summary of published literature from another team member but incorporated it into the document only after making substantive changes to it. A similar percent (25.9%, 14/54) received the summary from another team member and incorporated it with no or few changes. Only 11.1% (6/54) provided a cross-reference to a stand-alone summary of the published literature created by another team.

### Table 2. Baseline Characteristics

<table>
<thead>
<tr>
<th>Characteristics of Qualified Respondents (N=68)</th>
<th>N (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of years’ experience writing summary documents</td>
<td></td>
</tr>
<tr>
<td>5 years or more</td>
<td>50 (73.5)</td>
</tr>
<tr>
<td>More than 2 years and less than 5 years</td>
<td>15 (22.1)</td>
</tr>
<tr>
<td>Some experience, but less than 2 years</td>
<td>2 (2.9)</td>
</tr>
<tr>
<td>Missing data</td>
<td>1 (1.5)</td>
</tr>
<tr>
<td>Current work situation</td>
<td></td>
</tr>
<tr>
<td>Full- or part-time employees of a pharmaceutical or biotechnology company or contract research organization</td>
<td>46 (67.6)</td>
</tr>
<tr>
<td>Contract writers</td>
<td>20 (29.4)</td>
</tr>
<tr>
<td>Retired</td>
<td>1 (1.5)</td>
</tr>
<tr>
<td>Missing data</td>
<td>1 (1.5)</td>
</tr>
<tr>
<td>Region of residence</td>
<td></td>
</tr>
<tr>
<td>United States</td>
<td>54 (79.4)</td>
</tr>
<tr>
<td>European Union</td>
<td>7 (10.3)</td>
</tr>
<tr>
<td>Australia, New Zealand, and Southeast Asia combined</td>
<td>3 (4.4)</td>
</tr>
<tr>
<td>China, India, and Japan</td>
<td>3 (4.4)</td>
</tr>
<tr>
<td>Missing data</td>
<td>1 (1.5)</td>
</tr>
<tr>
<td>Region submitting drug applicationsa</td>
<td></td>
</tr>
<tr>
<td>United States</td>
<td>65 (95.6)</td>
</tr>
<tr>
<td>European Union</td>
<td>56 (82.4)</td>
</tr>
<tr>
<td>Japan</td>
<td>19 (27.9)</td>
</tr>
<tr>
<td>Other Regions</td>
<td>23 (33.8)</td>
</tr>
<tr>
<td>Missing data</td>
<td>1 (1.5)</td>
</tr>
</tbody>
</table>

Percentages will not sum to 100% because some respondents had submitted in more than 1 region.

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AMWA Journal / V32 N1 / 2017 / amwa.org
### Table 3. SCE Development, Part 1

<table>
<thead>
<tr>
<th>Lead Writer or Substantive Contributor to SCE (N=54)</th>
<th>N (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>2.7.3.1, Background and Overview</td>
<td></td>
</tr>
<tr>
<td>De novo text only</td>
<td>0</td>
</tr>
<tr>
<td>Mix of de novo and repurposed text</td>
<td>51 (94.4)</td>
</tr>
<tr>
<td>Repurposed text almost completely from another document</td>
<td>2 (3.7)</td>
</tr>
<tr>
<td>Provided with all text necessary to write the section</td>
<td>1 (1.9)</td>
</tr>
<tr>
<td>2.7.3.2, Summary of Results of Individual Studies</td>
<td></td>
</tr>
<tr>
<td>Included studies of efficacy and safety, summarizing efficacy methods and efficacy results only</td>
<td>31 (57.4)</td>
</tr>
<tr>
<td>Included studies of efficacy and safety, summarizing efficacy and safety methods and both efficacy and safety results</td>
<td>12 (22.2)</td>
</tr>
<tr>
<td>Included studies of whose primary objective was safety only, summarizing safety methods and safety results only</td>
<td>10 (18.5)</td>
</tr>
<tr>
<td>Not applicable</td>
<td>1 (1.9)</td>
</tr>
<tr>
<td>2.7.3.3, Comparison and Results Across Studies</td>
<td></td>
</tr>
<tr>
<td>Pooled efficacy data</td>
<td></td>
</tr>
<tr>
<td>Participated in decisions regarding analysis of efficacy data</td>
<td>25 (46.3)</td>
</tr>
<tr>
<td>Did not participate in decisions regarding analysis of efficacy data</td>
<td>24 (44.4)</td>
</tr>
<tr>
<td>Not applicable</td>
<td>4 (7.4)</td>
</tr>
<tr>
<td>Missing data</td>
<td>1 (1.9)</td>
</tr>
<tr>
<td>Efficacy data not pooled</td>
<td></td>
</tr>
<tr>
<td>Repurposed efficacy data from individual source documents such as CSRs</td>
<td>35 (64.8)</td>
</tr>
<tr>
<td>Received efficacy data from another team member</td>
<td>17 (31.5)</td>
</tr>
<tr>
<td>Not applicable</td>
<td>1 (1.9)</td>
</tr>
<tr>
<td>Missing data</td>
<td>1 (1.9)</td>
</tr>
</tbody>
</table>

Note: Lead writer: determined the regulatory content of a summary document, had written at least 50% of that document; substantive contributor had written at least 30% of a summary document in conjunction with the lead writer.

CTD, Common Technical Document; SCE, Summary of Clinical Efficacy, ie, Section 2.7.3 of the CTD.

### Table 4. SCE Development, Part 2

<table>
<thead>
<tr>
<th>Lead Writer or Substantive Contributor to SCE (N=54)</th>
<th>N (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>2.7.3.4, Analysis of Clinical Information Relevant to Dosing</td>
<td></td>
</tr>
<tr>
<td>Primarily responsible for writing this section, which requires de novo text</td>
<td>29 (53.7)</td>
</tr>
<tr>
<td>Received text from another team member</td>
<td>20 (37.0)</td>
</tr>
<tr>
<td>Not applicable</td>
<td>2 (3.7)</td>
</tr>
<tr>
<td>Missing data</td>
<td>3 (5.6)</td>
</tr>
<tr>
<td>2.7.3.5, Persistence of Efficacy or Tolerance Effects</td>
<td></td>
</tr>
<tr>
<td>Primarily responsible for writing this section, which requires de novo text</td>
<td>31 (57.4)</td>
</tr>
<tr>
<td>Received text from another team member</td>
<td>19 (35.2)</td>
</tr>
<tr>
<td>Not applicable</td>
<td>1 (1.9)</td>
</tr>
<tr>
<td>Missing data</td>
<td>3 (5.6)</td>
</tr>
<tr>
<td>Optional Section: Summary of Published Literature</td>
<td></td>
</tr>
<tr>
<td>Conducted own literature search and summarized publications (ie, wrote de novo text)</td>
<td>15 (27.8)</td>
</tr>
<tr>
<td>Received summary of published literature from another team member and made substantive changes to it</td>
<td>15 (27.8)</td>
</tr>
<tr>
<td>Received summary of published literature from another team member and made minor changes to it</td>
<td>14 (25.9)</td>
</tr>
<tr>
<td>Provided cross-reference to a stand-alone document that contained a summary of the published literature</td>
<td>6 (11.1)</td>
</tr>
<tr>
<td>Not applicable; have not written an SCE that contained a summary of the published literature</td>
<td>4 (7.4)</td>
</tr>
<tr>
<td>Optional Final Section: Provided de novo high-level summary of efficacy data</td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>42 (77.8)</td>
</tr>
<tr>
<td>No</td>
<td>8 (14.8)</td>
</tr>
<tr>
<td>Missing data</td>
<td>4 (7.4)</td>
</tr>
</tbody>
</table>

Note: Lead writer: determined the regulatory content of a summary document, had written at least 50% of that document; substantive contributor had written at least 30% of a summary document in conjunction with the lead writer.

CTD, Common Technical Document; SCE, Summary of Clinical Efficacy, ie, Section 2.7.3 of the CTD.
member. Finally, 77.8% (42/54) provided a final de novo section containing a high-level summary of the efficacy data presented in the document.

**SCS Development**
Fifty-seven of the 68 qualified respondents (83.8%) had been lead writers or substantive contributors to an SCS (Table 5). As for respondents who wrote SCEs, those who wrote SCSs primarily used a mix of de novo and repurposed content to develop the document. Although the SCS Guideline does not mandate an introductory section, 78.9% (45/57) wrote an introduction that they repurposed from the SCE, Section 2.7.3.1, *Background and Clinical Overview*; 14.0% (8/57) wrote a de novo introduction. For Section 2.7.4.1.1, *Overall Safety Evaluation Plan and Narratives of Safety Studies*, 54.4% (31/57) were part of a team that determined the overall safety evaluation plan. The majority (73.7%, 42/57) provided narratives that summarized the study methods and provided a summary of safety results only, while only 22.8% (13/57) took advantage of the electronic capacities of the CTD and provided a cross-reference to the SCE, Section 2.7.3.2, *Summary of Results of Individual Studies*. Most respondents (77.2%, 44/57) were primarily responsible for writing Section 2.7.4.5, *Safety in Special Populations*, which requires the creation of de novo text. The content of Section 2.7.4.6, *Postmarketing Data*, usually relies heavily upon data collected by a pharmacovigilance (PV) group. For this section, 56.1% (32/57) received content from the PV or other responsible group. However, 38.6% (32/57) were primarily responsible for writing this section.

Respondents used a variety of methods when incorporating references to the published literature into the SCS (an optional section); however, no one method predominated. Most respondents (89.5%, 51/57) provided a final de novo high-level summary of safety data presented in the document.

**ISE Development, Including Impact on the SCE**
Thirty-two of the 68 qualified respondents (47.1%) had been lead writers or substantive contributors to an ISE. Of these, 78.1% (25/32) multitasked, contributing to both an ISE and an SCE simultaneously: 65.6% (21/32) served as lead writers or substantive contributors for both documents, and 12.5% (4/32) served in this role for one document while making minor contributions to the other (Table 5). When a respondent wrote either the ISS or SCS and another writer wrote the corresponding document, 78.1% developed a plan with the other writer to ensure alignment of the documents. Almost 60% (59.4% 19/32) repurposed ISE content for the SCE. Almost 85% (84.4%, 27/32) were primarily responsible for writing the Discussion and Conclusions section of the ISE, a task that requires de novo writing.

**Table 5. SCS Development**

<table>
<thead>
<tr>
<th>Lead Writer or Substantive Contributor to SCE (N=54)</th>
<th>N (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>2.7.3.4, Analysis of Clinical Information Relevant to Dosing</td>
<td></td>
</tr>
<tr>
<td>Primarily responsible for writing this section, which requires de novo text</td>
<td>29 (53.7)</td>
</tr>
<tr>
<td>Received text from another team member</td>
<td>20 (37.0)</td>
</tr>
<tr>
<td>Not applicable</td>
<td>2 (3.7)</td>
</tr>
<tr>
<td>Missing data</td>
<td>3 (5.6)</td>
</tr>
<tr>
<td>2.7.3.5, Persistence of Efficacy or Tolerance Effects</td>
<td></td>
</tr>
<tr>
<td>Primarily responsible for writing this section, which requires de novo text</td>
<td>31 (57.4)</td>
</tr>
<tr>
<td>Received text from another team member</td>
<td>19 (35.2)</td>
</tr>
<tr>
<td>Not applicable</td>
<td>1 (1.9)</td>
</tr>
<tr>
<td>Missing data</td>
<td>3 (5.6)</td>
</tr>
<tr>
<td>Optional Section: Summary of Published Literature</td>
<td></td>
</tr>
<tr>
<td>Conducted own literature search and summarized publications (ie, wrote de novo text)</td>
<td>15 (27.8)</td>
</tr>
<tr>
<td>Received summary of published literature from another team member and made substantive changes to it</td>
<td>15 (27.8)</td>
</tr>
<tr>
<td>Received summary of published literature from another team member and made minor changes to it</td>
<td>14 (25.9)</td>
</tr>
<tr>
<td>Provided cross-reference to a stand-alone document that contained a summary of the published literature</td>
<td>6 (11.1)</td>
</tr>
<tr>
<td>Not applicable; have not written an SCE that contained a summary of the published literature</td>
<td>4 (7.4)</td>
</tr>
<tr>
<td>Optional Final Section: Provided de novo high-level summary of efficacy data</td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>42 (77.8)</td>
</tr>
<tr>
<td>No</td>
<td>8 (14.8)</td>
</tr>
<tr>
<td>Missing data</td>
<td>4 (7.4)</td>
</tr>
</tbody>
</table>

Note: Lead writer: determined the regulatory content of a summary document, had written at least 50% of that document; substantive contributor had written at least 30% of a summary document in conjunction with the lead writer.

CTD, Common Technical Document; SCE, Summary of Clinical Efficacy, ie, Section 2.7.3 of the CTD.
**ISS Development, Including Impact on the SCS**

Forty-two of the 68 qualified respondents (61.8%) had been lead writers or substantive contributors to an ISS. Of these, 78.5% (33/42) multitasked, contributing to both an ISS and SCS simultaneously: 64.3% (27/42) served as lead writers or substantive contributors for both documents, and 14.3% (6/42) served in this role for one document while making minor contributions to the other document (Table 6).

No formal guidance exists for the ISS (in contrast to the ISE); 57.1% (24/42) of respondents were provided with an ISS template for this document, and 42.9% (18/42) developed de novo a template based on the guidelines listed in 21 CFR §314.50(vi). When a respondent wrote either the ISS or an SCS and another writer wrote the corresponding document, 83.3% (35/42) chose to include a Pertinent Animal Data section in this document (required by 21 CFR §314.50(vi)). A majority (76.2%, 32/42) were primarily responsible for writing the Discussion and Conclusions section of this document, a task that requires de novo writing (Table 7).

**Challenges Related to Source Materials**

*Status of CSRs at the Time Summary Documents Were Started*

The majority of respondents (85.3%, 58/68) began writing a summary document before the CSRs in the development program had been finalized (Table 8).

*Errors in Final Tables and Listings*

The majority of respondents found errors in the final tables and listings for each of the 4 summary documents. All errors had the potential to compromise the accurate reporting of study-specific variables (Table 9).

**DISCUSSION AND CONCLUSIONS**

The inherent paradox of a summary document is that it must be succinct and simple, yet not simplistic, as well as encompassing and complex. That is, it must provide concise descriptions of key data presented in the drug application as well as overarching messages regarding those data. It also must be wide enough in scope and plentiful enough in detail to account for the primary, secondary, and exploratory findings of the major studies in the drug development program.

This pilot survey showed that the 68 qualified respondents who wrote any 1 of the summary documents (SCE, SCS, ISE, and ISS) made judicious use of specific methods to create content, skillfully managed the process of document creation, and overcame notable challenges associated with team collaboration, project oversight, and management of deliverables.

---

**Table 6. ISE Development, Including Impact on the SCE**

<table>
<thead>
<tr>
<th>Lead Writers or Substantive Contributors to ISE (N=32)</th>
<th>N (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Multitasking (worked on ISE and SCE simultaneously)</td>
<td></td>
</tr>
<tr>
<td>Lead writer for 1 document; substantive contributor to the other, n (%)</td>
<td>21 (65.6)</td>
</tr>
<tr>
<td>Lead writer for 1 document; minor contributor to the other</td>
<td>4 (12.5)</td>
</tr>
<tr>
<td>Lead writer for 1 document; did not contribute to other</td>
<td>3 (9.4)</td>
</tr>
<tr>
<td>Not applicable (never worked on a drug application that included both an SCE and an ISE)</td>
<td>4 (12.5)</td>
</tr>
<tr>
<td>ISE or SCE document written by respondent, the other by another writer</td>
<td></td>
</tr>
<tr>
<td>Developed alignment plan with other writer to ensure consistency between documents</td>
<td>25 (78.1)</td>
</tr>
<tr>
<td>Did not develop an alignment plan with other writer</td>
<td>3 (9.4)</td>
</tr>
<tr>
<td>Missing data</td>
<td>4 (12.5)</td>
</tr>
<tr>
<td>Content development</td>
<td></td>
</tr>
<tr>
<td>Repurposing of content</td>
<td></td>
</tr>
<tr>
<td>Repurred ISE content for SCE</td>
<td>19 (59.4)</td>
</tr>
<tr>
<td>Did not repurpose ISE content for SCE</td>
<td>2 (6.3)</td>
</tr>
<tr>
<td>Missing data</td>
<td>11 (34.4)</td>
</tr>
<tr>
<td>Discussion and Conclusions Section</td>
<td></td>
</tr>
<tr>
<td>Primarily responsible for writing this section (requires de novo writing)</td>
<td>27 (84.4)</td>
</tr>
<tr>
<td>Received content from another team member</td>
<td>4 (12.5)</td>
</tr>
<tr>
<td>Not applicable (not responsible for writing this section)</td>
<td>1 (3.1)</td>
</tr>
</tbody>
</table>

Note: Lead writer: determined the regulatory content of a summary document, had written at least 50% of that document; substantive contributor had written at least 30% of a summary document in conjunction with the lead writer.

CTD, Common Technical Document; ISE, Integrated Summary of Effectiveness; SCE, Summary of Clinical Efficacy (Section 2.7.3 of the CTD).
Table 7. ISS Development, Including Impact on the SCS

<table>
<thead>
<tr>
<th>Lead Writer or Substantive Contributor to ISS (N=42)</th>
<th>N (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Multitasked (worked on ISS and SCS simultaneously)</td>
<td></td>
</tr>
<tr>
<td>Lead writer for 1; substantive contributor to the other</td>
<td>27 (64.3)</td>
</tr>
<tr>
<td>Lead writer for 1; minor contributor to other</td>
<td>6 (14.3)</td>
</tr>
<tr>
<td>Lead writer for 1; did not contribute to other</td>
<td>7 (16.7)</td>
</tr>
<tr>
<td>Missing data</td>
<td>2 (4.8)</td>
</tr>
<tr>
<td>ISS Template</td>
<td></td>
</tr>
<tr>
<td>Provided with template</td>
<td>24 (57.1)</td>
</tr>
<tr>
<td>Developed template (requires de novo writing)</td>
<td>18 (42.9)</td>
</tr>
<tr>
<td>Alignment Plan (when ISS or SCS respondent written by respondent and the other document by another writer)</td>
<td></td>
</tr>
<tr>
<td>Developed alignment plan with other writer to ensure consistency between documents</td>
<td>35 (83.3)</td>
</tr>
<tr>
<td>Did not develop an alignment plan with other writer</td>
<td>5 (11.9)</td>
</tr>
<tr>
<td>Missing data</td>
<td>2 (4.8)</td>
</tr>
<tr>
<td>Inclusion of Pertinent Animal Data Section</td>
<td></td>
</tr>
<tr>
<td>Included this section</td>
<td>20 (47.6)</td>
</tr>
<tr>
<td>Provided electronic cross-reference to another section of the CTD</td>
<td>20 (47.6)</td>
</tr>
<tr>
<td>Did not include</td>
<td>2 (4.8)</td>
</tr>
<tr>
<td>Other Content Development</td>
<td></td>
</tr>
<tr>
<td>Repurposing of content</td>
<td></td>
</tr>
<tr>
<td>Repurposed ISS content for SCS</td>
<td>24 (57.1)</td>
</tr>
<tr>
<td>Did not repurpose ISS content for SCS</td>
<td>3 (7.1)</td>
</tr>
<tr>
<td>Missing data</td>
<td>15 (35.7)</td>
</tr>
<tr>
<td>Discussion and Conclusions Section</td>
<td></td>
</tr>
<tr>
<td>Primarily responsible for writing this section (requires de novo writing)</td>
<td>32 (76.2)</td>
</tr>
<tr>
<td>Received content from another team member</td>
<td>10 (23.8)</td>
</tr>
</tbody>
</table>

Table 8. Status of Source Materials

<table>
<thead>
<tr>
<th>Status of CSRs Prior to Beginning a Summary Document (N=68)</th>
<th>N (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Final (approved)</td>
<td>9 (13.2)</td>
</tr>
<tr>
<td>Not Final</td>
<td>58 (85.3)</td>
</tr>
<tr>
<td>Near final (CSR with stable unapproved data)</td>
<td>26 (38.2)</td>
</tr>
<tr>
<td>Draft data (CSR with draft data)</td>
<td>20 (29.4)</td>
</tr>
<tr>
<td>Shell (Methods section completed; placeholders for results)</td>
<td>8 (11.8)</td>
</tr>
<tr>
<td>Not started</td>
<td>4 (5.9)</td>
</tr>
<tr>
<td>Missing data</td>
<td>1 (1.5)</td>
</tr>
</tbody>
</table>

Table 9. Types of Errors in the Final Tables and Listings for the SCE, ISE, SCS, and ISS

<table>
<thead>
<tr>
<th>Errors Identified</th>
<th>N (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Errors in the Final SCE Tables and Listings (N=54)</td>
<td></td>
</tr>
<tr>
<td>Identified errors in number of efficacy parameters reported</td>
<td>41 (75.9)</td>
</tr>
<tr>
<td>Identified errors in patient disposition</td>
<td>43 (79.6)</td>
</tr>
<tr>
<td>Identified errors in other variables (demographics, primary efficacy measurements)</td>
<td>46 (85.2)</td>
</tr>
<tr>
<td>Errors in the ISE Final Tables and Listings (N=32)</td>
<td></td>
</tr>
<tr>
<td>Identified errors in number of efficacy parameters reported</td>
<td>30 (93.8)</td>
</tr>
<tr>
<td>Identified errors in patient disposition</td>
<td>30 (93.8)</td>
</tr>
<tr>
<td>Identified errors in other variables (demographics, primary efficacy measurements)</td>
<td>30 (93.8)</td>
</tr>
<tr>
<td>Errors in the SCS Final Tables and Listings (N=57)</td>
<td></td>
</tr>
<tr>
<td>Identified errors in number of safety parameters reported</td>
<td>48 (84.2)</td>
</tr>
<tr>
<td>Identified errors in other safety parameters (eg, adverse events)</td>
<td>51 (89.5)</td>
</tr>
<tr>
<td>Errors in the ISS Final Tables and Listings (N=42)</td>
<td></td>
</tr>
<tr>
<td>Identified errors in number of safety parameters reported</td>
<td>37 (88.1)</td>
</tr>
<tr>
<td>Identified errors in other safety parameters (AEs, results of laboratory investigations)</td>
<td>37 (88.1)</td>
</tr>
</tbody>
</table>

CTD, Common Technical Document; ISE, Integrated Summary of Effectiveness; ISS, Integrated Summary of Safety; SCE, Summary of Clinical Efficacy (Section 2.7.3 of the CTD); SCS, Summary of Clinical Safety (Section 2.7.4 of the CTD).

Note: Lead writer: determined the regulatory content of a summary document, had written at least 50% of that document; substantive contributor had written at least 30% of a summary document in conjunction with the lead writer.

ISS, Integrated Summary of Safety; SCS, Summary of Clinical Safety (Section 2.7.4 of the CTD).

For example, Section 2.7.2, Summary of Clinical Pharmacology; Section 2.4, Nonclinical Overview, Section 2.6, Nonclinical Written and Tabulated Summaries.
These results showed that respondents assumed lead roles when writing text for SCEs (79.4%) and SCSs (83.8%). As expected, more respondents were lead writers for SCEs and SCs than ISEs (47.1%) and ISSs (61.8%), as only US submissions require ISEs and ISSs. Most qualified respondents frequently created text by using a mix of de novo and repurposed content. Repurposing content is a strategy used to save time and ensure accuracy when it is necessary to create content for a document that is similar to content found elsewhere (eg, other sections of the drug submission or sources outside of the submission). Repurposing requires identification of relevant content, including data and adaptation of that content into another document. Beyond using copy-and-paste functions, repurposing requires thoughtful placement of content into the summary document. Thus, repurposing content can be just as challenging a task as creating content de novo. Respondents also wrote de novo text (eg, based on tables and listings created for pooled data); for specific sections of the various summary documents (eg, from tables and listings created especially for specific summary documents); for subsections of the SCE such as Sections 2.7.3.4, Analysis of Clinical Information Relevant to Dosing, and 2.7.3.5, Persistence of Efficacy or Tolerance Effects; for subsections of the SCS (Section 2.7.4.5, Safety in Special Populations); and for the Discussion and Conclusions section of both the ISE and ISS. Respondents also managed the process of document creation. Close to 50% participated in decisions regarding the analysis of efficacy data (46.3% for the SCE) and the overall safety evaluation plan (54.4% for the SCS). Most created plans with their writing counterparts to ensure alignment of the ISE with the SCE and the ISS with the SCS. Respondents also overcame notable challenges. A “best practice” in the field of medical writing for creation of scientifically accurate and regulatory-compliant clinical summary documents is working from finalized CSRs. This practice is intended to reduce inaccuracies, discrepancies, and unclear messaging, all of which can occur when the summary documents and CSRs are written simultaneously. However, for most respondents, the realities (time constraints, application deadlines) often clashed with best practice. The majority (85.3%) had to start writing summary documents before the CSRs had been finalized. They then confronted the additional challenge of maintaining consistency with the CSRs as the CSRs evolved to approval status and maintaining alignment of summary documents that were being written simultaneously, one by the respondent and the other by another writer. In addition, timelines for completion of the summary documents are often established on the assumption of project managers and upper-level executives that summary documents entail mostly a mechanical “copy and paste” from finalized CSRs. The corollary of this assumption is that a summary document—which optimally provides concise presentations of relevant data culled from the entire development program as well as key messages regarding the clinical implications of those data, including an assessment of benefits and risks of the drug product—can be written, reviewed, and approved quickly. Finally, the majority of respondents found errors in the final tables and listings generated for all 4 summary documents. The implications of this finding are important for 2 reasons: First, identification of errors belies the assumption of project managers and upper-level executives that tables and listings identified as “final” are flawless. This is often not the case. In fact, 75% to 94% of writers identified errors in the efficacy and safety parameters for the SCE, SCS, ISE, and ISS. Second, and crucially, any error in the final tables and listings compromises the scientific accuracy of the drug application and undermines the trust of the reviewers. Therefore, writers who identify and correct errors in the final tables and listings contribute to the integrity of the submission.

Limitations of the survey were its small sample size, the length of the survey (45 questions; the number of respondents tended to drop towards the end), a disproportionately high number of US respondents, the fact that the survey was conducted in English, that answers were subjective (respondents were asked to respond “generally,” eg, “when I write Section XXX, generally I …”), and that all responses were subject to recall bias. The small sample size was a function of survey participation by invitation only, performed to target writers who had in fact written summary documents. In addition, the survey was not validated as we were not aware of a validation tool for this type of endeavor. We also assumed that a lead writer or substantive contributor to any of the 4 summary documents created de novo text based on tables and listings generated specifically for the summary document but did not collect data for this variable.

Mitigating factors were that the overall response rate was excellent (46.8%, 88/188 invited participants), and that the majority of the qualified respondents (77.3%, 68/88) had 5 or more years’ experience writing summary documents. The results suggest that writers make substantive contributions to clinical summary documents as well as strategic contributions to the drug submission process. They create
de novo text and/or intelligently repurpose content for critical sections of each document (introductionary sections, sections that present and summarize data, and discussion and conclusions sections). They overcome the logistical challenge of starting a summary document prior to finalization of the CSR(s) on which that document is based and ensure alignment of that document with the final CSR. They identify and correct errors in the final tables and listings, thus contributing to the scientific accuracy of the data and the integrity of the drug application. Such activities belie the notion that a summary document is the result of a simplistic “copy and paste” process.

Acknowledgments
Kelly Blachford, Process Improvement Solutions, provided guidance regarding effective survey techniques and assistance with the PowerPoint presentation of the survey results delivered by Nancy R. Katz, DIA 8th Annual Clinical Forum, Paris, France, April 2015.

References
Report on the 2016 AMWA Membership Survey

by Gail Flores, PhD, and Stephen N. Palmer, PhD, ELS

INTRODUCTION
The mission of AMWA is to promote excellence in medical communication and to provide educational resources in support of that goal. For this reason, AMWA periodically surveys its membership in an effort to inform the development of new educational offerings and, more generally, to better serve the needs of AMWA members.

The AMWA Membership Survey is taken approximately every 3 years. Its purpose is to obtain information about who AMWA’s members are, obtain feedback about the AMWA membership experience, and gauge members’ perceptions of the various benefits that their membership carries. The results are used by AMWA leadership and staff to determine which of AMWA’s current offerings are best serving members, which ones need to be improved or better promoted, and which ones may need to be discontinued in favor of other offerings that would be of greater benefit. The survey results are also used to guide the development of new programs, products, and services.

MEMBERSHIP SURVEY METHODS
The survey was conducted in June-July 2016 and consisted of 26 questions, 4 of which were open-ended. The survey questions were developed primarily by the AMWA Executive Director and Deputy Director, with input from other staff members. Surveys were sent to all members for whom AMWA had an email address on file (~4100 members), and a reminder was sent 3 days before the survey closed. Twenty-three email invitations were returned as undeliverable. The invitation included a note that anybody who completed the survey by July 1 would receive a coupon code to receive 20% off an AMWA Online Learning offering.

A total of 1074 responses were received, making the response rate 26%. As planned, analysis was performed by using both Excel and SurveyMonkey. A limitation of the survey was that members who do not receive emails from AMWA were excluded. Furthermore, fewer participants answered questions at the end of the survey than at the start. Such “survey fatigue” might have affected the robustness of the data from responses to later questions.

WHO ARE WE?
One finding of the survey is that the age distribution of AMWA’s membership has changed since the previous survey, conducted in 2013. The age distributions of 2016 and 2013 survey respondents are shown in Table 1. Of the 5 age categories, the lowest 4 (20s, 30s, 40s, and 50s) have each lost 1 to 2 percentage points, while the percentage of respondents age 60 years and older has increased. It is not known whether this reflects the aging of current members, a drop-off in new memberships, or members entering the workforce later and/or staying in it longer. More than 50% of respondents have worked in the medical communications field for at least 10 years.

With respect to employment settings, 58% of respondents were employed, while 42% were freelance/self-employed. The most common types of writing were scientific publications and regulatory writing (Figure 1).

Table 1. Who We Are: Age

<table>
<thead>
<tr>
<th>Age Group (years)</th>
<th>2013</th>
<th>2016</th>
</tr>
</thead>
<tbody>
<tr>
<td>20s</td>
<td>4.4%</td>
<td>3.0%</td>
</tr>
<tr>
<td>30s</td>
<td>20.7%</td>
<td>19.7%</td>
</tr>
<tr>
<td>40s</td>
<td>25.1%</td>
<td>23.3%</td>
</tr>
<tr>
<td>50s</td>
<td>32.5%</td>
<td>30.2%</td>
</tr>
<tr>
<td>60+</td>
<td>17.4%</td>
<td>23.8%</td>
</tr>
</tbody>
</table>

WHAT IS AMWA DOING WELL?
Members’ overall feeling about AMWA is very positive: nearly 80% of respondents reported being satisfied or very satisfied with their AMWA membership experience. Furthermore, 76% of respondents consider their membership to be important, and more than 87% would recommend AMWA to their colleagues.

The 3 most commonly accessed benefits are the AMWA Journal and 2 relatively new benefits: the Engage online com-
munity, and the Medical Communication News curated-content electronic newsletter. Almost 80% of respondents reported that they read the AMWA Journal—approximately 40% read it online, 30% read the hard copy, and 14% do both.

Our membership is engaged! Seventy percent (657/938 responses) of respondents read or skim posts in the Engage online community.

Many respondents find Medical Communication News to be a valuable resource, most notably because it provides industry news and information (46% of respondents). Additional reasons include its relevant content, easy-to-read format, and information about products and services for medical communicators (Figure 2).

WHAT CAN AMWA DO BETTER?

Education was the most common answer (34%) to the question about what AMWA could do to improve members’ satisfaction ratings. Education was the most common theme (22%) among the answers to an open-ended question about “the one thing AMWA could provide to help you do your job better,” as well as the most common response (24%) to the question about what AMWA could do to improve member satisfaction.

Many respondents requested more low-cost or free educational offerings. They rated online education as the most important program they wanted AMWA to offer (4.37 on a 5-point scale). However, many members are not yet actively participating in AMWA Online Learning. As shown in Figure 3, 34% (314/925) of respondents have not participated in AMWA Online Learning, and 35% (320/925) have reviewed but not accessed online offerings.

With respect to AMWA resources, many members expressed a lack of awareness of some of the benefits AMWA has to offer, such as affiliation discounts. The Engage online community and Medical Communication News have been widely promoted by email (the same vehicle that delivered the survey invitation), the AMWA Journal, and social media; nevertheless, 20% (187/938) of respondents reported not being aware of Engage, and 18% of respondents reported not being aware of Medical Communication News.

Finally, approximately half of survey respondents do not participate in AMWA chapter activities. Chapters, in general, received neutral ratings regarding chapter programs and services, with approximately 25% of respondents desiring more local opportunities to network.

WHAT DO WE CARE ABOUT?

Members were asked to rate, on a 5-point scale, how important it is for AMWA to offer each of 9 different categories of programs or services. The 2 categories with the highest average ratings were online education (4.37) and conferences (4.33).

Virtually tied for third place were an online community for members (4.11), career management tools (4.10), and local in-person events (4.10). Less highly rated were professional certification (3.83), digital newsletters (3.75), a print journal or magazine (3.50), and volunteer opportunities (3.44). These ratings suggest that what members care about most is having...
opportunities for interactive learning and networking, both online and in person.

Members were also asked to rate each of 9 specific members-only benefits in terms of how valuable the member considered them to be. The most highly rated of these benefits was members-only free webinars (4.03). This was followed by affiliation discounts on products like EndNote and the *AMA Manual of Style* (3.74), AMWA’s Engage online community (3.74), the *AMWA Journal* (3.72), AMWA Jobs Online (3.72), and discounts on AMWA’s Online Learning activities (3.69).

Somewhat less highly rated were the AMWA Membership Directory (3.52), *Medical Communication News* (3.49), and the AMWA Freelance Directory (3.35).

One general conclusion that can be drawn from the results of the Member Survey is that AMWA members are busy professionals. The most common answer to a question about which late-night comedian respondents preferred was that they were either too busy or too tired to watch late-night television. Likewise, 26% of respondents to a question about *Medical Communication News* reported being too busy to read it. And 29% of respondents who said that they had not used any of AMWA’s online education activities cited lack of time as their main reason.

**LOOKING AHEAD**

Ensuring that members have a high-quality, high-value experience remains a priority for AMWA. This is the chief reason why AMWA continues to survey its members regarding what they get, and would like to get, out of their membership.

From the respondents’ answers to the open-ended questions in the survey, as well as the numerical ratings, several themes have emerged. Members want and value AMWA education—specifically, learning opportunities that are readily accessible online or in person. They prefer educational offerings to be low cost or free. And they have limited time, because they are busy professionals. These will be important factors to consider as AMWA continues to develop its educational resources.

---

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You’ve worked hard for years to become a skilled and highly qualified medical writer. You’ve devoted countless hours to honing your skills through continuing education, are highly specialized, perhaps with an advanced degree or specialty certification, and your eagle eye for grammar is unparalleled. You take pride in your work and produce a product that meets your clients’ needs and provides valuable information for the reader.

Unfortunately, the only people who can reap the full benefits and truly appreciate all of this are those who are fluent in your language (presumably English). In this increasingly—or perhaps I should say completely—globalized world, chances are that sooner or later your employer or one of your clients will need to make some of this elaborately crafted content available to native speakers of other languages, be it at home or abroad. Whether you are working in regulatory writing, clinical research, health care, or marketing, this material will need to be provided in a translation that reflects the quality of the original. It needs to be correct in terms of content, style, register (ie, the variety of language used in that particular setting), and terminology; be culturally appropriate; and meet regulatory or other requirements.

So how do you make sure the results of your hard work don’t get lost in translation?

**Step 1: Define who you need.**

In common vernacular, the term *translator* is often used incorrectly. Not to worry, though; this one is simple: In the translation and interpretation (T&I) industry, a translator is someone who works with written material, whereas an “interpreter” works in oral communication. This means that you would look for a translator to translate your clinical trial protocol but would hire an interpreter if you were taken to court in a foreign country. While some do “double duty” as translators and interpreters, many do not. It helps to know the difference, both to find the right person for the job and to show respect to your fellow language professional.

Could anyone who is bilingual be a translator? Could they just translate the words? This common fallacy about translation is akin to asking whether someone with a basic command of the English language and a medical dictionary could be a medical writer. An effective translator needs to be capable of understanding a complex text, recreating it in the same style and register, targeting the message to the appropriate audience, and preserving all the nuances of the terminology. These are highly technical skills that require experience and training beyond simple fluency in more than one language.

The best translators, like the best writers, also recognize the importance of a good editor. Translation typically follows a 3-step process: the first person translates, the second person edits, and either the translator or a third person does the final proof. In industry jargon, this is referred to as TEP (translation, editing, proofreading). Good translation service providers will adhere to some version of this model; it’s a good sign if your translator’s quote includes editing by another professional or suggestions for a colleague who can handle editing.

Finally, a word on machine translation (MT). This technology does have some uses, as it can allow for an approximation of the subject matter and contents of a particular document. However, it is in no way suitable for achieving a good outcome. Most MT outputs are an absolute minefield of errors that are, at best, embarrassing, and at worst,
deeply damaging to your business. However, MT should not be confused with translation memory tools. These tools are sentence-level and terminology databases that are widely used by translators as well as by agencies to ensure consistency and possibly save you some money, for instance, when updating an existing translation.

**Step 2: Determine what you need to have translated.**

Project clarity is essential before beginning your search for a translator. To or from what language or languages do you need your document translated? What is the scope of your project? What is your target group? Do you need a 1-page physician report translated from French into English? Or do you need 250,000 words of clinical trial documentation in 10 languages? Do you need 5 high-end marketing brochures adapted for maximum impact in China? Or 20 2-page patient education leaflets provided in Spanish for health care consumers in the United States? Depending on the answer, you may want to look for very different types of translation services providers.

Before you start looking, however, it’s a good idea to put your project together. Collect the documents you need to have translated, determine the volume, figure out your timeline, and talk to any stakeholders to find out what their needs are. Content should be extracted from websites, non-editable file formats (eg, PDFs), or files in graphic design formats (eg, InDesign or FrameMaker). This not only makes the process more straightforward, but also gives you a better idea of volume and will allow your provider to give you an accurate quote. While some translators will work with complex formats, their primary focus is on translating content; asking your translator to extract content will make the process longer and more costly—and may even limit the pool of translators who are willing to work on your project.

In short, you should be able to answer the following questions before beginning your search for your perfect foreign-language partner:

- Is your content extracted from any complex files and in an editable format (eg, Microsoft Word file)?
- What is your total volume of material to be translated (word count)?
- What is your timeline (keep in mind that 2,000 words or fewer per day is a realistic translation target)?
- Can you provide the translator with all applicable briefing information (content type, project goal, target audience, target country, etc)?

**Step 3: Choose to work with a freelance or an agency.**

The US translation market is dominated by large agencies of all types with varying reputations. If you need extremely large volumes translated into several languages, maybe even with a short turnaround time, an agency may be your best bet.

Agencies usually work with a large pool of freelances and can take the lead on project management if desired. Almost invariably, agencies claim that they have high-quality standards, only work with the best people in the industry, and have deep expertise in various fields—all at the best possible price. Unfortunately, some—not all—of the larger players are notorious for hard-selling additional services, hiring inexperienced college graduates as project managers in a high-pressure environment, and farming out the work to freelances who are all too often inexperienced, ill-qualified, poorly paid, and selected at random. Often, they split up large jobs into many small fragments and simply “glue” them back together, with an obvious effect on quality and consistency.

Of course, there are some good agencies and some good reasons for choosing an agency. Agencies may be a good choice if, for instance, you need large volumes translated quickly, if you require translation into more than 1 or 2 languages, or if you are working with languages of limited diffusion. When choosing an agency, look for a specialized translation service...
provider, many of whom tend to be smaller. Specialized agencies may work only in medical or pharmaceutical translation, might work exclusively in 1 or 2 languages, or may focus on marketing and advertising translation and “transcreation” (rewriting content to suit and appeal to the target market). These boutique agencies feature personalized service from their owners, who are knowledgeable, tend to hand-pick their in-house and freelance translators, and implement a high level of quality control for projects.

An individual freelance may be your perfect partner if you only need translation to or from 1 or 2 languages, have smaller projects (less than 20,000 words/month), and/or are willing to handle some of the project management yourself. With an individual freelance, you can precisely choose the specialization, directly communicate with your service provider, and get exactly what you need.

**Step 4: Know where to find translation professionals.**

Like other professions, translators (and interpreters) have professional associations. Most, if not all, of these will have searchable member directories. In the United States, the American Translators Association (ATA) allows you to search their directory at www.atanet.org for translators according to language combination, specialization, location, and ATA certification status. Another option would be to search the translators’ association in the country of your target language. The International Federation of Translators (FIT) provides a directory of European translators’ associations at www.fit-ift.org/annuaires-en-ligne-fit-europe-2/. For most other associations, a quick Google search for “translators’ association + country” should be a good start. LinkedIn is another good place to start your search for a translation professional. Don’t hesitate to contact translators in your network, even if they do not have the right language/subject matter expertise combination for your project. Much like medical writers, translators are generally a helpful bunch and can recommend colleagues who might be right for you.

In addition, there are online translation marketplaces such as ProZ.com. As the term “translator” is not regulated, these marketplaces can be a bit of a free-for-all. While there are certainly good people on these sites, there is also an abundance of less-than-professional service providers and those with little requisite experience. Prices tend to be low on these sites, but they come with the risk of poor service or a more involved process to obtain a high-quality final product. Like other professionals, good translators who have been in the business for a while tend to be busy and to not be actively looking for new clients on sites like these.

**Step 5: Find the right professional for your job.**

Anyone with bilingual abilities—with or without formal training—can call themselves a translator, so you’ll need to be thorough in your vetting of potential translation professionals. An added wrinkle is that if you’re looking for a translator you most likely don’t speak the target language, which makes it all the more difficult to evaluate the quality of work you receive.

So how do you separate the wheat from the chaff? As a rule, professionals in the field will hold some type of advanced degree. Some will have crossed over from other fields (eg, medicine, engineering, physics, law), and others may have completed a linguistics or journalism degree or even one of the more demanding, globally available graduate programs in translation. In addition, certain organizations, such as the ATA, hold certification exams, which can be a helpful indicator of quality.

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**Beware of anyone claiming to translate into and out of several different languages and in many different fields.**

A word of caution: Beware of anyone claiming to translate into and out of several different languages and in many different fields. With very few exceptions, translation professionals work from only 1 or 2 languages into their native language and specialize in only a handful of fields.

Also make sure to assess the specific market you are targeting. If you need to prepare documents for Hispanics in the United States, a translator for Iberian Spanish will not be able to provide the right kind of service. If you are targeting France, a French-Canadian translator might not be the right fit.

Finally, remember that to provide quality, a translator has to have not only excellent writing skills, but also the ability to correctly and appropriately analyze, comprehend, and...
transfer content, tone, style, and cultural elements from one language to another. While you may of course notice mistakes when a translator is communicating in a language into which he or she typically does not translate, it (hopefully) goes without saying that this should not be the case in the target language.

Evaluating a translator’s skills can be a challenge, as you—presumably—are not yourself a native-level speaker of the target language. The easiest way to make sure your larger project is in good hands is to assign a small test project to the translator and/or editor you are planning to use. Use this as a test case and have the result evaluated by someone who is competent in the field and by native speakers of the target language (eg, business contacts or employees of your company in the target country). Ask your reviewer to provide specific feedback on accuracy, terminology, flow, appropriateness for the target audience, etc. Some caveats to this approach: your feedback will depend on the personal style and cultural tendencies of your reviewer. Good judgment will be required to determine how heavily the reviewer’s feedback influences your hiring decision.

As an added bonus, this test case will give you a good idea about whether this is someone you would like to work with on a longer-term project. You can vet the translator–editor relationship by asking the editor for feedback on the translation. Remember to check back with your translator about the edits, changes, or feedback you receive, as this can provide valuable information about their working style.

**Step 6: Communicate with your translator.**
You’ve found the right person, signed the contracts, and are ready to go, but there is one more thing you need to do to ensure the best possible outcome: communicate with your translator!

Provide your translator with as much background information as you can, much like you would do when contracting with a medical writer or copywriter. What is the target group? What do you intend to achieve with this material? Do you need the target text to reflect the source as accurately as possible, or do you need it to truly speak to your audience? Bear in mind that translation is not a word substitution game and that there are things that linguistically and culturally just don’t “translate.” In addition, previously translated reference materials are extremely helpful to your translator. This is especially important if your content refers back to these materials and you need to maintain consistency to avoid confusing the reader.

In most cases, your translator will be external to your organization and may therefore be lacking information about certain aspects of your process or specific organization. Internal usage, acronyms, and terminology may need to be clarified to successfully translate your document. A good translator will likely have questions about intended meaning as they work. Be sure to plan for regular check-ins with your translator as the project progresses.

Finally, your translator could end up being your best proofreader. A translator’s job requires careful and thorough reading of the text. Don’t be surprised if the translator points out typos, errors, inconsistencies, or ambiguities in your original source content. Don’t take it as criticism—hiring a good translator can be one of the best things you can do for quality control!

**Conclusion**
A translator serves as a bridge not only between languages but between cultures, customs, and communities. Hiring the right translator can be the critical step that determines whether your ideas and message resonate with a global audience. Your efforts to find the best fit for your project and to cultivate a relationship with your translation professional will ultimately expand the reach of your written word.

**Acknowledgment**
I wish to thank Kim Korwek for her editorial assistance.

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**Author’s disclosure:** As a freelance translator who has worked for all types of clients, including translation agencies, the views expressed above are my personal opinion and a reflection of my experience in the T/I industry over the course of 21 years.
WRITING UNDER FIRE: SKILLS AND OPPORTUNITIES FOR WRITING IN A CRISIS

Speakers:
Angela N. Johnson, MSE, PMP, RAC
Senior Professional Band Clinical Writer, GE Healthcare, Waukesha, WI
*Catherine Cadogan, BS
Senior Professional Band Clinical Writer, GE Healthcare, Waukesha, WI
*Carrie Lauer, MS
Contract Clinical Writer, GE Healthcare, Waukesha, WI
*Presenters attended via phone.

By Charity Hix, MD
Medical writers face a myriad of challenges in their daily work. In the Fall 2016 edition of the AMWA Journal, authors Angela Johnson, Catherine Cadogan, and Carrie Lauer described their ongoing goal to collect and document medical writers' stories. In sharing writers' experiences, the authors seek to move beyond the technical aspects of writing and explore just who medical writers are and what hurdles they must overcome. The authors spoke at the 2016 Medical Writing & Communication Conference in Denver. In their session, “Writing Under Fire: Skills and Opportunities for Writing in a Crisis,” the authors shared writers’ personal stories of challenge and struggle. They then provided resources and solutions for addressing the most pressing daily “crises” medical writers face.

Challenges and Solutions
The stories shared to date suggest that writers are often not challenged by the act of writing, but rather by the interpersonal exchanges necessary to complete their tasks. “This is not entirely unique to our field,” noted Ms Johnson. “So much comes back to the dialogue on emotional intelligence right now.” She then provided suggestions for interacting confidently with stakeholders.

Bridging people and backgrounds
• Develop effective listening skills and foster communication to build relationships
• Establish mutual respect and use candid conversations to avoid misinterpretation
• Build common ground and strong relationships across teams
• Be aware of body language during face-to-face interactions
• Explore best practices for managing digital spaces
• Humanize the medical writing process with kindness, humor, and empathy

• Manage your energy and identify personal stressors
• Be self-aware of your own emotional quotient and seek to improve weaknesses
• Be kind to yourself and others

Self-doubt and fear
• Ask questions fearlessly and prepare thoroughly
• Value your work and expertise
• Establish mutual respect

In gathering writers’ stories, Ms Johnson stated, “You would be amazed at how many responses said, ‘I wasn’t acknowledged as an author.’” The biggest trend, she noted, was writers simply hesitating to speak their minds. She then discussed how writers can address power struggles and touched on authorship issues.

Dealing with pressure and power
• Identify others’ expectations at the project’s onset
• Define your ethics and don’t be afraid to “stick to your guns”
• Be cognizant of power structures in your situation and develop ways to manage them
• Appraise and apply the concepts of ownership, accountability, and responsibility

Navigating authorship and acknowledgement
• Communicate goals and expectations early by specifying details in contracts or project plans
• Refer to established guidelines and definitions for authorship
• Maintain documentation of communications
• Be willing to voice your opinions and concerns

Finally, Ms Johnson provided suggestions for writers whose crises and frustration stem from burnout or time-management issues.

Getting “unstuck”
• Develop strategies to cope with delays that are not in your control
• Identify processes for addressing frustrations (for example, the “5-Whys” method)
• Find a passion or spark in each project
• Use available motivational and organizational technology
• Know when to say “no” and avoid overload
• Be open to communicating stressors and mirror other writers who are successfully managing similar situations
• Devise long-term coping strategies for work–life balance
Managing review cycles and timelines
- Appropriately estimate the time needed for projects and don’t overcommit yourself
- Value your time and expertise during collaboration, research, and writing processes
- Start your work day early, build momentum, and maintain designated work hours
- Avoid last-minute stressors and use internal deadlines to break down large tasks

Despite the crises medical writers routinely navigate, Ms Johnson reminded the audience that “this field is exciting.” She explained most writers will be exposed to more depth of experience over their career than many other scientists or stakeholders. “Don’t forget that,” she encouraged. “It’s absolutely amazing.”

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Frick noted that editors may be involved in various “levels of editing,” which depend on the description of their assigned role (e.g., substantive content editing or basic proofreading). Her session focused on the resources that are useful in the final stages of editing that involve ensuring correctness and consistency, which are 2 of the “5 Cs” that guide good writing: complete, consistent, clear, concise, and correct. Frick organized the resources for editors into 6 categories, ranging from personal comfort to business resources. She used the recurring reminder that “nothing changes if nothing changes” to stress the need for editors to continue to adapt and update their skills portfolio throughout their career.

Spiritual and Self-Care Tools for Overworked Editors
Frick advised editors, first and foremost, to take care of themselves. Given the health detriments of sedentary work days, she said editors should consider it mandatory to exercise regularly and take relaxation breaks. Also necessary are ample sleep, a balanced diet, and an active social circle. To avoid a workaholic lifestyle, editors were counselled to “say no” to overwhelming numbers of assignments.

Physical Setup of Editing Space
Citing her experiences working in both small cubicles and dedicated office space, Frick noted that one’s surroundings can influence both mood and productivity. Natural light, functional furniture, and cabinet space can all make important differences. A change of place can help editors combat a work slump, as can other physical accommodations such as replacing the office chair with an exercise ball or using one’s non-dominant hand to operate the computer mouse. Attendees of the open session suggested using standing desks to get some exercise and noise-cancelling headphones or white noise machines to improve concentration when working in shared or noisy offices.

Hardware for Editors
Hardware is a critical component to an editor’s work; standard hardware options over the years have been desktop computers, laptops, and tablets. The idea of adding a second external screen strongly resonated with the attendees. With a photograph of her own 2-monitor desk setup, Frick illustrated the benefits: enlarged text, reduced toggling among windows, and less eyestrain. Another useful piece of equipment is a timer, which can be used to track productivity and to encourage regular work breaks.
Having the most useful software (Box 1) can also make work easier and more efficient. Below are a few highlights from the discussion on software.

- Microsoft Word is of course a standard program for editing. Frick noted several functions to maximize editing speed and efficiency:
  - Keyboard shortcuts. Frick said she couldn’t live without certain shortcuts, such as using CTRL + B/I/U to bold/italicize/underline text.
  - Lookup. Available through the tools menu or the right-click context menu, the lookup function pulls up a search engine result of selected text.
  - Global search and replace.
  - Macros. Pronounced to be indispensable, macros can be created to group multiple frequently used functions into a single command.
  - Line numbering. This function helps reviewers easily locate text.

- The customizable proofreading software PerfectIt was highly recommended, as was the screen capture tool SnagIt and the dictation software Dragon Naturally Speaking.

- Cloud-based software such as Grammarly was mentioned, but concerns were raised over the security and confidentiality of uploading documents into the cloud.

- A useful tip for new software users: Take advantage of free trial versions, even if for a limited time.

### Internet Tools for Editors

Frick also provided a list of online resources for various aspects of the editing profession (Box 2). A leading recommendation was for every editor to use time-tracking software to help keep an accurate record of editing metrics so that hourly rates can be periodically self-assessed. Using her own spreadsheet as an example, Frick demonstrated the items she considers essential to track for each assignment undertaken: total number of pages and words, time spent per page, words written per hour, and number of revisions.

### Analog Tools for Editors

Frick mentioned other key resources and tips:

- The importance of being familiar with style manuals was discussed, the most popular ones being from the American Medical Association (AMA) and the Associated Press (AP).
- Organizational style sheets: Frick encouraged creating one’s own custom organizational style sheet that lists preferred spellings and terms.
- Participating in local, national, or global organizations for editors such as AMWA can be highly educational.

The session ended with Frick reminding the attendees of the value of learning, emphasizing that to be an effective editor, staying up to date with language, grammar, and style changes is key.

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IT’S TIME FOR MEDICAL WRITERS TO GET BIG AND DIRTY: WRITING OPPORTUNITIES IN DATA, BIOMETRICS, AND TECHNOLOGY

Speaker:
Angela N. Johnson, MSE, PMP, RAC
Senior Professional Band Clinical Writer, GE Healthcare, Waukesha, WI

By Xin Liu
Innovations in technology have brought many changes to health care. Sophisticated medical devices and electronic health records have permeated hospitals and medical offices and generated reams of data.

In her open session at the 2016 Medical Writing & Communication Conference, Angela Johnson from GE Healthcare discussed the opportunities and challenges that “big data” provide for medical writers. The term “big data” refers to datasets whose size are beyond the ability of typical database software tools to capture, store, manage, and analyze.

“What does it mean to medical writers?” Johnson asked. “It means we will have more job opportunities. But it also means our clients will change and our regulatory environment will change.”

Johnson defined some key terms and outlined concepts related to big data and associated regulatory rules.

The Internet of Things in Health Care
“The Internet of things” refers to the ever-growing number of network-connected objects that send and receive data. In health care and medical research, this includes devices used by patients, physicians, and researchers to assist with diagnosing illness, monitoring various health-related parameters, and storing information. These devices create a large amount of data. A report for the European Commission described estimates that medical images alone will soon comprise 30% of all stored data in the world. Internet-connected devices are continuously growing and, by some estimates, are expected to make trillions of dollars in economic impact in the next decade.

According to Johnson, this exponential growth of data related to health care will present medical writers with 2 main challenges:
• Learning how to communicate with data professionals
• Understanding the regulatory rules of sharing and documenting medical data

Learning to Speak “Big Data” to Data Natives
Johnson introduced basic properties of big data, which can be characterized by 4 Vs:
• Volume: the scale of data
• Veracity: the uncertainty of the data
• Variety: the different types of data that are available for collection and analysis in addition to the structured data found in a typical database
• Velocity: the speed at which data are acquired and used, often in real time

“Data analytics” refers to what we do with data, which may include applying statistical techniques or using graphics to represent the data. In population health, there are 4 key types of data analytics:
• Descriptive analytics answer the question “What happened?” (For example: How many patients had low blood sugar?)
• Diagnostic analytics answer the question “Why did it happen?” (For example: What correlated with low blood sugar?)

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Box 2. Resources for Editors

**Websites for editing tools and tips**
- Purdue OWL (Online Writing Lab)
  https://owl.english.purdue.edu/owl
- Grammar Girl
  www.quickanddirtytips.com/grammar-girl
- OneLook Dictionary Search: database of dictionaries
  http://onelook.com

**Business-related blog posts written by Elizabeth Frick**
- The Freelancer’s Biggest Worry—Am I Losing Money When I Bid?
- Time Flies! Time Tracking Software for Independents
  www.stc.org/notebook/2013/03/13/business-matters-time-flies-time-tracking-software-for-independents

**Books on editing**
- *What to Charge: Pricing Strategies for Freelancers and Consultants* by Laurie Lewis
- *The Sense of Style* by Steven Pinker

**Checklists**
- AMWA member Kelly Schrank’s presentation on using checklists for efficient editing
  www.slideshare.net/kellyschrank/using-checklists-for-more-efficient-editing-handout
- *The Checklist Manifesto* by Atul Gawande
Predictive analytics answer the question “What is likely to happen?” (For example: How many patients will have low blood sugar next year?)

Prescriptive analytics answer the question “What should I do about it?” (For example: What change will reduce low blood sugar levels?)

Data analysts use various computer programming languages, software programs, and algorithms in their work. SAS, R, Python, and MATLAB are among the common programs used in data analysis.

Regulation of “Big Data”

Johnson provided an overview of some of the regulatory challenges posed by big data. In 2014, editors from Scientific America contemplated the privacy risks involved in the collection of biometric data, such as DNA and iris scans. “Current law is not even remotely prepared to handle these developments. The legal status of most types of biometric data is unclear… but the potential for misuse is glaringly obvious.”

Data privacy is just one consideration in the regulation and management of big data. Two other important considerations include interoperability and usability of data systems. “Interoperability” is the ability to safely, securely, and effectively exchange and use information among 1 or more devices, products, technologies, or systems. “Usability” is the extent to which designated users can use a product with effectiveness, efficiency, and satisfaction in a specified context.

Johnson noted that various governmental agencies and nonprofit organizations are involved in setting rules and standards for health care data exchange:

- The Office of the National Coordinator for Health Information Technology published a “roadmap” in 2015 outlining a series of goals for data interoperability and usability. The long-term goal is building a “learning health system” characterized by “continuous improvement in data exchange, information governance, interoperability, [electronic health record] usability, patient safety, provider satisfaction, and population health.”
- Health Level Seven International (www.hl7.org) is a not-for-profit organization dedicated to providing standards for sharing health information.
- Integrating the Health Enterprise (IHE) (www.ihe.net) is a nonprofit initiative by health care professionals and industry to improve the way computer systems share health care information.
- The International Organization for Standards (ISO) and the Institute of Electrical and Electronics Engineers (IEEE) provide a “family” of standards addressing the interoperability of personal health devices.

Johnson ended the session by noting that the purpose of writing is “to get ideas in your head into someone else’s head.”

Facing the skyrocketing volume of medical data, medical writers should learn to speak the language of data and catch up with the regulatory rules, and then we can clearly and accurately convey the information to our readers.

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References

American Medical Association (JAMA). “Unquestionably, it is the greatest factor of modern medical progress.”

Connor’s description held true through much of the 20th century, but medical journals have evolved quickly in the Internet age.

According to Michelle Dalton, ELS, founder of Dalton & Associates, a medical communications company, “that lauded and prestigious reign is no longer limited to just the clinicians.”

Today, medical journals may retain a primary audience of clinicians, but are also read by “you—Joe or Jane Patient—as you Google your disease state before going to see your doctor,” Dalton, said during her 2016 AMWA Medical Writing & Communication Conference presentation, “The Future of Print Medical Journals: Strategies for Medical Writers to Lead and Stay Relevant in a Changing Publication Arena.”

Journals operate in a highly competitive and fast-changing market and must speak the language of all information consumers, added co-presenter Caitlin Rothermel, MA, MPH, a principal at MedLtera, a virtual medical writing services company. Rothermel stepped in as co-presenter for Patti Peeples, RPh, PhD, chief executive and principal researcher of HealthEconomics.com, who was unable to attend the conference due to a hurricane in Florida.

“How do you hear medical writer opportunities in that? I think so!” Rothermel said.

To thrive in the new medical publishing landscape, writers should “think beyond the manuscript,” Dalton said. “We want to have you start thinking of yourselves as communications specialists, not just medical writers.”

Evolution of Medical Publishing

While continuing to serve their primary audience of physicians or medical researchers, medical journals may also see the benefit of addressing the lay audience. Exploring such trends in medical publishing can help writers see the value of broadening their perspectives. Trends include the following:

• Competition is increasing as new journals emerge, published by for-profit publishers and medical and academic associations, with some new journals published in an open-access format.
• Publication turnaround times are becoming shorter.
• More types of journals are considered valid options for publications required for academic advancement.
• Content is more reader-oriented, and journals are using multimedia, social media, online commenting, and other tools to increase reader engagement.
• Content is no longer strictly medical, but increasingly reflects political and cultural trends. President Barack Obama, for example, wrote an August 2, 2016, JAMA article spelling out progress and next steps for the Affordable Care Act. Medical journals are “seen as a way to get your policies out there,” Dalton said.
• Interactivity is vital. Journals are publishing articles early on the Web to get feedback and gauge their impact, then using that information to determine print schedules to maximize the impact factor, for example.

Rothermel cited Health Affairs as an example of a journal that embodies these trends. In addition to its mobile-friendly website that features content such as topical briefs and past articles related to current policy discussions, Health Affairs produces a podcast with associated articles, is active on social media, including Pinterest, and produces blogs, newsletters, and webinars.

How Medical Writers Can Adapt

So how can medical writers adapt and add value in this changing landscape?

“Essentially, you want to think about how everything you do can be repositioned and retargeted to have many different lives,” Rothermel said. “Reposition the manuscript as a newsletter or as social media shares or as a webinar. Propose these things to your client, and everyone does well.”

To act as a communications specialist is also to embrace more of a consultant’s role. When approaching a new project,
Orlando, Florida, is known throughout the world as a vacation destination, but we hope you will take the opportunity to mix a little business and pleasure in your attendance at the Medical Writing & Communication Conference this year! Mark your calendars now for November 1-4 . . . and maybe plan on a few days before or after to take advantage of our location. There will be plenty of time for professional development: you can attend open sessions on new topics, take exams to add to your credentials, participate in AMWA Workshops to increase your skills and knowledge, and gain new insights from award-winning speakers. But there will also be time to meet new people and see old friends, try new foods and drinks, explore new locales, and strengthen relationships with your colleagues through these adventures. It’s the perfect opportunity to open yourself to new experiences and reinvigorate your passion for your career or business.

**Amenities**

Before or after the conference you’ll be able to stay close and take advantage of all that’s at the doorsteps of the lovely Walt Disney World Swan and Dolphin, including a discounted hotel room rate. Or you can venture off the Disney property and explore Florida’s natural treasures, experience what’s been called a “golfer’s paradise,” or spend some time discovering the other theme parks in the area. For evening dinner excursions, Disney and Orlando offer a plethora of options. Staying at the conference hotel, you’ll be right next door to Disney’s BoardWalk Entertainment District, which offers dining, recreation, and entertainment options. Staying at the hotel also gives you access to free bus rides to Disney Springs, which offers even more dining and shopping options, and free boat transportation to Disney’s Hollywood Studios and Epcot—which will be offering the International Food & Wine Festival while we are there.
Programming

The Annual Conference Committee has been busy looking over the 2016 post-conference survey results for insights into what you want to see this year, discussing trends and topics of interest to the community, and recruiting folks, where necessary, to cover what you want to see at the conference. We’ve asked for sessions in the following areas:

• The Evolving Regulatory Landscape
• New Media Channels, Writing, Technology, and Software
• The Future of Continuing Medical Education
• Fresh Perspectives on Health Literacy and Lay Audiences
• The Business of Freelance
• Grant and Proposal Writing and Editing
• Staying Current (Professional Development Topics)
• Essential Medical Communication Skills (Writing and Editing)

Look for our article in an upcoming issue of the AMWA Journal and watch for communications from AMWA staff for more information on the conference schedule, workshops, and sessions. Be sure to visit www.amwa.org/conference for more information and to book your hotel room.

No matter when you arrive, or how long you stay, we are looking forward to seeing you in Orlando!
For months, we had been looking forward to our open session on social media and marketing at the 2016 Medical Writing and Communication Conference in Denver. With just a few weeks to go, our planning was just about complete when it became apparent that one of us (Jennifer) would not be able to travel because of an unexpected medical issue.

We began brainstorming about potential virtual options so that we both could continue to be part of the session. Should we host a Google Hangout? How about doing something via Skype? However, since most of the presentation covered the use of Twitter, it seemed especially appropriate to demonstrate one of its many features. A Twitter chat would allow Jen to interact directly with the audience by answering questions in real time from home, while Ruwaida hosted the live presentation in Denver.

What is a Twitter Chat?
A Twitter chat consists of a group of Twitter users who meet virtually at a predetermined time to discuss a specific topic, finding each other on the social media platform by using a specially designated hashtag.

Not only are Twitter chats useful in a conference setting, but they are also powerful tools for learning and networking. In fact, they are one of the best examples of community building on Twitter. A Twitter chat typically has a moderator or host who encourages interaction within the group. Twitter chats usually last about an hour, but people can join or leave the discussion at any time. In addition to the benefits of learning by virtual networking, these chats help foster deeper connections such as building advocacy, loyalty, and community, which ultimately can lead to an increase in exposure on social media, brand awareness, and new business opportunities.

All of these features of a Twitter chat made it perfect for the goals of our session on social media and marketing.

For our presentation, we created the hashtag #AMWAOS16. This hashtag allowed the audience—those in-person in Denver as well as anyone else paying attention virtually—to follow all the questions and answers surrounding the presentation in real time on Twitter. To encourage the audience to tweet to that hashtag, Ruwaida included the hashtag on each slide of the presentation and explained at the beginning of the presentation how it worked. Back at home, Jennifer had started the chat earlier in the day by encouraging people to later join the live Twitter conversation by using the #AMWAOS16 hashtag and reminding all in-person attendees of the time and place of the open session. The chat was very successful, and many audience members remarked how nice it was to have their questions answered virtually in real time without breaking up the flow of the presentation.

The chat is permanently archived on Twitter and can be easily accessed by searching the related hashtag. This allows people who have not attended the session to take a look at

### Twitter Chat Saves the Day

by Ruwaida Vakil, MS¹ and Jennifer Minarcik, MS²

¹Principal Medical Writer, ProMed Write LLC
²Principal, Jennifer Minarcik Biomedical Communications, LLC
some of the Q&A on Twitter. You can also print and email the chat history to all attendees after the session or remind them that they can look up the chat on Twitter.

Twitter chats are a versatile way to engage participants who attend a live conference presentation or even a webinar. The chat virtually extends the presentation’s audience. It is important to note that the Twitter chat was very efficient in this case because one of the presenters was not present and was able to Tweet and engage the audience virtually. In a typical presentation, it may be too strenuous for the presenters to complete the oral presentation as well as conduct a Twitter chat simultaneously, even if there are multiple presenters. However, Twitter chats can be initiated before or after the presentation to stimulate interest and more conversation around the topic.

Twitter chats are also a helpful way to learn about new topics and network with other health care professionals. Some organizations host weekly Twitter chat sessions to stimulate conversation around a “hot topic.” Examples include:

1. Healthcare Communications and Social Media (@HealthSocMed) #hcsm
2. Diversity in Medicine and HealthCare (@DIMAH) #DIMAH

Other key organizations, such as the FDA (@US_FDA), CDC (@CDCgov), and NIH (@NIH), host Twitter chats throughout the year. Medical communicators interested in attending these Twitter chats can simply follow the groups to ensure the upcoming Twitter chats appear in their news feed.

Tips for participating in a Twitter chat:
1. Be polite and positive.
2. Use Twitter handles when chatting with a particular participant in your tweets.
3. Avoid selling your products during a chat.
4. Always use the chat hashtag.
5. Follow up with people you have met on the chat.

Tips for hosting a Twitter chat:
1. Choose a brief, clear, and unique hashtag.
2. Set an appropriate tone for the chat by reminding participants to be polite and respect the opinions of the other participants.
3. Remind the audience that the chat is permanently archived and publicly available.
4. When you schedule your chat, consider your audience and time zones.
5. Plan the topics and potential questions in advance.
6. Encourage and engage your participants.

Authors’ disclosure: The authors note that they have no commercial associations that may pose a conflict of interest to this article.
How do you use LinkedIn to find new clients?

The world’s largest virtual networking event, LinkedIn is a powerful social media tool to attract and gain new clients. In fact, LinkedIn is today’s resume. It is absolutely essential for anyone interested in advancing his or her career, whether you are freelance or full-time. Simply having a LinkedIn profile is not enough to benefit from LinkedIn. Attracting and winning new clients starts with developing a compelling, client-focused profile. Therefore, you need to establish strategies that will attract clients, build relationships with prospective clients and colleagues, and expand your network.

You can start optimizing your LinkedIn profile by uploading a professional headshot and completing your profile to 95% or better completeness. Once you have done that, you will need to join LinkedIn groups that are unique to your field and post and respond to messages in those groups.

You can also reach out and directly market yourself to potential clients through LinkedIn by connecting with those who view your profile. Most clients are very busy. They may look at your profile but not get a chance to connect with you, even if they need freelance help. I proactively invite potential clients who have viewed my profile to connect with me. Being proactive and inviting people who view your profile to connect with you helps ensure that they think of you first when they need a freelance. Clients who view your profile are prospects who are already interested in you, so it is easier to introduce yourself and your business to them. I have received several new clients by connecting with these prospects. With a free account, LinkedIn lets you see the names of the last 3 people who viewed your profile.

LinkedIn publishing is also a great tool for blogs and content marketing. The post usually gets more traffic than a regular blog post on your website. Writing and publishing articles on LinkedIn Publishing (formerly Pulse) allows you to highlight your expertise and reach more colleagues and prospective clients. You can also see who has viewed your posts and reach out to connect with them. Marketing through LinkedIn is not in-your-face marketing; it is showing who you are and demonstrating your knowledge without specifically asking for a job.

—Ruwaida Vakil

LinkedIn is one of the best marketing tools to come around since I’ve been freelancing (17 years now). I don’t use it as much as I would if I were newer to freelancing and looking for more clients, but when I coach writers here’s what I suggest:

• Make sure your profile is well written and includes a professional headshot. Just like your website, it is your “introduction” to the outside world (ie, clients).
• Connect with everyone who contacts you, everyone you know, and everyone you’d like to know.
• Research potential clients by looking for companies in your space (ie, medical communication companies). Then do a search for people who work for that company and identify the most appropriate person to contact. Then use InMail (you have to pay a bit extra) to “email” them from LinkedIn with a letter of introduction. Conversely, ask a mutual connection to introduce you.
• Use LinkedIn to research clients who contact you.
• Follow the people you’re connected with and comment on any career changes they make, any articles they post, etc.
• Ask satisfied clients to write a recommendation (not endorsement) for your profile.
• Share writing samples on your profile.
• Write blogs and post to the Publishing tool. Everyone can see this content, not just your contacts.
• Post links in relevant groups to your blog and interesting articles. For instance, join groups related to pharmaceutical marketing and become active with postings and comments.

Pay for the enhanced version of LinkedIn. You’ll get to see who looks at your profile so you can follow up with them. You also get free InMails.

—Debra Gordon
How do you prepare estimates for writing or editing? Do you have a specific list of questions that help define the scope of the project?

I have a detailed system for preparing estimates that requires me to be very clear about the project type, scope, and parameters so I can clearly describe the cost to my clients and, ultimately, communicate the value they will receive.

These are the steps I take when preparing an estimate:

- Step 1: Identify the type of project (eg, manuscript, interactive sales training module, executive summary).
- Step 2: Identify the expected length of the deliverable, which might be measured in words, document pages (eg, in Word or PowerPoint), or published pages (formatted, printed); as well as the expected number of tables, figures, and references.
- Step 3: Identify the style of writing required (this can range from high science for healthcare professional audiences to plain language for patient audiences, with many points in between).
- Step 4: Identify whether the sources for the writing (eg, references) will be provided, or whether I have to research and procure them (exclusive of out-of-pocket expenses if applicable).
- Step 5: Identify the number of reviewers and revision drafts to be included in the estimate and, when multiple reviewers are involved, whether comments will be provided in a single compiled document or in separate documents.
- Step 6: Identify the number and length of teleconferences and face-to-face meetings that will be required.

As you can imagine, following these steps elicits a lot of questions, and clients don’t always have the answers. When they don’t, I make up the answer (either based on my gut feeling, past experience, or [usually] a combination of the two).

My estimates detail all the specifics of the deliverable, so if a client disagrees with a parameter I may have “made up,” that pressures them to give me a better parameter and gives me the basis for revising my estimate. When it comes to negotiating, if a client isn’t happy with my estimate, it’s sufficiently detailed that I can ask them which parameter of the deliverable is off base; and if nothing is off base, which parameter they’re willing to live without. My position is that my estimates are always accurate for the scope of work involved and, therefore, if the client thinks my estimate is too high, one of us has misjudged the scope. This way there is always a basis for negotiation without me simply lowering my project fee.

—Brian Bass

I have a creative brief I give to clients that asks them to describe the parameters of the project (word count, referencing requirements, deadline), the audience, the project goals, any information they’ll provide, the number of interviews/meetings required, number of revisions, and budget (if they have one).

I then use that to prepare a project rate based on my knowledge of the market and past experience.

—Debra Gordon

First, let’s clarify: an “estimate” differs from a “quote” and a “proposal.” Here we are addressing a project estimate—an approximate calculation of the cost of a specific project. This means you provide an estimate of the approximate total number of hours and/or the approximate total cost of the project—usually as a range (eg, from S$X to S$Y or from XX to YY hours, depending on various factors)—plus out-of-pocket expenses, travel expenses, costs for reprints and supplies, etc.

If you have never written a particular type of project (eg, a product monograph, a sales training piece, a review article, CSR, white paper) then you probably do not have enough experience to estimate the job. You should be 100% honest about it so the client knows that this will be your first experience writing this type of document. (Both AMWA and common ethics mandate this level of honesty.) But not to worry: some clients will assign a project to a newbie who lacks experience with their specific type of project—reasons include nepotism, proximity, medical expertise, a significantly lower hourly rate, and so on. In such a case, ask the client for their budget ceiling and do the work for the amount they specify; it will be a great learning experience. However, if you have extensive experience, be careful not to underestimate.

In truth, project estimates depend entirely on the type of project. That said, following are some steps that work for me. As I cannot provide an algorithm for all project types in this column, I chose randomly to focus my answer on a monograph or review article for print media.

1. Clearly define the project, its objectives/purpose, intended audience, and scope. Usually I do this on the phone with the client and then elaborate and confirm in an email. Be very clear about exactly what is the deliverable, from the client’s point of view.
2. Begin with a written outline, preferably annotated (ie, a list of each chapter or heading, with a précis, number of tables/graphs, and list of references that will be used for each section). This may be provided by the client (or the primary author), developed in concert with the client or author, or created yourself after a conversation in which the project has been well defined and discussed. If a well-annotated outline cannot be provided by the client or author or deve-
op ed together on the phone, then develop one yourself and make sure the client signs off on it. Misunderstandings on
the outline/scope of the project can increase your time and costs later. (You may ask to be paid for the time developing
and finalizing an outline, or you could consider this part of marketing/selling time—the work you do before “closing” a
sale and signing the contract. This is a judgment call.)

3. Clarify the extent of background material to be used and who will provide it. In my opinion, it is best if the client
provides all references and other background materials for a sponsored monograph as well as journal articles related
directly or indirectly to their products. But not all clients will do this, so you need to factor in the time and cost for
searching, selecting, and obtaining published articles and/or books. You must also submit a reference list to the client
and/or primary author for their approval. For a larger project, I use an outside search group to do the research
and obtain the papers for me—better still is to use the client’s subscription service so that I have no out-of-pocket expense. I do not spend much time trying to find “free” articles for such projects—the client needs to understand s/he has to pay for background material, and if you simply bill your time hourly for the search, they don’t always “get it” about the actual time/costs for this process. When working for a pharma/biotech company, you may find that their staff, the primary author, or their key opinion leaders have already determined a body of literature they would like used as background for a monograph or review article.

4. Establish the timing for receiving all background material. Try to get everything at once, not piecemeal, as this has a significant impact on the overall cost of a job.

5. Determine whether the client will be providing the graphs/illustrations. If you are supplying graphic materials and need to hire a graphic artist to create them, this out-of-pocket cost (plus markup) is part of the overall job cost. If you develop the graphics/illustrations yourself, the time required can be extensive, depending on how many and what types of graphs you need. (Tables are created by the medical writer ~98% of the time.)

6. Ask how many people you will be dealing with during the process. One project manager and one medical expert is preferable, but sometimes you must interact with several people who have different expertise—another factor that can increase the time and cost of a job.

7. How many reviewers will there be and who makes the final decisions? The number of reviewers and the time they take for reviewing is important to clarify, as is the voice of the “final vote.”

8. Will contradictions among reviewers be reconciled by the project manager before you receive the revision(s), or is this something you will be required to do as a medical writer? Integrating multiple revisions can be time-consuming if some reviewers disagree and you have to reconcile the issue(s), so factor this into your estimate.

9. How many different copies of the manuscript will you receive after reviewers have made their input? Obviously, it is ideal for the project manager to reconcile all differences and amalgamate various reviewers’ comments—but this is rare, so keep this in mind when preparing an estimate. The more copies you need to integrate, the longer it takes.

10. How many reviews will be covered by your initial estimate? Generally I offer an estimate that includes the initial draft based on the agreed-upon outline and references, plus one reasonable revision. A reasonable revision consists of editing only. Adding new sections, new tables/graphs, and new references—or asking for a major overhaul of the structure of the paper/monograph—is not part of a “reasonable revision” because the outline was agreed upon at the outset; therefore, anything new added (i.e., “scope creep”) necessitates a revised estimate or should be charged by the hour. If you wish your initial estimate to cover multiple revisions, just be sure to account for the time this will require.

11. How long do reviewers get to take before returning the manuscript? Long review times not only delay your payments but also can increase your time/cost because you may have moved on to another completely different project and not remember everything 100% on the initial project when it finally comes back 4-6 months later. This is a real issue if you undertake numerous projects on widely different topics. In my opinion, the reviewers should turn around their review copies within 2 to 3 weeks, no longer.

12. Will you be the person handling the submission/publishing process? For a review article, clarify whether it is solely for print publication or if the paper will have to be organized for Internet publication as well. Sometimes both are required, and the online versions usually require extra work because of supplemental materials. The primary author should do the final submission, but some companies ask the writer to handle it. For a printed monograph, confirm that you are providing copy only (plus tables/graphs) and that the client or their graphics person will handle book design, layout, and printing.

There is a “rule of thumb” about estimating, as follows: After receiving all of the material mentioned earlier, and after reviewing them carefully, visualize, based on your own experience with similar projects, how long this is going to take. Try to visualize the entire process, including all the numbered points mentioned above. Come up with the total number of hours you believe it will take. Then double those hours and add another
20% for profit. (It is a peculiarity of human nature that we almost always think we can do things in half the time it really takes.) As many experienced professionals have testified, this method very often turns out to be the right amount.

One final point: be sure to specify in advance your terms of payment. While this is technically part of the contract and not the estimate, I like to discuss it at the get-go, so there are no misunderstandings or bad feelings when payment is due. Because if the terms of payment are unacceptable to you, why bother taking the time to prepare a project estimate? Good luck!

—Cathryn Evans

Here is a list of questions that I use to help define the scope of many of my editing projects:

• Is the document ready to be edited, or is it still being worked on?
• How much work might there be? How long do you anticipate the editing part will take?
• What are the components of the project (manuscript, slides, storyboard, video transcript, workshop materials, etc)? Is the project part of a series in which I need to match an already established style?
• What format is the document in—hard copy, Word, Adobe, etc?
• What is the total page/word/slide count? If slides, do the Notes need to be edited, or just the slides?
• What kind of an edit is needed: proofing, copyediting, developmental editing, rewriting, and style comparison? Is the client looking for minimal cleanup—just fixing grammar, punctuation, and spelling errors?
• What about consistency in capitalization, styles, sentence structure? Any need to look at formatting? Organization? Is this a first edition, a revised edition?
• How should edits be indicated (marked-up hard copy, Track Changes, double underlines, Comments)? How shall an edited file be sent (email attachment, FTP site, Dropbox, etc)?
• How many revisions need to be reviewed?
• Does the job entail reviewing a bibliography, reference list, or index? If a bibliography or reference list is included, does the client require that each reference be checked for complete information against PubMed, the Library of Congress, or Amazon (as appropriate)?
• How many figures and tables are there? What kind of formatting is required for the tables? For the figure legends?
• Is any fact-checking involved? If yes: Will the client provide PDFs of all the references?
  –Should all mathematical calculations be checked for accuracy?
  –What is the annotation style required in the file?
• Will the file and references eventually go through medical review?
• Will the project include a cleanup round after the author has reviewed the editing?
• What is the schedule/deadline for this project?
• What style guide and dictionary should be followed? The 9th or 10th AMA Manual of Style? (Primary difference between editions is inclusion of issue numbers in references with the 10th edition.)
• Is there a style sheet or standards document? If not, would the client expect/like one to be created?
• Who would the contact person be? Does the contact person prefer to communicate by phone or email? Would I interact with any other team members? Is there any direct author contact?
• Would the client require a signed contract/nondisclosure agreement, etc?
• What is the project budget?
• What are the payment terms (specifically, the client’s payment cycle, eg, net 30 or net 45)? Does the client pay in increments?

—Melissa L. Bogen, ELS

Q  How much time do you spend marketing your business versus billable time spent on client projects?

A  There’s no magic formula for hours spent on marketing versus client work. How much time you need for marketing your business depends on what you’ve already done, where you are in your freelance career, and how much business you’re looking for. Every freelance needs a client-focused LinkedIn profile and website, a strong network, and a system for following up with prospects and colleagues. This is your basic marketing infrastructure, which takes more time to develop than to maintain.

In general, new freelances need to spend more time on marketing than seasoned freelances, but even successful freelances need to do “active” marketing occasionally. The best ways to get great clients are: (1) targeted direct email to carefully researched prospects, (2) networking, and (3) consistent follow-up with prospects and key colleagues. Developing prospect lists and crafting emails targeted to each prospect takes a lot of time but is very effective. When you’re doing this, you might spend 20-50 hours a month on marketing, until you’ve achieved your goals for billable hours.

Networking is really difficult to quantify. It includes volunteering for AMWA and other professional associations, staying in touch with key colleagues, social networking, attending
conferences and meetings, etc. Outside of the time you spend volunteering and attending conferences and meetings, plan to spend about 3-6 hours a month on networking if you’ve already got a strong network and up to 10 hours a month if you’re still building your network.

One of the biggest returns on your investment in marketing time is following up regularly with prospects who’ve expressed interest in you but haven’t yet hired you, and key colleagues, who are a great source of referrals. Doing follow-up takes about 2-5 hours a month.

Some experts suggest spending a certain number or percentage of hours on marketing each week. That doesn’t work because some weeks you have more client work than others. When you’re short on billable work, use the extra time for marketing. Here are some very rough monthly estimates for marketing time versus billable time:

- New freelance: 20% billable work and 60% marketing
- Seasoned freelance reaching income goals with all/most new business from referrals: 65% billable work and 15% marketing
- Freelances between these extremes: 45% billable work and 35% marketing

The remaining 20% of your time is for general business administration.

—Lori De Milto

In May 2015 I had an opportunity to present a webinar on “The Secret Marketing Tactics of Top Freelances.” It was the most challenging presentation I’ve ever developed for myself because I haven’t done much “traditional” marketing for more than a decade. I had to force myself to finally analyze the little things I do every minute of every day to market my business and figure out why they work.

(I can’t go into all the details of these tactics here, but the webinar is available on the AMWA website. Simply go to Live Webinars from the homepage, click the Live Webinars tab in the left column, then click on the link for On-Demand Video, where you can search for it.)

I have my listing in the AMWA Freelance Directory, which last year alone brought me a new client who added 14% to my bottom line in just 6 months. My Freelance Directory listing works for me constantly. And the thing I realized as I prepared my 2015 webinar is that I market myself constantly, too. So 100% of my time is spent marketing my business. Last year I had 722 billable hours. I probably had a little bit more than that because I’m not great at capturing every minute of every day. In reality, I probably “work” about 50 hours a week and sometimes more, because I have a team of writers who work with me on projects in a subcontracting capacity, and of course, that adds to both my work load and my bottom line. After deducting 4 work weeks from the year for vacations, personal time, and professional development, I “work” about 2,400 hours a year. That means my billable time is about 30% of my total working time, so 70% of my marketing time is not billable.

But here’s the thing—the things I do to market my business collectively enable me to earn enough money when I’m “on the clock” to more than pay for the time I can’t bill. I charge by the project and am paid for the value of my work rather than for my billable time. That’s the value of effective marketing.

—Brian Bass

**Open Session Summaries continued from page 25**

help the client create a roadmap focused on a very specific research set. Study journal options and align the client’s communications goals with a particular journal. Offer a plan to improve the client’s messaging, tools, channels, and content, and you can adjust your fees accordingly for these services.

According to Rothermel, “the way audiences are receiving scientific and medical information is really evolving quickly. It would be great for us to be on the forefront with our clients on this.”

Lisa Carricaburu is managing editor of Informatics-Decision Support at ARUP Laboratories in Salt Lake City.

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**RESOURCES**


Advancements in body armor, helmets, and combat medicine have enabled military soldiers to survive devastating injuries that would have killed their predecessors in previous conflicts. Although these protective measures are credited with increased survival rates, they have not succeeded in preventing traumatic limb amputations. In fact, the number of soldiers requiring limb amputations during the Iraq and Afghanistan Wars were twice as high as those seen in the Vietnam War. Furthermore, almost all traumatic limb amputations sustained during the Iraq and Afghanistan Wars were processed at Walter Reed Army Medical Center, the world’s premier leader in combat amputee rehabilitation and prosthetic care.

In *Run, Don’t Walk*, Adele Levine recounts her time as a physical therapist in the amputee clinic of Walter Reed, from 2005 until its closure in 2011. For her, days in the amputee clinic were long, hectic, and intense, with more than a hundred soldiers being treated daily. Visitors at the clinic often observed soldiers with abdominal wounds, walking on prosthetic legs, or pushing wheelchairs with amputated arms. These horrors of war were further compounded by the struggle of soldiers to restore their sense of self as well as adapt to their changed bodies.

Levine’s ultimate goal was to facilitate the return of soldiers to an active lifestyle in the civilian world. The passion and dedication with which she treated the wounded could be seen throughout her patients’ rehabilitation. At the same time, through the course of each soldier’s rehabilitation, Levine found her own strength—a strength that would sustain her through her own father’s diagnosis and eventual death. In many ways, Levine healed as she facilitated the healing of her patients. This unique and thought-provoking book tackles the labor-intensive and painful process of an amputee’s journey and the effect that process has on the health care provider. This book is a great read for wounded soldiers, health care providers, and anyone who wants to be reminded of hope.

Some psychological and cognitive injuries are far worse than the physical injuries of combat. These are the invisible wounds of war. The increasing incidence of post-traumatic stress disorder (PTSD) and depression among returning soldiers is of grave concern. It is the responsibility of our nation, the Department of Veterans Affairs, and the US health care system to care for our military soldiers, some of whom face a lifetime of costly and constant medical treatment. It is a great honor and privilege to care for the great warriors of this country.

**Reviewer:** Tara Ann Cartwright, PhD

*Tara Ann is a medical writer and editor in Research Triangle Park, North Carolina.*
Small: Life and Death on the Front Lines of Pediatric Surgery

Catherine Musemeche, MD
Lebanon, NH, Dartmouth, 2014; Hardcover; 224 pages, $22.34.

Author Catherine Musemeche, MD, picked a perfect title. Just the single word Small. Her subtitle places the subject in context: Life and Death on the Front Lines of Pediatric Surgery. As a pediatric surgeon and skilled, imaginative writer, Musemeche’s book offers a compelling account of the dexterous precision needed to repair life-threatening conditions in infants, newborns, and neonates. Drawing on her medical training and practice, Musemeche states, “There is no such thing as a routine operation in a baby.”

The Case of “Baby A”

One memorable case Musemeche describes is the birth of “Baby A” by cesarean section. “Slippery loops of intestine hung free from her tiny belly like a tangle of garden hose, having escaped her body through a hole in her abdominal wall…. Instead of leaving her abdomen, rotating and reentering as programmed in the first trimester of pregnancy, they had stalled in transit, like an astronaut locked out of the space station with no way back inside.” Yet, of all congenital abnormalities, gastroschisis is now among the most repairable thanks to advances in pediatric surgery.

Not Just “Little Adults”

The title refers not only to the patients, but also the need for small surgical implements appropriate to the task. Musemeche recounts a colleague’s experience serving in Afghanistan: “All my equipment was for adults. Whenever a kid got wounded, I would try to improvise because everything was smaller. Their limbs are smaller. Airways smaller. Smaller organs.”

Children’s bodies, we learn, are also proportioned differently from adults. “The physiology, the growth rate, the activity level, and many bodily functions are distinctly different from those of adults,” writes Musemeche. A child’s bones are softer than an adult’s. Growth plates on either end are uniquely susceptible to injury.

To become recognized as a medical specialty, pediatric surgeons had to possess the imagination to adapt or invent surgical implements and materials suited to their tiny patients. Musemeche conveys fascinating accounts of such achievements.

There is the 6-month-old infant born with severe scoliosis and 7 missing ribs hindering lung development. The boy’s clinical dilemma came to the attention of Dr Robert Campbell, who was an engineering student before entering medical school. He consulted on this patient’s debilitating condition (thoracic insufficiency syndrome) and imagined a way to fashion a replacement chest wall.

“Campbell went home that same night,” writes Musemeche, “and sketched out a chest wall using tools and materials he worked with every day.” He visualized using Kirschner wires—smooth, stainless steel pins to set bone fragments—by positioning the pins across the chest wall gap. Campbell worried that if the pins shifted they might puncture the child’s heart or erode into his spinal cord. This prompted Campbell to consider turning the pins 90 degrees, running up and down the chest cavity. Campbell and a colleague performed the novel operation. A postoperative X-ray showed that the artificial chest wall not only stabilized lung function but unexpectedly straightened the curvature in the patient’s spine.

The Flip Side of the Coin

Despite the success of such procedures—some the first of their kind—there are many instances when such small patients cannot be made whole. Musemeche would be disingenuous if she did not include such instances. She describes a 3-day-old baby airlifted to the pediatric hospital at 3 AM on Christmas Eve with necrotizing enterocolitis destroying the...
Re-humanizing Medicine: A Holistic Framework for Transforming Your Self, Your Practice, and the Culture of Medicine

David R. Kopacz


Re-humanizing Medicine by David R. Kopacz is an incisive reflection on the existing medical practices of an increasingly corporatized world. At the same time, it seeks to teach the medical and health care community how to correct that dehumanized outlook by being more compassionate and holistic.

The book is structured into 5 major sections. The first section outlines the paradigms of contemporary medical practice, citing various examples of dehumanization creeping into the business-oriented model of medical practice. The second section introduces the principles of holistic medicine—healing that integrates the well-being of body, mind, and spirit of an individual. The third part is a comprehensive guide for how to transform oneself into a compassionate and well-rounded individual embodying a deep sense of humanity. The fourth part is an extension of the third, teaching physicians (and others) how to incorporate holistic principles into their own practices. The fifth part is directed towards rehumanizing the entire culture of medicine.

New concepts in holistic medicine are explained vividly with the help of anecdotal references wherever applicable. The self-help sections, dealing with the hows of practicing holistic medicine, have been kept succinct, sometimes listed under bullet points. Throughout the book, the author has given an honest, simple, yet engaging voice to an otherwise complex subject.

Considering the absurdly frenetic pace of modern medical practice, this book does an excellent job of nourishing the soul of practicing physicians first, thereby helping them to regain their humanity. This, in turn, may translate into a more humanized treatment of patients and, ultimately, establish a pathway to a whole new paradigm of medical practice. I particularly liked the many personal reflections and insights that the author shared in this compelling and well-researched treatise on transforming the traditional technology-driven practice of medicine into a more holistic practice.

This book definitely suits the needs of the medical community (physicians, clinicians, nurses, medical students, and other health care providers) with its thoughtful guidance and realistic approach, offering solutions to the existing problems of the frustration-laden, modern-day practice of medicine. It is also an informative and readable book for anyone interested in the evolution of medical practice throughout the ages.

This book helps us to understand, appreciate, and correct the wrongs of modern-day medicine by inspiring us to be more connected—to be more human.

Reviewer: Debamita Chatterjee

Debamita is a graduate of the University of Rochester in biomedical sciences. She has written for the University of Rochester Medical Center and journals including eLife and The Scientist.

Small review continued from previous page

newborn’s vulnerable intestine. Upon opening, the “putrid stench of dead gut mixed with anaerobic bacteria wafts up through the turbid swirl…the worst possible feeling washes over me—*I am not going to be able to save this baby.*”

Musemeche is ever cognizant that, although they are not in the operating room with the patient and surgeon, anxious parents are an unseen specter of such cases. “Parents have a unique stake in the health of a child,” Musemeche writes. This triumvirate—the small patient, the pediatric surgeon, and the courageous parents—plays the lead role in this excellent read.

Reviewer: William Van Nostran

William Van Nostran is a medical writer in the Rebecca D. Considine Research Institute at Akron Children’s Hospital in Akron, Ohio.
Although clinical research is increasingly incorporating the patient’s perspective earlier in the drug development process, one may wonder whether this patient-centered focus is also being applied to the doctor-patient relationship. Consider “Mrs Garcia,” who repeatedly visited the emergency room because she kept missing her dialysis treatments. After each visit, she was discharged with the usual instructions stressing the importance of keeping her dialysis appointments. Sadly, this pattern continued until a resident asked her why she kept missing her appointments and discovered Mrs Garcia had to care for her children, who were in a hospital far from the dialysis treatment center. In response, the inpatient team arranged for Mrs Garcia to receive her dialysis treatments at the same hospital where her children were staying; thereafter, she kept her appointments and no longer had to visit the emergency room.

The story of Mrs Garcia underscores how important a physician’s communication and thinking skills are. A patient may not receive appropriate care because, despite years of intensive medical education and training, physicians may miss contextual clues, or relevant factors in the patient’s life, such as concern about finances, caring for a parent or child with medical needs, or the death of a child. If physicians are missing contextual clues that would suggest a different treatment approach than evidence-based medicine or clinical practice standards, how would that affect the treatment plan? This is a central question that Saul J. Weiner and Alan Schwartz attempt to address in Listening for What Matters: Avoiding Contextual Errors in Health Care.

Saul Weiner, who is a physician, and Alan Schwartz, who is a Professor of Medical Education, spent nearly 10 years searching for answers to this central question. Determining whether or not physicians were missing contextual clues would require more information than what appears in a patient’s chart. Taking into consideration how other industries record phone calls for quality improvement, the authors suggested a similar approach could be used to achieve their objective, creating audio recordings of physician-patient interactions. Unannounced standardized patients (USPs)—actors who go undercover to portray patients—were recruited to audio-record their interactions with real physicians. The physicians were informed of the study beforehand and could choose to decline participation. Chapters 2 through 4 painstakingly describe their study methods, including steps taken to obtain institutional review board approval. The physician-USP audio recordings, patient charts, and medical bills were analyzed to determine whether physicians detected contextual clues and, if so, whether these clues factored into their treatment plans. The authors found that physicians were more likely than not to miss contextual clues, and if they did ask additional questions based on these clues, they were less likely to select the appropriate treatment.

The authors questioned whether failure to consider contextual clues may result in too little care, too many treatments, or both. Because such information was difficult to measure in their study with the USPs, the research team evaluated real patient-physician interactions in an observational study (Chapter 3—The Problem is Everywhere) and developed a basic tool to evaluate how well physicians
listen for these clues and design appropriate treatment plans (Chapter 4—What We Hear that Physicians Don't). The audio recordings were used to classify physician communication behaviors, and the authors were able to identify 6 characteristics based on critical thinking and good communication skills that best describe a physician who contextualizes care.

Because these skills are not formally taught in medical school, the authors developed and evaluated a workshop on medical decision making for fourth-year medical students. The preliminary findings were positive, and a great example of this program's success was the resident who asked Mrs Garcia why she was missing her dialysis appointments. Despite the successes of this pilot and subsequent expansion of this model to include other members of the health care team, there are challenges to overcome if these gains are to last. The authors envision a quality improvement model in which audio recordings could be used as a source of feedback to improve decision-making skills. In addition, they hope this decision-making model will be incorporated in the medical education curriculum. It is not yet certain whether healthcare providers agree with all of their recommendations. Regardless, people in the healthcare field, regulators, medical educators, and patients may find this an interesting and informative perspective of the patient-physician relationship.

Reviewer: Eileen M. Girten, MS

_Eileen is a Principal Medical Writer with inVentiv Health Clinical._
By now you know that AMWA leaders have been extensively involved in reviewing and updating our association’s governing documents. We’ve engaged in this painstaking process because of the importance of ensuring that AMWA’s documents are in line with current-day best practices and laws. Remember, our governance documents are more than 50 years old, and a great deal has changed in the world, including the nonprofit association world. With greater government scrutiny on nonprofit associations, we wanted to make sure that we had dotted all our “i’s” and crossed all our “t’s.” We also wanted to make sure that the association is operating as efficiently as possible.

The goal of our EC discussions about engaging employers and decision-makers was 2-pronged: list employers of medical communicators and discuss how to demonstrate the value of AMWA to employers and hiring managers.

Although the process of updating our governance documents is essential, we do not want it to consume all of our time. It is vital that we continue to work on developing programs, resources, and services that meet our members’ needs. To that end, we devoted most of our January 2017 Executive Committee (EC) meeting to discussions of how to best set priorities to achieve our strategic goals while remaining fiscally responsible.

To best meet the current needs of medical communicators, we need to know the trends in our industry. Yet, documenting trends in medical communication has rarely been done in AMWA. During our strategic planning initiative in 2015, our planning facilitators emphasized the importance of knowing the trends in our field in order to best position our association to thrive and achieve its goals. At that time, we researched multiple industry trends and then surveyed our members to determine which of several trends were of most concern. At our January EC meeting we re-examined these trends and reviewed the results of the survey, discussing whether these trends still existed or how they had changed, and adding more recent trends to the list. Our current EC has broad representation, with writers from the regulatory, freelance, continuing medical education, patient education, and marketing worlds. Because of this breadth, we were able to discuss a wide range of trends across multiple settings. We talked about how these trends affect medical writers in general as well as AMWA in particular and how AMWA can support the resultant changing needs of medical communicators. Descriptive lists of the trends will help us develop conference sessions, other educational activities, resources, and services for our members. We also established a working group that will write an article about the trends for an upcoming issue of the AMWA Journal.

The EC also gathered in small groups to discuss 2 targeted topics: attracting mid- and advanced-level professionals and engaging employers and decision-makers. According to recent AMWA surveys, our members who have been in the field for at least 5 or 6 years want and need more education targeted to their point on the career path. To supplement
these results, an Education Subcommittee surveyed hiring managers to determine the needs of this subgroup of medical communicators. Our small-group discussions took this work one step further and focused on what educational activities would be of the greatest benefit. Notes from these discussions have been distributed to Education and Annual Conference committees to help them in their work of developing online education activities and conference programs geared toward this subgroup of medical communicators.

The goal of our EC discussions about engaging employers and decision-makers was 2-pronged: list employers of medical communicators and discuss how to demonstrate the value of AMWA to employers and hiring managers. AMWA currently has approximately 4,400 members, but we all know that there has to be more of us out there engaged in medical communication! We've long asked “How do we find them?” We are determined now to answer that question. We brainstormed about specific employers as well as employer types; our next step will be to contact these employers to describe AMWA as a valuable resource for their medical communicators.

The discussions at the EC meeting also helped to create a list of topics for the AMWA blog. If you haven't checked out the blog on the AMWA website (www.amwa.org), you should. We're planning on blogs to educate and entertain you throughout the year, and we're excited that Jim Cozzarin, the Journal's new editor in chief, will share the blog space with us.

The AMWA blog is just one way I'm fulfilling my priority of enhancing communications with members. Also look for special notes in AMWA Updates to help keep you informed of AMWA initiatives. An additional—ambitious—goal is to visit as many chapters as I can during my tenure. I am committed to ensuring that AMWA is valuable to every member and that members are engaged in the association. I urge all of you to be engaged—at all, it's your association.

blog!

You may have noticed that AMWA Engage has introduced a new blog feature (http://engage.amwa.org/browse/blogs). This member benefit allows more immediate communication of important content—helping AMWA keep its members informed in a timely manner.

I will be taking advantage of this medium to bring information to you in between our quarterly issues. In this way the journal fulfills its goal of communicating information and resources to our members... through a new medium.

In our initial series of blogs, the Journal seeks to inform you of additional resources available through “sister” organizations in our industry. For example, this month’s blog will introduce you to the International Society for Medical Publication Professionals (ISMPP). You can learn a little more about that organization and link to information about the latest incarnation of the Good Publication Practices (GPP3) and about ISMPP’s new Global Transparency Committee. You can also learn about educational webinars and programs offered by ISMPP.

Look for additional blogs from the Journal each month.

The Journal should be all about communicating content of interest to our members, and the Journal blog is my first effort in expanding that communications footprint!

I hope you enjoy the blog, and I welcome your feedback.

—Jim
American Medical Writers Association

By Julie L. Phelan, MD, MBA / AMWA Treasurer and President, Biomedisys, Chicago, IL

I am pleased to provide this annual financial report for the American Medical Writers Association (AMWA) for the fiscal year ending June 30, 2016. AMWA began the fiscal year in a strong financial position and had prepared for a year of program growth and investing in the future. We are pleased to report the successful launch of the online learning and certification programs. We are also pleased to report a successful audit performed by Abercrombie and Associates, an independent auditing firm, culminating in an unqualified or “clean” opinion. As anticipated, the fiscal year ending June 30, 2016, was another year of investing in AMWA’s future.

Financial Performance Trends
AMWA’s operations generated a net loss of $148,652 for the fiscal year ending June 30, 2016. A net loss was budgeted as part of a concerted effort to invest in the future. The actual loss exceeded the budgeted loss by approximately $18,000—primarily due to a decline in our invested reserves consistent with market performance.

As shown in Figure 1, while membership revenue remained relatively steady, we experienced growth over the previous year in both our annual conference revenue and our certificate and onsite corporate training program revenue. These primary sources generated more than 80% of our total revenue.

Managed expenses for the fiscal year ending June 30, 2016, were consistent with those of the previous year and were within 3% of the overall budget. Figure 2 reflects our efforts to manage growth as we work to expand our programs. In 2016, AMWA incurred $1,987,753 in total expenses, as compared with $1,985,711 in 2015. AMWA continued to make significant investment in online education this year, incurring $292,513 in related expenses. We anticipate that this will be a great source of revenue for AMWA in the future while providing a valuable learning service and experience for our members.

AMWA also made a major investment in the Medical Writing Certification Examination this year. Approximately $48,000 of resources was invested in administering and promoting the certification program. Finding new ways to brand AMWA and to attract new members is an important goal that will continue.

AMWA is actively investing in programs, products, and services that bring value to members and the medical writing community (Figure 3). Implementation of the certification program and enhanced educational offerings, particularly online products, will require the continued investment of resources. Consistent with the approved budget for the current fiscal year (June 1, 2016, through December 31, 2016), AMWA has committed to continue funding these initiatives.
Reserves
Reserves are the accumulation of funds over time that enable the organization to withstand an emergency or to invest in new programs (Figure 4). Unrestricted reserves of 6 to 12 months of annual operating expenses represent a standard target for not-for-profit organizations. With budgeted annual operating expenses of $2,048,830 for the fiscal year from July 1, 2016, to June 30, 2017, the target for AMWA’s reserves ranges from $1,024,400 to $2,048,830. AMWA’s current reserve level of $1,136,000 remains within the targeted range.

Financial Position
An organization’s financial position is reflected in its asset and liability holdings. AMWA is well positioned to pay its obligations and invest for the future. Total assets were $2,297,594 as of June 30, 2016, and the organization’s liabilities totaled $862,317. The majority of AMWA’s assets are liquid, including cash, CDs, and mutual funds (Figure 5).

Conclusion
AMWA continues to be in a secure financial position. The future of the organization depends on a stable membership base and growth of our educational offerings. Targeted investment in these areas began in fiscal year 2012-2013 and will continue into fiscal year 2017-2018.

Acknowledgments
Thanks to Calibre CPA Group PLLC for providing the financial data and to the members of the 2015-2016 Budget and Finance Committee for their review of reports and budgets: Chris Wogan, Theresa King-Hunter, Leslie Neistadt, Judi Pepin, Deb Whippen, and Jeannie Woodruff, and ex officio members Steve Palmer, Lori Alexander, and Susan Krug.

Author contact: Julie@biomedisysinc.com
AMWA Collaborates With EMWA and ISMPP on Joint Position Statement

In a continuing effort to ensure high-quality standards for medical communicators, AMWA has worked with the European Medical Writers Association (EMWA) and the International Society for Medical Publication Professionals (ISMPP) to develop a joint position statement on the role of professional medical writers. The statement, released on January 17, 2017, is the first unified position on the role of professional medical writers from these 3 leading professional organizations.

The Joint Position Statement explains the value of professional medical writing to evidence-based medicine by summarizing current evidence on the professional medical writer’s role in the ethical, accurate, and timely disclosure of research results in medical and scientific publications, including abstracts, posters, and oral presentations.

“This Joint Position Statement describes, for the first time, a global standard for professional medical writers. This will serve as a valuable reference for ethical publication practices worldwide,” says Art Gertel, AMWA Past President.

Building on Good Publication Practice (GPP3) guidelines and International Committee of Medical Journal Editors (ICMJE) recommendations, the Joint Position Statement describes best practices for professional medical writers and provides a template for appropriately disclosing medical writing support.

The Joint Position Statement supplements AMWA’s own statements on ethical publication practices, including the Code of Ethics and the Position Statement on the Contributions of Medical Writers to Scientific Publications. All of these publications are available on the AMWA website at http://www.amwa.org/position_statement.
When assisting authors with communication of the results of company-sponsored research, they must:

- follow Good Publication Practice (GPP3) guidelines and International Committee of Medical Journal Editors (ICMJE) recommendations\(^1,2\)
- consult appropriate reporting guidelines (eg, CONSORT\(^20\) and others collated by the EQUATOR network\(^21\))
- ensure that the authors and sponsors are aware of their obligations under these guidelines\(^1,2,20,21\)
- keep up to date with advances in medical communications ethics and best practices.

**Responsibilities of authors who collaborate with professional medical writers**

Authors who choose to collaborate with a professional medical writer on manuscripts or congress presentations must:

- ensure that they, as authors, have access to all relevant information (eg, protocols, statistical analysis plans, statistical analyses, and clinical study reports)
- provide intellectual input before writing commences and throughout content development
- ensure that the final text fully reflects the views of, and is approved by, all authors
- affirm the appropriateness of the final choice of journal or congress
- acknowledge the provision of medical writing support, including the nature of the support, and the name, highest relevant qualifications (eg, degree or professional credential), and affiliation of the professional medical writer accountable for the support provided, and acknowledge the funding sources for the provision of medical writing support (see Box)
- recognize as a co-author all contributors (including a professional medical writer) who meet the ICMJE authorship criteria.\(^1\)

**Box. Example of template disclosure statement for professional medical writing support.**

“The authors thank [name and qualifications] of [company, city, country] for providing medical writing support/ editorial support [specify and/or expand as appropriate], which was funded by [sponsor, city, country] in accordance with Good Publication Practice (GPP3) guidelines (http://www.ismpp.org/gpp3).”

**References**


Joint Position Statement continued from previous page


How Would You Rate the Journal?

The Journal is the flagship publication of the association—it is your journal! As such, your opinion is valuable to us.

What do you think of your journal? What works for you? What could be better? What enhancements would you like to see? Please share your opinion by participating in our Journal Survey!

Watch your email, or log onto the Issues Online page for members-only access to the survey. We will collect responses until April 15 and use those responses to help guide future developments.

Your voice matters... please join your colleagues in rating the Journal!

I look forward to your responses.

—Jim

www.amwa.org/online_learning

Online Learning

With AMWA Online Learning, you have access to the latest training, education, and resources available for medical communicators – at any time.

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- Watch on-demand recordings of AMWA Live Webinars
- Find resources, digital publications, and more.
n 1981 I took second place in the Mentor Optimist’s Oratorical Contest. Asked to speak on the topic of “our biggest challenge for the future,” I chose to speak about communication.

Without communication, I posited, we are isolated and without any sense of community. An individual may rise to dizzying heights of knowledge and insight, yet without the ability to communicate those ideas, that achievement means nothing. It is by communication that we share our thoughts, insights, desires, hopes, and dreams, forming individual relationships and forging communities. Communication requires the honest, unbiased, mutual effort of both the speaker and the listener. Ongoing complete and transparent communication allows individuals to convey new ideas and insights, understand and appreciate different perspectives, and rationally resolve disputes, thereby strengthening the community. When communication stops, the community fails.

Is this assertion still relevant today? Perhaps.

And so, communication, in one form or another, has remained a lifelong passion of mine. My first job after graduation was in teaching. After 2 years teaching English at the junior-high school level and 5 years at the high-school level, I transitioned into professional editing at a law book publisher. There I learned the craft of proofreading and copyediting under the tutelage of a senior editor who had begun her career when they were still pressing hot lead. (Do you know why they call the variable spacing between lines of type “leading”? Do you know how the en dash and em dash got their names? I do!)

After 5 years of team-proofing the Ohio Revised Code and editing various legal practice manuals, among other tasks, I made the happy transition to medical editing at ProEd Communications, a health science communications company near Cleveland, Ohio. There I’ve continued to hone my skills and stoke the fires of my interest in medical and regulatory communications over the past 22+ years.

Early in my tenure at ProEd, I found the community that is AMWA.

Make no mistake, AMWA is a community—and I’m happy to be a part of it. We are a community of medical communicators, dedicated to growing our profession. We are a community of colleagues, dedicated to ongoing professional development. We are a community of friends, dedicated to enhancing existing friendships and forging new relationships, welcoming others and encouraging them to join our community. With a diverse, global membership numbering in the thousands, we are a unique community indeed, bound by our common desire to support one another and to live up to our vision of AMWA as the Resource for Medical Communicators.

As president of AMWA nearly a decade ago, I was honored and privileged to serve as chief steward of our community for a little while. Now, I am honored and privileged to serve again—this time as Editor in Chief of our flagship publication. A humbling challenge, and one I am excited to face!

I have been fortunate indeed to have a great deal of help getting started in this new position. First, I must thank Vicki White, my predecessor as editor. Not only did the journal flourish under her tenure, but she has been a generous and genuine guide through these first few weeks. Kirby Snell, the journal’s managing editor, has become a fast friend and has been invaluable in shepherding the various components of the journal through the publication process. Rachel Spassiani has been a tremendous help as my primary contact on the AMWA staff. And I’ve been in regular contact with Amy Boches, our Graphic Designer; Ann Winter-Vann, our Publications Administrator; Susan Krug, our Executive Director; and Lori Alexander, our President. I’m also getting to know the wonderful, talented, and dedicated volunteers comprising our Editorial Board and serving as Section Editors, Regular Contributors, and Editors at Large. I’m truly grateful to have such a wellspring of talent to help keep the journal moving forward. It really does take a village . . . or a community!

But we will, of course, need your help to be successful. Just as AMWA is your community, this publication is your journal—your voice, your medium of communication with others in our Association and with the world at large.

So tell me . . . what would you like to communicate?

Author contact: JournalEditor@amwa.org.
Instructions for Contributors

Unless otherwise noted, submit manuscripts and suggestions for content to the Journal Editor at JournalEditor@amwa.org.

**FEATURE-LENGTH ARTICLES**

Feature-length articles include topical features, original research in medical communication, and Science Series articles.

**Topical Features**
The AMWA Journal invites manuscripts on areas of interest to medical communicators, including topics within such broad categories as regulatory writing, continuing medical education, patient education, medical marketing/advertising, public relations, medical journal management, publication ethics, health policy, etc. The AMWA Journal especially encourages the submission of articles on the theoretical underpinnings of specific types of medical communication. AMWA Journal readers are primarily practitioners (not academics), and application of theory to practice is an essential component of manuscripts. **Word Count:** 3,000 words (plus an informative abstract of 250-300 words)

**Original Research**
The AMWA Journal invites manuscripts reporting original research on written communication, publication trends, and medical communicators’ productivity and value added. **Word Count:** 3,000 words (plus an informative abstract of 250-300 words)

**Science Series**
The Science Series accepts manuscripts that provide an overview of a specific anatomic or physiologic topic (e.g., body system), disease or condition, diagnostic method (e.g., laboratory tests, imaging systems), or type of treatment (e.g., devices). **Word Count:** 3,000 words (plus an informative abstract of 250-300 words)

**OTHER TYPES OF ARTICLES**

**Around the Career Block**
The Around the Career Block section accepts manuscripts that provide advice on career-related issues, profiles of professional organizations, and first-person accounts of educational experiences.

**Career-related Articles**
These articles address topics that are relevant to the career development of medical communicators. Areas of interest include job hunting, developing a portfolio, interviewing techniques, hiring guidance, performance evaluation, mentoring programs, performance goals, etc. **Word Count:** 750-1,500 words

**Profiles of Professional Organizations**
These profiles help readers discover or better understand organizations that address specialty niches and may therefore be a useful supplement to AMWA membership. **Word Count:** 600-1,000 words

**First-person Accounts of Educational Programs**
These articles provide overviews of educational programs designed to enhance the knowledge and skills of medical writers and editors. **Word Count:** 600-1,000 words

**Commonplaces**
Commonplaces is devoted to the exchange of ideas between teachers of medical communication and practitioners. Contact Commonplaces Editor Lora Arduser (ardusell@ucmail.uc.edu) with article ideas.

**Media Reviews**
The Media Reviews section includes reviews of books, websites, and other media that are of practical value or topical interest for medical writers and editors

**Practical Matters**
The Practical Matters section accepts manuscripts that provide practical guidance to medical writers and editors (at all levels of experience) for improving the skills involved in their daily work activities in a variety of medical communication settings. **Word Count:** 750-1,800 words

**Regulatory Insights**
This section provides information of particular interest to communicators who write or edit documents related to the pharmaceutical or device industries. **Word Count:** 750-2,000 words

**Social Media**
The Social Media section includes articles focusing on the use of social media and networking in the medical communication industry.

**Tech Talk**
The Tech Talk section includes articles about technology topics, that may of interest to biomedical communicators. **Word Count:** 500-1,000 words

**Statistically Speaking**
This section covers statistical concepts of interest to medical communicators.

**Everyday Ethics**
The Everyday Ethics section includes topics related to ethical situations encountered by medical communicators in any or all branches of the profession. Well-considered and professional approaches to situation management are included.

**OTHER SECTIONS**

**Sounding Board**
The Sounding Board is a forum for members’ opinions on topics relevant to medical writing and editing. Contact the Journal Editor to seek approval for the topic before preparing and submitting a manuscript. **Word Count:** 750-1,000 words

**Letters to the Editor**
Letters to the Editor provide an opportunity to comment on topics published in the Journal. Letters should refer to contents within the past two issues. **Word Count Limit:** 500 words

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