MEDICAL WRITING CERTIFICATION EXAMINATION CANDIDATE STUDY GUIDE

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About the Medical Writing Certification Program

The Medical Writing Certification Commission (MWCC), in collaboration with the American Medical Writers Association (AMWA), developed the Medical Writer Certified (MWC®) credential, which distinguishes professional medical writers. The MWC credential is a rigorous, examination-based professional certification. Professionals with this credential have demonstrated their broad understanding of medical writing core competencies. The MWCC developed the certification program in an evidence-based manner, with input from professionals from a broad range of medical writing backgrounds and specialties. To learn more about the program, visit the following sites:

- Overview of the MWC program:
  - http://www.amwa.org/mwc.
- Applicant eligibility:
  - http://www.amwa.org/page/MWC_Apply and
  - http://www.amwa.org/page/mwc_faq/#Eligibility.
- Examination registration:
  - http://www.amwa.org/resource/resmgr/certification/Forms/2018/MWCHandbook2018.pdf.

Examination Preparation Recommendations

The MWCC developed this study guide to help candidates prepare for the examination, and the MWCC recommends reading the guide thoroughly before beginning preparation. Completing the example questions will help acquaint candidates with types of questions in the examination. Studying the Examination Content Outline will help candidates identify topics covered in the examination and delineate areas where knowledge gaps may exist and thus to which topics extra preparation time might well be devoted. Resources are listed to aid candidates in locating study materials.

The Examination Content Outline delineates the core competencies—ie, knowledge, skills, and abilities (KSAs)—of professional medical writers. Carefully studying this outline will allow MWC candidates to

- Become familiar with the approximate percentage of each content area tested.
- Know the topics and medical writing tasks that are associated with each content area and accordingly may be tested for on the exam.
- Inventory their current knowledge related to each content area.
- Build a study plan based on their knowledge inventory; for example, candidates unfamiliar with regulatory writing probably should study materials in that area.

The following is an example of an examination-preparation sequence that a candidate may find helpful:

- Use the Examination Content Outline and the Example Topic and Subtopic Categories available in this Study Guide to help identify the various areas of medical writing.
- Identify competencies and related topics that are unfamiliar.
- Study material about the identified unfamiliar topics. The Selected Examination Preparation Resources section of this guide lists some materials that may be helpful.
- Candidates are not expected to have detailed knowledge of all topics. For example, there are many document-specific guidelines. Knowing every guideline in detail is not necessary. However, being aware that such guidelines exist, knowing the names of core industry guidelines, and knowing major points of these guidelines would be reasonable to expect.

The MWC examination is a robust test of professional competency. Having at least 2 years of medical writing experience, possessing a broad understanding of medical writing competencies, and filling knowledge gaps before taking the examination are important aspects of preparation. However, they do not guarantee passing the examination.

Medical Writing Certification Examination Content

The Medical Writing Certification Examination content is based on the definition of a medical writer and the associated Examination Content Outline shown below.

The 125-question multiple-choice examination is completed via computer-based answer entry at a testing center. The examination is in English and taken over a 2.5-hour period. Questions that are answered incorrectly or that are unanswered are treated the same (i.e., wrong answers are not subtracted from right answers); therefore, candidates should try to answer every question. There is no penalty for incorrect answers, and all questions are weighted equally.

Medical Writing Definition

The MWCC defines medical writing based upon the definition of a medical communicator developed by AMWA.

- Medical writers write, edit, or develop materials about medicine and health. They do this by gathering, evaluating, organizing, interpreting, and presenting information in a manner appropriate for the target audience. Professional medical writers also have communication expertise, awareness of ethical standards, and health care knowledge.

Examination questions cover several types of medical writing, including

- Patient education brochures, news articles, web content, and books for the public.
- Journal articles for health care professionals and biomedical researchers.
- Continuing education monographs for health care professionals.
- Regulatory documents for government agencies.
- Grant proposals for funding agencies.
- Sales training and marketing materials for the pharmaceutical industry.

Examination Content Outline

The knowledge, skills, and abilities (KSAs) of the Examination Content Outline are divided into 5 domains associated with the definition of a medical writer: Gathering, Evaluating, Organizing, Interpreting, and Presenting. The examination questions address all 5 domains, with the approximate percentage of questions per domain weighted as shown below. Whether an MWC candidate passes the examination, however, is based only on the total score; a specified score need not be achieved in each domain. Candidates should use the Examination Content Outline to guide examination preparation and thus help ensure the appropriate knowledge and critical thinking skills necessary to earn the MWC credential. The

outline lists KSAs according to domain and thereby delineates the 5 domains. All areas of the outline are represented on the examination, and all examination questions relate directly to the items within each of these 5 domains. However, not every item will (or could) be covered on an individual exam form. The Examination Content Outline follows:

1. **Gathering** (16% of content)
    A. Determine purpose of document
    B. Identify context for document
    C. Identify target audience
        1) Assess needs
        2) Identify knowledge gaps
    D. Select appropriate output type (e.g., publications, regulatory documents, continuing medical education materials, patient education)
    E. Identify appropriate outlet (e.g., target journal, other print media, web)
    F. Apply effective processes to gather information
        1) Conduct a literature search (e.g., PubMed/MEDLINE)
        2) Elicit information from collaborators and stakeholders (e.g., interview researchers, statisticians, clinicians, patients, regulators, thought leaders)
        3) Identify other relevant sources (e.g., websites, databases, data outputs, clinical guidelines)
        4) Identify relevant writing guidelines, instructions, and ethical standards (e.g., journal instructions for authors, grant application instructions, regulatory requirements)
        5) Identify relevant document models and templates
        6) Identify necessary forms and supporting materials (e.g., permission to reprint, disclosures, copyright)
2. **Evaluating** (19% of content)
    A. Evaluate collected information with regard to
        1) Content (ie, quality and relevance, level of evidence)
        2) Audience (ie, appropriate and relevant to needs)
        3) Context (ie, credibility of sources and suitability for purpose)
    B. Perform fact or data check
    C. Identify inconsistencies in data or other content presented
    D. Conduct critical review of a draft
        1) Assess quality of writing (e.g., clarity, readability, usability, logic, organization, consistency)
        2) Provide constructive criticism
            a) Provide options for solutions
            b) Craft appropriate queries
        3) Evaluate representation and description of data
        4) Recognize ethical considerations with respect to self and others (e.g., conflict of interest, disclosure, authorship, plagiarism, duplicate publications)
    E. Evaluate for completeness, fair balance, and absence of bias
    F. Determine appropriate level(s) of editing (e.g., proofreading, microediting, macroediting)
    G. Implement best approach to resolve issues (e.g., author disagreements, scope change, unexpected delays)
3. **Organizing** (19% of content)
    A. Determine correct organization of a document (e.g., IMRAD)
    B. Identify and prioritize key elements of content

C. Structure content to communicate message
D. Develop an outline
E. Apply templates and guidelines to documents (e.g., CONSORT, ICMJE, FDA, ICH, PRISMA, ACCME, HIPAA, health literacy)
F. Determine structure of tables and figures to best communicate data
G. Determine which references to cite in a document
H. Comprehend processes of developing and disseminating documents (e.g., news releases, publications, grant and regulatory submissions)
I. Design project work plan
    1) Determine deliverables
    2) Develop timeline
    3) Recognize roles, responsibilities, and processes
J. Track progress and status of project
K. Determine process for tracking changes and version control
L. Recognize and apply appropriate software and technology to use in developing the document

4. **Interpreting** (19% of content)
    A. Comprehend relevant medical and scientific content
        1) Understand terminology
        2) Understand concepts (e.g., cellular and molecular level, organism level, and population level)
        3) Understand study design (e.g., clinical trial, case control, longitudinal study)
        4) Understand statistical concepts (e.g., *P* value, confidence interval, power)
    B. Interpret clinical and numerical data
    C. Derive key message(s)
    D. Determine inferences, implications, or clinical relevance
    E. Synthesize and integrate information
    F. Revise or repurpose existing content
    G. Comprehend review processes (e.g., peer review, grant review, regulatory review)
    H. Respond to reviewers' comments
        1) Interpret feedback from reviewers
        2) Determine appropriate responses
5. **Presenting** (27% of content) [communicating via an output, usually a written document]
    A. Present the message logically and coherently (ie, tell the story)
    B. Retain the intended meaning of source materials or original document
    C. Communicate scientific content appropriately
    D. Communicate statistical content appropriately
    E. Develop clear, concise prose
    F. Write an abstract (e.g., for presentation or publication) or executive summary
    G. Tailor prose to the audience
    H. Build logical and science-based arguments
    I. Apply proper mechanics
        1) Apply rules of grammar, spelling, and punctuation
        2) Apply proper word usage (general and medical), correct nomenclature, and nondiscriminatory language
        3) Construct effective sentences
        4) Construct effective paragraphs (e.g., topic sentences, transitions, repetition of key terms)

5) Apply techniques for cohesion between paragraphs and sections

J. Apply principles of proofreading
K. Apply basic principles of design and layout (e.g., document, slide, poster, web)
L. Apply principles of visual presentation of data (e.g., tables, figures)
M. Write document to adhere to standardized formats, guidelines, instructions, and ethical standards
N. Maintain confidentiality of information (e.g., patient, proprietary)

Example Topic and Subtopic Categories

MWC candidates may interpret some Examination Content Outline items as too vague to help preparation directly. For example, under the *Interpreting* domain, one item is "Comprehend relevant medical and scientific content." This skill is important for a medical writer but would not be easily addressed in an examination. In studying, candidates should address concrete examples, such as those in the list of sample topics below. Understanding topic key concepts and core terms is important. The topics listed are only examples, and other topics could be included in the examination.

- Continuing medical education
  - Needs assessment
  - Learning objectives
  - Independence from commercial interest
- Epidemiology/Research
  - Bias, confounding, and interaction
  - Incidence versus prevalence
  - Phases of drug development
  - Study design (e.g., clinical trial, cohort, case-control, cross-sectional)
  - Systematic reviews and meta-analysis
- Ethical principles
  - Authorship criteria
  - Conflicts of interest
  - Copyright
  - Fair/balanced content
  - Privacy/confidentiality
- Mechanics of writing
  - Grammar
  - Parallelism
  - Proofreading
  - Punctuation
  - Sentence structure
  - Writing and editing skills
- Medical writing competency
  - Role in document development
  - Role in data disclosure
  - Core knowledge, skills, and abilities
- Patient/health education
  - Lay words for medical terms
  - Plain language definition
  - Suitable mediums for audience
  - Techniques for assessing understandability
  - Writing for reading comprehension levels

- Project management
  - Coordinating authors or reviewers
  - Managing document development timelines
  - Using document management tools and processes
- Publication practices
  - Author guidelines
  - Consolidated Standards of Reporting Trials
  - Good Publication Practice
  - Journal targeting
  - Prepublication embargo
  - Publication planning
  - Responding to reviewers
- References and literature searching
  - Database search term use
  - Fair/balanced searching
  - Source credibility
- Regulatory submissions
  - Clinical Investigational Brochure structure
  - Clinical Study Report content
  - Common Technical Document structure
  - Data safety monitoring plan
  - New Drug Application versus Investigational New Drug Application
  - Regulatory document types and purposes
  - Substantial evidence
- Research grant application
  - Application process
  - Differences between grant proposals and other document types
- Statistical concepts and analysis reporting
  - Confidence interval
  - Effect size
  - Measures of central tendency and variability
  - Multiplicity (i.e., multiple testing)
  - Risk ratios, odds ratios, and relative risk
  - Sensitivity and specificity
  - Statistical tests and statistical significance
  - Type I and II errors (false-positive or negative studies)
- Terms and their usage
  - Clinical research terms
  - Digital Object Identifier
  - International System of Units
  - Institutional Review Board
  - Medical communication terms
  - Medical terms
  - Protocol deviation
  - Publication bias
  - Serious Adverse Event

Example Questions

The questions listed below are representative examples of those on the certification examination, and an answer key is provided in the next section.

Representative Example Questions

1. The beginning of the Discussion section in a scientific article should

   A. Answer the question(s) posed in the Introduction.
   B. Review the literature related to the field.
   C. State the strengths and limitations of the study.
   D. Explain the significance of the results.

2. A medical writer receives an assignment to produce a multimedia project that will involve multiple vendors. The client wants the project to be rolled out in conjunction with a new product, for which there is a firm deadline. Which task is MOST appropriate for the medical writer to undertake first to complete the project?

   A. Given the deadline, propose alternatives to a multimedia project.
   B. Monitor the budget weekly and send vendors weekly invoices.
   C. Create a timeline for each vendor's deliverable items.
   D. Begin to create a draft script for the project.

3. A study comparing the risks of postoperative complications for 2 surgical procedures found a 2-fold difference. An analysis stratified by patient smoking status found a risk ratio of 4.75 among smokers and 1.0 among nonsmokers. Which of the following BEST explains these results?

   A. Confounding
   B. Interaction
   C. Information bias
   D. Selection bias

4. When conducting a needs assessment for an accredited-provider continuing education activity for nurses, a medical writer should identify the

   A. Gap between best practice and the nurses' current practice.
   B. Gap between the nurses' interests and current knowledge deficits.
   C. Nurses' rank-ordering of their current learning needs.
   D. Nurses' self-identified current practice interests.

5. A medical writer recognizes that abbreviations are

   A. Universally used across languages.
   B. Used only in titles and headers.
   C. Avoided in lengthy publications.
   D. To be defined when first used.

6. When submitting a regulatory marketing application for a new drug, the medical writer needs to know that the Common Technical Document (CTD) format includes

   A. The summary and overview documents in Module 2.
   B. The Clinical Overview in Module 3.
   C. The Clinical Study Reports in Module 4.
   D. The Nonclinical Study Reports in Module 1.

7. Which is the BEST title for a grant proposal based on preliminary studies that showed that microRNA-based therapy may reverse right ventricular hypertrophy and improve pulmonary arterial hypertension and survival in rats?

   A. MicroRNA-based therapy reverses right ventricular hypertrophy and improves pulmonary arterial hypertension and lifespan
   B. Studies of microRNA-based therapy in rats with pulmonary arterial hypertension
   C. Improvement of right ventricular hypertrophy, of pulmonary arterial hypertension, and of lifespan after microRNA-based therapy
   D. MicroRNA-based therapy for treating right ventricular hypertrophy and improving survival in a rat model of pulmonary arterial hypertension

8. When evaluating a specific website as a potential resource for information, which of the following criteria is MOST important for the medical writer to consider?

   A. The reputation and background of those who have created the website
   B. Whether the treatments discussed have been approved by regulatory authorities (e.g., U.S. Food and Drug Administration)
   C. The number of references and patient testimonials cited to support the potential treatment claims
   D. Potential conflict of interest if the products being discussed are sold by the website sponsor

9. A researcher asks a medical writer to review a draft manuscript and provide critical comments and suggestions. The medical writer notices that the narrative describing a table is not consistent with the data presented in the table. What should the medical writer do?

   A. Ignore it since the scientific peer reviewers did not see it as a problem.
   B. Query the author about the apparent discrepancy.
   C. Correct the discrepancy in the text so that it matches the table.
   D. Evaluate the data in the table to determine the problem.

10. The results from a placebo-controlled clinical trial of a new antihypertensive treatment are mean difference in blood pressure=1.2 mmHg ($P < .001$). Which of the following BEST describes these results?

    A. Clinically important and statistically significant
    B. Clinically important but not statistically significant
    C. Not clinically important but statistically significant
    D. Not clinically important and not statistically significant

11. To assess the potential effect of drinking wine on the risk of fatal myocardial infarction, researchers collected the cardiac mortality rate and per capita wine consumption for 30 countries and found a correlation coefficient of -0.75. What type of study design is this?

    A. Cohort
    B. Case-control
    C. Ecologic
    D. Cross-sectional

12. In the following sentence, which word or words are used incorrectly?

    The patient died of pneumonia, which was due to immune suppression from a large dosage of azathioprine.

    A. Died of
    B. Which
    C. Due to
    D. Dosage

Answer Key

References are noted for each answer listed. The full citations for references are provided in the *Selected Examination Preparation Resources* section.

1. **The correct answer is A.** The opening of the Discussion should succinctly answer the research question(s) posed at the end of the Introduction, ie, state the conclusion that can be drawn from the data that were presented in the Results. This is the author's chance to frame the discussion of the results. The rationale is that readers remember best what comes first and last, so the author needs to take advantage of the beginning of the Discussion to state what was found. In the middle section of the Discussion, the author will explain the significance of the results in light of others' work and mention any limitations of the study. The Discussion is never the place for a literature review. Only literature directly related to the results of the author's study should be discussed.

   References: Lang (2010: 161), Zeiger (2000: 183-184)

2. **The correct answer is C.** Creation of a timeline before beginning work will allow the writer to understand what needs to be delivered and communicate with the client about potential scheduling constraints, which is important given the firm deadline and the complexity of typical multimedia projects. This step will help the writer, in collaboration with the client, to determine an appropriate scope for the project.

   References: Project Management Institute (2011: 1)

3. **The correct answer is B.** "Two explanatory variables are said to interact if the effect of one explanatory variable on the response variable depends on the level of the second explanatory variable. Interaction implies that the explanatory variables should be considered together, not separately" (Lang & Secic, 2006: 98). In this question, smoking status affects the effect of the independent variable (surgical procedure) on the outcome/dependent variable (postoperative complications) because the risk is present (risk ratio=4.75) only for smokers, ie, not for nonsmokers (risk ratio=1.0).

   References: Lang & Secic (2006: 98, 112), Fletcher, Fletcher, & Fletcher (2012: 76).

4. **The correct answer is A.** According to the updated Accreditation Council for Continuing Medical Education (ACCME) criteria, continuing education for health care professionals must focus on the educational needs that underlie the professional practice gaps of the targeted learners (Competency Area 2). A practice gap is defined as the difference between current practice and best practice. Thus, in writing a needs assessment, which justifies the need for a continuing education activity, a medical writer must first identify the practice gap and describe how the proposed activity will provide the education to bridge that gap.

   Reference: Massy (2010: 6-9), Alliance for Continuing Education in the Health Professions (ACCME; National Learning Competencies: Area 2)

5. **The correct answer is D.** The normal practice in medical writing is to define abbreviations on first mention (except, for instance, if they are standard abbreviations for units of measure).

   References: American Medical Association (2007: 357), Gastel (2010: 42), Lang (2010: 38)

6. **The correct answer is A.** As defined in the International Council for Harmonization (ICH) guidelines, Common Technical Document (CTD) for the Registration of Pharmaceuticals for Human Use (M4), Module 2 contains the overviews and summaries of information contained in Modules 3, 4, and 5.

   References: International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use, M4: The Common Technical Document (2016: 2-4), Wood & Foote (2009: 148)

7. **The correct answer is D.** Answer A claims too much for a project that is based on preliminary studies (ie, …reverses right ventricular hypertrophy) and doesn't mention the species or population of the study. Answer B mentions the species, but the title is vague. Answer C has too many prepositional phrases and a nominalization as the first word. Answer D is best because it is specific, indicates the research area and goals of the project, and includes the variables and species.

References: U.S. National Institutes of Health: National Institute of Allergy and Infectious Disease (June 30, 2016), Lang (2010: 143-147), Zeiger (2000: 300-302)

8. **The correct answer is D.** The information being presented should be considered by the writer in the context of potential bias stemming from the commercial purpose of the website. For choice A, reputation is subjective and although background may give insight into qualifications, it is not always a reliable indicator of information quality. Similarly, for choice B, the regulatory status of a treatment being discussed does not guarantee the quality of the information being presented. Regarding choice C, the number of cited references or anecdotes alone would not be a sufficient indicator of information quality; these would need to be verified and considered in terms of level of evidence.

   References: American Medical Association (2007: 168), U.S. National Library of Medicine (July 1, 2015), Cornell University Library (September 12, 2017)

9. **The correct answer is B.** According to widely accepted international guidelines for scientific manuscripts, authors must approve the final version of the document. They must also agree to be accountable for all aspects of the work and to ensure that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved. Querying authors about an apparent discrepancy will allow the authors to fulfill their responsibility. Even if a medical writer believes he or she knows how to correct the discrepancy, this decision is the responsibility of the authors.

   References: International Committee of Medical Journal Editors (2017: 2), Einsohn (2011: 41)

10. **The correct answer is C.** While the result presented indicates that it is unlikely to have arisen by chance (ie, it is statistically significant given that P<.001), the magnitude of the average effect anticipated (1.2 mmHg) is quite small (not clinically important).

    References: Lang & Secic (2006: xvii–xix), Lang (2007: 317-319)

11. **The correct answer is C.** This is an ecologic study because the exposure variable (drinking wine) and outcome variable (fatal myocardial infarction) are measured/characterized by the average of the group (in this case, by country), rather than being measured on individual study participants as they would be in the other 3 listed study designs.

    Reference: Fletcher, Fletcher & Fletcher (2012: 202)

12. **The correct answer is D.** Dosage would imply the regimen of azathioprine prescribed rather than the individual quantity given. The wording “died of” is preferred according to the AMA Manual of Style, although some publications may allow “die from.” “Which” is used correctly in answer B to introduce a nonrestrictive clause. “Due to” is an adjectival phrase, modifying pneumonia. The words “caused by” can be substituted for it, which is another way to know that it is used correctly in this instance.

    References: American Medical Association (2007: 318, 391-392), Witte (2011: 82, 115)

Selected Examination Preparation Resources

Work experience should provide much of the knowledge needed to successfully complete the examination. However, the examination will cover many aspects of medical writing. Thus, MWC candidates should assess their knowledge base related to the Examination Content Outline and focus preparation efforts on areas of perceived gaps. Below are examples of types of study materials that may aid candidates in examination preparation. A MWC candidate will not need to study all resources listed, nor study references in their entirety; instead, the focus should be on addressing perceived gaps in knowledge or experience.

It is important to understand that—

- It is likely that not all examination content is specifically covered in the listed resources.
- The number of resources listed under a topic is not linked to the amount of examination content related to that topic; rather, the amount of examination content for each topic is based upon the weighting in the Examination Content Outline.

- The content domains tested on the MWC examination—Gathering, Evaluating, Organizing, Interpreting, and Presenting—are italicized and in brackets after each numbered category.
- Resources were last tabulated/updated and Website resources were last accessed on February 8, 2018.
- For resources with multiple editions, it is best to consult the most recent edition.

A. General References Applicable to All Areas of Medical Writing

1. **Epidemiology/research** [*Evaluating, Interpreting*]
    a. Fletcher RH, Fletcher SW, Fletcher GS. *Clinical Epidemiology: The Essentials.* 5th ed. New York, NY: Lippincott Williams & Wilkins, 2012. 272 pages.
2. **Ethical principles** [*Organizing*]
    a. Hamilton C. Essential Ethics for Medical Communicators. Rockville, MD: American Medical Writers Association, 2011. 70 pages.
3. **Mechanics of writing** [*Presenting*]
    a. Alperin LM. *Punctuation for Clarity and Style.* Rockville, MD: American Medical Writers Association, 2011. 156 pages.
    b. American Medical Association. *AMA Manual of Style: A Guide for Authors and Editors.* 10th ed. New York, NY: Oxford University Press, 2007. 1010 pages.
        i. Online version: http://www.amamanualofstyle.com/.
    c. Council of Science Editors. *Scientific Style and Format: The CSE Manual for Authors, Editors, and Publishers.* 8th ed. Chicago, IL: The Council of Science Editors in Cooperation with the University of Chicago Press, 2014. 840 pages.
        i. Online version: http://www.scientificstyleandformat.org/Home.html.
    d. Einsohn A. *The Copyeditor's Handbook. A Guide for Book Publishing and Corporate Communications.* 3rd ed. Oakland, CA: University of California Press, 2011. 576 pages.
    e. Witte F. *Basic Grammar and Usage.* Rockville, MD: American Medical Writers Association, 2011. 216 pages.
    f. Witte F. *Sentence Structure and Patterns.* Rockville, MD: American Medical Writers Association, 2011. 202 pages.
4. **Medical writing competency** [*Gathering, Evaluating, Organizing, Interpreting, Presenting*]
    a. Clemow DB, Wagner B, Marshallsay C, et al. Medical Writing Competency Model – Section 1: Functions, Tasks, and Activities. Ther Innov Regul Sci. 2018:52(1):70-77.
    b. Clemow DB, Wagner B, Marshallsay C, et al. Medical Writing Competency Model – Section 2: Knowledge, Skills, Abilities, and Behaviors. Ther Innov Regul Sci. 2018:52(1):78-88.
5. **Project management** [*Organizing*]
    a. Babler SD, ed. *Pharmaceutical and Biomedical Project Management in a Changing Global Environment.* Hoboken, NJ: John Wiley & Sons, 2010. 400 pages.
    b. Hamilton C. *Essential Ethics for Medical Communicators.* Rockville, MD: American Medical Writers Association, 2011. 70 pages.
    c. Project Management Institute. *Practice Standard for Scheduling*. 2nd ed. Newtown Square, PA: Practice Management Institute, 2011. 130 pages.

6. **References and literature searching** [*Gathering and Evaluating*]
    a. Cornell University Library. Evaluating Web Pages: Questions to Consider. Last updated September 12, 2017. https://olinuris.library.cornell.edu/ref/research/webeval.html. (free)
    b. U.S. National Library of Medicine. Evaluating Internet Health Information: A Tutorial from the National Library of Medicine. Last updated July 1, 2015. https://medlineplus.gov/webeval/webeval.html. (free)
    c. U.S. National Library of Medicine. PubMed Tutorial. Last updated August 25, 2016. http://www.nlm.nih.gov/bsd/disted/pubmedtutorial/cover.html. (free)
7. **Statistical concepts and analysis reporting** [*Evaluating, Interpreting, Presenting*]
    a. Harvey B. Statistics for Medical Writers and Editors. Rockville, MD: American Medical Writers Association, 2011. 96 pages.
    b. Harvey BJ, Lang TA. Hypothesis testing, study power and sample size. Chest 2010;138(3): 734-737. doi: 10.1378/chest.10-0067. (free)
    c. Lang TA. Documenting research in scientific articles: guidelines for authors: 2. Reporting hypothesis tests. Chest 2007;131:317–319. doi: 10.1378/chest.06-2087.
    d. Lang TA, Secic M. How to Report Statistics in Medicine: Annotated Guidelines for Authors, Editors, and Reviewers. 2nd ed. Philadelphia, PA: American College of Physicians, 2006. 490 pages.
8. **Terms and their usage** [*Presenting*]
    a. Gastel B. *Elements of Medical Terminology.* Rockville, MD: American Medical Writers Association, 2010. 92 pages.
    b. Hamilton C. *Tables and Graphs.* Rockville, MD: American Medical Writers Association, 2012. 110 pages.

B. Resources for Specific Areas of Medical Writing

1. **Continuing medical education**
    a. Accreditation Council™ for Continuing Medical Education. About Us. http://www.accme.org/about-us. (free)
    b. Accreditation Council™ for Continuing Medical Education. Tutorial (video). http://www.accme.org/education-and-support/video/tutorial. (free)
    c. Alliance for Continuing Education in the Health Professions (ACCME). National Learning Competencies. http://www.acehp.org/p/cm/ld/fid=15. (free)
    d. Davis D, Barnes B, Fox R, Eds. *The Continuing Professional Development of Physicians: From Research to Practice.* Chicago, IL: AMA Press, 2003. 400 pages.
    e. Massy K. CME Basics. Criterion 2: Identifying and Analyzing Professional Practice Gaps. September 2010. http://eo2.commpartners.com/users/acme/downloads/Almanac_Article_Basics_Sept.pdf. 3 pages. (free)
2. **Patient/health education**
    a. Centers for Disease Control and Prevention. Health literacy. www.cdc.gov/healthliteracy. (free)
    b. Fagerlin A, Zikmund-Fisher BJ, Ubel PA. Helping patients decide: ten steps to better risk communication. J Natl Cancer Inst. 2011;103:1436–1443. (free)

c. FDA Office of Prescription Drug Promotion. https://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDER/ucm090142.htm. (free)

d. Federal Plain Language Guidelines, Rev. 1, May 2011. http://www.plainlanguage.gov/. (free)

e. Gastel B. *Health Writer's Handbook.* 2nd ed. Ames, IA: Blackwell Publishing, 2004. 366 pages.

f. Institute of Medicine. *Health Literacy: A Prescription to End Confusion*. Washington, DC: National Academies Press; 2004. 268 pages. http://www.nationalacademies.org/hmd/Reports/2004/Health-Literacy-A-Prescription-to-End-Confusion.aspx. (free)

g. Paling J. Strategies to help patients understand risk. BMJ. 2003;327:745–748. (free)

h. U.S. Office of Disease Prevention and Health Promotion (ODPHP). Health Literacy Online: A Guide for Simplifying the User Experience. 2nd ed. Updated June 8, 2016. https://health.gov/healthliteracyonline/full/. (free)

3. **Publication practices** [*Presenting*]

a. European Association of Science Editors (EASE). Guidelines for Authors and Translators of Scientific Articles to be Published in English. November 2017. http://www.ease.org.uk/publications/author-guidelines-authors-and-translators/. (free)

b. Gastel B, Day RA. *How to Write and Publish a Scientific Paper.* 8th ed. Santa Barbara, CA: Greenwood, 2016. 326 pages. (Includes chapters on writing grant proposals and writing for the public.)

c. International Committee of Medical Journal Editors (ICMJE). Recommendations for the Conduct, Reporting, Editing, and Publication of Scholarly Work in Medical Journals. Updated December 2017. http://www.icmje.org/icmje-recommendations.pdf. 19 pages. (free)

d. International Society for Medical Publication Professionals (ISMPP). Good Publication Practice-3 (GPP3) Guidelines, 2015. http://www.ismpp.org/gpp3. (free)

e. Lang TA. *How to Write, Publish, & Present in the Health Sciences: A Guide for Clinicians & Laboratory Researchers.* Philadelphia, PA: American College of Physicians, 2010. 387 pages. (Includes a section on writing grant proposals.)

f. The EQUATOR (Enhancing the Quality and Transparency of Health Research) Network. Reporting guidelines for main study types. http://www.equator-network.org/.(free)

g. Zeiger M. *Essentials of Writing Biomedical Research Papers.* 2nd ed. New York, NY: McGraw-Hill, 2000. 440 pages.

4. Regulatory submissions

a. DeTora L, Ed. *Regulatory Writing: An Overview.* Rockville, MD: Regulatory Affairs Professionals Society (RAPS), 2017. 234 pages.

b. European Medical Writers Association, American Medical Writers Association. Clarity and Openness in Reporting: E3-based (CORE) reference. Version 1.0. May 3, 2016. http://www.core-reference.org/. (free)

c. International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH). http://www.ich.org/home.html. (free)

i. ICH Guidelines. http://www.ich.org/products/guidelines.html. (free)

ii. M4: The Common Technical Document. http://www.ich.org/products/ctd.html. (free)

d. U.S. Food and Drug Administration. FDA drug approval process infographic. https://www.fda.gov/Drugs/ResourcesForYou/Consumers/ucm394839.htm. (free)

e. U.S. Food and Drug Administration. ICH (International Council for Harmonisation) Guidance Documents. www.fda.gov/ScienceResearch/SpecialTopics/RunningClinicalTrials/GuidancesInformationSheetsandNotices/ucm219488.htm. (free)

f. Wood LF, Foote M, Eds. *Targeted Regulatory Writing Techniques: Clinical Documents for Drugs and Biologics.* Basel; Boston, MA: Birkhäuser, 2009. 238 pages.

5. Research grant application

a. U.S. National Institutes of Health: National Institute of Allergy and Infectious Disease. Apply for a grant. June 30, 2016. https://www.niaid.nih.gov/grants-contracts/apply-grant. (free)

b. Yang OO. *Guide to Effective Grant Writing: How to Write a Successful NIH Grant Application.* 2nd ed. New York, NY: Springer, 2012. 90 pages.

C. Additional resources on the AMWA website

1. AMWA Education, Online Learning. Includes documents, interactive learning resources, and on-demand videos, many complimentary for AMWA members. http://amwa.mycrowdwisdom.com/diweb/catalog/t/5259/c/184/n/0.
2. *Guidelines for Document Designers* is a short, practical, evidence-based handbook for writers and editors. https://eric.ed.gov/?id=ED221866. (free)
   a. A cleaner PDF is available for AMWA members: http://amwa.mycrowdwisdom.com/diweb/catalog/item/id/791910. (free)
3. Position Statements and Guidelines. http://www.amwa.org/page/Position_Statement. (free)
4. The complete list of AMWA Essential Skills Workbooks. (Self-Study). https://www.amwa.org/store/ListProducts.aspx?catid=549813.