Getting Organized to Write

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CHARACTERISTICS OF GOOD MEDICAL WRITING

- Thorough research
- Accurate information
- Logical organization
- Clarity of thought and writing
- Readability

"Chance only favors the prepared mind." *Pasteur*

Get Organized to Write

- Planning
- Freewriting
- Rewriting
- Editing

Keep writer's block at bay

PLANNING

- Determine your audience
- Know what you need to accomplish
- Learn about your subject
  - Develop your thesis
- Develop your protocol
- Work with the appropriate committee and staff members

AUTHORSHIP

- Determine listings for authors, contributors, and acknowledgments early in the process
- Disclose conflicts of interest that may bias work
- Disclose roles for author and sponsor in company-sponsored studies
- Remember, in references, often only the first 3 or 6 authors are named

AUTHORSHIP

Criteria for authorship*

- Participate sufficiently to take responsibility for the content, i.e., be able to defend the content and conclusions
- Make substantial contributions to each of the following areas:
  - Conception and design **or** analysis and interpretation of data
  - Drafting the manuscript **or** revising it critically for important intellectual content
  - Approving the version of the manuscript to be published

*Uniform Requirements for Manuscripts Submitted to Biomedical journals. International Committee of Medical Journal Editors. http://www.icmje.org/

CHOOSING A TARGET JOURNAL

Consider

- Appropriateness for your message
- Type and length of articles published
- Impact factor
- Likelihood of publication
- Journal circulation

PREWRITING WORKSHEET

Statistics

- Talk to a statistician before gathering data if you plan to apply statistical tests to the results
- Data from THI cannot be presented without staff approval (in abstracts, posters, or manuscripts)
- Surgical data cannot be presented without approval of the appropriate surgeons
- Contact Mac Elayda, MD, or Mike Wilson, MD, for initial approvals of studies
- Contact Mac Elayda, MD, when data will be presented (THIRDBase and other data)

THIRDBase

Comprehensive, longitudinal clinical registry of outcomes of over 200,000 patients treated at THI since 1960

- Includes information about demographics; CV risk factors for various outcomes; medical histories; physical findings; cardiac catheterization procedures; surgical and percutaneous interventions; complications; selected laboratory values; and follow-up
- Maintained by the department of Biostatistics and Epidemiology
- Contact: Mac Elayda, MD, PhD (832-355-2345; melayda@heart.thi.tmc.edu)

WRITING A MANUSCRIPT USING THI/SLEH DATA

- Complete Clinical Research Committee: Protocol for Initial Data Request or Publication or an SLEH Request for Expedited Review (IRB)
- Submit the protocol to the IRB with a cover letter (or the review form)
- Request expedited review under provision 3, “study of existing data, documents, records, pathological specimens, or diagnostic specimens.” Permission not required if patients enrolled in IRB-approved protocol.
- Request approval of patients’ physicians
- Access sample documents (protocol, letters, etc.) at www.texasheart.org/scipub.html)

Handout

Clinical Research Committee: Protocol for Initial Data Request or Publication

- Discuss any potential manuscript with the appropriate staff members and chief of service before submitting a request to the IRB

HANDOUTS

Sample Letters

- IRB database query
- IRB manuscript/case report query
- Request to use patient data

Sample letter

(Date)

Frank A. Redmond, MD, PhD
Attention: Joan R. Scott, CIM
Institutional Review Board
St. Luke's Episcopal Hospital
6720 Bertner Avenue, MC 3-288
Houston, Texas 77030

Re: (Project title)

Dear Dr. Redmond:

I am planning to publish a (database/manuscript/case report) about (state purpose).

I am requesting expedited approval of the above-referenced project under provision 8, "the study of existing data, documents, records, pathological specimens, or diagnostic specimens." The Protocol and Initial Data Request/Manuscript Form is attached for your review. I will be responsible for contacting physicians whose patient data will be used in the analyses.

If you need additional information, I can be reached at (include phone number). Thank you for your consideration.

Sincerely,

(Name, address, including mail code)

(If you have any concerns or questions, contact Joan Scott, IRB Coordinator, 832-355-3347. Submissions may be made directly to the IRB office, Room B501-C, directly across from the blue elevators, 5th floor.)

INSTITUTIONAL REVIEW BOARD GUIDELINES

- Reviews all clinical (research) investigations that include human subjects, as regulated by the FDA
- Complete IRB protocol. Check calendars (see handouts)
- SLEH IRB not required for Baylor-approved studies
- Request expedited review (see form in handout)
- Detailed instructions and investigator guides: www.SLEH.com/research
- Contact Cheryl Fullmer, RN, MBA

Institutional Review Board

- Dr. Frank Redmond, chair
  - Dr. Arthur Bracey, vice-chair
  - Dr. Kelly Larkin, vice-chair
- Cheryl Fullmer, Director, Department of Research
  - Extension 5-6801; cfullmer@sleh.com
- Dominique Cross, Research Compliance Coordinator
  - Extension 5-5125; dcross@sleh.com
- Angie Esquivel, IRB Coordinator
  - Extension 5-3347; aesquivel@sleh.com
- Cassandra Anderson, Administrative Assistant
  - Extension 5-3710; canderson@sleh.com

Chart Reviews (IRB)

- Complete a written request describing your research study
- Complete and IRB Waiver of Authorization Form (so the IRB can waive the consent and authorization)
- Obtain your chief of service's signature on the request
- Submit 1 original set of these documents to the IRB office (or bring to Dept. of Research, Suite O-510)
- Expedited review may be requested by completing an Expedited Review form
- Receive approval letter from IRB chair granting approval (pending next IRB meeting)

Expedited Review

For minimal risk protocol amendments and chart reviews:

- Complete expedited review form
- Send Expedited Review Form and applicable documents to IRB coordinator
- Receive approval letter from IRB chair granting approval (pending next IRB meeting)

IRB MANUSCRIPT GUIDELINES

Publications/Manuscripts

- If a researcher intends to publish the results of such research as emanating from SLEH/THI, a copy of the research article must be submitted to the Principal Investigator's SLEH/THI Chief of Service before publication. If the manuscript is published, a copy of the published manuscript must be submitted to the IRB. St. Luke's Episcopal Hospital shall be acknowledged in all published research involving SLEH patients.

OVERSIGHT OF ANIMAL PROTOCOLS

Institutional Animal Care and Use Committee (IACUC)

- Oversees specific use of animals in biomedical research protocols in adherence to federal regulations
- Contact Melissa Moon (832-355-3121; mmoon@heart.thi.tmc.edu)

Research Review Committee (Office of Research Administration)

- Reviews scientific integrity of protocols and their adherence to the mission of THI
- Contact Mike McGee (832-355-3400)

Information about preparing applications involving research animals

http://www.niaid.nih.gov/ncn/clinical/researchanimals/tutorialanimalpf.htm

IACUC

Submitting Protocols/Information for Investigators

Non-clinical laboratory study protocol; requires lay summary

- Submit to IACUC Secretary (MC 1-268)
- Will be assigned to research coordinator to help develop protocol and to manage the study

IACUC

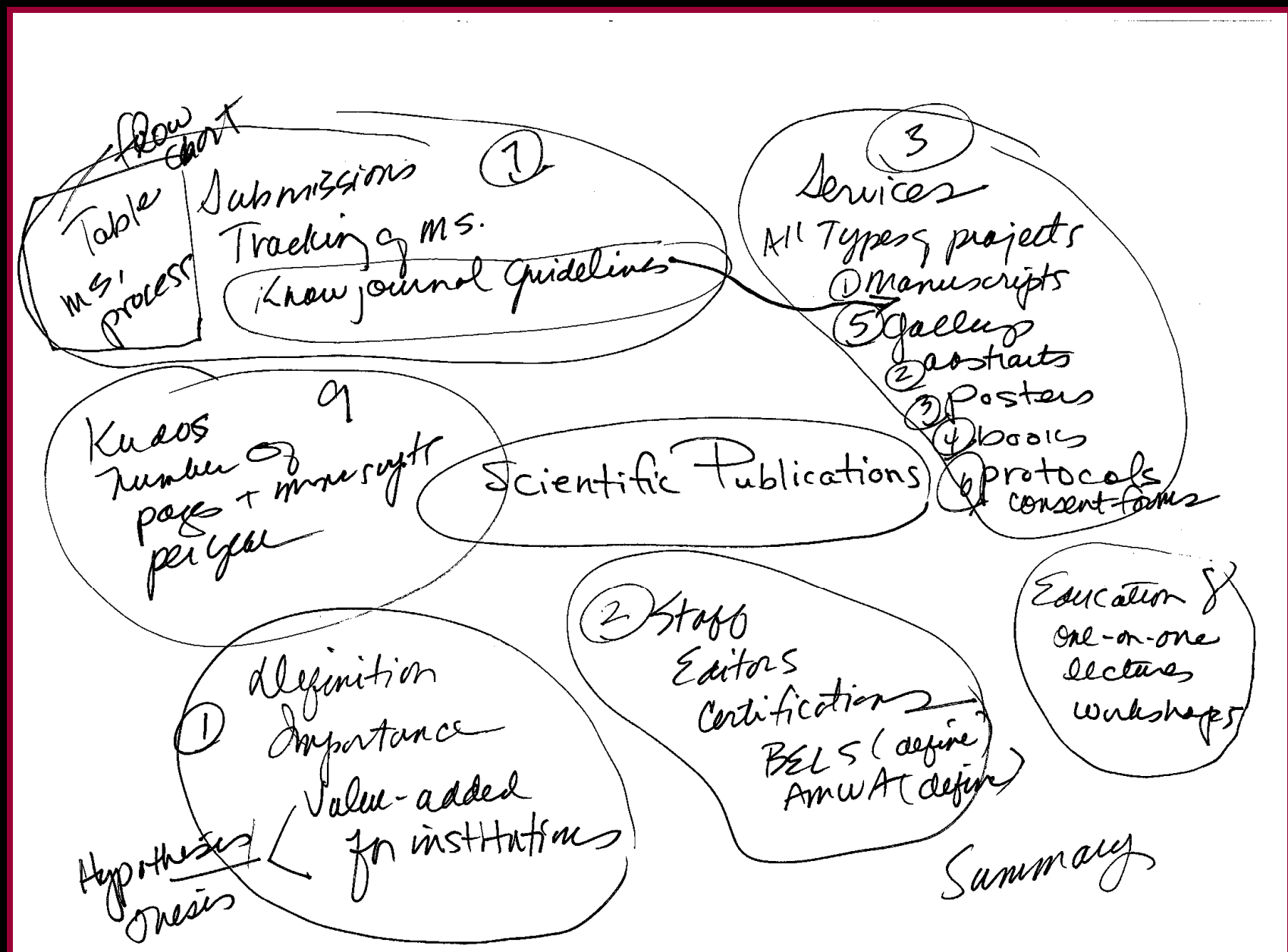
- Currently 9 members, chaired by A.J. Marian, MD. Includes veterinarian, statistician, scientists, community representatives; requires lay summary
- Meets first Wednesday of the month (protocol deadline: 5 days before the meeting)
- Contact Scientific Publications for help with summaries

MANUSCRIPT REQUIREMENTS

- IRB approval required for all research manuscripts involving human subjects (prospective studies, clinical trials, and retrospective database reviews)
- Patient approval required for case reports in which the patient can be identified
- IACUC and Research Review Committee approval for all manuscripts based on animal studies
- Protocols may contain provisions for manuscripts

THE WRITING PROCESS: OUTLINING

- Ensures direction. Builds consensus
- Use a system that works for you
- Brainstorming
  - Mind maps
  - Cluster diagrams
  - Idea trees
  - Sticky notes


Flow chart
Table
MS' process
Submissions
Tracking of MS.
Know journal guidelines
1
3
Services
All Types of projects
1 Manuscripts
5 Galleys
2 abstracts
3 Posters
4 books
6 protocols
consent-forms
Scientific Publications
Kudos
Number of
pages + manuscript
per year
1 Definition
Importance
Value-added
for institutions
Hypothesis
Thesis
2 Staff
Editors
Certification
BELS (define)
AMWA (define)
Education
one-on-one
lectures
workshops
Summary

OUTLINE

Include

- Thesis, headers, relevant points, information that supports your thesis
- Possible tables and figures

Remember

- Audience (readers, peer reviewers, peers)
- Ideas cause most writing problems, not grammar
- You CAN write if you can outline

WHAT IF YOU CAN'T GET BEYOND YOUR OUTLINE?

- Do more research
  - Review articles
  - Key articles
  - Experts/authors
- Check coherence with transitions

MEDICAL PRACTICE: PAST, PRESENT, FUTURE

COLLABORATIVE PLANNING

Discuss your message (purpose, key points) or outline with someone else

- Helps crystallize your ideas
- Helps you recognize incongruous ideas
- Helps you create new ideas
- Helps you articulate key points
- Ensures that the correct message is conveyed
- Ensures that data is analyzed correctly
- Come to publications/research meetings

FREEWRITING (GENERATING IDEAS)

Brainstorm to stimulate creative thought:

- Use your outline as a guide
- Don’t try to write polished prose
- Write sections of the paper
- Don’t censor. Write whatever you think about, but stay focused on the topic
- Don’t stop writing to rewrite

PLAGIARISM AND COPYRIGHT INFRINGEMENT

- Learn about US laws (plagiarism, copyright infringement, fair use), which differ from laws and practices in other countries
  - Take the CME-accredited course on "Ethics, Plagiarism, and the Internet" on the Texas Heart Institute's website: http://texasheart.org/cme/ethics/index.html
- Avoid direct plagiarism, mosaic plagiarism, unacceptable paraphrasing, and insufficient acknowledgment
  - Do not use the exact wording from another paper in your paper—even when you cite the source; rewrite in your own words
  - Use quotation marks when you borrow blocks of text

REWRITING

Write for your reader …

Avoid writer-centered prose

- Produced by freewriting
- Focused on the writer
- Characterized by missing referents, inappropriate language (eg, jargon), underdeveloped ideas, unfocused discussions, gaps in logic, missing background, lists, extraneous information

"Technical writing is still storytelling. You want the reader to like your story whether it's a protocol, a manuscript, or a submission."

— *Sherwin Nuland, MD*
AMWA McGovern Medalist

READER-CENTERED PROSE

Change writer-centered prose to reader-centered prose:

- Know your reader
- Find a common focus of interest
  - What do you want the reader to think?
  - What does the reader need to know?
  - How much background does the reader need?
- Keep the writing simple. Use cues: purpose statement, headers, transitions, key words, topic sentences, standard sentence patterns

Table 1. Taxonomy of Problems and Frequency of Resultant Changes in 12 Papers

Problem	No. of Changes
Too much information	
Too detailed	31
Redundant	18
Extraneous	**111**
Too little information	
Not enough detail	47
Missing	**212**
Emphasis needed	17
Inaccurate information	
Incorrect	29
Inappropriately synthesized	32
Inadequately synthesized	11
Misplaced information	
Alternative location preferred	26
Inappropriate location	4
Structural problem	17
Total changes	**555**

Source: Purcell GP, Donovan SL, Davidoff F: Changes to manuscripts during the editorial process: characterizing the evolution of a clinical paper. JAMA 1998;280(3):227-228.

Table 2. Distribution of the 2 Most Frequent Problems by Information Type*

Information Type	No. (%) of Extraneous Information	No. (%) of Missing Information
Background	16 (14)	39 (18)
Conclusions	2 (2)	11 (5)
Experimental data	43 (39)	49 (23)
Future work	2 (2)	10 (5)
Limitations	0	22 (10)
Outcome measures	9 (8)	10 (5)
References	12 (11)	17 (8)
Statistical methods	11 (10)	17 (8)
Study population data	5 (5)	6 (3)

*Information types are more fully described in Purcell, et al.[5] Percentages do not add up to 100 because information types t hat contained less than 5% of the total changes were not included in the table.

Source: Purcell GP, Donovan SL, Davidoff F: Changes to manuscripts during the editorial process: characterizing the evolution of a clinical paper. JAMA 1998;280(3):227-228.

REWRITE

- Expand, delete, reorganize
- Eliminate unfocused information; add relevant information
- Does each paragraph function well in the overall plan?
  - Does your argument unfold well?
  - Are there any contradictions?
  - Were you ever confused as you read?
  - Did you have to reread anywhere?
  - Are your conclusions obvious?

REWRITING IS NOT A SIGN OF FAILURE

"I'm probably the world's worst writer, but I'm the world's best rewriter."

— *James Michener*

EDITING

- Send your manuscript to the editors in Scientific Publications
- Detect, diagnose, revise: Learn the rules
  - http://refdesk.com (links to a variety of sites)
  - www.bartleby.com/64 *(American Heritage Book of English Usage)*
  - http://owl.english.purdue.edu/owl (writing tools and resources)
  - http://education.yahoo.com/reference/thesaurus (thesaurus)
  - http://www.online-medical-dictionary.org (medical dictionary)
  - http://grammar.ccc.commnet.edu/grammar (grammar)
  - http://www.bartleby.com (variety of links)
- Buy a copy of the AMA Manual of Style (10th Edition)

WRITER'S BLOCK

Causes of writer's block:

- Internal criticism
- Unrealistic expectations—produce anxiety
- Fear of failure, of being found a "fraud"
- Perfectionism. Insecurity over perceived incompetence
- Impatience, depression, environment
- Rigidity
- Procrastination—evaluation anxiety
- Too busy

DEVELOP STRATEGIES FOR OVERCOMING WRITER'S BLOCK

Use problem-solving principles:

- Relax. Rest if tired
- Write in a pleasant environment; set aside a time and place
- Have a daily goal; make notes to prompt you where to begin next
- Limit social interruptions and telephone calls
- Begin writing with a pleasant activity or brief ritual
- Write regularly (photo exercise, dictionary exercise, longhand, writers' exercise [someone you admire], journal)
- Understand the format, e.g., biomedical paper
- Break down large, complex assignments
- Set realistic deadlines
- Reward yourself when you've finished a task
- Be a time manager. Don't multi-task
- Recognize the difference between perfection (leading to endless torment) and excellence (leading to happiness)

DEVELOP STRATEGIES FOR OVERCOMING WRITER'S BLOCK

Use problem-solving principles:

- Don't be a perfectionist. Remember your deadline
- Control your internal critic. Think positive
- Remember your other successes
- Find a "friendly" critic
- Be aware of burnout symptoms (restlessness, tedium, and cynicism). Cure burnout with planning
- Recognize technical writer's block:
  - Learn more about your audience, purpose, or topic. Do more research
- Let your thoughts incubate
- Beware of the "mastery model": if writing's not easy for me, I must not be cut out for it

Get Organized to Write

- Plan
  - Explore the problem; do background work (protocols, IRB, IACUC); make an outline
- Freewrite
  - Write what you know; fill in details later
- Rewrite
  - Think about what is important to your study and what your reader needs to know; add those details
- Edit
  - Call Scientific Publications when you are ready to turn over your draft

Keep writer's block at bay!

THANK YOU

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