







Communicating Research Results

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Purpose

- Guidelines and techniques in communicating research results through
 - the scientific research abstract and
 - poster presentation

within a well-organized scientific framework.

Outline of Presentation

- State of the Art of Publication in the Philippines
- Sources of guides for scientific paper writing
- Guides for Making a Structured Abstract
- Guides for Making a Scientific Poster

Scientific Research Activities

- POGS receives
 - 75-90 interesting case papers each year
 - 50-60 research papers per year
 - 20-26 interesting case papers from PGH
 - 12-16 research papers from PGH
- Only top 3 IC papers and 3 Research Papers get published in the PJOG
- ☐ Maybe 1-2 get published in the Acta Medica Philippina
- NO PAPER GETS PUBLISHED IN THE INTERNATIONAL JOURNALS

Scientific writing

Scientific Paper

- Scientific paper writing skills need to be formally taught.
- Formal courses
 - DCE beginning 2nd semester 2005-6
 - CPH DEBS starting this year
- Informal Courses
 - PCS writing
 - POGS writing and editing

- Needs a seasoned person to assist in the writing of the paper
- Report read in the department or staff conference is NOT the format for the paper writing
- ☐ Standard formats have been described (ICMJE)
- □ Need to institutionalize the CONSENT BY AUTHORS FOR PUBLICATION

Scientific Research Paper

- First publication of original result
- Contains sufficient information to enable peers to assess observations, repeat experiments and evaluate intellectual processes
- In a journal or other resource readily available to the scientific community (including the web)
- PROBLEM IN THE PHILIPPINES TOO MANY JOURNALS ATTEMPT TO PUBLISH
 - Every new medical society or college or department – first project = journal

Standards for Medical Publishing

☐ International Committee of Medical Journal Editors

ICMJE

☐ Committee of Publication Ethics – Code of Conduct for Editors of Biomedical Journals

A code of conduct for editors of biomedical journals

A suggested code of conduct for editors to guide them towards being fair to authors, researchers, and readers \



Preamble

Editors of biomedical journals should be responsible for everything published in their journals. They should strive to meet the needs of readers and authors; constantly improve the journal; ensure the quality of the material they publish; champion freedom of expression in science and health care; maintain the integrity of the scientific record; preclude business needs from compromising intellectual standards; and always be willing to publish corrections, clarifications, retractions, and apologies when needed.

Any deviation from this code of conduct could be misconduct and should be pursued in the first instance through the journal's complaints procedure. If the matter is unresolved, a complaint may be referred to COPE. (The process for dealing with complaints against editors referred to COPE is described below.)

Quality and correcting the record

Editors should take all reasonable steps to ensure the quality of the material they publish, recognising that journals and sections within journals will have different aims and standards

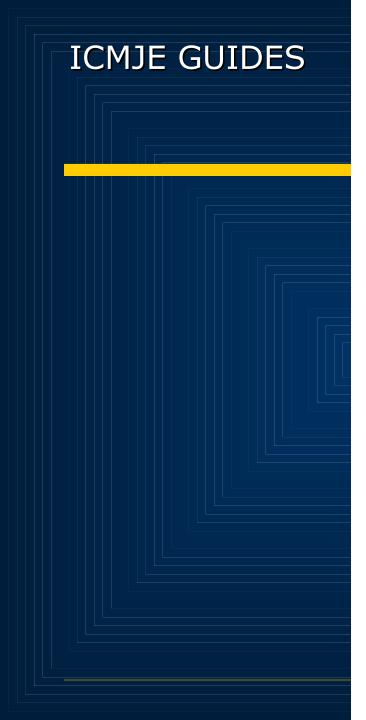
Descriptions of peer review processes should be published, and editors should be ready to justify any important deviation from the described processes. Journals should have a declared mechanism for authors to appeal against editorial decisions.

Whenever it is recognised that a significant inaccuracy, misleading statement or distorted report has been published, it must be corrected promptly Full Screen value.

An apology must be published whenever appropriate.



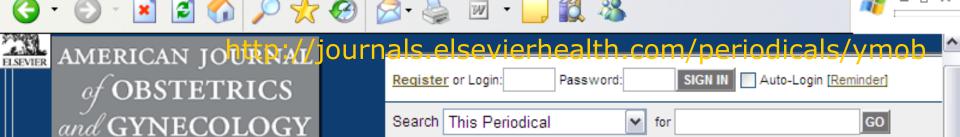
If after an appropriate investigation articles prove to be fraudulent or contain major errors that are not apparent from the text, the articles should be retracted. The word retraction should be used in the title of the retraction to ensure that it is picked up by indexing systems.



- IV. Manuscript Preparation and Submission
 - A. Preparing a Manuscript for Submission to Biomedical Journals
 - General Principles and Reporting Guidelines
 - a. General Principles
 - Reporting Guidelines for Specific Study Designs
 - Title page
 - 3. Conflict of Interest Notification Page
 - 4. Abstract and Key Words
 - Introduction
 - Methods
 - Selection and Description of Participants
 - Technical Information
 - c. Statistics
 - Results
 - Discussion
 - References
 - General Considerations Related to References
 - b. Reference Style and Format
 - Tables
 - Illustrations (Figures)
 - Legends for Illustrations (Figures)
 - Units of Measurement
 - 14. Abbreviations and Symbols
 - B. Sending the Manuscript to the Journal
- V. References
 - A. Print References Cited in this Document
 - B. Other Sources of Information Related to Biomedical Journals

What to do before submission First submissions to *The Lancet*:

- Covering letter
- Manuscript two copies double-spaced with word count for text alone on front page
- ☐ Figures two sets
- Authors' contributions and signatures
- Conflict of interest and source of funding
- Patients' consent and permission to publish
- □ In-press papers one copy of each with acceptance letters
- Acknowledgments include written consent of cited individual
- Personal communications include written consent of cited individual
- Protocols and CONSORT details for randomised controlled trials
- ☐ We encourage disclosure of correspondence from other journals and reviewers, if previously submitted, and we might contact relevant editors of such journals
- Use of copyright-protected material signed permission statements from author and publisher needed



American Journal of

Obstetrics Gynecology

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• Editorial Board

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August 2005 | Vol. 193, No. 2

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Welcome to the New American Journal of Obstetrics and Gynecology Online

The site now contains additional features and a new look-and-feel. Full-text articles are available to personal subscribers starting from 1994 through the present. Access to abstracts is complimentary. Click here for additional information.

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American Journal of Obstetrics and Gynecology, "The Gray Journal," presents coverage of the entire spectrum of the field, from the newest diagnostic procedures to leading-edge research. The Journal provides comprehensive coverage of the specialty, including maternal-fetal medicine, reproductive endocrinology/infertility, and

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PREPARING THE STRUCTURED ABSTRACT

- □ Based on ICJME guidelines
- □ EJ Huth, Writing and Publishing in Medical Sciences
- Iles RL, Guide to Better Medical Writing
- ☐ Hall GM, How to Write a Paper

Sample Abstract

Advances in ____ have allowed physicians to be more aggressive in the management of _____. Sometimes this change is dependent on the willingness on our part to look at these so-called techniques with an open mind rather than through incredulous eyes. When adopted in mentality and practice, these advances have led to better outcomes and more meaningful survival for our patients.

....

This new model of treatment requires that specialists stay abreast of developments not only on his particular field but also in one another's. For instance it is valuable for a specialist to know the latest trends in _____ management as it affects surgical decision-making and in order to participate in the multi-disciplinary process.

Comments

- Too non-specific
- Vague??
- Looks like a generic template, with fill in the blanks
- □ Not reflective of what will be presented in the paper
- ☐ Gives an impression that the author has not prepared the full paper yet.

IV.A.4. Abstract and Key Words

An abstract (requirements for length and structured format vary by journal) should follow the title page. The abstract should provide the context or background for the study and should state the study's purposes, basic procedures (selection of study subjects or laboratory animals, observational and analytical methods), main findings (giving specific effect sizes and their statistical significance, if possible), and principal conclusions. It should emphasize new and important aspects of the study or observations.

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The Abstract

- This serves as a miniaturized study report.
- ☐ The TITLE and the ABSTRACT will be read by more people than any other part of the paper.
- Usually follows the structured format and the non-structured format.
- The STRUCTURED ABSTRACT will reveal key features in the study, that will help readers determine if they want to read the whole paper.
 - Iles RL, Guide to Better Medical Writing, 1997

TYPES OF ABSTRACTS

- ☐ INFORMATIVE ABSTRACTS
 - Summarizes what the paper actually says.
 - Each section/ heading should have at least one sentence, if using the structured format
- ☐ INDICATIVE ABSTRACTS
 - Simply indicates what the paper is about and does not summarize what it says.
 - Used for articles or reviews that contain a large amount of detail that is not readily boiled to a few main points.
 - Huth EJ, Writing and Publishing in Medicine, 3rd ed. 1999

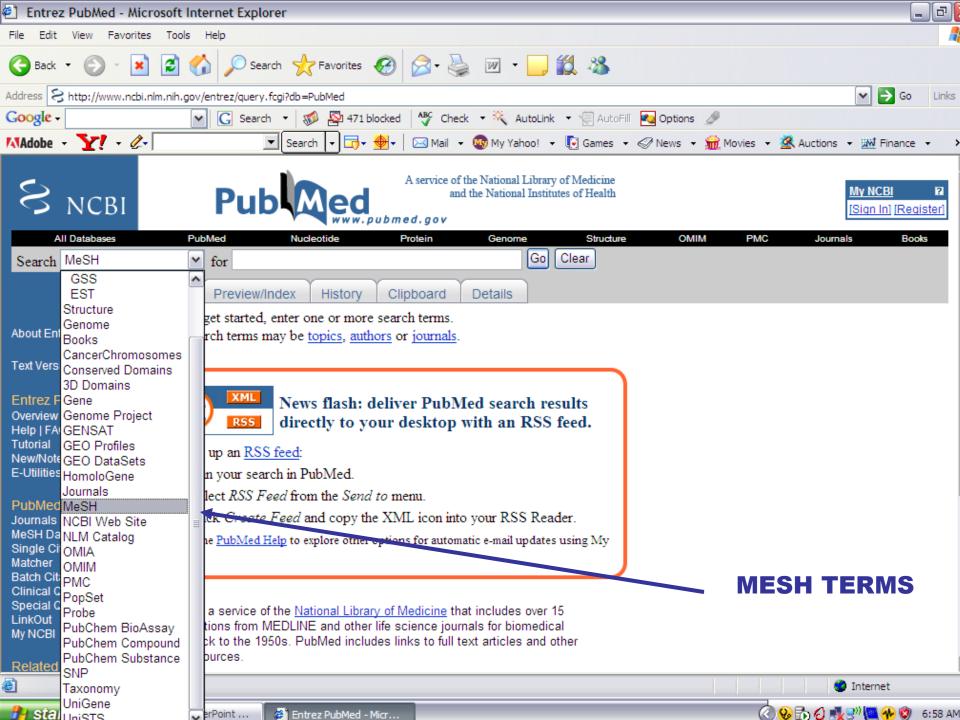
Key Information in Structured Abstracts

- OBJECTIVE exact question addressed
- DESIGN basic one used in the paper
- SETTING location and level of care
- PATIENTS OR PARTICIPANTS includes the manner of selection, numbers of participants who entered and completed the study.
- INTERVENTION or treatment
- MEASUREMENTS OR RESULTS methods
- CONCLUSIONS may include clinical applications
 - Ann Int Med 1987 106: 598-604

IMRAD

- ☐ Introduction, Methods, Results, and Discussion, + Recommendation
- Authors need to coordinate closely with editors in using such required publication formats and should submit material for potential supplementary electronic formats for peer review.
- DOUBLE SPACE ALL PAGES INCLUDING TABLES, REFERENCES, LEGENDS

Some journals request that, following the abstract, authors provide, and identify as such, 3 to 10 key words or short phrases that capture the main topics of the article. These will assist indexers in cross-indexing the article and may be published with the abstract. Terms from the Medical Subject Headings (MeSH) list of Index Medicus should be used; if suitable MeSH terms are not yet available for recently introduced terms, present terms may be used.



International survey on variations in practice of the management of the third stage of labour

Mario R. Festin, Pisake Lumbiganon, Jorge E. Tolosa, Kathryn A. Finney, Katherine Ba-Thike, Sangai Chipato, Hernando Gaitán, Liangzhi Xu, Sompop Limpongsanurak, Suneeta Mittal, Abraham Peedicayil, Noor Pramono, Manorama Purwar, Sheela Shenoy, Katherine Ba-Thike, Sangai Chipato, Abraham Peedicayil, Noor Pramono, Manorama Purwar, Sheela Shenoy, Katherine Ba-Thike, Sangai Chipato, Abraham Peedicayil, Noor Pramono, Manorama Purwar, Sheela Shenoy, Katherine Ba-Thike, Sangai Chipato, Abraham Peedicayil, Manorama Purwar, Manorama Purwar, Manorama Purwar, Sheela Shenoy, Manorama Purwar, Manorama Purwar

Objective To determine the use of the active management of the third stage of labour in 15 university-based obstetric centres in ten developing and developed countries and to determine whether evidence-based practices were being used.

Methods From March 1999 to December 1999, the Global Network for Perinatal and Reproductive Health (GNPRH) conducted an observational, cross-sectional survey to assess the use of the practice and its components. Prospective data on patient characteristics and the interventions used in the management of the third stage of labour were collected using standardized methods. Data on approximately 30 consecutive vaginal deliveries in each centre (452 in total) were included.

Findings Significant intracountry and intercountry variation in the practice of the active management of the third stage of labour was found (111/452 deliveries used active management), which confirmed the existence of a large gap between knowledge and practice. **Conclusion** Areas identified for improvement are the urgent implementation of the evidence-based clinical management practice defined as the active management of the third stage of labour; increased accessibility to systematic reviews in developing countries; and the conduction of clinical trials that assess the impact of this intervention in other settings.

Keywords Labor stage, Third/drug effects; Postpartum hemorrhage/drug therapy; Oxytocin/therapeutic use; Umbilical cord; Delivery, Obstetric/methods; Hospitals, University; Evidence-based medicine; Cross-sectional studies; Multicenter studies; Developed countries; Developing countries (source: MeSH, NLM).

Indicative Abstract - Sample

This review covers the many different adverse effects that have been reported for the drugs most widely used in the treatment of breast cancer. It considers them as generalized systemic effects and by body systems. An attempt has been made to assess their life-threatening security and to suggest how patients can be monitored for their early detection.

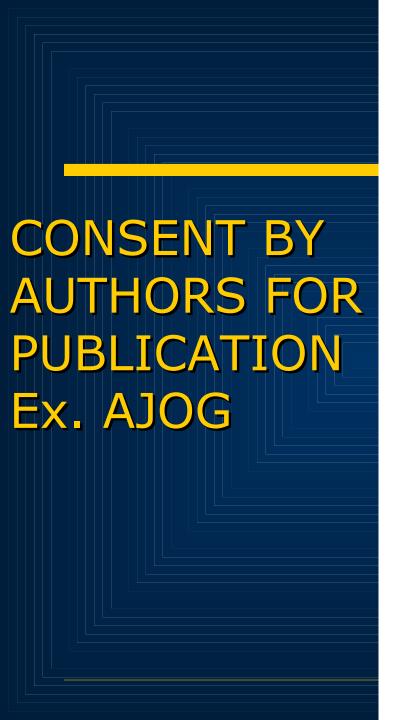
Huth EJ, Writing and Publishing in Medicine, 3rd ed. 1999

TIPS for writing abstracts

- Ideally, write the abstract after the full paper has been written.
- ☐ In the first sentence/section, describe the STUDY DESIGN (question investigated and how)
- Do not repeat information that is in the title.
- List the more important results, using sentence fragments where appropriate to save space.
 - EX. Major findings: Fewer seizures (1.1/day vs. 5.2/day, p<0.02), more undisturbed sleep (median 6 hr vs 3 hr, p<0.001)
- Names of statistical tests need not be noted
- Do not put information in abstract that is not in the main paper.
 - ☐ Iles RL, Guide to Better Medical Writing, 1997

Abstract Submission

- ABSTRACTS WHEN SUBMITTED ARE RARELY EDITED AND TYPESET. (Camera-ready).
- Type within the prescribed area.
- Appropriate size typeface/font, and printed by high quality laser printer
- Errors in SPELLING, GRAMMAR, OR SCIENTIFIC FACT will be reproduced exactly as you type them.
- Look at the abstract instruction for SUBJECT CATEGORIES, and for venue, oral/poster.
 - Hall GM, How to Write a Paper, 3rd Ed. BMJ Books 2003



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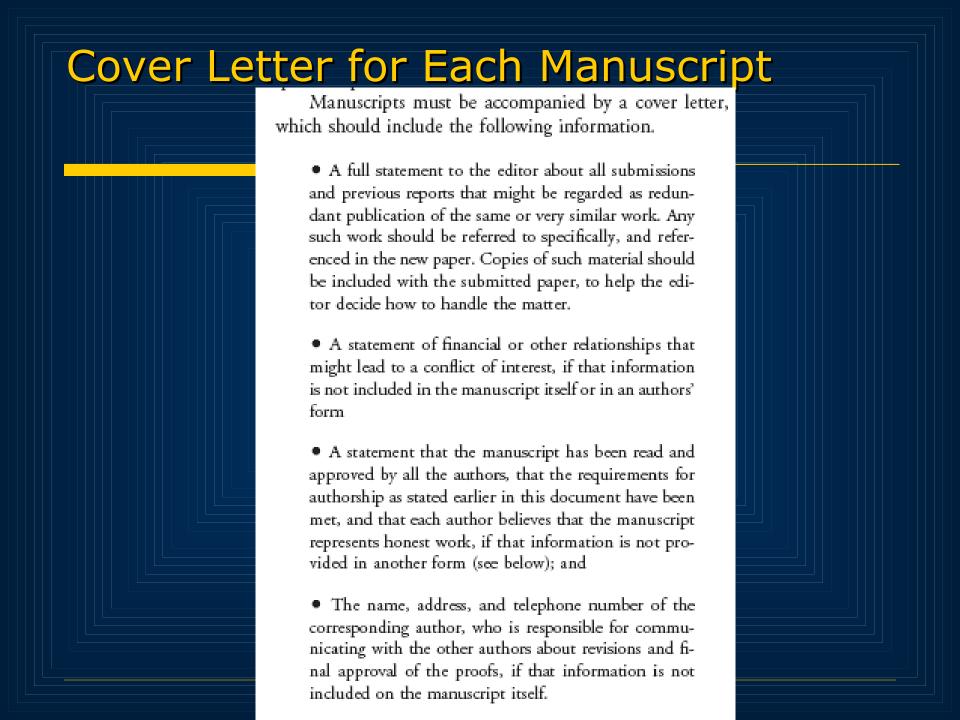
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The Review Process

- ☐ The journal will acknowledge the receipt of the paper. This does not mean it will be published.
- ☐ They will respond to you whether the paper will be reviewed by the journal or not.
 - The paper's content may not be aligned with the agenda or niche of the journal.
- Once informed for review, await the response.
 May need to follow up if no response.
- ONCE REVIEWERS RESPOND, ANSWER THE COMMENTS OR QUERIES UPON RESUBMISSION.

Journal Impact Factors

- □ Journal Impact Factor is from Journal Citation Report (JCR), a product of Thomson ISI (Institute for Scientific Information).
- JCR provides quantitative tools for evaluating journals.
- The impact factor is one of these; it is a measure of the frequency with which the "average article" in a journal has been cited in a given period of time.

Journal Impact Factors

The impact factor for a journal is calculated based on a three-year period, and can be considered to be the average number of times published papers are cited up to two years after publication. For example, the 2006 impact factor for a journal would be calculated as follows:

A = the number of times articles published in 2004-5 were cited in indexed journals during 2006

B = the number of articles, reviews, proceedings or notes published in 2004-5

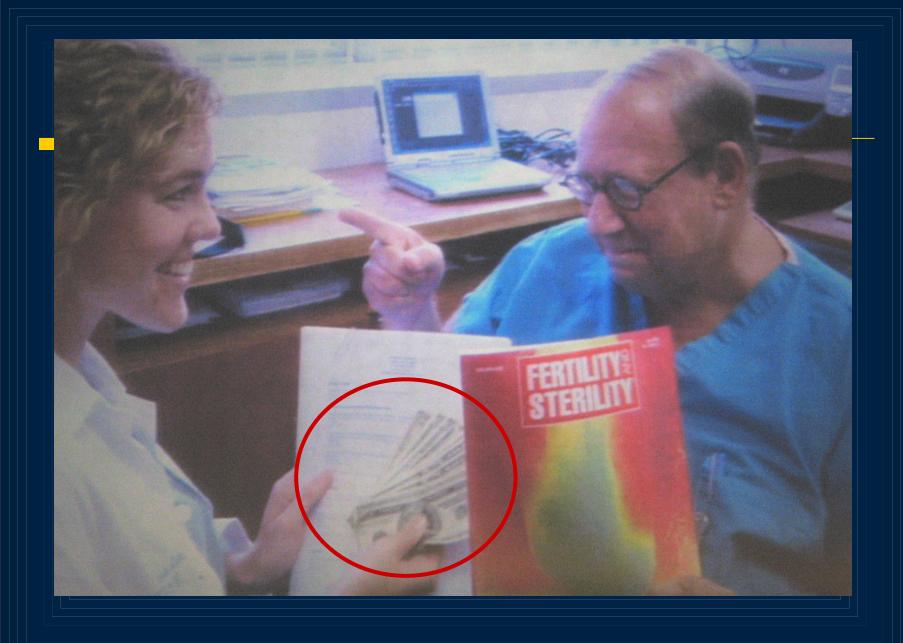
2006 impact factor = A/B

(note that the 2006 impact factor was actually published in 2007, because it could not be calculated until all of the 2007 publications had been received.)

2003 SCIENCE CITATION INDEX RANKING

(Category: Obstetrics & Gynecology; Total field= 53 journals
JOURNAL IMPACT FACTOR

| | 2003 | 2002 | 2001 | 2000 |
|------------------------------------|-------|-------|-------|-------|
| Human Reproduction Update | 3.731 | 3.710 | 2.969 | 2.887 |
| Fertility and Sterility | 3.483 | 3.202 | 2.960 | 2.854 |
| Menopause | 3.319 | 3.217 | 3.305 | 2.273 |
| Human Reproduction | 3.125 | 3.253 | 2.987 | 2.997 |
| Obstetrics & Gynecology | 2.957 | 2.482 | 2.196 | 2.091 |
| Placenta | 2.706 | 2.359 | 2.521 | 2.587 |
| Am J Obstetrics & Gynecology | 2.518 | 2.556 | 2.871 | 2.519 |
| Gynecologic Oncology | 2.431 | 2.115 | 2.200 | 1.972 |
| J of the Soc for Gyn Investigation | 2.291 | 2.440 | 2.830 | 2.184 |
| Intl J of Gynecologic Pathology | 2.159 | 1.848 | 1.454 | 1.508 |
| Maturitas | 2.045 | 2.068 | 1.640 | 1.402 |











SCIENTIFIC POSTER PRESENTATION

- □ What it is.
- Parts
- ☐ Tips

THE POSTER

- A poster is simply a static, visual medium (usually of the paper and board variety) that you use to communicate ideas and messages.
- The difference between **poster** and **oral** presentations is that you should **let your poster do most of the 'talking';** that is, the material presented should convey the essence of your message.
- A POSTER EXHIBIT IS NOT A JOURNAL ARTICLE, and people do not have time to read long text. Use outlines with bullets.

THE POSTER

- ☐ You have to 'stand-by-your-poster'!
- Prour task as the presenter is to answer questions and provide further details; to bask in praises or suffer difficult questions; and to convince others that what you have done is excellent and worthwhile.



PARTS OF A SCIENTIFIC POSTER -1

- Title page, telling others the title of the project, the people involved in the work and their affiliation.
- Summary of the project stating what you have set out to do, how you have done it, the key findings and the main results.
- Introduction that should include clear statements about the problem that you are trying to solve, the characteristics that you are trying to discover or the proofs that you are trying to establish. These should then lead to declarations of project aims and objectives.

PARTS OF A SCIENTIFIC POSTER -2

- Theory or Methodology section that explains the basis of the technique that you are using or the procedure that you have adopted in your study. You should also state and justify any assumptions, so that your results could be viewed in the proper context.
- Results section that you use to show illustrative examples of the main results of the work.

PARTS OF A SCIENTIFIC POSTER -3

- Conclusion section, listing the main findings of your investigation, and
- Further Work section that should contain your recommendations and thoughts about how the work could be progressed; other tests that could be applied, etc.

THE POSTER

- So, before you rush away to put pen to paper or fingers to keyboard, spend a few moments or even hours to **plan** your presentation.
- Unlike oral presentations, where some skilled or experienced speakers may be able to divert attention from a poorly planned presentation, with posters, poor planning is there for all to see.



Guide Questions for Posters

- What is the objective of the investigation?
- Has someone done the work before?
- How have I gone about with the study?
- Why did I follow this particular route of investigation?
- What are the principles governing the technique that I am using?

Guide Questions for Posters

- What assumptions did I make and what were my justifications?
- What problems did I encounter?
- What results did I obtain?
- Have I solved the problem?
- What have I found out?
- Are the analyses sound?

Presenting the Content

Keep the material simple

- Make full use of the space, but do not cramp a page full of information as the result can often appear messy
- Be concise and do not waffle. Use only pertinent information to convey your message
- Be selective when showing results. Present only those that illustrate the main findings of the project. However, do keep other results handy so that you may refer to them when asked

Presentation Format

- Use colors sparingly and with taste
 - Colors should be used only to emphasise, differentiate and to add interest. Do not use colors just to impress!
 - Try to avoid using large swathes of bright garish colors like bright green, pink, orange or lilac. Yuck!!
 - Pastel shades convey feelings of serenity and calm while dark bright colors conjure images of conflict and disharmony.
 - Choose background and foreground color combinations that have high contrast and complement each other black or dark blue on white or very light grey is good.

Presentation Format

- Use colors sparingly and with taste
 - It is better to keep the background light as people are used to it (for example newspapers and books)
 - If you insist on having a dark background, use colored paper so that you would not have to spray white paper with ink. Not only is this cheaper, you would also not face the problem of a soaked and distorted page.
 - Avoid the use of gradient fills. They may look great on a computer display, but unless you have access to a high resolution printer, the paper version can look really tatty.

POSTER COLORS

The choice of a background color is up to you. However, softer colors (pastels & greys) may work best as a background - they are easiest to view for hours at a time, and offer the best contrast for text, graphic, and photographic elements.

Blue on Red appears blurry to the human eye.

Yellow on white is hard to read

Red on Blue appears blurry to the human eye.

Font Guidelines

- Do not use more than 2 font types
 - Too many font types distracts, especially when they appear on the same sentence
 - Fonts that are easy on the eyes are Times-Roman and Arial.

This is Times-Roman

This is **Arial**

FONT CASE

- Titles and headings should appear larger than other text, but not too large. The text should also be legible from a distance, say from 1.5m to 2m.
- Do not use all UPPER CASE type in your posters. It can make the material difficult to read. Just compare the two sentences below:

WHAT DO YOU THINK OF THIS LINE WHERE ALL THE CHARACTERS ARE IN UPPER CASE?

What do you think of this line, where only the first character of the first word is in upper case?

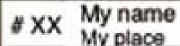
POSTER STYLES

Maintain a consistent style

- Inconsistent styles give the impression of disharmony and can interrupt the fluency and flow of your messages.
- Headings on the different pages of the poster should appear in the same position on all pages.
- Graphs should be of the same size and scale especially if they are to be compared.
- If bold lettering is used for emphasis on one page, then do not use italics on others.
- Captions for graphs, drawings and tables should either be positioned at the top or at the bottom of the figure.

POSTER LAYOUT

- Arrangement of poster components should appear smooth
 - Preparing sections of the poster on A4 sized paper before sticking them onto mounting boards or display stands.
 - Remember that you are using posters to tell a story about what you have done and achieved. As in report writing, the way you arrange the sections should follow the 'storyline'.
 - Sometimes it is helpful if you provide cutouts of arrows to direct attention to the sequence of the presentation
 - Use a new page/sheet to start off a new section



substance X induces Y-cells

Context:

Y-cell require induction substance x may be the inducer because: we know virtually nothing about X, but we had some on the shelf.

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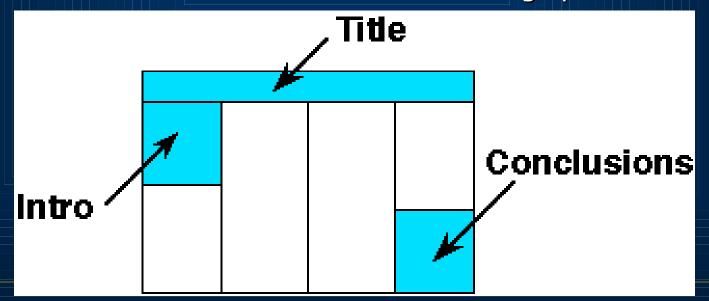
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- Place the elements of the poster in position:
- The title will appear across the top.
- A brief introduction will appear at the upper left.
- The conclusions will appear at the lower right.
- Methods and Results will fill the remaining space.

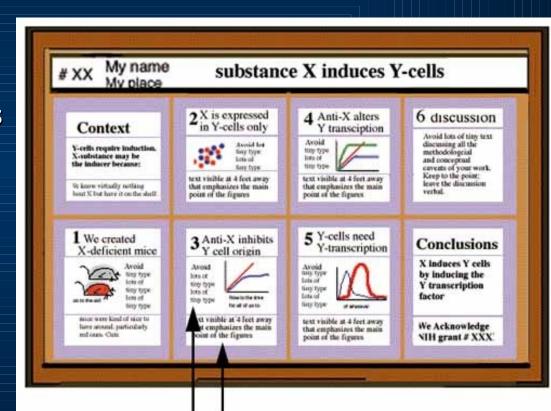


The Title

- This part of the poster includes the title of the work, the authors names, & the institutional affiliations. Think BIG!
- ☐ The title should be readable from 15 20 feet away.
- ☐ If space permits, use first names for authors to facilitate interactions.
- Middle initials and titles are seldom necessary.
- Use abbreviations where possible.

Poster Text

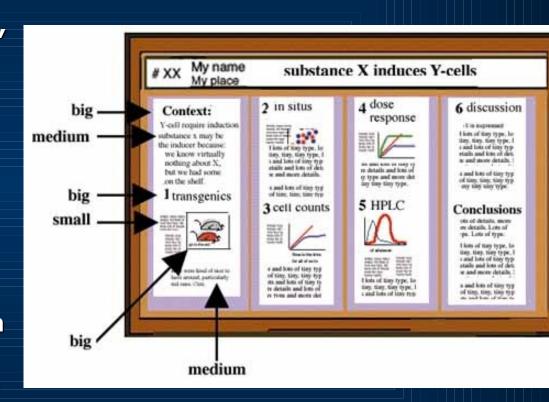
- Double-space all text,
- -using left-justification;
- text with even left sides and jagged right sides is easiest to read.
- The text should be large enough to be read easily from at least 6 feet away.



Text is readable at a distance

Poster Text

- For section headings (e.g., Introduction), use boldface, maybe about 36-42 point. For supporting text (e.g., text within each section & figure captions), use about 24-28 point (boldface, if appropriate).
- In general, use font sizes proportional to importance:
- largest type Title
- next largest type Section headings
- medium type Supporting material
- smallest type Details

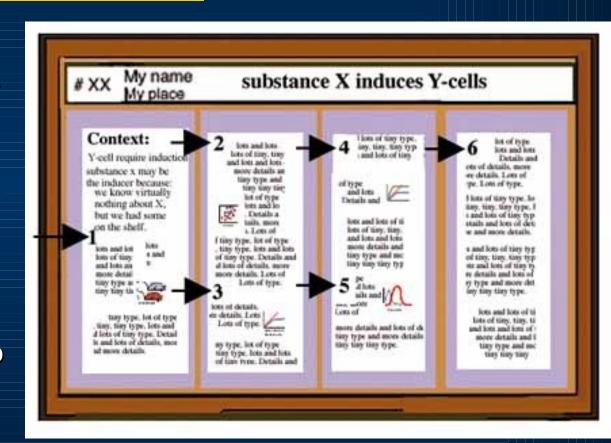


SEQUENCING

- A poster should use photos, figures, and tables to tell the story of the study. For clarity, present the information in a sequence that is easy to follow:
- Determine a logical sequence for the material you will be presenting.
- Organize that material into sections, e.g., Introduction, Methods, Results, Discussion, Conclusions, &, if necessary, Literature Cited. (Avoid using too many citations. If only a few are used, a literature cited section is unnecessary. Instead, cite as follows in the text: Clinton, B. 1993. Auk 107:234-246.).

SEQUENCING

- ☐ You may wish to use numbers to help sequence sections of the poster.
- ☐ Arrange the material into columns.
- The poster should not rely upon your verbal explanation to link together the various portions.



TOO MUCH TEXT!!!



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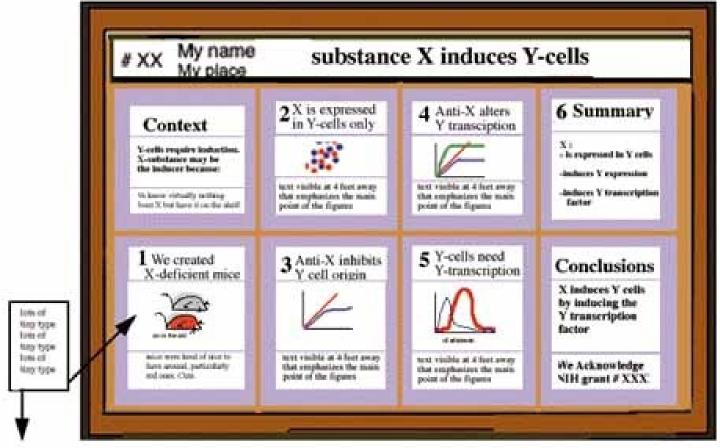
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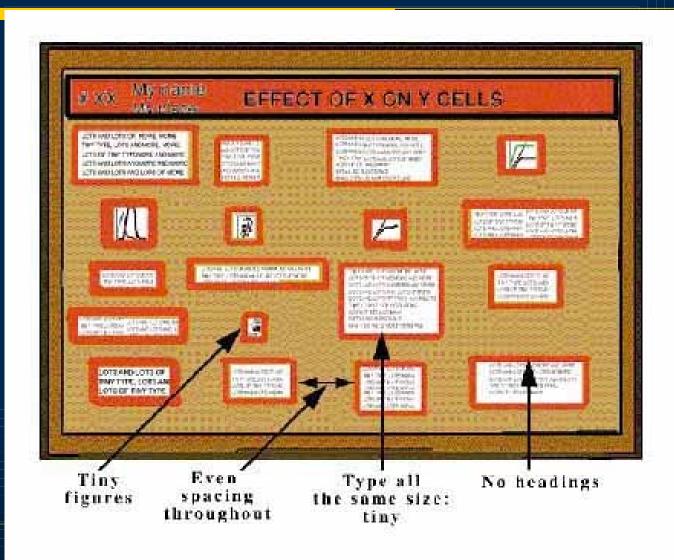
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Text should support graphics.



Discard details

Look critically at the layout. Some poster 'experts' suggest that if there is about 20-25% text, 40-45% graphics and 30-40% empty space, you are doing well.



POSTER GUIDELINES

- Use active voice when writing the text.
- Delete all redundant references and filler phrases (such as see Figure 1).
- ☐ An abstract may not be necessary. If you've kept the amount of text on your poster to a minimum, an abstract is likely redundant.

The poster is not a publication of record, so excessive detail about methods, or vast tables of data are not necessary. Such material can be discussed with interested persons individually during or after the session, or presented in a handout.

POSTER GUIDELINES

- □ FOR GRAPHS AND ILLUSTRATIONS:
- Show no mercy when editing visual materials!
- Use short sentences, simple words, and bullets to illustrate discrete points.
- Remove all non-essential information from graphs and tables.
- ☐ If possible, label data lines in graphs directly, using large type & color.

PRESENTING YOUR POSTER

- Design the poster to address one central question. State the question clearly in the poster, then use your discussion time with individuals to expand or expound upon issues surrounding that central theme.
- Provide an explicit take-home message.
- Summarize implications and conclusions briefly, and in user-friendly language.
- Give credit where it is due. Have an acknowledgments section, in smaller size type (14 18 point), where you acknowledge contributors and funding organizations.
- ☐ Vary the size and spacing of the poster sections to add visual interest, but do so in moderation.
- Do not wander too far away from your poster during the session; be available for discussion!









Communicating Research Results

- ☐ Mario R. Festin MD, MS, MHPEd, FPOGS, FPCS
- College of Medicine Philippine General Hospital
- University of the Philippines Manila









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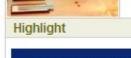
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Journal Selection Criteria of ISI

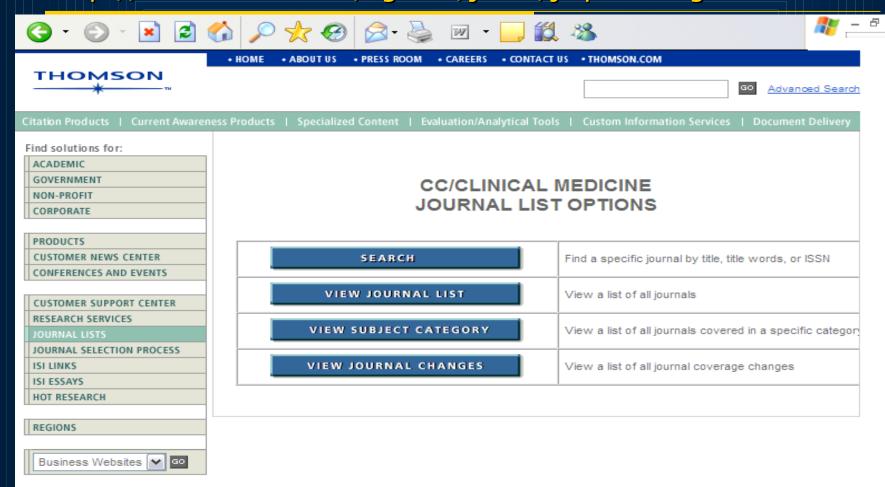
- The evaluation process consists of evaluation of many criteria such as, **Basic Journal Publishing Standards** (including Timeliness of publication, a adherence to International Editorial Conventions, **English Language Bibliographic Information** (including English article titles, keywords, author abstracts, and cited references.)
- ISI also examines the journal's **Editorial Content, the International Diversity of it authors and editors**. Citation Analysis using ISI data is applied to determine the journal's citation history and/or the citation history of its authors and editors.

Do you wish to submit a journal for evaluation?

- ☐ ISI needs at **least three consecutive current issues** to complete an evaluation.
- Please send the most current issue of the journal, and then each subsequent issues as soon as each is published to the following address:
- Publication Processing Department ISI
 3501 Market Street
 Philadelphia, PA 19104
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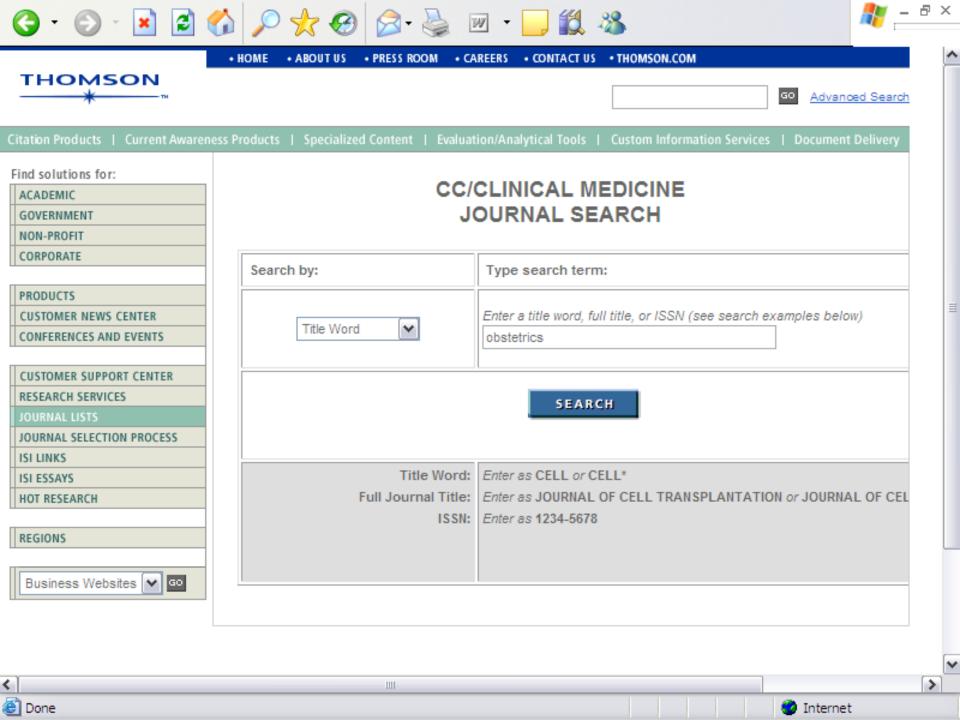
How do you know if a journal is an ISI journal?

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Standard International Journals

- New England Journal of Medicine
- Lancet
- Bulletin of the WHO
- Annals of Internal Medicine
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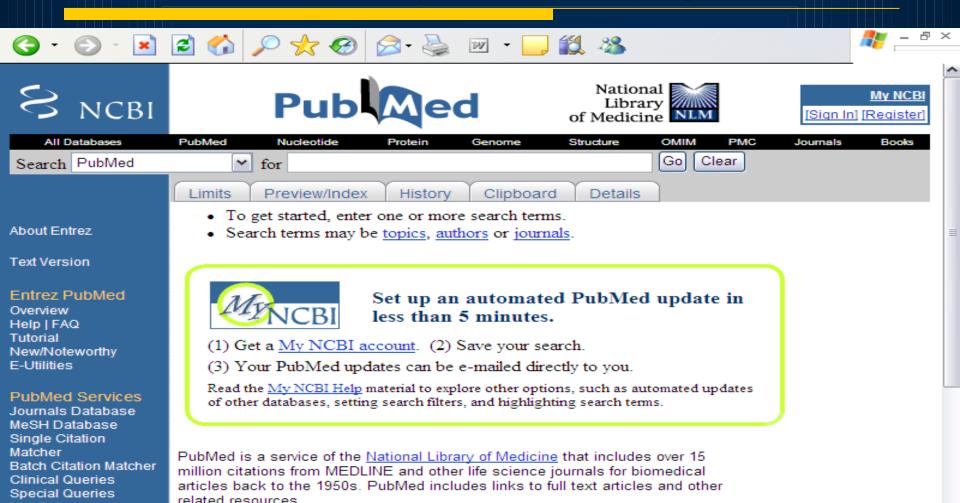
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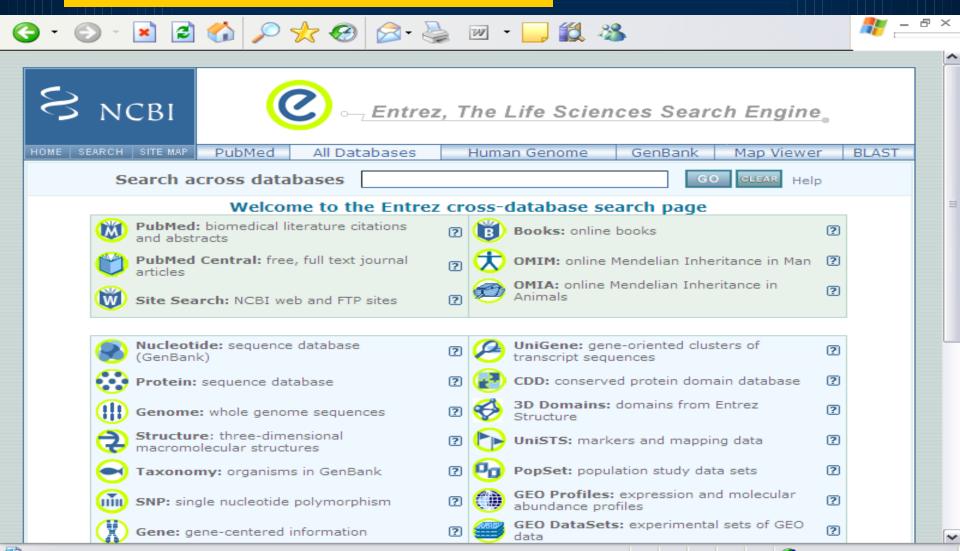
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International Council of Medical Journal Editors http://www.icmje.org/































International Committee of Medical Journal Editors

Uniform Requirements for Manuscripts

Statement of Purpose Ethical Considerations Publishing and Editorial Issues Manuscript Preparation References

About the ICMJE

Authors Use and Distribution Inquiries

URM Journals List

ICMJE Editorials

May 2005 Update on Trials Registration 2004 Update on Trials Registration Clinical Trial Registration Sponsorship, Authorship, and Accountability

Uniform Requirements for Manuscripts Submitted to Biomedical Journals: Writing and Editing for Biomedical Publication

Updated October 2004

The following information is available to be viewed/printed in Adobe Acrobat pdf format.

International Committee of Medical Journal Editors

I. Statement of Purpose

- A. <u>About</u> the Uniform Requirements
- B. Potential Users of the Uniform Requirements
- C. How to Use the Uniform Requirements
- II. Ethical Considerations in the Conduct and

































































ICMJE

Uniform Requirements for Manuscripts Submitted to Biomedical Journals: Writing and Editing for Biomedical Publication Updated October 2004

Interestional Committee of Medical Journal Editors

- I. Statement of Purpose
 - A. About the Uniform Requirements
- B. Potential Users of the Uniform Requirements C. How to Use the Uniform Requirements
- II. Ethical Considerations in the Conduct and Reporting of Research
- A. Authorship and Contributorship
 - 1. Byline Authors
- Contributors Listed in Adaptivelegements
- B. Editorship 1. The Role of the Editor

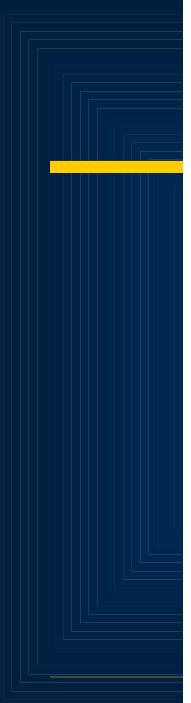
 - 2. Editorial Freedom
- C. Peer Review
- D. Conflicts of Interest
 - 1. Potential Conflicts of Interest Related to Individual Authori' Commitments
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 - 3. Potential Conflicts of Interest Related to Commitments of Editon, Journal Staff, or
- E. Privacy and Confidentiality
 - 1. Patients and Study Participants
- 2. Authors and Reviewers
- F. Protection of Human Subjects and Animals in
- III. Publishing and Editorial Issuer Related to Publication In Biomedical Journals
 - A. Obligation to Publish Negative Studies
 - B. Corrections, Retractions, and "Expressions of Concern*
 - C. Copyright
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- F. Supplements, Theme Issues, and Special Series
- G. Electronic Publishing
- H. Adventising
 - 1. Medical Journals and the General Media.
 - J. Obligation to Register Clinical Trials

- IV. Manageript Propagation and Submission.
 - A. Preparing a Manuscript for Submission to Biomedical Journals
 - 1. General Principles and Reporting Guidelines
 - a. General Principles
 - b. Reporting Guidelines for Specific Study Designa
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 - Conflict of Interest Notification Page
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 - Introduction
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 - a. Selection and Description of Participants
 - b. Technical Information c. Statistics
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 - 8. Discussion
 - 9. References
 - a. General Considerations Related to Refer-
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 - Tables
 - 11. Hartreions (Figure)
 - 12. Legends for Huntations (Figure)
 - 15. Units of Measurement
 - 14. Abbreviations and Symbols
 - B. Sending the Manuscript to the Journal
- A. Print References Cited in this Document
- B. Other Sources of Information Related to Biomedical Journals
- VI About the International Committee of Medical Journal Editors
- VII. Authors of the Uniform Requirements
- VIII. Use, Distribution, and Translation of the Uniform. Requirements
- IX. Inquiries

I. STATEMENT OF PURPOSE

LA. About the Uniform Requirements

A small group of editors of general medical journals met informally in Vancouver, British Columbia, in 1978 to establish guidelines for the format of manuscripts submitted to their journals. The group became known as the Vancouver Group. Its requirements for manuscripts, including formats for bibliographic references developed by the National Library of Medicine, were first published in 1979. The Vancouver Group expanded and evolved into the International Committee of Medical Journal Editors



II. ETHICAL CONSIDERATIONS IN THE CONDUCT AND REPORTING OF RESEARCH

II.A Authorship and Contributorship

II.A.1. Byline Authors

An "author" is generally considered to be someone who has made substantive intellectual contributions to a published study, and biomedical authorship continues to have important academic, social, and financial implications. (1) In the past, readers were rarely provided with information about contributions to studies from those listed as authors and in acknowledgments. (2) Some journals now request and publish information about the contributions of each person named as having participated in a submitted study, at least for original research. Editors are strongly encouraged to develop and implement a contributorship policy, as well as a policy on identifying who is responsible for the integrity of the work as a whole.

While contributorship and guarantorship policies obviously remove much of the ambiguity surrounding contributions, it leaves unresolved the question of the quantity and quality of contribution that qualify for authorship. The International Committee of Medical Journal Editors has recommended the following criteria for authorship; these criteria are still appropriate for those journals that distinguish authors from other contributors.

Guidelines for Authors

- Authorship credit should be based on 1) substantial contributions to conception and design, or acquisition of data, or analysis and interpretation of data; 2) drafting the article or revising it critically for important intellectual content; and 3) final approval of the version to be published. Authors should meet conditions 1, 2, and 3.
- When a large, multi-center group has conducted the work, the group should identify the individuals who accept direct responsibility for the manuscript (3). These individuals should fully meet the criteria for authorship defined above and editors will ask these individuals to complete journal-specific author and conflict of interest disclosure forms. When submitting a group author manuscript, the corresponding author should clearly indicate the preferred citation and should clearly identify all individual authors as well as the group

name. Journals will generally list other members of the group in the acknowledgements. The National Library of Medicine indexes the group name and the names of individuals the group has identified as being directly responsible for the manuscript.

- Acquisition of funding, collection of data, or general supervision of the research group, alone, does not justify authorship.
- All persons designated as authors should qualify for authorship, and all those who qualify should be listed.
- Each author should have participated sufficiently in the work to take public responsibility for appropriate portions of the content.









WHO International Clinical Trials Registry Platform

a new requirement for international publication

Technical Consultation on Trial Registration Standards

25-27 April 2005

Geneva, World Health Organization

Status of Publication of Clinical Trials

- ☐ What are usually published are clinical trials that :
 - Confirm or show new, positive, innovative, or important findings.
 - Come with large sample sizes or with many centers.
 - Are written by famous personalities or from well established institutions.
 - Come from well-supported agencies

Problem of **Publication Bias**

- Journals do not publish:
 - Repeats of already established studies
 - Studies which contradict or do not support present beliefs
 - Studies with small sample sizes which do not have good power or levels of significance
 - Studies from obscure institutions or unknown personalities
- Other papers do not reach regular journals

ICMJE

InternationalCouncil of MedicalJournal Editors

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Martin B. Van Der Weyden, M.D.

Editor, The Medical Journal of Australia

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Requirement of Trial Registration

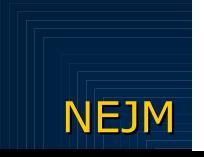
- The ICMJE wants to **ensure public access to all "clinically directive" trials** trials that test a clinical hypothesis about health outcomes (e.g., "Is drug X as effective as drug Y in treating heart failure?").
- The ICMJE think the public deserves to know about trials that could shape the body of evidence about clinical effectiveness or adverse effects
- The ICMJE require registration of all trials whose primary purpose is to affect clinical practice (phase 3 trials).

Why register?

- Obligation to participants, the public
- Address analysis, reporting and publication biases
- Contribute to systematic reviews
- Speed access to results
- Increase effectiveness of research funding
- Increase participation by patients, doctors, researchers

Registers exist but,

- Designed for different purposes
- Compliance is low
- Field fragmented
- Even systematic reviewers do not/cannot use them
- Awareness is low
- It is not easy to search for all relevant trials



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EDITORIALS



Is This Clinical Trial Fully Registered? — A Statement from the International Committee of Medical Journal Editors

In September 2004, the members of the litternation- es, trial authors and sponsors want to be sure that al Committee of Medical Journal Editors (KMJE) published a joint editorial aimed at promoting registration of all clinical trials. We stated that we will consider a trial for publication only if it has been registered before the enrollment of the first patient. This policy applies to trials that start re-cruiting on or after July 1, 2005. Because many ongoing trials were not registered at inception, we will consider for publication ongoing trials that are registered before September 13, 2005. Our goal then and now is to foster a comprehensive, publicly available database of clinical trials. A complete registry of trials wouldbe a fitting way to thank the thousands of participants who have place d themselves at risk by volunteering for clinical trials. They deserve to know that the information that accrues from their altruism is part of the public record, where it is available toguide decisions a hout patient care, and deserve to know that decisions about their care rest on all of the evidence, not just the trials that authors decided to report and that journal editors decide dto publish.

We are not alone in pursuing this goal. The World Health Organization (WHO), through meet-

they understand our requirements, so that reports of their research will be eligible for editorial review. The purpose of this joint and simultaneously published editorial is to answer questions about the ICMJE initiative and to bring our position into harmony with that of others who are working toward the same end.

Our definition of a clinical trial remains essentially the same as in our September 2004 editorial: "Any research project that prospectively assigns human subjects to intervention and comparison groups to study the cause-and-effect relationship between a medical intervention and a health outcome." By "me dical intervention" we mean any inte wention used to modify a health outcome. This definition includes drugs, surgical procedures, devices, behaviora ltreatments, process-of-care changes, and the like. We update our 2004 editorial to state that a trial must have at least one prospectively assigned concavent control or comparison group in order to trigger the se quise ment for registration.

Among the trials that me et this de finition, which need to be registered? The ICMJE wants to ensure

ICMJE Statement

- The research enterprise has an obligation to conduct research ethically and report it honestly.
- Unfortunately, selective reporting of trials does occur, and it distorts the body of evidence available for clinical decision making.
- When research sponsors or investigators conceal the presence of selected trials, these studies cannot influence the thinking of patients, clinicians, other researchers and experts who write practice guidelines or decide on insurance coverage.

ICMJE Statement

- The ICMJE member journals will require as a condition of consideration for publication, registration in a public trials registry.
- Trials must register at or before the onset of patient enrolment.
- Policy applies to any clinical trial starting enrolment after *July 1, 2005*, and for trials prior, registration by *September 13, 2005*.

ICMJE Statement

- The registry must be accessible to the public at no charge.
- ☐ It must be open to all prospective registrants and managed by a non-for-profit organization.
- There must be a mechanism to ensure the validity of registration data, and the registry should be electronically searchable.
- There is a list of recommended fields.
- www.clinicaltrials.gov US NLM





International Federation of Pharmaceutical Manufacturers and Associations

- http://www.ifpma.org/News/NewsRelatedDetail.aspx?nID=2205
- "The industry recognizes that there are important public health benefits, including increased confidence, associated with making clinical trial information more widely available to healthcare practitioners, patients and others",
 - said Dr. Harvey E. Bale, Director General of IFPMA.
- Beginning mid 2005, the industry will make the results public of trials that have taken place whether positive or negative but also information on those that are just being initiated.

| Tab | able 1. Minimal Registration Data Set.* | | |
|-----|---|--|--|
| | ltem | Comment | |
| 1. | Unique trial number | The unique trial number will be established be the primary registering entity (the registry). | |
| 2. | Trial registration date | The date of registration will be established by the primary registering entity. | |
| 3. | Secondary IDs | May be assigned by sponsors or other interested parties (there may be none). | |
| 4. | Funding source(s) | Name of the organization(s) that provided funding for the study. | |
| 5. | Primary sponsor | The main entity responsible for performing the research. | |
| 6. | Secondary sponsor(s) | The secondary entities, if any, responsible for performing the research. | |
| 7. | Responsible contact person | Public contact person for the trial, for patients interested in participating. | |
| 8. | Research contact person | Person to contact for scientific inquiries about the trial. | |
| 9. | Title of the study | Brief title chosen by the research group (can be omitted if the researchers wish). | |
| 10. | Official scientific title of the study | This title must include the name of the intervention, the condition being studied, and the outcome (e.g., The International Study of Digoxin and Death from Congestive Heart Failure). | |

| 13. Intervention(s) | A description of the study and comparison/control intervention(s). (For a drug or other product registered for public sale anywhere in the world, this is the generic name; for an unregistered drug the generic name or company serial number is acceptable). The duration of the intervention(s) must be specified. |
|--|---|
| Key inclusion and exclusion criteria | Key patient characteristics that determine eligibility for participation in the study. |
| 15. Study type | Database should provide drop-down lists for selection. This would include choices for randomized vs. non-randomized, type of masking (e.g., double-blind, single-blind), type of controls (e.g., placebo, active), and group assignment (e.g., parallel, crossover, factorial). |
| Anticipated trial start date | Estimated enrollment date of the first participant. |
| 17. Target sample size | The total number of subjects the investigators plan to enroll before closing the trial to new participants. |
| 18. Recruitment status | Is this information available (yes/no)? (If yes, link to information.) |

ethics board before commencing.)

depression).

12 months).

Research ethics review.

Condition

19. Primary outcome

Has the study at the time of registration received appropriate ethics committee ap-

The primary outcome that the study was designed to evaluate. Description should

include the time at which the outcome is measured (e.g., blood pressure at

The medical condition being studied (e.g., asthma, myocardial infarction,

proval (yes/no)? (It is assumed that all registered trials will be approved by an

from the ICMJE.

^{20.} Key secondary outcomes The secondary outcomes specified in the protocol. Description should include time: of measurement (e.g., creatinine clearance at 6 months). st The data fields were specified at a meeting convened by the WHO in April 2005; the explanatory comments are largely

Current status of trial registration and results disclosure

- International partnerships / collaborations can help:
 - To increase understanding of issues
 - To build trust among all parties
 - To facilitate buy-in (for initiatives) from the public, the research community and the governments
- ☐ The project was discussed at the WHA May 2005
- WHO role depends on support from the international community
- ICMJE published updated statement in NEJM May 2005



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Publication of Philippine RCTs

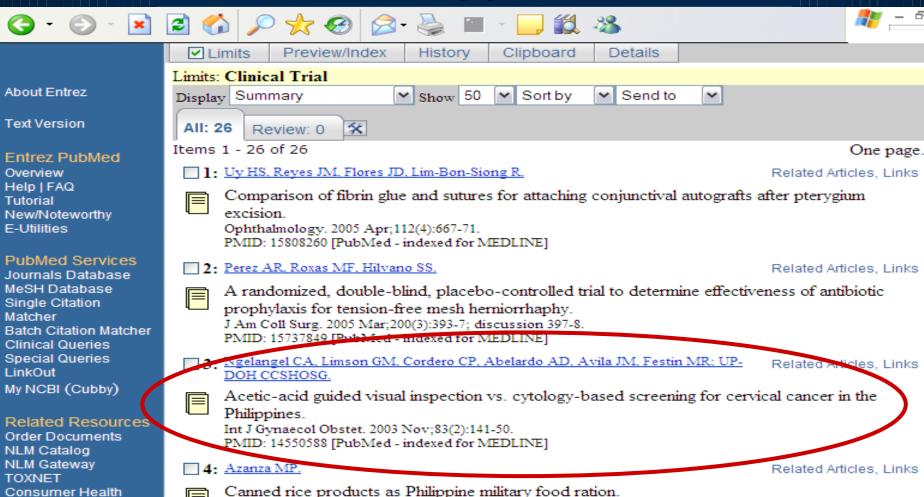
Int J Food Sci Nutr. 2003 May;54(3):235-40.

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Clinical Alerts

ClinicalTrials.gov

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Scientific Paper Publication in the University of the Philippines

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