2ND INTERNATIONAL CONFERENCE ON MEDICAL WRITING
5 – 7 MARCH 2015
AJMAN, UAE
CONFERENCE HIGHLIGHTS

TOM LANG
TOM LANG COMMUNICATIONS AND TRAINING INTERNATIONAL

International Committee of Medical Journal Editors: ICMJE

• Small, self-appointed working group of editors from general medical journals

• Meet annually and fund their own work

• Make recommendations for the conduct, reporting, editing, and publication of scholarly work in medical journals

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ICMJE Member Journals

Annals of Internal Medicine
BMJ
Canadian Medical Association Journal
Chinese Medical Journal
Ethiopian Journal of Health Sciences
JAMA
Nederlands Tijdschrift voor Geneeskunde
NEJM
New Zealand Medical Journal
Revista Medica de Chile
The Lancet
Public Library of Science (PLoS)
Tidsskrift for Den Norske Llegeforening
Ugeskrift for Laeger

World Association of Medical Editors: WAME

• Founded in 1995 by 22 medical journal editors and scientists from 13 countries on 5 continents

• An alternative to the ICMJE, which is small and exclusive

• Today has 1900 members from 1000 journals in 92 countries

World Association of Medical Editors: WAME

• Membership is open to "decision-making" editors of medical journals worldwide and to "scholars" in the field of scientific publishing

• Membership is free

Council of Science Editors: CSE

• Founded in 1957 by the National Science Foundation and the American Institute of Biological Sciences as the Council of Biology Editors

• Name changed to Council of Science Editors in 2000

• Today has 800 members

European Association of Science Editors: EASE

- Founded in 1982, in France by a merger of the European Life Science Editors' Association (ELSE) and the European Association of Earth Science Editors (Editerra).

- About 550 members from more than 50 countries

- American Association of Medical Writers (AMWA)
- European Association of Medical Writers (EMWA)
- International Society for Medical Publication Professionals (ISMAPP)
- The International Publication Planning Association (TIPPA) (industry-sponsored)

Writing a Program for Diabetes Screening

Professor Jaakko Tuomilehto
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Center for Vascular Prevention Danube-University Krems, Austria

Diabetes Research Group King Abdulaziz University Jeddah, Saudi Arabia

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Screening

The early detection of
- disease
- precursors of disease
- susceptibility to disease

in individuals who do not show any signs of disease

Types of screening

Case finding
Mass screening – whole populations
Selective screening – high risk groups
Multi phase screening – several diseases at once
Surveillance (repeated observation)

Wilson Junger 1968

Purpose of Screening

To reduce morbidity and mortality

To apply a relatively simple, inexpensive test to people who are asymptomatic, for the purpose of classifying them with respect to their likelihood of having a particular disease

Diagnosis = Screening

Screening tests can also often be used as diagnostic tests

Diagnosis involves confirmation of presence or absence of disease in someone suspected of or at risk for disease

Screening in practice

for prevalent disease
and susceptible to benefit from treatment

for risk of future disease
and susceptible to benefit from preventive intervention

Examples of Screening Tests

Questionaires
Clinical Examinations
Laboratory Tests
Genetic Tests
Imaging

Validity of Screening Tests

Key Measures

Sensitivity
Specificity
Positive Predictive Value
Negative Predictive Value

Paneth

Sensitivity

The proportion of all those who have the disease that are picked up by the test (true positive rate)

Sensitivity = $\dfrac{\text{Number who have the disease AND test positive}}{\text{Number who have the disease}}$

Specificity

The proportion of all those who don't have the disease who test negative (true negative rate)

Specificity= $\dfrac{\text{Number who don't have the disease AND test negative}}{\text{Number who don't have the disease}}$

False positive (FP) – False negative (FN)

FP = The proportion of all those who don't have   the disease who test positive

FN = The proportion of all those who have the   disease who test negative
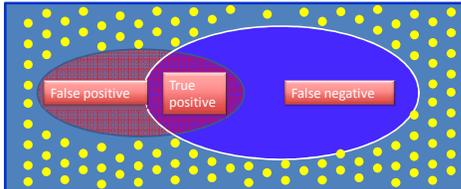
Screening Principles

Sensitivity
- the ability of a test to identify those who have a disease

Specificity
- the ability of a test to identify those who do not have the disease

Criteria for a Successful Screening Program

Disease
- present in population screened
- high morbidity or mortality; must be an important public health problem
- early detection and intervention must improve outcome

Criteria for a Successful Screening Program

Disease
- The natural history of the disease should be understood, such that the detectable sub-clinical disease stage is known and identifiable

Criteria for a Successful Screening Program

Screening Test
- should be relatively sensitive and specific
- should be simple and inexpensive
- should be very safe
- must be acceptable to subjects and providers

Criteria for a Successful Screening Program

Must be able to offer something to those who screen positive

- Facilities for diagnosis and appropriate treatment must be available
- It is unethical to offer screening when no services are available for subsequent treatment

Is screening for diabetes justified?

Common and serious enough ?
Natural history understood ?
Is there a simple effective screening test ?
Is treatment available ?
Is intervention/screening effective ?

Screening Strategies

High-Risk Approach

Cost-effective

Intervention appropriate to the individual

Subjects motivated

Fails to deal with the root causes of disease

Small chance of reducing disease incidence at the population level

Population Approach

Potential to alter the root causes of disease

Large chance of reducing disease incidence

Small benefit to the individual

Poor subject motivation

Problematic risk-benefit ratio

Prevalence of diabetes according to BMI
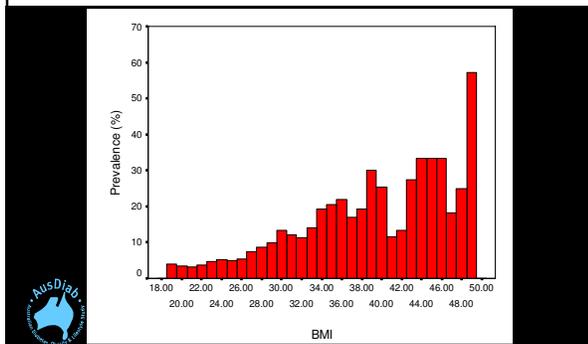
Summary

Assessing disease screening programs is complex

Proof of the value of screening for type 2 diabetes is lacking, but there is reasonable supportive evidence

Screening programs for type 2 diabetes should start with simple 'self-complete' screening tools

Statistical Concepts
in Clinical Research

Finely crafted medical writing—
Because publication is the final stage of research

Problem #1:
Authors are using only basic statistics if they use any at all

30

The Underuse of Statistical Analyses

- Many articles (up to 80% in some journals) use no or only descriptive statistics

- 60% to 90% contain only the statistics taught in 1st-semester statistics classes

- Maybe 20% use more advanced methods (e.g., multivariate analysis, ROC analyses)

31

Problem #2:
Authors using statistics make lots of mistakes

32

The High Rate of Statistical Errors

- Up to 70% of articles reporting statistics have statistical flaws

- Up to 10% have fatal statistical or design flaws

- Even Cochrane reviews and technology assessments often have serious methodological flaws

33

Problem #3:
Not many people know about problems 1 and 2

34

Analyzing Paired Data Separately

Paired data come from the same or matched subjects and must be analyzed together

- When the pairing is lost, group means can be misleading

- Also, the number of improved patients should be reported, as well as changes in mean values

35

Using Descriptive Statistics Correctly

Use the mean and standard deviation *ONLY* to report normally distributed data

Otherwise, use the median and interquartile range or range to report nonnormally distributed data

36

Using Descriptive Statistics Correctly

Characteristics of the normal distribution:
The mean, median, and mode are equal
The distribution is symmetrical
The area under the curve is known:
68% of the data is within ± 1 SD of the mean
95% is within ± 2 SD of the mean
99% is within ± 3 SD of the mean

37

Identifying the "Unit of Observation"

In a study of 50 eyes, the number of patients could range between 25 and 50

What does a 50% success rate mean? Half the eyes improved? or half the patients?

38

Identifying the "Unit of Observation"

Patients vs. Characteristics

39

When we clarify meaning, we sometimes coincidentally reveal it . . .

40

Practice vs. Research   Belmont Report

"Practice":
Interventions that are designed solely to enhance the well-being of an individual patient or client and that have a reasonable expectation of success. The purpose of medical or behavioral practice is to provide:
- ✓ diagnosis,
- ✓ preventive treatment or therapy
- ✓ to particular individuals.

"Research":
Activity designed to:
- ✓ test an hypothesis,
- ✓ permit conclusions to be drawn, and thereby to develop or contribute to generalizable knowledge
- ✓ Research is usually described in a formal protocol that sets forth an objective and a set of procedures designed to reach that objective.

Basic Ethical Principles   Belmont Report

1. **Respect for Persons.** -- Respect for persons incorporates at least two ethical convictions:
   - ✓ that individuals should be treated as autonomous agents,
   - ✓ that persons with diminished autonomy are entitled to protection.

2. **Beneficence.** -- Persons are treated in an ethical manner not only by respecting their decisions and protecting them from harm, but also by making efforts to secure their well-being.
   - ✓ do not harm and
   - ✓ maximize possible benefits and minimize possible harms.

3. **Justice.** -- Who ought to receive the benefits of research and bear its burdens? This is a question of justice, in the sense of "fairness in distribution" or "what is deserved."
   - ✓ to each person an equal share,
   - ✓ to each person according to individual need,
   - ✓ to each person according to individual effort,
   - ✓ to each person according to societal contribution, and
   - ✓ to each person according to merit.

Declaration of Helsinki (1964)

WORLD MEDICAL ASSOCIATION DECLARATION OF HELSINKI
Ethical Principles for Medical Research Involving Human Subjects

Adopted by 18th WMA General Assembly, Helsinki, Finland, June 1964
Amended by the:
29th WMA General Assembly, Tokyo, Japan, October 1975
35th WMA General Assembly, Venice, Italy, October 1983
41st WMA General Assembly, Hong Kong, September 1989
48th WMA General Assembly, Somerset West, Republic of South Africa, October 1996
52nd WMA General Assembly, Edinburgh, Scotland, October 2000
53rd WMA General Assembly, Washington 2002 (Note of Clarification on paragraph 29 added)
55th WMA General Assembly, Tokyo 2004 (Note of Clarification on Paragraph 30 added)
59th WMA General Assembly, Seoul, October 2008
64th WMA General Assembly, Fortaleza, Brazil, October 2013

Of Special Interest…

25. Authors, editors and publishers all have ethical obligations with regard to the publication of the results of research. Authors have a duty to make publicly available the results of their research on human subjects and are accountable for the completeness and accuracy of their reports. They should adhere to accepted guidelines for ethical reporting. Negative and inconclusive as well as positive results should be published or otherwise made publicly available. Sources of funding, institutional affiliations and conflicts of interest should be declared in the publication. Reports of research not in accordance with the principles of this Declaration should not be accepted for publication.

Institutional Review Boards (IRBs)

46.107 IRB membership.
(a) Each IRB shall have at least 5 members, with varying backgrounds to promote complete and adequate review of research activities commonly conducted by the institution. The IRB shall be sufficiently qualified through the experience and expertise of its members, and the diversity of the members, including consideration of race, gender, and cultural backgrounds and sensitivity to such issues as community attitudes, to promote respect for its advice and counsel in safeguarding the rights and welfare of human subjects. In addition to possessing the professional competence necessary to review specific research activities, the IRB shall be able to ascertain the acceptability of proposed research in terms of institutional commitments and regulations, applicable law, and standards of professional conduct and practice.

Criteria for Approval of Research

a. Risks minimized
b. Favorable risk-benefit ratio
c. Equitable subject selection
d. Informed Consent sought
e. Informed Consent documented
f. Data monitored for SAFETY
g. Privacy protected; confidentiality maintained
h. Safeguards for vulnerable individuals

IRBs in Publications

- In reporting research involving human or animals, the authors should state whether there was ethical clearance by institutional or national review committees. It no formal committees exist they should state that the research was performed in accordance to Declaration of Helsinki latest version).
- Having ethical committee approval does *not* preclude editors from making their own judgment about the conduct of a trial.

Nuremburg Code (1949)

1.The voluntary consent of the human subject is absolutely essential. This means that the person involved should:

✓ have legal capacity to give consent;

✓ be so situated as to be able to exercise free power of choice, without the intervention of any element of force, fraud, deceit, duress, over-reaching, or other ulterior form of constraint or coercion;

✓ have sufficient knowledge and comprehension of the elements of the subject matter involved as to enable him to make an understanding and enlightened decision.

Applications   Belmont Report

Applications of the general principles to the conduct of research leads to consideration of the following requirements:

1. **Informed Consent** -- Respect for persons requires that subjects, to the degree that they are capable, be given the opportunity to choose what shall or shall not happen to them.
 Information.
 - ✓ the research procedure,
 - ✓ their purposes,
 - ✓ risks and anticipated benefits,
 - ✓ alternative procedures (where therapy is involved),
 - ✓ statement offering the subject the opportunity to ask questions
 - ✓ to withdraw at any time from the research.

Comprehension. The manner and context in which information is conveyed is as important as the information itself.
Voluntariness. An agreement to participate in research constitutes a valid consent only if voluntarily given. This element of informed consent requires conditions free of coercion and undue influence.

Assent

- In case of children and adolescents, the parents and guardians must consent for their child to join a study, but children should have a part in this decision making. If they are capable of doing so, when the child is asked to have a part in the decision, this is called assent.
- The age for asking assent is somewhat variable. Some have advocated above 7 years but others have mentioned 12 to 18 years of age.
- The assent form is usually much simpler than the IFC forms and the investigator has to explain the trial in simple language so that the child can understand and then to sign the form.
- This process shows that the investigator respects the child/adolescent and in turn this will increase the commitment of the participant in doing what is required from him/her.

Clinical Trial Registration (I)

- What is a clinical trial: "any research study that prospectively assigns human participants or groups of humans to one or more health-related interventions to evaluate the effects on health outcomes."
- The ICMJE decided that from July 1, 2005 no clinical trials will be considered for publication unless they were included on a clinical trial registry.
- If one is uncertain if their trial needs to be registered or not, it is best to register it or to consult the editorial office of the journal they wish to publish their study.

Clinical Trial Registration (II)

- In October 2008, the revised Declaration of Helsinki stated that "Every clinical trial must be registered in a publicly accessible database before recruitment of the first subject."
- The WHO states that the mission of its clinical trial registry portal is "to ensure that a complete view of research is accessible to all those involved in health care decision making. This will improve research transparency and will ultimately strengthen the validity and value of the scientific evidence base."

Clinical Trial Registration (III)

The ICMJE accepts registration in the following registries:
- www.anzctr.au
- www.clinicaltrials.gov
- www.ISRCTN.org
- www.umin.ac.jp/ctr/index/htm
- www.trialregister.nl
- https://eudract.ema.europa.eu
- Any primary registry that participates in the WHO International/Clinical/Trials/Portal (http://www.who.int/ictrp/network/primary/en/index.html)

Note: ICMJE is cooperating with WHO to adopt WHO policy with respect to registry language. Minimal data in English is needed in order to help in searching.

Animal Research

Authors should include:
- Details of animal welfare (species, number, gender, age, weight, housing condition, welfare, training and fate of animal at the end of the experiment).
- All relevant details of steps to reduce animal suffering (include all details in Methods section).
- All authors are strongly urged to comply with institutional, national and international guidelines on animal research (i.e. ARRIVE guideline, study of Animal Behaviour/Animal Behaviour Society Guidelines for the Use of Animals in Research, International Association of Veterinary Editor's Consensus Author Guidelines on Animal Ethics and Welfare).
- Referees are asked to express any ethical concerns regarding animal experimentation and misuse or maltreatment of animals.
- A brief statement indicating the institutional and/or licensing body approving the experiments must be included in the article.

What are posters?

Posters at scientific meetings are:
Enlarged, graphical presentations of research data
Abstracts represent
- Citable references
- Rapid publications

Advantages of posters

Can be studied at the viewers leisure
Offer personal contact with the author
Are more comprehensive than an oral presentation
Can be more memorable than a talk
Value can be prolonged through handouts
Can be fun

Disadvantages of posters

The viewer is not comfortably seated
It is easy for the viewer to walk away
If a poster is dull, the viewer may 'switch off'
Time-consuming to produce
Difficult to decide what to leave out

Two examples

Award winning
Not so good.....

Most common complaints

Type too small or hard to read
Too much unnecessary data
Confusing organisation
Lack of headings
The information is not newsworthy

Planning your poster – key steps

Abstract accepted

Write poster text

Layout the text

Print the poster

Poster planning

What does the abstract say?
What results are available?
Who is the target audience?
When is the poster to be presented?

Poster text - approach to writing

Write in defined sections
Respect target length
** (overall 600-900 words)**
Emphasise results
Write methodology and results first

Poster layout - what to consider?

Where is the meeting?
  – Secretariat requirements and stipulations (size, orientation)
Graphics should predominate
Presenter contact details
Poster number

Layout - general rules

Maximum use of white space

- Poster must be eye-catching
- Be creative (use colours and unusual formats)
- Locate tables and figures near relevant text
- Use upper and lower case type
- Type in uneven line lengths (not fully justified)

Software options

Word
PowerPoint
Quark
Adobe printshop

Appropriateness

Is the written piece a suitable poster?
Is it suitable for the target audience?
  – Tone, content, language
Does it include the right messages?
Does it have the appropriate content?

Accuracy

Data
– In text, tables and figures
The right words
– Terminology and abbreviations
Spelling
Style
– Followed guidelines, citations match references

Readability

Order
Flow
Well written?

Appearance

- Location of sections/ figures/ tables
- Balance
- Size of text/ easy to read

Conclusions

Be clear, concise and avoid unnecessary detail…

Maximum use of white space

Scientometrics

Any Index in the world has a tool & unite for measurement.
The Scientometrics is the methods & tools which makes us enable to measure the sciences produced by a researcher, department, university, journal or a country.
Scientometrics is the knowledge to measure science!

Informetrics

"The study of the application of mathematical methods to the objects of information science" (Nacke, 1979, p. 220).

Perhaps the most general field covering all types of information regardless of form or origin (Egghe, L. & Rousseau, 1988).

Impact Factor

It is a Citation based metrics based on the average number of times an article published in a journal has been referenced by authors in other journals.
Developed by Eugene Garfield 1960
It is calculated taking into account the number of citations to articles published in journals in the last two years
IF= Number of citations in a given year Number of source articles in the previous 2 years

Impact Factor **Formula** & **Calculations**

Suppose there is a journal, published some papers in 2010 & 2011:

Item	2010	2011	Total
Total Papers Published	130	170	300
Citations Achieved in 2012	240	360	600

$$\text{Impact Factor} = \frac{\text{Citations}}{\text{Papers}} = \frac{600}{300} = 2 \quad \text{IF}$$

Impact Factor **Calculation**

Citations in the current JCR year to articles published in the previous two years divided by the number of articles published in the previous two years.

$$IF = \frac{\text{Citations in 2012 to articles published in 2010 + 2011}}{\text{Total 2010 + 2011 Papers}}$$

Drawbacks of IF

For calculation and evaluation ISI uses its own database with over nine thousand journals to caluclate IF
Any citation in a journal outside ISI database is not included
Manipulation and artificially boosting of IF by journals
Journals use reviewers and ask authors to cite papers published in their journal to improve IF
Publication of commentaries to increase

DORA Declaration

Approved by 150 scientists 75 scientific organizations at American Cell Biology Meeting San Francisco 2012
Stop using IF to to judge an individual scientists work
IF should not be used for funding, scientists appointment and academic promotions
(www.ascb.org/SFdecleration.html)

h-Index

It is used to quantify the scientific output of an individual researcher
Developed by Jorge E. Hirsch in 2005
He proposed that h Index should be defined as the number of papers with citation number ^_h
h-index is intended to measure simultaneously the quality and quantity of scientific output.

Ref: Hirsch JA. An index t o quantify an individual's scientific research output. Proceedings of the National Academy of

Calculation of h Index

It can be even manually determined using citation data bases or using automatic tools.
Scopus and Web of Knowledge provide automated calculators
You just require total number of papers published and number of citations for each paper to calculate h-Index
Harzing's Publish or Perish programme calculates the h-index based on Google scholar entries

h-Index

Articles	Number of Citations
1	65
2	55
3	47
4	37
5	15
6	6 = h-index
7	5
8	3
9	2

Advantages of h-Index

It relies on citations to a scientist's paper

It is not dramatically skewed by a single well-cited, influential paper.

It is not increased by large number of poorly cited papers.

It minimizes the politics of publication.

It is good for comparing scientists within a field at similar stages in their career

It may be used to compare not just individuals but also departments, programs or any group of scientists

Different h-Index

Each database id likely to produce a different h-index for the same scholar because of different coverage

Web of Knowledge has strong coverage of journal publications but poor coverage of publications prior to 1966

Google Scholar has the best coverage of conferences and most journals

Scopus has limited coverage of pre 1990 publications

Conference proceedings are considered

Multi-author h-Index

Developed by Screiber was first described in his paper How to share the fame in a fair way, hm modifies h for multi-authored manuscripts.
New J of Physics 2008;10(040201-1-8.

It uses fractional paper counts instead of reduced citation counts to account for shared authorship of papers and then determines the multi-authored hm index based on the resulting effective rank of the papers using undiluted

Average annual increase in individual h-index

Publish or Perish 4.3 calculates the average annual increase in hl,norm, called hi annual. It is useful as

It removes to a considerable extend any discipline-specific publication and citation patterns that otherwise distort the h-index

It also reduced the effect of career length and provides a fairer comparison between junior and senior researchers.

It is meant as an indicator for an individual average annual research

Criticism of h-index

h-index does not account for typical number of citations in different fields. Citation behaviour is affected by field-dependent factors

h-index discards information contained in author placement in author's list which could be significant

It has slightly less predictive accuracy and precision than the simpler measure of mean citations per paper but it was not supported by another study.

It is a natural number which reduces its

Drawbacks of h-Index

It counts a highly cited paper regardless of why it is being references eg., for negative reasons

It ignores the number and position of authors on a paper.

It limits authors by the total number of publications so people with shorter career are at a disadvantage.

It has relatively low resolutions hence many scientists end up in the same range since as it gets increasingly difficult to increase the h-index, the

m-Index

It was introduced by the creator of the h-index

It is defined as h-index divided by the number of years since the researcher's first publication.

M-Index averages periods of high and low productivity throughout a career which may or may not be reflected of the current situation of the scientist

It is unaffected by small number of exceptionally well cited articles like Reviews

g-Index

It is said that researchers who have published some landmark paper should get a proper credit

g-Index was developed for this reason.

Like the h-index when a researcher's publications are listed in decreasing order of citations received, the g-index is the largest number of such that the top g articles received in total at least g2 citations.

Hence a few well cited papers can significantly increase the g-index relative to the corresponding h-index

e-Index

It aims to address the number of excess citations above and beyond the h-index

e-Index is defined as the square root of the sum of the excess citations in the papers that contributed to the h-index

Medical Editor

A Medical Editor has to be the keeper of the conscience of a profession and if he tries to live up to this ideal, he will always be getting into trouble

Hugh Clegg
Editor BMJ 1947-1965