Improving reporting for observational studies: STROBE statement

Technical meeting on the reporting of human studies submitted for the scientific substantiation of health claims

EFSA Parma – 20 November 2013

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Outline

- **Need for better reporting of observational research**
- **STROBE statement**
- **Case study: a health claim**

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- **Need for better reporting of observational research**
- **STROBE statement**
- **Case study: a health claim**

An early call for complete reporting

"A basic principle can be set up that … it is at least as important **to describe the techniques employed and the conditions in which the experiment was conducted, as to give the detailed statistical analysis of results**."

Daniels M. Scientific appraisement of new drugs in tuberculosis. *Am Rev Tuberc* **1950**;61:751-6

Anectodal evidence of poor reporting

"Our readers would be amazed to learn how often we have to remind authors to simply mention **where and when** their study was conducted."

Alfredo Morabia, Editor *Preventive Medicine*

Evidence of poor reporting

- Most empirical evidence on reporting is from randomised trials

- But similar concerns apply to other types of studies:
  - Diagnostic accuracy studies
  - Observational studies
    - case-control / cohort / cross-sectional studies
    - studies based on routine databases
  - Prognostic studies
  - Qualitative studies
  - Systematic reviews

Reporting of case-control studies

Lee *Br J Psychiatry* 2007

- "The reporting of methods in the 408 identified papers was generally poor, with basic information about recruitment of participants often absent …"

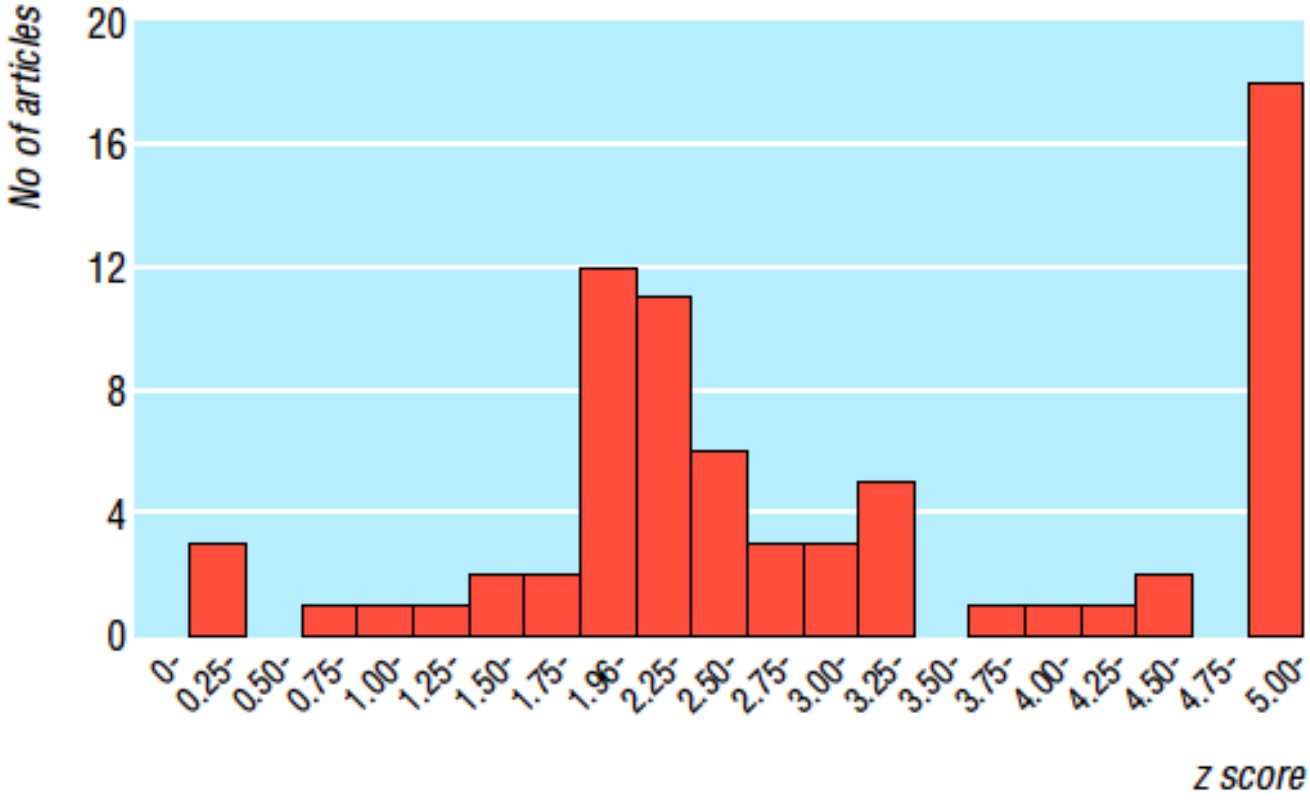
- "Poor reporting of recruitment strategies threatens the validity of reported results and reduces the generalisability of studies."

Survey of observational studies

Pocock *BMJ* 2004

- Examined 73 published in Jan 2001 in general medical & specialist journals, mostly case-control or cohort studies
- Rationale behind choice of confounders usually unclear
- Extent of adjustment varied greatly
- Many exposures, outcomes, subgroups in same study
  - Multiple statistical tests of hypotheses
  - High probability of spurious findings for associations
  - Risk of overinterpretation

Clustering of p-values around 0.05



P value	No of articles
<0.0001	23
0.0001-	5
0.001-	9
0.01-	12
0.02-	7
0.03-	4
0.04-	3
0.05-	2
0.1-	2
0.2-	6

Distribution of P values for first primary result in each article and corresponding absolute values of standardised normal deviates z (two sided P=0.05, 0.01, 0.001, and 0.0001 correspond to z=1.96, 2.58, 3.29, and 3.89, respectively)

Pocock *BMJ* 2004

Credibility of epidemiology is at stake

“ The credibility of risk factor epidemiology can withstand only a limited number of false alarms ”

Alvan Feinstein 1981

The epidemiologists

Have they got scares for you!

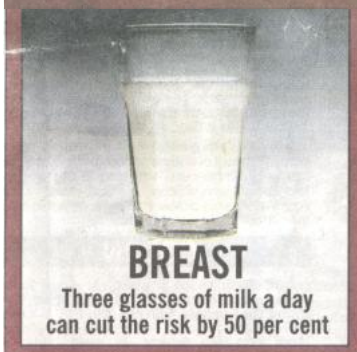
John Brignell

IUMSP

decine sociale et préventive, Lausanne

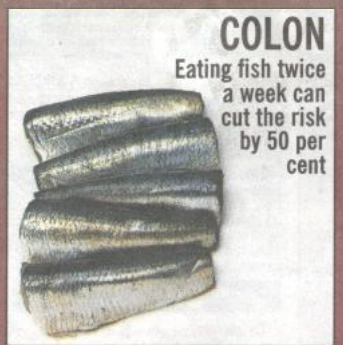
Eat to beat the big C

There may not be a cure for cancer yet, but research shows how even small changes in diet can dramatically reduce your risk of getting it

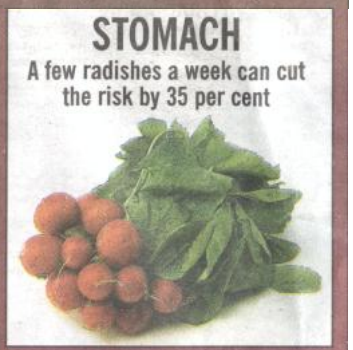


BREAST
Three glasses of milk a day can cut the risk by 50 per cent

OVARIAN
Five carrots a week can cut the risk by 50 per cent



COLON
Eating fish twice a week can cut the risk by 50 per cent



STOMACH
A few radishes a week can cut the risk by 35 per cent

MOUTH
Six sweet potatoes a week can reverse cancer of the mouth

LUNG
Eating tomato ketchup every day can cut the risk by 25 per cent

LIP
Wearing lipstick can cut the risk by 50 per cent

SKIN
Lemon tea can cut the risk by 70 per cent

Pictures: PSC

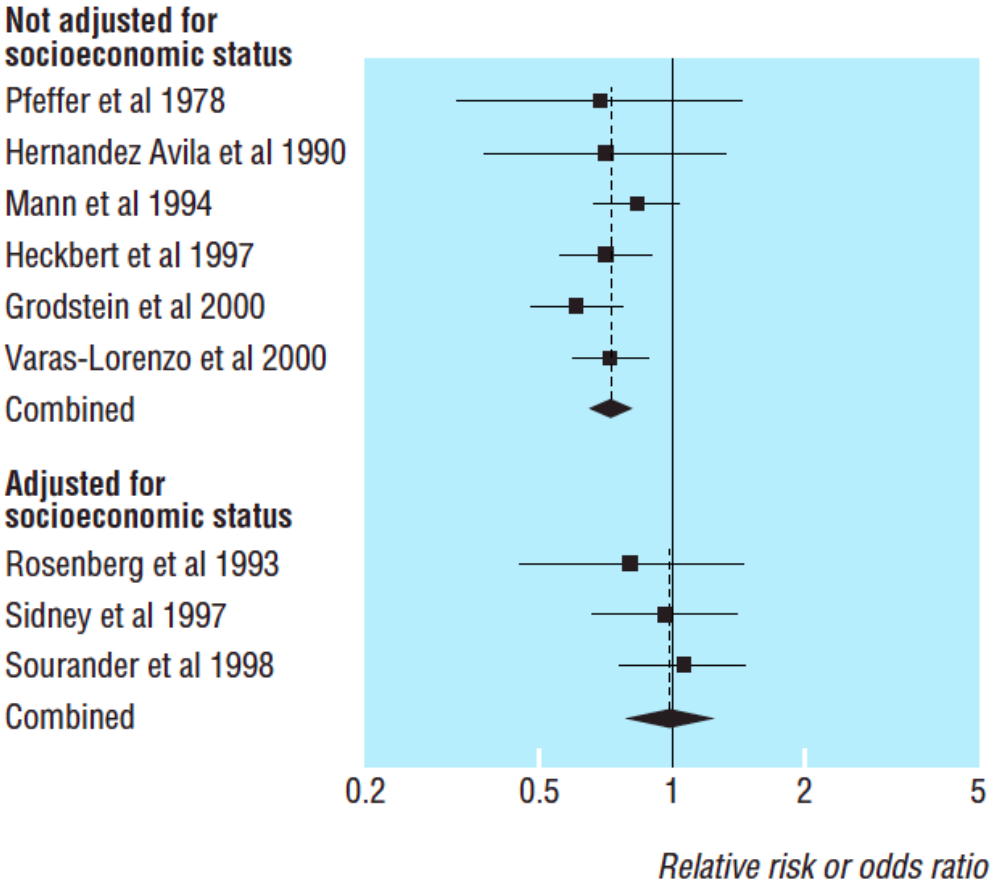
The scandal of poor epidemiological research

Reporting guidelines are needed for observational epidemiology

- Compared to CONSORT additional complexity with reporting guideline for observational studies
- Several main types of observational studies: cohort, case-control, cross-sectional
- Even well-conducted observational studies might still be misleading if important confounders are missed, not measured precisely, not known...
- In articles, additional importance of interpretation & discussion because of many choices made (e.g. for adjustment for confounding)

von Elm Egger BMJ 2004

Impact of adjustment for SES



Meta-analysis of cohort studies and case-control studies of hormone replacement therapy and coronary heart disease. There is little evidence for a protective effect when analyses are adjusted for, in contrast to studies not adjusted for, socioeconomic status. Adapted from Humphrey et al, reference 7 (Ann Int Med 2002)

Consequences of poor reporting

- Reliability of individual studies cannot be assessed
  - If methods not described in detail, weaknesses may not be apparent
- A body of evidence cannot be used for further decision making e.g. policy regarding a health claim
- Consequences for
  - Other researchers
  - Professional users: clinicians, policy makers, regulators
  - Lay users: patients, consumers

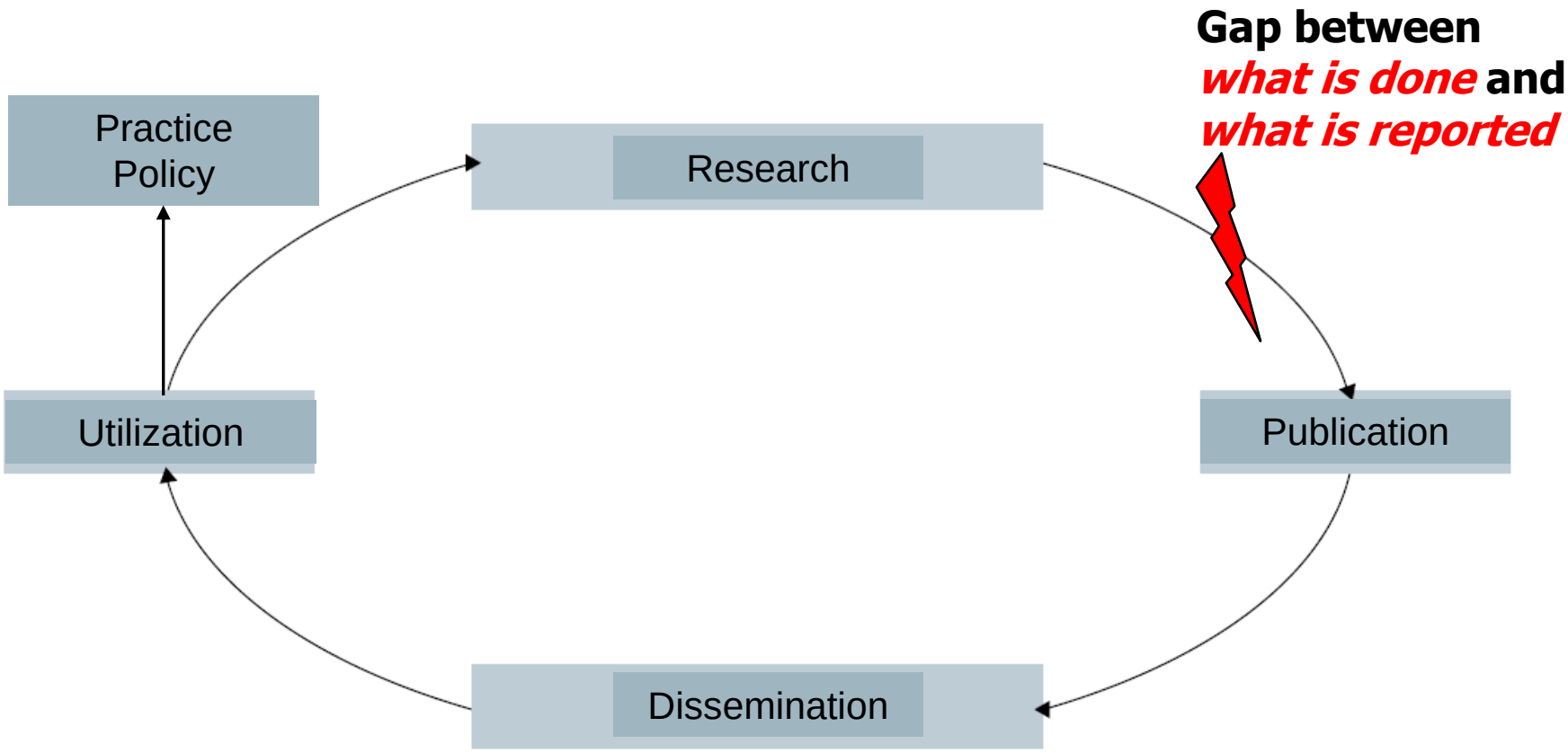
Outline

- Need for better reporting of observational research
- **STROBE statement**
- Case study: a health claim

Reporting guidelines

- Established by international collaborative groups incl. researchers and editors
- RG specify a minimum set of items required for a clear and transparent account of **what was done** and **what was found** in a study
- Usually checklist, flow diagram, explicit text
- They focus on issues that might introduce bias into health research
- Should be based on evidence if available.
  If not, consensus opinion.

Knowledge translation



STROBE Statement

- Collaborative effort of working group since 2004
- Checklist of 22 essential items that should be reported for a **cohort, case-control / cross-sectional study**
- Published 2007 in several journals (open access)
- Translations available
- Comprehensive explanatory paper (E&E) with examples of good reporting
- Several extensions:
  STREGA, STROBE-ME, RECORD

www.strobe-statement.org

	Item number	Recommendation
TITLE and ABSTRACT	1	(a) Indicate the study's design with a commonly used term in the title or the abstract (b) Provide in the abstract an informative and balanced summary of what was done and what was found
INTRODUCTION		
Background/ rationale	2	Explain the scientific background and rationale for the investigation being reported
Objectives	3	State specific objectives, including any prespecified hypotheses
METHODS		
Study design	4	Present key elements of study design early in the paper
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection
Participants	6	(a) *Cohort study*—Give the eligibility criteria, and the sources and methods of selection of participants. Describe methods of follow-up *Case-control study*—Give the eligibility criteria, and the sources and methods of case ascertainment and control selection. Give the rationale for the choice of cases and controls *Cross-sectional study*—Give the eligibility criteria, and the sources and methods of selection of participants (b) *Cohort study*—For matched studies, give matching criteria and number of exposed and unexposed *Case-control study*—For matched studies, give matching criteria and the number of controls per case
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable
Data sources/ measurement	8*	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group
Bias	9	Describe any efforts to address potential sources of bias
Study size	10	Explain how the study size was arrived at
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen, and why
Statistical methods	12	(a) Describe all statistical methods, including those used to control for confounding (b) Describe any methods used to examine subgroups and interactions (c) Explain how missing data were addressed (d) *Cohort study*—If applicable, explain how loss to follow-up was addressed *Case-control study*—If applicable, explain how matching of cases and controls was addressed *Cross-sectional study*—If applicable, describe analytical methods taking account of sampling strategy (e) Describe any sensitivity analyses

RESULTS		
Participants	13*	(a) Report the numbers of individuals at each stage of the study—e.g., numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed (b) Give reasons for non-participation at each stage (c) Consider use of a flow diagram
Descriptive data	14*	(a) Give characteristics of study participants (e.g., demographic, clinical, social) and information on exposures and potential confounders (b) Indicate the number of participants with missing data for each variable of interest (c) *Cohort study*—Summarise follow-up time (e.g., average and total amount)
Outcome data	15*	*Cohort study*—Report numbers of outcome events or summary measures over time *Case-control study*—Report numbers in each exposure category, or summary measures of exposure *Cross-sectional study*—Report numbers of outcome events or summary measures
Main results	16	(a) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (e.g., 95% confidence interval). Make clear which confounders were adjusted for and why they were included (b) Report category boundaries when continuous variables were categorized (c) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period
Other analyses	17	Report other analyses done—e.g., analyses of subgroups and interactions, and sensitivity analyses
DISCUSSION		
Key results	18	Summarise key results with reference to study objectives
Limitations	19	Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence
Generalisability	21	Discuss the generalisability (external validity) of the study results
OTHER INFORMATION		
Funding	22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based

*Give such information separately for cases and controls in case-control studies, and, if applicable, for exposed and unexposed groups in cohort and cross-sectional studies.

Note: An Explanation and Elaboration article discusses each checklist item and gives methodological background and published examples of transparent reporting. The STROBE checklist is best used in conjunction with this article (freely available on the Web sites of *PLoS Medicine* at http://www.plosmedicine.org/, *Annals of Internal Medicine* at http://www.annals.org/, and *Epidemiology* at http://www.epidem.com/). Separate versions of the checklist for cohort, case-control, and cross-sectional studies are available on the STROBE Web site at http://www.strobe-statement.org/.

doi:10.1371/journal.pmed.0040297.t001

OPEN ACCESS Freely available online PLOS MEDICINE

Strengthening the Reporting of Observational Studies in Epidemiology (STROBE): Explanation and Elaboration

Jan P. Vandenbroucke[1], Erik von Elm[2,3], Douglas G. Altman[4], Peter C. Gøtzsche[5], Cynthia D. Mulrow[6], Stuart J. Pocock[7], Charles Poole[8], James J. Schlesselman[9], Matthias Egger[2,10*] for the STROBE Initiative

1 Department of Clinical Epidemiology, Leiden University Medical Center, Leiden, The Netherlands, 2 Institute of Social & Preventive Medicine (ISPM), University of Bern, Bern, Switzerland, 3 Department of Medical Biometry and Medical Informatics, University Medical Centre, Freiburg, Germany, 4 Cancer Research UK/NHS Centre for Statistics in Medicine, Oxford, United Kingdom, 5 Nordic Cochrane Centre, Rigshospitalet, Copenhagen, Denmark, 6 University of Texas Health Science Center, San Antonio, United States of America, 7 Medical Statistics Unit, London School of Hygiene and Tropical Medicine, London, United Kingdom, 8 Department of Epidemiology, University of North Carolina School of Public Health, Chapel Hill, United States of America, 9 Department of Biostatistics, University of Pittsburgh Graduate School of Public Health, and University of Pittsburgh Cancer Institute, Pittsburgh, United States of America, 10 Department of Social Medicine, University of Bristol, Bristol, United Kingdom

- Examples of good reporting
- Explanatory text
- Key concepts in text boxes (definitions / study conduct)

STROBE explanatory paper: key concepts

STROBE Explanation and Elaboration

Box 6. Missing data: problems and possible solutions

A common approach to dealing with missing data is to restrict analyses to individuals with complete data on all variables required for a particular analysis. Although such 'complete-case' analyses are unbiased in many circumstances, they can be biased and are always inefficient [108]. Bias arises if individuals with missing data are not typical of the whole sample. Inefficiency arises because of the reduced sample size for analysis.

Using the last observation carried forward for repeated measures can distort trends over time if persons who experience a foreshadowing of the outcome selectively drop out [109]. Inserting a missing category indicator for a confounder may increase residual confounding [107]. Imputation, in which each missing value is replaced with an assumed or estimated value, may lead to attenuation or exaggeration of the association of interest, and without the use of sophisticated methods

Example of good reporting: item 8

8 Data Sources/Measurement: For Each Variable of Interest Give Sources of Data and Details of Methods of Assessment (Measurement). Describe Comparability of Assessment Methods If There is More Than One Group

Example 1

"Total caffeine intake was calculated primarily using US Department of Agriculture food composition sources. In these calculations, it was assumed that the content of caffeine was 137 mg per cup of coffee, 47 mg per cup of tea, 46 mg per can or bottle of cola beverage, and 7 mg per serving of chocolate candy. This method of measuring (caffeine) intake was shown to be valid in both the NHS I cohort and a similar cohort study of male health professionals (. . .). Self-reported diagnosis of hypertension was found to be reliable in the NHS I cohort."[60]

Has it improved reporting ?

- We don’t know yet
  - More evidence available for RCTs
  - Difficult to identify specific impact of a guideline
- Some evidence from experimental studies using RGs during peer review (Cobo BMJ 2011)
- Any effect depends on endorsement / enforcement of journals
- Empirical studies keep identifying deficiencies in reporting

Outline

- Need for better reporting of observational research
- STROBE statement
- **Case study: a health claim**

Health claim from an EFSA application

„...supports the development of healthy and strong bone in children“

Target population: „infants & young children (<3 yrs.)“

ESFA Journal 2013, 11(7) 3331

Intervention study used for application

0021-972X/06/$15.00/0
Printed in U.S.A.

The Journal of Clinical Endocrinology & Metabolism 91(12):4866–4872

doi: 10.1210/jc.2006-1391

A Randomized Controlled Study of Effects of Dietary Magnesium Oxide Supplementation on Bone Mineral Content in Healthy Girls

Thomas O. Carpenter, Maria C. DeLucia, Jane Hongyuan Zhang, Gina Bejnerowicz, Lisa Tartamella, James Dziura, Kitt Falk Petersen, Douglas Befroy, and Dorothy Cohen

Context: The role of magnesium (Mg) as a determinant of bone mass has not been extensively explored. Limited studies suggest that dietary Mg intake and bone mineral density are correlated in adults, but no data from interventional studies in children and adolescents are available.

Objective: We sought to determine whether Mg supplementation in periadolescent girls enhances accrual of bone mass.

Design: We carried out a prospective, placebo-controlled, randomized, one-year double-blind trial of Mg supplementation.

Setting: The study was conducted in the Clinical Research Centers at Yale University School of Medicine.

Patients or Other Participants: Healthy 8- to 14-yr-old Caucasian girls were recruited from community pediatricians' offices. Dietary diaries from over 120 volunteers were analyzed, and those with dietary Mg intake of less than 220 mg/d were invited to participate in the intervention.

Intervention: Magnesium (300 mg elemental Mg per day in two divided doses) or placebo was given orally for 12 months.

Main Outcome Measure: The primary outcome measure was interval change in bone mineral content (BMC) of the total hip, femoral neck, Ward's area, and lumbar spine (L1–L4) after 12 months of Mg supplementation.

Results: Significantly increased accrual ($P = 0.05$) in integrated hip BMC occurred in the Mg-supplemented *vs.* placebo group. Trends for a positive Mg effect were evident in the pre- and early puberty and in mid-late puberty. Lumbar spinal BMC accrual was slightly (but not significantly) greater in the Mg-treated group. Compliance was excellent; 73% of capsules were ingested as inferred by pill counts. Serum mineral levels, calciotropic hormones, and bone markers were similar between groups.

Conclusions: Oral Mg oxide capsules are safe and well tolerated. A positive effect of Mg supplementation on integrated hip BMC was evident in this small cohort. (***J Clin Endocrinol Metab* 91: 4866–4872, 2006**)

Intervention study: Carpenter 2006

Results

Study population

A total of 122 subjects were screened, 50 subjects enrolled, and 44 completed the study. Dro
(15%) for the placebo and two
supplemented group. Reasons g

TABLE 3. Combined overall hip measures of bone mass (as change from baseline)

	Least square mean (g)	SE	*P* value
BMC			
Entire cohort			0.0534
Treatment	1.0542	0.06014	
Placebo	0.9688	0.05903	
Tanner 1/2 group			0.2967
Treatment	0.9822	0.06178	
Placebo	0.9324	0.06055	
Tanner 3/4 group			0.0991
Treatment	1.1262	0.0734	
Placebo	1.0052	0.07077	
BMD			
Entire cohort			0.8444
Treatment	0.1163	0.03524	
Placebo	0.1143	0.03513	
Tanner 1/2 group			0.6357
Treatment	0.09897	0.03543	
Placebo	0.1044	0.03531	
Tanner 3/4 group			0.5854
Treatment	0.1337	0.03685	
Placebo	0.1242	0.03657	

8-14 yr. old girls
with low Mg intake

N=50 (not 120)

Primary outcome:
p=0.053 (not sign.)

2 observational studies

Current Research

The Relationship of Dietary and Lifestyle Factors to Bone Mineral Indexes in Children

WENDY BOUNDS, PhD, RD; JEAN SKINNER, PhD, RD; BETTY RUTH CARRUTH, PhD, RD; PAULA ZIEGLER, PhD, RD

ABSTRACT
Objective To identify factors related to children's bone mineral indexes at age 8 years, and to assess bone mineral indexes in the same children at ages 6 and 8 years.

Conclusions Because many nutrients are related to bone health, children should consume a varied and nutrient-dense diet.
J Am Diet Assoc. 2005;105:735-741.

Osteoporos Int (1999) 9:532–535

Osteoporosis International

Influence of Pre-adolescent Diet on Quantitative Ultrasound Measurements of the Calcaneus in Young Adult Women

M. C. Wang[1,2], E. C. Moore[1], P. B. Crawford[3], M. Hudes[3], Z. I. Sabry[3], R. Marcus[4,5] and L. K. Bachrach[1]

Departments of [1]Pediatrics, [2]Health Research and Policy, and [4]Medicine, Stanford University School of Medicine, Stanford, California; [3]School of Public Health, University of California, Berkeley, California; and [5]Musculoskeletal Research Laboratory, Geriatric Research, Education, and Clinical Center, Veterans Affairs Medical Center, Palo Alto, California, USA

Observational study: Bounds 2005

Current Research

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WENDY BOUNDS, PhD, RD; JEAN SKINNER, PhD, RD; BETTY RUTH CARRUTH, PhD, RD; PAULA ZIEG

ABSTRACT

Objective To identify factors related to children's bone mineral indexes at age 8 years, and to assess bone mineral indexes in the same children at ages 6 and 8 years.

Conclusions Because many health, children should c dense diet.

J Am Diet Assoc. 2005;10

Exposure:

diet 2-8 yrs; 11 components incl. Mg

Outcome:

BMC & BMD at 8 yrs.

Adjustment:

sex, height, weight, BMI, age

Small coeff. & p=0.05

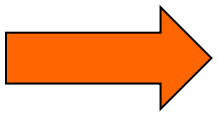

Table 3. Multivariate regression models predicting children's[a] total BMC[b] and BMD[c] at 8 years old

Independent variable	β	Partial R^2	*P* value
BMC Model 1[d] (R^2=0.69, F=20.71, *P*<.0001)			
Protein intake (g)[e]	(+) 2.40	0.08	.008
Height (cm)[f]	(+) 9.49	0.50	.0005
Weight (kg)[f]	(+) 7.22	0.05	.01
Age (y)[f]	(+) 33.97	0.02	.01
Sex[g]	(−) 61.33	0.04	.02
BMC Model 2[d] (R^2=0.69, F=20.08, *P*<.0001)			
Phosphorus intake (mg)[e]	(+) .11	0.05	.01
Height (cm)[f]	(+) 8.28	0.50	.002
Weight (kg)[f]	(+) 8.36	0.07	.003
Age (y)[f]	(+) 39.82	0.03	.007
Sex[g]	(−) 68.04	0.03	.008
BMD Model 1 (R^2=0.19, F=5.88, *P*=.005)			
Protein intake (g)[e]	(+) .001	0.07	.04
Sex[g]	(−) .02	0.12	.03
BMD Model 2 (R^2=0.19, F=5.68, *P*=.006)			
Magnesium intake (mg)[e]	(+) .0002	0.07	.05
Sex[g]	(−) .02	0.12	.03

[a]n=52 children at 8 years of age.
[b]BMC=bone mineral content (g).
[c]BMD=bone mineral density; calculated as g/cm^2.

efsa
European Food Safety Authority

The EFSA Journal (2007) 530, 1-44

Parma, 23 July 2007
SP/NDA/CLAIMS/WD/1, Rev 4-Final

SCIENTIFIC AND TECHNICAL GUIDANCE FOR THE PREPARATION AND PRESENTATION OF THE APPLICATION FOR AUTHORISATION OF A HEALTH CLAIM

Opinion of the Scientific Panel on Dietetic Products, Nutrition and Allergies

Adopted on 6 July 2007

ESFA Guidance document 2007 Appendix I:

- references some reporting guidelines
- mirrors some STROBE items
- more specific for exposure information
- no item on methods for bias & multiple testing

8. Study quality. Please check the appropriate columns in the table below. If copies/reprints of published studies or full study reports of unpublished studies do not contain enough data to assess some of the points below, please tick the "No" or "Unknown" boxes as appropriate

	Yes	Partially	No	Unknown	N/A[1]
1. Power calculations performed					
2. Baseline characteristics of subjects reported					
3. Subjects inclusion and exclusion criteria specified					
4. Definition of cases explicit					
5. Condition of cases reliably assessed and validated					
6. Controls selected from the source of population of the cases					
7. Information on background dietary habits provided					
8. Information on physical activity provided					
9. Information on smoking/alcohol drinking provided					
10. Information on medication use provided					
6. Information on other risk factors provided					
11. Information on the distribution of prognostic factors provided					
12. Groups comparable at baseline for relevant risk factors/potential confounding variables					
13. Exposure ascertained					
14. Dose-response relationship between exposure and outcome demonstrated					
15. Outcome assessors blinded to exposure status					
16. Appropriate duration of follow-up for outcome to occur					
17. Surrogate markers of the claimed effect validated analytically					
18. Surrogate markers of the claimed effect validated biologically					
19. Drop out rates and reasons similar among groups					
20. Adequate adjustment for the effects of confounding variables					
21. Statistical methods appropriate					
22. Dose-response relationship between exposure and outcome statistically significant					

[1] N/A=*Not applicable*

Improving reporting of observational studies - some key aspects

- STROBE is designed as tool for authors, editors, reviewers and readers
- Not a tool to assess methodological quality, but can be used to assess completeness & accuracy of reporting
- Adherence does not guarantee a high-quality study but more transparency about what was done
  - Users can judge themselves whether they trust in study results or not

Reporting vs. methodological quality

"Accurate and transparent reporting is like turning the light on before you clean up a room: It doesn't clean it for you but does tell you where the problems are."

Davidoff, Ann Intern Med 2000

➔ **Weak studies can be reported well.**

Well-conducted studies can be reported weakly.

Policy and practice

The Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) statement: guidelines for reporting observational studies

Erik von Elm,[a] Douglas G Altman,[b] Matthias Egger,[a] Stuart J Pocock,[c] Peter C Gøtzsche,[d] & Jan P Vandenbroucke[e] for the STROBE initiative

Abstract Much biomedical research is observational. The reporting of such research is often inadequate, which hampers the assessment of its strengths and weaknesses and of a study's generalizability. The Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) initiative developed recommendations on what should be included in an accurate and complete report of an observational study. We defined the scope of the recommendations to cover three main study designs: cohort, case-control and cross-sectional studies. We convened a two-day workshop, in September 2004, with methodologists, researchers and journal editors to draft a checklist of items. This list was subsequently revised during several meetings of the coordinating group and in e-mail discussions with the larger group of STROBE contributors, taking into account empirical evidence and methodological considerations. The workshop and the subsequent iterative process of consultation and revision resulted in a checklist of 22 items (the STROBE statement) that relate to the title, abstract, introduction, methods, results and discussion sections of articles. Eighteen items are common to all three study designs and four are specific for cohort, case-control, or cross-sectional studies. A detailed *Explanation and elaboration* document is published separately and is freely available on the web sites of *PLoS Medicine* and *Epidemiology*. We hope that the STROBE statement will contribute to improving the quality of reporting of observational studies.

Bulletin of the World Health Organization 2007;85:xxx–xxx.

Introduction

Many questions in medical research are investigated in observational studies.[1] Much of the research into the cause of diseases relies on cohort, case-control, or cross-sectional studies. Observational studies also have a role in research into the benefits and harms of medical interventions.[2] Randomized trials cannot answer all important questions about a given intervention. For example, observational studies are more suitable to detect rare or late adverse effects of treatments, and are more likely to provide an indication of what is achieved in daily medical practice.[3]

Research should be reported transparently so that readers can follow what was planned, what was done, what was found, and what conclusions were drawn. The credibility of research depends on a critical assessment by others of the strengths and weaknesses in study design, conduct, and analysis. Transparent reporting is also needed to judge whether and how results can be included in systematic reviews.[4,5] However, in published observational research important information is often missing or unclear. An analysis of epidemiological studies published in general medical and specialist journals found that the rationale behind the choice of potential confounding variables was often not reported.[6] Only few reports of case-control studies in psychiatry explained the methods used to identify cases and controls.[7] In a survey of longitudinal studies in stroke research, 17 of 49 articles (35%) did not specify the eligibility criteria.[8] Others have argued that without sufficient clarity of reporting, the benefits of research might be achieved more slowly,[9] and that there is a need for guidance in reporting observational studies.[10,11]

Recommendations on the reporting of research can improve reporting quality. The Consolidated Standards of Reporting Trials (CONSORT) statement was developed in 1996 and revised 5 years later.[12] Many medical journals supported this initiative,[13] which has helped to improve the quality of reports of randomized trials.[14,15] Similar initiatives have followed for other research areas—e.g. for the reporting of meta-analyses of randomized trials[16] or diagnostic studies.[17] We established a network of methodologists, researchers, and journal editors to develop recommendations for the reporting of observational research: the Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) initiative.

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doi: 10.2471/BLT.07.045120
(Submitted: 20 June 2007 – Final revised version submitted: 13 August 2007 – Accepted: 20 August 2007)

STROBE Statement

The Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) statement: guidelines for reporting observational studies

Erik von Elm, Douglas G Altman, Matthias Egger, Stuart J Pocock, Peter C Gøtzsche, Jan P Vandenbroucke for the STROBE initiative

Much biomedical research is observational. The reporting of such research is often inadequate, which hampers the assessment of its strengths and weaknesses and of a study's generalizability. The Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) initiative developed recommendations on what should be included in an accurate and complete report of an observational study. We defined the scope of the recommendations to cover three main study designs: cohort, case-control, and cross-sectional studies. We convened a 2-day workshop in September, 2004, with methodologists, researchers, and journal editors to draft a checklist of items. This list was subsequently revised during several meetings of the coordinating group and in e-mail discussions with the larger group of STROBE contributors, taking into account empirical evidence and methodological considerations. The workshop and the subsequent iterative process of consultation and revision resulted in a checklist of 22 items (the STROBE statement) that relate to the title, abstract, introduction, methods, results, and discussion sections of articles. Eighteen items are common to all three study designs and four are specific for cohort, case-control, or cross-sectional studies. A detailed Explanation and Elaboration document is published separately and is freely available on the websites of *PLoS Medicine* and *Epidemiology*. We hope that the STROBE statement will contribute to improving the quality of reporting of observational studies.

Introduction

Many questions in medical research are investigated in observational studies (1). Much of the research into the cause of diseases relies on cohort, case–control, or cross-sectional studies. Observational studies also have a role in research into the benefits and harms of medical interventions (2). Randomized trials cannot answer all important questions about a given intervention. For example, observational studies are more suitable to detect rare or late adverse effects of treatments and are more likely to provide an indication of what is achieved in daily medical practice (3).

Research should be reported transparently so that readers can follow what was planned, what was done, what was found, and what conclusions were drawn. The credibility of research depends on a critical assessment by others of the strengths and weaknesses in study design, conduct, and analysis. Transparent reporting is also needed to judge whether and how results can be included in systematic reviews (4, 5). However, in published observational research, important information is often missing or unclear. An analysis of epidemiological studies published in general medical and specialist journals found that the rationale behind the choice of potential confounding variables was often not reported (6). Only few reports of case–control studies in psychiatry explained the methods used to identify cases and controls (7). In a survey of longitudinal studies in stroke research, 17 of 49 articles (35%) did not specify the eligibility criteria (8). Others have argued that without sufficient clarity of reporting, the benefits of research might be achieved more slowly (9), and that there is a need for guidance in reporting observational studies (10, 11).

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Lancet 2007; 370:

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Aims and use of the STROBE statement

The STROBE statement is a checklist of items that should be addressed in articles reporting on the three main study designs of analytical epidemiology: cohort, case–control, and cross-sectional studies. The intention is solely to provide guidance on how to report observational research: it is not prescriptive either for designing or conducting studies. Also, while clarity of reporting is a prerequisite to evaluation, the checklist is not an instrument to evaluate the quality of observational research.

See also:

Web-Only
Explanation and Elaboration article
Conversion of graphics into slides

Available online at www.sciencedirect.com
ScienceDirect
Preventive Medicine 45 (2007) 247–251
www.elsevier.com/locate/ypmed

The Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) Statement: Guidelines for reporting observational studies☆,☆☆

Erik von Elm[a,*], Douglas G. Altman[b], Matthias Egger[a,c], Stuart J. Pocock[d], Peter C. Gøtzsche[e], Jan P. Vandenbroucke[f]
for the STROBE Initiative

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Abstract

Much biomedical research is observational. The reporting of such research is often inadequate, which hampers the assessment of its strengths and weaknesses and of a study's generalizability. The Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) Initiative developed recommendations on what should be included in an accurate and complete report of an observational study. We defined the scope of the recommendations to cover three main study designs: cohort, case–control and cross-sectional studies. We convened a 2-day workshop in September 2004, with methodologists, researchers, and journal editors to draft a checklist of items. This list was subsequently revised during several meetings of the coordinating group and in e-mail discussions with the larger group of STROBE contributors, taking into account empirical evidence and methodological considerations. The workshop and the subsequent iterative process of consultation and revision resulted in a checklist of 22 items (the STROBE Statement) that relate to the title, abstract, introduction, methods, results, and discussion sections of articles. 18 items are common to all three study designs and four are specific for cohort, case–control, or cross-sectional studies. A detailed Explanation and Elaboration document is published separately and is freely available on the websites of PLoS Medicine, Annals of Internal Medicine and Epidemiology. We hope that the STROBE Statement will contribute to improving the quality of reporting of observational studies.

Keywords: Epidemiology; Observational studies; Quality of reporting; Reporting guidelines

Introduction

Many questions in medical research are investigated in observational studies (Glasziou et al., 2004). Much of the research into the cause of diseases relies on cohort, case–control, or cross-sectional studies. Observational studies also have a role in research into the benefits and harms of medical interventions (Black, 1996). Randomised trials cannot answer all important questions about a given intervention. For example, observational studies are more suitable to detect rare or late adverse effects of treatments, and are more likely to provide an indication of what is achieved in daily medical practice.

Research should be reported transparently so that readers can follow what was planned, what was done, what was found, and what conclusions were drawn. The credibility of research depends on a critical assessment by others of the strengths and weaknesses in study design, conduct, and analysis. Transparent reporting is also needed to judge whether and how results can be included in systematic reviews (Egger et al., 2001). However, in published observational research important information is often missing or unclear. An analysis of epidemiological studies published in general medical and specialist journals found that the rationale behind the choice of potential confounding variables was often not reported (Chan et al., 2004). Only few reports of case–control studies in psychiatry explained the methods used to identify cases and controls. In a survey of longitudinal studies in stroke research, 17 of 49 articles (35%) did not specify the eligibility criteria. Others have argued that without sufficient clarity of reporting, the benefits of research might be achieved more slowly, and that there is a need for guidance in reporting observational studies (Ioannidis et al., 2004; Vandenbroucke, 2004).

Recommendations on the reporting of research can improve reporting quality. The Consolidated Standards of Reporting Trials (CONSORT) statement was developed in 1996 and revised five years later. Many medical journals supported this initiative, which has helped to improve the quality of reports of randomised trials. Similar initiatives have followed for other research areas—for example, for the reporting of meta-analyses of randomised trials or diagnostic studies. We established a network of methodologists, researchers, and journal editors to develop recommendations for the reporting of observational research: the Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) Initiative.

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www.annals.org
Ann Intern Med. 2007;147:573-577.
For author affiliation, see end of text.

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Strengthening the reporting of ob studies in epidemiology (STROBE guidelines for reporting observati

Poor reporting of research hampers assessment and makes it less use of methodologists, researchers, and journal editors sets out guidelines observational studies

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The workshop was funded by the European Science Foundation (ESF). Additional funding was received from the Medical Research Council Research and Development Programme and the Medical Research Council Health Services Research Collaboration and the National Health Services Research & Development Methodology Programme.

Editors' note: In order to encourage dissemination of the STROBE Statement, this article is freely accessible on the Web site of EPIDEMIOLOGY *(www.epidem.com) and will also be published in* Annals of Internal Medicine, BMJ, Bulletin of the World Health Organization, The Lancet, PLoS Medicine, *and* Preventive Medicine. *The authors jointly hold the copyright of this article. For details on further use, see the STROBE website (www.strobe-statement.org). Related articles appear on pages xxx, xxx, xxx, xxx, xxx and xxx.*

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ISSN: 1044-3983/07/1806-0800
DOI: 10.1097/EDE.0b013e3181577654

STROBE Initiative

The Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) Statement

Guidelines for Reporting Observational Studies

Erik von Elm, Douglas G. Altman,† Matthias Egger,*‡ Stuart J. Pocock,§ Peter C. Gøtzsche,¶ and Jan P. Vandenbroucke‖ for the STROBE Initiative*

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(*Epidemiology* 2007;18: 800–804)

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Reporting guidelines initiatives

1996	**CONSORT**	RCTs (revised 2001 & 2010)
1999	QUOROM	Meta-analyses of RCTs
2000	MOOSE	Meta-analyses of obs. studies
2003	STARD	Diagnostic studies
2004	TREND	Non-randomised studies
2007	**STROBE**	Case-control / Cross-sectional / Cohort studies
2007	COREQ	Qualitative studies
2008	SQUIRE	Quality improvement studies
2009	**PRISMA**	Syst. reviews & meta-analyses (replacing QUOROM)
2013	SPIRIT	Protocols of RCTs

See: EQUATOR Library for Health Research Reporting