GENERAL

Indian Journal of Pharmacology (IJP), an official publication of the Indian Pharmacological Society, is currently published the Medknow Publications, Mumbai, India. It is published bimonthly in February, April, June, August, October and December every calendar year. It is listed in Biological Abstracts/Biosis, Chemical Abstracts, EMBASE/Excerpta Medica, CAB Abstract, Global Health, Excerpta Medicinal and Aromatic Plants Abstracts, Health Reference Center Academic, InfoTrac One File, Expanded Academic ASAP, NCI Current Contents, Indian Science Abstracts, InMed, and MedInd.

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SCOPE

Indian Journal of Pharmacology accepts, in English, Review articles, articles for Educational forum, Original research articles, Rapid communication and Research letter. Articles concerning fundamental and clinical aspects of pharmacology, chemotherapy, ethnopharmacology, pharmacoepidemiology and molecular pharmacology will be considered. Articles of general interest discussing methods, therapeutics, medical education, interesting websites, new drug information and commentary on a recent topic are also welcome.

Review articles and Educational forum: Review articles are written by researchers of considerable experience in the field concerned. The author should review the recent trend or advances in that field in the light of his own work.

However, when an author has not done enough original work on a topic but nevertheless wants to share the knowledge on recent advances/trends which may be useful for post-graduate students, he may do so by writing an article for Educational Forum.

The major portion of above articles should deal with the upto-date developments in the field in the last 3-5 years. Authors are advised to search Medline and other databases on the Internet, apart from collecting information using conventional methods.

Research papers:

Original research work will be considered under this section depending on the volume and quality of work.

Methods:

Articles on new methods/procedures on drug evaluation, testing and analyses will be published. Innovative studies on established methodologies and their modifications will also be considered. The articles must be supported by data.

Rapid communication:

An article will be accepted for rapid communication if it merits priority publication. The decision of acceptance or otherwise will be communicated within 4 weeks of receipt of the manuscript and accepted articles will be published in the following issue.

Research letters:

Preliminary work with hard data can be published as a Letter. Brief research communications will also be accepted under this section.

Correspondence:

Comment(s) on previously published articles, items of current interest and articles of general interest and views can be submitted for this section.

Computers:

Articles on computing and computer programs related to pharmacology research and/or teaching are welcome under this section. The source code (or the executable file) of the program must be sent in a diskette for evaluation. Articles describing commercial software related to pharmacology are also welcome.

Teaching aids:

Reports on the innovative use of teaching aids are welcome under this section. The report must give adequate details so that others can try.

Case reports:

The journal welcomes adverse drug reaction reporting and interesting case reports pertaining to pharmacotherapy.

Meeting reports:

Conference (pharmacology) reports can be submitted for publication.

Web-wise:

Interesting and useful websites can be reviewed under this section. Contact the Chief Editor for guidelines.

Molecules of the millennium:
Information on new drugs under investigation can be published. Contact the Chief Editor for guidelines.

Fillers:
The readers can send in brief write-ups for fillers. This may include anecdotes, pictures and photographs.

If your proposed contribution does not fall under any of the above categories, please contact the Chief Editor.

EDITORIAL POLICY

Indian Journal of Pharmacology considers only original communications/articles/write-ups submitted exclusively to the journal. Prior and duplicate publications are not allowed. Publication of abstract under conference proceedings will not be considered as prior publication. It is the duty of the authors to inform the IJP about all submissions and previous reports that might be regarded as prior or duplicate publication.

Manuscripts for publication will be considered on their individual merits. All manuscripts will be subjected to peer review. Normally manuscripts will be sent to at least two reviewers and their comments along with the editorial board's decision will be forwarded to the contributor for further action. The authors may suggest not more than 5 referees working in the same area for evaluating the manuscript. However, the IJP reserves the right to choose referees (even the one not suggested by the authors).

The editorial board may invite articles for review section or educational forum from those with considerable standing in the field. However, such an invitation does not automatically guarantee their publication. These articles will also be subjected to review process and accepted only if found suitable. Unsolicited articles for review and educational forum sections will also be considered.

The IJP insists on ethical practices in both human and animal experimentation. Evidence for approval by a local Ethics Committee (for both human as well as animal studies) must be supplied by the authors on demand. Animal experimental procedures should be as humane as possible and the details of an aesthetics and analgesics used should be clearly stated. The ethical standards of experiments must be in accordance with the guidelines provided by the CPCSEA (animal) and ICMR (human). The journal will not consider any paper which is ethically unacceptable. A

statement on ethics committee permission and ethical practices must be included in all research articles under the 'Materials and Methods' section.

Authors must be careful when they reproduce text, tables or illustrations from other sources. Plagiarism will be viewed seriously. Please See Section 10.

All accepted papers are subject to editorial changes.

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IJP uses Manuscript Management System (MMS) installed in the website (www.ijp-online.com) and manuscripts can be submitted through the MMS. Log on to website and click 'Manuscript submission" and follow the instructions.

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Manuscripts submitted by e-mail should be sent as attached files (in MS-Word format) only.

Through post-Paper copy

Three copies of each manuscript may be submitted to the Chief Editor. The copies must be legible. Lack of contrast and faded or/and worn out appearance will lead to rejection.

Final, accepted version of the manuscript must be submitted on a diskette or by e-mail only.

Through post-Electronic copy

An electronic version of the manuscript may be submitted on a PC diskette or a compact disk or through e-mail. The running text has to be in MS-Word

format (*.pdf format is not acceptable). The figures may be embedded in the Word file or submitted as separate files and should be created using MS-Excel. If any other software is used the graphic files may be converted to *.pcx, *.tiff, *.jpg format. It is desirable that these details are mentioned in the covering letter. The diskette must be clearly labelled. The label must contain the title of the manuscript and the corresponding author's name, affiliations, title and address.

The diskette or the CD must be properly packed in order to prevent damage during postal journey. The authors should use only new diskettes. The diskettes/CDs are not returnable. The IJP office is not responsible for any damage occurring to the diskette during postal transit.

Note: Those who submit manuscripts electronically (via e-mail, on a diskette or through website) need NOT submit paper copies. The authors are strongly recommended to submit the manuscripts electronically. However they must submit the Authors' declaration and Copyright transfer (Annexure I) on paper along with a covering letter.

Undertaking

The manuscript must be submitted with a statement, signed by all the authors, regarding the originality, authorship and transfer of copyright as per the format given in Annexure I.

Mailing address

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PREPARATION OF THE MANUSCRIPT

Authors should keep their manuscripts as short as they reasonably can.

Manuscripts should be typed double spaced on one side of good quality A4 size paper. Page number should appear in the upper right hand corner of each page, beginning with the title page.

The language of manuscript must be simple and explicit. The authors who are not confident are advised to consult those experienced in scientific writing and communication. Papers in recent issues of the Indian Journal of Pharmacology should be consulted for the general format adopted in respect to various elements of a paper.

Research papers

It should be arranged into the following sections:

1) Title page,
2) Abstract and Key words,
3) Introduction,
4) Materials and Methods,
5) Results,
6) Discussion,
7) Acknowledgement,
8) References,
9) Tables,
10) Figures.

The total number of words should not exceed 3200.

Title page

It should be paginated as page 1 of the paper. It should carry the title, authors' names and their affiliations, running title, address for correspondence including e-mail address and also a list of number of pages, figures and tables.

Title:
Must be informative, specific and short and not exceed 150 characters.

Authors and affiliations:
The names of authors and their appropriate addresses should be given.

It should be made clear which address relates to which author.

Running title:
It is a short title printed in the journal at the right top corner of right hand page of the article (except the lead page). A short running title of not more than 50 characters should be given.

Address for correspondence:

The corresponding author’ s address should be given in the title page. The fax number (if available) may be mentioned. The e-mail ID of the corresponding author or the contact e-mail ID must also be provided.

Abstract and key words

Abstract:

It must start on a new page carrying the following information: (a) Title (without authors’ names or affiliations), (b) Abstract, (c) Key words, (d) Running title. It should not exceed 250 words excluding the title and the key words. The abstract must be concise, clear and informative rather than indicative. New and important aspects must be emphasized.

The abstract must be in a structured form consisting of OBJECTIVES, METHODS, RESULTS and CONCLUSIONS briefly explaining what was intended, done, observed and concluded. Authors should state the main conclusions clearly and not in vague statements. The conclusions and recommendations not found in the text of the article should not be given in the abstract.

Key words:

Provide 3-5 keywords which will help readers or indexing agencies in cross-indexing the study. The words found in title need not be given as key words.

Use terms from the latest Medical Subject Headings (MeSH) list of Index Medicus. A more general term may be used if a suitable MeSH term is not available.

Introduction

It should start on a new page. Essentially this section must introduce the subject and briefly say how the idea for research originated. Give a concise background of the study. Do not review literature extensively but provide the most recent work that has a direct bearing on the subject. Justification for research aims and objectives must be clearly mentioned without any ambiguity. The purpose of the study should be stated at the end.

Material and Methods

This section should deal with the materials used and the methodology - how the work was carried out. The procedure adopted should be described in sufficient detail to allow the experiment to be interpreted and repeated by the readers, if necessary. The number of subjects, the number

of groups studied, the study design, sources of drugs with dosage regimen or instruments used, statistical methods and ethical aspects must be mentioned under the section. The methodology - the data collection procedure - must be described in sufficient detail. If a procedure is a commonly used one, giving a reference (previously published) would suffice. If a method is not well known (though previously published) it is better to describe it briefly. Give explicit descriptions of modifications or new methods so that the readers can judge their accuracy, reproducibility and reliability.

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The doses of drugs should be given as unit weight per kilogram body weight e.g., mg/kg and the concentrations should be given in terms of molarity e.g., nm or mM. The routes of administration may be abbreviated, e.g., intraarterial (i.a.), intracerebroventricular (i.c.v.), intra-gastric gavage (i.g.), intramuscular (i.m.), intraperitoneal (i.p.), intravenous (i.v.), per os (p.o.), subcutaneous (s.c.), transdermal (t.d.).

Statistical Methods: The variation of data should be expressed in terms of the standard error of the mean (SEM) or the standard deviation (SD), along with the number of observations (n). The details of statistical tests used and the level of significance should be stated. If more than one test is used it is important to indicate which groups and parameters have been subjected to which test.

Results

The results should be stated concisely without comments. It should be presented in logical sequence in the text with appropriate reference to tables and/or figures. The data given in tables or figures should not be repeated in the text. The same data should not be presented in both tabular and graphic forms. Simple data may be given in the text itself instead of figures or tables. Avoid discussions and conclusions in the results section.

Discussion

This section should deal with the interpretation, rather than recapitulation of results. It is important to discuss the new and significant observations in the light of previous work. Discuss also the weaknesses or pitfalls in the study. New hypotheses or recommendations can be put forth.

Avoid unqualified statements and conclusions not completely supported by the data. Repetition of information given under Introduction and Results should be avoided. Conclusions must be drawn considering the strengths and weaknesses of the study. They must be conveyed in the last paragraph under Discussion. Make sure conclusions drawn should tally with the objectives stated under Introduction.

Acknowledgements

It should be typed in a new page. Acknowledge only persons who have contributed to the scientific content or provided technical support. Sources of financial support should be mentioned.

References

It should begin on a new page. The number of references should normally be restricted to a maximum of 25 for a full paper. Majority of them should preferably be of articles published in the last 5 years. Avoid citing abstracts as references.

Papers which have been submitted and accepted but not yet published may be included in the list of references with the name of the journal and indicated as “In press”. A photocopy of the acceptance letter should be submitted with the manuscript. Information from manuscript “submitted” but “not yet accepted” should not be included.

Avoid using abstracts as references. The “unpublished observations” and “personal communications” may not be used as references but may be inserted (in parentheses) in the text.

References are to be cited in the text by superscribed number and should be in the order in which they appear. References cited only in tables or in legends to figures should be numbered in accordance with a sequence established by the first identification in the text of the particular table or illustration. As far as possible mentioning names of author(s) for reference should be avoided in the text.

The references must be verified by the author(s) against the original documents. The list of references should be typed double spaced following the Vancouver style. Examples are given in Annexure II.

Download a PowerPoint presentation on common reference styles and using the reference checking facility on the manuscript submission site.

Tables

Each table must be self-explanatory and presented in such a way that they are easily understandable without referring to the text. It should be typed with double spacing and numbered consecutively with Arabic numerals. Provide a short descriptive caption above each table with foot notes and/or explanations underneath. The number of observations, subjects and the units of numerical figures must be given. It is also important to mention whether the given values are mean, median, mean±SD or mean±SEM. All significant results must be indicated using asterisks. Appropriate positions for the tables within the text may be indicated.

Check list for Table

- Serially numbered?
- Short self explanatory caption given?
- Columns have headings?
- Units of data given?
- 'n' mentioned?
- Mean ± SD or Mean ± SEM given?
- Statistical significance of groups indicated by asterisks or other markers?
- P values given?
- Rows and columns properly aligned?
- Appropriate position in the text indicated?

Figures

Each figure must be numbered and a short descriptive caption must be provided. All significant results should be indicated using asterisks. For graphs and flow charts, it is not necessary to submit the photographs. A manually prepared or computer drawn figure (with good contrast) on a good quality paper is acceptable. Raw data for graphs must be submitted when the article is accepted for publication. This will enable the editorial office to draw the graph on computer and incorporate it in the text at an appropriate place.

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Identify each figure/diagrams on the back with a typed label which shows the number of the figure, the name of the leading author, the title of the manuscript and the top side of the figure. The approximate position of each figure should be marked on the margin of the text.

Three figures per article will be printed free of charge. The authors will be charged for additional figures. The contributor(s) must bear the full cost of printing color plates if any.

Legends for figures should be typed under the figure if possible or on a separate sheet.

Large/complex tables or figures may be submitted in "Final Print (camera ready) format" which will be scanned and printed as such.

Check list for Figure

- l Serially numbered? l Self explanatory caption given?
- X and Y axes graduated?
- X and Y axes titled (legend)?
- Units mentioned (if necessary)?
- Different symbols/markers for different groups given?
- SD or SEM represented (graphically)?
- Statistical significance indicated?
- Approximate position in the text marked?

Checklist for RCT

The authors reporting randomized controlled trial (RCT) should refer the checklist (Annexure III). The relevant items of the checklist may be referred for reporting other trials.

Rapid communications

The manuscript should not be divided into sub-sections. It may have up to 1200 words (including a maximum of 6 references) and one figure or one table.

Research Letter

A letter can have a maximum of 800 words (including a maximum of 4 references) with one simple figure or table. The manuscript should not have sub-sections.

Review articles and Educational forum

These should contain title page, summary (need not be structured) and key words. The text proper should be written under appropriate sub-headings. The authors are encouraged to use flowcharts, boxes, cartoons, simple tables and figures for better presentation. The total number of text words should not exceed 6400 and the total number of figures and tables should not be more than 10.

Methods

The format and other requirements are same as that of short communication.

Correspondence, Computers, Teaching aids, Case reports

There is no fixed format for articles published under these sections. The length should not exceed 1400 words.

Molecules of the Millennium, Web-Wise, Meeting reports

Contact the Chief Editor for guidelines for preparation of these articles.

Fillers

The write-up must be brief and should not exceed 300 words. Interesting pictures and photographs may be submitted.

REVISED MANUSCRIPT

The authors should revise the manuscript immediately after receipt of the comments from the IJP. A note mentioning the changes incorporated in the revised text as per referee's comments (point by point) should be sent. The revised manuscript has to be submitted in duplicate along with the annotated original paper within 3 months; else the manuscript will be considered withdrawn by the authors.

Calling for revision does not guarantee acceptance. Those revised manuscripts which underwent major revision are likely to be sent to referees for evaluation. If the authors have substantial reasons that their manuscript was rejected unjustifiably, they may request for reconsideration. The correspondence in this regard should be sent in triplicate.

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Proofs will be sent to the corresponding author for final checking. It is the authors' responsibility to go through the proof meticulously and correct errors if any. Correction should be restricted to printer's error only and no substantial addition/deletion should be made. Proofs may be sent by e-mail, if the corresponding author has an e-mail address.

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Article type	Abstract: No. of words	Key words: No. of words	Running title No. of characters	Text: No. of words	Sub-headings	Tables: max. No.	Figures: max. No.	Number of references
RA & EF	≤ 250	3-5	≤ 50	≤ 6400	Variable	Total of ten		≤ 100
RP	≤ 250	3-5	≤ 50	≤ 3200	Standard	Total of six		≤ 25
ME	≤ 150	3-5	≤ 50	≤ 1600	Standard	Total of two		≤ 12
RC	NR	NR	≤ 50	≤ 1200	No SH	Total of two		≤ 6
LE	NR	NR	≤ 50	≤ 800	No SH	Total of two		≤ 4
CO	NR	NR	≤ 50	≤ 1400	Variable	Total of two		≤ 4
CP	NR	NR	≤ 50	≤ 1400	Variable	Total of two		≤ 4
TA	NR	NR	≤ 50	≤ 1400	Variable	Total of two		≤ 4
CR	NR	NR	≤ 50	≤ 1400	Variable	Total of two		≤ 4

RA=Review Article; EF-Educational Forum; RP=Research paper; RC=Rapid communication; ME=Methods; LE=Research Letter; CO=Correspondence; CP=Computer; TA=Teaching Aid; CR=Case Report; NR=Not Required; SH=Sub-headings.

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    - Title of manuscript

- Full name(s) and affiliations of author(s); institution(s) and city(ies) from which the work originated.
- Name, address, telephone and fax numbers and e-mail address of corresponding author
- Running title
- Number of pages, number of figures and number of tables.

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- Article proper (double spaced)
- Acknowledgements (separate sheet)
- References
- Tables
- Figures/photographs and legends
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ANNEXURE I

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the work described in the manuscript is my/our own and my/our individual contribution to this work is significant enough to qualify for authorship.

no one who has contributed significantly to the work has been denied authorship and those who helped have been duly acknowledged.

I/we also agree to the authorship of the article in the following sequence:

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2.---------- ----------

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AUTHORSHIP AND RESPONSIBILITIES

- Anyone who makes significant intellectual contribution must be given authorship.
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- Authors should be ready to take public responsibility for the content of the paper.
- All the authors in a manuscript are responsible for the technical information communicated. For this reason it is necessary that all

authors must read and approve the final version of the manuscript before signing the consent and declaration form.

*Conflicts of interests if any, the details must be declared in a separate sheet.

» ANNEXURE II

EXAMPLES OF REFERENCES - VANCOUVER STYLE
(from Uniform Requirements for Manuscripts, www.icmje.org)

Articles in Journals

1. Standard journal article

List the first six authors followed by et al. (Note: NLM now lists up through 25 authors; if there are more than 25 authors, NLM lists the first 24, then the last author, then et al.)

Vega KJ, Pina I, Krevsky B. Heart transplantation is associated with an increased risk for pancreatobiliary disease. Ann Intern Med 1996 Jun 1;124(11):980-3.

As an option, if a journal carries continuous pagination throughout a volume (as many medical journals do) the month and issue number may be omitted.
(Note: For consistency, the option is used throughout the examples in Uniform Requirements. NLM does not use the option.)

Vega KJ, Pina I, Krevsky B. Heart transplantation is associated with an increased risk for pancreatobiliary disease. Ann Intern Med 1996;124: 980-3.

More than six authors:
Parkin DM, Clayton D, Black RJ, Masuyer E, Friedl HP, Ivanov E, et al. Childhood leukaemia in Europe after Chernobyl: 5 year follow-up. Br J Cancer 1996;73:1006-12.

2. Organization as author

The Cardiac Society of Australia and New Zealand. Clinical exercise stress testing. Safety and performance guidelines. Med J Aust 1996; 164: 282-4.

3. No author given

Cancer in South Africa [editorial]. S Afr Med J 1994;84:15.

4. Article not in English

(Note: NLM translates the title to English, encloses the translation in square brackets, and adds an abbreviated language designator.) Ryder TE, Haukeland EA, Solhaug JH. Bilateral infrapatellar seneruptur hostidligere frisk kvinne. Tidsskr Nor Laegeforen 1996;116:41-2.

5. Volume with supplement

Shen HM, Zhang QF. Risk assess-ment of nickel carcinogenicity and occupational lung cancer. Environ Health Perspect 1994;102 Suppl 1:275-82.

6. Issue with supplement

Payne DK, Sullivan MD, Massie MJ. Women's psychological reactions to breast cancer. Semin Oncol 1996; 23(1 Suppl 2):89-97.

7. Volume with part

Ozben T, Nacitarhan S, Tuncer N. Plasma and urine sialic acid in non-insulin dependent diabetes mellitus. Ann Clin Biochem 1995;32(Pt 3):303-6.

8. Issue with part

Poole GH, Mills SM. One hundred consecutive cases of flap lacerations of the leg in ageing patients. N Z Med J 1994;107(986 Pt 1):377-8.

9. Issue with no volume

Turan I, Wredmark T, Fellander-Tsai L. Arthroscopic ankle arthrodesis in rheumatoid arthritis. Clin Orthop 1995;(320):110-4.

10. No issue or volume

Browell DA, Lennard TW. Immuno-logic status of the cancer patient and the effects of blood transfusion on antitumor responses. Curr Opin Gen Surg 1993:325-33.

11. Pagination in Roman numerals

Fisher GA, Sikic BI. Drug resistance in clinical oncology and hematology. Introduction. Hematol Oncol Clin North Am 1995 Apr;9(2):xi-xii.

12. Type of article indicated as needed

Enzensberger W, Fischer PA. Metronome in Parkinson's disease [letter]. Lancet 1996;347:1337. Clement J, De Bock R. Hematological complications of hantavirus nephro-pathy (HVN) [abstract]. Kidney Int 1992;42:1285.

13. Article containing retraction

Garey CE, Schwarzman AL, Rise ML, Seyfried TN. Ceruloplasmin gene defect associated with epilepsy in EL mice [retraction of Garey CE, Schwarzman AL, Rise ML, Seyfried TN. In: Nat Genet 1994;6:426-31]. Nat Genet 1995;11:104.

14. Article retracted

Liou GI, Wang M, Matragoon S. Precocious IRBP gene expression during mouse development [retracted in Invest Ophthalmol Vis Sci 1994; 35:3127]. Invest Ophthalmol Vis Sci 1994;35:1083-8.

15. Article with published erratum

Hamlin JA, Kahn AM. Herniography in symptomatic patients following inguinal hernia repair [published erratum appears in West J Med 1995;162:278]. West J Med 1995;162: 28-31. Books and Other Monographs (Note: Previous Vancouver style incorrectly had a comma rather than a semicolon between the publisher and the date.)

16. Personal author(s)

Ringsven MK, Bond D. Gerontology and leadership skills for nurses. 2nd ed. Albany (NY): Delmar Publishers; 1996.

17. Editor(s), compiler(s) as author

Norman IJ, Redfern SJ, editors. Mental health care for elderly people. New York: Churchill Livingstone; 1996.

18. Organization as author and publisher

Institute of Medicine (US). Looking at the future of the Medicaid program. Washington: The Institute; 1992.

19. Chapter in a book

(Note: Previous Vancouver style had a colon rather than a p before pagination.) Phillips SJ, Whisnant JP. Hypertension and stroke. In: Laragh JH, Brenner BM, editors. Hyperten-sion: pathophysiology, diagnosis, and management. 2nd ed. New York: Raven Press; 1995. p. 465-78.

20. Conference proceedings

Kimura J, Shibasaki H, editors. Recent advances in clinical neuro-physiology. Proceedings of the 10th International Congress of EMG and Clinical Neurophysiology; 1995 Oct 15-19; Kyoto, Japan. Amsterdam: Elsevier; 1996.

21. Conference paper

Bengtsson S, Solheim BG. Enforce-ment of data protection, privacy and

security in medical informatics. In: Lun KC, Degoulet P, Piemme TE, Rienhoff O, editors. MEDINFO 92. Procee-dings of the 7th World Congress on Medical Infor-matics; 1992 Sep 6-10; Geneva, Switzerland. Amsterdam: North-Holland; 1992. p. 1561-5.

22. Scientific or technical report

Issued by funding/sponsoring agency: Smith P, Golladay K. Payment for durable medical equipment billed during skilled nursing facility stays. Final report. Dallas (TX): Dept. of Health and Human Services (US), Office of Evaluation and Inspections; 1994 Oct. Report No.: HHSIGOEI69200860.
Issued by performing agency: Field MJ, Tranquada RE, Feasley JC, editors. Health services research: work force and educational issues. Washington: National Academy Press; 1995. Contract No.: AHCPR282942008. Sponsored by the Agency for Health Care Policy and Research.

23. Dissertation

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» ANNEXURE III

Checklist for reporting RCT
from www.consort-statement.org)

PAPER SECTION and topic	Item	Description Reported on	Page #
TITLE & ABSTRACT	1	How participants were allocated to interventions (e.g., "random allocation", "randomized", or "randomly assigned").	
INTRODUCTION Background	2	Scientific background and explanation of rationale.	
METHODS Participants	3	Eligibility criteria for participants and the settings and locations where the data were	

		collected.	
Interventions	4	Precise details of the interventions intended for each group and how and when they were actually administered.	
Objective	5	Specific objectives and hypotheses.	
Outcomes	6	Clearly defined primary and secondary outcome measures and, when applicable, any methods used to enhance the quality of measurements (e.g., multiple observations, training of assessors).	
Sample size	7	How sample size was determined and, when applicable, explanation of any interim analyses and stopping rules.	
Randomization--Sequence generation	8	Method used to generate the random allocation sequence, including details of any restriction (e.g., blocking, stratification).	
Randomization--Allocation concealment	9	Method used to implement the random allocation sequence (e.g., numbered containers or central telephone), clarifying whether the sequence was concealed until interventions were assigned.	
Randomization--Implementation	10	Who generated the allocation sequence, who enrolled participants, and who assigned participants to their groups.	
Blinding (masking)	11	Whether or not participants, those administering the interventions, and those assessing the outcomes were blinded to group assignment. When relevant, how the success of blinding was evaluated.	
Statistical methods	12	Statistical methods used to compare groups for primary outcome(s); Methods for additional analyses, such as subgroup analyses and adjusted analyses.	
RESULTS Participant flow	13	Flow of participants through each stage (a diagram is strongly recommended). Specifically, for each group report the numbers of participants randomly assigned, receiving intended treatment, completing the study protocol, and analyzed for the primary outcome. Describe protocol deviations from study as planned, together with reasons.	
Recruitment	14	Dates defining the periods of recruitment and follow-up.	
Baseline data	15	Baseline demographic and clinical	

		characteristics of each group.	
Numbers analyzed	16	Number of participants (denominator) in each group included in each analysis and whether the analysis was by "intention-to-treat". State the results in absolute numbers when feasible (e.g., 10/20, not 50%).	
Outcomes and estimation	17	For each primary and secondary outcome, a summary of results for each group, and the estimated effect size and its precision (e.g., 95% confidence interval).	
Ancillary analyses	18	Address multiplicity by reporting any other analyses performed, including subgroup analyses and adjusted analyses, indicating those pre-specified and those exploratory.	
Adverse events	19	All important adverse events or side effects in each intervention group.	
DISCUSSION Interpretation	20	Interpretation of the results, taking into account study hypotheses, sources of potential bias or imprecision and the dangers associated with multiplicity of analyses and outcomes.	
Generalizability	21	Generalizability (external validity) of the trial findings.	
Overall evidence	22	General interpretation of the results in the context of current	