

Assessment of study design criteria of articles in the Annals of College of Medicine, Mosul 1990-2000

Bassam A Al-Neema

Summary:

Background: The assessment of the methodology of the articles published in medical journals is crucially needed to improve their performance.

Aim: The present investigation is done to assess the main study design methods followed in the articles published by the journal of *the Annals of College of Medicine, Mosul* in Iraq during the period 1990-2000.

Materials and methods: A cross sectional study design was chosen to examine the study methods of 13 issues of the Annals which were containing 145 published articles.

A modified selected tool for assessing published articles according to their research design include: study aims and objectives, methodology used, sample selection, methods of randomization and blind allocation, potential sources of bias and methods of data analyses. The researchers were categorized according to their departments, as clinical & basic sciences.

Results: It was seen that 58.6 % of the researches chose case reports and case series, 15.2 % used clinical trials, 13.7 % used case control designs, and 9.7 % used cross sectional methods. Only one research used the cohort study methods (0.7 %). The present study showed that more than two thirds of all the clinical departments used the case reports and case series designs, and the clinical trials were used by 16.2 % of investigators in departments of Medicine and Surgery. Furthermore, 54.5 % of Anatomy, and 64.7 % of Biochemistry researchers used case reports and case series methods in their studies.

Conclusion & Recommendations: Most of the case reports and case series design in the *Annals of the College of Medicine* in Mosul were significantly well defined according to the average criteria. While most of the case control and clinical trial articles were significantly written with ill defined criteria. This necessitates the need for more efforts to be directed to tackle all the required criteria in the design and analysis of these studies.

Key words: Assessment, criteria, design, appraisal

Introduction:

Researchers whether they were administrators, educators or clinicians frequently use standard critical appraisal tools to evaluate the quality of published research reports. However, there is no consensus regarding the most appropriate critical appraisal assessment for health research. The empirical basis for construction of the assessment is evaluating the method by which overall quality of the study will be established.^[1]

Case reports and case series are merely observation of interesting clinical cases; they are useful to focus interest on cases, or series of cases, about their characteristics (prognosis, diagnosis, treatment and etc.). Cross sectional study design is useful in determining the prevalence of diseases.

Other types of observational studies of the analytic researches are of greater value to guide clinical choices, such as the case-control and cohort designs.

Case-control designs are studies comparing cases (patients with a certain disease and studied factor) with a control group that should contain people from the same population, with the same possible risk-factors. The cohort study has the same purposes of the case-control, but differs because in

cohort study the evaluation of risk-factors predates the event of interest.^[2]

In order to determine whether a medical procedure is useful in the treatment of certain diseases, experimental studies (using clinical trials) are carried out. Using this study, it is possible to measure the benefits of a drug, surgical methods or any intervention, in comparison with another intervention, drug or placebo.^[3]

The selected tools for assessing published articles according to their research design include (with some modifications):^[1, 4]

- 1- Study aims and objectives.
- 2- Methodology used, which encompassed method of identification of relevant studies and adherence to study protocol.
- 3- Sample selection, which ranged from inclusion and exclusion criteria, to homogeneity of groups.
- 4- Method of randomization and blinding of allocation.
- 5- Method of blinding.
- 6- Method of data analyses.
- 7- Potential sources of bias.

The journal of the Annals of the College of Medicine, Mosul is a well known scientific reference source of publication in Mosul.

It was established in 1966, and published at a rate of two issues per year on average.

The present study aims to assess the main study design methods of the articles published in this journal during the period 1990-2000, and to distribute the study methods used by researchers in the journal according to their departments, as clinical sciences & basic sciences.

Materials and Methods

Study setting:

The official permission was obtained from the Dean of Mosul College of Medicine and the Vice President for scientific affairs in Mosul University in 18th of March 2007. The journal department was visited, and all the articles published in the journal were obtained.

Study design:

A review of the study design methods of all articles published in this journal during the period of 1990-2000 was done.

Study sample:

All the articles published in the journal during the period of 1990-2000 were included in the analysis. The article of one researcher from outside Mosul college of Medicine was excluded from the sample. The full text of each article was obtained from the main journal.

The general criteria for each research were determined as follows:

- 1-Study aim and objectives i.e. the question or questions being addressed or the hypothesis being tested.
- 2-Type of study method (including study setting, obtaining administrative and formal consent from the study population, study period, study sample and design, the technique used and methods of analysis used).
- 3-The department of every investigator participated in the research.

Specific study design criteria were only used for cross sectional, case control, cohort and the experimental clinical trial studies, which include:

- 1-The studied subjects, whether they were the total study population or a sample of it.

Methods of sample selection.

The included and excluded persons in the research population.

The possible sources of bias in the selection process?

Determining the appropriate sample size.

Demonstrating the selection of control group.

Then separate approaches were required when determining the next step depending on whether the research presented is an observational (i.e. a cross sectional or an analytic study estimating quantities or relationship) or an experiment (i.e. clinical trial).

For an observational (i.e. a cross sectional or analytic) study the following questions were assessed:^[5]

Data collection process (including questionnaire design and pre-testing).

The techniques used to handle non response and/or incomplete data?

Determining the measurements and instruments used supported by quality assurance.

While for an experimental approach, the questions assessed included:^[5]

- 1- Assigning the subjects to treatments; randomly or in some other way.
- 2-Demonstrating the control group included (placebo, untreated controls, both or neither).
- 3-The methods of treatments comparison? The outcome of response measured.
- 4-The measurements and instruments used supported by quality assurance.

The articles which were assessed according to these criteria were categorized into:

- Well defined: if the researchers mentioned clearly all the elements of criteria of assessment.
- Ill defined: if the researcher did not fulfill all the elements of criteria of assessment.

The collected data were presented in suitable tables, percentages were calculated and the differences between groups were tested using z test one proportion. The significance was considered at p level of 0.05 and below.

Results

During the study period 13 issues of Annals of the College of Medicine, Mosul was obtained including 145 published articles. These articles were reviewed in respect to their study design according to the criteria mentioned before.

The types of study methods used by the authors are shown in Table (1).

This table demonstrates that more than half of the articles (58.6 %) chose case reports and case series designs, 15.2 % used clinical trials, 13.7 % of the designs were case control and 2.1% performed mortality statistics. Only one research used the cohort study methods (0.7 %).

Table-1 Types of study used by the researchers of articles published in the Annals journal of the College of Medicine, Mosul (1990-2000)

Study method	No.	%
1-Case report & Case series	85	58.6
2-Cross sectional	14	9.7
3-Case control	20	13.7
4-Cohort	1	0.7
5-Clinical trial	22	15.2
6-Mortality statistics	3	2.1
Total	145	100

Table (2) illustrates the distribution of study methods followed by authors in the clinical departments. More than seventy percent (71.5%) of the researchers were from the departments of Medicine and Surgery.

Two thirds (67.4%) of authors in the clinical departments used case reports and case series designs. The lowest fraction is seen amongst the

pediatricians (37.5%) while the highest proportion (80.6%) is present in the department of Surgery. Case control design was used in (11.6%) of the articles, and the highest proportion was reported among the pediatricians. Cohort study design was exhibited only in one article; the researcher was from the department of Medicine.

Table-2 Distribution of clinical researchers according to the study methods used and their departments in the Annals of the College of Medicine, Mosul (1990-2000)

Study method	Medicine		Surgery		Gynecology& obstetrics		Radiology		Pediatrics		Total	
	No	%	No	%	No	%	No	%	No	%	No	%
Case report & series	24	64.9	25	80.6	6	60.0	6	66.7	3	37.5	64	67.4
Cross section	2	5.4	1	3.2	1	10.0	2	22.2	0	0.0	6	6.3
Case control	4	10.8	0	0.0	1	10.0	1	11.1	5	62.5	11	11.6
Cohort	1	2.7	0	0.0	0	0.0	0	0.0	0	0.0	1	1.1
Clinical trial	6	16.2	5	16.2	1	10.0	0	0.0	0	0.0	12	12.6
Mortality statistics	0	0.0	0	0.0	1	10.0	0	0.0	0	0.0	1	1.1
Total	37	100.0	31	100.0	10	100.0	9	100.0	8	100.0	95	100.0
	(38.9)		(32.6)		(10.5)		(9.5)		(8.4)			

Distribution of study methods followed by authors in the basic science departments is demonstrated in Table (3). Half of the study methods used (50.5%) were either case reports or case series.

Clinical trial was followed by 21.1% with a highest figure shown by Pharmacology department (53.9%). Cross sectional study was followed by more than one third (36.4%) of articles published by Community Medicine.

A cohort study was performed by authors in the departments of Biochemistry and Anatomy. Moreover, mortality statistics was carried out by

(18.2%) of the Community Medicine researchers.

Assessment of the study design criteria is presented in Table (4). Overall a significantly higher proportion of well defined criteria is shown (p=0.001). Taking each design separately, an article with cross sectional design has a significantly higher proportion of ill defined criteria (p=0.001). Similarly articles with case control design and clinical trial both of them reported ill defined criteria in a highly significant way (p=0.001) in both instances.

Table-3 Distribution of basic sciences researchers according to the study methods used and their departments in the Annals of the College of Medicine, Mosul (1990-2000)

Study method	Pathology and Forensic medicine		Biochemistry		Pharmacology		Physiology, Biology & Physiques		Microbiology		Anatomy		Community Medicine		Total	
	No	%	No	%	No	%	No	%	No	%	No	%	No	%	No	%
Case report & Case series	11	61.1	11	64.7	6	46.2	5	38.5	6	50.0	6	54.5	3	27.3	48	50.5
Cross section	3	16.7	1	5.9	0	0.0	2	15.4	2	16.7	0	0.0	4	36.4	12	12.6
Case control	2	11.1	3	17.6	0	0.0	3	23.1	2	16.7	0	0.0	1	9.1	11	11.6
Cohort	0	0.0	1	5.9	0	0.0	0	0.0	0	0.0	1	9.1	0	0.0	2	2.1
Clinical trial	2	11.1	1	5.9	7	53.9	3	23.1	2	16.7	4	36.4	1	9.1	20	21.1
Mortality statistics	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	2	18.2	2	2.1
Total	18	100.0	17	100.0	13	100.0	13	100.0	12	100.0	11	100.0	11	100.0	95	100.0
	(18.9)		(17.9)		(13.7)		(13.7)		(12.6)		(11.6)		(11.6)			

Table-4 Assessment of the main study design criteria mentioned in the articles published in the Annals of the College of Medicine, Mosul (1990-2000)

Study method	Study design criteria mentioned in the articles				Totals		P value
	Well defined		Ill defined				
	No	%	No	%	No	%	
1-Case report & series	69	71.1	16	33.3	85	58.6	0.001
2-Cross section	9	9.3	5	10.4	14	9.7	0.001
3-Case control	7	7.2	13	27.1	20	13.7	0.001
4-Cohort	---	---	1	2.	1	0.7	---
5-Clinical trial	9	9.3	13	27.1	22	15.2	0.001
6-Mortality statistics	3	3.1	---	---	3	2.1	---
Total	97	66.9	48	33.1	145	100	0.001

Discussion:

The present study aimed to examine the study design criteria used by the researchers in the Annals of the College of Medicine, Mosul during the period of 1990-2000. This journal is a well known medical periodical publishing scientific articles in Mosul. The period of 1990-2000 was periods of sanction to the whole of Iraq were the editorial board of journal faced various difficulties in publishing the articles on the best standards.

Different methods of assessment were used to evaluate articles written in medical journals. Assessment may be based on whether the studies used qualitative or quantitative data.^[6]

Quantitative research should begin with an idea (usually articulated as a hypothesis), which then, through measurement, generates data and, by

deduction, allows a conclusion to be drawn. Qualitative research, in contrast, begins with an intention to explore a particular area, collect "data" (observations and interviews), and generate ideas and hypotheses from these data largely through what is known as inductive reasoning.^[7]

Other types of assessments concentrate on type of study design used by the research or the techniques used by it or some other aspects.^[8]

The method which was adopted in the present study based on assessing study design criteria fulfilled by the medical research published in one of the well known scientific journal published in Iraq and in the region.

It was seen that more than half of researches in this journal (58.6 %) chose case reports and case series. Other less frequent study designs were

clinical trial, case control design, cross sectional methods and only three of researches used the cohort study methods.

Case reports and case series are detailed presentation of a single case or a handful of cases. They present an important way in which new or unfamiliar diseases or manifestations or associations of diseases are brought to attention of the medical community. Approximately 20-30-% of the original articles published in major general medical journals is studies of 10 or fewer patients.^[9]

The present study showed that more than two thirds of all the clinical departments used the case reports and case series designs, and the clinical trials were used by 16.2 % of investigators in departments of Medicine and Surgery.

Many, if not most, of the clinical contributions represent further validations of clinical practice or its underlying knowledge base. This means that, clinical researches in allied health are very much "applied" researches. Within allied health clinical research, this emphasis is magnified at the "person," or individual level, where considerable attention is given to concepts of function and effectiveness.^[10]

Cross sectional studies were used by one third of Community Medicine researchers, while 18.2 % of them preformed mortality statistics analysis.

Movement toward increasing use of cross-sectional studies, analytic study designs, and statistical methods—representing greater emphasis on needs assessment for health education, health education program development, and program evaluation—indicates the need for better quantitatively trained health educators.^[11, 12]

Diseases can be studied cross-sectionally as well as longitudinally. The cross sectional method compares different age groups observed at one point in time, whereas the longitudinal method makes repeated observation of a single cohort as age changes. Cross sectional method is simpler but has limitations. Cross sectional studies (descriptive and analytic) can both contribute to health care of a specific group or community and serve as a research method for the attainment for a generalizable new knowledge.^[13]

A study was conducted in Mosul city in Iraq, 2005, to evaluate the risk factors of benign breast diseases. This study used a case control design for the purposes of the study (210 cases and 210 controls), as it provides efficient means to study rare diseases, it allows researchers to investigate several risk factors and can give suggestive evidence of causal relationship.^[14]

The well known follow up Framingham study of cardiovascular disease which begun in the late forties, had used the longitudinal cohort study design, and included 5127 men and women who were between 30 and 62 years of age at the time of study. Many exposures were assessed including

smoking, obesity, elevated blood pressure, elevated cholesterol levels and other factors. This study design is used mainly to obtain important inferences about causal relationship.^[15]

Most of the case reports and case series design in the Annals of the College of Medicine, Mosul were significantly well defined according to the average criteria. While most of the case control and clinical trials researches were significantly written with ill defined criteria.

It is necessary to assess the methodological quality of analytic and the randomized controlled trial studies and emphasizing on the sampling techniques. The importance of the sampling methods used for example may reveal sampling error, which cannot be avoided completely.

Experimental researches involve studies in which one group which is deliberately subjected to an experience is compared with a control group which had a similar experience.^[16]

A study assessed different randomized controlled trial design choices in medical practice, reported that randomized controlled trials have seen limited use in education because of concerns surrounding intervention fidelity, politics in assignment, and concerns that study outcomes had limited utility. Nevertheless, these study designs are used for many purposes. They can be used for evaluating new drugs testing new programs and new ways of organizing and delivering health services.^[17]

Another aspect to be emphasized in reading research reports is the type of measures that are used, the reliability and validity of the measures and of data collection tools, and methods used to minimize bias in the measurement of outcomes. Reliability refers to the degree to which a measure gives the same result twice (or more) under similar circumstances; Validity is the ability of a measurement tool to accurately measure what it is intended to measure.^[18]

In the present study none of the published articles had determined whether the data collection tools used were valid or reliable.

The present study concluded that the main type of study design used in the *Annals of the College of Medicine, Mosul*, (1990-2000) were case reports and case series. These studies though enrich the clinical skills are the least type of studies in the evidence of disease causation and disease risk and can not represent the total picture of the disease among the general population.

On the other hand, analytic and experimental designs are significantly important and are less frequently chosen by the researchers in the journal. Most of these designs are written without clear definition. This necessities the need for more efforts to be directed to tackle all the required criteria in the design and analysis of these studies.

References

- 1- Katrak P , Bialocerkowski A E , -Westropp N M , Kumar VS Grimmer KA: A systematic review of the content of critical appraisal tools. *BMC Medical Research Methodology* 2004, 4:22
- 2- Schoenbach VJ, Rosamond WD: Understanding the Fundamentals of Epidemiology an evolving text. Department of Epidemiology School of Public Health, University of North Carolina at Chapel Hill. Fall 2000, Edition. P: 209-251.
- 3- Park K: Parks textbook of Preventive and social medicine. Jabalpur, India 17th ed. 2002, p: 44-108.
- 4- Clarke M, Oxman AD: Cochrane Reviewer's Handbook. Oxford: The Cochrane Collaboration, 2003.
- 5- Beaglehole R, Kjellstrom T: Basic epidemiology. World Health Organization, Geneva 1993, p: 145-153.
- 6- Susan M. Jack, R.N: Utility of Qualitative Research Findings in Evidence-Based Public Health Practice. *Public Health Nursing* 2006, 23 (3) P: 277.
- 7- Greenhalgh T, Taylor R: How to read a paper: Papers that go beyond numbers (qualitative research). *BMJ* 1997, 315(7110):740.
- 8- Mulhall A: Nursing, research, and the evidence [editorial]. *Evidence-Based Nursing* 1998, Jan; 1:4-6.
- 9- Fletcher RH, Fletcher SW, Wagner EH: Clinical Epidemiology. The Essentials. 3rd ed 1996 Lippincott Williams Company p: 208-28
- 10- Selker LG: Clinical research in allied health. *J Allied Health* 1994, Fall; 23(4):201-28.
- 11- Al-Jammas EK: Quality assessment and assurance of continuing medical education in the college of Medicine University of Mosul. Ph D Thesis, College of Medicine University of Mosul 1996. 1-20
- 12- Merrill R M: Perspective: Have the Focus and Sophistication of Research in Health Education Changed? *Health Education & Behavior* 2007, Vol. 34, No. 1, 10-25.
- 13- Abraham J H. Cross sectional studies. In: Oxford Textbook of Public Health. Detels R, McEwen J, Beaglehole R. Oxford University press 4th ed. 2002 section 6.3 p: 509-28.
- 14- Al-Asaady EA: Risk factors of benign breast diseases. 2005, M Sc Thesis Mosul University p: 57-77
- 15- Gordis L: Epidemiology. Updated edition, 2004, Elsevier Saunders Philadelphia. chap 9, p: 149-159
- 16- Adetoknbo O, Herbert L: A Short Textbook of Public Health Medicine for the Tropics. 2003 4th ed. London P: 31-47.
- 17- John H. Hitchcock, Chuck Wilkins, Joseph Dimino, Russell Gersten. Evaluating the Collaborative Strategic Reading Intervention: An Overview of Randomized Controlled Trial Options *Practical assessment research and evaluation* 2009 Volume 14, (2) p: 531
- 18- AlKafajei A: Problem-Based Learning in epidemiology. Simulated exercises from the practice of public health medicine. Mosul University press 1st edition 1998, p: 11-118

Lecturer, Department of Community Medicine, College of Medicine, Mosul University