

REVIEW ARTICLE

LIMITATIONS AND DELIMITATIONS IN THE RESEARCH PROCESS

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Abstract

Introduction: Many authors tempt to balance the recognition of shortcomings and study limitations with the risk of having their paper rejected. Yet, before any attempt to run a study, a researcher needs to recognise the meaning and operational definitions of the terms ‘limitations’ and ‘delimitations’ in biomedical research. **Aim:** to define, review and elaborate how limitations and delimitations are currently acknowledged in the nursing and biomedical literature and their implications in health care studies. **Methods:** A critical literature review was undertaken, focusing on papers debating the core essence of research limitations and associated concepts. Initial searches yielded >300 papers of which only 25 were appropriate for this paper’s needs. **Results:** It is evident that any research attempt inevitably carries limitations and delimitations regarding its underlying theories, study design, replication potential, shortcomings in data collection and questionnaire design, insufficient subgroups or data for robust statistical analysis, narrow time span for data collection, lack of consideration for seasonal differences and missing data, causal relationships, measurement errors, study setting, population or sample, ethical parameters, data collection/analysis, result interpretations and corresponding conclusions. Delimitations require challenging the assumptions of the researchers and openly exposing shortcomings that might have been better tackled. Some authors cite study limitations solely because it is required by journal policy. Under these circumstances, the weakest limitation may be put forward in an attempt to ‘safeguard’ the study’s chance of being published. Researchers need to be aware of the wide range of limitations and delimitations and address them early in the research process **Conclusions:** Constructive rethinking and restructuring of the global nursing and biomedical research agenda is necessary to upgrade the profession and reassure the public. Thus, authors should openly and extensively report their research limitations, delimitations and assumptions in order to improve the quality of their findings and the interpretation of the evidence presented. On the contrary, when any of these key elements are neglected, overlooked or hushed, the study kudos is jeopardised.

Keywords: Study Limitations, Methodology, Nursing Research

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Introduction

In today's highly competitive culture of international publishing, many authors are rather tempted to balance the recognition of shortcomings and study limitations with the risk of having their paper rejected.¹ In this respect, this critical discussion paper was developed through analysis and self-reflection by the author, a researcher in the health care sector, who has also experience as editor and reviewer of national and international nursing publications.

Before any attempt to run a study, one needs to grasp the fundamental principles which make a paper suitable or not for publication and acceptable to a wider readership base. Thus, as a first step, a researcher needs to recognise the meaning and operational definitions of the terms 'limitations' and 'delimitations' in biomedical research which include the following:

Limitations of any particular study concern potential weaknesses that are usually out of the researcher's control, and are closely associated with the chosen research design, statistical model constraints, funding constraints, or other factors. In this respect, a limitation is an 'imposed' restriction which is therefore essentially out of the researcher's control. Still, it may affect the study design, results and ultimately, conclusions and should therefore be acknowledged clearly in the paper when submitted. For example, when exploring participants' responses to a survey, the researcher may be limited to access only a small geographical

area which would not provide an overall scope of responses.²

Thus, in quantitative studies, that sample would not have been representative and when doing qualitative research, data saturation would not have been achieved. With regards to measurements and testing, the research tool itself may be a limiting factor by providing 'narrow results'. For example, a set of good reliable scales would be perfect for weight measurements but would provide only one of two essential parameters for estimating body mass index. Time is another factor that may limit a study by distorting results. For example, a study on dietary habits may limit the extent of the conclusions drawn, depending on the time of year data were gathered. In addition, greater societal circumstances and financial trends that may coincide with the study period should be acknowledged as such.³

Data analysis methodology is another area of potential limitation. For example, most qualitative methodologies cannot be truly replicated (as in controlled experimental conditions) and therefore are unable to be verified per se. With regards to quantitative statistical analysis, most models can easily determine correlation between two or more variables, but again, not causation per se. Thus, all of the above limitations must be clearly stated so that results are not distorted and misinterpreted by the wider readership. Unfortunately, when reporting results, '*author excitement*' may easily overlook this important aspect of conducting and reporting research.⁴

Delimitations are in essence the limitations consciously set by the authors themselves. They are concerned with the definitions that the researchers decide to set as the boundaries or limits of their work so that the study's aims and objectives do not become impossible to achieve. In this respect, it can be argued that delimitations are in the researcher's control. Thus, delimitations are mainly concerned with the study's theoretical background, objectives, research questions, variables under study and study sample. The alternatives to these and reasons for rejecting them, e.g. the particular sampling technique chosen out of many available, should be clearly presented so that the reader is fully informed.^{5,6}

In a way, delimitations are not as much as "*why I did this*" but rather "*why I did not do it like this*". Reasons for rejecting a certain course of action during the research process and the options available should also be cited. Then, a brief rationale should be provided. Usual reasons for choosing a particular sampling technique for example are related to available resources, local circumstances (practical access), ethical and permit considerations or time constraints. In this light, delimitations are not positive or negative but rather a detailed account of reasoning which enlightens the scope of the study's core interest as it relates to the research design and underpinning philosophical framework.⁷

Aim

The goal of this critical discussion paper was to review and elaborate how limitations and

delimitations are currently acknowledged in the nursing and biomedical literature and their implications in health care studies. A further objective is to examine briefly the implications of limitations in biomedical studies and patient care per se.

Methods

A critical literature review was undertaken, focusing on recognised scholarly papers debating the core essence of research limitations and associated concepts. Key words used included research limitations, delimitations, assumptions and biases within a 20 year time span in Medline and Google Scholar databases. Initial searches yielded more than 300 papers which were concerned with particular (often clinical) limitations within specific research fields such as the limitations in cancer studies or animal models and not the research process itself. Close scrutiny of abstracts concluded that only 25 articles could be used for this paper's needs. As this is a discussion and position paper, findings are incorporated in the discussion.

Discussion

In any given study, potential study limitations may include assumptions regarding underlying theories, causal relationships, measurement errors, study setting, population or sample, data collection/analysis, result interpretations and corresponding conclusions. Furthermore, failure to measure important aspects and potential confounding variables are also common study limitations while the remaining refer to aspects of applicability of the results to clinical practice, i.e. external validity. All of

these may contain potential factors that could induce uncertainty in a study overall. Some uncertainty in biomedical research is inevitable but open communication about it can inform readers on the validity and applicability of a study's findings. It is therefore important to recognize the uncertainties within research findings which should be explicitly expressed in research papers.⁸

A fundamental form of limitation is when scientists are restricted in their research scope due to ethical concerns.⁹ One of the pillars for establishing limitations to research is the Harm Principle established by John Stuart Mills (based on the Hippocratic Oath) whereby an inquiry is limited if the outcomes of the research might cause harm especially to vulnerable groups or individuals.¹⁰

Thus, as much as researchers may carefully plan and design their study, it is inevitable they will face some limitations which are not always identified at the beginning, before conducting the research. For example, in most health care research, it would be ideal to conduct a qualitative study before designing a quantitative one as this would inform and improve the methodology of the latter.¹¹ Yet, in most instances, this may not be possible due to limited time and other resources.

According to Morris et al.,¹² when credible clinical evidence is lacking, then the consequences on patient's care and outcomes may be dramatic. Thus, limitations in biomedical studies may carry a further effect on clinical decisions and desired health outcomes. According to Boyko, although randomized controlled trials (RCTs) are the gold standard for treatment efficacy; they are in most

cases costly and sometimes lengthy.¹³ In this case, observational research can be used instead. However, an awareness of the benefits and limitations of observational research needs to be exercised as there is a potential for bias. As clinical decisions often involve a degree of uncertainty it could be argued that such research needs to be at a level of certainty sufficient to influence diagnostic and/or treatment decisions albeit less certain than RCTs.¹⁴

In this light, Rubin & van der Laan¹⁵ suggested that a means of minimising study limitations is personalised medicine by the use of replication. They argued that working towards more tailored therapies, could provide additional evidence of safety and efficacy before pharmaceutical drugs can be marketed. However, their model of patient simulations based on two active RCTs of antibacterial drugs for the treatment of skin and skin structure infections gave poor results and the authors concluded that statistical approaches to personalized medicine will often face difficult challenges. Yang and Rannala,¹⁶ used a Bayesian modeling approach to generate posterior probabilities, i.e. when relevant background is taken into account. The statistical performance of their method incorporated simulations but again, limitations in their proposed statistical approach remain evident.

With regards to data collection, when an on-line tool is to be used, an inherent shortcoming is that the questionnaire needs to be shorter than a 'paper and pencil' one.¹⁷ A long self-administered questionnaire risks 'participant fatigue' and consequent higher drop-out rate. This limits the study as some of the potential (polarised) participants' views

would not be represented in the results. An inherent limitation on a self-administered survey, is that the researcher cannot control the course of the investigation and clarify any questions from respondents. Another built-in limitation of a self-administered questionnaire is missing data due to respondent withdraws or failure to fill in the whole survey, but since this is nowadays usually done as postal or more likely an online survey, the researcher cannot prevent this from happening.^{18,19}

The specific period when a survey is distributed is in itself a limiting factor, for example when a study on university students is conducted during summer and particularly during August. During this time most of the students are not in the university or tend to spend a limited amount of time on the university websites so they may not easily come across and answer a survey. Also, the time span of a survey may have an impact on the sample size. Again, when looking at the previous example with the study population of university students, it is unlikely that a big sample size is to be achieved during summer months. As a consequence of a limited sample size, outcomes may be unevenly distributed regarding participants' parameters. Therefore, some socio-demographic characteristics may need to be grouped in order to form bigger sub-groups such as the ethnicity of the students. Thus, instead of many ethnic groups, ethnicity may be limited to only Black, White or Other. Furthermore, when the research design incorporates a non-probability or convenience sampling, this may also lead to sampling biases and corresponding limitations. When a sample has not been chosen randomly, this

can result in a non representative population, thus the results cannot be generalised to the rest of the student population.²⁰

Some studies within the nursing paradigm gather data through self-reporting questionnaires in order to identify relationships between variables. By using these, the researcher relies on the honesty of the participants and the problem starts at the point where the respondent is willing to disclose the truth or not.²¹ It is a common problem in behavioural research that the questionnaire involves personal and sometimes indiscreet questions; however, most studies try to avoid seeking invasive personal data and the survey questionnaires are usually anonymous. Still, there may be some participants that do not want to report their actual, true responses and therefore this can constitute another limitation to a study. The semi-structured, open-ended interview is a gold standard alternative for questionnaires in qualitative health research. Yet, despite its methodological merits, a long interview is unsuitable when participants find content sensitive to discuss, or when they have restricted communication skills. Thus, researchers who explore emotionally sensitive topics should look for alternative data collection methods and careful wording that lead to uninhibited emotional expression.²²

Last but not least, the use of Likert scale on the questionnaire can be a limiting factor when asking attitudes or behavioural questions. Many participants may avoid selecting the extreme measures 'Strongly Disagree' and 'Strongly Agree' and prefer choosing middle measures like 'Agree' and

'Disagree'; this could lead to masking of the intensity of the real attitudes and behaviours of the participants.^{23,24}

Although unbiased and frank discussion and detailed presentation of a study's limitations are the core part of scientific integrity, too few papers in the medical literature openly admit to how limitations could affect their findings and interpretations. Morris and Ioannidis explored some philosophical and scientific underpinnings of clinical research and corresponding evidence within the patient-clinician arena.¹² They suggest that due to lack of credible evidence making correct clinical choices is often a low-probability exercise. Thus, when study limitations are not clearly expressed, the findings may wrongly guide clinical practice to an extent where these may become the new 'unquestionable' therapeutic or interventional norm.

In every day rhetoric and daily interactions, assumptions cannot be avoided as every viewpoint holds to some degree a concealed assumption. Research assumptions are essentially issues, ideas, or positions found anywhere from the beginning of the study design to the final report, that are taken for granted and viewed as reasonable and widely accepted. Regarding nursing studies, the researcher may assume for example that the respondents will show true responsiveness to a face-to-face interview. Yet, in reality, some respondents may intend to answer in terms of 'what the researcher wants to or would be pleased to hear'. According to Hyland,²⁵ authors should be presenting a proposition as an opinion rather than a fact, i.e. should "hedge" their statements. Thus, by using

hedging, authors can express an element of uncertainty about their study's validity in order to prevent readers from accepting strong or definitive statements without critical interpretation.

Although a conscientious author seeks to report his results by avoiding unfair assumptions, all too often nursing literature is littered with crude examples of stereotyping or over-generalizations. A typical example has just been provided in the preceding sentence where the assumption was made that 'most authors are male!'. Similarly, in many nursing journals, the prevailing culturally associated assumption is that nurses are female. Yet, research assumptions and biases are so commonplace and inherit to the content of any study, Leedy and Ormrod (2016) state that, "...without them, the research problem itself could not exist".⁶ Thus, as long as these are spelled out clearly in either the study limitations section or in the discussion, the author is covering for potential pitfalls. Yet, even more importantly, an investigator needs to clarify and record all identified assumptions.

Although not identical, often limitations and assumptions are viewed interchangeably as of the same essence and hence, grouped together. Therefore, a researcher should not only cite them distinctively (e.g. in the Methods and Discussion/Conclusions sections respectively), but also take adequate steps that these are not contradicting each other both at a theoretical and practical level. For example, if a particular statistical test is used which has inherited limitations concerning data distribution, when reporting results, generalizations should be avoided. In this respect, it becomes apparent that

a study's limitation is totally outside that researcher's control, while an assumption is somewhat. Yet, both should be clearly addressed.

Thus, in order to optimise a study from contemplation to completion, a valid self-reflective exercise during all research stages should be exercised. That is, the investigator should challenge his/her own biases, judgments and assumptions, whether personal or in an assumed wider socio-cultural context. In this respect, self-reflection exercises may turn uninformed assumptions to informed opinions. Unfortunately, some authors cite study limitations solely because it is required by journal policy. Furthermore, under these circumstances, the weakest limitation may be put forward in an attempt to 'safeguard' the study's chance of being published.

Conclusions

Serious rethinking and restructuring of the global nursing and biomedical research agenda is necessary to upgrade the profession and reassure the public. Authors should report their research limitations, delimitations and assumptions in order to improve the quality of their findings and the interpretation of the evidence presented. On the contrary, when any of these key elements are neglected, overlooked or hushed, the study kudos is jeopardised. However, when a solid study elaborates on its limitations, delimitations and assumptions, it is more likely to be cited and may also act as a benchmark for future nursing research endeavors.

Overall, study limitations, delimitations and

assumptions should be put in the context of the entire paper. In this respect, authors will tend to present a proposition as an opinion rather than a fact. Thus, researchers will be exposing the possible uncertainties of the study and the readership will decide more easily if the findings are supporting weak or definitive conclusions or if further studies are definitely needed before clinical practice can be informed accordingly.

This paper itself has its limitations as it was designed as a critical analysis rather than an extensive literature review whereby biomedical literature would have been scrutinised for individual limitations. For example, a detailed assessment of all relevant papers (in the region of thousands) would have revealed all recorded limitations within the selected papers referring for example to aspects of internal validity which could distort the results. Delimitations of this paper include the lack of depth when statistical techniques were discussed and presented in the text. Assumptions of this paper include that the basic premise that all aspects of the notions of Limitations-Delimitations-Assumptions have been adequately covered and thoroughly discussed

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