

Review articles

Essential aspects in the design of data collection instruments in primary health research

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ABSTRACT

Objective: to investigate the literature production on the design of forms for research in the health area and describe the most relevant concepts and precepts of the topic.

Methods: an integrative literature review in the PubMed and Scielo databases with the key words: survey, constructing, questionnaire, formulary, development and design in various combinations, including articles published in any language in the last ten years. The survey returned 1,480 articles, and after reading and critically reviewing the abstracts according to the objective of the study, 16 articles were selected for complete reading. Information regarding aspects that were most relevant to the objective of the study was analyzed, as well as its recurrence in the selected articles.

Results: the reading of the 16 articles resulted in three categories, based on the recurrence of the themes: structure, validation and sampling.

Conclusion: clarity in the formulation of the questions was the most valued aspect in the structure of the instrument. As for validation, the realization of pilot tests was considered fundamental. Finally, the method of administration and adaptation of the questionnaire to target population was considered fundamental.

Keywords: Health Surveys; Surveys and Questionnaires; Methodology; Review

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INTRODUCTION

Health research involving human beings consists of generating new knowledge through the use of the scientific method to identify and deal with health problems. Knowledge acquired through research is considered a global public good¹. The Committee for Health Research and Development, created in 1987 based on the premise of comprehensive analysis of health conditions and health research, pointed out that research is essential for health actions and health promotion, and it is also necessary to contribute to new ideas and alternative interventions².

In Latin America, health research is concentrated in some countries, that happen to be the largest economies: Mexico, Chile, Brazil and Argentina. These countries contribute with 90% of the total Latin American investment in research and development³. Among Latin American countries, Brazil has a high production in the areas of public health, biotechnology and pharmacy. Over the past two decades, the focus on reducing poverty, child and maternal mortality, and combating HIV, malaria and other diseases has given impetus to improvements in health care and investments in this area. The understanding is that investments in health research have a direct effect on meeting the aforementioned goals³.

Scientific research requires extensive planning, human and material resources, time and effort. The application of instruments such as questionnaires and forms is an effective way to collect population data with relative logistical practicality.

Health research instruments are essential tools to gather information from individuals that represent a given population since health research has diverse objectives, from those focused on experiments (e.g. search for a new drug treatment, a new intervention), to those of observational nature (e.g. assessment of risk factors, assessment of quality of health care, description of indicators). Each objective of health research should be interconnected to the feasible dimensions. For example, the study of patient perceptions regarding health treatments is an important tool to identify strengths, weaknesses and unmet needs in health services as well as to identify changes in patient satisfaction over time^{4,5}.

For the development of scientific research with primary sources, it is necessary to formulate clear and functional instruments during the planning stage of the study. They should contemplate questions that will originate variables to enable a response directly

associated with the objectives of the study. In addition to assessing what they are proposing, they should have stability, i.e., they should present similar results in test and retest when subjects are in the same health condition⁶. Some errors are recurrent in this field; some of them are related to the layout of the instrument: too small font size; too long instrument; selection of an opportunistic sampling that excludes certain groups that would be of interest to the research⁷.

The design of an instrument is an extremely important aspect to ensure that the data will be accurately collected and the results will be interpretable and generalizable⁶. The form of application (postal delivery, telephone, face-to-face or the Internet), taking into account the particularities of the study design⁶ appropriately targeted to the study population, as well as validation, are also questions to be evaluated for the creation of effective and efficient instruments. All this must be taken into account, since a biased tool sent to an unrepresentative sample will not provide useful information, but rather distort the possible actual results of the research.

The reality of health research, especially of observational nature, is that studies do not always present adequate rigor for the creation of research instruments, this fact is observed in publications of studies whose data collection tools are not validated and/or their interpretations are not clear, leading to unintelligible data or erroneous conclusions⁸.

Given the importance of planning in research, the objective of this study is to survey the literature on the design of health research forms and describe the most relevant concepts and precepts of the theme.

METHODS

This is a study with data collection from secondary sources, through an integrative review of the literature performed in the Scielo and Pubmed databases. The keywords “survey”, “constructing”, “questionnaire”, “formulary”, “development” and “design” were used, resulting in 1,480 indexed articles with selection filter set for articles published from 2006 to 2016, in any language, and without design restriction. After reading and critically analyzing the titles and abstracts, taking into account the proximity to the objective of the present research, the articles that did not present in the description the context of design of questionnaires/instruments/forms and/or validation studies were excluded. At the end, 16 articles were selected. The selected articles were read in full length, and

the information on journal and year of publication, objective, type of study involving the elaboration of the research instrument, aspects considered for the elaboration of the research instrument, bias of assessment, attention to the application of a pilot study to test the instrument of data collection, and influence of the type of population on the application of instruments, were factors to be considered, among others. The content

was categorized according to the aspects most relevant to the nature of this work and the frequency in which it appeared in the selected literature. Methodological and theoretical issues associated with the preparation of a health research instrument were evaluated and a list of guidelines for decision making at each stage of such development were presented (Figure 1).

Search strategy	Initial result	Result after analysis
SURVEY [Title/Abstract] AND Constructing [Title/Abstract] AND ("2006/04/23"[PDAT] : "2016/04/19"[PDAT]) -PUBMED	201	0
((survey[Title/Abstract] OR QUESTIONNAIRE[Title/Abstract]) OR formulary[Title/Abstract] AND designing[Title] AND ("2006/04/23"[PDAT] : "2016/04/19"[PDAT]) -PUBMED	115	9
(survey[Title] OR questionnaires[Title]) AND development [Title] AND ("2006/04/24"[PDat] : "2016/04/20"[PDat]) -PUBMED	581	2
(ti:((questionnaire) AND (elaboration) OR (design))) -SCIELO	583	0
Questionnaire [Title] AND developing [Title] AND ("2006/04/30"[PDat] : "2016/04/26"[PDat])	61	0
Similar articles for PubMed (Select 17239058)	419	5

Figure 1. Summary of search strategies in Pubmed and Scielo

LITERATURE REVIEW

Main findings

Among the 16 selected articles, three distinct categories were found based on the recurrence of the themes: structure, validation and sampling (population studied). Aspects related to the structure were described in 10 articles (62.5%); those related to the population (subjects of the research/sampling/form of administration) appeared in 10 (62.5%); aspects related to validation appeared in 8 articles (50%), with emphasis on pilot studies that were recurrent in 75% of articles that addressed validity. Each aspect was then discussed and the most relevant concepts were highlighted.

Structure

Before preparing a new instrument, it is recommended that a literature review be done to verify if there is no validated instrument for the theme in question; if a data collection tool (research tool) needs to be created, a search in the literature for the recommended scale and items (categories) more relevant to respond to the purpose of the study should be done. In quantitative studies, once the main research items are defined,

the questions should be prepared so as to provide variables on each of these items, whereas in qualitative studies they should provide answers that are coherent with the guiding question without the need for systematized items^{7,8}.

An instrument with an adequate structure should consider the type of question (objective, subjective), the language used, which must be appropriate for the studied population and the order of the items. Questions should be formulated so as to ensure that each is easy to understand, free from information bias, and appropriate to the level of education and culture of the participants⁷⁻⁹.

Given that the order of the questions influences the answers, the literature indicates that questions should be organized from the easiest to the most difficult; from the general to the specific; from the factual to the abstract. Clinical and demographic data should be left to the end of the instrument because they are easier and potentially intrusive^{5,6,9,10}. Controversial or emotive items should not be placed at the beginning of the instrument^{5,9}.

In addition to the questions, researchers should consider the best response format (open, closed, dichotomous, multiple choice, ordinal, among others).

In cases of scale, the choice should be designed to contribute positively to data collection and to the purpose of the study^{7,11}.

Closed questions are easier to analyze and apply, but the downside is that they reduce the number of possible responses. This way of questioning can provide summary information and reduce the misinterpretation bias of what was written by the participants. In turn, open questions allow respondents to put their own answers that increase the range of possible answers and of individuality. With these type of questions, researchers can often measure the importance of a particular subject better, but the analysis and comparison is challenging. In general, an effort needs to be put to the formulation of objective questions, while in the case of open questions, the effort will be concentrated on data interpretation; the fact is that the choice for either of the options will depend on the objective and the study design^{5,6,8,10}.

Validation

Validity is the degree of congruence between what the instrument proposes to measure and what it actually measures; a valid tool should question what the researcher wants to ask and the questions should be formulated in such a way that the interviewee understands the purpose of the question.

There are four different dimensions in the validity of an instrument: apparent validity (logical dimension), content validity (face), concept or construct validity, and criterion validity¹².

Apparent validity (or logical dimension) refers to the extent to which it seems that the instrument measures what it proposes to measure in the view of specialists and of the subjects themselves. This validity must be verified at the time of structuring the instrument, because when the issues do not have logical validity, it is highly likely that individuals will refuse to answer the questions. However, in specific cases, in order to achieve apparent validity, the instrument must undergo a pilot test with the target population (e.g. if the target respondents are diabetic patients, so one of these respondents should comment on his understanding of the instrument). Any uncertainties and doubts should be clarified until the question becomes easy to understand. When instruments are extensively tested and correctly calibrated for their target, they can be considered accurate^{5,6}. In some cases, it may be interesting to formulate questions without logical validity, because in sensitive or controversial issues, the use of

questions with too much apparent validity may cause the subjects decide not to respond or distort their response¹².

Content validity (or face validity) refers to the opinion of the expert on whether the items in the scale represent the domains or concepts proposed for the research. It is therefore considered that an instrument is valid if it considers all aspects related to the concept studied. For example, a teacher gives a course consisting of five classes, each with a different content, and he decides to evaluate how much the students learned through a test. In order for the content to be valid, the test must contain a set of questions that is representative of the contents given in all the five classes, with the same number of questions about each class¹³. This dimension of validity is related to the composition of an instrument; it evaluates whether it contains a representative sample of the components of the construct to be measured. This validation involves the systematic analysis of the contents of the measuring instrument to determine whether the questions are relevant and the essential characteristics of the construct are represented in the appropriate proportions. Content validity assessment is based on judgments from different sources (review of medical literature, expert opinion, pilot studies)^{8,9}.

The validity of a construct (or concept validity) evaluates the extent to which the instrument reflects the theory of the phenomenon or of the concept to be measured. It ensures that the measurements resulting from the responses can be considered and used as a measure of the phenomenon studied. The measurement of the theoretical concepts requires the prior identification of the content of the instruments that they used and the elaboration of a conceptual model to help interpret the obtained results. That is, if a test that intends to measure speech changes, whether phonetic or phonological deviations, effectively measures such changes, as proposed by TERDAF¹⁴ or it has concept validity. Factor analysis is a statistical technique that can be used to determine the constructs or domains in the developing measure, that is, it groups responses according to the underlying factors^{9,12}.

Criterion validity is the type of validity that is commonly referred to when validating an instrument. It involves the following steps: identifying a relevant and reliable external criterion; obtaining a representative sample of the subject for the population in which the instrument will be used; applying the instrument and obtaining a score for each subject, and evaluating each of the individuals with the external reference value¹². For

example, for an instrument that evaluates intelligence, a relevant criterion could be school performance¹³.

A valid instrument, whether questionnaire or form, should be simple, feasible and acceptable to patients, users and researchers (viability); reliable and accurate (reliability); appropriate to the research problem (content validity); reflecting the theory underlying the phenomenon or concept to be measured (construct validity); and able to measure changes, both in different individuals and in the responses of a single individual over time (sensitivity to changes)^{8,12}.

Sampling (research subjects/form of administration)

Once the research question is defined, the target population must be established⁷, which can have people, houses, organizations or other aggregates as a unit, in order to enable the researchers to achieve the planned objectives, including the design and application of the instrument. After this step, and according to the study design and structure of the research, the sampling method should be defined.

As for data collection, the research tools can be self-administered or interviews can be applied via facilitator (interviewer). Self-administered instruments are more widely used. They must have clear instructions and questions and follow a logical order to ensure a high response rate, which is lower in this method when compared to other ones. However, respondents are more likely to respond sincerely without the presence of

an interviewer. On the other hand, when an instrument is applied by an interviewer, the questions can be more complex, as they can be clarified. However, the presence of an interviewer may pressure respondents to give what they deem to be “appropriate” rather than true answers. Furthermore, this last method consumes much more time and resources. The form of administration must be adapted to the target population, to the research resource structure, and to what is intended to be achieved with the application of the instrument^{5,6}.

Poor data collection is a barrier to high-quality research¹⁵ because no statistical technique, no matter how sophisticated it is, can correct data whose collection was poorly planned. The data collected must be truly capable of responding to the question of interest and all relevant information must be recorded in a way that allows it to be easily used for further analysis. Poorly designed forms often have high levels of missing data. An obvious consequence is that this reduces the number of individuals that can be included in the study and consequently the possibility of an effect being detected, if it exists. The script for collecting secondary data (for example, searching for information in medical records) should also be systematized and, as far as possible, follow the aspects described above.

Figure 2 describes the main themes described in each integrative review study.

Journal/Year of publication	Author (s)	Title of the article	Objectives	Description
Archives of Disease in Childhood Education, 2016	Thwaites Bee, D. and Murdoch-Eaton, D. ⁽⁷⁾	Questionnaire design: the good, the bad and the pitfalls.	To describe the development of a questionnaire: advantages, disadvantages and challenges.	It shows considerations about sampling; design, types of questions/scales; administration and pilot test. Examples of what to do (or not to do) in this process are presented.
Nurse Researcher, 2016	Doody, O.,Bailey,M.E. ⁽¹⁶⁾	Setting a research question, aim and objective.	To describe the development of a research question, objective and purpose.	It presents considerations regarding the development of a research question and its objectives, and subsequently of the types of questions/scales; sample; administration and pilot test.
Journal of Korean Academy of Nursing, 2015	Song,Y.et al. ⁽¹¹⁾	Methodological issues in questionnaire design.	To discuss the design of questionnaires and the factors that should be considered when using existing scales.	It describes the process of preparing questionnaires and adapting existing ones, as well as aspects related to administration; design; pilot test; sample and combination of qualitative and quantitative methods.
BMC Medical Research Methodology, 2014	Dell-Kuster, S. et al. ⁽⁴⁾	Designing questionnaires: healthcare survey to compare two different response scales.	To intra-individually compare two types of response scales to five general questions to assess patient perception of hospital care.	It presents types of scales/questions (design); intra-individually compares responses on two types of scales.
Annals of the Royal College of Surgeons of England, 2013	Jones, T.L. et al. ⁽¹⁷⁾	A quick guide to survey research.	To address the key aspects of designing, implementing and analyzing a research, as well as focus on techniques that improve response rates.	It describes guidelines on how to assemble, apply and analyze instruments based on administration; design; pilot test; sample.
Medicine 20, 2013	Jones, T.L. et al. ⁽⁵⁾	Development of a questionnaire and cross-sectional survey of patient eHealth readiness and eHealth inequalities.	To develop and validate a self-administered questionnaire and a scoring system to assess the patient's e-Health readiness.	It demonstrates the preparation of a self-administered questionnaire, including sampling, administration and pilot testing.
Journal of the Pakistan Medical Association, 2012	Kazi, A.M. and Khalid, W. ⁽¹⁰⁾	Questionnaire designing and validation.	To provide a basic introduction and overview of questionnaires for epidemiological studies.	It provides examples of common problems, solutions and guidelines for developing and adapting questionnaires, such as: types of questions; language; design; administration; validation and pilot test.
Journal of Trauma and Acute Care Surgery, 2012	Bobrovitz, N. et al. ⁽¹⁸⁾	The development and testing of a survey to measure patient and family experiences with injury care.	To develop and test a research instrument to measure the patient's and family's experiences with treatment of serious injuries.	It describes the development and testing of a questionnaire to measure traumatic experiences from the point of view of the patient and the family. It describes the use of pilot tests and elucidates aspects of sampling and validity.
Canadian Journal of Anesthesia, 2012	Bryson, G.L. et al. ⁽⁹⁾	The science of opinion: survey methods in research.	To provide a guide for those conducting surveys based on questionnaires and for interested readers of surveys.	It highlights several key principles of successful research from the point of view of the sample and the population, as well as aspects about administration; pilot test; creation and reduction of items.
Otolaryngology - Head and Neck Surgery, 2011	Slattery, E.L. et al. ⁽¹⁹⁾	A practical guide to surveys and questionnaires.	To present a practical guide to understand the research methodologies and the design of questionnaires, including the concepts of validity and reliability, and how surveys are administered.	In addition to addressing topics such as: design; order and structure; sample; administration; validity and reliability; and pilot testing, it also deals with possible biases in assessment.
Phlebology,2011	Smith, C.J. ⁽¹⁵⁾	Designing a research study.	To analyze the design and data collection phases of a research study.	It addresses the phases of conception and data collection of a research study, demonstrating questions about population, sample and administration.

Journal/Year of publication	Author (s)	Title of the article	Objectives	Description
Journal of Wound Ostomy & Continence Nursing, 2010	Pittman, J., Bakas, T. ⁽²⁰⁾	Measurement and instrument design.	To discuss the theoretical issues that are fundamental for the development of instruments, including conceptual models, selection of instrument types, design and construction of questionnaires, establishment of content validity, determination of reliability and determination of validity.	It describes fundamental theoretical questions for the development of instruments, design and construction of questionnaires, and establishment of reliability and validity.
Medical Teacher, 2009	Burford, B. et al. ⁽²¹⁾	Asking the right questions and getting meaningful responses: 12 tips on developing and administering a questionnaire survey for healthcare professionals.	To provide simple guidelines on some of the potential pitfalls in the development and execution of research studies, and how to avoid them.	Twelve guidelines for formulating a questionnaire are presented, among them: design, sample and reliability, validity and pilot test; and aspects of financial and time planning, bringing real examples of the situation in each of the steps.
Reumatología Clínica, 2009	García de Yébenes Prous, M.A. and Rodríguez Salvanés, F. ⁽¹²⁾	Validation of questionnaires.	To describe the methodology for a study of feasibility, reliability and validity of questionnaires: how scales or measurement instruments allow obtaining and quantifying data to compare information.	It gives details of the fundamental aspects of validity and reliability.
Journal of Clinical Nursing, 2007	Rattray, J. and Jones, M.C. ⁽⁸⁾	Essential elements of questionnaire design and development.	To raise awareness about issues related to the creation of questionnaires and the subsequent psychometric assessment, and provide strategies to enable researchers to design and develop their own instruments and assess the quality of existing instruments.	It addresses psychometric evaluation issues and provides strategies to enable researchers to design and develop questionnaires through different types of questions/scales; creation and selection of items; ordering of questions; pilot test; validity, reliability and quality.
Malaysian Family Physician, 2006	Jenn, N.C. ⁽⁶⁾	Designing a Questionnaire.	To describe guidelines for building questionnaires and the implications of not following them.	It explains how to design a questionnaire considering the analysis of the answers. It synthesizes aspects of validity and reliability and pilot test; as well as aspects linked to the design, the types of questions and the order; translation and administration.

Figure 2. Description of the main findings of each article of the integrative review

CONCLUSION

As for the structure, keeping the clarity in the formulation of the questions was the most valued aspect, while in validation, the realization of pilot tests stood out. As for the population, the way of administration (interview, the internet, among others) and the adaptation of the instrument to that sample of subjects were outstanding aspects. Proper planning of the health research form can minimize possible biases and errors in the conduction of the scientific studies.

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