

Questionnaire development: 1. Formulation

Linda Del Greco, EdD
Wikke Walop, PhD

This article is the first of a five-part series designed to acquaint the reader with the process of questionnaire construction. Such information can help in reviewing research studies that have used questionnaires, in selecting a questionnaire for one's use or in formulating a questionnaire. This series is not meant to be definitive but, rather, is presented as a convenient introduction to the development of questionnaires. For a more in-depth view of the topic the reader should consult the "Additional reading" suggestions at the end of this article.

Throughout this series "questionnaire" refers to a set of questions asked by an interviewer, who then records the answers, rather than a set of questions completed by a respondent, as with mailed questionnaires. Interviewer-administered questionnaires are usually used to determine how individuals or groups differ with respect to certain traits or variables and should not be confused with those that are used to predict or evaluate health.¹

Frequently in research articles, only a single sentence is devoted to the development of the questionnaire: "A 42-item questionnaire, developed by the authors, was administered to all subjects." For the experienced researcher this statement resurrects images of the arduous process of developing the questionnaire; for the neophyte the sentence conveys the idea that questionnaires are casually constructed. In fact, the process is complex and includes defining the domain, determining the types of questions and formulating them, establishing validity and reliability, translating, summarizing the results and pretesting.

From the Department of Epidemiology and Biostatistics, McGill University, and the Division of Clinical Epidemiology, Department of Medicine, Montreal General Hospital

Reprint requests to: Dr. Linda Del Greco, New York Hospital, 21 Bloomingdale Rd., White Plains, NY 10605, USA

Defining the domain

Before the questions can be designed, it is necessary to have a clear idea of what is being investigated. This process of defining the domain is not as obvious as it appears. Ideas that seem clear in daily conversation quickly become murky when scrutinized. For example, a routine question when recording a patient's history is "Has there been a change in your appetite?". The patient's answer may refer to energy intake, anticipation of meals, attitude toward eating and going to restaurants, taste of food, or a combination of these. When the domain is well defined within the scientific community, and the researcher agrees with the extant formulation, it need not be redefined, and the researcher may proceed directly to formulating questions.

The domain is usually defined by gathering information from as many relevant sources as possible, such as the literature and experts in the field. The information gathered from experts would be categorized by the research team and then evaluated by a second group of experts. Through this process of establishing content validity the domain and the terms of reference are delineated. Content validity will be addressed in depth in part 2 of this series.

Determining the types of questions

The types of questions must be determined before the questions can be drafted. Most questionnaires contain a variety of question types, depending on the information sought.

Open-ended questions

Open-ended questions, such as "How would

you describe the pain you feel?", allow the subject to answer freely in his or her words. Such questions can be a rich source of responses and are used in particular to determine feelings or opinions. A disadvantage to this approach is that the data must be summarized for computation and statistical analyses, and the diversity of answers is lost. In addition, because someone has to interpret and categorize each answer, inferential error may be introduced. Sometimes the answers are best used verbatim to illustrate a point under discussion rather than as a summary statement. Moreover, such responses depend on the subject's ability and willingness to recall events or feelings.

Closed questions

Closed questions, such as "Are you feeling any pain now?", force the subject to select from among the answers already chosen by the researcher. The subject does not have to rely on recall since the choices provided may prompt memory. The choices must be all-inclusive and mutually exclusive. These questions have the advantage of being easy to administer; in addition, the resulting data are easy to summarize. However, subjects may resent a forced choice, particularly concerning emotions or personal matters, and they may tire of long lists of choices and then not complete the questionnaire.

Semi-closed questions

Semi-closed questions, such as "When you were discharged from the hospital were any of the following medications prescribed?: pain killers, antibiotics, sleeping medication or other medications (please specify)", offer the subject a limited number of choices to facilitate recall and the freedom to include additional information.

Vocabulary

The vocabulary is determined by identifying who can best provide the information being sought. Medicine, like other professions, has a specialized vocabulary. Therefore, when drafting questionnaires it is important to ensure that the appropriate vocabulary is used. For example, "radical mastectomy", "modified mastectomy" and "breast amputation" are distinct and meaningful terms to physicians. However, for the lay person the use of "mastectomy" in general or "surgical removal of breast" may be more appropriate.

In general, familiar words are better than complex ones whose meanings are either unknown or unclear to the public. Payne² rated 1000 familiar words as being problem-free, problematic or having multiple meanings. If subjects do not understand a word or phrase, they may guess at its

meaning to avoid embarrassment, and this may result in inaccurate responses. Similarly, slang, ethnic or regional words are to be avoided because they may not have the same meaning for all subjects or may be objectionable or misunderstood.

Formulating the questions

There are several important warnings to bear in mind while drafting questions. Avoid ambiguous words; for example, in the question "Do you often have nosebleeds?", the word "often" is ambiguous, and its meaning will likely vary from person to person. The question would be better if worded "How many nosebleeds have you had in the past 2 weeks?".

Avoid double-barrelled questions such as "Are you in favour of performing tubal ligations on single and married women?". The question calls for a Yes or No response, but it cannot be accurately answered if the respondent favours the procedure for only one of the two groups mentioned.

Avoid leading questions such as "Don't you think pain killers should be available on demand?". The phrase "Don't you think" indicates that the researcher has already determined the preferred answer, and its use might encourage the respondent to agree.

Double negatives in a sentence cause confusion and lead to uninterpretable responses. "Do you think that *lack* of money is *not* an issue in obtaining health care?" would be more clearly stated as "Do you think that *lack* of money *is* an issue in obtaining health care?".

Issues in format

An important goal in designing a questionnaire is to maintain the respondent's compliance and interest. Therefore, questions of high relevance are placed at the beginning of the questionnaire, and those used to check the consistency of answers are placed at the end. Moreover, embarrassing or sensitive questions are usually placed at the end; such questions include those on age, income, education, ethnic background, sexual behaviour and the use of alcohol or drugs.

Questions on a given topic are usually clustered, to facilitate not only memory but also the use of skip patterns. For example, when one is gathering information on general health all the questions about menstruation would be clustered. The first question would determine whether the subject menstruates. For women who do not menstruate and for men the interviewer should be directed to skip to the next set of questions. However, if applicable questions are inadvertently skipped, important information will be lost.

The areas discussed in this paper set the stage for the first draft of the questionnaire. How to

ensure a valid and reliable questionnaire will be covered in the next issue.

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ELDERLY:

The recommended dosage of NOROXIN* in elderly patients with normal renal function for their age is the same as given for adults above.

IMPAIRED RENAL FUNCTION:

In patients with a glomerular filtration rate of less than 30 mL/min./1.73 m² (0.50 mL/s/1.73 m²) but greater than 6.6 mL/min./1.73 m² (0.11 mL/s/1.73 m²) the recommended dose is one 400 mg tablet once daily. (See PRECAUTIONS.)

When only the serum creatinine level is available, the following formula (based on sex, weight, and age of the patient) may be used to convert this value into creatinine clearance. The serum creatinine should represent a steady state of renal function.

Males:
$$\frac{\text{Weight (kg)} \times (140 - \text{age})}{72 \times \text{serum creatinine (mg/100 mL)}}$$

Females: 0.85 x above value

To convert to international units multiply result by 0.01667

The administration of NOROXIN* to anuric patients is not recommended.

CHILDREN:

The safety and efficacy of NOROXIN* in children have not been established. NOROXIN* should not be used in patients in whom epiphyseal closure has not occurred (see WARNINGS).

DOSAGE FORM

Ca 9642 — NOROXIN* (norfloxacin) 400 mg Tablets are oval shaped, white, film coated compressed tablets scored on one side and engraved MSD 705 on the other.

Availability

Available in bottles of 30 tablets.

HUMAN PHARMACOLOGY

NOROXIN* is rapidly absorbed following oral administration. In healthy volunteers 30-40% of

an oral dose of NOROXIN* is absorbed. This results in a serum concentration of 1.5 mg/L being attained approximately one hour after administration of a 400 mg dose. Mean elimination half-life is approximately 3 hours.

Norfloxacin is eliminated through metabolism, biliary excretion, and renal excretion. After a single 400 mg dose of NOROXIN*, mean antimicrobial activities equivalent to 164, 338, 632 and 126 µg of norfloxacin/g of feces were recovered over 0-12, 12-24, and 24-36, and 36-48 hours respectively.

Norfloxacin exists in the urine as norfloxacin and six metabolites. The parent compound accounts for over 70% of total excretion.

Renal excretion occurs by both glomerular filtration and tubular secretion, as evidenced by the high rate of renal clearance (approximately 275 mL/min.). After a single 400 mg dose, urinary concentrations reach a value of 200 or more mg/L in healthy volunteers and remain above 30 mg/L for at least 12 hours. 25-30% of the drug is recovered in the urine within 48 hours.

In healthy elderly volunteers (67-74 years of age with normal renal function for their age), norfloxacin is eliminated more slowly because of their slightly decreased renal function. Drug absorption appears unaffected. However, the effective half life of norfloxacin in these elderly subjects is 4 hours.

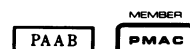
Following a single 400 mg dose of norfloxacin, the excretion of the drug in patients with creatinine clearance greater than 30 mL/min./1.73m² is similar to that of healthy volunteers. In patients with creatinine clearance less than 30 mL/min./1.73m² but greater than 6.6 mL/min./1.73m², less than 10% of an oral dose was excreted in urine. The mean elimination half-life is 6.5 hours. Drug absorption appears unaffected by decreasing renal function.

At a serum concentration of 2.5 mg/L the human serum protein binding is 10-15%.

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