Contemporary Themes

Design of forms for clinical trials (3)

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If one accepts that the design of the forms used in clinical trials is important, and that there is behavioural research which might be drawn on to improve their design, the question now is how can such improvements be achieved. One mistaken view is to hope that when behavioural scientists have explored all the many facets of form design there will arise a set of guidelines that guarantee success. Certainly, summaries are available of the research on graphic communication,¹⁻³ and we give a synopsis of our major conclusions in this paper. There are also discussions of questionnaire design⁴ and of alternative production methods.⁵ But many of the problems of designing forms are not straightforward—for example, issues about the content of the form cannot be decided from a set of guidelines.

Procedures for constructing forms

The design process might be thought of as in some senses analogous to smoothing the surface of a rough piece of wood. There is no single "best" way, nor is a single tool adequate for the task. Different procedures are appropriate depending on the current unevenness of the surface and on the degree of smoothness required. The points of difficulty within a trial form (corresponding to the unevenness of the wood) may be located and cured by a range of research techniques as diverse as surveys, field trials, and laboratory-based explorations.⁶ Perhaps the most readily available index of the frequency of trouble spots on a form may be the length of the guidelines issued to the form-filler. These accompanying notes are often several pages long, certainly too long to expect the reader to remember all the information in detail. It might be a hallmark of a well-designed form that all necessary information is included on the form where the form-filler most needs it.

A more sensitive index of difficulty within a form may be obtained from pretesting the draft version. In fact, this may be the only procedure for detecting certain ambiguities, since misunderstandings arise from too many sources for it to be possible to catalogue them all in a set of guidelines. The more thoroughly the form can be piloted across all its stages from distribution, through completion, to data analysis, the more likely it is that the final document will be adequate for its intended purpose. Even "simulations"—for example, asking medical students to complete the forms from case-history data—may often have their own inherent problems.⁷

But authentic piloting is time-consuming. Many of the rough edges could be removed if some informed criticism were readily available.⁸ It might be a useful service if those organising clinical trials could be provided with a "forms advice centre" along the lines of the randomisation centre provided at Oxford. Possibly such a centre might draw on the combined skills of a multi-disciplinary team of experts in statistical analysis, graphic design, and cognitive psychology. Computer programs have been developed which can help in the design and production of forms.⁹ What is needed is a means of easily tapping the relevant skills.

Would the provision of such a centre be too costly? In general, attention to the design of a measuring instrument can hardly be less important than the activity of going ahead and measuring. As with other measuring devices, errors that are systematically related to the design of a form will not necessarily be random. It follows that no statistical procedures, such as increasing the sample size, will eradicate misinformation obtained from the form. The only safeguard is design procedures that ensure a minimal level of adequacy. In time, the adoption of such procedures will lead to experience which can be used to provide clinical trials with well-designed forms.

Summary of recommendations for designing forms

THE PRINT

Select a print size comparable with that used for text in newspapers.

Select a print font that will allow for image degradation if the form is photocopied.

Use lower-case letters for text rather than all capitals.

Printed words are easier to read than most typescript, because typewriters usually allot each character the same space.

The spacing between words should be uniform, even if this gives a ragged right-hand margin.

Print colour should fall within specified contrast limits, and it should have some consistent communicative function—for example, to differentiate notes from questions—rather than be used as decoration; but this information will be lost if the form is photocopied.

THE LAYOUT

Spacing between lines needs to be greater for longer lines.

White space should reflect the meaningful groupings within the material—for example, interline spacing should be in proportion to the "size" of the block, perhaps twice as much between separate sections as within sections. Form-fillers need to be able to see the "path" from question to question through the form.

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When there is no need to align the right-hand margin then the end of the line can be chosen to reflect the natural breaks within the text. Hyphenation of words at the end of a line should be avoided.

Gaps between questions and the location of the answer space should be kept as small as possible.

Similarity of format across questions will help the form-filler and reduce the accompanying instructions and notes.

THE QUESTIONS

Free response questions—

- (a) Provide enough room for the answer to be written.
- (b) Answers become less legible in character segmented spaces—for example

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 or

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Yes/No questions—require a response to what does apply—for example, ticking or circling—rather than asking people to delete what does not apply.

Sentence-style questions—for example, “the patient has trouble sleeping/waking.”

- (a) These are answered more easily when the alternatives come at the end rather than at the beginning of the sentence.
- (b) Ask for an affirmative response rather than a negative one (that is, circling or underlining rather than deleting).
- (c) When there are only two alternatives the sentence style question may be easier than the corresponding yes/no question.

Multiple-choice questions

- (a) Simple ticking responses are more accurate than many coding responses.
- (b) An appropriate sequence for the response options may save the form-filler time—for example, either by clearly representing some quantitative progression, or by having the most probable options first.

Matrix questions

- (a) Have a separate column for each question.
- (b) Organise the row and column information so that the information along one side can be easily remembered, because the form-filler may stop rereading it as he works through the matrix.

- (c) Require simple ticks in the cells rather than code numbers or letters.

MISCELLANEOUS

Notes and instructions

- (a) Blocking questions into sequences with uniform response requirements may reduce the number of instructions needed.
- (b) Instructions are often forgotten or ignored by form-fillers, so it is better to provide the information at the locations where it is needed rather than on accompanying sheets.

Language

- (a) Keep it simple. This usually, but not always, means short.
- (b) Use two separate questions rather than one complex conjunction or conditional.
- (c) Lists and other alternatives to prose paragraphs are sometimes much easier to use.

Pretesting—however informal, it is *essential* that the form should be given to some people to complete, to verify, to code, to punch. This is the only way of checking the form's adequacy.

Exceptions to guidelines—Many of the statements in these three articles require qualification. They should be treated as indicators of likely troublespots rather than as infallible prescriptions for avoiding disaster.

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Should a patient with otosclerosis be advised not to take aspirin?

Otosclerosis is a disease of bone affecting the labyrinthine capsule. Deposits of new bone occur that are at first vascular—the stage of otospongiosis—and later become sclerotic—the stage of otosclerosis. When the deposits impinge on the footplate of the stapes they prevent its normal movement, which results in a conductive deafness, and this is a common cause of deafness in early and middle life. In many patients there is an associated sensorineural deafness, which is believed to be the result of interference with the circulation of the inner ear by the new bony deposits. This may produce tinnitus. Aspirin has no effect on otosclerosis but as large doses may produce tinnitus in some patients this might contraindicate taking this drug if the patient with otosclerosis has an associated tinnitus.

Is there an association between left-handedness and stutter?

Early reports suggested that most stammerers occurred in left-handed children made to use the right hand, but this theory has not been confirmed, and nowadays few therapists or theorists believe this. Interestingly, left-handedness is commoner in twins, 10% being sinistral as opposed to the expected 4%. Over 5% of twins stammer, which is more than five times the expected number, and a genetic link between twinnings, stammering, and sinistrality has been suggested. EEGs in some cases show that the alpha rhythm is more symmetrical in stammerers (normally the alpha waves are of lower

voltage on the dominant side); this suggests less complete dominance but there is no statistical difference between stammerers and non-stammerers. Although the theory of stuttering associated with conflict between the two sides of the brain has lost currency, there is still no reason to suppose that as a group stutters have any particular physical distinguishing features, anymore than they have particular neurotic or personality characteristics that distinguish them from non-stutterers.

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Is a laboratory test to establish the diagnosis of angioedema readily available?

C1 esterase inhibitor (C1INH) and C4 concentration are reduced both during and, usually, between attacks of angioedema. The two forms of hereditary angioedema, deficiency of C1INH (80% of patients) and non-functioning inhibitor protein (20%), will be detected by measuring C4 together with C1INH. Simple immunochemical methods for measuring C1INH and C4 concentration are well established, and antibody is commercially available. Functional assays of C1INH are performed in some specialised laboratories.