Contemporary Themes

Design of forms for clinical trials (2)

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When devising a form that is easy to complete, it should be remembered that the language and layout are not independent factors—for example, not only may questions be phrased so that they are easier to understand, but they may be structured so that the amount of reading the form-filler needs to do is reduced.

In the questions about the lymph nodes in table I the form-filler must read several of the options marked N0 to N4, before the intention of the question becomes clear. An alternative question would be "If yes, what was the evidence of regional lymph node involvement?" This would enable a reduction of the wording in the first three options as follows: "N0—None, N1—single node, N2—multiple nodes."

A second interaction between language and layout is evident in table I, for the structure of the question on lymph nodes appears to be ambiguous. It is not clear where to go if the answer to the first question, "Was lymphography performed?" is No. Should the form-filler jump straight to the question on metastases? The sentence beginning "If No, a final decision . . ." appears to be a note, yet it is not typographically differentiated from the questions as were the other notes on the page. Consequently, it appears to be a precondition for answering the lymphadenectomy question—that is, "If No . . . was lymphadenectomy performed?" But this question would seem relevant even if the previous answers had been Yes. The trial organisers may see omissions on this question as evidence of the form-filler's haste or carelessness, but this is not necessarily the case. Such errors arise as a direct consequence of particular ways of asking questions.

The use of different typefaces to distinguish notes from questions is likely to help form-fillers, but some of the other typographic features shown in table I are less helpful—for example, it has been known since 1914 that it takes people longer to read material set in capitals.¹ Estimates suggest that it takes 12% longer to read a passage set in capitals compared with the same material in lower case,² probably owing to a large increase in the number of fixation pauses while reading material in capitals.³ Evidence such as this should be borne in mind when considering computer printed information—for example, the diaries of regimens. If the computer peripherals permit a mixture of upper-case and lower-case letters then there is no problem; but if the hardware will permit only the use of capitals then the time saved on production must be offset against the time lost when actually using the information.

It may appear self-evident that the presentation should help in finding one's way around the question page, but exceptions are common—for example, in the lower half of table II, there is no at-a-glance information indicating which answer boxes belong with which questions. It would have been possible for the four multiple-choice options on the extension of tumour to be put on the same line. If the presentation appeared too cramped then the text for "partially fixed" and "not palpable" could be written on two lines—just as it is in presenting the options for the question about quadrant involved. The use of both vertical and horizontal white space can clarify the underlying structure of written material.⁴

Response factors

Completing the form illustrated in table II would have been quicker if the Yes/No questions had been provided with boxes which could be ticked rather than requiring the words Yes and No to be written. Moreover, ticking boxes tends to be quicker when the boxes are located very close to the question. Table II shows several unnecessary gaps—for example, "Height above anal verge," and "Barium enema." If there is a need for answer boxes to be vertically aligned it may be helpful to have the text set to an even right hand margin rather than a left hand one, thus reducing the gap between question and answer.

Research has shown that it is better to mark the answer which does apply—for example, circling or underlining—rather than deleting what does not apply.⁵ In all cases, instructions telling the form-filler how to respond are necessary. These will be more useful if given before rather than at the end of the question. Without such instructions the response may be ambiguous—for example, if the form-filler puts a cross in a yes/no box, is such a cross a "deletion" or a vote for that answer?

There are several different methods for recording the date. Where international comparisons are concerned, explicit guidance must be given as to the order of day and month. In the USA 11/12/79 means 12 November not 11 December. Perhaps a safer procedure is to have the form-filler enter the month as three letters—for example, 11 DEC 79—but this risks transcription errors if the coder has to convert the entry into some computer-compatible numerical format.

Whatever decisions are taken about the expression of the date, there remain alternative typographic options which physically constrain this expression on the page. Sometimes a three-box system is used, with a box for day, month, and year. Sometimes this is subdivided to give a six-box system (see table II). On other occasions the answer box is a single wide space. Research studies have examined ease of completion and subsequent legibility when forms make use of individual character separators as in the six-box system.^{6,7} In principle, this kind of segmentation could also be used when the months are recorded alphabetically. The research showed that both the writer and the subsequent reader found it easier to deal with the unconstrained,

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TABLE IV—Wide gaps between options and boxes increase errors

Nipple		35
Unchanged		1
Recently retracted		2
Paget's disease		3
Nodes in ipsilateral axilla		36
Not palpable		1
Small mobile		2
Large mobile		3
Nodes in opposite axilla		37
Not palpable		1
Small mobile		2
Ipsilateral arm circumference		
15 cm below acromion	38	cm or . . . inches
15 cm below olecranon	39	cm or . . . inches
Ipsilateral shoulder abduction		40
0- 45°		1
45- 90°		2
91-180°		3

caution in taking such decisions. When a coding procedure for denoting a subset of multiple-choice options was compared with a simpler procedure where the form-filler ticked alongside each relevant option, the coding system was found to be more error-prone.⁹ Moreover, this study suggested that as the questions become more difficult, so the relative advantages of the simpler coding systems become greater.

Coding the completed forms

The preceding discussion has concentrated on the form-filler's problems, because it is obviously important that data is recorded accurately. But consideration of the needs of the data processing department will also have to be given at the design stage. Some forms use a layout in which a column is left for a coder to transform the data into a format that can be easily punched—for example, table III. Table IV illustrates another

format designed to be a convenient punching document. The wide gaps between the multiple choices and the response codes will not help the coder or form-filler, but the inclusion at the top of each set of multiple-choice options of a number that corresponds to the column number on a punch card may well improve the form's usefulness as a punching document.

The apparent efficiency of designing forms which can pass directly from the form-filler to the key-punch operator may be spurious. The form will have to be checked for omissions or mistakes. An intervening coding operation which generates the required punching format may be one way of making this checking procedure more thorough, as well as reducing the problems of the form-filler.

Again, it is an obvious point, but one that is sometimes overlooked: consistency in the use of reference codes will reduce errors arising at the coding stage. Consistency within a form should be relatively easy to achieve. Where several follow-up forms are included in a trial the consistency should extend across all forms. We have seen sets of trial forms including two centres, where the coding for the centres was reversed on one of the forms. Similarly the use of number codes such as (1) and (2) for Yes and No answers needs to be consistent throughout a form. It may seem logical that additional options such as "sometimes" should come between Yes and No, but if people have become used to a particular association for a code they may respond from habit rather than heed the revised instructions for a specific question.

Procedures for achieving well designed forms will be considered in the next article.

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References

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² Tinker, M A, and Patterson, D G, *Journal of Experimental Psychology*, 1928, **12**, 359.
³ Tinker, M A, and Patterson, D G, *Journal of Experimental Psychology*, 1939, **25**, 528.
⁴ Hartley, J, *Designing Instructional Text*. London. Kogan Page, 1978.
⁵ Barnard, P, et al, *Journal of Occupational Psychology*, in press.
⁶ Barnard, P, and Wright, P, *Ergonomics*, 1976, **19**, 81.
⁷ Barnard, P, et al, *Ergonomics*, 1978, **21**, 73.
⁸ Wright, P, and Barnard, P, *Applied Ergonomics*, 1978, **9**, 7.
⁹ Wright, P, et al, *Human Factors*, 1977, **19**, 83.

A patient long accustomed to moderate alcohol consumption and cigarette smoking has had to give up both. The subsequent depression is proving hard to treat. What is the prognosis and treatment of this withdrawal symptom?

Although a period of unhappiness and a sense of loss is not uncommon after giving up alcohol and cigarettes, this usually passes off as other pleasures are pursued, and it is rare for depressive illness to supervene. The form of the question suggests that there may be additional features, and it is relevant to ask why the patient was so advised. Possibly an underlying physical illness for which advice was given had depressant effects. Certain drugs used in treatment may also be associated with depressive illness and resistance to treatment. Most patients feel better after giving up alcohol and cigarettes, and as the case mentioned is unusual, it would be best to survey comprehensively all other possible causes of treatment resistance in depressive illness, and then review the management and specific treatment used.

How common is pine tree resin allergy and pine tree basidiospore allergy in Britain? Does it affect only pine forest areas and what are the best treatments, prevention, etc? Are foresters' families affected?

Allergic contact dermatitis has been reported in foresters and carpenters handling the wood of various species of pine tree. The

relative rarity of such reports may not reflect the true incidence of the condition. The suspected diagnosis should always be confirmed by patch tests. Lichens growing on the bark of trees may also cause allergic dermatitis. Pine resins contain several substances capable of inducing allergic sensitisation. It helps the patient if the sensitiser(s) can be identified, as further contact should be avoided. To achieve this it may be necessary to avoid contact not only with the wood but also with commercial products (such as polishes or turpentine) derived from pines. Resin can contaminate clothing and in this form it might, at least in theory, induce or provoke recurrences of dermatitis in members of a forester's family.

Mitchell, J, and Rook, A, *Botanical Dermatology*, p 578. Philadelphia, Lea and Febiger, 1979.

Is hormone treatment likely to be effective in preventing the growth of facial hair in a 75-year-old healthy woman?

The explanation of the growth of facial hair in elderly women is unknown. It presumably is due to a lengthening of the growth cycle rather than change in rate of growth and is probably analogous to the growth that occurs after middle age in men, which is most apparent on the eyebrows, nostrils, and ears and may indeed represent a late cutaneous response to androgen. If so it might respond to cyproterone acetate but I know of no trials of this.