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.

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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,

TABLE I—*Capitals slow readers. Question on lymph nodes is ambiguous*

Part II Classification of the disease

Primary (mark whichever is applicable)

T0 : TUMOUR NOT PALPABLE

T1 : TUMOUR INTRA CAPSULAR, SURROUNDED BY PALPABLY NORMAL GLAND

T2 : TUMOUR CONFINED TO GLAND, SMOOTH NODULE DEFORMING CONTOUR BUT LATERAL SULCI AND SEMINAL VESICLES NOT INVOLVED

NB More invasive tumours are not eligible for this trial

Lymph Nodes

WAS LYMPHOGRAPHY PERFORMED? .....

IF SO, WAS A POSITIVE DIAGNOSIS POSSIBLE? .....

IF YES: (mark whichever is applicable)

N0 : NO EVIDENCE OF REGIONAL NODE INVOLVEMENT

N1 : INVOLVEMENT OF SINGLE REGIONAL NODE

N2 : INVOLVEMENT OF MULTIPLE REGIONAL NODES

N3 : FIXED MASS ON PELVIC WALL INTO SPACE BETWEEN THIS AND THE TUMOUR

N4 : INVOLVEMENT OF JUXTA-REGIONAL NODES

IF NO, A FINAL DECISION MUST BE MADE AT THE 3-MONTH FOLLOW-UP

WAS LYMPHADENECTOMY PERFORMED? .....

IS SO, WAS THERE MICROSCOPIC EVIDENCE OF METASTASIS? .....

Metastases

SERUM ACID PHOSPHATASE (STATE UNITS) .....

DESCRIBE RESULTS OF BONE SCAN .....

DESCRIBE RESULTS OF CHEST X-RAY .....

NB Patients with *definite* distant metastases are not eligible for the trial

single, wide answer space. Legibility was impaired to the extent that it took an estimated 7% longer for readers to deal with alphanumerics in character segmented spaces where the characters were separated by small vertical marks (along the baseline). When full boxes separated each character (as in table II), the legibility reduction was 3% and the material took 10% longer to write.

A particular difficulty with character separators is correcting errors. If the form-filler misses out zeros, the six-box format draws his attention to this fact, but the altered figures may be difficult to read. Here it may be preferable to leave the zeros to be provided by the coder or data processor. The use of boxes may help the coder check that all the information is there and in the right format for punching, but this help must be weighed against the hindrance which boxes cause to others dealing with the form.

Responding to multiple choice questions

Table III illustrates some of the problems that may arise with multiple-choice questions. When there is a range of answer options for a question such as "Type of first palliative therapy" it is relatively simple for the form-filler to tick or circle one option and for the coder to transfer the option number to the coding boxes on the right-hand side of the page. Nevertheless, when the same set of options applies to several questions, as it does in the questions about "present state," it is less obvious how answers should be recorded. The combination of multiple options and multiple questions is basically a matrix. The question could be presented as such perhaps with the response options (1)-(6) as the headings for six separate columns. The form-filler need tick only the appropriate cell. In a discussion of some of the factors that influence the effects of row and column information in a matrix, it has been suggested that the column headings should contain the simpler (easier to remember) information, and the more complex information should be in the row headings.[8] For information such as that in table III there may be very little difference between these alternatives. Since the previous questions had the answer options listed vertically, however, there might be some advantage in maintaining this in the matrix layout.

The question format illustrated in table III prompts the query that it might be possible in some circumstances to dispense with the interim coding of answers and have the form-filler record the answer itself in a code that is compatible with data processing requirements. Research findings urge

TABLE II—*Segmented answer spaces reduce legibility. Lower part of form is haphazard*

REGISTRATION & TREATMENT FORM

Where a question offers a choice of answers, tick the appropriate box or boxes.

Name of patient: *TRIAL NUMBER* ☐☐☐☐

Age: ☐☐ yrs Date of entry to trial ☐☐☐☐☐☐

Sex: ☐ Male ☐ Female Name of surgeon: .....

Name of hospital: ..... Name of Radiotherapist: .....

Hospital number: ..... Radiotherapy number: .....

Treatment allocated: ☐ No pre-operative radiotherapy ☐ Single Fraction ☐ Multiple Fractions

1. *PRIMARY TUMOUR ASSESSMENT*

Rectal Digital Examination:

Extension of tumour ☐ Mobile ☐ Partially fixed ☐ Fixed ☐ not palpable

Sigmoidoscopy:

Quadrant involved ☐ Anterior ☐ Posterior ☐ Right lateral ☐ Left lateral

Height above anal verge ☐☐ cm

Biopsy—Is there histologically proved adenocarcinoma ☐ Yes ☐ No

Barium Enema: ☐ Done ☐ Not done

If done, give precis report .....

.....

TABLE III—*Problems with multiple-choice questions*

FOLLOW-UP SHEET—CONFIRMED RECURRENCE

Type of first palliative therapy
(1) Local surgery
(2) Local XRT
(3) XRT—menopause
(4) XRT—elsewhere
(5) Endocrine drugs
(6) Endocrine surgery
(7) Chemotherapy
(8) Combined
(9) Other
☐

Effect of above at assessment date
(1) Complete remission
(2) Partial remission
(3) No change
(4) Mixed result
(5) Progressive disease
(6) Doubtful—for review
☐

Present state

Local disease	(1) None	☐
Regional disease	(2) Doubtful still	☐
Contralateral disease	(3) Already confirmed	☐
Skeletal disease	(4) More extensive	☐
Visceral (organ) disease	(5) New doubtful	☐
Soft-tissue disease	(6) New confirmed	☐

If *previously* none or doubtful and now new confirmed, insert histological type and date ☐☐☐☐☐☐

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 acromian	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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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.