A BASIC PROGRAM FOR CONSTRUCTING A DISPENSING LIST FOR A RANDOMISED CLINICAL TRIAL

In any randomised double-blind clinical trial a dispensing list must be drawn up, and it is also usually necessary to prepare sealed envelopes containing details of the medication in case of emergency, as well as labels for the supplies of drug. These are tedious tasks, prone to error, and ideally suited to the computer.

Small computers based on microprocessors are becoming increasingly common in laboratory and office. However, obtaining software is often a problem, and can indeed be more costly than the computer itself. It therefore seemed useful to publish details of the program which is in routine use in our own clinical trials. The program is set up for a Cromemco System 2 machine, and is written in BASIC.

We have used this program in a number of studies. As an example, in a clinical trial of a new antidepressant (Loudon, Tiplady, Ashcroft & Waddell, 1981), patients were allocated to one of two treatment groups, zimelidine or amitriptyline. Drugs were administered as capsules containing 100 mg zimelidine or 75 mg amitriptyline. Dosage was one capsule nightly for the first two weeks, then two capsules nightly for the remainder of the 12-week study period. We decided to randomise in blocks of six, and to prefix the patient numbers with the letter B.

On RUNNING the program, the operator is first asked the study number, which can be up to 11 characters. The number of treatments (maximum 9) and the names of the treatments (maximum 30 characters each) are then entered, followed by the patient numbers and the block size required. The dispensing list is then constructed and printed. Output is formatted for A4 paper, and the program stops to allow change of paper. The sequence is shown in Figure 1. The program will reprompt the operator if the input is inconsistent, e.g. if an attempt is made to draw up a list for 20 patients randomised in blocks of 8.

Having prepared a dispensing list, we now need the sealed envelopes. The full name of the treatment, as entered in the previous stage, is printed on a slip of paper (we use compliments slips). A wages envelope is used to contain the slip. We recommend this type of envelope because it is not semi-transparent as white envelopes often are.

The last stage is to print the labels. The program uses 70 mm × 36 mm self-adhesive labels, one-across. This gives eight lines each of 26 characters. The format of the first four lines is fixed, and is used for study number, patient number, and a space for the patient's

name. The operator then enters the number of labels required per patient, and sets up the format for the bottom four lines of the label. The program then offers a check for the correct alignment of the labels in the printer, and then prints the required number of labels.

We have found the program easy to use. Once it is set up for the system, no particular knowledge of computers is required, since the program prompts the user for the information required.

A listing of the program follows. Little modification is likely to be necessary to use the program on other systems.

THE PROGRAM

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10 REM * THIS PROGRAM CREATES A DISPENSING LIST FOR UP TO
NINE TREATMENTS
20 REM WITH OR WITHOUT BLOCKS
30 INPUT "What is the trial name/number? ";NS
40 INPUT "How many treatments? ";T
50 IF N<=9 THEN 70
60 PRINT "Number of treatments is at present limited to 9." :
GOTO 40
70 DIM AS(30*T)
80 FOR N=1 TO T
90 PRINT "What is the full name for treatment ";N
100 INPUT AS((30*N-30),(30*N-1))
110 NEXT N
120 INPUT "Enter prefix to patient number if there is one:
";PS
130 INPUT "First patient number? ";A
140 INPUT "Last patient number? ";C
150 P=C-A+1
160 IF INT(P/T)=P/T THEN 190
170 @ : @
180 PRINT "No. of patients must be a multiple of ";T : GOTO
130
190 INPUT "Is randomisation in blocks required? (Y/N) ";YS
200 IF YS="N" THEN B=P : GOTO 280
210 INPUT "Size of blocks? ";B
220 IF INT(B/T)=B/T THEN 250
230 @ : @
240 PRINT "Block size must be a multiple of ";T : GOTO 190
250 IF INT(P/B)=P/B THEN 280
260 @ : @
270 PRINT "No. of patients must be a multiple of block size." :
GOTO 130
280 S=1
290 DIM S(P)
300 REM * AT THE BEGINNING OF EACH BLOCK, SET COUNTERS TO
ZERO
310 FOR Q=1 TO P/B
320 REM * P/B IS THE NUMBER OF BLOCKS
330 FOR Z=1 TO T
340 A(Z)=0
350 NEXT Z
360 RANDOMIZE
370 R=INT(10*RND(2))
380 IF R>T THEN 370
390 IF R<1 THEN 370
400 IF A(R)=B/T THEN 370
410 REM * B/T IS THE NUMBER OF OCCURRENCES OF EACH
TREATMENT PER BLOCK
420 S(S)=R
430 S=S+1
440 A(R)=A(R)+1
450 FOR L=1 TO T
460 IF A(L)<B/T THEN 370
470 NEXT L
480 NEXT Q
490 @ : @ : @
500 INPUT "Insert A4 Paper. Press [CR] when you're ready! ";YS
510 PRINT CHR$(23)
520 FOR F=1 TO P
530 @ : @ "Patient No. ";PS;F+A-1;" Treatment
";AS((30*S(F)-30),(30*S(F)-1))
540 IF INT(F/28)=F/28 THEN @ CHR$(20) : INPUT "Change paper!
Press [CR] when you're ready ";YS : @ CHR$(23)
550 NEXT F
560 PRINT CHR$(20)
570 @ : @ : @
590 INPUT "How many sealed envelopes do you need for each
subject? ";M

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600  @ : @
610  FOR N=1 TO P
620  FOR J=1 TO M
630  PRINT"Enter a compliments slip, or similarly sized
piece of paper"
640  @ : INPUT"Press [CR] when you're ready ",Y$
650  PRINT CHR$(23)
660  PRINT"Patient Number ",P$;N+1
670  PRINT"Treatment ",AS((30*S(N)-30),(30*S(N)-1))
680  @ : @ : @
690  PRINT CHR$(20)
700  INPUT"Enter a wages envelope. Press [CR] when you're
ready ",Y$
710  PRINT CHR$(23)
720  PRINT N$;"-";P$;N+1
730  @ : @
740  @ : @
750  PRINT"This envelope contains"
760  PRINT"details of the medication"
770  PRINT"being given to the"
780  PRINT"above patient."
790  PRINT CHR$(20)
800  NEXT J
810  NEXT N
820  INPUT"Do you wish to print labels for these patients?
(Y/N) ",Y$
830  IF Y$="N" THEN 1650
840  SET 0,-1
850  DIM L$(25)
860  OUT 1,12 : @ : @ : @ : @ : @ : @
870  PRINT"This program prints labels size 2 3/4 x 1 7/16
inches"
880  PRINT"one across. Format is as follows:"
890  @ : @ : @ TAB(20);"Study No. Patient No."
900  @ TAB(20);"Patient name:" : @ : @ : @
910  @ TAB(20);"Four lines which can"
920  @ TAB(20);"be defined individually"
930  @ TAB(20);"for each label if"
940  @ TAB(20);"necessary" : @ : @ : @
950  INPUT"Enter the number of labels to be printed for each
patient "N
960  DIM M$(104*(N+1))
970  FOR J=0 TO 3
980  PRINT"Is line ";J+5;," the same for each label? (Y/N)
"; : INPUT " ",Y$
990  IF Y$="Y" THEN PRINT"Enter line ";J+5; : INPUT " ",L$ :
GOTO 1220
1000  IF Y$="N" THEN 1260
1010  GOTO 1180
1020  FOR K=0 TO N-1
1030  M$(104*K+26*J,104*K+26*J+25)=L$
1040  NEXT K
1050  GOTO 1300
1060  FOR K=0 TO N-1
1070  PRINT"Enter line ";J+5;," for label ";K+1;
1080  INPUT " ",M$(104*K+26*J,104*K+26*J+25)
1090  NEXT K
1100  NEXT J
1110  INPUT"Do you need to check paper alignment? (Y/N) ",A$
1120  IF A$="N" THEN GOTO 1440
1130  PRINT CHR$(23)
1140  PRINT TAB(3);"*****"
1150  FOR I=1 TO 7
1160  PRINT TAB(3);""
1170  NEXT I
1180  PRINT CHR$(20);
1190  GOTO 1310
1200  PRINT CHR$(23);
1210  FOR Z=A TO C
1220  FOR I=0 TO N-1
1230  PRINT
1240  PRINT TAB(3);N$;" Patient No. ";P$;Z
1250  @ TAB(3);"Patient name:"

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1530  @ : @
1540  FOR J=0 TO 3
1550  L$=M$(I*104+26*J,I*104+26*J+25)
1560  PRINT TAB(3);L$(-1)
1570  NEXT J
1580  NEXT I
1590  NEXT Z
1600  PRINT CHR$(20)
1610  END

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RUN

What is the trial name/number? A01-020How many treatments? 2

What is the full name for treatment 1

? Zimelidine (100 mg/capsule)

What is the full name for treatment 2

? Amitriptyline (75 mg/capsule)Enter prefix to patient number if there is one: BFirst patient number? 1Last patient number? 12Is randomisation in blocks required? (Y/N) YSize of blocks? 6

Insert A4 paper. Press <CR> when you're ready!

B1	Zimelidine (100 mg/capsule)
B2	Amitriptyline (75 mg/capsule)
B3	Zimelidine (100 mg/capsule)
B4	Zimelidine (100 mg/capsule)
B5	Amitriptyline (75 mg/capsule)
B6	Amitriptyline (75 mg/capsule)
B7	etc.....

Figure 1 Video screen display and print out from stage one of the program—the setting up of the dispensing list. Operator entries are shown underlined, while the print-out is enclosed within the box.

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Reference

- LOUDON, J.B., TIPLADY, B., ASHCROFT, G. & WADDELL, J.L. (1981). Zimelidine and amitriptyline in the treatment of depressive illness in general practice. *Acta Psychiat. Scand.* **63**, suppl. **290**, 454–463.