RECORDING AND ANALYSIS OF CLINICAL DATA

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SUMMARY

A data card is described for the recording of information about patients and clinical drug administrations or other procedures. The card is suitable for punching on to two 80-column IBM cards for computer handling. A programme has been written for simple statistical tests.

There are a number of situations in which "value" judgements must be made upon patients, for instance in the evaluation of analgesics, sedatives, tranquillizers, anti-emetics and other drugs with actions that can best, or perhaps only, be assessed from the patient's appearance or his subjective report of his feelings. It then becomes necessary, in the analysis of results, to relate these judgements of drug effect to other factors such as age, weight, sex, time of day and so forth.

We have been faced with this problem in our clinical studies of analgesics, in which patients are seen at intervals by specially trained nurses who are required to keep records of their—and the patients'—impressions of pain and its relief. Clearly, a standard form of data sheet is desirable, so that "scores" and side-effects can be recorded in consistent fashion, so that other relevant factors are not overlooked and so that eventually the results of consecutive studies, or of studies carried out in different hospitals, can be compared.

In the United States, data forms have been devised for use in these circumstances, such as the SKI form (used at the Sloan Kettering Institute in New York) and the National Analgesia Study Data Form; it is from these forms, and the concepts underlying their application, that our present card has been developed. We began by using the National Analgesia Study Data Form, but it has some limitations when used for our purposes and it is in any event applicable only to analgesic investigations. We modified it to form our own "Analgesia Card" which was used with success for about 1,200 drug evaluations; it then occurred to us that with only slight alteration this card could be made to serve a multitude of purposes and we now describe our "Clinical Investigation Card One" which is currently in use.

Figure 1 is an example of the card. It provides for the recording of all basic data about the patient and the investigation in question, together with up to four variables and a considerable number of contingencies—for instance, side effects—which can be designated at will. All information is entered in numerical form, so that keypunching presents no problem; the card consists of 160 columns (the boxes are called columns because each box, from a series of cards, becomes a column of data) and can thus be punched on to two standard IBM cards for computer analysis. The card is 8½ x 5¼ inches, the standard demy-octavo paper size, which is a convenient size and shape to handle; the actual contents will also fit a card 210 x 148 mm so that a new block need not be made when this in due course becomes a standard paper size (A5). The card is supplied as a flimsy top copy gummed along the upper edge to a stiffish second copy; it is printed on NCR paper so that carbon paper is not needed. This ensures that two identical records are obtained, one of which can be retained while the other is dispatched for punching. The block for printing was made from a double size sheet of white card on which ChartPak strip boxes were applied and captions were typed with a standard IBM electric typewriter.

Our current studies afford an example of the way the CIC One card is used. The five top columns indicate the study number and the number...
of the patient in the study; the illustrated example is of the fifth patient in study 49. A code number is used for the hospital and ward, and for the drug administered. Time 0 is the time when observations begin, in this case the time of drug administration. The dose of the drug is recorded in mg with the appropriate exponent, using a pre-arranged convention according to which 6 denotes $10^1$; the dose is therefore 1200 mg. Variable one, in this example, is pain intensity as judged by the patient (1=mild; 2=moderate; 3=severe). The 0 column records the pain intensity before drug administration. The time interval column signifies that assessments were made at hourly intervals; therefore, column “one” of variable one records pain intensity 1 hour after treatment, column “two” records intensity 2 hours after, etc. Total change is derived by subtracting each hourly score from the initial score, and summing these differences. The appearance of nines after 4 hours is a “sign off”, indicating that subsequent scores are to be disregarded because a further drug had been given; this agrees with the entry 5 in column 159 which means, according to the study code, that the time interval to the next drug administration was between 4 and 5 hours (a 0 in column 159 would have signified that no subsequent drug was given, and this would have told the investigator, and the computer, that there were no further cards for this patient). Variable two is the investigator’s opinion of the degree of pain relief (0=None; 1=poor; 2=moderate; 3=good); scoring obviously begins at hour one.

Side effects are graded, 1=mild; 2=moderate; 3=severe; and entered in columns 137–155, using once again, a pre-arranged study code (137=headache; 138=nausea, etc). Variables three and four are not in use in this study and the first seven columns of variable four are therefore used to repeat the study number, number of patient in the study, the “order in round” and “round”; this serves to match the two IBM cards of a pair.

This description of the use of the card, although incomplete, should suffice for illustration. We have two nurses using these cards at present, and after a little practice they have found them
easy to fill in. A copy of the study code is carried for reference and it takes very little time to enter the appropriate numbers directly into the proper columns. The drug and dose are entered at the end of the study when the key to the "randomization" is available.

It will be evident that no modification of this card would be needed for a study of sedatives or other drugs producing "subjective" effects. Furthermore, an "objective" phenomenon such as change in blood pressure, or grip strength in rheumatoid arthritis could well be entered as a variable; it was with this type of measurement in mind that a "scale" column was provided.

A FORTRAN IV programme has been written for use with this card, enabling means and standard errors to be printed for each variable, at each time interval, and for each total change, and t-test comparisons to be made between all pairs of variables at each time interval and in total. This programme provides for the drop-out of cases at successive time intervals as "sign off" indications are received. Further programming is in progress to enable variable scores to be related to factors such as age and sex, and to study side effects. For the purpose of computer analysis the nature of the data is immaterial; the same programme will operate on the same columns whether they contain pain intensity scores or volumes of urine secreted. The card and the programme thus make a versatile combination which facilitates both the recording and the analysis of clinical data.

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ENREGISTREMENT ET ANALYSE DES DONNEES CLINIQUES

Sommaire
On décrit une carte pour la notation des renseignements sur les malades, l'administration clinique des médicaments ou d'autres techniques. La carte convient pour les machines électroniques IBM. Un programme a été écrit pour des tests statistiques simples.

ZUSAMMENFASSUNG
Es wird eine Daten-Karte zur Registrierung von Angaben über Patienten, klinische Applikationen und andere Vorgänge beschrieben. Die Karte eignet sich zur Übertragung auf eine "two 80 column" IBM Lochkarte und somit zur Verwendung in Elektronenrechnern. Es wurde ein Programm für einfache statistische Untersuchungen geschrieben.