The Technology of Diabetes Care

Converging Medical and Psychosocial Perspectives

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Evaluating New Technologies: Psychological Issues in Research Design and Measurement

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New technology needs to be properly evaluated if it is not to be inappropriately advocated or inappropriately discarded. In this chapter it is argued that proper evaluation of new technologies for diabetes care requires that psychological issues be considered. Evaluation studies are rarely designed with a view to measuring or controlling for psychological variables. The physician may focus on the particular needs of the individual patient in the consulting room, when that patient's preferences, motivations, lifestyle and priorities are often considered in deciding treatment regimens and in solving problems with diabetes control but in the context of a study evaluating a new form of technology the focus changes. The study is designed and the data analysed with a view to answering a question which, typically, is something like 'Is this new treatment useful in improving the blood glucose control of Type 1 diabetic patients?'. The individuals disappear. Psychological variables disappear. From such a study the physician aims to determine the effects of a treatment on metabolic control not in individual patients, but in a group of patients.

The fate of new technologies is usually decided on the strength of such studies. For those technologies which survive such evaluation, the physician is then faced with the task of advising an individual patient about the pros and cons for that individual of using the new technological aid to diabetes management, equipped only with information about medical outcomes averaged over groups of selected patients. Such information is not very helpful in predicting whether the new treatment will suit the needs of the particular individual in the consulting room. In this chapter I will consider the origins of the most commonly used form of clinical trial design, the randomised controlled trial, then elaborate further on earlier arguments against the use of standard randomised controlled trial designs and in favour of alternative designs (Bradley, 1988; Brewin and Bradley, 1989). These arguments will be applied in considering the problems of evaluating the use of new technologies for diabetes management.

Early Resistance to Clinical Trials

It is interesting to note that as recently as the late 1940's the great majority of the medical establishment viewed with deep foreboding the idea of applying scientific methods to the evaluation of medical treatments. The randomised controlled trial was regarded with distrust by many who resisted any change from the traditional methods which relied on clinical experience. Indeed, despite the importance and influence of Cochrane's (1972) book on effectiveness and efficiency, which put randomised controlled clinical trials on the map in the early seventies, the influence of the controlled clinical trial was still not universal. Armstrong (1977) provided an anthology of quotes from early opponents to randomised controlled trials to indicate the nature of their worries about scientific methods replacing clinical observation as the main source of data for comparing treatments. The fears expressed in the 1940s may be seen to have some foundation when we consider the way that randomised controlled trials tend to be used today. There were three sets of fears expressed which can be summarised as follows:

1. Scientific trials would be inhumane;
2. Scientific trials would ignore individual differences;
3. Scientific trials would be misleading.

The first fear was essentially that patients would not be considered as people in clinical trials. Grieve (1945) was concerned that,

> 'Medicine ... must have its philosophers if the patients are to be treated as human beings and not as a series of laboratory exercises',

and later wrote,

> 'In our scientific quest let us ever remember that presently much neglected part of man, his soul, has a right to consideration as well as the mechanics of his feet or the biochemistry of his brain' (Grieve, 1946).

We should remember that currently much neglected aspect of humans, their psyche, not least because that psyche will have a powerful influence on the mechanics of the feet and on the biochemisty of the brain. Psychological processes and outcomes are rarely considered in clinical trials and yet can be crucial determinants of medical outcomes.

The fear that scientific trials would ignore individual differences was summed up by Ambrose (1950) in the simple observation, made with reference to the use of antihistamine in the treatment of the common cold and in protest against findings of a Medical Research Council trial, 'Some people do respond and others do not'. Differences which are important and meaningful are frequently relegated to the status of noise in the pursuit of a straightforward answer. Moynihan (1930), in an address published in the Lancet, wrote that the great advances resulting from clinical observation were

> 'disparaged and in danger of being forgotten. The method of experiment has captured the fancy of many members of our profession, and by reason of the precision of its facile results has created a degree of confidence which has never attached itself to clinical observation alone'.

This very phenomenon which Moynihan described can be seen in studies involving continuous subcutaneous insulin infusion (CSII) pumps (externally worn pumps for the continuous delivery of insulin) where researchers have hoped to answer the question 'Do CSII pumps control blood glucose levels better than injections?' without recognising that neither pumps nor injections can operate independently of the active involvement of the individual using them. Where I depart from Moynihan is with the view he expressed about the problem of individual differences in response to treatments:

> 'The very complexity of the problem renders it impossible to consider alongside the methods of the laboratory. In hominal research we are able to control only a few specific features; the majority are altogether beyond our control, unapproachable and immutable.'

While it may be difficult to consider the complexities of individual differences between patients, it is not impossible. Psychological differences are perhaps among the most complex of individual differences yet psychological factors can certainly be measured and investigated using scientific methods. Individual differences can be a focus of study but they rarely are.

Towards More Meaningful Clinical Trials

Lack of concern with psychological factors and with individual differences generally can lead to highly misleading conclusions. New treatments may be inappropriately discarded or inappropriately advocated because:

a. metabolic outcomes were the only outcomes considered and/or
b. the treatments were evaluated on groups of patients selected according to inappropriate selection criteria, and benefits or harmful consequences to individuals were ignored.

Consideration of Psychological as well as Metabolic Outcomes

In a randomised controlled trial of a new treatment compared with a conventional treatment, metabolic outcomes may be no better than with conventional treatment although psychological outcomes may well have shown benefits if they had been measured. Conversely metabolic outcomes may indicate significant advantages over conventional treatment while psychological outcomes may have shown unwanted damaging consequences of the new treatment. In clinical trials of CSII, metabolic outcomes typically suggest that

CSII should not be offered because it is not associated with any better blood glucose control than can be achieved using multiple injection therapy and multiple injection therapy is cheaper (eg Marshall *et al.*, 1987). Psychological outcomes, on the other hand, have suggested that CSII should be offered. In a feasibility study in Sheffield where patients with Type 1 diabetes were offered the choice of CSII, intensified conventional treatment, or conventional treatment, it was found that although improvements in glycaemic control were similar for patients using CSII and for those using intensified injection regimens, only the group of patients using CSII reported a significant improvement in their satisfaction with treatment (Lewis *et al.*, 1988).

In the ideal world there is no reason why psychological outcome measures should not always be included in clinical trials evaluating new treatments. In reality, such trials are usually designed by medical personnel who typically do not have the knowledge or experience of dealing with psychological constructs and their measurement. However, in recent years there has been a growing interest in measuring subjective experience of health, psychological well-being and quality of life. The lack of readily available reliable and valid psychological outcome measures has often been given as the reason why such outcomes were not measured and policy decisions were based on clinical judgement supported only by measures of metabolic and clinical outcomes.

Psychologists have until recently found difficulty in persuading funding bodies to give the development of such measures sufficient priority. It is interesting to note that despite the increased availability of measures of psychological outcomes over the past few years there remains a good deal of anxiety and suspicion about the reliability and validity of these measures (often called 'soft'measures) which are unfamiliar to physicians. Meanwhile biochemical measures with which clinicians are only too familiar (often called 'hard' measures) are accepted without a second thought, glycosylated haemoglobin being a common example (Home, 1990). Concern is expressed that, for example, psychological outcomes may be influenced by such factors as the weather, with warm summer days being associated with more positive affect than cold winter days. How can we use an outcome measure that is so susceptible to external influence? The knowledge that weight and blood glucose control also vary with the seasons is curiously often ignored, such measures commonly being used without thought for their reliability and validity. Koran (1975a and b) reviewed what little evidence was available on the reliablity of clinical methods and data and showed that there were no grounds for complacency. It may be hoped that one of the spin offs of medical researchers learning to assess the reliability, validity and suitability of psychological outcome measures for clinical trials may be that they come to reassess other more familiar and taken-for-granted measures. They may come to recognise that these so-called 'hard' measures often have soft centres.

A variety of psychological outcome measures is now available and more are being developed. Papers describing the development of such measures now appear in clinical medical journals (eg Bradley and Lewis, 1990;

Nicassio *et al.*, 1985) and are thus being brought to the attention of physicians directly rather than via their social science colleagues. McDowell and Newell (1987) have compiled a useful guide to scales and questionnaires for measuring health. This guide is a valuable tool for researchers trying to find a suitable off-the-peg measure though it should be borne in mind that scales developed on non-diabetic populations may not be appropriate for people with diabetes. The chapter by Meadows in the present volume considers how psychological outcomes can be measured. Here I simply illustrate the need to measure such outcomes if a realistic evaluation of a treatment is to be made.

Consideration of Individual as well as Group Differences

When focusing on groups of patients the researcher attempts to answer the question 'Which treatment is best for this population as a whole?' It could be that in a randomised controlled trial comparing two treatments, half the patients allocated to the new treatment do exceptionally well and half allocated to the conventional treatment do exceptionally well, so that the researcher concludes there is no difference between the treatments. The group focus suggests that there is no advantage in offering the new treatment although for individual patients this may be quite untrue. It may make a great deal of difference to their psychological and metabolic well-being if they can have the choice of treatment. Randomised controlled trials are not incompatible with an individual focus though in practice most randomised controlled trials have an exclusively group focus. Individual differences are not usually considered or analysed and where they are, only metabolic/ clinical variables are usually considered.

Choice of Appropriate Selection Criteria and Recruitment Procedures

If we investigate demographic and psychological variables to see which kind of patients benefit from a treatment and which do not benefit then we can gather systematic data about the appropriateness of the selection criteria in that particular trial. At present, however, while scientific principles may guide the design of a clinical trial, the selection criteria are determined by such factors as clinical judgement and unsubstantiated beliefs about what kind of people will be suitable, or, by criteria used in an earlier study and unthinkingly applied again.

Selection criteria which superficially appear to be simple and straightforward may sometimes mask a multitude of complex psychological factors that may influence supposedly clinical variables in ways that go unrecognised. An example is provided in a review of implantable insulin pumps (Selam, 1988) where two studies were described as 'very comparable in terms of ...patient selection' yet the selection criteria were simply 'CSII treated Type 1 diabetes of long duration'. The comparability of the two studies of implantable

pumps will therefore depend on the selection criteria used in allocating CSII which may or may not be very comparable. We need to know what the patients were told about CSII, what they expected from CSII and why they thought that the treatment might suit them. Sometimes the patient may simply have followed the advice of their doctor that CSII was the best treatment even though remaining sceptical about the suitability of the treatment for themselves.

In the Sheffield feasibility study of CSII versus conventional treatments, patients were recruited into the study with a talk on the three treatment options. They were told among other things that 'the evidence suggests that CSII pumps will control your blood sugar better than injections'. Before any changes were made to the treatment regimen patients in this study completed a series of psychological measures including a scale to measure Perceived Control over diabetes. It was found that the patients who chose the pumps were more likely to be those with a stronger sense of Medical Control over their diabetes (ie those attributing diabetes-related outcomes to the medical staff and the treatment prescribed). Those with a stronger sense of Personal Control over their diabetes (believing in their personal responsibility and control over outcomes) were not more likely to choose to use CSII (Bradley *et al.*, 1987). The patients most likely to opt for CSII were those who were looking for a medical solution to their diabetes but they had been misled. The CSII pump is only as good at controlling blood glucose levels as its owner enables it to be. The patients with the highest sense of Medical Control among the CSII users turned out to benefit the least from the pump. They had higher HbA_1 levels after 12 months of treatment indicating worse blood glucose control (Bradley *et al.*, 1987) and they were more likely to experience diabetic ketoacidosis while using CSII (Bradley *et al.*, 1986).

The Sheffield study was described as a feasibility study. Patients chose their treatment group. They were not allocated at random. The interaction between the recruitment procedures chosen by the doctors and the beliefs and preferences of the patients became clear in this study where the factors influencing patients' choices were a focus of the investigation. Randomised controlled trials cannot offer immunity from the effects of patients' preferences and beliefs. It is usually assumed that random allocation is the best way of arriving at two similar groups of patients but when patients' reasons for participating in the trial and their preferences for treatments are considered, the justification for this assumption is called into question.When patients agree to participate in a clinical trial a problem arises if that is the only chance that they have of using a new form of treatment (Bradley, 1988). If patients recruited into the study all believe they will prefer the new treatment under evaluation to the conventional comparison treatment (patients preferring the other treatment having chosen it outside of the clinical trial), random allocation of patients to treatment is likely to lead to one group being disappointed with the treatment allocated and another group that is not. The problem is illustrated in Figure 1 where patients in the two treatment groups develop differences following randomisation. These may include differences in their

expectations of treatment outcome, enthusiasm for participating in the study, tolerance of inconvenience or discomfort, all of which are likely to have more to do with whether or not the treatment allocated was the preferred form of treatment than with any pharmacological or physiological effects of the treatments. Similar problems are just as likely to arise in randomised controlled trials where patients are crossed over to two or more treatments as in trials with separate parallel treatment groups. Patients may have greater expectations of one treatment than another, may be more enthusiastic about one leg of the trial than the other and so on. The likelihood of such problems arising depends on the context of the study, including the way in which the treatments were presented, and the patients' reasons for agreeing to participate.

In randomised controlled trials, all patients recruited have to be prepared to use any of the treatments being studied. In such trials of CSII versus intensified conventional treatments which were carried out before CSII became more routinely available, it is likely that many if not all patients agreed to

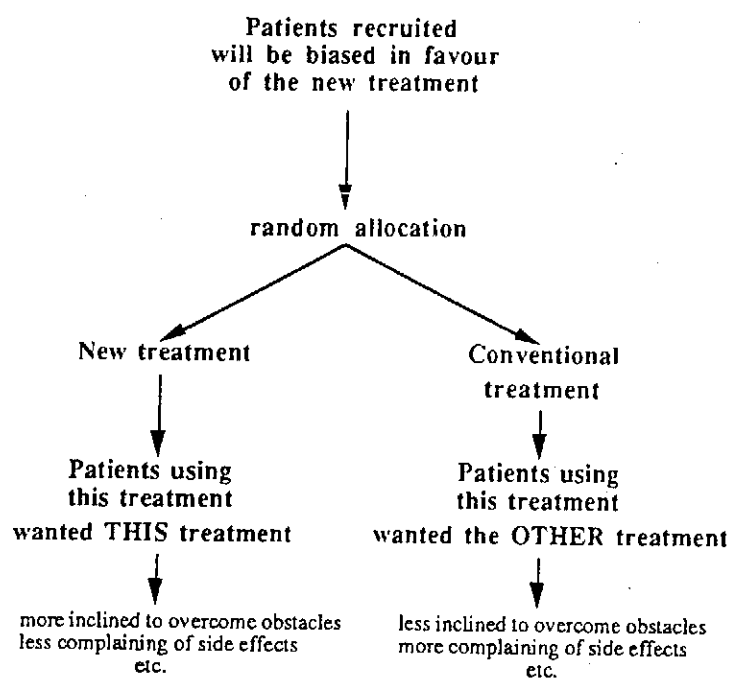

Figure 1. The problem of random allocation creating differences between groups, in trials involving a new treatment which is only available within the trial.

participate in the study because they thought that they would prefer to use CSII. Because CSII was not routinely available, the only opportunity they had to try CSII was by agreeing to the randomization. Those patients who were not prepared to have their treatment allocated at random were not studied. Typically, patients declining to take part in such studies have been the far greater proportion of those invited to participate (Grimm *et al.*, 1987). Unless baseline data are collected on the subjects who decline to take part in the randomised controlled trial, the researchers and everyone else will remain ignorant of the non-representativeness of the sample being randomised.

In summary, there are two problems which usually go unnoticed but may have profound implications for the results of a study and the conclusions about the value of a new treatment. First, randomisation is intended to ensure that differences between the groups not due to intervention are equalised but in this context may actually cause differences in the groups being compared. Secondly, those patients who agree to participate in the study may not be representative of the population as a whole. The conclusions may then be misleading and cannot be generalised. One possible approach to dealing with these problems is matching patients on motivational criteria.

Matching Patients on Motivational Criteria

In theory we could match patients randomised to each treatment group on motivational criteria if we recruited into the trial only those patients who were equally prepared to use any of the treatments involved. In practice this would be likely to be difficult, especially if the treatments were very different. For example, it is hard to imagine that any patient would be equally prepared to use any of the three treatments in the Sheffield CSII feasibility study (CSII, intensified conventional treatment, or conventional treatment). Furthermore, if there were any such willing patients they would be unlikely to be representative of potential users of any one of the treatments alone. We might allocate patients to the treatment of choice rather than on a random basis as was done in the Sheffield feasibility study and explore the factors determining preferences, though the patients in each treatment group will differ on numerous other criteria and differences between groups must be interpreted with great care. Brewin and Bradley (1989) suggested an alternative design which may offer the best of both randomised controlled trial and non-randomised feasibility study designs.

A part-randomised, part-patient-preference-determined design

Brewin and Bradley's (1989) suggested alternative to randomised control trial and non-randomised feasibility study designs will here be applied to a hypothetical study to evaluate glucose sensors; the development of which is described by Pickup in this book. Pickup points out that glucose sensors will not benefit all patients, and cautions that they should not be used

indiscriminately. Glucose sensor technology, especially if it were linked to an alarm to signal hypoglycaemia, would be particularly useful for those patients who have lost the warning symptoms of hypoglycaemia (see chapter by Hepburn and Frier). For such individuals, the advantages of a device that allows them to avoid the dangers and embarrassments of unpredictable episodes of unconsciousness might be expected to outweigh the disadvantages of wearing the device. However, for people who have adequate warning symptoms of hypoglycaemia, a glucose sensor would offer less obvious advantage, and the disadvantages would be likely to be more annoying in the absence of any clear benefits. It would be possible to describe a subsample of the diabetic population for whom glucose sensors are anticipated to be useful from which individuals would be recruited into studies evaluating the new technology. Certain objective criteria for recruitment could be set out, such as evidence of hypoglycaemic unawareness, or a history of night time hypoglycaemic reactions. However, not all patients with hypoglycaemic unawareness or recurrent hypoglycaemia will be prepared to use glucose sensors and some may prefer to continue to use intensive blood glucose monitoring even if this means tolerating more hypoglycaemic episodes rather than wear a glucose sensor device. Other patients may be prepared to try glucose sensors but have not tolerated intensive blood glucose monitoring.

Figure 2 illustrates Brewin and Bradley's design which would accommodate patients with a preference for one of the two treatments to be compared, as well as patients with no particular preference. Those patients with a preference for one or other form of treatment would be allocated their preferred treatment. Those patients with no preference would be allocated a treatment at random. Thus there would be a maximum of four treatment groups for study. Groups 3 and 4 would be the nearest equivalent to groups formed in randomised controlled trials with two advantages over those of a standard randomised controlled trial. First, patients in the two groups could be expected to be equivalent in terms of their motivation to use the treatments to which they were allocated at random. The second advantage is that the study would not exclude patients who did have a preference for one of the treatments, but instead would study those patients in one of two separate groups, groups 1 and 2. Comparison of outcomes of group 3 vs group 4 will give us an estimate of the relative value of glucose sensors and blood glucose monitoring for this group of patients where there were no strong preferences to influence the results. Comparison of groups 1 and 3 will give us an estimate of the role of motivational factors in determining the value of glucose sensors. If outcomes in group 1 are significantly better than outcomes in group 3 then motivational factors can be seen to be important. Similarly, comparison of groups 2 and 4 gives us an estimate of the role of motivational factors in blood glucose monitoring. Comparing all four groups provides yet more useful information. If, for example, groups 1 and 3 who both used glucose sensors had significantly better outcomes than group 4 (who had no initial preference and were randomly allocated blood glucose monitoring) but no better than group 2 who

were allocated blood glucose monitoring because of an initial preference, then it might be recommended that in future, those patients who strongly prefer blood glucose monitoring to glucose sensors be provided with blood glucose monitoring but all other patients meeting the selection criteria used in this study should be recommended to use glucose sensors.

It may be that there are no patients who prefer one of the treatments over the other in which case the classic randomised controlled trial will result because there will be no groups 1 and 2. However, the preferences of the patients will have been investigated and the possibilities of such preferences biasing the outcomes will have been excluded. More likely, there will be some patients preferring one treatment but none preferring the other and a three group study would result with only a subset of comparisons possible. More likely still, there would be patients with preferences for each of the treatments and patients without preferences but the numbers of patients in each group would vary considerably. In the event that there were too few patients who had no preference to allow randomisation, the study would be limited to groups 1 and 2 in the manner of a feasibility study and the

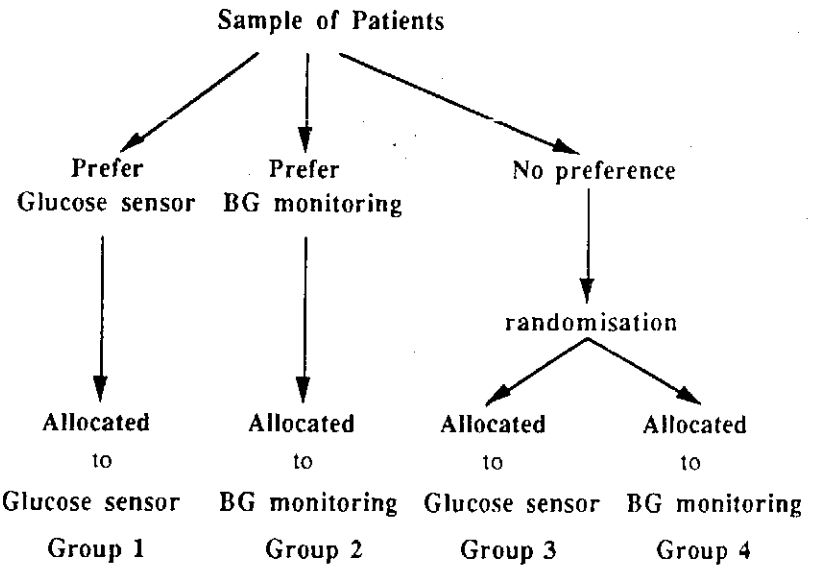

Figure 2. An alternative design to randomised controlled trials for comparing the effects of two treatments, glucose sensors and blood glucose monitoring, while controlling for motivational factors.

conclusions that could be drawn would be limited accordingly. Under this last circumstance of few patients having no preference a variant of this design might be considered whereby half the patients preferring glucose sensors be allocated blood glucose monitoring and half the patients preferring blood glucose monitoring be allocated glucose sensors. Such a design would serve the purpose of controlling for motivational factors though the number of patients willing to be recruited into such a study would be likely to be reduced with a consequent reduction in the representativeness of the sample and would not offer the same advantages as the design portrayed in figure 2.

Since writing the 1989 paper one study has been identified which used such a design to study opiate withdrawal. Gossop *et al.* (1986) assigned patients to inpatient versus outpatient treatment on the basis of strong preference, or randomisation where preference was not strong. Twenty of the sixty subjects studied were willing to accept either in- or out-patient treatment and treatments were allocated to these subjects at random. The forty subjects who expressed a strong preference appeared to be approximately equally divided as to preference for in-patient or out-patient treatment. Thus the study had four groups of adequate size to allow analysis of the data in the manner outlined above. Unfortunately the researchers lost the advantage of the design by combining the groups into in-patient and out-patient samples and testing the significance of differences between these two groups without regard for initial patient preferences and the method of allocation to groups. Thus the design appeared to be employed simply as a device for encouraging subject recruitment into the study rather than as a means of investigating the role of motivational factors in determining treatment efficacy. Fortunately the numbers expressing a preference for each of the treatment options appeared to be evenly distributed (actual numbers were not given and can only be derived approximately). Had the numbers differed substantially, the procedure of combining for analysis randomised and preferred groups would have hopelessly confounded the two variables of preference versus no preference and in- versus out-patient treatment. Whether or not the preferences are evenly distributed the analysis of four separate groups would provide considerably more useful information and is the method of analysis recommended for future studies.

Another researcher who has considered patient preferences is Marteau (1989) who, in the course of pilot work for an evaluation study involving random allocation, investigated patients' preferences for different approaches to preparing them for routine prenatal screening tests (Marteau, 1989). She asked pregnant women if they had a preference for one of the four interventions which were: information to be given

1. in a booklet,
2. during routine antenatal care,
3. at an extra antenatal class or
4. both in a booklet and in an extra class.

Approximately 50% of the women preferred one of the four interventions while 50% had no preference. Preferences were not evenly distributed across the four options. The recruitment procedure was then reconsidered to try and understand why patients were avoiding two of the options (options 1 and 2). The description of the treatment options was modified slightly and the pilot repeated. Preferences were found to be equalised across the four options. These pilot studies suggested that a) we can discover preferences that we did not anticipate if we make a point of investigating preferences, and b) we can sometimes influence patients' preferences very easily with minor changes of wording or emphasis. Several studies are now being planned to use the design suggested by Brewin and Bradley (1989). One study, recently funded by the Scottish Home and Health Department, will evaluate a new method of termination of pregnancy in the first trimester, comparing the new treatment with standard surgical treatment and assigning patients to treatment group according to patient preference, allocating at random only those women who have no preference (Naji, 1990).

In figure 2, the focus was on the issue of patients' preferences and the possibilities of building this variable into the study design. Other ways in which psychological variables might be incorporated into this study have already been addressed earlier in this chapter in other contexts and include

1. the measurement of psychological as well as metabolic outcomes,
2. the investigation of individual differences,
3. determination of selection criteria and recruitment procedures.

If selection criteria are limited to metabolic outcomes it may well be that patients who could benefit from the new technology are not even considered for inclusion in the study. It may be that some patients who have not experienced hypoglycaemic attacks and who have maintained excellent blood glucose control have achieved this only at the expense of considerable personal effort with frequent blood testing, painful fingers and heightened levels of anxiety about the possibility of blood glucose fluctuations which may go unnoticed. Such patients may be motivated to try glucose sensors but the success of the new technology would for them be measured not in terms of improved control and reduced hypoglycaemic episodes, but in terms of improved psychological well-being and satisfaction with the treatment regimen required to attain near-normoglycaemia. If evaluations of new technology exclude such patients, an excellent opportunity to demonstrate the advantages of the technology will be lost. A variety of selection criteria may of course be included, as they often are in clinical practice, and the outcomes associated with the different selection criteria may be investigated in within-group analyses of subgroups of patients.

A range of analyses investigating individual differences would include analyses of the within-group variability in outcomes. Some patients may demonstrate considerable benefits while others in the same treatment group

demonstrate no such benefits or even experience unwanted effects from the treatments. Investigation of such differences to try and predict outcomes on the basis of psychological, clinical, metabolic, demographic and other variables measured at the start of the study will be likely to improve our understanding of the processes involved and increase the chances of using the technology appropriately in future. Recruitment procedures are rarely determined, adhered to and described with the same attention to the importance of scientific rigour as are other aspects of clinical trials although recruitment procedures may themselves be regarded as worthy cases for study. In clinical trials which have to settle upon one method of recruitment, pilot work, such as that carried out by Marteau and described above, may be required to determine appropriate procedures for the purposes of that study. Written information for patients being recruited into the study will serve two important purposes; first it will increase the chances of recruiting patients in a uniform fashion and, secondly, the information can be reported verbatim in publications of the study and may be taken into account by readers trying to make sense of differences between the findings of two otherwise apparently similar studies.

Measurement of Psychological Processes

Measures of psychological outcomes are only one subset of psychological measures that should take their place in clinical trials of new technologies in diabetes care. Measures of psychological processes are also important. Without measures of the psychological processes involved all we can do is establish the nature of the outcomes in any particular study. If we are to be able to understand the reasons for the outcomes and increase the chances of improving the outcomes in future studies then we need to include measures of psychological processes. Such measures might include measures of health beliefs and perceptions of control over diabetes which were useful in understanding reasons for different levels of glycaemic control in the patients choosing to use the different treatment options in the Sheffield feasibility study (Bradley *et al.*, 1987), and the reasons for a high incidence of diabetic ketoacidosis among CSII users in that study (Bradley *et al.*, 1986). Other measures that may help to account for individual differences in treatment efficacy, or between-group and between-study differences in outcomes might be measures of patients' knowledge about their diabetes and its treatment, their expectations of the treatments to be evaluated, and measures of the extent to which individuals adhered to the study protocol. With measures such as these and intelligent data analysis we can determine, for example, why glucose sensors are associated with better or worse outcomes than self monitoring of blood glucose. We could better establish the characteristics of the glucose sensor technology, and its use in any particular study, which are responsible for the outcomes obtained. Equipped with such information we would be better able both to improve on glucose sensor technology and to design more appropriate user-friendly technologies in the future.

Summary and Conclusions

Psychological variables need to be considered in

1. measuring outcomes such as patient satisfaction with a new treatment and their psychological well-being for consideration alongside metabolic outcomes in evaluating new technologies in diabetes management,
2. investigating individual differences in expectations of, responses to and outcomes associated with new treatments,
3. determining selection and recruitment criteria,
4. measuring processes such as adherence, knowledge and beliefs with a view to understanding individual and group differences in treatment outcomes.

The psychological variables considered here can indeed be studied with the benefit of scientific methods. Clinical trials which consider and investigate psychological variables may overcome the fears of the early resistance movement against "scientific" clinical trials by becoming more humane, less misleading and more scientific.

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