



Editorials

Military doctor

The late Major General William Officer said that he required his medical officers to give one hundred per cent as soldiers and one hundred per cent as doctors. With the recent deployment of the medical services of the Armed Forces to support the British military effort in the Gulf it is worth examining this requirement to determine whether General Officer's criteria are appropriate and whether they can be met.

The first reaction is that the medical officer of the Armed Forces may be serving in the Royal Navy, the Army or the Royal Air Force. Each service has its own special requirements for medical support in times of war but it is essential that the management of casualties should follow a coordinated plan. The direction of the three medical services under a Surgeon General at the Ministry of Defence has ensured that this is the case and that there is close cooperation between the three medical services at all levels from Forward Treatment Unit back to National Health Service Hospitals in the United Kingdom. It is essential that every medical officer understands the special requirements of his or her own service in the maintenance of the health of the Force, in appropriate deployment to their special tasks and the threats inherent in their deployment and in current military weapons technology.

In the Gulf area it can be readily appreciated that the climate imposes its own burdens which can be greatly added to by the threat of chemical weapons. The vast areas of empty desert pose special difficulties in the collection, first aid, treatment and evacuation of casualties to base hospitals in Saudi Arabia and to hospital ships prior to evacuation by air to the United Kingdom. Ten years ago the military medical professors coordinated regular courses of instruction in war surgery and war medicine, held at the Royal Army Medical College but involving participants from all three services and including reserve medical and nursing officers. Guest lecturers included senior doctors from the Middle East with recent combat experience. These courses began before the Falklands Campaign (1982), which was a testing ground for all three medical services and the experience so gained was fed

back in to these instructional courses and also in to the Annual Field Exercises of forward Medical Units of the Regular and Reserve Forces.

The Armed Forces Medical Services in peace time cannot effectively employ the number of doctors and nurses required for operational support in war. Fortunately the system of granting short service commissions to doctors and nurses with an emphasis on training for their peace time and war time roles has provided a large pool of experienced medical and nursing staff on the regular reserve or serving with volunteer reserve units. Thus the reserve units are as well trained as their regular colleagues and the volunteers bring to their tasks an enthusiasm and commitment which is impressive to behold.

Medical resources on a battlefield will always be limited by the war environment. The enormous technical advances in surgery which have transformed the outlook for patients with congenital or degenerative conditions may not have immediate application on the battlefield but the developments in resuscitation, intensive care and anaesthesia which has accompanied them have greatly increased the chances of survival of the seriously injured. Surgery and medicine on the battlefield are aimed at preserving life and minimizing disability¹. By the time the patients reach base hospital they should be in a stable condition and ready for restorative treatments, convalescence and rehabilitation.

All medical and nursing disciplines can make a significant contribution to the medical care of our sailors, soldiers and airmen. From the medical support in the front line through the dramatic intervention of the surgical teams and the specialist support of the physicians to the psychiatric social worker back in the United Kingdom all have been trained and exercised in their role, and those of us who can only watch and wait are assured that they carry it out with the utmost professional dedication.

Major General Robert Scott
Totnes, Devon

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Single-case research designs for the clinician

Introduction

Single-case study designs¹⁻³ are an attempt to formalize clinical stories. These designs take as their

basis the clinical process where the illness is assessed and diagnosed, a treatment is prescribed, the patient is monitored during the application of that treatment, and the success of the treatment is then evaluated. However, the validity of this therapeutic 'success' is open to question. There may be a subjective bias influenced by the expectations of the clinician and the

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patient. Similarly, the patient may appear to improve through willingness to please the physician. In some cases, the disease may have run its course and improvement would have occurred without a therapeutic intervention. Finally, the initial assessment of the patient may have represented temporary extreme values which are lessened at a subsequent assessment; ie a 'regression towards the mean'.

The experimental approach attempts to accommodate these difficulties by systematically varying the management of the patient's illness during a series of treatment periods⁴ using randomization of treatment periods and blind assessment. In the single case approach the patient is the source of his or her own statistic, randomized treatment and blind assessment may be incorporated within the therapeutic plan. The patient is not compared with a group norm, his or her progress is in accord with individual constitution, which is subject to statistical verification using the analysis of data trends⁵⁻⁷.

Single-case research designs are not a unified approach. There are differing levels of formality and experimentation: ie randomized single-case study designs, often called N=I studies^{4,8,9} and single-case experimental designs^{2,10}. A common feature of these designs is that they stay close to the practice of the clinician. An advantage is that there are no difficulties of recruiting large groups of patients, or having to collect and analyse large data sets.

A criticism of group designs is that they mask individual change¹¹. Improvement or deterioration is not evident for particular patients. Furthermore, the results of large-scale trials are not always easy to translate into clinical terms for the practitioner. Single-case designs highlight individual change in daily clinical practice. Furthermore the dilemma of clinical priorities or research priorities is minimized. This type of research is applied as part of the clinical treatment and is relevant to both clinician and patient. In some cases patient and clinician are the researchers⁴.

The principal feature of single-case study designs is that they are feasible. The problems of recruitment are minimized, the study is cheap and the results are generally evident. Much research flounders because of the difficulties of finding large groups of patients with similar symptoms, a lack of resources (time, personnel and money) or an absence of clear statistical analysis which is often compounded by initial confusions in the methodological approach. In this approach each person serves as his or her own control. Effective treatments are linked with specific patient characteristics which are immediately relevant to the clinician and the patient. Any decisions about the design of the trial, and the choice of outcome measures, can be made with the patient⁹. The primary focus of the research is upon the treatment benefit for the individual, whereas conventional studies are more concerned with changes in groups of patients. A weakness of single-case designs is that, while individual change is specific, it is difficult to argue for a general validity of the treatment. To overcome this problem it may be feasible for groups of co-operating practitioners to collect single case data according to a common format and then analyse that collected data as a group.

The first step in this approach is to identify the target behaviour. This can be a symptom or physical sign, a result of a test, or an indicator suggested by

the patient. This is negotiated with the patient and is understood by both clinician and patient as being appropriate and relevant to the patient's well-being or clinical improvement. A *critical feature* of this target behaviour is that it will be susceptible to rapid improvement when therapy begins. This target behaviour then becomes the *baseline* measure in an initial period of observation. The initial period of observation is sometimes called the 'A' phase. The intention of this phase is to enable a stable pattern or trend to emerge. This is based on the natural frequency of the symptoms. Any treatment effects can then be seen clearly in contrast to this baseline. It is important that the method of measuring the observed behaviour is specified accurately. There can of course be more than one form of assessment; the clinician may want to rely upon physiological, immunological or biochemical markers while the patient may devise a self-report index. Apart from its clinical value, the choice of measure has a secondary research value. If the case study is to be part of a systematic research approach the measure will need to be replicable. Similarly, if the research is also intended to speak to other practitioners it is important to develop a measure which they can validate.

The development of a specific evaluative index¹², or battery of tests, is an important task which challenges the clinician to relate theory to clinical practice. The main requirement of such an index is that it will be sensitive to change over time and will include all the clinically important effects. It is important to be able to link those clinical changes to the treatment.

Once the baseline has been established then the agreed treatment variable is introduced. There can be multiple treatment courses during this period, and these can include placebo. In the randomized case design these treatment courses are randomly assigned. This design is strengthened by the possibility for the patient and the clinician to be blind to the treatment variable if a medicament is used. Where the patient and clinician cannot be blind to the treatment intervention an external assessor can be blind to the treatment period. Such an external assessor can also act as a monitor of the trial and halt the trial if it is in the best interests of the patient.

Where the treatment variables cannot be randomized, single-case experimental designs are used with an assessor blind to the treatment phase. The initial baseline 'A' period is followed by a treatment period, 'B'. This is an improvement on the case history in that it offers comparative data in two clear phases. This design can be extended by an additional assessment 'A' phase. There are problems here in that a decision about when to stop treatment has to be made, and the treatment may not be continued to conclusion. This is compounded by the difficulty of ending on a 'no treatment' phase.

If a further treatment period is introduced, then an 'A B A B' design occurs. The intention in these designs is to keep the length of the treatment phases identical. These designs can become quite complex and include composite treatments. Parts of the treatment can then be omitted or included systematically. For example; after the baseline data are gathered, 'A', then a composite treatment is administered 'BC'. This could be a treatment which included manipulation of the body and a medicament. In the following phase the medicament could be withdrawn, the 'B' phase. The

next phase returns to the composite treatment. This then becomes an 'A BC B BC' design.

Multiple baseline designs have been used to test some psychological behaviour approaches^{10,13}. The treatment variable stays the same, but there are multiple baseline target behaviours of differing duration. Ideally these target behaviours are specific and independent.

The patient diary can be part of an evaluative index. In diary studies the principal collector of data is the patient. The use of subjects making their own assessments of symptomatology is not new¹⁴, and offers a non-intrusive means of gathering data. The use of diaries in clinical practice has several advantages. First, there is the opportunity to provide a daily scoring which eliminates recall error and produces consistent reporting. Second, there is a comprehensive view of the person's health¹⁵. Third, symptoms are treated as episodes rather than solely static events^{16,17}. Fourth, diffuse conditions are included which may not be disabling or necessitate intervention but which contribute to the profile of the patient's symptomatology.

In single-case designs there are possibilities for a statistical analysis of each single study^{1,9}. However, the main appeal of working in this way is that daily measures are plotted on a chart and can be seen by eye. Clinical improvement can also be assessed by reports from the patient and various persons connected with the patient (spouses, relatives, experts) who can also suggest that the change is of applied significance.

Statistical analysis can be used where subtle significant changes occur in the data which are not immediately visually apparent, or where many variables are collected from an individual and need to be correlated one with another. If data are serially dependent then it is possible to perform a *time series analysis* of the data. This provides important information about the different characteristics of behaviour change across phases, and a statistic which indicates significant change⁵. Such time series analysis requires large samples of data points to select the processes within the series itself. This time series analysis of data has proved to be clinically relevant. It has been demonstrated that the time series analysis of serum creatinine levels from renal transplant patients is sensitive enough to detect transplant rejection which precedes that of experienced clinicians⁶. Furthermore, time series analysis of trends in data can also be sensitive to the circadian rhythms of physiological processes and influence the administration of drug regimens⁷.

A difficulty which can arise in single-case studies is when they are used following a period of standard treatment which has not worked. Some general improvement may occur which is nothing to do with the treatment being used but is a 'regression towards the mean', ie the tendency of an extreme value when it is remeasured to be closer to the mean. This can be overcome by including a washout period between the treatments. Such a period would serve to establish the patient's eligibility for the trial. Following this there would be a set of measurements which would be considered as the baseline data. The consistent recording of longitudinal multiple data in these studies requires great perseverance on behalf of the collector and the patient. This is mitigated by the sample size of one.

Perhaps the major criteria for using a single-case design are that the treatment should exert its effect in a moderately short time, and the effect will be temporary and reversible once treatment is discontinued. If not, then a group design must be considered. These single-case methods are generally reliant upon a stable baseline period in the 'A' phase. This means that they are not particularly relevant to acute or labile problems. They are appropriate for chronic problems, or patterns of recurring behaviour, which have become stable over time.

The advantages of these single-case research designs are their flexibility of approach and the opportunity to include differing levels of rigour. Such designs are appropriate for practitioners wishing to introduce research into their own practice, and particularly for developing hypotheses which may be submitted for other methods of clinical validation at a later date. Furthermore, with the development of statistical methods suitable for the monitoring of subjective, rhythmic or episodic data, which is not dependent upon the collection of equally spaced recording, and which provides a method which can detect changes and also discriminate between those changes⁵, clinicians have an opportunity to validate their clinical finding. This analysis is pertinent to the individual in that they are always compared to their own individual physiology.

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Community and asylum care: plus ça change

Controversy still surrounds the future of Britain's mental hospitals¹ despite 15 years of consistent Government policy². Little attention has been paid to the lessons of the past, despite parallels between contemporary developments and those of 150 years ago³. Common themes are therapeutic optimism, the expansion of the scope of cure and political economy. The latter is made much of elsewhere⁴⁻⁶. The 19th century-built asylums are now seen as a bad thing, but this in itself is not new. What is different about this revolution in mental health is the absence of the wider societal changes which characterized the 19th century revolution⁷. The pressure for change has been directed at stamping out organizational bad practice. The therapeutic revolution of rehabilitation and normalization can be seen as being more apparent than real.

Scull⁷ argues that the 'asylum' movement did represent a major shift in the way the insane were treated. This change was mirroring wider societal/philosophical changes which laid emphasis on individual responsibility and rationality. As the industrial revolution progressed and the system of feudal patronage broke down, the industrious poor came to be valued chiefly in terms of the marketability of their labour. Thus, it became increasingly important to distinguish the deserving poor (who were supposedly incapable of supporting themselves) from the undeserving poor (who were poor, but were supposedly capable of earning a wage and could therefore support themselves). The insane were seen as being part of the deserving poor and so were separated out. This was most efficiently done by bringing them together in one place.

However, the 'Reformers' (such as Tuke and Connolly) envisaged 'the model institution' where the patient might be returned to good health, not just warehoused. The treatment in these institutions ('moral treatment') identified the social environment as being the therapeutic agent, acting through the patient's mind⁸. Two aspects of the social environment were regarded as especially important. First, the attitudes and demeanour of the attendant staff, were significant. In Tuke's words 'treating the patient as much in the manner of a rationale being as the state of his mind will possibly allow . . . whatever tends to promote the happiness of the patient is therefore considered of the highest importance in a curative point of view' (Tuke 1813⁹). Secondly, the

physical environment of the asylum was significant. Turner³ quotes Browne writing in the 1830s:

'Conceive a spacious building resembling the palace of a peer, airy, and elevated and elegant . . . the sun and air are allowed to enter at every window . . . the inmates all seem to be activated by the common purpose of enjoyment, all are busy and delighted by being so.'

However, the asylums quickly came to be perceived as falling far short of the ideals of the Reformers. Mortimer Granville (quoted by Scull⁹), for example, in 1887 described the Middlesex County asylum at Colney Hatch (later to be called Friern Hospital) as a:

'colossal mistake . . . it combines and illustrates more faults in construction and errors of arrangement than might have been supposed possible in a single effort of bewildered or misdirected ingenuity . . . the wards are long, narrow, gloomy and oppressive, the atmosphere of the place dingy, the halls huge and cheerless. The airing courts, although in some instances carefully planted, are uninviting and prison-like.'

The Reformers plans for achieving more cures thus depended on the virtues of staff morality and landscape architecture. These plans for 'moral cure' seemed to be destroyed by:

- (1) Increasing numbers of the insane, few of whom seemed to be curable. They soon filled up the existing services defying the reformers notion that people would return to good mental health and the community.
- (2) The pressure to economize in the light of the demise of Britain's international competitiveness at the end of the 19th century.
- (3) The medical profession's keenness to monopolize the care of the mentally ill^{9,11}, required them to have large hospitals like those of their medical colleagues.

Scull⁷ argues that 'there was a change in the cultural meaning of madness' in the 19th century. This involved a change in perspective consistent with an increasingly technological age, when people came to be seen as less 'god given'. They were seen as rational beings, internally motivated and regulated by rules internalized from the environment. Similarly, the insane came to be seen as rational beings, capable of being influenced by the same forces as those acting upon sane people. Previously the insane were seen as having lost entirely the human features of reason, and were left in a state of 'animality'¹⁰. These changes helped fuel 'the moral outrage which did so much to animate the lunacy reformers . . .' of the 19th century⁷. Today there is no equivalent radical change in the perception of the mentally ill. On the contrary