Research ethics committees and military defence

Ethics committees are essential to examine proposals for research on human volunteers. Additional and special problems are encountered in the military defence environment. Some of the procedures developed to deal with the work of the armed services may have relevance to the broader ‘civilian’ approaches to the ethical aspects of volunteer studies on humans.

Research on human volunteers at Ministry of Defence (MoD) establishments is subject to ethical review as is research on volunteers in civilian institutions. As this is not generally known, it is perhaps timely to place on record the need for research which involves human studies within the MoD, the ethical problems that may be raised and the consequential importance of having ethics committees to which matters can be addressed. This paper is based on my experience as chairman of the ethics committees connected with the Army Personnel Research Establishment and the Chemical and Biological Defence Establishment.

Need for research

There is a long tradition of research on human volunteers in the Services dating back at least to the First World War when, for example, it became necessary to study the effects of poisonous agents at the establishment which was the forerunner of the Chemical and Biological Defence Establishment (CBDE) [1]. Work on human factors—climate, diving, clothing, stress and endurance—has been vigorously pursued for many years, achieving a more formal status with the development of operational research as a discipline during the Second World War [2] and the emergence of controlled trials shortly thereafter [3]. In many of the early studies the investigators acted as their own trial subjects but volunteers were also required. New areas of research that involve human subjects continue to emerge in the defence field: for example, the work of experimental psychologists in developing man/machine interfaces which exploit human strengths (psychomotor skills, reasoning) and guard against weaknesses (decline in vigilance and failure of effective monitoring), and human factors in issues associated with such new technologies as virtual reality and distributed interactive simulation. There is also a continuing need for research as weapons, equipment and tactics develop and the scene of possible engagements changes. It is important, however, to distinguish in the military context between research and development (R & D), which requires the deliberate use of volunteers who are asked to participate in the relative uncertainty of a study, and training which can expose the serviceman (this term now covers both sexes) to possible physical and emotional hazards. For the first an ethics committee has responsibility. For the second it lies with the Service authority acting through a commanding officer who adheres to military regulations rather than a code of ethics code. This individual will have or will seek out expert advice about what is physiologically or psychologically allowable. The distinction between the two circumstances of study and military practice is usually clear-cut but there are borderline instances. One such potential grey area could be a training session where troops may be in danger which is not obvious to the responsible officer. However, usually the commanding officer, by his instincts, experience and training, is unlikely to subject his servicemen to undue hazards; his task is to train people to work efficiently for him in both peace and war. To a large extent his peacetime career depends on this and in war lives turn on his abilities.

Need for ethics committees

Given that volunteer studies will continue for the foreseeable future, it is now a universally conceded principle that they must be assessed by ethics committees which use the same guidelines—derived from the Declarations of Helsinki and Geneva—as do all others. They have been well summarised by the Royal College of Physicians and are continually brought up to date [4,5]. It is worth emphasising that in the military context one area that is not the concern of a committee considering research in human subjects is tendering advice on the morality of deployment of a particular weapon or weapon system.

Special considerations

The axiomatic need for ethics committees in relation to research in human subjects has been recognised by most MoD establishments. In addition, as a result of wide-ranging discussions over the past two years, a Defence Council Instruction which covers many of the issues addressed in this paper will shortly be promulgated. However, in relation to military defence, there...
are some special considerations in research with humans.

Security

It is inevitable that some research with human volunteers will be in support of the national security of the UK and its allies. It would be damaging to national security if potential aggressors became aware of the capabilities and deficiencies of British equipment and practices. Sensitive information must be protected and in consequence members of ethics committees in defence establishments must observe the Official Secrets Act (OSA) which ensures that matters which could hazard the security of the UK are not divulged. That this is so does not in any way permit a change in the ethical standards by which the work is judged.

However, this may have two consequences. First, some individuals might feel that it is incompatible with their standards that they should be asked to approve work which is not in the public domain and consider further that there is an inhibiting restriction about discussions that may have to take place in camera. It is certainly true that signing the OSA is a (minor) limitation of freedom. The matter can only be resolved by individuals deciding for themselves whether or not they wish to be involved with an ethics committee which works within such terms of reference. It is my view that the need for proper assessment of ethical standards of research on human volunteers outweighs the potential restrictions imposed by the OSA. It can also be reasonably argued that effective security and defence against aggressors is of itself an ethical reason for supporting defence research. Furthermore, it is impossible to rule out the simple, if old-fashioned, element of patriotism, though others may take a different attitude.

The second consequence, which is an extension of the same argument, is that the duty imposed on an ethics committee of being accountable—chiefly by the open publication of an annual report—is similarly restricted. Again it is my belief that the need for effective assessment of ethical standards negates this constraint. The recent move towards increased openness by government may reduce these problems still further.

Membership and conditions of service

Within the above restraints for individuals, we have endeavoured to recruit along the lines specified by the Royal College of Physicians [4] and have not found difficulty in doing so. It is of course especially useful if the lay members, the general practitioner or others, have service experience though this should not be, and is not, regarded as a precondition for membership. The senior military officer of the establishment—the individual responsible for the welfare of any Service personnel, including volunteers, who are stationed there—is also a member and acts as an additional lay person. The MoD, through the establishment concerned, undertakes to indemnify the independent members of the committees from claims, meets all expenses and, in view of the work required, pays a modest consulting fee. It could be argued that the system of internal appointment of a chairman through recommendation by management (for example the establishment director or director general), and the reimbursement of expenses and fees, might undermine independence. However, it is my firm opinion that the essential integrity of the scientific community renders this unlikely. It is also difficult to see a workable alternative, though it might be feasible to set up a formal system of consultation and recommendation from professional bodies such as one of the Royal Colleges.

Chain of command

Levels of command and control are inherent in the military environment, and indeed the whole structure of the MoD is implicitly organised around this concept. Nevertheless, it is equally the case that an ethics committee must be truly independent and free to insist on—rather than merely advise—whatever action is dictated by its views on the ethics concerned. Such independence is understandably difficult to comprehend for those unaccustomed to the hierarchy of command but has been accepted without question once the difference in the structure has been made clear. A special relationship and depth of understanding is therefore required, so that, though an ethics committee is seen to be functioning independently, it is not regarded as a ‘loose cannon’ which might willfully roll across the gun decks of the ship of state. In particular, the body or establishment with which an ethics committee works must understand that the latter is not under an obligation to be primarily accountable to a director or some controlling body such as a council, except that it must work within its terms of reference. The committee’s primary concerns are consideration for the study volunteers and, as discussed in more detail below, the scientific community in the establishment.

Nevertheless, in spite of this independence, the committee must seek to keep the organisation informed of the reasons for its decisions. There are two methods by which this can be achieved: production of an annual report for the controlling organisation, accompanied by publication within the limits imposed by the OSA; and, as is the case at CBDE, having the chairman of the ethics committee an ex officio member of the council of the organisation. To date these methods have worked well.

Protection of investigators

The perceived features of some of the research work carried out for the MoD renders scientific staff, in the climate which currently surrounds research on human
volunteers, susceptible to public criticism which may be informed or otherwise. This is not, of course, unique to research work done for the Services but is especially apparent therein. In consequence, ethics committees have more need to protect investigators from ill-informed criticism than may be the case in civilian life. We have found it increasingly important to get researchers to couch their research submissions in terms that bring out clearly the need to make Service personnel fit to carry out their military functions. To do so creates a pre-emptive counter to possible future (mis)interpretations and allegations that the work is being driven only by scientific curiosity or, in more sensational terms, by the ‘mad scientist’ syndrome. Consent forms have to be carefully designed to make crystal clear what is to be done and why this is needed. We are perhaps over-concerned in this area, but few who are experienced in dealing with the criticism of research on volunteers would deny that the wind of change, if not of outright criticism, is crisper and cuts more coldly with each passing year. It is also desirable that a research protocol that begins in the laboratory but will move on to studies on volunteers be assessed by the ethics committee as early as possible so that snags do not occur during the development of the work. We try to develop interaction with the research workers concerned so that they can plan their total experimental programme to take into consideration what future rather than present attitudes might be.

Committee work

To achieve some of the objectives I have outlined—trust between the independent committee and management, protection of investigators and long term planning—military defence ethics committees have a more focussed role than that commonly associated with district committees in the Health Service. We mostly deal with relatively closely defined fields of science. This helps us, in modern jargon, to be more proactive than reactive. We endeavour to keep ourselves informed of the work going on in the establishments by arranging a demonstration of some aspect of this to follow most of our meetings. As occasion arises we circulate our views to all scientific workers. In addition, free exchange of opinions is greatly assisted by having a scientific officer within the establishment as secretary to the committee. Finally, not only as a means of clarifying our own minds about an individual proposal but also as a method of feeding back our views to the scientific community within the establishment, we usually ask the investigator to come to our meeting to explain in general what the work is about, to respond to our questions and to clear up any ambiguities or, if possible, to resolve our doubts. Though we do not constitute ourselves as an ethical inquisition, we and the investigators have found these exchanges in the committee useful for maintaining high standards of assessment.

The threshold for submission of a protocol for ethical approval is kept very low for the reasons that have already been discussed. In effect any work that requires human volunteers is passed before the committees, though the labour of doing this is much reduced by the development of generic protocols, which I describe later. The forthcoming Defence Council Instruction, in addition to giving guidelines which aim at making a distinction between research and training, sets out general advice on the type of study which should be referred for ethical approval and the channels through which further information can be obtained. Such an instruction has more weight than the rather loose constraints that presently exist in civilian life.

We strongly discourage ‘chairman’s action’. Not only does this practice run counter to the ethos of ethics committees which should work on the premise of joint decisions after debate from several angles but it also encourages research workers, be it ever so slightly, to delay submission of a proposal until there is looming urgency to gain approval against some deadline. I sometimes feel—perhaps with a degree of cynicism based on my own former activity in clinical research—that there is then an implicit hope that the protocol will be approved without having to go through detailed critical survey by the committee. Be this as it may, it is my experience that the chairman often fails to see matters of considerable importance to the volunteer or investigator and, moreover, may not appreciate that the study is poorly designed. The last, as is broadly agreed, is not currently regarded as the primary concern of local research ethics committees who should receive for review only proposals that have been subject elsewhere to critical analysis of their scientific content. Nevertheless, few who have served on research ethics committees will have failed to realise that on occasion there is a scientific case for rejecting a project because of its inadequate design and lack of credibility in achieving its ends. The point has recently been well made by McIntosh [6] and by Altman [7] as well as in the popular scientific press [8].

Imperatives of time and the needs of the Services may occasionally require action by the chairman but we make it clear to scientific staff that good planning will usually foresee the need for a submission in time to coincide with a meeting of the committee. The chairman’s approval is granted only with concurrent circulation of a full text of a protocol and the opportunity for members of the committee to disagree. One such disagreement leads to refusal of consent to proceed until a meeting can be held. A formal submission and reconsideration is in any event mandatory at the next meeting of the committee.

Ethics committees have frequently been criticised for not monitoring what is going on in the prosecution of the work they have approved. To meet this need at least in part, each meeting of our committees receives
a report of the number of studies done under specific protocols, the occurrence of 'adverse reactions' or other unexpected events and the action taken. The easy availability of such information is underpinned by computer-based recording systems designed to generate the statistics as a by-product of the research being done. The figures eventually form the basis of one section of the annual report.

Volunteers

There are three possible methods of obtaining volunteers, two of which are in current use; the third is under consideration. For much of the work in the military field it is essential that the subjects have specific military knowledge. It is not much use trying to study the ability to strip and re-assemble an automatic weapon in test circumstances if the subject is not acquainted with the weapon. In consequence, the first two methods recruit from within the Services. At one establishment, this is by a round robin through the appropriate channels, soliciting volunteers and explaining in general terms the importance of the research programme and what is needed from those who consent to be subjects. At the other, using the same mechanism of communication, personnel are asked to volunteer for a posting of varying length which will then integrate them into a cohort which is available for research according to the needs of the establishment over the period. Both these methods have advantages and disadvantages which are largely self-evident. The first is more suited to getting as representative a sample as possible of service personnel which is at the same time relatively naive about the projects. The second is desirable for more complex experiments in human factors research where some experience on the part of the volunteer can be useful in generating consistent results.

Both these methods have to meet the rightly rigorous demands of detailed documentation within the Services. It has to be possible for a volunteer to withdraw at any time from a study without giving reasons; at the same time all volunteers must be reassured that if they do so this will not affect their subsequent Service career. Finally, if, in the course of human study, the establishment uncovers evidence bearing on the health of the volunteer, the latter must be made aware that it is essential that this information be available to the responsible Service unit. These matters require very careful drafting of forms of consent and the development of a process of communication with the Service volunteers which is more precise and overt than that often followed in civilian life. The ethics committees plays an important part in the design of forms and in determining methods of communication with volunteers.

The third method of obtaining volunteers is to create a civilian cohort analogous to the military one. This would not be suitable for circumstances in which military experience is a prerequisite or the OSA is involved (though it could be possible to clear the members of such a cohort through the appropriate machinery) but, provided that selection procedures can be developed which ensure the comparability of the civilian cohort to the Service personnel in relation to which the study is being done, could well find a place in human factors work. Because many studies are expensive to mount and time-critical, to have such a group readily available would simplify planning and make for efficient use of facilities. Moreover, in this cost-conscious age, it would be cheaper than using fully trained Service people.

Whatever the origin of volunteers in the future, there is an ethical necessity to provide full rights and facilities for legal redress and possible compensation should an untoward event take place. An extension of this is required to indicate to the volunteer that in certain circumstances a sympathetic view would be taken of the need to consider 'no fault' compensation. These matters are carefully explained to every volunteer.

Generic protocols

The system described here may appear to be somewhat involved and potentially too heavy. To this end, and because much of the work of the Army Personnel Research Establishment and the Chemical and Biological Defence Establishment is well within accepted ethical standards and with known and often trivial risks, the ethics committees, in conjunction with the establishment scientists, endeavour to construct generic protocols and generic procedures under whose authority studies can then be undertaken without detailed reference on each occasion to the committee. This task is not as easy as it might appear. The balance between freedom for the scientists and necessary vigilance by the committee has to be finely struck. However, it is proving a worthwhile exercise and, as experience accumulates, will indubitably reduce both committee work and the burden of drafting detailed submissions. There is a commitment to formal review of generic protocols after a defined time—usually two years.

Discussion

Though there are obvious differences of attitude and different needs in research on human volunteers which takes place within the MoD and its associated establishments and that commonly going on in the NHS and academic institutions, there is much to be learnt procedurally from our experience. Can we continue to rely in civilian life on broadly based ethics committees that do not actively seek to inform themselves professionally on the subject matter submitted to them? To achieve this and undertake an increasing role in the scientific as well as purely ethical assess-
ment of protocols, do we need a change in terms of reference and membership of research ethics committees? Can we still regard the work of such ethics committees as voluntary rather than a task which deserves to be recognised in some way? Can we countenance differences in outcome of assessments between ‘chairman’s action’ without creating a reference standard such as conformity to a generic protocol? Is enough attention paid by ‘civilian’ committees to the need to provide research workers with at least a partial carapace with which to discourage or deflect criticism that is uninformed or on occasion mischievous? The answers to these perhaps mundane though important questions—and there may well be others that I have failed to ask—could be obtained both by further debate and research. The account I have given of the developing ethics apparatus in some areas of the MoD is designed to encourage both.

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