Rights, obligations and utility in sports medicine research.

OLIVIER, S.

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S Olivier MA (Rhodes)
University of Zululand

ABSTRACT
Sports Medicine is concerned with rehabilitation and performance in both elite and nonelite athletes. Continued research is crucial towards progress in these areas, and subjects are increasingly being subjected to manipulative and invasive experimental methods. In examining current research practices, this paper questions whether we ought to rank consequentialist principles over nonconsequentialist ones. The history of cases of abuse of human subjects is considered, and the argument is presented that official endorsement is not a sufficient guarantee against exploitation. The concept of Informed Consent is examined in some detail, and guidelines are presented as to when obtaining consent is deemed necessary. Further, journal review results seem to indicate that in a large number of cases, consent is either not reported, or is not obtained. Finally, the paper discusses the use of "captive" subject populations, and here issues such as coercion and sanction are examined. Whilst cautioning against an over-cautious approach to research ethics, the paper holds that researchers should be aware of the potential for conflict between virtue and self-interest. Finally, it is concluded that Sports Medicine researchers should be guided by deontologic rather than consequentialist ethical principles.

Sports Medicine and Research

Sports Medicine is primarily concerned with the rehabilitation and performance of both elite and nonelite athletes. Both areas depend on research in order to make progress, and this research may be either therapeutic or nontherapeutic, both forms (but particularly the latter) contributing to improvements in sports performance. This paper focuses on non-therapeutic research in Sports Medicine, and evaluates the practice of research ethics in terms of consequentialist and deontologic approaches.

Research per se is concerned with (usually) novel techniques used to develop or contribute to generalizable knowledge.[1] Research in Sports Medicine can be seen to be critical and exhaustive investigation that aims, through systematic observation or experimentation, to elicit new information about human performance. From this it follows that while procedures may be rigorously evaluated and controlled, results and possible negative consequences cannot always be accurately predetermined. Recent decades have witnessed a dramatic increase in research across disciplines, and Sports Medicine is no exception. The commonly accepted "progress imperative" view of science demands that research subjects be increasingly subjected to manipulative and possibly invasive experimental methods.

Such procedures, whilst increasing knowledge, may be maleficent, and it is necessary to question whether our research ranks consequentialist principles over nonconsequentialist ones. Rifkin[2] contends that Western medical science continues to move towards utilitarianism. On the other hand, Brodie & Stopani[3] state that current societal opinion reflects the present ethical belief that it is more important to avoid risk to a subject than to gain future benefit or advance knowledge. There is thus perhaps a need to examine whether research in Sports Medicine practises 'bottom-line' ethics which is concerned only with winning and losing, or virtue ethics which is also concerned with how you play the game.

The abuse of human subjects

History provides numerous chilling examples of the abuse of human subjects, such abuses commonly justified through appeals to the beneficial consequences of medical research. Space precludes going into detail - suffice to say, that evidence exists regarding the harmful exploitation of research subjects, such as the Tuskegee study, experiments on concentration camp inmates in Nazi Germany, and experiments conducted by the Japanese on 'prisoners-of-war.'[1,3]

In some cases utilitarian rationalisation protected researchers from prosecution, the argument being that the benefits to medical science far outweighed the harm to a few individuals. The rationalisation behind this was that such valuable results were unobtainable elsewhere due to more stringent controls. These cases mentioned exemplify extreme examples of human subject abuse, but do bring to the fore issues such as maleficence and a disrespect for subjects as persons. Furthermore, a broad issue that ought to

Address for correspondence:

Steve Olivier
HMS Department,
University of Zululand,
South Africa
Tel: 27 351 93916
e-mail: solivier@pan.uzulu.ac.za

concern all researchers utilising human subjects is raised, namely that of the conflict between moral principles and self interest.

Given the rise to prominence of Bioethics, it could be argued that a repeat of abuses mentioned above is not likely to occur. Caution should however be exercised before accepting such an argument, as progress demands, and society continues to encourage, human experimentation. An examination of pre-World War II Germany shows that regulations on medical ethics were comprehensive and protective towards subjects, yet physicians perpetrated abuses, indicating that official endorsement is not a sufficient guarantee against exploitation of human subjects. Pettit[5] concurs with this, contending that self-regulation offers the most effective protection for research subjects. Formalising ethical practices may thus be a necessary, but not sufficient, condition for the prevention of subject abuse. If this is accepted, then research involving human subjects needs to be constantly reviewed and justified after consideration of ethical principles such as respect for persons, beneficence, nonmaleficence, justice, veracity, fidelity, privacy, confidentiality and universalizability.

Informed consent

Informed Consent is a controversial concept. Difficulties with adequate compliance exist, and critics contend that as generally understood and applied, it is of limited value in protecting research subjects from possible abuse. Advocates for Informed Consent however counter that research subjects are at present better protected than was the case in the past, and that the imperfections of the concept should not necessarily result in us discarding the process. Despite debate about the merits and adequacy of the concept, there does nevertheless seem to be considerable consensus about the moral importance of Informed Consent in Western Medical research.

Informed Consent has been defined as the knowing consent of an individual ... able to exercise free power or choice without inducement or any element of force, fraud, deceit, duress, or other form of constraint or coercion.[6(p41)] In the Informed Consent process, subjects must be fully informed of the risks, procedures, and potential benefits, and that they are free to end their participation in the study with no penalty whatsoever.[7] Further, the communication process in an Informed Consent context requires that '... it is given in the full, or clear, realization of what the tests involve, including an awareness ... of risk attached to what takes place.[8(p203)]

When should Informed Consent be obtained? A policy statement in Medicine & Science in Sports and Exercise[6(p41)], states that ... any experimental subject or clinical patient who is exposed to possible physical, psychological, or social injury must give Informed Consent prior to participating in a proposed project.' In addition, the journal has a publication requirement which necessitates that authors take all appropriate steps in obtaining the Informed Consent of any and all human subjects employed by investigators submitting manuscripts for review, and authors are required to indicate that consent was obtained. Lastly, what elements should be included in the construction of an Informed Consent document?

Kroll[9(p35)] summarises a set of basic elements that ought to be included in an Informed Consent document as follows:

> "A statement that the study involves research, an explanation of the purposes of the research and the expected duration of the subject's participation, a description of the procedures to be followed, and identification of any procedures that are experimental.
>
> A description of any reasonably foreseeable risks or discomforts to the subject.
>
> A description of any benefits to the subject or to others that may reasonably be expected from the research.
>
> A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject.
>
> A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained.
>
> For research involving more than minimal risk, explanations as to whether any compensation will be provided in case of injury and whether any medical treatments are available if injury occurs and, if so, what they consist of or where further information may be obtained.
>
> An explanation of whom to contact for answers to pertinent questions about the research and research subjects' rights, and whom to contact in the event of a research-related injury to the subject.
>
> A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled."

Earlier it was noted that general agreement exists as to the moral importance of obtaining subject consent in Western research. It was also however noted that critics feel that, as generally applied, Informed Consent offers inadequate protection to research subjects. The latter scenario is plausible if the obtaining of Informed Consent is largely ceremonial. Journal reviews indicate that in some cases the procedure is either not reported (a serious omission in its own right) (see Table I), or is not obtained. Focusing on cases where it is obtained, we need to question whether or not there is a meaningful exchange of information. The process should ideally be participatory (i.e. a two-way process), and the information presented should be clear and comprehensible. Clarity and comprehension are particularly important in a multicultural society such as South Africa, and researchers should consider the potential need to present information in the subjects' preferred language.

Having examined the concept of Informed Consent, we can now explore the issue of whether or not the process, as described, is applied in research in the field. A review of the literature reveals that many studies either do not take cognisance of, or merely pay lip-service to the principles which form the construct of a code of ethics. Pettit[5] reports that in 1966 Henry Beecher of Harvard Medical School published a survey of ethical behaviour in clinical research in the *New England Journal of Medical Research*. In an examination of the major journals, he found 50 examples of ethically dubious research on human subjects. Consent was mentioned in only two of these articles. Table I indicates that in selected journal searches conducted by the author, Informed Consent was reported in relatively few papers.[1]

[1]*For the purposes of the South African journal review it was deemed not necessary to obtain consent for papers concerned with case histories, analyses of injuries, technical or biochemical information, surveys, review articles, mathematical models, and research on nonhumans. It was considered necessary for research utilising 'captive' populations such as students, school children, tournament participants, employees, patients, inmates etc, where subtle forms of coercion may operate even if that is not the intention. Also, in research concerning minors, it was deemed necessary for written parental informed consent to be obtained.*

Table I: Reporting of Informed Consent in selected journals. Brodie & Stopani (1990)

Journal	Consent Appropriate	Consent Reported	% Reported
SA Medical Journal (1994)	42	9	21.4
SA Journal for Sport, PE & Rec (1982 - 1992)	109	14	12.8
Ergonomics SA (July 1989 - July 1993)	20	1	5
SA Journal of Sports Medicine (1990-)	13	9	69.2
British Journal of Sports Medicine[3]	81	14	17.3

On the positive side in the South African reviews, some authors indicated that some form of consent was elicited, that subjects were volunteers, or that Ethics Committee approval had been obtained. It must be stressed that the negative results do not necessarily mean that consent was not obtained, nor that subjects were abused or exploited. The potential for abuse however exists, and '... we must be aware of the rights of subjects and not take the expedient route to conduct our research'.[7(p65)] Again whilst not indicating abuse, the reviews above introduce the possibility that many researchers either do not take cognisance of, or merely pay lip-service to, the principles which form the construct of a code of ethics. From this the conclusion could be drawn that insufficient attention is being paid to this controversial yet necessary facet of research ethics. Perhaps the researchers or their defenders would counter that consent was obtained but was not reported in the manuscripts. This however will not do. Non-reporting raises doubt about the omission of a commonly accepted research ethics practice.

Captive populations

The concept of Informed Consent has important implications for research in Sports Medicine, where subjects are often drawn from 'captive' populations, such as patients, students, tournament participants, team members etc. Such subjects may either perceive an element of coercion in participation, or an element of sanction attached to non-participation.

In cases such as this, the issue becomes one of how free subjects are, rather than just one of how informed they are, and researchers need to question whether or not utility trumps the right to self-determination of subjects. In these scenarios it is necessary to consider whether the autonomous choice of subjects is valued intrinsically rather than extrinsically. In other words, is autonomy valued for its own sake or merely used towards justification for research.

Patrick[10(p637)] states that '... critical to scientific success is a ready supply of experimental subjects ....'. The crucial phrase here is 'ready supply', and it is acknowledged that recruitment is easiest if one has a large captive population in an institution, or presumably if one has access to such a population, e.g. patients, participants in a tournament etc.

Coercion and sanction are the important elements to consider when recruiting volunteers from captive populations. Zelaznik[7] reports that regulations at Purdue University preclude investigators from recruiting subjects for research from classes conducted by the investigator. The reason for this is obvious: Students could perceive that volunteering may improve their grade, or conversely that not volunteering could be to their disadvantage. Thus either coercion or sanction or both could be perceived. This requirement obviously limits the amount of research, and investigators will contend that it hampers their productivity and retards the advancement of knowledge. There may be sympathy for such claims, but the issue is not whether research is conducted, but whether subjects are coerced.

There is a further, more subtle form of coercion that undoubtedly takes place in research settings. In Sports Medicine for example, an authority figure (e.g. coach, administrator etc) could tacitly approve a study by making contact with the subjects on behalf of the researcher. Relatively uninformed individuals are likely to ignore a violation of their autonomy if the possibility of sanction is perceived. If such an authority figure gives permission for persons to be

utilised as research subjects, should a researcher proceed with data collection? The answer is no. Individuals should consent, and coercion or threat of sanction should not be elements in the process. Further, such authority figures should not be involved in the research process in any way, nor should they have any access to data.[7]

This is not to suggest that progress in research should be retarded through petty regulations. Rather, researchers should be left with the thought that they ought to be aware of the potential for conflict between virtue and self-interest, and that research should be guided by deontologic rather than consequentialist ethical principles.

Conclusion

The paper has reported guidelines as to when obtaining consent is deemed appropriate, and has presented evidence that indicates that researchers either do not obtain consent (or at least don't report it), or that they merely pay lip-service to the concept. With regard to 'captive' subject populations, the absence of coercion and threat of sanction in the consent process has been emphasized. It has been noted that Sports Medicine relies heavily on research, and that its subject base is often drawn from 'captive' populations such as patients, tournament participants etc. Progress has demanded that such subjects be increasingly subjected to invasive procedures, and the history of research in the twentieth century provides abundant evidence supporting the contention that individuals are open to exploitation. Whilst it is problematic, Informed Consent as a principle is intended to safeguard experimental subjects from abuses. As such, it should serve as a reminder to researchers that they ought to be aware of the potential for conflict between self-interest and virtue.

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