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THE ETHICS OF SCIENTIFIC RESEARCH (WITH PARTICULAR EMPHASIS ON EXERCISE AND MOVEMENT SCIENCE) (English translated version)[1]

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ABSTRACT

Aragón-Vargas, L. F. (2015). Systematic review. The Ethics of Scientific Research (with Particular Emphasis on Exercise and Movement Science). **PENSAR EN MOVIMIENTO: Revista de Ciencias del Ejercicio y la Salud, 13(2),** 30-54. This paper reviews how we arrived at the current state of affairs in the ethical practice of scientific research, discussing some issues that are particularly pertinent to the exercise scientist. The paper focuses on two major areas of ethics in science. The ethical principles for biomedical research involving human subjects are presented and discussed using the three basic principles from the Belmont Report (autonomy, beneficence, and justice) as a guide. The ethical presentation and publication of data are discussed as an update or expanded comment on the ten topics covered by Roy Shephard in his *Ethics in Exercise Science Research* paper from 2002. The manuscript closes with a reflection on personal responsibility and its importance in every scientific endeavor: placing all responsibility for action on those scientists or physicians doing the experiments was not sufficient to prevent all types of human research abuses in the first half of the twentieth century. However, intricate and cumbersome external review and approval procedures generate the perception that the system should be more than enough to ensure good practices, a perception that may dangerously prevent the scientists from assuming their individual responsibility.

The progress of science has produced innumerable benefits to humanity, but there is an ever-present, sobering responsibility to obtain results without sacrificing our most precious values. Crucial research with humans for the continued advances in education, psychology, and medicine, must be balanced with a non-negotiable respect for the dignity of all human beings; every individual is worth protecting from the occasional excessive zeal of scientists, which can cause enormous harm if left unchecked. In this context where moral excellence or failure can be

[1] Also available in Spanish, the original peer-reviewed version.

quite significant, the ethical conduct in science emerges as a central topic.

As desirable as it would be that the frame of reference for ethics in human research would have developed from the philosophical and ethical discussion of the practice of medicine and science, the fact is that the major steps in this area were taken as a response to horrific cases of experimentation on human beings (Evans, 2010). The study of the natural course of untreated syphilis (even after treatment was available in 1945) in 399 Afro American men from 1932 to 1972 in Tuskegee, Alabama, supported by the United States Public Health Service, and the medical experiments with concentration camp prisoners in Nazi Germany during World War II (including the hypothermia experiments of Dr. Sigmund Rascher) are widely known (Bulger, 2002b). Less known are the sexually transmitted disease experiments on Guatemalan mental health patients performed by U.S. scientists from 1946 to 1948, which prompted Secretary of State Hillary Clinton to issue an apology to the Government of Guatemala after they were discovered in 2010 (McNeil, October 1, 2010), or the Japanese biological warfare experiments on Chinese prisoners-of-war between 1930 and 1945 which resulted in an estimated 3000 deaths (in comparison, McNamee and colleagues estimate that about 1750 prisoners were involved in the Nazi experiments (McNamee, Olivier, & Wainwright, 2007, p. 220)).

The attention focused, therefore, on preventing similar occurrences, while a necessary discussion on other bioethics issues such as what type of research should be prioritized, how to select the beneficiaries of medical breakthroughs like transplants, when does human life start or end, and whether there should be limits on medical procedures and research, became a second priority. The good side is that professional codes of conduct and landmark documents for biomedical research were published: the 1949 Nuremberg Code (Assistant Secretary for Health, 2005), the 1964 World Medical Association Declaration of Helsinki, now in its 10th version (World Medical Association, 2013), and the 1979 Belmont Report (The National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, 2002). The Council for International Organizations of Medical Sciences (CIOMS) published its own International Ethical Guidelines for Biomedical Research involving Human Subjects in 1982, 1993, and 2002; a new version is due in 2015 but it had not been released at the time this manuscript was prepared. The World Health Organization published the Standards and Operational Guidance for Ethics Review of Health-Related Research with Human Participants in 2011 (World Health Organization, 2011), to guide the research ethics committees responsible for reviewing and overseeing the ethical aspects of research, together with the scientists involved in health research.

Researchers who work in exercise science and human movement science have typically based their ethics on those documents used for conventional biomedical research. There are three recent documents more specifically addressed to exercise science: Jago and Bailey's considerations for pediatric exercise science research (Jago & Bailey, 2001), Shephard's summary from 2002 (Shephard, 2002) and Harriss and Atkinson's editorial in the International Journal of Sports Medicine (Harriss & Atkinson, 2013). In addition, several professional organizations such as the American College of Sports Medicine (ACSM) and the British Association of Sport and Exercise Sciences (BASES) have their own codes of conduct and different types of guidelines. There is, however, limited discussion of the many particular issues

faced by the exercise scientist who works in research: besides the papers cited above and a 2007 book by McNamee, Olivier, and Wainwright (McNamee et al., 2007), *Research Ethics in Exercise, Health, and Sport Sciences*, there are only a few articles and editorials (Brodie & Stopani, 1990; Macfarlane & Looney, 2011; Nevill, 2003; Olivier, 1995; Williams, Cobb, Rowland, & Winter, 2011).

The purpose of this paper is to review briefly how we arrived at the current state of affairs in the ethical practice of scientific research, and then to discuss in detail some issues that are particularly pertinent to the exercise scientist. Without claiming to make an exhaustive analysis, the paper will focus on two major areas of ethics in science. **The ethical principles for biomedical research involving human subjects** will be presented and discussed using the three basic principles from the Belmont Report (autonomy, beneficence, and justice) as a guide (The National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, 2002). **The ethical presentation and publication of data** will be discussed following the ten topics covered by Shephard (2002); a few of them will be selected for more in-depth analysis. I will close with **a reflection on personal responsibility** and its importance in every scientific endeavor: placing all responsibility for action on those scientists or physicians doing the experiments was not sufficient to prevent all types of human research abuses in the first half of the twentieth century. However, intricate and cumbersome external review and approval procedures may inadvertently promote the assumption that the system should be more than enough to ensure good practices; this may induce some scientists to abdicate their individual responsibility.

RESEARCH WITH HUMAN SUBJECTS

General accounts of international milestones in the development of current policies for medical research with human subjects are widely available. According to Bulger (2002b), these milestones include the publication of the Nuremberg Code in 1949 and the original Declaration of Helsinki by the World Medical Association in 1964, which were codes or guidelines that left all responsibility for compliance with the researcher, that is, they implied auto-regulation. Self-regulation is problematic, as demonstrated by the fact that the medical experiments carried out in Nazi Germany during the Second World War blatantly disregarded the *Richtlinien*, a stringent and exhaustive set of guidelines for research with humans established in 1931 by the Germans themselves, designed to protect their subjects (McNamee et al., 2007).

In his 2010 discussion on science, bioethics and religion, Evans (2010) identifies 1966 as the year for a move from general codes and self-regulation towards concrete review procedures, namely, the requirement to undergo external review from Institutional Review Boards (IRBs) prior to obtaining U.S. government funding for research. The U.S. Congress National Research Act of 1974 created a commission that worked on the basic ethical principles for research with human volunteers, resulting in the publication of the Belmont Report in 1979. Evans considers the three articulated principles from this report to be like *ends* or *goals* for society; this principled approach to bioethics was widely disseminated by Beauchamp and Childress with the publication of their 1979 book *Principles of Biomedical Ethics* (now in its seventh edition), probably the most influential textbook in bioethics. The system becomes then a very pragmatic

one where funding and the very legality of research projects are contingent upon approval from IRBs, which in turn evaluate every proposal in the light of three unquestionable specific criteria. All parties involved (governments, funding agencies, research institutions, researchers, and participants) are legally protected by this bureaucratic approach, but Evans (2010) complains that theologians and religious persons are marginalized from a necessary debate of profound unresolved bioethical issues. I would add that the system sometimes fails to achieve its goal, because of not unexpected imperfections.

In the particular case of Costa Rica, the supervision of medical research with humans began in 1972, even before the Belmont Report was published in the U.S. and before the Tuskegee experiment became public. That year, the Ministry of Health created a Human Medical Research Committee and regulated new drug trials; despite a number of rules and regulations decreed over several decades and applied in the socialized medicine system, the *Caja Costarricense de Seguro Social* (Bustos Monteiro, 2007), the process did not result in the expected rigorous regulations that some scientists expected. It was not until April of 2014—after a four-year gap when all clinical trials were suspended—that a national law was promulgated, Law #9234 for the Regulation of Biomedical Research (*La Asamblea Legislativa de la República de Costa Rica*, 2014). The oldest and best university in the country, the University of Costa Rica (UCR), created its own Institutional Review Board (called the Ethics and Science Committee, CEC) on May 10, 2000 (*Comité Ético Científico de la Universidad de Costa Rica*, 2007), and it was accredited by the National Council for Health Research (CONIS) in March of 2001. The University of Costa Rica published its ethics and science rules for research with human beings in June, 2000 (*Consejo Universitario de la Universidad de Costa Rica*, 2000). Several steps of institutional review are mandatory for any research project with humans at UCR, the last step being CEC review. Up until June 12 2015, the year 2000 UCR rules had not been updated after the promulgation of national law #9234.

Both the UCR rules and Costa Rica Law #9234 follow in the footsteps of international regulation: a bureaucratic approach that requires external review and oversight of all research projects. In the pages that follow, I will organize my discussion of the different issues following the three basic principles from the 1979 Belmont Report. When pertinent, I will make reference to our national law #9234 and to a few personal experiences at the University of Costa Rica.

A. Respect for persons (autonomy).

According to Bulger, this principle means that individuals must be "... treated as autonomous agents capable of self-determination (… and) persons with diminished autonomy are entitled to protection" (Bulger, 2002b, p. 119). Autonomy requires adequate information before a decision to participate is made—understanding of what exactly is being required of each subject and what benefits they can reasonably expect—and the opportunity to participate voluntarily, that is, free from any coercion or undue influence from the beginning to the end of the study—meaning they must understand that they have freedom to withdraw or stop their involvement at any point in time without penalties or loss of benefits. Persons with reduced

autonomy because of age, illness, or special circumstances, called vulnerable groups (children, elderly, mentally disabled, prisoners, others), are entitled to additional protection proportional to the risk of harm and the likelihood of benefit (Bulger, 2002b, p. 119). Many issues arise in the practical application of the autonomy principle.

Vulnerable groups. Exercise scientists and physical educators deal regularly with vulnerable groups. The most obvious ones are school children and adolescents who may be involved in education or health research studies for different purposes. The study must meet all the usual regulations but, in addition, underage participants must give their assent to participate, and written consent must be obtained from their legal guardian. It must be emphasized that every child and adolescent must be given the opportunity to refuse to participate, even if the legal guardian already approved participation.

The World Health Organization provides a comprehensive list of who is to be considered vulnerable: adolescents, children, elderly, pregnant women, prisoners, refugees, persons with mental or behavioral disorders, and persons who cannot give their consent (unconscious), but the cases are not clear-cut (McNamee et al., 2007, p. 152). Athletes may be considered a somewhat vulnerable group, because peer pressure from teammates or coaches may be particularly strong due to the natural group dynamics. Each team member should be able to decide if the coach will have access to his/her individual results. Even if the whole group receives information on the study at the same time, signing the forms in an individualized setting is encouraged; a “cool-off period” between explanation and form completion may also be provided to allow each individual to give due consideration to his or her participation. Olivier (1995) has discussed another way in which athletes may be considered vulnerable. He suggests that whenever an illegal or potentially illegal performance-enhancing substance is studied in humans, there is a potential for participants to experience first-hand its benefits, inducing them to continued use after the study is over.

Students as subjects. College students are a very convenient source of subjects for exercise scientists, but they may feel obliged to participate in their teacher's research, particularly if their class performance is not good. There are different ways to deal with this problem, but perhaps the best is to avoid having a researcher recruit participants from his/her own classes. Another option is to have a third party collect the information and codify it in order to safeguard the identity of each participant.

Deception. Adequate information means that the potential participant has a fair opportunity to understand exactly what will be required of him or her, but often times this knowledge is in conflict with the study objectives. As an example, a researcher tested whether she could acutely modify maximum strength performance by manipulating information on the actual weight that her subjects were attempting to lift. In such a case, the participants had to be deceived as to the true purpose of the experiment, but the IRB approved the study. Was this acceptable? McNamee and colleagues provide some guidance in this area:

> "We suggest that there are four basic conditions that may justify the use of deception in a study. First, the results of the study must be of significant import. Second, participants should not be likely to suffer physical, social or psychological harm. Third, the results could not be obtained in any other way. Fourth and finally, where appropriate, debriefing should take place." (McNamee et al., 2007, p. 139).

Harriss and Atkinson (2013) acknowledge the need to deceive in exercise performance studies and basically offer the same guidelines (making reference to the American Psychological Association's Ethical Principles of Psychologists and Code of Conduct), with one important addition: the option for participants to withdraw their data once debriefed at the conclusion of the study. Data withdrawal would certainly be painful for the researcher, but this option is a good way to preserve due respect to the participants.

Protection of privacy. Privacy and confidentiality are important for all human participants in exercise or human movement research, but they have some special implications for elite and professional athletes. Information about injuries, performance issues, illicit drug use or even bad nutritional habits may create serious problems if accessed by sponsors, team managers, coaches or the media. I was surprised to see that many athletes were reluctant to provide urine samples when I first started assessing acute hydration status by a simple test of urine specific gravity; they had to be reassured that the sample would be tested and discarded in their presence. It is good research practice to record all information using a code to identify each participant, and to carefully safeguard the code source. McNamee et al. (2007) provide examples of cases where the confidentiality of study results had to be broken for legal reasons.

B. Beneficence

"Beneficence requires that relevant positive efforts are made to secure the well-being of persons (do good, beneficence) and protect them from harm (do no harm, nonmaleficence)." (Bulger, 2002b, p. 119). The Belmont Report states that there are two general rules in this area: doing no harm, and looking for the best balance between possible benefits and possible harms. Oftentimes, the benefits should be foregone because of the risks (The National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, 2002).

Risk-benefit assessment. The criterion normally used to apply and evaluate this principle is to assess the balance between risks and benefits, a complex undertaking in many cases. Serious consideration should be given by both the researcher and the IRB to the possibility of obtaining the benefits using alternative methods, for instance, not using human beings. As explained in the Belmont Report, it is very likely that risk cannot be totally eliminated, but by paying attention to alternative procedures, it can often be reduced.

Sports and exercise science research protocols are (and should be) subject to the same

principles as any other biomedical study with human subjects, but many of them pose particular challenges to IRBs when attempting to assess the risks and benefits. The basic decision to classify a research protocol as therapeutic vs. non-therapeutic, or clinical vs. non-clinical, is not clear, and once made it is not helpful enough; alternative considerations may prove to be more useful in guiding the work of both researchers and IRBs. As an example, I propose considering a study designed to measure voluntary fluid intake of water and/or a commercially available sports drink when children exercise at a moderate intensity in a warm, climate-controlled laboratory. The children are to be recruited from local soccer clubs. For simplicity purposes, let us suppose that the benefits to both society and the individual participants—helping prevent dehydration in children during sports practice—have been shown to be moderate but unquestionable. The IRB, however, wants to decide whether this is clinical research, which may complicate the case rather than help in reaching a clear and just decision.

Other countries may have clear rules about research classification, but Costa Rica Law #9234, Article 2, states that the study is either (a) “experimental, clinical or interventional”, which according to the definition it is not because no experimental product, device or procedure is used, or (b) “observational, epidemiological or non-interventional”, a more appropriate classification except for the detail that the cited article requires participants not being subject to conditions controlled by the researcher. The fluid intake study is neither. The definitions of Law #9234, Article 2, are definitely imperfect, as too many research protocols in sports and exercise science would have the same difficulty. Given that IRBs have a tendency to be conservative, they will lean toward classifying such protocols as clinical, biomedical research, with all the rigor and complexity--often unnecessary--involved in the conduct of such studies.

As stated two paragraphs earlier, alternative considerations may prove more useful than classifying a study as therapeutic or non-therapeutic. Is the product, device, or procedure under study an experimental one, or is it commonly used in everyday life? Has the experimental procedure, device or product been safely used before? Is there an intervention, or are the participants being observed or measured as they do what they normally do, i.e., is this an experimental study, or is it descriptive, documenting what would happen anyway? Are the effects under study acute and easily reversible, or are they chronic and with longer-term consequences? How different are the exercise tasks in the study (type, duration, intensity) from the normal training and competition tasks of the athlete, fitness enthusiast, physically active person, or sedentary participants? The hypothetical study described above is using water and a commercially available product, both normally consumed by children. Voluntary fluid intake is the way that most humans replace fluids most of the time. The children will be measured as they exercise in similar conditions to those prevailing during a regular soccer practice. The possible dehydration resulting from the experiment is quantifiable and can be quickly corrected even before the children leave the laboratory. The intervention consists of allowing the children to drink only water during one laboratory visit, only sports drink during another, or both during a third. These considerations are likely to be more useful in determining the additional risk associated with participation in the study.

Observational, non-interventional research. A considerable number of exercise and sports science studies share what Heitman (2002) describes as the nature of epidemiologic research, which

> "is largely observational, and the interventions common in epidemiologic research are typically limited to medical examination, laboratory testing, and the taking of medical and social histories. Both epidemiologists and ethicists maintain that epidemiologic research presents few of the risks of harm to subjects posed by more traditional biomedical research." (Heitman, 2002, p. 155).

In the absence of intervention, the main ethical problem will be the use of the collected information (privacy and confidentiality). Therefore, after confirming that a physical activity, exercise or sport science study is merely observational, the focus of ethics review will likely be on how privacy and confidentiality will be protected. No data should be used for purposes other than those explicitly approved by each research participant, despite pressure from teachers, coaches, or the media.

Learning and performance vs. health studies. Many experiments in the exercise and sport sciences focus on effective methods to learn or improve specific skills, or on training methods, nutritional manipulations, or special devices to improve athletic performance. Unlike interventions that impact health, these typically have only acute or short-term effects which are reversible. As stated a few paragraphs earlier, this characteristic makes the risk of harm smaller, although it must be acknowledged that the benefits may be considered small as well.

Performance testing with athletes. Now let us consider the particular case of testing for maximum exercise performance. When testing for anaerobic performance with the Wingate test using a cycle ergometer, the subject is expected to make a maximum effort for 30 s, with the test administrator strongly encouraging and cheering throughout the effort. It is not uncommon for athletes to vomit after completing this test. Normal walking will not be possible for a short while (one to two minutes). The Nuremberg Code says that "the experiment should be so conducted as to avoid all unnecessary physical and mental suffering and injury." (Assistant Secretary for Health, 2005, #4). Is the participant being subjected to excessive physical and mental suffering? What is the risk? McNamee et al. express their concern that in a similar situation the participating athlete may be incurring excessive risk because of the reduced freedom to interrupt the test (2007, p. 77). I would argue that this athlete is not doing anything beyond the normal course of training and competition where he/she would be required to give maximum performance, and hence what would be considered high risk with a sedentary population, in this case may be a minimal risk. Going back to the concept of vulnerability discussed previously, athletes may be considered rather *strong* or *empowered* for some types of studies, as they know their own limits and capabilities better than most participants. This difference between *normal* subjects and athletes is seldom considered or discussed.

Why not animal studies? Some exercise science research questions like the metabolic adaptations that take place in skeletal muscle in response to endurance exercise are ideally addressed using animal models. Many other questions may be first explored in an animal model before using humans. Nevertheless, whenever sports skills are involved or when self-reports are necessary, it is not possible to forgo the human experiments.

The risk associated with exercise. Most sports and exercise science studies require participants to exercise in the laboratory, sometimes at a moderate intensity, other times to their maximum capacity. How hazardous is this? The risk of injury is not greater than that associated with exercise or sports participation, but there are other risks. On one hand, it is true that a planned bout of exercise for research purposes may increase the immediate risk of a heart attack by a factor of five to six (Shephard, 2002, p. 174), but on the other hand if the researcher is working with athletes or physically active people, this increased risk is something that the participants are undertaking voluntarily on a regular basis—a practice which will reduce overall, around-the-clock risk by about 50% (Powell, Thompson, Caspersen & Kendrick, 1987); furthermore, a properly equipped exercise science laboratory would be one of the safest places for such a terrible thing to happen. To facilitate a better decision, Shephard's advice should be considered:

> "In the context of exercise science, the research review committee should be provided with information on the risks of musculoskeletal injury, sudden cardiac death and heat stress, the proposed level of medical supervision and the extent of provisions that have been made to treat or to evacuate medical emergencies." (Shephard. 2002, p. 173).

Student research projects with humans are common in sports and exercise science, and they raise a number of ethical issues related to the principle of beneficence. There are widely different standards among IRBs for the evaluation of such projects. In many cases, it is argued that these proposals should be rejected because the benefits are likely small—due to relatively simple, short studies typical of a term project or a master's thesis—compared with the risks involved at the hands of less-than-expert researchers. The cost-benefit analysis must be balanced with a serious consideration of the fact that the main objective of student research projects is to train them in the right methods and procedures, not to do ground-breaking research (McNamee et al., 2007, p. 187). At the same time, it would be a terrible idea to exempt students from the rigorous training in ethics required of senior researchers, as implied by Article 51f of the Costa Rica Law #9234; graduate students in particular would be missing an ideal opportunity to acquire indispensable skills and knowledge.

A puzzling situation has surfaced in the Human Movement Science master's program at the University of Costa Rica, challenging the conventional system of external review and approval. This program requires every student to complete 50% of their credit-hours doing research projects. Most students complete two or three human research studies before they do

their master's thesis, but university regulations do not require them to undergo IRB review and approval except for the thesis (the students appreciate the streamlining, but the policy is inconsistent). Indeed, the university's only IRB **refuses** to review student projects, even if requested to do so, unless it is a thesis or doctoral dissertation. In the end, participants of student research projects are deprived of an objective, expert ethical review process as a result of a defect in the current rules and regulations.

When the departmental research committee recently pressed the IRB to justify their position, the response was that the students' advisors should assume the responsibility to supervise the ethical conduct of their research activities, which were not deemed research proper, but part of their class assignments. The only justification provided was that according to local university regulations, it was not their job to review student proposals for research with humans (this information is documented in official institutional correspondence, letters VI-2528-2011, EEFD-CI-001-2013, and VI-2138-2013). I have been unable to find a valid rationale for such a policy in any of the references listed at the end of this manuscript.

Replication of studies. There is an interesting contradiction in the analysis of the potential benefit of replicating a study in sports and exercise science (and biomedical science in general). Important results are supposed to be verified by the scientific community, but funding agencies and IRBs are extremely reluctant to approve research that only attempts to replicate someone else's work, considering there is very limited benefit. The contradiction is best captured in one single paragraph from Bulger (2002a): “Science should be original in content (i.e., something new that has not been done before and that **is not just a repetition of the work of others**). It should be done and then described **in a fashion that allows repetition by others**.” (p. 92, emphasis added). The solution: any research proposal that intends to replicate a study must include novel elements in it.

C. Justice

The principle of justice requires research subjects to be selected according to fair procedures and outcomes. The bottom question is who should receive the benefits of research and bear its burdens, as it would not be just, say, for a company to test a new drug on patients from Third-World countries and then provide the successful treatment only to those patients from rich countries who can pay for its cost. In sports science, an equivalent injustice would be to study an expensive, promising but somewhat risky sports supplement with a large group of average athletes, but once it has been proven effective, to select only the top five athletes in the country for free supplementation.

Placebo and control groups or conditions are essential to sports and exercise science research, but despite a sound scientific rationale for their use, they raise important ethics issues related to justice. No person, for instance, should be required to abstain from exercise over the course of a study, given what we know about the well-substantiated health benefits of regular

exercise. Patients who need treatment should not receive a placebo that will be less effective than known treatments, or at the very least they should have the same probability to be assigned to the control group as anyone else in the study, and there should be check points along the study when a decision could be made to halt the experiment if it became clear that the control (placebo) group was fairing more poorly (Shephard, 2002).

After some controversies with earlier versions, the 2013 update of the Declaration of Helsinki reads:

> Use of Placebo. 33. The benefits, risks, burdens and effectiveness of a new intervention must be tested against those of the best proven intervention(s), except in the following circumstances: Where no proven intervention exists, the use of placebo, or no intervention, is acceptable; or Where for compelling and scientifically sound methodological reasons the use of any intervention less effective than the best proven one, the use of placebo, or no intervention is necessary to determine the efficacy or safety of an intervention and the patients who receive any intervention less effective than the best proven one, placebo, or no intervention will not be subject to additional risks of serious or irreversible harm as a result of not receiving the best proven intervention. Extreme care must be taken to avoid abuse of this option. (World Medical Association, 2013, #33).

Perhaps the use of a placebo or control group is not so serious in the case of acute sports performance. In this type of studies, very common in exercise and sports sciences, the treatments can be switched after a wash-out period. This will not only apply justice, but it may also provide more solid evidence for the experimental treatment under study. The key here is the acute quality of the effects under study, together with the emphasis on sports performance rather than health.

ETHICAL PRESENTATION AND PUBLICATION OF DATA

> The essence of science is the pursuit, generation, and transmission of knowledge. The practical demands of these activities define an inherently moral social contract among researchers in which honesty, objectivity, and mutual trust are the standards of integrity and professional honor. Every scientist depends on the validity of others' work, whether as the foundation for new questions or as the conceptual framework in which new explanations are tested. Moreover, while individuals may conduct research, no single researcher can master every aspect of any issue—especially as multidisciplinary approaches become more common. Thus, the ethics of scientific research are based in practices designed to foster the growth of knowledge while reinforcing the bonds of the scientific community." (Heitman, 2002, p. 21).

Science is communicated and subjected to the scrutiny of the scientific community when study results are presented and published. Publication of results is not only highly desirable, but it is ethically mandatory. The Helsinki Declaration states: “Researchers have a duty to make publicly available the results of their research on human subjects and are accountable for the completeness and accuracy of their reports.” (World Medical Association, 2013, #36). The main reason for an obligation to communicate research results is that the monetary cost and human resources involved (both study participants and research personnel) in the study should be balanced by the scientific knowledge resulting from it. This knowledge needs to be scrutinized by the scientific community to contribute to the progress of science. The quote above from the Helsinki Declaration adds an important element to the communication duty: the responsibility to report information completely and accurately.

In the process of an ethical presentation and publication of data, a number of special issues arise. Perhaps the most publicized are cases of scientific fraud, but other issues are equally important. They are presented and discussed below following the ten topics presented by Shephard (2002). The increasingly important role of peer-reviewed journals in guaranteeing the integrity of science is highlighted.

1. Institutional Review

Today it is practically impossible to publish a study without prior IRB approval. As discussed elsewhere in this manuscript, the mandatory review process by IRBs or ethics and science committees plays an important role in the protection of human subjects and the quality of scientific knowledge. Some research types, however, may run into more difficulties when seeking IRB approval, including qualitative research and many exercise and sport science protocols. As discussed by McNamee et al. (2007), the tradition of ethics review is quantitatively oriented, making the qualitative approach (which involves very flexible, emerging research designs, unpredictable numbers of participants, and evolving research questions) extremely difficult to manage. This should never exempt qualitative studies from IRB review and approval, but perhaps it means that at least one IRB member should be trained in qualitative research. On a similar note, these review committees will seldom have members from the exercise and sports sciences, making it necessary for researchers to take special care to describe common methods and procedures in such a way that the elements often taken for granted in exercise and sport science studies are explicitly addressed. These include the stress and risk involved in proposed exercise protocols, the ordinary or extraordinary nature of the tasks or tests to be completed, and professional codes and standards for the scientific discipline. Being summoned by an ethics committee to respond to questions in person, rather than a nuisance, should be considered a good opportunity to share this information with the IRB. Finally, as exercise and sports science researchers, we must keep in mind that IRB forms and requirements may be imperfect, carefully considering what additional information might be necessary for our proposals to be judged fairly. Both Jago & Bailey (2001) and Macfarlane & Looney (2011) offer other recommendations to help expedite approval of exercise protocols.

2. Fraud and misconduct

The ideal quoted from Heitman at the beginning of this section requires sound training of scientists, clear institutional policies and a strong commitment from all parties involved, but shortcomings, irregularities and blatant violations occur. They are serious because they undermine the very foundations of science. Dale Benos and his colleagues quote Steneck's *Introduction to the responsible conduct of research* to define scientific misconduct as “fabrication, falsification, or plagiarism in proposing, performing, or reviewing research or in reporting research results... ” (Benos *et al.*, 2005, p. 59). They explain the key concepts:

> Fabrication is defined as recording or presenting (in any format) fictitious data. Falsification is manipulating data or experimental procedures to produce a desired outcome or to avoid a complicating or inexplicable result. Plagiarism is using someone else’s words, ideas, or results without attribution. (Benos *et al.*, 2005, p. 59).

This characterization of scientific misconduct may seem rather limited; Hillman (1997) used the term *parafraud* to refer to other behaviors not typified at the time as scientific misconduct *per se*, but clearly not acceptable by the academic community (especially in the last two decades or so) because they undermine the integrity of science. According to McNamee and colleagues (2007), these include refusing to respond to questions from colleagues, including one's name in an article without having made a substantial contribution, not publishing results that do not support one's hypothesis, arbitrarily leaving out some results of one's experiments, selective reporting of results in abstracts, and selective reporting of positive results or of subgroups and outcomes (McNamee et al., 2007, p. 125).

Weed (2002) highlights the need to distinguish between misconduct and error. Errors do occur, but the problem with misconduct is that it involves the intention to misrepresent or misappropriate data or ideas.

> To put the relationship of error to misconduct in perspective, it may be helpful to consider scientists' conduct to range across a continuum. At one end are serious forms of misconduct, followed by deceptive reporting practices and then, toward the middle, what might best be called sloppiness. At the other end of the continuum lies appropriate scientific and professional conduct, including unintentional error. (Weed, 2002, p. 79).

The actual detection, denunciation, and prosecution of scientific misconduct is a complex and delicate process, as illustrated by two very different cases from exercise and human movement science. The first case deals with two college undergraduates who designed an experiment to measure the association of voluntary drinking during high-intensity exercise and side stitch (exercise-related transient abdominal pain) with a *captive* population—their high-school physical education students. The experiment was approved at a time when the local university required informed consent but no IRB review, or it would have been rejected. The

students' advisor reviewed and approved their proposal and signed letters for the school principal requesting permission to do the experiment, but was not present during data collection. After several months, the advisor reviewed a few drafts of the report (an honor's thesis) until a final document was submitted to the committee. At that point, one of the committee members identified a major problem: the exercise performance scores were notoriously regular. **Data fabrication** was suspected, and the students were separately interrogated by the committee. They denied any wrongdoing, but were unable to provide their original data forms ("we threw them away after recording all our data in the computer worksheet"). Informed consent forms had supposedly been signed by all participants but were discarded after the school term was finished (?). The students failed their thesis but no charges were pressed by the school Chairman. Expulsion would not have been too severe.

The second illustration involves a publication about the effects of a sports drink and exercise on urolithiasis in rats, in the *Brazilian Journal of Medical and Biological Research* (Abreu, Bergamaschi, di Marco, Razvickas, & Schor, 2005). I read the published article with interest because I was a scientific consultant to the Gatorade Sports Science Institute® at the time. I had visited the authors' laboratory two or three years earlier and the research team was kind enough to give me a copy of the master's thesis with their complete study, a very carefully designed set of experiments that involved a considerable amount of work. But when the results came out in the peer-reviewed journal, I was not satisfied with the fact that the article selectively reported on only four of the nine rat groups in the study, concluding "However, the isotonic drink induced the formation of intravesical matrix, suggesting a potential lithogenic risk", (Abreu *et al.*, 2005, p. 577). The five groups which were left out—two of which also ingested the isotonic drink—did not confirm the findings from the four groups reported.

I wrote to the journal editor on August 3, 2006, presented my concern, submitted the evidence for **selective reporting of positive results**, and suggested this might be a case of scientific misconduct; perhaps a request for clarification to be published in the journal's letters to the editor would have been wiser as a first step! The editor forwarded my letter to the senior author of the manuscript, who sent an immediate response signed by him and the first author of the study. The response letter defended their right to select the data to be presented in a manuscript, explained that they had "... decided not to publish data with calcium oxalate implanted in the bladder since no significant results were obtained", clearly expressed how rude it was to question their work, but did not address my detailed, objective criticism of **their** presentation of **their** results. All three journal editors signed a letter dated September 14, 2006 saying "we understand your frustration" but that they found the senior author's argument convincing. They added "we do not see a bias in reporting, but rather selectivity that all authors of scientific papers must use – **especially in reporting data that do not lead to a significant result or conclusion**" (emphasis added). A follow up letter to the editors on November 28, 2006 received no response or action. The case is well documented and has much more detail than included here, but the presented highlights suffice to make the point: not all scientists have a clear understanding of the role each one of us plays in protecting the integrity of science.

Are scientific fraud and parafraud on the rise? The general perception is that they are, but there are also numerous efforts by journal editors, professional organizations, and regulatory

agencies to contain the problem (cf. International Council of Medical Journal Editors, 2014). I speculate that most scientists understand the importance to adhere to scientific research ethics. Even though his words were published thirty years ago, I concur with Sir Peter Medawar:

> Enough examples of fraud in science have been uncovered in recent years to have given rise to scary talk about 'tips of icebergs' and to the ludicrous supposition that science is more often fraudulent than not—ludicrous because it would border upon the miraculous if such an enormously successful enterprise as science were in reality founded upon fictions. (Medawar, 1984, p. 32).

3. Adequate evaluation of prior research

A thorough review of published research can save time and resources and help to design the best study for the questions at hand; it may even reveal that the study is unnecessary. In an age of impact factors, *altmetrics*, and limited, very competitive funding opportunities, it is also important to give credit to other scientists who have published important papers in the same area. Even after a best effort, important papers may be overlooked because they were published around the time of one's own submission.

4. Competent design and appropriate statistical analysis

Amateur scientists consider a negative-results study (when an expected effect was absent) as the worst possible outcome, but it can be worse: a study could give inconclusive, useless results because of poor design. Common problems in exercise and sport sciences research include sampling from physically active college students for an experiment intended to improve performance in elite athletes, using a sample that is too small to detect the expected difference, if it exists, and longitudinal studies that are too short for the intervention to be relevant simply because the duration matches the duration of a college term or semester (Shephard, 2002).

5. Fair presentation of data

It is difficult for passionate scientists who have spent months or years planning research, securing funds, obtaining IRB approval, collecting data, and analyzing the results, to be detached from their study and make an objective presentation of the data. Yet, that is our scientific obligation. A conscious effort must be made to identify the study limitations and to acknowledge the true importance of the findings. The relevance of a small, statistically significant difference will vary depending on the variables under study: a 0.2% improvement in sports performance from the use of an approved nutritional supplement will be very important, potentially meaning the difference between first and second place in many swimming or track and field competitions. Meanwhile, a 1% difference in fluid retention after ingesting two different rehydration beverages (say, 808 mL vs. 800 mL) will be considered negligible. Shephard (2002) highlights the importance of presenting a balanced account of the results to the popular media, lest they—or the researcher—get carried away with unwarranted interpretations of otherwise sound research.

6. Just attribution of authorship

The author of a published manuscript or book is “the person who 'originates or gives existence to' the work, the person who 'begets it'. 'Authorship' refers to 'the dignity of an author' and dignity is a distinctly moral concept. Authorship implies responsibility and accountability but it also brings with it any credit that may be deserved, depending on the quality and importance of the work.” (McNamee *et al.*, 2007, p. 110).

There are two main problems in the area of authorship. At one extreme is the unfair exclusion of one or more important contributors from the list of authors. At the other is the previously common practice of listing every single person who made a small contribution to the study. It is no longer acceptable to include assistants, friends, and laboratory directors as co-authors. Today, authorship is clearly recognized as both a privilege and a responsibility. Most journals and many professional organizations have established criteria for authorship. A common one is to restrict authorship to those who made significant contributions to at least three of five major aspects of the publication: financial support and resources, study design, data collection, statistical analysis and interpretation, and manuscript preparation (Cf. http://www.revistas.ucr.ac.cr/index.php/pem/about/submissions). Most journals require that all authors must have read and approved the manuscript version submitted, and many will publish the individual contributions in the body of the manuscript. A general rule is to only give authorship to those persons who could stand before a knowledgeable audience, present the study, and field questions.

When exercise scientists lack the statistical proficiency required by the study, they often recruit a skilled statistician. No authorship should be given unless this professional makes significant contributions to other parts of the study besides study design and statistical analysis. His/her participation should be gratefully recognized in the acknowledgments section, provided authorization has been obtained.

7. Publication bias

The distortion of scientific knowledge resulting from the selective publication of “positive” results is a hot topic in different areas of science. One result is that meta-analyses will have a tendency towards reporting positive effect sizes (Shephard, 2002), because they will combine only those studies that are published. In addition, as mentioned in the introduction to this section, there is a moral obligation to publish negative and inconclusive as well as positive results, or to make them otherwise publicly available.

For these reasons, I believe it is a mistake for Costa Rica Law #9234, Article 52, to make an exception allowing researchers not to publish studies which make little or no contribution to the body of knowledge. I do not know the policies in other countries about this issue, but I propose that even though it is more difficult to publish such information in important peer-reviewed journals, institutional repositories are always an open option for the dissemination of the results in the form of research reports.

8. Avoidance of redundant publications

Different types of wasteful or redundant publication are more or less difficult to establish.

Duplicate submission (the simultaneous submission of one paper to two or more journals "to increase the possibility of acceptance in the shortest time possible") or duplicate publication (publishing the same manuscript with few or no modifications in two or more journals) are totally unacceptable (Aragón-Vargas, 2014). Nevertheless, other cases of redundant publication are more difficult to judge, as the so-called *salami publications* or *slicing*. These are divided publications, "the breaking down of findings in a single piece of research into a string of papers, each of which is what Broad *(1)* has tagged as the 'LPU' or 'Least Publishable Unit'. The research could probably have been reported in a single paper." (Huth, 2002, p. 106).

The challenge becomes, in such cases, how to establish when a study has been divided into too many different manuscripts, as may be illustrated by three examples. Back in 1987, Knapik et al. published a paper entitled "Influence of a 3.5 day fast on physical performance"(Knapik, Jones, Meredith, & Evans, 1987). In 1988, the same group published "Influence of fasting on carbohydrate and fat metabolism during rest and exercise in men" (Knapik, Jones, Meredith, & Evans, 1988). A careful reading of the articles shows that they report exactly the same experiment with the same subjects but, as the titles show, the emphasis is different, reporting the results of different variables under study with only a small overlap. Could they have been reported as a single paper? Moreover, *should* they have been reported as a single paper? Any authors placed in a similar situation should consider that even though divided publication may have been common practice in the past, it is clearer that without a clear justification, today this might be considered wasteful and not a good scientific practice.

A useful case for discussion are two literature reviews on glycerol use for exercise-associated hydration and rehydration, published by van Rosendal and colleagues (van Rosendal, Osborne, Fassett, & Coombes, 2010; van Rosendal, Osborne, Fassett, & Coombes, 2009). Some scientists would consider these reviews to overlap too much to warrant publication as two separate papers, even though the authors state in one that the emphasis is on hydration and in the other that it is focused on cardiovascular factors and performance. The 2009 article acknowledged that the other was forthcoming, but the 2010 review did not mention the existence of the previous one.

Another case that provides important elements for this discussion are three papers by Moncada-Jiménez and colleagues (please note that I am one of the colleagues), based on the same experiment with the same group of subjects. One paper reported metabolism and duathlon performance resulting from two different short-term diets (Moncada-Jiménez *et al.*, 2009a), another one compared the acute hepatic response to initial endogenous hepatic energy levels (which differed according to the two short-term diets) and exercise-induced endotoxemia (including measurements of liver damage markers, body core temperature, and IL-6 responses) (Moncada-Jiménez *et al.*, 2010), and the third reported the association between the initial metabolic state with its accompanying exercise-induced endotoxaemia, and the appearance of gastrointestinal symptoms during the high intensity endurance exercise test (Moncada-Jiménez *et al.*, 2009b). Only one of these manuscripts made reference to another, but the analyses may be considered exhaustive and different enough to warrant separate papers; the experiment had been designed with those different objectives from the very beginning, considering the cost-benefit of running three separate experiments.

A key learning from this analysis of the topic of slicing is that whenever the same experiment or systematic review is reported as two or more scientific articles, two simple steps can promote transparency and allow editors, reviewers, and readers to make an informed judgment on whether the division was warranted. Authors are encouraged to mention their related papers in the introduction or the discussion of each manuscript and, if they are already accepted for publication, to provide the correct citation.

9. Freedom to publish data

As discussed earlier in this manuscript, there is a moral obligation to publish the results from all studies. Private sponsors, however, often include clauses in their research agreements to prohibit or delay publication in order to have a competitive edge. While this makes sense from a business point of view, it is not, as Shephard points out, "in the best interests of science or the general public" (Shephard, 2002, p. 179). A less aggressive policy involves a requirement that research results be cleared by the sponsors before publication, but that is still a contentious issue. Depending on the priorities of the parties involved, the freedom to publish may make it impossible to reach an agreement for a company or business to sponsor any studies at a research institution. A closely related topic, the policy of a private company regarding the publication of their own R&D studies, is beyond the scope of this paper.

10. Reducing conflicts of interest

According to the International Council of Medical Journal Editors, "a conflict of interest exists when professional judgment concerning a primary interest (such as patients' welfare or the validity of research) may be influenced by a secondary interest (such as financial gain). Perceptions of conflict of interest are as important as actual conflicts of interest." (2014, *Author Responsibilities-Conflicts of Interest*). In order to reduce these conflicts, they must first be identified.

> "Financial relationships (such as employment, consultancies, stock ownership or options, honoraria, patents, and paid expert testimony) are the most easily identifiable conflicts of interest and the most likely to undermine the credibility of the journal, the authors, and of science itself. However, conflicts can occur for other reasons, such as personal relationships or rivalries, academic competition, and intellectual beliefs." (International Council of Medical Journal Editors, 2014, *Author Responsibilities-Conflicts of Interest*).

One of the most widely publicized cases of supposed conflicts of interest in the exercise and sports sciences was recently published by Deborah Cohen (2012), claiming that the body of knowledge on hydration, sports performance, and health, has been distorted because of sponsorship from the sports drinks industry. In her journalistic work for the British Medical Journal, she states that consumers are the victims of a plot from sports drinks manufacturers, who have paid hundreds of scientists, together with scientific journals and major professional

organizations to twist the truth in order to benefit their marketing ambitions while public health is at risk. The article generated a very strong reaction from the scientific community, but it illustrates the complications of both actual and potential conflicts of interest.

Both researchers and institutions, as well as peer-reviewed journals, should take a few precautions revolving around the information that enables interested readers to make a sound judgment. Many organizations and some scientists have clear policies to avoid potential conflicts (e.g., rejecting financial support from tobacco or alcohol companies). Another simple practice to help reduce conflicts of interest is transparency. Revealing all potential conflicts of interest to the journal editors upon submission and the publication of that information with the manuscript, allows all persons involved to reach an informed decision about the extent of a possible conflict. It is possible for a scientist to find a published study unacceptable even though the journal editors decided the conflict of interest was not serious enough to prevent publication. The reader is invited to consider the following statement in Nelson & Robergs' 2007 paper *Exploring the potential ergogenic effects of glycerol hyperhydration*: “Although Dr Robergs is a paid scientific consultant to Hydrade Beverage Company (HBC), a company that distributes a drink that contains glycerol, this manuscript is in no way connected to HBC.” (Nelson & Robergs, 2007, p. 98).

The role of scientific journals

As the main agents for the publication of research, peer-reviewed journals are assuming increasing responsibility for the ethical presentation of scientific results. Journals are *gatekeepers*, with the power to require strict compliance to their policies. As more and more editorial boards and groups of editors adopt clear rules for institutional review, management of scientific misconduct, authorship, avoidance of redundant publication, and transparency of conflicts of interest, journals have become a major player in the external system of ethics review. Some journals have even implemented policies aimed at reducing the problem of publication bias! This general tendency will strengthen the external system of ethics in science.

PERSONAL RESPONSIBILITY

The first section of this manuscript presented the current practice of relying on an external system of properly conducted ethics scrutiny and approval for biomedical research with human subjects. While this has played an important role in the protection of both subjects and researchers, it is important to acknowledge that ethical action by following codes of conduct and procedures that have been established as safeguards has some serious limitations. One problem is that codes are not uniform, sometimes even contradicting each other. But a more serious one is that this system tends, by default, to suffocate serious reflection by the researchers, who may limit themselves to verifying whether all requirements are met. As an example, researchers at the University of Costa Rica currently face a bureaucratic tangle of requirements from the Vice-President for Research, the local research unit Scientific Council, the institutional Ethics and Science Committee, and the national CONIS, generating a feeling of despair and excessive interference with our science. I speculate that similar situations are

present at many other institutions, both in Costa Rica and in many other countries. This may have a totally undesirable consequence: a tendency to meet the absolute minimum requirements and get on with our experiments, unconsciously giving up the basic personal responsibility in conducting our research.

I recommend promoting a higher standard: while strictly following established procedures, each researcher should take his/her personal responsibility seriously, as if the external scrutiny and approval system did not exist. Ruth Ellen Bulger (2002c) states that it is necessary to "move beyond compliance to a culture of social responsibility", indicating that "self-regulation, not required classes, would be more in keeping with what it means to be a member of a profession. It is important to consider how faculty and their institutions can establish a culture in which there is a basic desire to do research ethically and responsibly." (pp. 251, 252). The idea is not new. Already in 1946, the famous physiologist Archibald Vivian Hill had written in *Chem. Eng. News 24*:1343: "What matters is that scientific men should argue and discuss the matter of scientific ethics as one of infinite importance to themselves and the rest of mankind with the same honesty, humility and resolute regard for the facts they show in their scientific work." (Quoted by Pigman & Carmichael, 2002, p. 103).

In fact, this personal responsibility is clearly stated in the main research ethics documents. The Nuremberg Code, for instance, reads "The duty and responsibility for ascertaining the quality of the consent rests upon each individual who initiates, directs, or engages in the experiment. It is a personal duty and responsibility which may not be delegated to another with impunity." (Assistant Secretary for Health, 2005, p. 127). The Declaration of Helsinki is more detailed:

> "It is the duty of physicians who are involved in medical research to protect the life, health, dignity, integrity, right to self-determination, privacy and confidentiality of personal information of research subjects. The responsibility for the protection of research subjects must always rest with the physician or other health care professionals and never with the research subjects, even though they have given consent." (World Medical Association, 2013, #9).

One specific area where this higher standard should be applied is precisely in obtaining informed consent. I deem it safe to say that most researchers understand informed consent to be *the form that subjects must sign*, rather than a process meant to guarantee that each potential participant enters the study voluntarily after understanding what his/her participation entails, that is, a process meant to safeguard the autonomy of each individual who chooses to participate in a study. A good verbal explanation of the study objectives and protocol to potential subjects, together with a cooling-off period for them to consider participation and ask questions to friends or colleagues before the official written consent form is signed, can make an important difference in showing respect for persons. Furthermore, because most exercise performance studies involve a familiarization trial or session, with the main goal to collect basic information and to allow each participant to become fully acquainted with the performance test(s) involved, the informed consent process may consist of two steps: one to explain the study and to obtain

written approval to participate in the familiarization trial, and another one to obtain written approval to participate in the actual study, immediately before the first experimental trial.

Confidentiality and privacy are typically understood as the practice of not using personally identifiable information in research presentations or publications. However, as McNamee *et al.* discuss in detail (2007, Chapter 5), the researcher should make a special effort to protect the confidentiality of all the information (both electronic and hard copies of the records) from potential prying or intrusion. Whenever the nature of the study does not require to link the data to specific persons, personal identity should be removed from all data records; if this is not possible for health or study design reasons, anonymous identifiers should be assigned to all data, and the key that links personal identification codes to anonymous identifiers should be kept in a secure place, separate from the data.

Regarding scientific misconduct, because of the indispensable element of trust in science, personal responsibility is serious business in the acquisition, presentation, and publication of data. "(...) even if some research fraud is inevitable, it is probably preventable, if not by the sponsoring institution, then by the principal investigator himself." (Petersdorf, 2002, p. 66). Every researcher must take seriously his/her obligation to learn science ethics and the best scientific practices, and to steer clear from deliberate misconduct and sloppiness. Ignorance is a very cruel companion, because it will induce considerable sloppiness but will refuse to share the scientist's responsibility when things go wrong.

The principal investigator is the expert, very likely the person who understands best the research background, protocols, and results in a particular area of knowledge. The main weight of the responsible conduct of research is on his/her shoulders. IRBs and all the system of research review and approval exist to protect scientists from their blind side: "No investigator can be totally objective in the sense of being free from personal belief and conceptual bias, and the distancing and isolation of an IRB or REC, coupled with a wide range of membership, serve to improve the objectivity of ethical decision-making." (McNamee *et al.*, 2007, p. 54). But the system is not meant to relieve scientists from their personal responsibility.

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