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The responsible conduct of research, including responsible authorship and publication practices

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Responsible conduct of research

When attempting to identify the norms for the responsible conduct in biomedical research, it is important to identify areas in which scientists have come to some agreement on what are accepted norms and areas in which such consensus has not been reached. It is also important to understand the principles that underlie such norms. Just as the Belmont Report (Department of Health Education and Welfare 1979) provided three guiding principles for research involving human participants (respect for persons, beneficence and justice), the principles underlying biomedical research ethics also need be to elucidated.

In an attempt to move toward defining these underlying principles for the responsible conduct of research, Bulger (1994) has suggested a possible way to classify responsibilities according to four guiding principles. She proposes the first principle as a constellation of values including honesty, integrity, truthfulness and objectivity in the way that scientists plan, execute, record, interpret and publish their work. These values have been uniformly singled out as the key to the doing of science well (National Academy of Sciences 1992). As scientists strive for objectivity, they benefit by the examination of their intellectual biases and elimination of conflicts of interest.

Second, is the way scientists show respect for the other, including the humane care and use of animal subjects, respect for human participants in clinical research, for students and other research collaborators, and for the environment. Scientists show respect for students and their collaborators by sharing data, products and information with them freely, and by the proper attribution of credit to them for their ideas and work. Demonstrating collegiality is important and yet difficult in the modern research setting (Bulger and Bulger 1992). Respect for the environment is shown by undertaking only important research so resources are not wasted. It is also demonstrated by thorough literature searches to prevent the useless repetition of work that has already been done.

The third principle relates to the competence of the trained investigators in obtaining and transmitting their research data. This includes using valid techniques and proper statistical evaluation. The results of one's study should be promptly published so that others can benefit from the fact that they were done.

Finally, the stewardship of society's resources relates to how scientists ply their trade and choose problems to be studied. Since much health-related research is funded by society, the scientist has an ethical responsibility to demonstrate good stewardship

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of the resources that are provided. Exactly how this responsibility is expressed is an area of disagreement among scientists. For some, it includes only a commitment to do the science responsibly and well. This is justified by the fact that it is hard to know just what basic science may become important to future progress. For others, it would include choosing a research topic of importance to society and its members. A further commitment would be to help identify and participate in the resolution of ethical quandaries uncovered by the science that the scientist produces (Reiser and Bulger 1997).

Although agreed-upon norms have been defined in some areas of scientific endeavour, the majority of situations that the scientist must address lie in grey areas that remain undefined, murky, with many pros and cons on how to proceed and little agreement among scientists as to a uniform solution (Jasanoff 1993).

In response to well-publicized incidents of misconduct in science, the National Institutes of Health, the principal source of funding for biomedical sciences in the U.S., required instruction in several areas of the responsible conduct of research for all fellows supported by National Research Service Award institutional training grants. Although the means by which this education was to be provided was not specified (e.g., classes, lectures or mentoring), the areas to be covered were conflicts of interest, authorship and publication, misconduct and data management (National Institutes of Health 1989; 1990).

In 2000, a more extensive instructional mandate was put forth by the Office of Research Integrity (ORI) of the Department of Health and Human Services, which required instruction in nine areas of the responsible conduct of research (RCR). The policy required instruction in the following: acquisition, management, sharing and ownership of data; mentor/trainee relationships; responsible authorship and publication practices; peer review and the use of privileged information; collaborative science; human-volunteer research; humane care and use of animals; research misconduct; and conflicts of interest and commitments. The instruction was to be for all "staff at the institution who have direct and substantive involvement in proposing, performing, reviewing, or reporting research, or who receive research training supported by PHS funds or who otherwise work on the PHS-supported research project even if the individual does not receive PHS support." Although this guidance was later suspended, some institutions have continued to move toward this type of instruction for various individuals involved with scientific research (US Department of Health and Human Services: Office of Research Integrity 2000).

Finally, in light of several instances of problems with research studies at Universities that involved human participants, the Office of Human Research Protections (OHRP) stopped human participants research at several major universities. OHRP subsequently has required that all investigators dealing with research involving human volunteers receive education before being allowed to do this type of research.

In response to ethical problems in biomedicine in the U.S., there have been calls for increased education and accreditation of investigators and administrators as well as increased audits to ensure that regulations are being met within the institutions in which the research is being done. Yet it is important to realize that creating and enforcing regulations provides a minimum level for ethical behaviour. Scientists must not be creating a culture of regulation, but a culture of conscience. In looking toward the future of the ethics movement in the biological and health sciences, Reiser (2002) reminds us that "This next phase of development in the biohealth sciences will produce new discoveries, but some will be of a different sort than those to which biohealth scientists are accustomed. Until this time biological scientists have single-mindedly explored the environment of nature. They must now turn their attention to the environment of their profession and focus their vision inward, on themselves".

Ethics of responsible authorship and publication

One of the nine areas in which the Office of Research Integrity required education was the ethics of authorship and publication practices. That is the area that I have been asked to address in more detail for this conference. Communication of research results is a central element in the doing of science; in fact, there is little reason to do scientific research if the results are not shared with others in the community. In addition, authorship with subsequent publication leads to several important outcomes for the individual scientist's career including the assignment of credit as well as responsibility for the research, the recording of the accomplishment as a measure of one's scientific performance, allowing the work to be repeated by others and thereby validated, and placing the work in perspective with other research already published in a way that allows scientists to build on the work of others.

Publication of research results in journals is the way that results have been recorded for centuries, and it remains the major way that scientists communicate. It relies on the ability of scientists to trust the work reported by others. As Steven Shapin (1995), sociologist of science, so aptly states, "It needs to be understood that trust is a condition for having the body of knowledge currently called science…To suggest that scepticism and distrust should be very much more common in science is, in effect, to take the position that much of our modern structure of scientific knowledge should be unwound, put into reverse, and ultimately dismantled. Instead of laboratories for the production of new knowledge, we should build great facilities for the close reinspection of what is currently taken to be knowledge. Grants will be given for checking routine findings: published reports will look more and more like laboratory notebooks: libraries will have to be expanded to house an unimaginable vast literature reporting upon acts of distrust: relations between scientists will become uncoordinated, unproductive, and unpleasant".

Even though scientific communication is of paramount importance, the present environment for authorship and publication is in a rapid state of flux. This is partly due to the changes in the way authorship is being defined, as well as to the marked and continued increase in research funding and the subsequent increase in the number of articles written and journals to publish them. In addition, there has been a marked growth of the impact of electronic resources being used by scientists to communicate their work. The laborious hand searches of published literature (with subsequent reprint collection) have been replaced by the almost effortless electronic literature searches with on-line access to many published abstracts and manuscripts. Major changes are occurring in the way scientists handle information that is published and even more drastic, even paradigmatic, changes are promised for the upcoming years.

Who are authors?

Profound changes in criteria for authorship have occurred during the last couple of decades and how the new authorship criteria are applied across laboratories. In past years, a scientist who has authored 500-1000 or more biomedical articles was greatly admired and often chosen for influential positions such as department chair. Yet in a 30- to 40-year career publishing that many papers would mean the publication of 1-3 different papers per month over the entire time span. How much effort such a person expended per manuscript was never questioned. In the present environment, publishing an entire intellectual piece of work is being encouraged, while publishing numerous small papers – previously referred to as the Least Publishable Unit (LPU) (Broad 1981) or the practicing of salami science (Huth 1986) – is criticized. In addition, the publication of the same material more than once (repetitive publication) is wasteful. In fact, if similar material is to be published in two places, it must be referenced to avoid self-plagiarism.

The definition of who deserves the title of authorship is being narrowed. The International Committee of Medical Journal Editors (2001) has published Uniform Requirements for Manuscripts Submitted to Biomedical Journals (www.icjme.org). Its published definition of authorship has been accepted as a standard by over 500 medical journals. The definition states that authorship should be based on three conditions: "1) substantial contributions to conception and design, or acquisition of data, or analysis and interpretation of data; 2) drafting the article or revising it critically for important intellectual content, and 3) final approval of the version to be published".

In addition the report states that "All persons designated as authors should qualify for authorship and all those who qualify should be listed". This is a strong statement eliminating both honorary (including those who do not meet the criteria for authorship) and ghost authorship (omitting anyone who does qualify for authorship). Yet Flanagin et al. (1998) have shown that these practices are still occurring in journals.

Along with authorship credit goes the responsibility for the work. The ICJME policy states: "Each author should have participated sufficiently in the work to take public responsibility for appropriate portions of the content. One or more authors should take responsibility for the integrity of the work as a whole, from inception to published article". Such a policy underlies the growing trend for journals to require authors to state the specific role of each author in the work. Standard practices would then advocate using the acknowledgments section, not author status, to give credit for those who have only provided various resources or help with the work, such as advice or manuscript review. In fact, Rennie, Yank and Emanuel (1997) have suggested that the term 'author' be replaced by the two categories of 'contributor' and 'guarantor', clearly indicating the role of each. They believe that such a system would be precise, understandable and fair, and would discourage misconduct. Although the suggestion of Rennie, Yank and Emanuel (1997) has not been accepted, the practice of listing the specific role of each author is expanding and partially fulfils their aim.

Self-regulation by journals

In light of the urgency in dealing with terrorism, including the harmful use of infectious agents by terrorists, two national meetings were held in the US in January 2003 that included scientists, publishers, security experts and government officials. The topic of the meeting was how journals and meetings of scientific societies could handle new scientific information both responsibly and effectively when safety and security issues raised by submitted papers could be exploited by terrorists and therefore should not be published. The group concluded that potential harm of publication could outweigh potential societal benefits. In such a case, the submitted paper should be modified or not published. Journals and scientific societies could encourage scientists to communicate this type of research results in other ways that maximize public benefit while minimizing risk of misuse (Journal Editors and Authors Group 2003).

The informatics revolution in authorship and publishing

The access to references and to published materials directly via the Internet or by library subscriptions allowing on-line access to reference databases and the published literature are revolutionizing how scientists use the literature available after about 1966. Internet access to resources provides rapid new ways to search the literature and therefore can increase the productivity of scientists. Internet access to published literature is available to scientists who lack extensive library or financial resources beyond a computer and Internet access. This is often the case for scientists in the developing world.

Medline (or comparable) access for identifying or checking references has become the standard for modern scientists and reviewers. Some journals have even made their entire publications available electronically, either to subscribers or to the general public. In 1999, Varmus proposed a broad new two-tiered initiative for improved access to the original manuscripts and to publications (see Marshall 1999b). The access to some of this previously published material is now becoming a reality as PubMed Central, a central repository containing a body of literature in the life sciences that can be easily searched on the Internet. Journals are being encouraged to distribute their publications in PubMed Central after a short (1-6-month) delay. Markowitz reports that some scientists are being encouraged not to submit manuscripts or to review manuscripts of others for journals not releasing their contents to PubMed Central (Marshall 1999a; Markovitz 2000).

In light of the rising costs of journal subscriptions and worldwide acceptance of the Internet as a valid publication medium, Markovitz (2000) proposed that scientists re-examine the current paradigm for publishing research according to present journal-publishing policy. He points out that scientific authors turn their copyright over to journals without any financial rewards. In fact, authors also may pay page charges or purchase reprints and their institutions must pay for subscriptions to these journals. In addition, scientists not only provide the articles to the journal but also provide free review services. If the authors were to retain copyright to their scholarly manuscripts, they could publish them on the Internet either with or without prior journal publication. Markowitz points out that if manuscripts were to be published directly on the Internet, then some type of peer-review system might need to be developed, perhaps paid for by the authors, their institutions or the commercial advertising presently being used to fund similar activities in journals (Markovitz 2000). However, an alternate kind of review system could be developed similar to that presently employed by Amazon.com and a growing number of retail on-line businesses, in which those reading the books or purchasing the products do a post-purchase review giving their assessment of the value of the purchase that is displayed on-line with the specifics of the book or product.

Markowitz (2000) sees many advantages to this type of web-based system. They include having rapid access to the contents, built-in cross-referenced hyperlinks, integrated searching, inclusion of original data, multimedia formats, less expensive than journal publication, more environmentally correct, available wherever one has computer access, and available to those without large financial backing. He points out that a similar freely accessible self-publication policy exists in the field of physics sponsored by the American Physical Society in co-operation with the Los Alamos

Laboratory (American Physical Society 2002). It is possible that such profound changes in how scientists communicate may lead to problems for scientific journals. In fact, publishing in journals as we know it might disappear, and be replaced only by electronic communication (Markovitz 2000). Although it is always difficult to undergo such a profound change in behaviour as such a change to publication on the Internet involves, the advantages to such a system must at least be considered.

Publication with a broader definition of scholarship

Authorship of original articles describing scientific research is still the coin of the realm in science. More recently, however, there has been a development of a broader definition of what scholarship entails including areas other than that limited to traditional scientific discovery. New ways of documenting scholarship besides journal publishing accompanies this movement. Such ways include the creation of a teaching portfolio. These ideas have been influenced by the perceptive book by Ernest Boyer (1990) titled “Scholarship Reconsidered: Priorities of the Professoriate”, in which he argued for a fuller range of scholarship. Boyer stressed the importance of creative new directions not only in the *scholarship of discovery* (increasing the stock of human knowledge), but the disciplined, investigative efforts of the *scholarship of integration* (giving meaning to isolated facts), *the scholarship of application* (the synthesis of traditions of academic life), and the *scholarship of teaching* (not just presenting the material, but transforming and extending it). Changes in academic promotion policies, at least at our University, are being affected by this new definition of scholarship. A more inclusive dynamic view of scholarship would continue to involve communication/publication of what has been learned, but would be enhanced by the use of broader multimedia forms of communication including video and audio presentations and artistic renditions. The review of the scholarship could be accomplished either before or after posting by input from the experts and consumers of the material.

Challenges lie ahead as scholars seek to balance the advantages of the tried and true means of journal publication with the possibilities becoming available for a vastly increased audience of computer-literate individuals.

(The opinions expressed in this article are those of the author and do not reflect opinions of the Department of Defense of the United States or of the Uniformed Services University of the Health Sciences, Bethesda, Maryland, USA.)

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