The Integrity of Research

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Editorial Note

This article is an expert report summarizing the distinguished lecture presented December 9, 2009 at the University of Botswana during the conference: *Retrieving the Human Face of Science: Understanding Ethics and Integrity in Healthcare, Medicine and Research.* A panel and general delegate discussion followed.

Authors' Note

The opinions represented in this text are those of the authors and do not reflect the official policy or positions of California State University, the United States Government, the Department of Defense, the Department of the Navy, or Navy Medicine. We thank the following delegates for their individual insights, which contributed to this discussion: Dr. A.M. Jeffery, Dr. Kevin Fitzgerald, Dr. Kevin Russell, and Dr. Ann Thomas.

Abstract

This text is the foundation from which a distinguished lecture was developed focusing on the necessity for research in healthcare carried out with attention to issues of integrity, the hallmark of all commendable research. A cautionary historical review of research misconduct and related topics is provided. Research within a cultural context and the related subject of international collaborations are also discussed.

Introduction

It is not often that we have an opportunity to discuss the integrity of research with

our colleagues, and it's even more uncommon to be presented with the opportunity to travel to the continent of Africa to discuss such issues. Yet that is where we, together with our expert panel, found ourselves in December 2009—speaking at the University of Botswana and interacting with our medical, nursing, and allied health colleagues.

We welcomed the chance to discuss research integrity, not with a regulatory eye, but with the aim of elucidating integrity as a necessary element of and, indeed, as synonymous with the conduct of excellent research. Why? Because research integrity requires a cultural shift in thinking beyond compliance; it includes excellence in scientific method, honesty in the selection of the test statistic, rigor in data collection and analysis, and the straightforward dissemination of findings and their realistic implications.

The Integrity of Research

A variety of definitions of research can be found in the scientific literature. As a framework for this discussion, health research was conceptualized as a formal, rigorous process requiring planned, systematic activity to discover new knowledge for the benefit of patients and society, including the study of the translation and application of evidence from research to clinical and public health or population-based practice (otherwise known as evidence based practice). This definition assumes that healthcare providers have a responsibility to ensure their patients receive care that reflects the most current knowledge available, and to understand the individual and larger societal-cultural matrix within which care is provided and research is conducted. This cultural matrix includes the learned and shared beliefs and values embedded in religion, kinship, politics, and language expression where the "individual and group identity" culture changes along predictable lines with changes in social, historical, physical, geographical, or technical realms of life.

First, Know Yourself

Fay (1996) provides us with additional tools as we strive to know ourselves, to care for others, and to conduct excellent research that demonstrates integrity. He asks us not to hide behind an illusory façade of neutrality to convince ourselves and others that we are objective, to acknowledge the intellectual equipment that we bring to the care and study of others, to be aware of the way we change those with whom we interact, to be accountable to those we are researching and caring for, to act in a way that is responsive to the evidence as best we can determine it, to assess explicitly what others do, and finally and perhaps most importantly, to seek out the criticisms of others with regard to our own research and care-giving activities. We put Fay's recommendations into action during the Botswana conference.

We asked participants to turn to the person on their left, state their name and describe for that person whatever it was that made them distinctly who they were. They could not use the usual descriptors (e.g., sex/gender, race/ethnicity, marital status, or occupation); rather, they were encouraged to use experiences, activities, and relationships in their lives that they believed made a significant contribution to who they are. This was supposed to be a five-minute exercise, but the audience asked for additional time, and we finally had to rather forcefully bring everyone back to the formal lecture. The exercise was an enjoyable one and, even more importantly, it provided examples of how significant experiences, activities, and relationships had affected individuals' lives—in some cases profoundly.

One participant shared his experience of having his original ideas and written materials "stolen" and later published in a peer reviewed journal. These events encouraged him to pursue a doctoral degree in the field of ethics. His comments could not have been more appropriate had he been "planted" as an overture to the next topic of discussion.

Research Integrity and Misconduct

Integrity has become a priority for universities, science foundations, academies, and health care organizations conducting research. The goal for healthcare research is the acquisition and application of new knowledge for the benefit of patients and society as a whole. Goal achievement requires excellence in scientific methods, honesty in data collection and analysis, and realistic interpretations of findings.

A simple yet encompassing definition of *research integrity* includes justice and honesty in proposing, conducting, and reporting research. A participant in the research integrity pre-conference workshop confided that she had developed the idea of writing an article on this topic and led discussions on the potential content for the manuscript. In developing the paper, she tried to contact the other prospective authors for collaboration, but they never returned her e-mails. Before she sent her paper to a journal editor, she was surprised and chagrined to see an article with her topic and ideas published—with her as sixth and last author. As with the previous example, this is a violation of integrity in the publication of one's creative work.

In contrast to research integrity, *research misconduct* is fabrication, falsification, or plagiarism in proposing, performing, or reviewing research, or in reporting research results. Fabrication includes deliberately manufacturing untruths and reporting them with the intent to deceive, or a failure to report research findings that contradict the investigators' hypotheses. Falsification is changing or omitting research data or results, and is usually done to enhance the significance of the research findings. Plagiarism is the act of making use of another's words, ideas, processes, and results without providing credit where it is due. Research misconduct does not include mistakes or inaccuracies made during the conduct of research and reporting of findings if they were innocent oversights, errors or omissions due to lack of knowledge or experience with research and publication.

Research misconduct has been a part of the literature since the 17th century. Duro Armen Baglivi (1668-1707) wrote a detailed report on the theft of his intellectual property in letters within a collection at the Library of Sir William Osler (Fatovic-Ferencic, 2007). According to the letters, this physician had invited a professor of medicine from Germany to review the manuscript he had written on patient care of wounds and ulcers. Without notice, the professor left with the papers. Dr. Baglivi's colleagues advised him to publish parts of the manuscript immediately and to report the theft to associates in Germany. Due to his swift action, publications on the subject never surfaced in Germany.

Research misconduct became a public issue in the United States in 1981. Characteristic cases were those of American physicians who fabricated research data and submitted fraudulent articles for publication in prestigious biomedical journals. In these instances, the physicians sought out and invited respected experts in the medical field as co-authors. When the researchers were exposed, those who accepted the gift of co-authorship and credit for work they never performed were suddenly indisposed to share responsibility for the fraudulent papers. These cases brought the issue of *gift co-authorship* to light. Gift co-

authorship was used to enhance the likelihood that the work would be published because well-known, respected experts in the field were listed on the manuscripts. In fact, gift co-authorship was one of the reasons that the US Public Health Service created the Office of Scientific Integrity in 1989.

With all that was done to bring the research misconduct issue to the forefront, problems still existed. Research administrators gave good directions, rule of law provided good answers, and ethics asked good questions, but there were still an increasing number of cases of scientific misconduct. One year, a Bell Labs physicist published one paper every eight days—later it was found that 17 of the papers had been fabricated (Jones, 2003). Gift co-authorship continued. In one case, 20 collaborators and co-authors were found to be involved in one scientific publication, with only one author actually participating in any of the conduct or analysis of the research study.

The BBC news reported a notorious case of fabrication of a study in 2006. A cancer researcher from Norway concluded that anti-inflammatory drugs reduced the risk of oral cancer. The author claimed to have received $10.5 million in funding to conduct the study, which had been published in prominent medical journals. After investigation, it was disclosed that the researcher had fabricated over 900 subjects and case histories for data collection and analysis.

The principles of *research ethics* are coextensive but not synonymous with research integrity. Research ethics integrate the responsibility for academic and professional development, research protections, public trust, and institutional development. Responsibilities for academic and professional development include maintenance of excellent standards of honesty, professionalism and scholarship. The researcher must engage in sound research methodologies, publication practices, and responsible authorship and be open to peer-review and scholarly critique. Principles of research ethics serve as a "code of conduct" and professional standards for the investigator. In academic or professional settings, the researcher has the responsibility of modeling ethical conduct and integrity as a leader, mentor, and role model. For students, academic integrity is a responsibility in all scholarly endeavors.

Responsibilities for research with human subjects incorporate protecting the rights, privacy and confidentiality of these participants, along with the integrity of the research data collected. Subject enrollment into a study should be preceded by a thorough explanation of the research and informed consent without coercion. Protections also apply to research with animals, including the humane treatment of animals monitored by a veterinarian, and research with any potentially hazardous materials, including protection of the environment during the conduct of research.

Public trust responsibilities include compliance with rules and regulations in the conduct of research, protection of human and animal subjects, socio-cultural sensitivity in research collaborations with human subjects, integrity in the use of funding awards, and openness and honesty about actual, potential, and perceived conflicts of interest. Researchers have a duty to refuse to engage in research misconduct and a commitment to report these matters to those responsible for overseeing research integrity.

Responsibilities for the development of sound institutional practices by investigators include a relevant mission statement in professional research and education departments, supportive technology programs and transfer services, sound policies for dissemination of research

findings, and translational research that benefits the public. Institutional policies should encourage interdisciplinary and collaborative research where all rules for the relationship and intellectual property are decided beforehand. Collaborative research, particularly international research collaborations, can enrich and challenge the research experience.

Challenges and Opportunities in International Research

International research collaborations are growing exponentially. In fact, networking at this very conference has already resulted in ideas for national and international research collaborations. Keeping in mind the theoretical underpinnings of the philosophy of *integrity* and *research* previously presented, these collaborations require knowledge of others' cultures, including languages, institutions, politics, and policies, and an understanding of the challenges that can and most assuredly will emerge during all phases of the research process.

Challenges that can and do occur when designing research include establishing the shared or agreed upon meanings of concepts and words. Diseases and illnesses must be fully defined and understood, the political and cultural appropriateness of research questions must be adequately vetted, and the availability of researchers to develop and conduct the research must be investigated and satisfied.

In a 2001 pilot study of the *Love Without Violence Empowerment Measure* conducted in South Africa with high school-attending youth, the word "belonging" was defined by participants in at least three different ways: belonging to a group of friends, translated into "gang;" a dyadic relationship of either two special friends or a girlfriend-boyfriend relationship; and finally, a member of a family group (Axman, 2009). In a follow-on evaluation of the *Love Without Violence* project, the lack of available researchers resulted in only a 4% exposure to the intervention under consideration. Inferring change due to the intervention alone or lack of change as failure of the intervention would not be realistic, responsible, or ethical.

Requirements of, and challenges to, planning international research collaborations include the need to establish a shared understanding of the meaning of adequate protection of human subjects, consent, privacy, and participants' rights. It is a simple fact that not all Institutional Review Boards (IRBs) are the same—even within one nation.

Obtaining informed consent from parents and assent from minors in school-based research is always a challenge for the researcher; however, in some countries a school has the legal status of *in locus parentis,* which means that during the time learners are in school, teachers and principals have the legal authority of the parent. The international researcher may be bound by his or her country-of-origin's regulations, which may require parental or legal guardian consent. Parents and guardians may not be familiar with providing informed consent, potentially creating unnecessary concern and suspicion about a research project and effectively limiting participation in that project.

International collaborations and cross-cultural research require attention to the community in which the research is being conducted. Community reactions to research may and do vary by region, state, or province, requiring careful consideration of the strategy for entre into each community.

In a 2005 community project developed to address the needs of Orphans and Vulnerable Children (OVC) in four provinces in South Africa, distal and proximal causes

were identified using participatory action (PA) approaches (Axman, Gray, & Blaschke, 2006). The perceived "causes" for the problem of OVC varied by community, as did the interventions chosen to address the problem. In Community One, the intervention was a Package of Care for the orphan or vulnerable child; in Community Two, a Parenting Skills Workshop was selected; a Drop-In-Center for Teens was recommended by the participants from Community Three; and funding for a Teen Pregnancy Prevention Program was requested by Community Four.

Creating and managing data sets, including ownership, access, and data control also present challenges during international collaborations. Related to data ownership is the matter of authorship, and within the broader topic of authorship are the differences inherent in writing style and etiquette. International collaborative agreements are entered into to address some of these issues, and the publication policies of leading health research journals can provide guidance.

Several institutions have attempted to address the need for guidance when creating international collaborative agreements in an effort to bridge the differences that have proven complex in past endeavors. Framed on principles of integrity, fairness, and confidentially, the definitions and recommendations provided by the following organizations' guidelines are excellent places from which to start to develop an understanding and address the intricacies of international research collaborations: the World Health Organization, the Organization for Economic Development, the U.S. Office for Human Research Protections, Georgetown University, and the John E. Fogarty International Center for Advanced Study in Health Sciences of the U.S. National Institutes of Health. This list is not exhaustive, and the reader is invited to explore the literature for additional resources.

Responsible Conduct of Research

Education programs dealing with responsible conduct in research were developed in the early 1980s in response to discoveries of research misconduct. Although research methods were part of the curriculum in medical and nursing education, there was obvious need for improvement. In the United States, the responsible conduct in research (RCR) rules are found in a variety of sources; they have evolved over time and are subject to continuing discussion and further development. One example of core elements for responsible conduct in research education is found in the original, though currently suspended, rule from the Office of Research Integrity, Department of Health and Human Services. This suspended rule has become one of the important guidelines for the following RCR educational core elements:

1. Data acquisition, management, sharing and ownership
2. Mentor and trainee responsibilities
3. Publication practices and responsible authorship
4. Peer review
5. Collaborative science
6. Research involving human subjects
7. Research involving animals
8. Research misconduct
9. Conflict of interest

These nine areas are not exhaustive. New areas that will require the attention of RCR education programs are emerging, and include financial stewardship, undue influence, interdisciplinary cooperation, globalization and multiculturalism, sponsored research regulatory requirements, institutional mission development and relevance, and sound strategic planning. Regardless of the selection of core elements, development of sound RCR education programs should include substantive formative and continuing education and demonstrated accountability.

Changing the Culture of Research: Final Thoughts

Responsible conduct in research is more than regulatory compliance; responsible conduct in research requires integrity as its core. Research as a culture is not a business or process for the humane good, but a holistic approach to discovery and to the genius that informs the care we provide to our patients. We must remind our seasoned experts and inculcate our new investigators and caregivers with the philosophical underpinnings and building blocks for exceptional research and care-giving, not just because we must follow the rules, but because it is the right thing to do. Each of us needs to remember, ultimately, why we do what we do… to speak for those who might otherwise not have a voice, to effect positive change, and, quite simply, *to make a difference.*

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