Authorship Issues Related to Software Tools

RANDOLPH A. MILLER, MD


The case report by Welker and McCue in the current issue of JAMIA1 raises a number of important ethical concerns, both directly and indirectly. First is the longstanding debate, discussed by Welker and McCue, about what constitutes authorship. Some recent reports2–6 suggest replacing “authorship” with “contributorship.” Under such a model, submitted manuscripts would list all individuals contributing to a publication, along with careful documentation of each individual’s actual contribution(s) to the work. This model would provide for only a small number of “key” project members, such as the principal investigator and individual(s) who both contribute in major ways and who also write large segments of the manuscript, to have “author” status.

Even short of authorship, there exists an ethical impetus to acknowledge important contributors to published works. One might address the dilemma presented in the case report by Welker and McCue simply by placing in the Acknowledgments section of a paper a citation to the original (local) developers of the software tools used. Similarly, the Acknowledgments section might also list the agencies that funded local development of software tools used.

Mechanisms exist for developers of biomedical software tools to describe their software, per se, in the literature. For example, JAMIA publishes Methods papers describing new approaches to a problem; Application of Information Technology papers describing new applications with an emphasis on general “lessons learned;” and Implementation Briefs, which provide helpful hints about a successful approach to an important common problem—even if such a solution is not novel. Analogous venues exist for describing software tools in other journals. Stead et al. pointed out in the first issue of JAMIA that the stage of a software project’s development and deployment determine the level of evaluation required for publication.7

Contrary to the position taken by Welker and McCue, the larger ethical issues surrounding use of intellectual property developed by others are not straightforward. Complex ownership and contributor relationships are rarely as simple as not claiming authorship credit if one “provided the pencil to Shakespeare that he used to write Hamlet,” or not claiming credit if one provided a piece of laboratory apparatus to a student for an experiment.1 Researchers developing novel analytical methods or novel software tools as the intellectual products of externally sponsored research are in general expected to share the results of their work by describing it in the peer-reviewed literature. However, unless pre-specified by the funding agency in a grant or contract, the obligation to share does not automatically extend to placing ownership of research-related intellectual property in the public domain, even though it is a good practice to do so. Placing original works in the public domain is one of many options available to developers of intellectual property, as discussed below. It would be unusual for a separate group of individuals to immediately claim the right to use or apply the “new” research results of an earlier group, prior to the time of first publication by the original developers.

However, making the results of research accessible to others, without restrictions, may mediate against ownership claims. How the release of the software tool occurs in part determines the obligations of others in using the tool. For example, in the case reported by Welker and McCue, consider a scenario in which the original software developers had released their tool for general use under a proviso (prospectively issued) that the tool developers made the release with the goal of identifying collaborators who could apply the tool to demonstrate its effectiveness for research, in order to publish a joint evaluation of the tool. Under such circumstances, at least the first “outside” group to apply the tool to their own research would be obligated to discuss, before any project was undertaken or paper written, issues of future authorship with the original software tool developers. Such discussions typically determine, prospectively, which individuals receive designation as potential authors, so that those persons can fulfill required obligations of authorship. However, in a different scenario, in which the tool developers issued no such request prospectively, and the tool was placed in general use without restrictions, it would be unreasonable to expect, several years later, that any application of the tool would encumber co-authorship rights for the original developers of the tool. It would be
especially unreasonable if an authorship request were made “post facto”, after a study using the tool had been completed and “written up” by another group. In between these clear-cut extremes lie gray zones where it may not be certain what the obligations of the second group are to the first group.

There are other ethical and legal issues related to the case report by Welker and McCue. As described, the process of using a “Clinical Viewer” tool to detect, in real time, patients eligible for a study, and to then enroll patients in a study, requires adherence with important HIPAA (Health Information Privacy and Accountability Act) regulations, and also requires prior institutional review board (IRB) approval for research on human subjects. Presumably, such safeguards were in place at the authors’ institution. A broader discussion of legal and ethical issues related to the use of clinical software systems has occurred over decades.8, 9

In the realm of bioinformatics (computational applications related to “molecular medicine”) software development, somewhat different paradigms and expectations have evolved. A common expectation of bioinformatics journals and reviewers is that publication of a software tool will be contingent upon its open availability, along with the availability of datasets described in the publication that are used to demonstrate the functionality of the tool. In some cases this is explicitly stated in instructions to authors. For example, Oxford Bioinformatics states “Software or data must be freely available to non-commercial users. Availability must be clearly stated in the article. Authors must also ensure that the software is available for a full TWO YEARS following publication. Web services should not require mandatory registration by the user.”10

In summary, the intellectual property issues associated with software development, and related issues of authorship are not simple. The case report by Welker and McCue helps to illustrate this point.

References


ERRATUM NOTICE

In EM Campbell et al., Types of Unintended Consequences of Computerized Physician Order Entry, JAMIA 2006; Vol 13 Number 5, Sept/Oct 2006, reference number four (4) was incorrect. The correct reference follows below.