

Can We Trust Your Data?

Research findings are not often retracted because of possible falsification of data. When medical treatment is based on falsified data, the potential for patient harm increases and lack of trust in the process that leads to evidence-based clinical decision making is substantial. A case involving a Duke University cancer physician-scientist who admitted basing human clinical trials of genomic signatures predicting chemotherapy sensitivity in breast, lung, and ovarian cancer on false data (Potti et al., 2006) is particularly egregious.

After concern about the Duke research was reported by statisticians in 2007, widespread coverage of the story broke in October 2009 when the details were published in *The Cancer Letter* (Goldberg, 2009). The intriguing story, quickly picked up by professional and consumer media, involves conflict of interest, a falsified curriculum vitae, and errors in the labeling of clinical response in some datasets on which treatment decisions for patients were based. The subsequent cascade of inquiries led to an audit by the U.S. Food and Drug Administration, cancellation of clinical trials that used the faulty gene-array screening tests to drive therapy, retraction of manuscripts published in professional journals such as *Nature Medicine*, *New England Journal of Medicine*, *Blood*, and the *Journal of Clinical Oncology*, as well as lawsuits on behalf of patients who claimed injury and harm caused by treatment selection based on the falsified data (Couzin-Frankel, 2011). Additional publication retractions, perhaps dozens, are expected. As a result of the Duke debacle, federal officials are stepping up efforts to educate researchers about when to seek regulatory approval before using experimental genomic and proteomic microarray tests in clinical trials (Goozner, 2011).

The *Oncology Nursing Forum* (ONF) publishes articles reporting oncology nursing research. ONF readers are beneficiaries of the efforts of a wide body of nurse scientists, most of whom conduct their studies in academic medical centers that require stringent oversight by institutional review boards before and

during the trial. Often, the manuscripts submitted by the principal investigators of these nursing research trials include a long list of coauthors who were, in some way, involved in the research. As editor, I recognize many of these coauthors as valuable and well-credentialed nurse scientists and assume that their contribution to the manuscript was more than just superficial. I also assume that all coauthors reviewed not only the structure of the manuscript, but also the validity of the data supporting the findings. ONF has a panel of more than 250 peer reviewers, many of whom are nurse scientists with years of experience in oncology nursing research. I depend on those expert reviewers to keep me—and

The articles in question were coauthored by well-respected scientists and clinicians. What went wrong? And how do we prevent this from happening?

the authors—honest. Without them, the risk of publishing questionable research would increase.

Oncology nurse researchers generally do not study and recommend specific cancer treatment. But they do study and make recommendations for symptom management, patient quality of life, supportive care interventions, and nursing education. The outcomes of those studies are as important to our patients as the medical or surgical management of their disease. It is critical for nurses and patients to know that the interventions have valid evidence behind them. Oncology nurses should base practice changes on strong evidence. Real evidence. Nurse clinicians may not have a deep understanding of the research methodology or statistics that lead the nurse scientist to state that the findings are solid, but they have to have confidence in the validity of research findings that change clinical practice.

The journals that have and will retract articles related to the Duke scandal also are peer-reviewed publications. The articles in question were coauthored by

well-respected scientists and clinicians. What went wrong? And how do we prevent this from happening again, or in ONF? Know your source. Investigate the investigator. Ask an expert nurse scientist to interpret source findings and point out any concerns. Listen to the peer reviewer who questions your data.

I am proud of the research articles published in ONF. I challenge nurse scientists who contribute to ONF to carefully assess any prior research on which they base their current work to avoid situations that would put their findings, their publications, and the journals that publish their work in jeopardy. I also challenge dissertation committee members and academic advisors to fully participate in review of coauthored manuscripts to lend their expertise, particularly to new researchers and authors, to ensure that the project, findings, and manuscript are valid and defensible. The case that prompted this editorial was embarrassing to Duke, troubling to the oncology community, but devastating to patients and families. Let's not let it happen here.

Susan Moore, RN, MSN, ANP, AOCN®, is an oncology nurse practitioner and consultant in Chicago, IL. No financial relationships to disclose. Moore can be reached at smoore46@sbcglobal.net.

Digital Object Identifier: 10.1188/11.ONF.615

References

- Couzin-Frankel, J. (2011). Flawed cancer trial at Duke spurs lawsuit. Retrieved from <http://news.sciencemag.org/scienceinsider/2011/09/flawed-cancer-trial-at-duke-sparks.html?ref=hp>
- Goldberg, P. (2009). Duke University suspends two clinical trials after journal paper questions assay validity. *Cancer Letter*, 35, 1, 7–8.
- Goozner, M. (2011). Duke scandal highlights need for genomics research criteria. *Journal of the National Cancer Institute*, 103, 916–917. doi:10.1093/jnci/djr231
- Potti, A., Dressman, H.K., Bild, A., Riedel, R.F., Chan, G., Sayer, R., . . . Nevins, J. (2006). Genomic signatures to guide the use of chemotherapeutics. *Nature Medicine*, 12, 1294–1300. doi:10.1038/nm1491