Research Registries and Trustworthiness of Industrial–Organizational Psychological Research

THOMAS A. STETZ
Hawaii Pacific University

MAHESH SUBRAMONY
Northern Illinois University

We believe that Kepes and McDaniel (2013) are highly accurate in their assessment of the current state of publishing practices in industrial and organizational (I–O) psychology research, and they make several useful recommendations for improvement. The focus of this article is on one of Kepes and McDaniel's key recommendations—research registries.

Kepes and McDaniel cite examples from medical clinical trial research supporting the idea of maintaining a database of all planned and implemented research, thereby (a) providing a more complete picture of the research in the field (not overly biased in favor of supported hypotheses), and (b) fostering research integrity by encouraging researchers to follow the documented protocol. However, medical research registries have travelled a long, difficult, and incomplete path.

Table 1 shows a few of the major milestones in the widespread adoption of medical registries over the past 45 years. Dickersin and Rennie (2003) note that computerized registries have existed since at least the 1960s, but it took 30 years of interest and discussion in the medical community before serious progress was made toward widespread use. It took Simes' (1986) seminal article on publication bias in medical research to attract widespread attention to the problem and heighten the importance and need of an international registry for all clinical trials. It is also essential to note that medical registries first took hold with the development of targeted specialty registries, but it took congressional action in the form of the Health Omnibus Programs Extension Act (HOPE) of 1988 mandating the Department of Health and Human Services to develop a data bank

Correspondence concerning this article should be addressed to Thomas A. Stetz.
E-mail: tastetz@yahoo.com
Address: Hawaii Pacific University, Honolulu, HI 96813

https://doi.org/10.1111/iops.12055 Published online by Cambridge University Press

of research information on ''immune deficiency syndrome.'' The HOPE Act later served as the model for the requirements found in the Food and Drug Administration Modernization Act (FDAMA) of 1997, which lead to the largest registry in use, ClinicalTrials.gov (Dickersin & Rennie, 2003). Unfortunately the FDAMA narrowly defined clinical trials that required registration and was largely ignored (Dikersin & Rennie, 2012). It then took another 10 years until an update to the law, the FDA Amendment Act (FDAAA) of 2007, broadened its scope and mandated its use.

Registrations have greatly increased during the past few years partly as a result of the International Committee of Medical Journal Editors' (ICMJE) policy requiring prospective registration of medical intervention trials as a condition of publication (De Angelis et al., 2004), civil penalties of up to $10,000 a day for noncompliance, and grant funding implications for researchers that the FDAAA (2007) established. Furthermore, in 2006, the World Health Organization declared support for clinical trials registration and launched a registry portal through which more than a dozen major registries from around the world can be accessed (http://www.who.int/ictrp/about/en/). Finally, clinical trial registries have been growing in numbers internationally with governmental mandates and support. For example, the Indian government has established the Clinical Trials Registry-India (http://ctri.nic.in/Clinicaltrials/login.php), and the European Community established the EudraCT (https://eudract.ema.europa.eu/). In sum, the development and adoption of medical registries has largely been driven by governmental action and financial support, widespread requirements stipulated by journal editors, and the support of other large-scale nongovernmental organizations.

Two years after their registration policy went into effect, ICMJE concluded that the results have been positive, ''overwhelming,'' and that the research community had embraced trial registration (Laine et al., 2007). However, there continues to be substantial problems with compliance and the completeness of data found in ClinicalTrials.gov (Dickersin & Rennie, 2012). For example, Earley, Lau, and Uhlig (2013) found a failure to consistently and clearly report an obviously important piece of information for clinical trials—the number of deaths. Dickersin and Rennie (2012) argue that even if every trial was completely registered the information would still be lacking because not enough useful data fields are required. Zarin et al. (2007) further identified several issues in implementing clinical trial registries including validating trial entry data, ability to meet the needs of a diverse user group, duplicate registration entries, consistent defining and naming conventions, coordination across different registries including actual study results, and maintaining confidentiality. A later study (Zarin et al., 2011) found that many trial sponsors are successfully meeting data entry requirements of the FDAAA but that others are struggling and that this is troubling given the registry's purpose and requirements. They concluded that the usefulness of ClinicalTrials.gov depends on the willingness of researchers to provide accurate and complete data in a timely manner. Dickersin and Rennie (2012) reached another slightly different conclusion from Zarin et al. (2011) stating that success not only depends on a culture of openness but also on the *energetic enforcement* (presumably enforcement of the legal and civil penalties allowed under the FDAAA). An openness culture is probably difficult to achieve given the competitive and highly profitable world of pharmaceuticals. Furthermore, a survey performed in 2006 (before enactment of FDAAA with civil penalties) found that only 25% of academic researchers were willing to disclose all items required by ClinicalTrials.gov (Scherer & Trelle, 2008). In addition, Prayle, Hurley, and Smyth (2012) found that only 22% of trials registered in ClinicalTrials.gov that were completed in 2009 met the results reporting requirement in the legislatively mandated time frame. Thus, *energetic enforcement* seems a wise though costly endeavor.

https://doi.org/10.1111/iops.12055 Published online by Cambridge University Press

Table 1. *Important Milestones in the Development and Widespread Adoption of Medical Intervention Registries*

Year	Milestone
1967	First computerized registry for trials of psychopharmacological agents developed by the U.S. National Institute of Mental Health.
1986	Simes publishes seminal article on publication bias that brings widespread acceptance of the value and importance of an international registry for all clinical trials.
1988	Health Omnibus Programs Extension Act mandated development of a database of AIDS clinical trials.
1997	FDA Modernization Act (FDAMA) requires the NIH to establish a clinical trial databank.
2000	ClinicalTrials.gov launched.
2004	ICMJE requires registration of clinical trials as a condition as a precondition for publication.
2006	World Health Organization launches International Clinical Trials Registry Platform.
2007	FDA Amendment Act broadens registry requirements and establishes noncompliance penalties.

The dirty details of implementation and enforcement make even good legislative and research ideas fade away. The medical community has had the benefit of time, laws, governmental support, and funding (at levels unimaginable to I–O), and even then registry implementation has proven difficult.

It is important to identify the underlying characteristics of medical research that lent themselves to the widespread acknowledgement of the need for clinical trial registries. We believe that the main reason for the adoption of registries in the medical field is that medical research is *directly* applied and has life, death, and monetary consequences. These characteristics further result in intense public interest and concern. I–O psychological research, as it stands, is unaffected by these concerns. Given a lack of an immediate, ''burning platform,'' are we as a field willing to implement a large-scale solution such as registries or modify established reviewing practices so accurately critiqued by Kepes and McDaniel?

Unlike the medical community, we cannot expect governmental financial support and mandates. Thus, the full weight of such an endeavor would fall squarely on our shoulders. The changes our field makes to enhance the trustworthiness of findings will be, by necessity, incremental. Just as targeted specialty registries first took hold in medical research, any successful implementation would likely follow this path as well. For example, consider standardized testing. This research area is directly applied and has directly observable consequences. As a result, it has garnered widespread public attention. It already has some associated forms of government oversight, regulation, and laws that impact its practice. Last, but definitely not least, standardized testing involves substantial sums of money. All of these characteristics seem similar to the medical intervention research.

Modification of reviewing practice will require major adjustments in journal and associations' missions to include exploratory work and replications—the new journal *Academy of Management Discoveries* seeks to do just that. It will also require the publication of replications in short-article format in our other mainstream journals and the serious acknowledgement of the problems created by 'theory-relevant beliefs.' But these will have to flow from editorial policies, and more importantly researcher, editor,

https://doi.org/10.1111/iops.12055 Published online by Cambridge University Press

and reviewer *practices*. Simply put, our field will need to transform its collective agenda from a narrow focus on generating theory-relevant knowledge to generating *rigorous* and *relevant* knowledge, which may or may not support existing theory. With a strengthened relationship between literature and practice the conditions will be right for further consideration of widespread registry use.

References

De Angelis, C., Drazen, J. M., Frizelle F. A., Haug, C., Hoey, J., Horton, R.,. . . Van Der Weyden, M. B. (2004). Clinical trial registration: A statement from the International Committee of Medical Editors. *New England Journal of Medicine, 351*, 1250–1251.

Dickersin, K., & Rennie, D. (2003). Registering clinical trials. *JAMA: The Journal of the American Medical Association, 290*(4), 516–523.

Dickersin, K., & Rennie, D. (2012). The evolution of trial registries and their use to assess the clinical trial enterprise. *JAMA: The Journal of the American Medical Association, 307*(17), 1861–1864.

Earley, A., Lau, J., & Uhlig, K. (2013). Haphazard reporting of deaths in clinical trials: A review of cases of ClinicalTrials.gov records and matched publications–a cross-sectional study. *BMJ Open, 3*(1), 1–9.

Food and Drug Administration Act. (2007). 105-115, 21 U.S.C., § 113.

Food and Drug Administration Amendments Act. (1997). 110-85, 21 U.S.C., § 801.

Health Omnibus Programs Extension Act. (1988). 100-607, 42 U.S.C., § 2317.

Kepes, S., & McDaniel, M. A. (2013). How trustworthy is the scientific literature in I-O psychology? *Industrial and Organizational Psychology: Perspectives on Science and Practice, 6*(3), 252–268.

Laine, C., Horton, R., DeAngelis, C. D., Drazen, J. M., Frizelle, F. A., Godlee, F., . . . & Verheugt, F. W. (2007). Clinical trial registration. *JAMA: The Journal of the American Medical Association, 298*(1), 93–94.

Prayle, A. P., Hurley, M. N., & Smyth, A. R. (2012). Compliance with mandatory reporting of clinical trial results on ClinicalTrials.gov: Cross sectional study. *BMJ, 344*. doi: http://dx.doi.org/10.1136/bmj.d7373

Scherer, M., & Trelle, S. (2008). Opinions on registering trial details: A survey of academic researchers. *BMC health services research, 8*(1), 18.

Zarin, D. A., Ide, N. C., Tse, T., Harlan, W. R., West, J. C., & Lindberg, D. A. (2007). Issues in the registration of clinical trials. *JAMA: The Journal of the American Medical Association, 297*(19), 2112–2120.

Zarin, D. A., Tse, T., Williams, R. J., Califf, R. M., & Ide, N. C. (2011). The ClinicalTrials.gov results database—update and key issues. *New England Journal of Medicine, 364*(9), 852–860.

https://doi.org/10.1111/iops.12055 Published online by Cambridge University Press