JOURNAL OF CLINICAL RESEARCH BEST PRACTICES

Vol. 9, No. 8, August 2013 "Happy Trials to You"

"Testing Treatments: Better Research for Better Healthcare, 2nd Edition"

Imogen Evans, Hazel Thornton, Iain Chalmers, and Paul Glasziou, 2011, 199 pages, free

Review by Norman M. Goldfarb

"Testing Treatments: Better Research for Better Healthcare, 2nd Edition" should be required reading, even for readers of the first edition. The newly rewritten and expanded edition provides many more eye-opening insights than the first edition (see: http://firstclinical.com/journal/2008/0804_Testing.pdf).

Clinical research professionals should find the chapter on regulatory excess of particular interest, including the following excerpt:

This book has been selected for

The First Clinical Research Bookshelf

Essential reading for clinical research professionals

DO REGULATORY SYSTEMS FOR TESTING TREATMENTS GET IT RIGHT?

Although the level of regulation can be reassuring, current regulatory systems impose very onerous burdens on anyone wishing to study a poorly evaluated treatment rather than offer it to patients in normal clinical practice. In many countries, the sheer complexity of the system — involving laws, agencies, codes of practice, and so on — is overwhelming and time-consuming. Researchers may need to get multiple approvals from different places and sometimes have to face resultant contradictory requirements.

Moreover, taken as a whole, the system can seriously discourage and delay the collection of information that would make healthcare safer for everyone. For example, data protection laws and codes of practice on confidentiality, although introduced with the best of intentions, have made it extremely difficult for researchers to collect routine data from medical records that may help to pinpoint treatment side effects. And for researchers planning clinical trials, it can take several years to get from a trial idea to recruiting the first patient, and even then recruitment to trials can be slowed by regulatory requirements. But while researchers try to get studies through the system, people suffer unnecessarily and lives are lost.

In practice, what this means is that clinicians can give unproven treatments to patients, as long as patients consent, if therapies are given within the context of "routine" clinical practice. By contrast, conducting any study of the same treatments to evaluate them properly would involve going through the protracted regulatory process. So clinicians are discouraged from assessing treatments fairly, and instead can continue to prescribe treatments without committing to addressing any uncertainty about them.

The regulatory system for research, in its preoccupation with risk and protecting potential research participants, has become over-protective and overlooks the fact that patients and the public are increasingly involved as partners in the research process. However, there is one encouraging note. Research regulators are beginning

to acknowledge that the "one size fits all" approach to research ethics review may be unnecessarily burdensome. In the UK, for example, procedures for "proportionate review" are now being evaluated to see whether a simplified and swifter review process can be safely used for research studies that do not raise any material ethical issues.

The book includes 13 chapters:

- New – but is it better?
- Hoped-for effects that don't materialize
- More is not necessarily better
- Earlier is not necessarily better
- Dealing with uncertainty about the effects of treatments
- Fair tests of treatments
- Taking account of the play of chance
- Assessing all the relevant, reliable evidence
- Regulating tests of treatments: help or hindrance?
- Research – good, bad and unnecessary
- Getting the right research done is everybody's business
- So what makes for better healthcare?
- Research for the right reasons: blueprint for a better future

The book is available at www.testingtreatments.org.

Reviewer

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