

**Alex Faulkner: Medical Technology into Healthcare and Society:  
A Sociology of Devices, Innovation and Governance  
Palgrave MacMillan: Basingstoke, England 2009. 264 pages.**

At a time when many are focusing on the allure of novel, and often genetically derived, health technologies (or the promises of them, and/or their possible ethical, legal, and social issues), Alex Faulkner's 2009 book displays a more down-to-earth focus. The main questions addressed by Faulkner are: what counts as 'evidence' concerning the safety, efficacy, and cost-effectiveness of medical devices; further, how *is* evidence constructed through a series of complex interactions between health technology regulators, parts of medical profession, patients, industry, the health system, and the technology itself; and finally, what can be the outcome of such evidence for the governance of such medical device in their innovation life-path into the clinic and into society?

In a move that diverges from the mainstream research on medical technologies, innovation, and society, Faulkner instead chooses to focus on more mundane medical technologies that are taken for granted not only in the field of STS but in medicine as well. This results in a series of case studies on artificial hips, prostate cancer tests, infusion pumps, and blood coagulation meters. The one case study that falls slightly outside of this trend is the last chapter on tissue engineering.

As a part of the wider Palgrave series on health, technology and society edited by Andrew Webster and Sally Wyatt, this book seeks to display the notable consistencies in which medical devices and innovation are promoted and controlled in social

and economic terms (p. 1). For Faulkner, healthcare today is highly technologically driven, but innovation and regulation of health technologies is distinctive from other kinds of innovation. He argues that 'regulatory regime-building has a constructive effect - establishing "rules of the game" through standards and other organizing principles - as well as a blueprinting effect in shaping innovation pathways of medical technologies' (p. 4).

In the beginning, Faulkner lays out the STS terrain upon which his case studies will follow. In his discussion of the science/technology/society relationship, he outlines key principles such as social shaping of technologies, co-constructivism, user studies, medicalization and technological zones, which he chooses not to apply rigidly throughout the case studies but instead to generally inform his analysis. These concepts are dealt with directly in the final chapter where he addresses the areas of convergence and divergence of these various devices.

Chapter 3 describes the world of medical devices and also makes clear how the case study chapters follow a comparative methodological framework in which the author 'first outline[s] the major dynamics of the innovation pathway of each device technology...[he then] identifies the stakeholders, including industry, regulatory agencies and users;...[then moves to describe the] the scientific, surveillance-related and other evidence constructed as salient to innovation and governance

[or what he calls the “evidentiality” of the medical device]; and [he explores] the governance process, including state and non-state actors, legislative and informal modes, national and EU-wide’ (p. 41).

Chapter 4 on artificial hips describes one of the first medical devices in the UK to be subject to health technology assessment (HTA), systematic reviews, and cost-effectiveness calculations. Not only are these some of the major neo-liberal evidential governance mechanisms that Faulkner explores throughout the book, but the chapter displays the lack of methodological robustness that was used in the construction of the various forms of evidence for the heterogeneous world of hip replacement systems. What Faulkner shows is that when professional groups, regulators (and even to a certain extent industry) go looking for evidence concerning safety, efficacy, and cost-effectiveness what is often uncovered is high levels of evidential uncertainty. The question that remains (for the technology and the various users) is what to do with and about that uncertainty?

Chapter 5 explores the policy problem concerning the possible introduction of mass screening for prostate cancer in the UK in the face of evidential uncertainty in which ‘action focused on issues of population-level effectiveness and iatrogenic healthcare risk, rather than technological safety’ (p. 94). Chapter 6 examines the heterogeneity of infusion pumps and complexity of their operation by users. There Faulkner shows, among other things, an ‘evaluation gap’ between the regulatory regimes which certify standardization of the device yet fail to address the usability of these devices and the safety implications resulting from non-standard interface systems.

A case of a non-clinical medical device is present in the author’s analysis of blood coagulation meters (i.e. Chapter 7). Here governance concerns centre on how the use

device disrupts the healthcare / homecare boundary, and what such disruptions mean for the ‘reconfiguration of accountabilities, the competences of users and technological quality control versus performance standards’ (p. 194).

Rather than examining the particular governance mechanism for tissue engineer and its evidential claims, Chapter 8 instead chooses to explore the contested definitions ‘of the material technology, the structuring of the rules of engagement for the scientific and entrepreneurial participants, the construction of regimes for the sourcing of human tissue and appropriate evidential rules for making product safety assessment’ (p. 195). The notion of ‘governance’ is helpful in describing and understanding ‘the complex social and discursive processes of regulatory state policy making that shape a new political economy, of which emerging and evolving biomedical device technologies and technological zones may be a part’ (p. 182).

Overall, there can be little doubt that regulation, evidence-based public policy, and other components of a ‘regulatory regime’ play a crucial role in the movement of healthcare devices into society. However, this does not amount to regulation and regulators being ‘in the drivers’ seat’. Instead, the work of Faulkner’s case studies shows the importance of the numerous connections and interdependencies that this regulatory regime has with other aspects of ‘society’ more broadly (i.e. health professional organizations, the media, publics and patient groups, academia, etc). As a result of these diverse and dynamic relationships that are specific to each and every medical device and technology, Faulkner’s own work can instead be seen to caution us against attributing an overly deterministic approach to these regulatory regimes. While Faulkner posits that the main theme of the book is to ‘understand the key social and evidential

dynamics in the innovation pathways into healthcare of different medical devices' (p. 13), for this reader the real value of the book is to be found in the information the authors provides about the *dynamics between* evidence-based movements and various components of society more generally.

In all, this is a very detailed and thorough account of how certain medical devices do (or do not) stabilize as a part of routine clinical practice and/or gain a position in the medical imaginaries of publics, regulators, policy makers, and health care professionals. While its focus is largely on the British (and to a lesser extent European) context this can -and should- be seen as a strength as the UK continues to lead in the international arena of health technology assessment and evidenced-based health policy. The book represents informative

reading for the STS scholars interested in knowledge claims and expertise, and of course those interested in the life-course of medical devices, particularly on a meso or macro level. Individual case studies and/or overview chapters stand to make worthy additions to course material at the undergraduate, graduate, and post-graduate levels. Further, this work would surely help to paint a more complete picture of the medical innovation process that would be valuable to regulators and policy makers in this area, and even designers of health devices.

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