# Evidence in interdisciplinary contexts: the value and ethics of randomised controlled trials

**ESRC Seminar Series, November 2013-2016**

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## Objectives

This seminar series brings together practitioners and academics to examine the social and economic consequences of the extensive use of randomized controlled trials (RCTs) in medicine, development and economics. RCTs are increasingly seen as the gold standard for evaluating policy interventions in the UK and internationally. Given their growing importance in policy-making, the series has four main objectives:

1) To investigate different disciplinary perspectives on the advantages and disadvantages of the increased use of RCTs in policy areas including, and beyond, clinical medicine, such as social welfare, legal and justice services, human rights and global development.

2) To explore the ethical challenges raised by the increased uses of RCTs in poor and middle-income nations where regulatory infrastructures often receive less investment than in northern nations such as the UK and the United States, and where the long-

term availability of medical care and social welfare is often scarcer than in wealthy nations.

3) To explore the socio-cultural, economic and institutional characteristics of researchers carrying out trials and trial participants, examining: i) the industries and academic institutions that are dominant in conducting trials, and ii) to what extent the setting of trials – i.e. national, international, public or commercial – affects the robustness, access and public value of RCT results.

4) To create a research network that endures beyond the three-year duration of the project through introducing specialists from different disciplines to each other and developing a sustainable platform for their discussions.

# Research Context

During the current climate of increased fiscal austerity, questions surrounding the effectiveness and sustainability of governmental and private-sector initiatives to increase social welfare have taken on heightened public and academic importance. More than ever, different stakeholders, from governments to civil society groups, want evidence of the benefit of boosting spending in some areas while reducing funding in others. Controlled trials promise to offer this evidence, providing causal confirmation of whether interventions led to a desired result or not. The methodological robustness and value of RCTs makes them powerful political and evidentiary tools. But what are their limitations, methodological, ethically and politically? Are they suitable for studying most social policies, and if not, why not? From medicine to economics, RCTs have generated considerable debate that has, to date, mostly been isolated to particular fields.

For decades, health practitioners and clinicians have called for better public access to commercially protected trial results, and shed light on how industry sponsorship of trials can bias trial results (Perlis et al 2005; Chalmers 1990; Jørgensen et al 2006). Building on their work, a growing number of social scientists have explored the social and economic implications of RCTs, examining, for example, how the geographical dispersion of trials affects the quality of reporting; the ethical and financial treatment of trial participants; and the availability of therapies in resource-scarce settings once trials are completed (Petryna 2007; Sunder-Rajan 2002; Kelly & Geissler 2012; Wahlberg and McGoey 2007; Sismondo 2009; Timmermans & Berg 2003; Will 2007).

This research has documented the vast geographic changes in location of trials and socio-demographic characteristics of trial participants in recent years. Forty years ago, the vast majority of RCTs worldwide were carried out in only a few high-income countries, something lamented by leading RCT proponents such as Archie Cochrane, who hoped that the global dispersion of trials would foster associated health and scientific benefits, such as strengthened epidemiological detection systems; increased capacity for public health delivery; and more science publications per capita (McKee et al 2012). Today, the geography of trials has changed dramatically: an estimated 100,000 clinical trials are being run across the globe, with over 40 per cent of trials taking place in “non-traditional research areas” – regions including sub-Saharan Africa that have a disproportionately small share in the world’s pharmaceutical markets (Petryna 2007; Mirowski and Van Horn 2005).

Despite the high number of pharmaceutical RCTs in developing regions, there is growing evidence that many of the health benefits and capacity-building hoped for by Cochrane have yet to materialize, leading to growing demands to either halt or minimize the number of unregulated trials in regions of Asia and Africa (c.f. Kay 2013). In global public health, the use of trials has raised questions about ethics regarding individual autonomy within clusters when an entire community is included in the trial (Edwards et al 1999; Hutton 2001), while development economists have been concerned about the appropriateness of trialled interventions when the problems that are being addressed reflect broader socio-economic structural inequalities that interventions would not remove (Deaton 2009).

In the area of law and criminal policy, growing interest in the usefulness of RCTs in determining appropriate criminal and penal policies is raising profound questions about the nature of 'effectiveness' (Wilcox, 2003; Shepard 2003; Wolff 2000) . Whether or not an RCT can point to a reduction in the levels of reoffending rates, the degree to which this effect be attributed to an intervention – as opposed to say contingent factors of environment and features of population – is harder to assess. Opponents insist that, in general, RCTs fail to produce convincing theories about why interventions work and thus, inhibit more creative thinking on rehabilitation, punishment and justice (Burnett and Shadd 2004; Hough 2007; Smith 2007). Economists are increasingly drawn to RCTs to produce evidence on what policies work best at alleviating poverty and fostering economic growth. (Banerjee & Duflo, 2012) As economists and policy-makers become increasingly interested in behavioural and happiness economics, RCTs have become a critical means of testing hypotheses about the limits of rational choice (Thaler & Sunstein, 2008; Dolan et al, 2011). Experimental economics therefore offers opportunities to supplement orthodox neo-classical economics with additional evidence on the conditions of certain types of individual and collective behavior and welfare. But this also raises sociological and ethical questions, namely whether RCTs in economics are 'merely' experimental, or whether they represent attempts to govern, perform or re-format economic reality (Muniesa & Callon, 2007; Mitchell, 2005).

These examples highlight the ethical, economic, scientific and social challenges raised by RCTs, underscoring the fact that controlled trials are not simply an influential scientific method: they are a valuable commercial and political commodity, highly useful to commercial firms and government bodies faced with regulatory and public pressures to demonstrate the benefits of a commercial product or a government policy.

## Programme Team

**Boraschi** is the project coordinator of Spaces of Evidence, as well as PhD student at the University of Essex. Her research explores the evidence base around HPV testing in cancer prevention services in the UK. Boraschi holds an MA in Media, Culture and Communication from Institute of Education, and was trained as a professional Information Designer (BA Hons). During her MA, she was selected to work as Research Assistant on the EU project *Civic-Web,* at the Centre for the Study of Children, Youth and the Media, (Institute of Education), where she analysed health web-sites targeting young people living in the UK. She currently works part-time in a world-leading publishing house designing science books for young adults.

McGoey is Lecturer in Sociology at the University of Essex and Co-Director of the Centre for Economic Sociology and Innovation (CRESI). She serves as a steering committee member for the World Health Organization's programme on "Women's health and children's health: Human rights

and evidence of impact" (2011-2013). She joined Essex following a PhD in Sociology at the London School of Economics, and two postdoctoral fellowships at the University of Oxford. Recent publications appear in the *British Journal of Sociology, BioSocieties, Third-World Quarterly*, *History of the Human Sciences* and *Science of Culture.* She is editor of *An Introduction to the Sociology of Ignorance: essays on the limits of knowing* (Routledge, 2014). With Matthias Gross, she is co-editor of the Routledge Handbook of Ignorance Studies (2015). She is a member of the Editorial Advisory Board of *Economy and Society*.

**Cartwright** is Professor of Philosophy, University of Durham. She recently served on the US National Research Council's Committee on Evidence for Use. She recently co-authored *Evidence-Based Policy: A Practical Guide to Doing it Better* with Jeremy Hardie, Vice President of the Royal Economic Society and former Chairman of the WH Smith Group. She collaborates with Eileen Munro (author of the 2011 Department for Education's *The Munro Review of Child Protection*) on a project on understanding the philosophical foundations of what is to count as evidence for child welfare policies and publishes widely on evidence for effectiveness.

**Davies** is Assistant Professor at the University of Warwick. He has worked for several policy think tanks, including The Institute for Public Policy Research and The Work Foundation. He is a Fellow of The Young Foundation and an Associate of Demos, and has published policy papers for The Employee Ownership Association and Policy Network. He is an Associate Editor at openDemocracy, for whom he has recently edited two essay series, one exploring the political and policy implications of the science and economics of happiness, and the other (entitled 'Uneconomics') seeking to broaden public debate about the discipline and methodologies of economics as a public and policy discourse.

**Harper** is Senior Lecturer at the University of Edinburgh. He has worked with the Government of Nepal in assisting them with implementing Global Fund grants for TB control (2008), and has been invited by both the WHO (2010) and the Gates Foundation (2010) to assist in the development of policy around general research and laboratory expansion for TB control.

**Kelly** is Lecturer at the University of Exeter has worked in close collaboration with researchers based at the Ifakara Health Institute in Tanzania and the Medical Research Council in The Gambia, and also been involved in research network (LAROCS) exploring the pathways and prevention of Lassa Fever in association with colleagues at Charite Berlin, MSF, WHO and the Health Protection Agency, and Allied Health Sciences in Sierra Leone. She is the founding member of Somatosphere, a collaborative website and blog covering intersections of medical anthropology, science and technology studies, bioethics and psychology.

**Sariola** is a Senior Research Fellow at the University of Oxford. She is part of the Wellcome Trust's Global Health Ethics Network that covers five WT-funded Major Overseas Programmes: research institutes in Malawi, Kenya, South Africa, Thailand-Laos and Vietnam. These institutes employ over 1500 scientists working on tropical and poverty-related diseases and have trial sites as all over the developing world. She is also part of Bioethics networks in South Asia that recently held policy-instructive meetings across South Asia about clinical trials and experimental public health interventions and consulted the Government of India on clinical trials regulation.