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COMMENTARY

Time to address the cultural issues of service and research in health

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Commentary on: Leeson V. C. and Tyrer P. The advance of research governance in psychiatry: one step forward, two steps back. *Epidemiology and Psychiatric Sciences* 2013; in press.

Randomized controlled trials (RCTs) are the core of evidence-based medicine and should be the driver for clinical service improvement. As Leeson & Tyrer point out, conducting clinical trials now requires a complicated set of activities, which may reduce the efficiency of research without any improvement in its quality and safety. These comments resonate strongly with experience in conducting clinical research in New Zealand. Frustrated researchers recently published a paper outlining the process required to obtain permission to begin their research study. The application required 16 separate steps and took many months (Loveday & Mitchell, 2010).

New Zealand produces reliable data around the number of clinical trials that are conducted. For example, we know that 900 clinical trials were conducted between 2005 and 2009. We also know that only 33 (4%) were in the area of mental health (Currie & Jull, 2012). This is actually an improvement during the period 1998–2003 when only 11 mental health clinical trials were registered. This was only 2% of the total (Jull *et al*. 2005). In contrast, the Health Technology Programme has 14% of their funded studies involving mental health treatments from Leeson and Tyrer's data. Even so, given the burden of illness that psychiatric illnesses impose there is clearly a gap between obtaining evidence and treatment need.

What about the particular difficulties in conducting clinical trials in patients with psychiatric illness? There is unfortunately little data about this, and none, to my knowledge from New Zealand. The following paragraphs are therefore anecdotal and based on our experience. The irony that calling for measures to help increase evidence-based psychiatry without having any reliable data to support these measures does not escape us. We have to start somewhere.

Leeson and Tyrer point out a halo effect with staff generalizing from patients who are psychotic and cognitively impaired to all patients with psychiatric illness and therefore acting as 'protectors'. In our experience a similar effect extends to ethics committees. Having conducted studies on patients with cancer, cardiac disease and hepatitis C as well as psychiatric disorders, we have noticed different levels of ethical scrutiny. In studies with psychiatric patients, Mulder (RM) was usually asked to be present in person at the ethics review, and was required to repeatedly modify the consent form into almost childish language and to ensure a complicated monitoring of risk. With non-psychiatric patients none of these measures were required. It might be argued that increased scrutiny is appropriate for a vulnerable group of patients. However, the scrutiny appeared more related to a somewhat patronizing view that all individuals with a mental disorder are less competent than the rest of the society. There is no evidence for this belief.

Similarly mental health staff often see trials as exploitive requiring them to act to protect their patients, yet there is no evidence that mental health patients are more at risk of exploitation than, for example, patients with cancer (and one could make a good case that they are less likely to be). As Leeson and Tyrer note the attitude is often based on lack of understanding about how RCTs are conducted and the fundamental concepts behind them. Some staff even support an ideology that all evidence obtained using 'quantitative' methods is exploitative and unreliable. Some of them who are more sympathetic still see treatment as usual as necessarily inferior to any experimental or new treatment and therefore perceive randomization as unfair. This also means that the clinical staff who facilitate research have to make

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time in their busy schedules and that their patients are over-represented in any studies.

Lesson and Tyrer also suggest that health managers and some clinicians consider that 'researchers … have the status of undesirable aliens when it comes to gaining access … (to patients medical records)… because confidentiality is considered to be breached if an individual who is not involved in the provision of care to a patient views identifiable clinical data'. Interestingly a patient advocacy group recently pointed out that with regard to outcome-based research being undertaken in public hospitals to help clinicians determine the best management for patients was ' …disingenuous …and that this (research) should be undertaken and indeed must happen to monitor, evaluate and improve access to services and outcomes for patients' (Holdaway R. for Beat Bowel Cancer). Managers and others with the 'alien' concept should bear in mind the purpose of what we do is to improve patients' health and to do this requires research and wider community expects this.

Health managers, while at times advocating evidence-based practice seem to prefer that the evidence base is obtained in other managers health services. Research is seen as time consuming and expensive. The idea that introducing untested treatments into health services without evaluating their efficacy is unethical does not appear one of their concerns. The irony in New Zealand is that it is much more difficult to evaluate a new treatment than to simply start doing it. The latter does not require patient consent or ethical approval.

While this commentary might appear to be largely negative there are signs that things may be changing. After repeated complaints about inefficiencies and delays (e.g., Loveday *et al.* 2010) the New Zealand House of Representatives set up an 'Inquiry into improving New Zealand's environment to support innovation through clinical trials'. Their recommendations were largely supported by the government and are now receiving feedback. Recommendations include: ethics committees will be expected to check that the proposed research has been appropriately peer reviewed rather than conducting peer review themselves; imposing a 35-day limit for full review; allowing some clinical trials an expedited review (less complicated forms and a 15-day limit) on the basis of risk, and clarifying that localities rather than the ethics committee are responsible for ensuring that local governance issues are addressed (Frizelle, 2012).

The introduction of trial registration (De Angelis *et al.* 2004) has meant greater transparency of what is behind a particular RCT. Researchers now know that certain trails are being or have been undertaken (if not published), who is funding them and what the primary outcome measure should be (or should have been). The data cannot be 'water tortured' into a positive 'other' outcome to create a headline. The International Committee of Medical Journal Editors (ICMJE) uniform conflict of interest form is another similarly important step in research transparency despite its somewhat cumbersome structure at present (Drazen *et al.* 2009).

Finally, an ongoing barrier to clinical trials is the attitude to research in the public health service. Many clinicians and most managers have been seduced to think that clinical service delivery is the goal and consider research something for someone else to have to deal with. This is largely due to institutional funding drivers, which have created a culture of service delivery as the only function of the public health sector. Until research is central and core to health care provisions (as patients expect) and funded as such we will struggle to have our voices heard and providing patients with the best treatment.

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Conflict of Interest

None.

Ethical Standards

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