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Mental Health Research Through Clinical Innovation or Quality Improvement – A Reflection on the Ethical Aspects

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ABSTRACT

When clinical services aspire to quality improvement, creative and innovative approaches to old problems are needed to drive such change. Whilst new efforts should be applauded, information on this topic can be somewhat grey from an ethical and research point of view. Within the mental health profession there is currently an expectation to routinely evaluate care and disseminate findings. The notion of service enhancements under the guise of routine practice is an interesting and untested ethical issue. Should clinical innovation continue to enjoy such impunity as patient autonomy is often compromised as they are often compelled to accept treatment under the coercion of mental health legislation? We believe that it should not. All involvement in any form of research is voluntary, thus patients should also have the right to decline participation in quality projects if they wish to do so.

Key words: quality research; mental health; ethics; consent; risk assessment; consumer.

Progress in the art and science of mental health care depends upon innovation in clinical settings. In the research setting, the oversight of ethics committees and scientific peer review enables such innovation to occur in a manner that avoids much of the adverse consequences of the past. Such consequences emerge from ethical lapses or poor and unsafe scientific method (Roberts, 1998).

When clinical services aspire to quality improvement, creative and innovative approaches to old problems are needed to drive such change. Whilst the barriers to quality improvement usually arise indirectly from resource restrictions, bureaucratic inertia or systemic resistance, very little consideration has been given to the need for the kind of oversight considered imperative for safe and ethical research. Should clinical innovation continue to enjoy

such impunity? We believe that it should not.

In contemporary mental health care settings, both new and old approaches to care are stimulating change. The drive for change derives, in large part, from the allure of new treatments or new research findings, however this is frequently balanced by the realization that change for change sake is not always for the better. Moreover, in teaching hospitals both clinical and academic staff seek to develop research hubs of specialty within their service. This process of change often attracts additional resources to a clinical service, enhances institutional esprit de corps and stimulates research and publication.

Approaches to Limiting Risk

Which of the preconditions to ethical conduct of scientific research should be expected of such clinical innovation? In the first instance, the moral reckoning that followed the “doctors trial” at the Nuremberg War crimes trials in 1945 emphasized the centrality of informed consent to any research involving the interests of patients (Lifton, 1986). In New South Wales, the use of “Deep Sleep Therapy” at Chelmsford hospital was a tragic example of clinical innovation which led to significant harm. In this instance, a dangerous treatment was implemented in the name of innovation without any process of informed consent, peer review or ethical oversight and dozens of patients died or were seriously harmed. Community outrage in the aftermath of this tragedy led to profound changes to mental health laws and clinical governance in Australian healthcare institutions (Lawrence, 1991; Lupton, 1993).

Consent to innovative treatment programs is intrinsically problematic in mental health settings as patient autonomy is often compromised. The capacity for research subjects suffering serious mental illness episodes to consent to research participation has been discussed elsewhere (Appelbaum & Roth, 1982) – in many instances potential recipients of the new treatment are compelled to accept it under the coercion of mental health legislation—such as the out-dated practice of surgical sterilization of psychiatric inpatients in the United States during the first half of the 1990s (Grob, 1980). Moreover, acute psychiatric settings engender a culture of submission in both their design and operation; the presence of symbols of coercion such as seclusion rooms, locked doors and security infrastructure perpetuate the exercise of power typical of the asylums described by Goffman (1961) and Foucault (2006).

The second precondition to ethical research is the expectation of scientific rigour. Such enquiries are to be conducted in a methodologically sound way and likely to produce further knowledge that is beneficial (American Psychiatric Association’s Task Force on Research Ethics, 2006). Ethical and scientifically rigorous research is never the pretext for the self-serving imposition of idiosyncratic views about mental illness or its treatment. Clinical research innovation should only occur on the basis of a coherent, evidence-based argument justifying its potential benefits balanced with the demonstrable risks (Miller & Joffe, 2009).

The involvement of consumers and their carers in the development

and operation of mental health services has been a characteristic of the field in the last few decades (Horsfall, Cleary, Walter, & Malins, 2007; Lammers & Happell, 2004). Since the early 1990’s the presence of a consumer ‘voice’ has become a necessary step in policy development and implementation in mental health care in liberal Western democracies. Despite this, it seems that academic enterprises clad in “quality improvement” or “service development” garbs can often by-pass this by not seeking the views of the service users.

Towards Better Mental Health Research

The reality of mental health care is one of limited resources and seemingly limitless demand. As such, resources may be diverted from established models of care to academically driven service developments, creating further pressure on existing services. Moreover, staff are often expected to accommodate additional demands upon their time including, for example, the expectation of their arranging and coordinating appointments or the collection of data for research, rather than clinical purposes. Additionally, if limited health resources are spent on investigations to gather data of questionable clinical significance (as against academic necessity), this also adds to the ‘footprint’ of such services. Some medical tests can be justified because they are a requirement for admission to a psychiatric hospital (Zun, Hernandez, Thompson, & Downey, 2004), while others seem to be more beneficial to the academic-clinician than the patient as they have poor clinical utility for the individual.

One of the essential features of ethical research is clear communication of the potential benefits of a study to participants. This is a necessary step in obtaining informed consent. More significantly, making potential research subjects in clinical care settings aware of their right to refuse to participate in these programs is problematic in that such patients may fear that their clinical care may be affected. In settings of involuntary psychiatric treatment, such consent may be provided under the auspices of the law, which overrides the patient’s right to refuse any form of therapeutic intervention.

Studies based upon the acquisition of a database of biological material for later genetic testing or other future biological analysis place clinical research subjects in a dilemma. In these situations patients are required to endure potentially invasive procedures for no clinical benefit with the added anxiety aroused from the uncertainty around the future use of their tissue samples. Moreover, these patients may be concerned that the results of the analysis of their tissue samples may have a clinical significance which may not be readily available to them at a future time (Merlo, Vahakangas, & Knudsen, 2008). Moreover, clinical improvement can also include non-biological innovations that that impact on patient ethics that involve non-routine procedures.

So how can clinical innovation and academic progress not be stifled by such concerns? Whilst ethics committees, whose focus and remit are research projects, cannot and should not be tasked with an oversight role in clinical innovation, they do provide a potential model of such a process. In the first instance, any data collected

from a clinical service that is to be used for any publication or teaching purposes should be subject to the same conditions as any funded research – consent, confidentiality, peer review of methods and subject safety. Second, the primary task of service innovation should be improved patient care, not the progression of a particular academic agenda. Third, broad consultation from all relevant stakeholders from consumers and their advocates to government departments is a requirement of any such process. The likely impact of such service innovations on the existing services should be evident from such a process.

Clinical settings provide fertile ground for the generation of valuable knowledge about mental health care and the marriage of academic and clinical concern is vital to progress in the field. Much academic misconduct and ethically questionable practice occurs as a result of a failure of oversight and broad reflection of the implications of different processes (Spece & Bernstein, 2007; Steneck & Bulger, 2007). Rather than stifle progress, the kind of concerns we have highlighted should facilitate the important contribution that academic-clinical innovation should offer.

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