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Assessment of outpatient commitment in randomised trials

The randomised controlled trial (RCT) is the gold standard of research and the clearest way to establish causal certainty. This design, however, was misapplied in three RCTs of involuntary outpatient civil commitment (also known as community treatment orders).[1–3] In contrast with the positive outcomes regarding outpatient commitment in epidemiological studies,[4,5] a subsequent Cochrane review of these RCTs,[6] suggested that outpatient commitment "was no more likely to result in better service use, social functioning, mental state or quality of life compared with standard 'voluntary' care". This conclusion is potentially harmful for patients in need of oversight to protect their health and safety, and that of others. The conclusion is also unjustified because the outpatient commitment RCTs have major design, measurement, implementation, and analytical flaws.

Design flaws in the three outpatient commitment RCTs, such as how the comparison groups were defined, mean that they do not adequately assess the effectiveness of involuntary outpatient commitment. For example, in the North Carolina outpatient commitment trial,[1] individuals who had committed a recent serious act of violence involving injury or use of a weapon were explicitly excluded and in the New York outpatient commitment trial "persons with a history of violence" were excluded.[3] Although outpatient commitment behavioural criteria vary across jurisdictions, statutory agreement is almost universal that one behavioural criterion precipitating outpatient commitment (as opposed to regular release) is imminent danger of harm to self, or others.[7–9] Failing to include individuals who had committed a recent serious act of violence involving injury or use of a weapon or those with a history of violence limits the generalisation of the trials'[1,3] findings to patients who are not deemed to be violently dangerous and, therefore, to a limited subset of patients likely to be placed on outpatient commitment in most jurisdictions.[9]

Involuntary outpatient commitment, like parole and probation in a criminal justice setting, enables care outside of hospital, even though the patient meets the behavioural standards for involuntary detention in hospital. It provides for the delivery of needed treatment via community-based service, or by providing supervision that enables rapid return to hospital for evaluation when the patient is refusing to participate in their contracted treatment program. Patients refusing to participate in their required outpatient commitment community-based mental health care are, in all but a small number of jurisdictions, subject to mandatory return to hospital. However, the North Carolina outpatient commitment statute did not allow for direct involuntary return to hospital for patients who declined treatment.[10] North Carolina law requires a sanction for non-adherence and a "pick-up order" (law enforcement transport) to an outpatient site, then an urgent outpatient evaluation that could but does not have to include involuntary inpatient commitment.

The New York outpatient commitment RCT[3] did not enforce the statutory mandate of involuntary return to hospital for patients declining treatment.[7] As noted, outpatient commitment treatment mandates come in two forms: community-based mental health services and protective oversight enabling return to hospital for needed treatment. However, if the hospital return provisions are not enforced,[1] delivery of needed treatment within hospital is prevented, rather than the imminent danger.

Given that both trials did not include violent patients,[1,3] and one did not have provision for enforcing protective oversight,[3] calculations reported in the Cochrane review[6] of the numbers needed to treat are overestimates, because these RCTs excluded the individuals most likely to benefit from, or denied some individuals the likely benefit of, involuntary outpatient commitment intervention.[1,3]

Another outpatient commitment RCT, done in England,[2] found no difference between two versions of outpatient commitment, both requiring involuntary participation in treatment, but with different lengths of compulsory supervision. The absence of a difference was reported as an absence of effectiveness of community treatment orders and, by generalisation, all outpatient commitment.

The studies also err in their outcome measurements used to assess effectiveness—ie, the number of days saved in hospital admissions after outpatient commitment assignment, and prevention of hospital admissions measured by number of patients readmitted to hospital.[1–3] Outpatient commitment allows for early

release from hospital after an episode of illness. Without outpatient commitment, patients would remain in hospital for as long as they continued to meet the standard for commitment. By randomly assigning patients to treatment groups at hospital release rather than after admission to hospital, the three RCTs[1–3] discount the primary effect of involuntary outpatient commitment—ie, they fail to count the days saved due to the early release, made possible by the outpatient commitment order.

With regard to the methods used to assess the number of days in hospital following the outpatient commitment assignment date, the investigators of all three RCTs[1–3] made two additional errors. First, if days accrued as a result of readmission to hospital following termination of an outpatient commitment because of treatment refusal were counted, then the effort to get the patient the treatment they need by returning them to hospital (one key element of outpatient commitment) would have been conflated with the outcome. Second, if the length of a hospital stay after outpatient commitment was affected by a new episode of illness following the termination of a successful period of supervision, then the studies would have been treating outpatient commitment as something it is not. Outpatient commitment does not function like a vaccine—it has no carryover inoculation after its completion and cannot prevent new episodes of illness. Outpatient commitment provides enforced protective oversight and access to needed treatment while it is in force. There is no reason, therefore, to expect outpatient commitment and control groups to have different hospital-admission rates after the outpatient commitment period is completed (the hypothesis of the 3-year follow-up of the England RCT).[11]

Furthermore, the studies incorrectly selected outcomes that are not part of outpatient commitment law. Although providing the least restrictive alternative for provision of needed care is an objective of outpatient commitment law, preventing hospital admission (at the cost of protecting health and safety from immediate threats) is not specifically mentioned in outpatient commitment statutes. The RCTs[1–3] also assessed general symptom severity, quality of life, and social functioning measures, which do not directly represent the statutory objectives of outpatient commitment, despite being desirable outcomes.[6]

Flaws in implementation of these RCTs[1–3] led to no differences being detected between comparison groups. In the New York RCT,[3] police did not enforce a breach of the order by returning the patient to hospital. Such enforced returns to hospital, in association with an outpatient commitment order, reduce a patient's chances of committing crimes against other people or becoming a victim of such crimes. In the New York trial,[3] both the outpatient commitment and control groups had committed an equal amount of recorded violence at the end of follow-up. Would an enforced return to hospital have led to less violence in the outpatient commitment group, since it would have removed patients from potentially dangerous situations? Had proper enforcement occurred, might this trial have deemed outpatient commitment a failure because patients in the outpatient commitment group would have been returned to hospital more frequently, even though such returns potentially prevented threats to the safety of self and others? The trial in England[2] compared outpatient commitment of a fixed duration with outpatient commitment with a flexible duration; however, when a person was deemed to need the type of supervision provided in the comparison group, that patient received such supervision and crossed over to the opposite condition. Physicians who did not want to assign patients to brief outpatient commitment declined to participate in the trial. Both acts confound the trial's results.

Analyses of the RCTs' outcomes were based on single variable outcome mean differences and single variable odds ratios, when multivariate analysis adjustments for differences occurring after randomisation were required. The authors of the England RCT have published a 3-year follow-up, but did not use multivariate adjustment for group differences following randomisation and crossover.[11]

The outpatient commitment RCTs provide an excellent example of Fisher's proof,[12] showing that when no statistically significant differences are obtained in an experiment, the proper conclusion is that the researcher has failed to find a difference, as opposed to the conclusion put forward by these studies:[1–3] that there is no difference. Yet the findings of these studies, or in fact the absence of findings, are cited more frequently than epidemiological studies and are given more value in the scientific community, perhaps to the peril of patients subsequently denied outpatient commitment oversight.

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I declare no competing interests.

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