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Evidence and ethics in medical research

A surprising number of ethical issues concerning clinical trials are closely interrelated with methodological/evidential issues. In my first talk I showed that whether or not you are likely to think that a particular trial ought to be undertaken at all may, in cases like ECMO, crucially depend on what you think are the epistemic advantages of the trial methodology – what you think is the value in terms of increased rational confidence in the effectiveness of the proposed treatment once the trial has been performed in a certain way. In this second lecture I look at a series of other methodological issues that have significant ethical overtones. I investigate in particular so-called “mega-trials”: multi-centre trials involving 1000s of patients (in one recent case getting on for 20,000 patients) that have become fairly commonplace in, for example, cardiology. Among the methodological issues that are raised especially sharply by mega-trials is the relatively underemphasized question of “external validity” (is it reasonable to believe that the result “generalises” from the study population to the “target population”?) Another more obvious issue is the smallness of the effect that can be expected (the whole rationale for performing *mega-trials*). There are reasons to question whether these mega-trials in fact establish anything at all – which in turn of course highlights ethical concerns for the patients involved in them. Moreover, even if such trials are taken as establishing an effect, there are issues, stemming from the smallness of this effect, as to whether they should be made the basis for treatment. I show that the usual defence of mega-trials on this score is obviously faulty. In the process I show that the question of how results of clinical trials *are reported* itself raises important ethical concerns.

Αίθουσα Διατμηματικού Εργαστηρίου Πληροφορικής
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και, με τηλεδιάσκεψη, αίθουσα Σεμιναρίων 2, της Ιατρικής Σχολής
(κεντρικό κτίριο Ιατρικής, 1^{ος} όροφος, πτέρυγα 9^Α-13, Βούτες, Ηράκλειο)
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