medical care, complications, and degree of functioning and pain) differed significantly between the groups, but patients' satisfaction was greater among patients treated at home.

Clustering in trials needs more recognition

Clustering in clinical trials randomising individuals needs to receive more attention in statistical analysis, discussion of the results, and drawing conclusions, argue Lee and Thompson (p 142). Reviewing all non-cluster randomised trials published in the *BMJ* during 2002, they found that 19 out of 42 trials showed clustering that was likely to affect their results, but only one attempted to take the issue into account. The authors show by example how clustering can affect a trial's results and conclusions.

POEM*

Blood transfusion might increase ACS mortality

Question: Does a blood transfusion in anaemic patients with acute coronary syndrome (ACS) improve survival?

Synopsis: Although blood transfusions are routinely performed for patients with ischaemic heart disease who develop anaemia during hospitalisation, evidence of benefit is uncertain. In this cohort (prospective) study the investigators analysed data from 24 112 subjects enrolled in three large international trials of patients with acute coronary syndromes evaluating various antithrombotic regimens. Analysis was limited to patients with complete data on transfusion and occurrence of bleeding. All end points were evaluated by individuals blinded to treatment group assignment and by whether subjects had received blood transfusions. Because blood transfusion was a post-randomisation event left to the discretion of the treating clinician, associations between transfusion and primary and secondary end points were evaluated by using multiple logistic regression techniques to evaluate independent variables and control for confounding factors. A total of 2401 patients (10%) had at least one blood transfusion during their hospitalisation. Transfusion was independently related to an increased risk of death at 30 days (hazard ratio 3.94; 95% confidence interval 3.26 to 4.75). The predicted probability of death was higher when a transfusion was performed for haematocrit values higher than 25%, with no benefit or risk detected for transfusions given for values lower than 25%. A previous trial (*New England Journal of Medicine* 2001;345:1230-6) showed a benefit of selective transfusion in elderly patients hospitalised with acute coronary syndrome and anaemia (haematocrit $<33\%$) on admission (not developing during hospitalisation).

Bottom line: Blood transfusion in otherwise stable patients with acute coronary syndrome who acutely develop anaemia during hospitalisation may increase the risk of death, especially if the haematocrit level is higher than 25%.

Level of evidence: 2b (see www.infopoems.com/levels.html). Individual cohort study or low quality randomised controlled trials $<80\%$ follow up.

Rao SV, Jollis JG, Harrington RA, et al. Relationship of blood transfusion and clinical outcomes in patients with acute coronary syndromes. *JAMA* 2004;292:1555-62.

* Patient-Oriented Evidence that Matters. See editorial (*BMJ* 2002;325:983)

Editor's choice

Trial results: the next battle

Drug companies last week announced a plan to make results from clinical trials of new drugs publicly available (p 109). Summary results of completed, industry sponsored trials will be disclosed regardless of outcome, say trade associations of the world's drug companies. On the face of it, this move is one to be cautiously welcomed.

Cynically, you might argue that recent alarms about the safety of highly prescribed drugs and subsequent plunges in share price for AstraZeneca, Pfizer, and Merck—described by the *Financial Times* as "a painful six months for the pharmaceuticals industry"—may have inspired this display of virtue. Political and public pressure, and the threat of future legislation, for full disclosure of clinical trial results, particularly in the United States, is another driver of change. An initiative by leading medical journals, including the *BMJ*, to consider for publication only trials recorded in public registries is a small but important nudge towards transparency (*BMJ* 2004;329:637-8).

A new drug industry initiative focusing on trial results may leave you with the impression that the issue of trial registration has been resolved. But it hasn't. For several years, some companies have registered ongoing trials but this system has failed: it is voluntary and few trials are registered. Medical journals will begin implementing their registration policy in July, although it is unclear how successful it will be. There are thousands of other journals for drug companies to choose.

The next battleground was always going to be full disclosure of trial results, but it is a battle begun before the first one—around trial registration—has run its course. None the less, the drug company initiative is a step in a direction that should meet with approval from journals, politicians, and the public. But how might the proposal be improved?

The sting in the tail is, once again, the voluntary nature of the proposal—unless it is mandatory it will not work or be trusted. Another issue is how effectively the system will be enforced and who will monitor it? For example, if a drug company says it is participating, how can we be sure it is playing by the rules? Finally, the deal is that companies can present data on their own websites. How will this information be harmonised or how effective will be the mechanism to link these websites? Presenting information on all sorts of different websites in all sorts of different ways will be problematic.

As companies dither over whether or not to join this venture and whether or not to cloak their commercial interests, they should remember that it is participants in those trials, who presumably entered them for personal gain and the public good, who are as much owners of that "proprietary" information as the companies. It may take several years to judge this initiative's success, by which time legislation may have made it mandatory.

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