Allocation concealment is neglected in papers and protocols

Allocation concealment is inadequately reported in most published randomised controlled trials, as well as in the corresponding trial protocols. In a cohort study of

102 sets of publications and trial protocols approved by the scientific and ethical committees for Copenhagen and Frederiksberg, Pildal and colleagues (p 1049) found that allocation concealment was not clearly reported in 96 out of 102 published articles. Protocols of only 15 of these 96 trials had adequate allocation concealment (16%, 95% confidence interval 9% to 24%).

POEM*

Probiotic is useful for ulcerative colitis

Question In patients with ulcerative colitis currently in remission, is the probiotic *Escherichia coli* Nissle 1917 as effective as standard treatment to prevent relapse?

Synopsis Probiotics are live, but non-pathogenic, micro-organisms that are used to alter the microbial balance in the intestinal tract. Although most probiotics are Gram positive species (*Lactobacillus* spp), *E coli* Nissle 1917 (EcN) is a Gram negative probiotic of a different strain than toxic *E coli*; it may work by causing an immune response or preventing invasion of other bacteria. The investigators enrolled 327 patients with ulcerative colitis in remission who had had at least two acute attacks. The 327 patients were assigned to receive EcN probiotic 200 mg once daily or controlled release mesalamine (called mesalazine outside the United States) three times daily for 12 months. The patients were seen monthly for three months, then every three months for the remainder of the study period. The study was not tightly performed—32% of patients were entered incorrectly or not followed up appropriately. Dropouts were common; by the end of the study, 50% of patients receiving EcN and 43% of patients receiving mesalamine had discontinued because of various problems or protocol violations. The authors do not mention whether additional therapy could be used or how acute relapse was managed, although they prohibited patients from using antibiotics, sulfonamides, or steroids at entry to the study. The main outcome was the number of patients experiencing a relapse during the 12 months of the study, as measured by an undescribed clinical activity index. In patients who maintained therapy (per protocol analysis), 36.4% of the patients in the EcN group relapsed compared with 33.9% of patients receiving mesalamine. Relapse rates were similar between the two groups on intention to treat analysis (45.1% v 37.0%). Discontinuation rates due to adverse effects were similar in the groups. The study had a power of 20% to find at least a 20% difference (not a 20 percentage point difference) in the rate of relapse, if one exists.

Bottom line Treating ulcerative colitis with the probiotic *E coli* Nissle 1917 is as effective as prophylactic mesalamine in preventing relapse. This non-pathogenic bacterium is not available in any products that I could locate, and the strain (Nissle 1917) is crucial.

Level of evidence 1b— (see www.infoPOEMs.com/levels.html). Individual randomised controlled trials (with a wide confidence interval).

Kruis W, Frick P, Pokrotnieks J, et al. Maintaining remission of ulcerative colitis with the probiotic *Escherichia coli* Nissle 1917 is as effective as with standard mesalazine. *Gut* 2004;53: 1617-23.

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

Editor's choice

Triumph of the white male

The winner of the United Kingdom's election will come as a surprise to the nation's 9-13 year olds. A survey of these future voters revealed that footballer Wayne Rooney would make the best prime minister. Second to Rooney in this most perceptive of pre-election polls was schoolboy wizard Harry Potter. Failing that Charlie from "Busted," a defunct teen pop band, was best equipped to lead the country in any future wars or fiscal negotiations. Tony Blair, who has a taste for many of the attributes desired by his country's children—a love of football, music, and, his critics will say, a recently acquired taste for fiction—came in a respectable fourth.

By all accounts this has been the most negative and personalised election campaign in the history of British politics. Researchers from Loughborough University calculated that 43% of television and press coverage showed politicians attacking rivals. Voters turned their backs on this mudslinging and the tabloid press devoted more space—some by a factor of 10—to the marital strife of England's football captain than to publication of the attorney general's advice on going to war in Iraq. Health, which invariably tops the list of issues that matter to voters, received 3.5% of media coverage. Education fared little better at 3.7%. The subject that was most likely to topple Mr Blair was the issue of trust, something that is also a fundamental challenge for modern healthcare systems: trust between doctors and patients, doctors and managers, and doctors and politicians.

The children's poll also confirmed the durability of the stereotype of a white male as head of state—a stereotype that presents problems for research and clinical practice. With the white male overrepresented as a participant in research, the question arises as to the applicability of those research findings to other groups. What meaning do the reams of evidence based guidance have for a black woman? These are difficult and potentially incendiary issues, but developments in pharmacogenetics have reopened the debate on whether response to drug treatment is determined by genetic differences.

Pharmacogenetics, say Taslin Rahemtulla and Raj Bhopal, will refine our understanding of these issues, and doctors should adopt an open minded but critical stance (p 1036). A new drug called BiDil, a polypill combining isosorbide dinitrate and hydralazine, will soon be approved by the US Food and Drug Administration to treat heart failure in African-American patients only. Yet claims of a biological basis to racial and ethnic variations in therapeutics have proved to be overstated, warn Rahemtulla and Bhopal. Racial and ethnic variations continue to confuse and perplex researchers, clinicians, policy makers, and journal editors, with a possible breakdown of trust with non-white consumers of health care. Solutions are essential, preferably before Wayne Rooney becomes prime minister.

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