and the billing data for medical services about one month late, so we were able to present findings seven weeks after the trial ended. Normally observational analysis is delayed because historical controls are assembled after the policy and complex adjustments are required.

### Limitations of this trial

The main surprise was the non-compliance in the control group, causing the estimates of drug savings to be \$C8 in the randomised analysis and \$C24 per patient month in the observational analysis. The noncompliance resulted from a change that Pharmacare made to the protocol at the last minute, which can be avoided in future policy trials. Wanting to underscore the independence of the evaluation from the government, Pharmacare sent letters announcing the policy change six weeks in advance to all doctors in the province. Control doctors were not told of their exemption until they received a separate letter from the investigators two weeks later. Many control doctors either overlooked the second letter or decided to switch patients to inhaler drugs in anticipation of the new policy. Although our cluster randomised, delayed control design is open to such bias, it is the most practical approach that can be integrated in the dynamic process of policy making.

### Sensitivity analysis

In a sensitivity analysis correcting the randomised analysis for non-compliance, the two evaluation designs gave remarkably concordant results. This shows that, in the absence of randomisation, contemporary techniques for longitudinal data analysis have a good chance of producing valid evaluations of the impacts of drug policies.

#### Conclusion

We have shown the feasibility of a low cost randomised policy trial and its concordance with a parallel observational study and conclude that randomised evaluation is a promising new avenue for collaboration between decision makers and researchers that can produce rapid, rigorous, relevant evidence.

## Contributors: See bmj.com

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Competing interests: MM was an employee of British Columbia PharmaCare and is an employee of the Ministry of Health on extended leave. BC has received contracts from PharmaCare to advise on drug policy. BC has received unrestricted research funding from GlaxoSmithKline, unrelated to this research. RJG has received unrestricted research funding from AstraZeneca unrelated to this research.

Ethical approval: The institutional review boards of the Brigham and Women's Hospital and the University of British Columbia approved the study protocol.

- Abel-Smith B, Mossialos E. Cost containment and health care reform. A study of the European Union. Health Policy 1994;28:89-132.
- Ess S, Schneeweiss S, Szucs T. European healthcare policies for controlling drug expenditure. *PharmacoEconomics* 2003;21:89-103. McFadden ER: Improper patient techniques with metered dose inhalers: clinical consequences and solutions to misuse. *J Allergy Clin Immunol* 1005:56:579-93 1995:96:278-83
- Pounsford JC: Nebulizers for the elderly. Thorax 1997; 52(suppl 2):S53-55

# What is already known on this topic

Metered dose inhalers are less expensive than nebulised drugs and deliver respiratory medications to the lung better

Randomised trials in selected patients show that inhalers have similar or better outcomes than nebulisers

Randomised policy trials that evaluate restrictions on reimbursement for drugs are regarded as not feasible or expensive

### What this study adds

Restricting reimbursement of nebulisers in favour of inhalers does not trigger adverse outcomes in

Randomised drug policy trials are feasible and likely to be concordant with observational evaluations if implemented carefully

- Bourgault C, Elstein E, Le Lorier J, Suissa S. Reference-based pricing of prescription drugs: exploring the equivalence of angiotensin-converting-enzyme inhibitors. *CMAJ* 1999;161:255-60.
- Thomas M, Mann J. Increased thrombotic vascular events after change of statin Lancet 1998:359:1830-1
- Muers MF. Overview of nebuliser treatment. Thorax 1997;52(suppl 9)·S25-30
- Canadian Asthma Consensus Conference (CACC). Summary of recom-
- mendations. Can Respir J 1996;3:89-100.
  Schneeweiss S, Maclure M, Soumerai SB, Walker AM, Glynn RJ.
- Schneeweiss S, Macture M, Soumeral SB, Walker AM, Glyfin RJ.
   Quasi-experimental longitudinal designs to evaluate drug benefit policy changes with low policy compliance. J Clin Epidemiol 2002;55:833-41.
   Deyo RA, Cherkin DC, Ciol MA. Adapting a clinical comorbidity index for use with ICD-9-CM administrative databases. J Clin Epidemiol 1992;45:613-9.
- 11 Zelen M. Author's reply to compliance, bias, and power in clinical trials. Biometrics 1991;47:778-9.
- 12 Bowton DL, Goldsmith WM, Haponik EF: Substitution of metered-dose inhalers for hand-held nebulizers: success and cost-savings in a large,
- acute care hospital. *Chest* 1992;101:305. 13 Jasper AC, Mohsenifar Z, Kahan S, Goldberg HS, Koerner SK. Cost-benefit comparison of aerosol bronchodilator delivery methods in hospitalized patients. *Chest* 1987;91:614. (Accepted 7 January 2004)

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## **Corrections and clarifications**

Training for patients in a randomised controlled trial of self management of warfarin treatment and Coeliac disease and schizophrenia: population based case control study with linkage of Danish national registers

The layout of these two consecutive short reports, by Ellen Murray et al and by William Eaton et al respectively, went haywire at the final stage of page production, and the resulting errors were not spotted before publication (21 February, pp 437-438, 438-9). Each article should have had a table of data, but the Murray paper somehow attracted the Eaton table as well as its own; the Eaton paper was published without its table. The bmj.com versions have been corrected.

Review of prevalence data in, and evaluation of methods for cross cultural adaptation of, UK surveys on tobacco and alcohol in ethnic minority groups The authors of this paper, Raj Bhopal and colleagues, have alerted us to an error in the data in table 1 (10 January, pp 76-80). In the sixth row of data (self reported smoking, any tobacco products), the value for Pakistani men is 28 (not 8, as stated).

Reid refuses to accept all recommendations of Blofeld report We wrongly stated in this news article by Mark Gould (21 February, p 423) that Professor Kamlesh Patel was a member of the Blofeld team (which looked into the death of David "Rocky" Bennett, who died in an NHS psychiatric unit in 1998, after a struggle with nursing staff). He was not.