

PUBLISHED VERSION

Lu, Tim Yu-Ting; Pink, Jennifer A.; Whitten, Lauren E.; Hill, Catherine Louise; Adams, Robert John; Gibb, Catherine

[A champion-driven pathway towards quality improvement in the medical management of osteoporotic fractures](#) Medical Journal of Australia, 2006; 185(6):341-342

This article is available from the Medical Journal of Australia at:

http://www.mja.com.au/public/issues/185_06_180906/letters_180906_fm-2.html

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- 341 **Early medical abortion in Australia: more common than statistics suggest?**
Caroline M de Costa
- 341 **A champion-driven pathway towards quality improvement in the medical management of osteoporotic fractures**
Tim Yu-Ting Lu, Jennifer A Pink, Lauren E Whitten, Catherine L Hill, Robert J Adams, Catherine Gibb
- 342 **Clinical trials of unapproved medicines in Australia**
Jonathon Rankin, Jenny Mason, Neil Kottege, Natasha Y Andersson
- 343 **The repeating history of objections to the fortification of bread and alcohol: from iron filings to folic acid**
Hasantha Gunasekera
- 344 **Weight management in general practice: what do patients want?**
Claire Hewat

Early medical abortion in Australia: more common than statistics suggest?

Caroline M de Costa

TO THE EDITOR: Since my article on medical abortion was published in the Journal,¹ I have received some information from colleagues, and from women who have undergone abortions, about the current practice of medical abortion in Australia. I believe this may be of interest to readers of the *MJA*.

More than a dozen practitioners have informed me that they have used misoprostol or methotrexate/misoprostol combinations to induce early abortion (before 9 weeks' gestation) outside of hospitals, and a number of women have reported undergoing such abortions. The number of cases involved in this anecdotal sample is at least several hundred annually.

Induced abortion using methotrexate/misoprostol was practised in the United States up until the introduction there of mifepristone/misoprostol regimens in 2000.^{2,3} There is wide experience of this drug combination reported in the medical literature, and the consensus is that, in the short term at least, it is safe and effective, although less effective than the mifepristone/misoprostol combination.²⁻⁴ Both drugs are licensed for purposes other than abortion in Australia, as elsewhere (misoprostol for treatment of gastric ulceration; methotrexate as a cytotoxic agent, and for psoriasis and rheumatoid arthritis), but the use of drugs "off-label" is an acknowledged medical practice.⁵ Misoprostol in particular is widely used in obstetrics for cervical ripening and treatment of postpartum haemorrhage.⁵

These early abortions take place "under the radar" in the sense that there is no specific Medicare item number; the administration of the drugs occurs in the course of a standard consultation. There is nothing irregular about this, but it does mean that the inaccurate data we currently have on the number of abortions performed in Australia are even more inaccurate than initially thought. It should be noted also that misoprostol alone or in combination with other prostaglandins is being used in Australian hospitals, as overseas, in a more evident manner for the induction of late abortion in cases of severe fetal abnormality detected after 13 weeks' gestation.⁵ As well, methotrexate is commonly used in the treatment of early, unruptured ectopic pregnancy, in doses well below those used in oncology.

The communications I have received on the subject lead me to believe that medical abortion is currently extensively practised in Australia.

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A champion-driven pathway towards quality improvement in the medical management of osteoporotic fractures

Tim Yu-Ting Lu, Jennifer A Pink, Lauren E Whitten, Catherine L Hill, Robert J Adams and Catherine Gibb

TO THE EDITOR: The Australian Fracture Prevention Summit held in 2002 recognised osteoporosis as a major public health issue. Despite this, several Australian studies have found that a majority of patients with osteoporosis-related fractures do not receive appropriate evaluation and treatment as recommended by the clinical guidelines.¹⁻⁴

In 2003, the Queen Elizabeth Hospital, a tertiary referral hospital which services the north-western suburbs of metropolitan Adelaide, implemented a novel approach to improve the secondary prevention management of patients admitted to the orthopaedic unit with fragility fractures. The strategy was based on the "plan-do-study-action" principle of medical quality improvement, with the primary goal of enhancing performance.⁵

Before commencing, a retrospective case-note review of 40 consecutive patients who had been admitted to the orthopaedic unit with osteoporotic fractures revealed that, at discharge, none were receiving any medication for osteoporosis.

Patients over the age of 50 years who had been admitted with fragility fractures were identified from computer records. With the support of a physician and junior medical staff, a clinical pharmacist provided individual counselling, written materials and osteoporosis therapy. The rate of medication prescription was initially assessed at discharge. In a follow-up telephone interview, participants were queried about the continuation of osteoporosis therapy, performance of investigations by general practitioners, and history of falls.

Over a 10-month period, of 259 patients admitted with fragility fractures, 228 patients (88%) were prescribed osteoporosis therapy (calcium, vitamin D and risedronate) on discharge. Of those eligible, 65 patients participated in the follow-up audit. Forty-eight patients (74%) continued to take medications for osteoporosis as initially prescribed; only 28% had had laboratory investigations for osteoporosis and 31% a bone mineral density test. In addition, three patients had experienced recurrent falls complicated by further fragility fractures.

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The appointment of an allied health champion with clinical backup from a general physician appeared to have achieved a high level of initiation and continuation of osteoporosis pharmacotherapy in at-risk patients during hospital admission. The low rate of follow-up investigations is consistent with previously published data suggesting poor community-based follow-up after hospital discharge of patients admitted for osteoporotic fractures.

The major limitation of this clinical pathway is the low rate of patient participation in the follow-up audit. Therefore, the results of follow-up data cannot be said to be representative of the cohort.

This study highlights the importance of the participation of GPs in maintaining patient compliance with hospital-initiated programs, especially those involving chronic illnesses.

Acknowledgements: We would like to thank Mr C Butcher, Head of the Orthopaedic Unit at the Queen Elizabeth Hospital, for his ongoing support of this program. We are grateful for the medication provided by Aventis Pharma.

Competing interests: Aventis Pharma provided risedronate for the research.

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Clinical trials of unapproved medicines in Australia

Jonathon Rankin, Jenny Mason,
Neil Kottege and Natasha Y Andersson

TO THE EDITOR: The Experimental Drugs Section (EDS) of the Drug Safety and Evaluation Branch of the Therapeutic Goods Administration (TGA) administers the clinical trial notification (CTN) and clinical trial exemption (CTX) arrangements for unapproved medicines used in clinical trials. These arrangements provide an avenue of "exemption", whereby medicines that have not been approved for marketing in Australia are able to be supplied to patients within the context of a clinical trial approved by a human research ethics committee working under the guidelines of the Australian Health Ethics Committee (a subcommittee of the National Health and Medical Research Council). Although these arrangements

1 Clinical trials of unapproved medicines, by body system and therapeutic area, July 2004 to June 2005*

Body system/therapeutic area	Number of trials
Neoplastic disorders	252
Cardiovascular system	78
Central nervous system	71
Immunology	64
Endocrine and metabolic disorders	60
Infections and infestations	42
Musculoskeletal system	36
Genitourinary system	28
Analgesia	20
Respiratory system	16
Alimentary system	15
Skin	13
Eye	7
Surgical preparations	5
Nutrition	3
Ear	2
Unspecified†	27
Total	739

* Based on clinical trial notification and clinical trial exemption data. † "Unspecified" refers either to trials that were not directed toward a body system or trials in which the system could not be determined from the information on the clinical trial notification form. ◆

2 Clinical trials of unapproved medicines, by trial phase, July 2004 to June 2005*

Trial phase	Number of trials
Phase 1	87
Phase 2	259
Phase 3	277
Phase 4	53
Other†	63
Total	739

* Based on clinical trial notification and clinical trial exemption data. † "Other" denotes trials that were not nominated in a particular phase or to which these designations were not relevant. ◆

cover only clinical trials in which unapproved medicines are used, a substantial number of such trials are carried out in Australia each year. (Clinical trials using unapproved *medical devices* that also use the CTN/CTX arrangements are administered by the TGA's Office of Blood, Devices and Tissues and are not included in these statistics.)

The EDS often receives queries from stakeholders requesting some form of basic statistical data with respect to clinical trial activity in Australia. The EDS intends to begin use of a new database in 2007 for recording CTNs and CTXs notified to the TGA. It is hoped that this will enable us to publish a basic statistical subset of clinical trial information on an annual basis. As a prelude to this capability, we have manually compiled a few simple statistics on clinical trials notified within the financial year 2004-05.

Box 1 breaks down the trials conducted into various body systems or treatment areas. There were 739 separate clinical trials of unapproved medicines commenced over the 1-year period. As many of these are multicentre trials, there are a much greater number of actual trial sites involved. (A good measure of the number of trial sites is simply the raw CTN notification figures, numbering 2776 for the same period.)

Box 2 breaks down the trial numbers into the various phases of drug development. Although this is not relevant to all trials, these figures give an indication of the main areas of drug development research currently being conducted in Australia.

Given the number of multicentre trials being carried out, we did not think it useful to break down trial numbers by state and territory. We trust that these data convey

some idea of current clinical trial activity with respect to unapproved medicines in Australia.

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The repeating history of objections to the fortification of bread and alcohol: from iron filings to folic acid

Hasantha Gunasekera

The recent viewpoint by Kamien¹ is timely, given Food Standards Australia New Zea-

land is currently advocating for the mandatory fortification of all bread-making flour with folic acid (80–180µg per 100g of bread). The proposal is now before the Australia and New Zealand Food Regulation Ministerial Council, and a decision is imminent.

In 1991, the Medical Research Council Vitamin Study Research Group reported a randomised double-blind trial conducted at 33 centres in seven countries. Periconceptual folic acid supplementation had a 72% protective effect against neural tube defects (relative risk, 0.28; 95% CI, 0.12–0.71).² Because folic acid supplementation is ineffective when started after the pregnancy is confirmed, fortification of staple foods such as bread remains best practice.

The United States started mandatory fortification of enriched cereal-grain products a decade ago. As expected, there has been an increase in the population geometric mean concentrations of serum folate and red blood cell folate,³ and a corresponding

reduction in the number of babies born with debilitating neural tube defects.⁴

The benefits are clear and the risks are vague. Historical concerns that folic acid supplementation could mask pernicious anaemia and cause cancer have not been substantiated by international experience in more than 50 countries.

Australian health professionals have a brief window of opportunity to join Maberly and Stanley⁵ and advocate for mandatory fortification in spite of commercial objections, which are based on market-share concerns for existing “designer” products. If we educate and inform our patients and the community at large, the decisionmakers should finally get the message and this cheap, safe and effective public health policy would be implemented — a decade overdue.

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Weight management in general practice: what do patients want?

Claire Hewat

TO THE EDITOR: Tan et al¹ found that patients value key elements of successful weight management, including advice on healthy eating and exercise and regular follow-up. Accredited practising dietitians (APDs) provide all of these things and have the qualifications, skills and time to work with people to effectively manage weight. APDs use the Obesity Best Practice Guidelines of the Dietitians Association of Australia, providing evidence-based dietary therapy.

By working alongside general practitioners to provide individual advice, APDs ensure the best outcomes for patients. A considerable number of patients surveyed said that referral to a dietitian would be useful and that they would be likely to follow their GP's advice if referral was recommended.

The weight management roles of GPs and APDs are complementary and, by addressing any patient concerns and providing a referral to an APD, GPs can help their patients achieve their weight management goals.

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The Medical Journal of Australia (MJA) is published on the 1st and 3rd Monday of each month by the Australasian Medical Publishing Company Proprietary Limited, Level 2, 26-32 Pyrmont Bridge Rd, Pyrmont, NSW 2009. ABN 20 000 005 854. Telephone: (02) 9562 6666. Fax: (02) 9562 6699. E-mail: medjaust@ampco.com.au. The Journal is printed by Offset Alpine Printing Ltd, 42 Boorea St, Lidcombe, NSW 2141.

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27,649 circulation as at
24 April, 2006



ISSN 0025-729X