Research update
Pelvic organ prolapse physiotherapy (POPPY)

With a prevalence of up to 50% in women over 40 years and up to 75% in women attending gynaecology clinics, pelvic organ prolapse (POP) is considered a major health issue. Symptoms of POP impact significantly on quality of life for women, affecting physical health and well-being, ability to exercise and personal relationships. In the absence of rigorous evidence for the effectiveness of conservative management, surgery is currently the first line treatment for POP, but is not always successful. There is a clear imperative for effective, low-risk, low-cost treatment strategies for POP.

Background
Pelvic organs are suspended within the pelvis by elastic fibro-muscular fascia and also actively supported from below by the pelvic floor muscles (PFM, levator ani). Failure of these mechanisms leads to herniation of the pelvic organs to and through the levator ani. To date, treatment has been predominantly surgical to correct the anatomical fault of the suspensory tissues, however there is on average a 30% re-operation rate for prolapse surgery, although re-operation rates are reduced in women with stronger PFM. Pelvic floor muscle training is used by physiotherapists to manage prolapse symptoms by strengthening the supportive muscular diaphragm. However, unlike pelvic floor muscle training (PFMT) for urinary incontinence, for which there is high level evidence, there have only been few poorly designed studies to determine whether this muscular training is effective for POP. The results of a feasibility study undertaken in preparation for this trial suggested that women receiving PFMT tended to have better prolapse symptom outcomes. A large RCT (POPPY) will test these findings.

Aims
This study has two independent but complementary parts. Part 1 will contribute to an international randomised controlled trial (RCT), POPPY (UK), examining the effectiveness and cost-effectiveness of physiotherapist-delivered PFMT in the management of POP in women. This RCT will be conducted in the UK, New Zealand and Australia. In Part 2, POPPY (Australia), we will evaluate whether changes in PFM function are associated with changes in prolapse symptoms. We hypothesise that PFMT: 1) is effective in reducing prolapse-specific symptoms, prolapse severity and the need for further treatment (particularly surgical prolapse repair); 2) is cost effective in reducing prolapse-specific symptoms, prolapse severity and the need for further treatment; and 3) reduces prolapse-specific symptoms by improving PFM function.

Research plan
The Australian arm of the POPPY (UK) study will contribute 36 subjects to the international POPPY trial data. The POPPY (Australia) study will recruit 180 subjects, to investigate the mechanisms underlying changes in PFM function associated with changes in prolapse-related symptoms. This study will enrol women over 18 years of age who present to gynaecology clinics with prolapse of Stage I, II or III. Subjects will be recruited through four Australian sites (St George Hospital Sydney, The Queen Elizabeth Hospital Adelaide, Monash Medical Centre Melbourne and The Royal Women’s Hospital Melbourne). Subjects will be assigned randomly to a PFMT group, or to a control group receiving lifestyle advice to minimise risk factors for prolapse. Randomisation will be ‘blocked’ according to centre, stage of prolapse and surgery status (considering or not considering surgery). All subjects will be assessed at baseline, 6 and 12 months following enrolment. The primary...
outcome measure for the POPPY (UK) study is the prolapse symptom score; and for POPPY (Australia) PFM strength measured by vaginal manometry. Other outcome measures include: prolapse-related quality of life, prolapse severity (POP-Q assessment), need for further prolapse treatment, and 2-D and 3-D transperineal ultrasound. Analysis will be by intention to treat. The primary and secondary outcomes will be compared between the intervention and control groups at each time point using generalised linear models (analysis of covariance) that adjust for the centre, stage of prolapse and surgery status factors and baseline characteristics.

Outcomes and significance
If PFMT for POP is found to be effective and cost-effective, implementation of this low-risk intervention in the primary care setting in Australia and other countries will lead to a substantial improvement in women’s quality of life, will reduce progression of the condition and reduce the need for or delay expensive surgery, thereby reducing the burden on the health care system.

This trial is poised to commence following ethics approval from the relevant Hospital Ethics Committees. Funding for the trial is provided by a grant received from the National Health and Medical Research Council (NHMRC) Australia. The trial is registered with the Australian New Zealand Clinical Trials Registry (ANZCTR) and details of this trial can be found at <www.ANZCTR.org.au/ACTRN12608000113358.aspx>.

References
5. Hay-Smith EJC & Dumoulin C. Pelvic floor muscle training versus no treatment, or inactive control treatments, for urinary incontinence in women. Cochrane Database of Systematic Reviews 2006; (1).