Reviewer's report

Title: Characteristics of patients initiating raloxifene compared to those initiating bisphosphonates

Version: 1 Date: 13 June 2008

Reviewer: Suzanne Cadarette

Reviewer's report:

Authors aim to compare characteristics between patients initiating raloxifene vs. bisphosphonates for the prevention and treatment of osteoporosis.

Authors raise some great discussion points, such as:
- limitation of their study in not having formulary information
- clarifying that they studied Medicare patients with employer benefits
- the fact that comparative effectiveness studies must take important differences in patient characteristics into consideration

Major compulsory revisions
Changes to the study design and analysis will facilitate interpretation:
1. Restrict study to women. Raloxifene is approved to prevent and treat osteoporosis among postmenopausal women. Including men who essentially only contribute to bisphosphonate use can introduce bias.

2. Restrict analyses to new users of either agent (so comparing treatment decision to start pharmacotherapy).

3. Include only oral bisphosphonates approved for OP, i.e., exclude etidronate and daily use of 40mg alendronate and 30mg risedronate (approved for Paget’s disease of bone, not OP).

4. Exclude:
   a. Patients with Paget’s diagnosis of bone
   b. Any prior raloxifene or any prior bisphosphonate (thus limit to new users of either agent)—as mentioned above

5. Add multivariable logistic regression (raloxifene as the outcome) to determine independent association between each covariate and prescribing.

Minor essential revisions
1. Figures 1 and 2 and not helpful because the information is contained in the table. Suggest that authors omit these figures.

2. Follow current standards for reporting of observational studies (STROBE). In particular, a STROBE figure will help readers follow cohort assembly, exclusion
etc.

3. Update literature review. MacLean AnnInternMed 2008;148:197-213 (systematic review of OP treatment effects) + recent letters to the editor is particularly relevant, as is our recent study that found similar differences in background risk between raloxifene and bisphosphonates (Ann Intern Med 2008;148:637-46).

4. Page 8, 2nd paragraph. Please clarify that you do not have prescriber ID number and thus are approximating…

5. Consider adding other potential correlates of raloxifene prescribing, e.g., Mammography, stroke, DVT, diagnosis of osteoporosis

Discretionary revisions
Including an appendix with claim codes used to define background covariates may help to improve transparency of this work.

**Level of interest:** An article of limited interest

**Quality of written English:** Acceptable

**Statistical review:** Yes, and I have assessed the statistics in my report.

**Declaration of competing interests:**

I declare that I have no competing interests