Reviewer's report

**Title:** A Randomized Trial of an Intervention to Improve Use and Adherence to Effective Heart Disease Prevention Strategies

**Version:** 1  **Date:** 4 August 2011

**Reviewer:** Stephen D Persell

**Reviewer's report:**

The authors performed a randomized trial that tested the feasibility of introducing a preventive cardiology decision aid and tailored adherence promoting messages into primary care. There were some beneficial effects observed on the adoption of preventive strategies, primarily aspirin.

**MAJOR**

Some information about the implementation and feasibility are provided but additional details would be welcome. It would be interesting to know more about the steps that were required to get patients' risk factors into the system. It would also be interesting to know more about the physical work flow that was required to deliver the intervention in the actual clinical setting. (Was a private exam room with a computer required? How did this impact the clinic? Was the RA needed to stay with the patient?)

The primary outcome of the study, as it is calculated, is likely to introduce errors in the estimated effects of initiating antihypertensive therapy.

For example: a 55 year old man with untreated hypertension (SBP 155), total cholesterol 240, HDL 35, nonsmoker, has a hard CHD FRS of 27%. Initiating antihypertensive therapy and lowering the SBP to 135 yields a FRS of 28% (clearly an underrepresentation of the benefit of treating his hypertension). ([http://hp2010.nhlbihin.net/atpiii/calculator.asp?usertype=prof](http://hp2010.nhlbihin.net/atpiii/calculator.asp?usertype=prof))

Therefore, it would be preferable to calculate the change in risk based on the observed reductions in risk found in clinical trials of interventions to treat hypertension or hyperlipidemia (as you have done with the assumed risk reduction from aspirin use).

The aspirin effects for primary prevention observed in the 2009 individual participant level meta-analysis seems like it would be preferable to use for the risk assumptions in the primary analysis since it includes more contemporary studies than the 2002 meta-analysis. This should either be changed, or compelling justification for why the more recent meta-analysis results were not used should be provided.

Since the baseline CHD risk is not provided, the reader is not able to tell if the groups started with similar risk. The paper could be improved by adding baseline CHD risk and risk factor levels to table 1 or 2. Baseline risk factor data could be
added to table 4 for the subgroups with high cholesterol or hypertension.

Please clarify if all patients had repeat lipid levels performed at 3 months.

MINOR

Abstract, methods:
Remove word “innovative”. Purely descriptive terms are preferable. Add brief description of what kind of patients were subjects.

Describe the primary outcome more explicitly (risk of what CHD events over what timeframe).

Methods:
Explicitly state the CHD endpoints that were part of the FRS used. Was it the endpoint from the 1998 Wilson paper (which includes angina) or “hard CHD endpoints” as used in the Framingham model suggested for use in guidelines like the NCEP ATP III which only includes cardiac death or MI?

Briefly describe the opt out procedure.

Describing the intervention as “theory-driven” is not informative by itself. You could either elaborate more or remove this label.

In describing the delivery, I would suggest not stating that their physician “had the opportunity to manage their risk factors” since this relies on unmeasured assumptions.

Results:
State if personnel time was required while patients used the decision aid.

Discussion:
The trial registration site does not seem to include pre-specified sub-group analyses. If this was pre-specified, this should be noted in the methods. If not, then this description could be removed from the discussion.

Page 15 paragraph 3 should read …cholesterol-lowering medication adherence.

A limitation that could be mentioned is that since physicians could have both intervention and control patients, there could have been a spill over effect (physicians treated their control patients differently than they otherwise would have). This may or may not have been compensated for by including physician random effects.

Tables:
Generally, the tables lack sufficient detail to stand on their own. It would be preferable to add additional details to the tables including definition of the CHD risk, units of measurement and other clarifying details. In table 1, what is planned
best evidence interventions? Table 3: what is “Any chosen therapy, including other”

**Level of interest:** An article of importance in its field

**Quality of written English:** Acceptable

**Statistical review:** No, the manuscript does not need to be seen by a statistician.

**Declaration of competing interests:**

I declare that I have no competing interests