Reviewer's report

Title: SMART: Self-Management of Anticoagulation, a Randomised Trial

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Version: 2 Date: 12 May 2003

Reviewer: Jennifer Elston Lafata

Level of interest: A paper of considerable general medical or scientific interest

Advice on publication: Unable to decide on acceptance or rejection until the authors have responded to the compulsory revisions

The manuscript presents a protocol for a randomized clinical trial designed to evaluate the clinical and cost-effectiveness of self-management compared to standard care for patients on long-term oral anticoagulation. The described trial is timely and appears generally appropriate to address the study objectives in a valid manner. There are only a few (mostly minor) concerns that need to be addressed.

Discretionary Revisions

* No details are provided on the specifics of the planned cost-effectiveness analysis. For example, it is unclear exactly what cost information will be available, the data sources for this information, and from whose perspective the analyses will be conducted. Nor is the cost modeling alluded to in the study aims described with any specificity. The protocol description could be strengthened by a more detailed description of the planned methodology that will be used to address the cost related aim.
* It sounds like more information could be presented in terms of subject recruitment both in terms of numbers and characteristics of subjects. Of particular interest to the readership is likely to be information regarding ability to self-manage.

Compulsory Revisions

* The hypotheses to be tested should be specified.
* 'Near patient testing' should be defined/described as what is meant by this term may not be apparent to all readers.
* There is insufficient detail regarding exactly what constitutes 'standard care.' I believe it to be anti-coagulation clinic management--but this is not stated until almost the end of the "trial procedure" section. Furthermore, there is no description of what should be expected in terms of frequency of testing or clinic contact in this arm. Such information should be added to the manuscript.
* There is no description of how 'percent time in range' will be estimated.
* It is unclear whether the power calculations address the potential for non-independence among
patients being cared for within the same clinic.
* The planned statistical analyses are not described. What specific tests were used for the power calculations? Will there be any multivariable analyses? sub-group analyses?
* The standardized assessment tools that are being used (e.g., SF-12, quality of life, and anxiety trait instruments) should be referenced.

(I noticed at least once the use of 'data was.' This should be changed to 'data were.')

**Competing interests:**

None declared.