Reviewer's report

Title: Developing Clinical Practice Guidelines: Types of evidence and outcomes; values and economics, synthesis, grading, and presentation and deriving recommendations

Version: 2 Date: 8 August 2011

Reviewer: Tim Stokes

Reviewer's report:

1. This is the second of three papers that together constitute an overview of clinical guideline development that is both very timely and important. The authors are collectively the international leaders in the field of guideline development methodology and their work in the 1990s and subsequently has been very influential in forming the methods of national guideline developers such as NICE in the UK. There is a need to update the original work of these authors (BMJ 1999) and the paper uses relevant more recent publications to update key aspects of guideline development methods. It is aimed at a general readership and is at an appropriate level of detail.

2. This specific paper clearly summarises its key areas. The comments below constitute discretionary revisions (except 5 - minor essential).

3. p. 6 intermediate outcomes, surrogate outcomes and surrogate measures. In the text only intermediate outcome and surrogate measure are explicitly defined. It would be useful to have a definition of surrogate outcome as well. It might be useful to reference this to standard epidemiological definitions here such as those of the IEA (e.g., Last, Dictionary of Epidemiology).

4. Incorporating economic considerations in guideline development. p. 15-16. One major national guideline developer - NICE - does require that its Guideline Development Groups are required to make decisions based on the best available evidence of both clinical and cost effectiveness. It is noted that NICE clinical guidelines do routinely conduct de novo health economic modelling of key questions as well as review the existing cost effectiveness literature. It notes that "only rarely will the health economic literature be comprehensive enough and conclusive enough that no further analysis is required. Additional economic analyses will usually be needed (NICE Guidelines Manual 2009 7.1.3 - http://www.nice.org.uk/media/68D/29/The_guidelines_manual_2009_-_Chapter_7_Assessing_cost_effectiveness.pdf)". It would be helpful if this point was referenced. In terms of the authors' statement (p. 15) that "there is no clear role for a multi-disciplinary guideline development group in deriving recommendations around the clinical decision - the 'right decision' is produced by the model" this is debatable. NICE would argue that there is a clear role for the GDG in terms of deriving recommendations around the clinical decision and makes clear recommendations as to how to involve the GDG in this process (see 7.2.1 NICE GM 2009).

5. wording recommendations. McDonald reference - not cited.
**Level of interest:** An exceptional article

**Quality of written English:** Acceptable

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

**Declaration of competing interests:**

I am employed by a UK NHS organisation (NICE) that has as one of its remits the development of clinical guidelines for use in the NHS.