Reviewer's report

Title: Radiological informed consent in cardiovascular imaging: towards the medico-legal perfect storm?

Version: 1 Date: 5 July 2007

Reviewer: karen thomas

Reviewer's report:

This is a very important topic for discussion in the medical literature, and the authors have made a good attempt to tackle it. However, there are some changes which should be considered.

General
Title
The title does not accurately reflect the contents of this review. The authors use multiple examples from non-cardiovascular imaging. Either the title needs broadening to include all imaging, or the examples in the text should all be relevant to cardiovascular work.

General comments
1 Some of the commentary is emotive and may be considered inappropriate for a scientific journal. This risks the very real concerns highlighted in the paper being dismissed for the wrong reasons. It is important that this does not occur.

Examples include
Abstract page 2, line 19-22
Introduction, final part of last sentence, page 3, line 16-17
Page 9, lines 4-6
Page 5, line 2. Remove the word stunning.

2 Greater discussion of the many benefits brought by radiological procedures involving ionizing radiation to patients should be included. The impact on patient care of modern CT and cardiac catheterization must be appreciated. It is important that we achieve a good balance in this issue, so that patients are genuinely informed but without such alarmism that patients are reluctant to undergo investigations in which benefit to them would outweigh risks. The issue of risk and benefit balance needs highlighting to a greater extent.

-------------------------------------------------------------------

Major Compulsory Revisions (that the author must respond to before a decision on publication can be reached)

Abstract
3 The authors suggest consent forms should spell out effective dose, lost life expectancy, equivalent number of CXR, excess risk of cancer. There is no discussion of the difficulty in obtaining this information for each investigation, and of the problems in gaining a consensus on the figures. Will all institutions be required to produce effective doses for procedures in their department, which may not be directly equivalent to those quoted in the literature. Will patient age be factored in? Which background radiation figure should be used, as this varies across the world? The many practical difficulties in such a prescriptive suggestion must be discussed.

4 Introduction
The end of the final sentence ‘too sensitive to paternalism….medicine’ should be removed. This is a statement of personal opinion, and is not an aim of the study.

5 Line 10,11 Aims. Point 1 – the review covers all procedures involving ionizing radiation, not just nuclear medicine. The sentence also is not clear grammatically ----suggest it should be - To assess the information perceived by patients on the radiation doses associated with common radiological procedures.

Patients unawareness of radiological risk

6 Line 21-22. The authors are making assumptions not supported by the paper they quote (9). Their statement that parents were kept uninformed is not supported by the paper, and is prejudicial, implying a clear intent.

7 The risk quoted in the following sentence should be changed. An abdominal CT in 1 year old is approx. 10mSv and carries risk of 1 in 1000 according to BEIRVII.

8 Line 23-24. There is no agreement between pediatricians. The number quoted is merely the most frequent answer given to a single question in one survey. This is not the same as an agreement.

9 Page 4, line 1-4. I do not know which paper this sentence refers to. If it is reference 10, then this needs further explanation of the study involved. The final sentence, line 4-5 does not make grammatical sense.

Physicians unawareness of radiological risk

10 This section should be summarized further and shortened. The comments on underestimation of doses can be put together, followed by those on lack of awareness that US or MR do not involve ionizing radiation.

11 Page 5, Line 5, Change 40% to Forty percent. Reword the sentence – Forty percent of pediatricians underestimated by up to 100 times the dose of a pre and post contrast Head CT. 4% thought that abdominal ultrasound was associated with ionizing radiation.

12 Figure 2. The annotation ‘Pediatricians, Sick Childrens Hospital, Toronto’ is inaccurate. The survey involved pediatricians from the Greater Toronto Area practicing in a wide variety of hospital and clinic settings. The Figure legend is inaccurate - needs changing- the absolute majority did not underestimate by 100
or more fold. Also, no statement is provided whether the authors have permission to reproduce this, and the other figures in the manuscript.

13 The last sentence, lines 7-10 belongs in the section on informed consent and should be moved. The final comment that this explains why many inappropriate tests occur, does not directly follow and should be removed or rephrased.

Informed consent – how it is

14 Page 5, Line 11-12. It is not the consent forms themselves that use these three approaches – although it could be argued that there are three possible ways to look at risk communication in medicine. This needs rephrasing

15 Page 5, Line 11, I was not aware that obtaining written informed consent for nuclear medicine studies is routine. If this is the case in Italy, or other specific countries this should be stated. As I understand, there are no differences in the manner of consent obtained between nuclear medicine and other radiological procedures in the UK or North America.

16 Page 6, line 15. Interesting information regarding research scans. It is not however stated what type of nuclear medicine scan is being referred to by the given quote.

17 Page 6, line 23-25. This excellent point should be moved to the section on ‘how it should be’

Informed consent – how it should be

18 Page 7, lines 6-12. Again it is not the consent form that is ideal, but the consent process. These sentences need rephrasing, to make it clear that it is the authors suggestion/opinion that formal informed consent should be obtained for procedures involving high radiation doses, and that they believe certain information should be included on the form.

19 The authors must discuss the fact that despite the progress made in the scientific literature towards establishing radiation doses of various investigations, there is still a long way to go towards a comprehensive knowledge of all we do. The difficulties of institutional doses versus those quoted in the literature must be discussed, and also the difficulty in pediatric cases, when risk estimates vary considerably with age.

Towards the perfect legal storm

20 Page 9, line 4-6. needs rephrasing.

---

Minor Essential Revisions (such as missing labels on figures, or the wrong use of a term, which the author can be trusted to correct)

Introduction page 3, line 9. Sentence does not make sense.
Page 8, line 7. change to billions of examinations
Page 7, Line 2 – units are not really esoteric – there are however many varied units involved. Remove this word
Figure 2 legend – majority, commas instead of period
Table 1 legend – thallium spelling

Discretionary Revisions (which the author can choose to ignore)

What next?: Unable to decide on acceptance or rejection until the authors have responded to the major compulsory revisions

Level of interest: An article of importance in its field

Quality of written English: Needs some language corrections before being published

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