Reviewer's report

Title: Development of a comprehensive list of criteria for evaluating consumer education materials on colorectal cancer screening

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Reviewer: Paolo Giorgi Rossi

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Major revisions

Balance and neutrality. Screening programs are a preventive public health campaign in which the health system takes the initiative to actively contact a well defined group of healthy population to propose an intervention made of test assessment and eventually treatment. This framework, being valid only for cervical cancer, breast cancer and colorectal cancer, defined by the EC recommendations in 2003, makes impossible a neutrality of the message: I cannot invite you and being neutral about your response. The Health systems, inviting you, is implicitly responsible for the effectiveness of the intervention and it is explicitly auspiciating, encouraging, your participation. This is clearly stated in all the screening recommendation that are aimed at high coverage and equity in access. On the other hand any citizen had the right to participate or not, has the right to know all the benefits and the risks ad has the right to be informed in way that is effective and comprehensible.

In this framework neutrality is not a criterion, nor a value: I cannot invite you being neutral, this would be schizophrenic for the Health system. If you invite someone to a party you cannot say that it is the same for you if he or she came or not, you can say that he or she is free to come or not according to his /her will and interests, but you must say that you will be happy if he or she will come. This is implicit in the active action of inviting.

The concept of neutrality is central in clinical informed consent when more options are plausible. In this case the only topic that could require neutrality is the choice between the two options: FOBT and colonoscopy.

The second point is the effect of detailed information on access and specifically equity of access. There are evidences that a more detailed invitation letter could increase inequality in access, discouraging people that are less educated. (Segnan N, Senore C, Giordano L, Ponti A, Ronco G. Promoting participation in a population screening program for breast and cervical cancer: a randomized trial of different invitation strategies. Tumori 1998; 84: 348-53. for a review see Spadea T, Bellini S, Kunst A, Stirbu I, Costa G. The impact of interventions to improve attendance in female cancer screening among lower socioeconomic groups: a review. Prev Med 2010 Apr; 50(4):159-64. Epub 2010 Jan 20). Furthermore one of the trial cited as effectiveness of EBHI on informed consent had a strong negative effect on participation (Simth 2009). According to EC
recommendations, but also on ethical value of the intervention, our goals are to implement screening programs with high participation rate and low inequalities. It is evident that we are facing a dilemma, without any easy solution: we must obtain high participation, particularly for low education level groups, but we also must give correct information to allow a conscious participation. This is challenging, because it has technical solutions (there could be methods more effective in improving informed choice not affecting participation than others, and research is needed for this), but there are also ethical issues in where we can put the right threshold between negative effects on participation or equity and a correct and complete information; for this second point researchers and health professionals cannot decide by themselves, the society must fix the ethically acceptable balance, and obviously it will be different according to cultural and political point of view. This point should be discussed, not acknowledging the complexity and the political level of some of the aspects, it is risky and can give the impression of a supremacy of technicians also in ethical issues.

Minor essential
Pag 4 lines 2-4: “However, in recent years, it became clear that the benefits of some procedures may have been overestimated and their risks underestimated [1].” This sentence is vague and absolutely does not apply to colorectal cancer screening: from initial trials we did not have any evidence about incidence reduction, that is now clear for FOBT and sigmoidoscopy; endoscopy adverse effects were emphasised since the very beginning in CRC screening, but the adverse effects rate decreased in the last years; over diagnosis has been postulated since the beginning for colorectal cancer, but actually the effect of over diagnosis has been overcome by the incidence reduction of adenomas.

Methods
How did the authors define the correct answers? It is not clear the role of literature and the role of experts. For example over diagnosis is mentioned for T1 with a reference to the EU GGLL. The issue of over-diagnosis in presence of a decrease in overall incidence is somewhat tricky. The real problem is over-treatment of pre-invasive lesions, that obviously is much larger than the incidence reduction, but is also much less harming that the treatment of an invasive cancer. Nevertheless the problem is how the correctness of the sentence has been established: EU GGLL or expert?

Results
Pa 14 example 7: please explain briefly the criteria, they can be reported as in the table with two or three words.

Discussion
See main comments.

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'