Author's response to reviews

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

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Author's response to reviews: see over
Dear Editors:

Enclosed for your consideration is a revised manuscript

**MS: 413332259631000 "Development of a comprehensive list of criteria for evaluating consumer education materials on colorectal cancer screening".**

We gratefully acknowledge the comments and suggestions received from the referees. In the following, we are giving a point-by-point response to the concerns. Our answers are marked with an arrow and italicised.

**Referee 1:**

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 auspicating, 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 and 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.

→ We think one has to differentiate between the invitation letter and the enclosed leaflet (information material) as it is done in the EC guidelines. ("Use of a non-tailored leaflet for the general population is advised;

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1 European Commission: European Guidelines for Quality Assurance in Colorectal Cancer Screening and Diagnosis. Luxembourg; 2010
the leaflet should be included with the invitation letter. Information about CRC screening risks and benefits, CRC risks (incidence and risk factors), meaning of test results, potential diagnostic tests and potential treatment options should be included. While an invitation must not be neutral concerning the participation, the patient information material should be neutral in terms of delivering information about benefits and risks, being balanced and unbiased (Bunge et al. 2010, EC guidelines). Such "neutral" information should even be possible, if the authors of the information are not neutral about the uptake of the audience.

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.

We think that there is a third option of non-participation. The EC Guidelines on Colorectal Cancer Screening clearly say in the Communication chapter 10 "It implies that these patients know the pros (benefits) and cons (harms) of screening and are aware not only of all the risks and benefits of participation in screening but also of non-participation (Raffle 1997; Austoker 1999; Goyder, Barratt & Inwig 2000)." The guidelines recommend further: "Developing communication strategies in CRC screening programmes is important to ensure that as many of the target population as possible receive the relevant information to be able to make informed decisions about whether or not they wish to attend for CRC screening."

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, Stibu 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.

The challenge of high participation and informed choice is of high importance. In our opinion, a comprehensive discussion about the possible conflicting aims of increasing participation rates and at the same time improving an informed decision-making would go beyond the scope of this manuscript. We also see the problem that EBHI might even deter less educated people from screening. We include a paragraph concisely discussing this subject: "The ethical goal of EBHI to enable as many of the target population to make an informed decision whether or not to participate in CRC screening may be conflicting with the aim of achieving a high uptake [50]. There is inconclusive evidence on detailed information material, it may have a positive or no effect on participation [5, 8] or may even increase non-attendance [6]. Non-attendance based on an informed choice has to be accepted, while non-attendance arising from the EBHI itself and not from an informed choice is not desirable. EBHI especially may deter socioeconomically disadvantaged people and those with low health literacy from participating in screening [51] resulting in higher health inequalities. Further research is needed to improve participation and informed decision-making in CRC screening programs.

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3 European Commission: European Guidelines for Quality Assurance in Colorectal Cancer Screening and Diagnosis. Luxembourg; 2010
4 Raffle AE. Information about screening—is it to achieve high uptake or to ensure informed choice? Health Expect 2001;4:92–8.
explore tailored communication strategies for deprived target groups focusing on increasing knowledge and understanding to promote an informed choice-making.”

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 syngmoidoscopy; 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.

This sentence introduces into the subject and refers to cancer screening in general. Until now evidence on benefits of colonoscopy from RCT is still lacking. Nevertheless, a colonoscopy is an invasive procedure that even, though extremely rarely, leads to cases of death, and thus being the first screening procedure with such a potentially grave adverse effect. In Germany a total of seven deaths were documented between 2003 and 2008 related to screening colonoscopy (Pox et al. 2012).

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?

As mentioned in the manuscript, the answer manual providing the correct answers was made by literature searches (we changed the word “systematic” into “selective” literature searches) focusing on systematic reviews, S3 guidelines and HTA reports. We did not use experts’ knowledge to generate the manual. External experts reviewed the list of criteria.

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

We added this information.

Referee 2:
1. Page 4 EPHI standards, instead of EBHI.
   → We have corrected this.

2. In the presentation of Results. Development of List of Criteria section (pag 9): “single criteria were grouped into to seven categories” correct to “single criteria were grouped into seven categories”.
   → We have corrected this.

3. Still in page 9, “single criteria were grouped into to seven categories”, the category “formal issues” is erroneously listed twice.
   → We have corrected this.

4. In the Discussion section is stated that “The final manual-based list of criteria contains 230 criteria in seven categories”. It was previously mentioned that the seven categories were further aggregated into four domains, it

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is not clear to me if this is an error in the text, or if the manual actually grouped the criteria in the 7 categories and not the 4 domains.

→ We corrected the sentence into “…criteria in four domains.”

5. Table 2, page 29, it is not clear the difference between the two criteria n. 15 "The disease risk compared to other cancer disease risks is stated" and n. 16 "The disease risk compared to that of other types of cancer is stated". They both sound the same to me, requiring the material to compare the risk of colorectal cancer to the risk of other cancer types.

→ We have corrected this into:

“15. The disease risk compared to other cancer disease risks is stated.
16. The disease risk compared to other risks is stated.” Other risks comprise traffic accidents for example.

Referee 3:

Introduction. Context of colorectal cancer in Germany would be desirable on p. 5. What are the screening rates and how does it compare to other countries or rates in Europe overall; are there differences in screening by tests since the assessment rates 2 different testing modalities?

→ As it is not our aim to work towards campaigns or modification in the materials for increasing the screening rates, in our opinion, the quality assessment of the flyers and leaflets is independent from the screening rates. High quality information material should be offered to everybody being in the target group, in times/regions with low participation as well as in cases of very high participation rates. We rate these two screening tests, because those two were payed by the statutory health insurance in the context of colon cancer screening as we mentioned in the introduction: “In Germany, persons aged 50 and older who have statutory health insurance have free access to colorectal cancer (CRC) screening tests, including the fecal occult blood test (FOBT) and (since 2002) screening colonoscopy.” We do not think that further information on the context of CRC screening in Germany is helpful for this methodological article.

Methods could improved in the following manner:

- outline who conducted the data

→ We added: “These researchers also applied the list of criteria in step 3 of this project that is not within the scope of this article” on the existing information in the manuscript.

- methodological considerations section on page 6 is not written as a narrative; perhaps this should be presented in a table

→ We think that the considerations should be mentioned and described in a continuous text and we numbered the single points to give a better overview.

- pp.10-13, examples of the rating by criterion are offered; may want to reduce of these examples

→ The number of examples is chosen to provide the reader a comprehensive insight into the list of criteria and its application.

- how were the criteria discussed by the panel and determination made on criteria to keep;

→ We had telephone interviews with the experts; the experts made no proposals to delete certain criteria, though most of the experts noticed the high number of criteria. In contrast, the experts made further suggestions for items, most of them were added to the list. As outlined in the discussion, the list rather presents a maximum content of information and not all of them are essential for high-quality information. We discussed that further development to determine mandatory criteria is necessary and this decision process, for example using Delphi method, should include consumers and experts views.
more details about instruction given would be helpful.

➔ We build up a manual to provide the rater with the correct answers and to support the rating. As written in the text, we relied on systematic reviews, S3 guidelines or HTA-reports and we discussed the significance of the manual as well as associated problems. Providing the complete manual would go beyond the scope of this article.

-p.16, Table 5 presents ratings of materials (13) by these criteria but we observe that most items related to risks and benefits of screening are not reported; what are the implications of those findings - do print materials have to be augmented with patient education/informed decision making since the materials fail to offer this information.

➔ The intention to present this table was to give an example, how the results of the ratings could be presented, and whether this type of presentation is suitable. One result of the chosen topic of "risks and adverse effects of screening colonoscopy” that can easily be detected via this type of presentation is that information on this topic is often missing in the brochures. As this manuscript focuses on the development of the list of criteria and not on the results, we would like to show only some results to illustrate the application of the developed list of criteria. As a consequence, we chose a more precise title of the table: Presentation of exemplary rating results of risks and adverse effects of screening colonoscopy in 13 brochures (11 criteria).

Implications

The Discussion could be much improved. Does this assessment offer guidance for health educators developing print education on cancer screening?

➔ Yes, we think so. The list of criteria can be helpful to have a look on the extremely broad range of possible formal, content-related aspects an education material could cover. Furthermore, we tried to point out the importance of information not only being mentioned, but also being correct, up-to-date, unbiased and understandable. So, among others, the development of new material might be one application of the list, also addressed in the conclusion.

Several limitations are presented throughout and a focus on implications of the criteria and its utility for the field of cancer education would be valuable to understand; what are areas of further research

➔ We had proposed further development of the list in order to get ratings on the level of categories or domains and to define mandatory criteria for short and more detailed information materials. Another area of further research we mentioned in the discussion is to examine, whether materials that meet the EBHI criteria according to the list enable the reader to make an informed choice.

Research: Further refinement of items perhaps by ratings and interrater reliability analysis may be warranted? Does the assessment of the criteria need further testing and validation?

➔ We assume that further work is necessary to select the criteria that are essential for a high-quality information. This might be done within a Delphi process including consumers and experts views as proposed in the discussion.

Use: Who is best suited to use these ratings? Should panels review materials and provide feedback and list quality colorectal materials for public use on a website? What if most print materials are scored poorly--what is the consequence of that - small media needs to be supplemented by one on one or group education to promote screening? informed decision making? Practical implications would be helpful

➔ These questions are very important. However, as described in the conclusions, we consider our list “as a first step toward thorough evaluation of specific information materials for adherence to EBHI standards”, and
therefore, had mentioned in the conclusions “It may also be used to revise existing leaflets or to develop health information materials on colorectal cancer screening”. In our opinion, a comprehensive discussion about the handling of score poorly material would go beyond the scope of this methodological article.

Table 1 presents a nice summary of the domains for the criteria; it is fairly detailed; how detailed do colorectal cancer materials have to be in order to address most of the criteria in the specific content areas; most educational print material are fairly concise so the inclusion of these materials may suggest longer print educational materials; would this have implications for designing educational materials.

→ Our list is not meant in a way that each of the criteria has to be covered in a high quality health information material. The list of criteria rather represents the maximum technically possible content of information material. As we had discussed, “it would be reasonable to differentially define essential criteria for short information materials like flyers and for more detailed materials like brochures. It would also be reasonable to select these mandatory, material-specific criteria in a Delphi procedure including experts and consumers. Obviously, expert and consumer opinion is needed to explore the importance of each criterion for further summary assessments and to develop specific assessment lists of criteria for short and more detailed information materials.”.

Figure 1 presents a succinct flowchart of the methods; however usually systematic reviews present articles/documents found at each stage; consider making these additions.

→ Figure 1 presents a flowchart of the project as a whole, whereof the systematic literature research is only one part. As we did a stepwise literature research, examining and documenting only additional literature, no information is available about the total number of found literature. We added the information that “This search yield a total of 3,097 documents that were stepwise selected on the level of title, abstract and full text.”.

Additional changes:
We modified table 5: Assessment of the presentation of risks and adverse effects of screening colonoscopy: We changed the colours into a non-coloured presentation and adjusted the corresponding description in the text.
We also made some formatting changes (e.g. references).

We confirm that this manuscript has not been published elsewhere and is not under consideration by another journal. All authors have approved the revised manuscript and agree with its submission to BMC Public Health. We look forward to your reply and thank you for considering this manuscript.

Yours sincerely,

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