

Author's response to reviews

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

Authors:

Maren Dreier (dreier.maren@mh-hannover.de)
Birgit Borutta (Borutta.birgit@mh-hannover.de)
Seidel Gabriele (Seidel.gabriele@mh-hannover.de)
Kreusel Inga (Kreusel.inga@mh-hannover.de)
Juergen Toepfich (juergen.toepfich@bzga.de)
Eva M Bitzer (bitzer@iseq.org)
Marie-Luise Dierks (Dierks.marie-luise@mh-hannover.de)
Ulla Walter (Walter.ulla@mh-hannover.de)

Version: 4 **Date:** 27 August 2013

Author's response to reviews: see over



Medizinische Hochschule Hannover

Institute for Epidemiology, Social Medicine
and Health System Research

Dr. med. Maren Dreier, MPH

Telefon: 0511 532- 2192

Fax: 0511 532- 53 47

E-Mail: dreier.maren@mh-hannover.de

Medical School Hannover
Institute for Epidemiology, Social Medicine and
Health System Research -OE 5410-
Carl-Neuberg-Straße 1
30625 Hannover
www.mh-hannover.de/spr.html

MHH - Institut für Epidemiologie, Sozialmedizin und Gesundheitssystemforschung – OE
5410 – 30625 Hannover

Editorial Office
BMC Public Health

Ihr Zeichen

Ihre Nachricht vom

Mein Zeichen

27. August 2013

Dear Editors:

Enclosed for your consideration is a revised manuscript

MS: 4133332259631000 "Development of a comprehensive list of criteria for evaluating consumer education materials on colorectal cancer screening".

We gratefully acknowledge the comments of the first reviewer as he is addressing basic problems. In the following, we are giving a point-by-point response to his concerns, hoping to convince him. Our answers are marked with an arrow.

1) the problem of what is correct. It is very difficult to produce EBHI based on guidelines that are not evidence based (recommending colonoscopy and not flexosigmoidoscopy).

The concept of correctness is a novel strategy in assessing the quality of patient information. In our opinion, EBHI does not mean, that the content, in our case the different CRC screening procedures, has to be evidence-based. EBHI should provide an overview on several options and to inform on the benefit and harms of these options. It is true that colonoscopy in contrast to sigmoidoscopy is lacking evidence from RCT. What EBHI should do is to indicate this lacking evidence to the reader.

2) the concept of neutrality: participation is always a possible choice, of course, but it is not a recommended option. For example not undergoing conisation if you have a cervical intraepithelial neoplasia grade 3 it is obviously a choice for the women, but I cannot be neutral when I present the informed consent for the conisation, because conisation is recommended, surveillance not. In all the EU guidelines the concept of neutrality is not mentioned at all. The rationale for the recommendation to put information not in the letter proposing the appointment was to avoid information overload and maintain the letter easy to read and understand even to low educational level people, to favour neutrality of information and enthusiasm in the invitation.

Yes, the guidelines say that a high participation rate is needed for quality reasons. That is the public health view. However, screening uptake of a single person is based on the individual's perspective, attitudes, needs and preferences. In our opinion, there are some differences between colon cancer screening and the example with the already diagnosed neoplasm above. In screening, only a very small minority of (healthy) screening participants will have a crucial benefit in terms of a higher life expectancy due to colon cancer screening compared to individuals not participating. The vast majority will never get colorectal cancer and will have no benefit. The individual cannot know, if and in which way screening will have a possible benefit or possible disadvantages for him or her. Therefore, screening should remain an individual choice depending on personal attitudes, beliefs and their perception of benefits and risks. For that reason information materials from our point of view should indeed be neutral about his or her uptake and should inform in a neutral, balanced way in order to enable the individual to make an informed choice.

All in all, we feel that the term "neutrality" may be misleading. We understand neutrality as making no direct recommendations to participate or not using persuasive language. To make it more clearly, we changed the words into: p16 "The last domain comprises seven criteria for assessment of neutral and balanced presentation" instead of "assessment of neutrality".

3) do the authors have any suggestion to put in a plain language the level of evidence? In the example 3 "According to experts, more than three-quarters of CRC patients could be saved by early screening colonoscopy." Why do they say that there is no mention of the level of evidence? According to experts could be the plain language for low level... May be it is wrong when there are also case control studies... This is just to say that interpretation of what is correctly translated to plain language is not easy.

Thankyou, this is definitely correct, it is a mistake in our manuscript (obviously mixed up with the example below that has identical words) that we corrected immediately. Phrases like this are indeed acceptable to describe the evidence level. (Though, we had also discussions in our working group if this could probably lead to a false perception of the recipient, assuming that an "experts view" might be more reliable than study results, in contrast to its evidence level.)

4) the long paragraph on overdiagnosis reports a reference to the EU Guidelines, where it is mentioned only as matter of research for pathology, not as matter of public health. In fact since we cannot distinguish overdiagnosed cancer, over-diagnosis can only be defined epidemiologically at a population level. If a screening produces a reduction of incidence (surely sigmoidoscopy evidence level A, but also FOBT with some observational studies) overdiagnosis not only cannot be distinguished, but if we measure it, it will be negative (less than zero). I really cannot understand why information material about colorectal cancer should mention overdiagnosis.

We think there are several points to take into account.

First, overdiagnosis in case of colorectal cancer screening was included in the criteria list, because the vast majority of adenomas will not lead to colonic cancer and therefore not impair the patient's life quality and - expectancy. Even if the extent is still unknown, it is something that can be referred to in information material. Secondly, even a correctly diagnosed (and removed) colorectal cancer could constitute an overdiagnosis, if the patient dies because of another disease before dying from that cancer, there would not be an extended lifespan due to screening. In our opinion, overdiagnosis cannot be excluded because of a reduction in incidence and mortality. It might be that the reduction would be even higher in the absence of overdiagnosis and that the actual reduction reflects a combined effect. Finally, our list of criteria includes a maximum of content, and not all criteria are essential for a high quality information material.

As a consequence, we changed the paragraph on overdiagnosis from "However, there is potential concern about overtreatment of early T1 carcinomas leading to increased morbidity and mortality [47]." into: "Nevertheless, the extent of overdiagnosis or overtreatment of harmless polyps that would never turn into cancer, in colorectal cancer screening is unknown and may be low as there are strong hints that colonoscopy will decrease CRC incidence like it is already shown for flexible sigmoidoscopy-based screening [47].." and also omit one sentence on the explanation of overdiagnosis.

Minor points

The sentence at the beginning of the introduction is still vague and not correct for colorectal cancer, particularly for FOBT and flexosigmoidoscopy.

We refer (among others) to the conclusions of a Cochrane review on FOBT by Hewitson et al. (2011): “Harmful effects of screening include the psycho-social consequences of receiving a false-positive result, the potentially significant complications of colonoscopy or a false-negative result, the possibility of overdiagnosis (leading to unnecessary investigations or treatment) and the complications associated with treatment.” Nevertheless, we changed the second sentence in our introduction focussing on communication of benefits and risks: “However, in recent years, it became clear that the communication of screening measures may have overstressed their benefits and disregarded their risks [1].”

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 again for considering this manuscript.

Yours sincerely,



Maren Dreier, MD, MPH