Author’s response to reviews

Title: Using Intervention Mapping to develop a programme to prevent sexually transmittable infections and HIV among heterosexual migrant men.

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Author’s response to reviews:

Dear editor,

Please find enclosed our revised manuscript entitled "Using Intervention Mapping to develop a programme to prevent sexually transmittable infections and HIV among heterosexual migrant men." by Mireille E.G.Wolfers et al. (MS: 2034236425111032)

We much appreciate the reviewers comments and believe that these have helped us to further improve the manuscript. In the primary prevention research literature, especially related to health or precautionary behaviours, there is a great lack of detailed descriptions of how such behaviour change interventions were developed. It is very encouraging that your journal does consider publishing papers that do provide such detailed descriptions. In this letter we give an account of how we have used the reviewers comments to adjust our manuscript.

If we summarize the overall content of both reviewers comments, we believe that the expert in the field of health promotion and health education regards our manuscript as an important paper because of the fact that detailed descriptions of intervention development is necessary for progress in the field; however the reviewer of the medical field has its doubts. We hope that our revised manuscript can be accepted for publication in your journal.

Reaction on comments of Jonathan Zenilman

1. From reading the paper, it is difficult to ascertain what the overall objective was--Is this a practice-based approach to using the models for developing interventions? Is this a qualitative/descriptive analysis? Is it a controlled trial?

The overall objective was indeed to describe the theory and evidence-based development of HIV/STI prevention interventions using Intervention Mapping (IM). IM is a recent protocol that guides careful theory-driven development of health promotion interventions. This protocol still needs to prove itself, in terms of effectiveness, but also in terms of applicability outside academia. Our intention is to illustrate and describe the application of the IM protocol in a regional Public Health Service environment.

2. The IM approach is described--However, this reviewer is not clear whether IM represents a truly new approach towards developing interventions--or , is it a systematization of previously described approaches?.

IM is a framework for effective decision making at each step of intervention planning, implementation and evaluation and is based on the importance of planning programs that are based on theory and evidence. It has been used to develop intervention programs for a range of health behaviours since 1998 and its first
publication in 2001 by Bartholomew and colleagues has now been revised in a 2nd edition (2006). However, it can still be regarded as novel in its truly stepwise and structured approach towards intervention development. Descriptions of application of IM outside academia are still lacking.

Reaction on comments on Daniel Edward Wight

This paper should stand on its own without the need for readers to turn to Bartholemew's original paper/book on Intervention Mapping (IM). However, there are some very confusing aspects of the different steps of the IM model. This might be due to confusion in the original model, in which case the authors should comment explicitly on it's limitations. Alternatively it is due to the authors' poor presentation of the original model, in which case this should be rectified. For instance:

1a) p.3 'The second step is... selecting objectives... for the programme' but in Figure 1 programme outcomes are decided in Step 1.

1b) p.3 The terms 'performance objectives' and 'change objectives' are very unhelpful, since their meaning is far from clear: the worst kind of jargon. Why not 'immediate objectives' v. 'long-term objectives' or 'initial change' v. 'subsequent change' or 'pre-requisites for change' v. 'desired change'? We understand that the terms 'performance objectives' and 'change objectives' is confusing without prior knowledge of IM and without Bartholomew et al's book on the side. We have now further explained the different types of objectives.

From page 3, line 16 -30: The needs assessment finishes with defining (behavioural) outcomes. Outcomes are the most distant objectives in the IM model. Outcomes are derived from the needs assessment and should be formulated in terms of reducing health problems or in terms of the desired behavioural or environmental changes that are linked to the health problems identified in the needs assessment. For this project the behavioural outcome of the project was 'consistent condom use among heterosexual migrant men for the prevention of HIV and STI with new and casual partners'. In the next step of IM a further specification of objectives is made. First the behavioural outcomes are delineated into component parts, i.e. specific actions that should lead to the desired behaviour, the so-called performance objectives (PO; what the target group members need to do as a result of the programme, see Table 2). Then the most important and changeable behavioural determinants of these performances should be identified. Subsequently, change objectives are formulated; those are the most immediate targets of a program to be accomplished and are stated in terms of what a person exactly needs to learn to enable performance of the specific behaviour changes.

Combining the PO with the most important and changeable determinants results in matrices that help in the identification of intervention possibilities. An example in the present project is the specification of which preparations are needed to always carry condoms (Table 3).

1c) p.3 Seems very odd that useful theory is selected in Step 3, after the goal-setting process. Is the theory chosen on the basis of how well it fits with the previously decided objectives, or does one's theoretical approach determine one's understanding of what objectives are possible? Most people who value a theoretical approach would assume the latter. This must be clarified.

Theory is used in different steps of the IM model. First behavioural determinant theory is used to understand and explain the problem behaviours in the needs assessment phase. Later in the IM process, after specification of the so-called change-objectives, behaviour change theory is used to select and specify the specific intervention strategies and methods that should lead to the desired changes.

We have clarified this at page 3, line 14-16:

Subsequently, the behavioural risk factors that contribute to these problems should be identified, and the individual and environmental determinants of the risk behaviours should be investigated based on
behavioural determinant theory.

We have also added a sentence on the explanation on the use of theory in the different steps of the IM model:

Page 3, line 30 until page 4, line 3: After this goal-setting process, IM step three is the selection of useful theory-based and evidence-based learning and behaviour change strategies that are applicable to the performance objectives. The behavioural determinant theory is used in the needs assessment to identify goals. In this step, specific behaviour change theories are used to inform intervention development.

1d) p.4 What is meant by 'theoretical methods' (p.4)? Although there is this reference to 'theoretical methods', the description of Step 3 at the bottom of p.4 seems to be entirely atheoretical.

In step 3 of IM process, after specification of the so-called change-objectives, behaviour change theory is used to select and specify the specific intervention strategies and methods that should lead to the desired changes. We have conducted a search in the literature for useful strategies and methods that would match the change objectives. To explain this better we have added the words that the practical intervention techniques were derived from theory based methods: page 5, line 24-26: This led to the choice of several ideas for practical intervention techniques, derived from theory-based methods which were identified in the literature, on which the project group based a first draft.

In the results section we describe findings of the literature review on theory and methods:

Page 9, line 26 until page 10 line 3: There is limited systematic evidence available on effective methods for prevention of STI and HIV in heterosexual men [5]. In a systematic review of Elwy et al [5] on interventions for heterosexual men for the prevention of HIV/STI no single intervention could be identified as being more effective than others to change behaviour, increase knowledge or measure an intention to change. Methods in this review that are possibly applicable to the PO in our project are condom skill training, peer education, discussion in groups and individual counselling, focus on barriers to change, social aspects of condom use, video portrayal of acceptable normative condom behaviour, giving information, provision of condoms. Furthermore training with feedback has been found to be effective in promoting condom use [36-39].

We now have added more information on the theory and methods that we used to design the intervention.

Page 10, line 4-11: Based on the review of the literature, social cognitive theory was used to target self-efficacy, behavioural skills for condom use and preparative behaviour like carrying and negotiating condom use {Kalichman, 1996 #94; Kalichman, 1997 #95; McKay, 2000 #91; Kelly, 1992 #96; Schaalma, 1996 #98}. Methods for intervention were also derived from theory on implementation intentions for preparative behaviour like carrying condoms, plan to buy and store condoms {Abraham, 1998 #97}, and from inoculation theory for countering negative arguments not to use condoms. Moreover, the methods used provided information on risks and STI, persuasive arguments to use condoms {Schaalma, 1996 #98} and anticipate a negative consequence after unsafe sex to change knowledge and outcome expectancies {Kalichman, 1996 #94} {Kok, 2004 #99}.

Was the intended mechanism of the intervention, or a 'logic model', ever identified? In the Discussion (p.10) it is implied that this was a 'theory led intervention'. But I missed any statement of what the theory was.

The theories used in the needs assessment are now described on page 5, lines 1-4:

The group discussions were conducted based on an interview guide that was informed by social cognitive theory {Baranowski, 2002 #1075} and social-ecological models {Sallis, 2002 #100} of health behaviour. Therefore, behavioural determinants at the personal (outcome expectations, attitudes, self-efficacy) and at the environmental levels were discussed in the groups.

Theory used in step 3 are now described at page 10, lines 4-11.
Based on the review of the literature social cognitive theory was used to target self efficacy and behavioural skills for condom use and preparative behaviour like carrying and negotiating condom use (Kalichman, 1996 #94; Kalichman, 1997 #95; McKay, 2000 #91; Kelly, 1992 #96; Schaalma, 1996 #98). Methods for the intervention were also derived from theory on implementation intentions for preparative behaviour like carrying condoms, planning for buying and storage of condoms (Abraham, 1998 #97), from inoculation theory for countering negative arguments not to use condoms. Moreover, methods used were providing information on risks and STI, persuasive arguments to use condoms (Schaalma, 1996 #98) and anticipating regret to anticipate on negative consequence after unsafe sex to change knowledge and outcome expectancies (Kalichman, 1996 #94) (Kok, 2004 #99).

2. In the discussion the difficulties of applying the IM model are mentioned (p.10). The authors should be more explicit about whether the IM model is too complex and demanding, or whether they were simply not given enough time to follow it. This is extremely important since a main contribution of this paper could be a critique of IM.

We indeed think that IM is rather complex, time-consuming and in its complete application appears too demanding for developing prevention in a public health service, where only limited time and resources are available. Although IM is a valuable checklist and guidance to take the right steps in developing an intervention, the risk is an endless process of doing research into determinants, developing matrices for different levels for different behaviours, moving back to previous steps if a decision does not work out. To apply IM exactly according to the instructions provided by Bartholomew et al is therefore difficult in the practice of a public health organisation. We have added these comments in the discussion section: Page 13, line 4-10: Although IM is a valuable checklist and guidance to take the right steps in developing an intervention, it does include the risk of remaining in a lengthy endless process of doing further research on determinants, developing matrices for more and more specified performance objectives, and moving back and forth between intervention development, pre-testing and further exploratory research. The time and resources to do this are not available in the day-to-day practice of a municipal public health service, and applying IM according to the full instructions is therefore difficult in the practice of local and regional public health promotion.

3. More details need to be provided about how the data were collected. Were group discussions in ethnic-specific groups (p.4)? How were participants selected? Were they original friendship groups or strangers? This is very important in terms of the kind of interaction between them. How long were group discussions?

There is confusion about whether the authors started with six ethnic groups or five. How were respondents selected for the 'separate interviews'? How representative were they?

We have elaborated more on the composition of the groups, on how they were recruited and if they knew each other. Also we have added information on the duration of the discussions.

Page 4, line 17-26:

Separate group discussions were conducted with AC men between 16 and 25 years old (n=5, three men originating from Surinam, one originating from the Dutch Antilles, and one from Cape Verde; average age 21) and with AC men above 25 years (n=3, two three men originating from Surinam and one from Cape Verde; average age 30), and with married TM men (n=13; average age 39) and unmarried TM men (n=17; average age 18). MPHIS health educators from these communities recruited the respondents for the group discussions from their networks and during regular health education activities. They also put announcements on poster boards at community centres. Most of the participants in the group of younger AC men and the married TM men knew each other and decided to join the discussion together. The married TM men were recruited at a garage which serves as a meeting place, so some of them were friends. The older AC men were strangers to each other.

The respondents of the focus groups were not very representative, a small number, especially difficult to recruit the Afro-Caribbean men for the group discussion. We have already described this in the discussion as a limitation of the study.
To further describe the respondents we have added some demographic characteristics of the respondents on page 4, line 26-29:

The respondents were more educated than average migrants in the Netherlands: two-thirds of the men had a low education and one-third had a higher education. The young and unmarried men were born in the Netherlands or had migrated in their early childhood to the Netherlands. Of the older or married respondents, 75% migrated to the Netherlands at an adult age.

On p.5 it is stated that 'more information on certain determinants' was gathered. Which determinants?

We have added explanation on these determinants in brackets. Page 6, line 6-7: (i.e. specific outcome expectancies regarding condoms, and perceived availability and accessibility of condoms)

On p.9 it is stated that the 'intervention was tested among 72 men....'. How were these men selected and how was it tested?

We have added some lines on the pilot in which we tested the intervention: page 12, line 13-18: The intervention was tested among 72 men in August 2005. On different locations where the MPHS health educators work, they played the card game with men from the appropriate target groups. These outreach locations were an urban festival, a soccer tournament, meeting spots in the city center and in a Cape Verdian church. A small questionnaire was handed out before and after the game for evaluation. The game of cards was received very well: the men could identify themselves very well in the situations and the game led to discussions on safe sex.

We also added some text on the revisions made in the cardgame after the pretest:

Page 11 line 27 until page 12 line 6:

The prevention officer, who was very experienced in working with the AC target group, sketched the situations and tools to bring to a date. To match the learning objectives, some revisions were made in collaboration with the researcher. For example, adding a playing card with the subject alcohol is a means to discuss the influence of alcohol on unsafe sexual behaviour. Then, a professional designer made a first prototype of the playing cards. These were tested among AC men during regular health education activities. The images of the cards needed some revision, a picture of a sexy women was put on the back of the playing cards, and some of the situations were described somewhat less explicitly (e.g. the statement that he is anticipating that he is having sex with a women at her place was revised to she asks him to go home with her). The men also wanted the real life situations described more explicitly; for example, it needed to be stated clearly that in a certain situation the man was single, or the man had two women. Also the colours of the cards were changed.

4. Since the data collected were qualitative, the description of findings (e.g. p.6-7) would be greatly improved with some quotations to illustrate the points.

We have added three quotations from the focus group discussions:

Page 7, line 28-29:

"(....) You can simply look at a girl and see if you can trust her. How she acts and treats you. If she takes the pill it can happen that you will do it without (a condom). And I think that is just normal to do it without (a condom)."

Page 8, line 10: "Because the woman you are marrying is always 100% virgin. So you are always the first one"

Page 8, line 22-24:

"(....) If you are already involved in it, when you are just starting, and you know it will lead to it, that you are going to make love, than the girl has to say it. Usually it is the girl who says: do you have a condom? If I say
no, and she says she hasn't one either. Then you are out of luck"

5. Since the paper is all about the development of two interventions, it is rather important that some of the programme components were not tested. It should be clarified which components were not tested and why they were not tested (p.9). Furthermore, the crucial step of 'designing' the playing cards should be described in detail, with any piloting and subsequent revision clearly documented.

We have added some more lines on the pretesting, reasons for not pretesting certain elements, difficulties we experienced while pretesting:

Page 11, line 16-25

It took more time than planned to organise the groups for the intervention, as a consequence only one session could be held for each group instead of the two sessions that were scheduled. The exercise for forming implementation intentions ("plan your sex") and the assignment for buying condoms were therefore omitted (see Table 4). The assignment for buying condoms was skipped because this topic was also incorporated as an assignment in the game "Never Lose Face". The exercise ("plan your sex") included a video or DVD fragment; recorders to play the tape were not always available at the sites. Furthermore, the young men did not want to choose a partner and interview each other in pairs as was the purpose of the assignment. They preferred to speak in the group instead of one-to-one, so this assignment was carried out as a group discussion. Because this item could not be carried out as planned and because of time restrictions, it was omitted in the following groups.

And page 12 line 1-6:

The images of the cards needed some revision, a picture of a sexy women was put on the back of the playing cards, and some of the situations were described somewhat less explicitly (e.g. the statement that he is anticipating that he is having sex with a women at her place was revised to she asks him to go home with her). The men also wanted the real life situations described more explicitly; for example, it needed to be stated clearly that in a certain situation the man was single, or the man had two women. Also the colours of the cards were changed.

6. In the Discussion (bottom p.10) the authors state that it was very useful for health workers and researchers to collaborate on this intervention. This is very plausible, and an important point, given the difficulties in cross-sector collaboration. However, given importance of this point it would be useful to expand on what was added from each sector in developing the interventions together. If I remember right, Bartholemew et al. discuss this issue, and the challenges involved have been discussed by Wight and Abraham, 2000, 'Health Educ. Research'.

We have elaborated more on the different roles of the project group members in the discussion section.

Page 14, line 3-13:

The project is practice-driven; a prevention officer working in the MPHS was responsible for the original plan for developing interventions for migrant men with the guidance of the IM protocol. University-based experts got involved with further development of the plan. During the development phase, the prevention officers and researcher worked together closely. Because of their experience with health education among the target groups, the prevention officers were best suited to suggest the further details of the intervention so that it would fit in with their routine of prevention work and the preferences of the target groups. The researcher guaranteed that the plans were in accordance with the theoretical strategies and fitted within the change objectives matrices. The main tasks of the health policy adviser, who was also experienced in IM, were to make sure that the targets of the subsequent steps were reached, and to organize and manage the consultancies with the experts and brainstorm sessions.

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Minor Essential Revisions (such as missing labels on figures, or the wrong use of a term, which the author
1. Abstract. 'There is little experience with carefully developed interventions in the HIV/STI prevention field...' Similar statement on p.10. This is greatly overstated. There are now several carefully developed interventions that have been documented (e.g. Obasi et al., 2006, 'AIDS Care'; Flowers et al., 2002, 'Int J. STD AIDS'; Wight and Abraham, 2000, 'Health Education Research' and many more, e.g. cited in 'Effective Sexual Health Interventions' Stephenson, Imrie and Bonell, 2003.

Maybe we should have been more explicit on the availability of such interventions in the Netherlands for our target groups. We have changed this into: There is little experience with carefully developed interventions in the HIV/STI prevention field aimed at heterosexual target groups in the Netherlands.

2. p.2 'attention for the sexual health of heterosexual men is relatively new...' This is not accurate. Better to state: 'There has been little specific targeting of heterosexual men to improve their sexual health.' We have changed this as we can agree with this refined comment. (page 2, line 10-11)

3. p.2 '..the proficiency of the applicability of...' Do you mean 'how practical'? We have replaced the word 'proficiency' with 'ability' (page 2, line 19), also in the abstract (page 1, line 14).

4. p.4 '...focus group interviews...' is confusing. Should either be 'group discussions' (or 'focus group discussions' if want to use jargon) or 'interviews'. The latter are generally understood to be individual, and can be structured, unstructured or in-depth. We have adapted the terms according to this suggestion, we use the word 'group discussions' now.

5. On p.5 there is possible ambiguity about ethnic classification. Does 'non-Dutch' ethnicity mean non Dutch citizens, or non white? These persons are Dutch citizens but belong to ethnic minority communities: they themselves, or one of the parents were migrants. We have changed the word 'non-Dutch' ethnicity to 'persons of ethnic minority communities' page 6 line 21-22)

6. Some confusion over 'personal' and 'socio-cultural' factors. Association of condoms with prostitution (p.6) is a socio-cultural factor. We agree with the reviewer that association of condoms with prostitution is more accurate classified as a socio-cultural factor than as an personal (attitude). We have corrected this in the manuscript. (page 7, line 23 and page 8, line 6)

7. Bottom of p.7, social norms are not personal determinants. We agree with the reviewer, only subjective norms are personal determinants, social norms are external determinants. We have moved the social norms to the external determinants. (page 9, line 17)

8. Top p.8: should give some examples of how the interventions were 'tailored culturally'. We have added some examples of how the interventions were 'tailored culturally' in the paragraph "Step 4: design a programme plan. One example for the Turkish/ group and one example for the Afro-Caribbean
Page 11, line 8-12: To make the interventions culturally appropriate, the pictures with young men making statements about safe sex comprise some statements that refer to the taboo on premarital sex and negative anticipated reactions of the family if an STI or unwanted pregnancy occurs as a consequence of safe sex (for example: "My family does not need to know I use condoms, but the girl has to!" and "I don't like problems, I use a condom").

Page 12, line 7-9: In the playing cards the situations are adapted to common practices in relationships of Afro-Caribbean culture. For example, one of the situations is about a man who lives together with one woman, but also has sexual relations with another.

In the paragraph on step 2 we refer to this paragraph for examples page 9, line 18-20: Socio-cultural determinants were considered not to be changeable in a short intervention, but were used to tailor the interventions culturally (some examples are given in the next section which describes step 4 of IM).

9. p.8 Lack of evidence on sexual health interventions with heterosexual men is overstated. 'limited' might be better than 'little'. If authors went beyond those interventions exclusively targeted at heterosexual men they would find plenty of evidence of effectiveness of different kinds of interventions.

We agree with the reviewer (page 9, line 26) and we have changed the word into 'limited evidence'.

10. p.10 It is not clear why 'self-efficacy' and 'social influence' were initially chosen. Why did this make the interventions more expensive?

We now have described some examples to illustrate which interventions we considered to use to change 'self-efficacy' and 'social influence' and which were not feasible within the available time, budget and competence of the MPHS migrant prevention workers and health educators.

Page 13, line 24-27: For example, a more intensive approach needs to be used for the AC-men, such as a theatre play performed on popular festivals with AC audience to portray positive norms on safe sex, a popular rapper rapping on negative and positive outcome expectancies of unsafe sex, and training peers/opinion leaders as condom experts.

11. Figure 1: This should be modified to address the points made above (Major point 1). Should not be reference to PRECEDE model when this is not described.

We have removed the words PRECEDE model in figure 1, and added the words 'or problem analysis'

In Step 2 should clarify what the determinants are of.

We have added in the figure 1 in step 2 at the 3rd bullet: 'of the target behaviour of the at risk group

Step 4: why is development of materials and pretesting not a step in itself?

In the IM model these are important tasks within the step of programme development. It requires specific time and skills to do, in the IM protocol a lot of attention is given to this process. It could be very well named a step in itself, however we are describing the IM model as it was developed and reviewed in 2006.

For this study it was not necessary to obtain approval from a medical ethical committee since we have not performed medical research on humans or on identifiable human material or data. The research described in this manuscript only concerns group discussions with people who remained anonymous. Under the Dutch regulations for medical and social scientific research no approval of a medical ethical committee is necessary. Of course all participants at the group discussions were verbal informed about aims, topic and
procedure of the group discussions and at the start of every group discussion an informed verbal consent was obtained from the study participants. We have included in the methods section that we obtained verbal consent of the participants of the group discussions (Pag 5, line 6: Group discussions started after a informed verbal consent was obtained)

We sincerely hope you will find our revised manuscript suitable for publication in BMC Public Health, and we look forward to hearing your decision in the near future.

Yours sincerely,

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