Informed Health Choices

Assessing potential adverse effects of an educational intervention: protocol for development and evaluation of questionnaire items [Version 1, awaiting peer review]

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Colophon

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Abstract

Background

Researchers often overlook potential adverse effects of educational and public health interventions. Adverse effects of an intervention are increases in adverse outcomes, or decreases in beneficial outcomes, attributed to the intervention in a randomised trial. In a previous study, we developed a framework of potential adverse effects of an intervention intended to improve critical thinking about health choices: the IHC secondary school intervention. The framework includes potential effects on both students and teachers. In this study, building on the framework, we will develop and evaluate (validate) questionnaire items (questions), for measuring outcomes identified in the development of the framework. In a separate, subsequent study, we will conduct a quantitative evaluation of the items.

Objectives

1. Prioritise potential adverse effects of the IHC secondary school intervention, for the 1-year-follow-up assessments of the trials of the intervention
2. Develop and evaluate questionnaire items for measuring potential adverse effects, focusing on those that we have prioritised

Methods

The overarching steps of this study are 1) prioritising outcomes included in the framework developed previously; 3) brainstorming and drafting questionnaire items; and 3) conducting a qualitative evaluation of the items.

Results

Results of the study will include:

- a set of potential adverse effects (increases in adverse outcomes) prioritised for the trials of the IHC secondary school intervention, and
- measures of potential adverse outcomes that have been qualitatively evaluated.

Background

Researchers often overlook potential adverse effects of educational and public health interventions [1–4]. When they do evaluate the intended effects, this might show a lack of effect, or paradoxical effect, but not other adverse effects ("side effects") [1–4]. An effect of an intervention is an increase or decrease in an outcome attributed to the intervention, meaning adverse effects of the intervention are increases in adverse outcomes, or decreases in beneficial outcomes, attributed to the intervention in a study. Researchers assess effects in randomised trials (comparisons between interventions) by measuring and comparing outcomes in the intervention and control arms.

In a previous study [5], we developed a framework of potential adverse effects of an intervention intended to improve critical thinking about health choices: the IHC secondary school intervention. The framework includes potential effects on both students and teachers. In this study, building on the framework, we will develop and evaluate (validate) questionnaire items (questions), for measuring outcomes identified in the development of the framework. We will use the items in the 1-year-follow-up assessments of randomised trials of the intervention [6–8].

Other researchers can use our approach to developing and evaluating the items—if not the items themselves—to assess potential adverse effects of other educational interventions, especially interventions intended to improve critical thinking in general or specifically about health choices. In a separate, subsequent study, we will conduct a quantitative evaluation of the items. In a parallel and corresponding study, we are developing and evaluating items for assessing intended use or "transfer" of what students have learned.

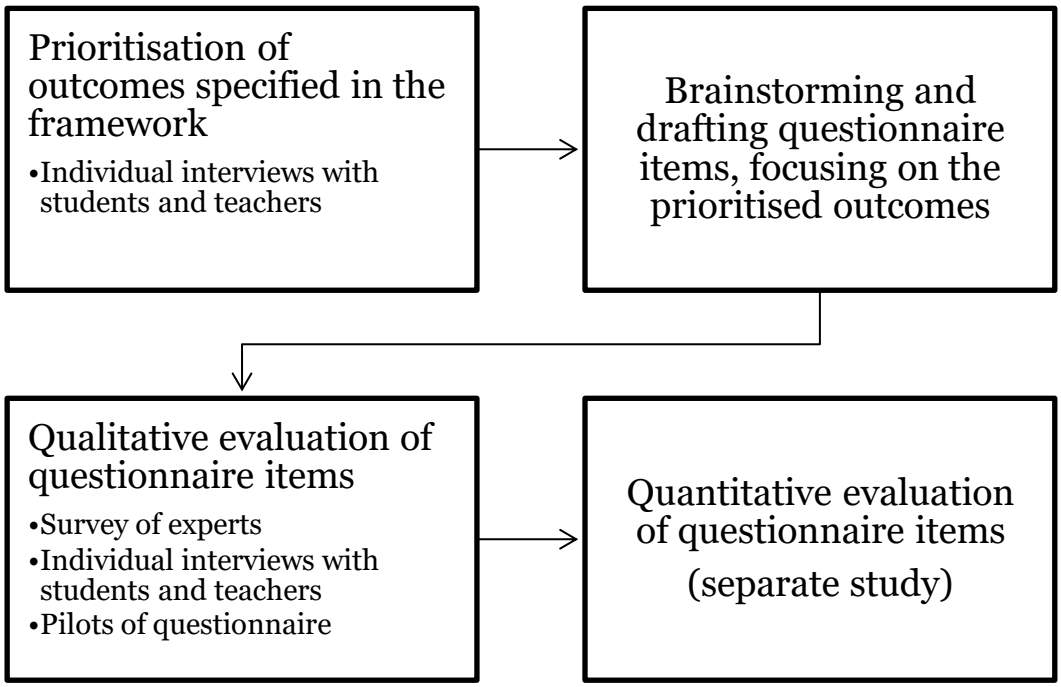
Objectives

3. Prioritise potential adverse effects of the IHC secondary school intervention, for the 1-year-follow-up assessments of the trials of the intervention
4. Develop and evaluate questionnaire items for measuring potential adverse effects, focusing on those that we have prioritised

Methods

Our overall approach is largely based on the development and evaluation of instruments (questionnaires) with items from the Claim Evaluation Tools item bank [9,10]. **Figure 1** shows the overarching steps of this study, leading into the separate study in which we will quantitatively evaluate the items developed in this study. We will consider changes to the draft items during and after the qualitative evaluation. Where feasible, we will combine data collection for this study together with data collection for the development and evaluation of items for assessing intended transfer of learning.

Figure 1. Overarching steps of the study.



We will store anonymous qualitative data on the server provided and managed by the Norwegian Health Network for the Norwegian Institute of Public Health. We will not store the names of participants or schools, or any sensitive data. When we record interviews, we will only record audio. We will transcribe each recording, then delete it. We will store the recordings and quantitative data locally, in each country.

Prioritisation of outcomes: Group interviews with stakeholders

In this step, we will build on a preliminary prioritisation of outcomes for the process evaluations associated with the trials of the intervention [5]. We will interview individual students and teachers from the intervention arms of the trials, exploring whether they have experienced or observed potential adverse effects of the intervention, as well as what potential adverse effects they generally consider most likely and important. If time, we will also explore any ideas they have for the content and format of the draft items (see "Brainstorming and drafting items", below). Appendixes 1 and 2 are the initial interview guides.

To start, we will interview three students and two teachers from each of the intervention arms of the three trials. After which, we will consider whether it is feasible and worthwhile to conduct additional interviews with students or teachers who received the intervention, or interviews with other stakeholders, such as parents, curriculum developers, or teachers at schools in the intervention arms who did not participate in the trials but teach students who received the intervention. We will end the interviews after 1 hour maximum.

We have chosen individual rather than groups interviews for two reasons. First, the interview topic might be unfamiliar or strange to participants, based on findings from the development of the framework [5]. Individual interviews are logically more appropriate for exploring knowledge that is taken for granted and not readily articulated [11]. Second, it is possible that participants will find the topic uncomfortable, since it might involve criticising the beliefs, behaviour, or work of others, for example our work developing the intervention. To help mitigate this second challenge, we will first ask participants about potential beneficial effects of the intervention that they have experienced or observed.

We will conduct a thematic analysis [12] of the collated data from all the interviews, including the following steps:

1. Pilot a spreadsheet for tagging the data
2. Review and tag each data point with an initial theme
3. Compare and harmonise tags and themes
4. Organise the data by theme, in a document
5. For each theme, suggest implications for the prioritisation of outcomes
6. Compare suggestions and agree on implications

Two members of the research team will complete each step. If and where the two are unable to harmonise judgements or agree on implications, a third team member will arbitrate.

Brainstorming and drafting items

We will brainstorm and draft items for each prioritised outcome. We will draft ≥4 items for each outcome, so we can potentially remove items that we find are problematic without having to replace them. We will then decide whether to brainstorm and draft additional items for the non-prioritised outcomes in the framework. This decision will depend on practical considerations, including the number and complexity of the remaining outcomes, as well as time and resources.

Qualitative evaluation of items

Survey of experts

To evaluate the degree to which the items are sufficiently complete and sensible measures of the outcomes of interest—i.e., test face or content validity [13], or sensibility [14]—we will survey researchers and others with relevant expertise, including members of our international advisory network [15]. We will develop the survey after drafting the items, using Nettskjema, an online survey tool developed and hosted by the University of Oslo [16]. We will ask the experts to evaluate both the content and format of the items, including understandability, relevance, and acceptability of terminology, examples, and instructions.

We will conduct a thematic analysis [12] of the collated survey data. The steps of the analysis will correspond with those listed under "Prioritisation of outcomes: Group interviews with stakeholders", above. However, in this analysis, we will tag each data point with both the relevant outcomes and draft items, rather than themes. In the last step, we will agree on whether to retain, revise, remove, or replace each item.

Individual interviews with students and teachers

To further evaluate the degree to which the items are sufficiently complete and sensible, we will interview individual students and teachers. We will ask each participant to "think aloud" as they respond to the questions or tasks, before asking any specific questions about content or format. We will develop the interview guides after addressing the survey findings.

We will only include students and teachers who are unfamiliar with the intervention since we want respondents in the control arms of the trials to understand the items despite their unfamiliarity. In other words, we will exclude participants in the development of the intervention or in the intervention arms of the trials. To start, we will interview at least 5 students and 3 teachers in each of Kenya, Rwanda, and Uganda.

We will consider changes to the draft items after every interview, based on the latest data and preliminary findings. We will do a final, thematic analysis [12] of the collated data from all the interviews, taking the same steps as in the analysis of the survey data (see "Survey of experts", above).

Pilots of questionnaire

We will pilot the remaining items together, as an instrument. To start, we will include two classes of students in each country—one class that is familiar with the intervention, and one that is not—and their teachers. We will use the data from students to estimate the potential power of the instrument to detect differences between students in the intervention and control arms of the trials. We will not use the data from teachers this way, since it is infeasible to recruit a large enough sample of teachers to produce a meaningful estimate.

We will record the total time it takes each participant to respond to all items. These results will help inform whether to include the final items in the questionnaire used for the primary outcome in the trials—the "Critical Thinking about Health Test" [6–8]—or administer them as a separate instrument to subgroups of the trial participants. Furthermore, we will inspect the responses visually, to evaluate whether participants understood the instructions and format of the items. Where visual inspection suggests there might be a problem with instructions or format, we will consider and agree on any changes to address the problem.

Quantitative evaluation of items

In a separate, subsequent study, we will evaluate the psychometric properties of the items. If feasible, we will complete this quantitative evaluation and address any problems that it reveals (i.e., revise, remove, or replace items) before the 1-year-follow-up assessments of the trials. If a quantitative evaluation is not feasible before the 1-year-follow-up assessment, we will use data from that assessment to evaluate the items and report any problems. There are different quantitative tests of validity [13]. The appropriate test or tests that we use will depend on the final format and content of the items. It is likely that our sample of teachers will be too small to quantitively evaluate items for teachers, in which case we will report and discuss this limitation when reporting relevant results of this study and the trials.

Results

Results of the study will include:

- a set of potential adverse effects (increases in adverse outcomes) prioritised for the trials of the IHC secondary school intervention, and
- measures of potential adverse outcomes that have been qualitatively evaluated.

Ethics

Participation in this study is voluntary and does not involve likely or serious risks to participants. The survey will include a description of how we will manage and use the survey data. Because responses to the survey will be anonymous, we will not seek written consent from respondents. Rather, we will include a statement that responding implies consent. For the interviews, we will seek written ascent and consent, unless the participant has already provided necessary ascent or consent for the entire evaluation stage. We will obtain, or confirm that we have obtained, separate ascent and consent to being audio-recorded.

The Norwegian Institute of health is the project's lead partner. As required by the institute—to comply with the European General Data Protection Regulation—we have completed a data privacy impact assessments (DPIAs) for the entire evaluation stage of the project, including this study. The Data Protection and Chief Information Security Officers at the institute provided feedback on the DPIAs, and the relevant senior advisor at approved them. Furthermore, as required by the funder, the Research Council of Norway, we have created a data management plan for the entire project, which we are updating continuously and will submit to the council at the end of the project. Since the project will not generate new knowledge about health and disease, it falls outside the remit of the Regional Committee for Medical Research Ethics [17], in Norway, which the committee has confirmed.

In Kenya, we will obtain ethics approval from Masinde Muliro University of Science and Technology Institutional Ethics Review Committee and the Kenya National Commission of Science and Technology Institute, as well as approval from the Ministry of Education and the Teachers Service Commission, nationally and at the county-level. In Rwanda, we will obtain ethics approval from the Rwandan National Ethics Committee. In Uganda, we will obtain ethics approval from the School of Medicine research ethics committee at the Makerere University College of Health Sciences, and from the Uganda National Council for Science and Technology.

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Appendix 1. Guide for interviews with students.

Pre-interview

Table 1. Data about interview.

Date	Country	Interviewer	Notetaker(s)	Setting

Table 2. School data. ☐

Location *Urban; semi-urban; semi-rural; rural*	***Funding*** *Private; public; other (specify)*	**Other relevant data about school**

Part 1: Practicalities

- Introduce interviewer and notetaker(s). ☐

- Introduce the topic, goal, and structure of the interview:

- *We would like to interview you for a study.* ☐

- *The topic of the interview and the study is possible disadvantages of the "Be Smart about Your Health" lessons.* ☐
- *The goal of the interview is to learn from your experiences.* ☐
- *We will share what we learned with others, mainly researchers, in an article about the study.* ☐

- *The interview will last for maximum 1 hour.* ☐
- *We can take a break whenever you want.* ☐

- *We will start the interview by providing a little more information about the topic and goal.* ☐
- *Then we will ask a few questions about you.* ☐

- *Then we will ask about any disadvantages you have experienced or observed.* ☐
- *If time, we will also ask you about how to measure whether other students have experienced any disadvantages.* ☐

• Emphasise:

- *The goal of the interview is not to test you, and there are no wrong answers.* ☐
- *If anything is unclear, please let us know, so we can explain better.* ☐
- *And please let us know if you would like any information in another language.* ☐

- *We will not share your real names, or the name of your school, in the article or anywhere else.* ☐
- *It will not be possible to identify you by reading the article.* ☐

- *We would like to audio-record the interview.* ☐
- *We will use the recording to write what you said, so we do not misunderstand or overlook anything.* ☐
- *We will delete the recording when we are finished writing what you said.* ☐
- *We will not share the recording with anyone else.* ☐

- *You can leave the interview at any time, without giving any reason.* ☐
- *Unless we have already published the article, you can ask us to delete what you have shared with us, without giving any reason, and we will delete it.* ☐

• Take questions. ☐

• If obtaining ascent, review content of ascent form, and take questions. ☐
• Confirm previous ascent or obtain written ascent to participation and recording, respectively. ☐

• Ask participant to choose alias and write it on name tag or place card. ☐

• Start recording. ☐

Part 2: Explanation of topic and goal.

- *The topic of this interview is possible disadvantages of the "Be Smart about Your Health" lessons.* ☐

- *Our goal is to learn from your experiences.* ☐
- *This will help us when we develop written questions or tasks for measuring whether students have experienced disadvantages of the lessons.* ☐
- *And it can help us develop better teaching and learning resources.* ☐
- *It might also be helpful to others, mainly other researchers.* ☐

- *An "advantage" is something you want (something desirable).* ☐
- *A "disadvantage" is the opposite: something you do not want (something undesirable).* ☐
- *Some of the "Be Smart about your Health" lessons are about advantages and disadvantages of health actions—do you remember anything from those lessons?* ☐

- *In general, school has important advantages.* ☐
- *However, actions we take in school might also have disadvantages.* ☐
- *For example, spending more time on one subject, leaves less time for other subjects.* ☐

- Take questions. ☐

Part 3: Participant background

- *We want to know a little about the students we interview.* ☐
- *This will help us when we consider how similar or different your experiences might be compared to those of other students, who we do not interview.* ☐

1: *Please answer a few questions about yourselves:*
- *What are your ages?* ☐
- *What forms are you in?* ☐
- *What are your favourite subjects at school?* ☐
- *What are your least-favourite subjects?* ☐

Table 3. Participant data. ☐

Alias	Gender	Age	Form	Favourite subject	Least-favourite subject

Part 4: Experiences and observations of adverse outcomes

2: *If you experienced any advantages of the "Be Smart about your Health" lessons, can you give any examples?* ☐

- Clarify, if necessary:

- *If you did not experience any advantages of the "Be Smart about your Health" lessons, that is fine and helpful for us to know.* ☐

- Prompts, if necessary:
    - Learning
    - Enjoyment

3: *If you experienced any disadvantages of the "Be Smart about your Health" lessons, can you give any examples?* ☐

- Prompts:
    - Conflict
    - Conflict with parents
    - Other

4: *Thinking about any disadvantages you experienced, which of those disadvantages do you think are most important?* ☐

5: *If you saw other students experiencing disadvantages of the lessons, can you give any examples of this?* ☐

6: *If there are disadvantages of the lessons that you think most students might experience, what are those disadvantages?* ☐

Part 5: Measuring adverse outcomes

- Skip this part of if short on time.

- *Interviewing many students like this would take a lot of time.* ☐
- *Therefore, we are trying to develop some written questions for measuring how many students experienced any disadvantages of the "Be Smart about your Health" lessons.* ☐

7: *If you were to write questions to find out whether another student has experienced any disadvantages of the lessons, what might those questions be like?* ☐

Part 6: Conclusion

8: Allow notetaker to ask questions and comment. ☐

9: *Is there anything that we could have done differently, to improve your experience of this interview?* ☐

Prompts:

- Practical information ☐
- Explanation of the topic or goal ☐
- Questions ☐

10: *Do you have any other comments or questions?* ☐

Thank participant and stop recording. ☐

Appendix 2. Guide for interviews with teachers.

Pre-interview

Table 4. Data about interview.

Date	Country	Interviewer	Notetaker(s)	Setting

Table 2. School data. ☐

Location *Urban; semi-urban; semi-rural; rural*	***Funding*** *Private; public; other (specify)*	**Other relevant data about school**

Part 1: Practicalities

- Introduce interviewer and notetaker(s). ☐

- Introduce the topic, goal, and structure of the interview:

- *We would like to interview you for a study.* ☐

- *The topic of the interview and the study is possible disadvantages of the "Be Smart about Your Health" lessons.* ☐
- *The goal of the interview is to learn from your experiences.* ☐

- *We will share what we learned with others, mainly researchers, in an article about the study.* ☐

- *The interview will last for maximum 1 hour.* ☐
- *We can take a break whenever you want.* ☐

- *We will start the interview by providing a little more information about the topic and goal.* ☐
- *Then we will ask a few questions about you.* ☐

- *Then we will ask about any disadvantages you have experienced or observed.* ☐
- *If time, we will also ask you about how to measure whether other teachers or students have experienced any disadvantages.* ☐

• Emphasise:

- *The goal of the interview is not to test you, and there are no wrong answers.* ☐
- *If anything is unclear, please let us know, so we can explain better.* ☐
- *And please let us know if you would like any information in another language.* ☐

- *We will not share your real names, or the name of your school, in the article or anywhere else.* ☐
- *It will not be possible to identify you by reading the article.* ☐

- *We would like to audio-record the interview.* ☐
- *We will use the recording to write what you said, so we do not misunderstand or overlook anything.* ☐
- *We will delete the recording when we are finished writing what you said.* ☐
- *We will not share the recording with anyone else.* ☐

- *You can leave the interview at any time, without giving any reason.* ☐
- *Unless we have already published the article, you can ask us to delete what you have shared with us, without giving any reason, and we will delete it.* ☐

• Take questions. ☐

• If obtaining consent, review content of consent form, and take questions. ☐
• Confirm previous consent, or obtain written consent to participation and recording, respectively. ☐

• Ask participant to choose alias and write it on name tag or place card. ☐

• Start recording. ☐

Part 2: Explanation of topic and goal.

- *The topic of this interview is possible disadvantages of the "Be Smart about Your Health" lessons.* ☐

- *Our goal is to learn from your experiences.* ☐
- *This will help us when we develop written questions for measuring whether teachers and students have experienced disadvantages of the lessons.* ☐
- *And it can help us develop better teaching and learning resources.* ☐
- *It might also be helpful to others, mainly other researchers.* ☐

- *An "advantage" is something you want (something desirable).* ☐
- *A "disadvantage" is the opposite: something you do not want (something undesirable).* ☐

- *Some of the "Be Smart about your Health" lessons are about advantages and disadvantages of health actions.* ☐
- *In general, school has important advantages.* ☐
- *However, actions we take in school might also have disadvantages.* ☐
- *For example, spending more time on one subject, leaves less time for other subjects.* ☐

- Take questions. ☐

Part 3: Participant background

- *We want to know a little about the teachers we interview.* ☐
- *This will help us when we consider how similar or different your experiences might be compared to those of other teachers, who we do not interview.* ☐

1: *Please answer a few questions about yourselves:*
- *How many years have you worked as a teacher?* ☐
- *What forms do you teach?* ☐
- *What subjects do you teach?* ☐

Table 3. Participant data. ☐

Alias	**Gender**	**Years of teaching experience**	**Forms**	**Subjects**

Part 4: Experiences and observations of adverse outcomes

2: *If you experienced any advantages of the "Be Smart about your Health" lessons, can you give any examples?* ☐

- Clarify, if necessary:

- *If you did not experience any advantages of the "Be Smart about your Health" lessons, that is fine and helpful for us to know.* ☐

- Prompts, if necessary:
    - Learning
    - Enjoyment

3: *If you experienced any disadvantages of the "Be Smart about your Health" lessons, can you give any examples?* ☐

- Prompts:
    - Conflict
    - Stress
    - Waste of time or resources
    - Other

4: *Thinking about any disadvantages you experienced, which of those disadvantages do you think are most important?* ☐

5: *If you saw your students or anyone else experiencing disadvantages of the lessons, can you give any examples of this?* ☐

- Prompt:
    - Conflict between students and parents
    - Other

6: *If there are disadvantages of the lessons that you think most teachers or students might experience, what are those disadvantages?* ☐

- Prompts:
    - Students
    - Teachers
    - Others

Part 5: Measuring adverse outcomes

- Skip this part of if short on time.

- *Interviewing many teachers and students like this would take a lot of time.* ☐

- *Therefore, we are trying to develop some written questions for measuring how many teachers or students experienced any disadvantages of the "Be Smart about your Health" lessons.* ☐

7: *If you were to write questions, to find out whether another teacher or a student has experienced any disadvantages of the lessons, what might those questions be like?* ☐

Part 6: Conclusion

8: Allow notetaker to ask questions and comment. ☐

9: *Is there anything that we could have done differently, to improve your experience of this interview?* ☐

Prompts:

- Practical information ☐
- Explanation of the topic or goal ☐
- Questions ☐

10: *Do you have any other comments or questions?* ☐

- Thank participant and stop recording. ☐