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Measuring ability to assess claims about treatment effects: The development of the "Claim Evaluation Tools"

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Keywords: evidence based medicine, shared decision making, health literacy, outcome measurement, multiple-choice, patient education

Abstract

Objectives: To describe the development of the Claim Evaluation Tools, a battery of multiple-choice items, to measure people's ability to understand and apply Key Concepts needed to assess claims about treatment effects.

Setting: Methodologists and members of the community in Uganda, Rwanda, Kenya, Norway, United Kingdom and Australia.

Participants: We used purposeful sampling of people with expertise in the Key Concepts, as well as patients and members of the public from both low and high-income countries in the iterative development of the items. This included four processes: (1) determining the scope of the Claim Evaluation Tools and development of items; (2) expert item review and feedback (n=63); (3) cognitive interviews with children and adult end-users (n=109); and (4) piloting and administrative tests (n=956).

Results: The Claim Evaluation Tools currently consists of between four and six multiple-choice items addressing each of the Key Concepts. Each item begins with a scenario intended to be relevant across contexts, and which can be used for children (from 10 years old and above), adult members of the public as well as health professionals. Methodologists and people with expertise in the Key Concepts judged the items to have face validity, and end-users judged them relevant and acceptable in their settings. In response to feedback from methodologists and end-users, we simplified some text, explained terms where needed, and redesigned formats and instructions.

Conclusion:
The Claim Evaluation Tools include a battery of objective and flexible multiple-choice items, from which researchers, teachers and others can select those that are relevant for specific purposes or populations. These evaluation tools are being managed and made freely available for non-commercial use (on request) through the website Testing Treatments interactive (testingtreatments.org).

Strengths and limitations of this study

- To our knowledge, this is the first attempt to develop a set of evaluation tools that objectively measure people's ability to apply Key Concepts people need to know to assess claims about treatment effects
- This development was led by researchers in high and low income countries, including feedback from people with methodological expertise and members of the public
- Based on qualitative and quantitative feedback, the Claim Evaluation Tools were found to have face validity and relevant in the studied contexts
- There are many ways of developing evaluation instruments. We chose to use a pragmatic and iterative approach, but the reliability of the items remains to be tested.

Background

There are endless claims about treatments in the mass media, advertisements and everyday personal communication (1-4). Such claims may include strategies to prevent illness, such as changes in health behaviour or screening: therapeutic interventions; or public health and system interventions. Many claims are unsubstantiated, and many patients and professionals alike may neither know whether the claims are true or false, nor have the necessary skills or tools to assess their reliability (5-11). As a result, people who believe and act on unvalidated claims may suffer by doing things that can be harmful, and by not doing things that can help. Either way, personal and societal resources for health care will be wasted (12).

The Informed Healthcare Choices (IHC) project aims to support the use of research evidence by patients and the public, policymakers, journalists and health professionals. The multidisciplinary group responsible for the project includes researchers in six countries - Norway, Uganda, Kenya, Rwanda, United Kingdom and Australia. The project is funded by the Research Council of Norway and has been responsible for developing and evaluating resources for two strategies to improve people's ability to assess claims about treatment effects. The first strategy involves the use of resources in primary schools to improve children's ability to assess claims about treatment effects. The second strategy uses podcasts to improve the ability of parents of primary school children to assess claims about treatment effects. We have piloted these resources in Uganda, Kenya, Rwanda and Norway, and the effects of the resources will be tested in randomized trials in Uganda (13, 14).

The IHC project group began by developing a list of Key Concepts that people need to understand to assess claims about treatment effects (15). This was done by using the second edition of the book "Testing Treatments" as our starting point, and by doing a literature review to identify Key Concepts and a review of critical appraisal tools for the public, journalists and health professionals (11, 15). The list of Key Concepts (Table 1) which emerged from this process was revised iteratively based on feedback from members of the project team and the IHC advisory group. The latter includes researchers, journalists, teachers and others with expertise in health literacy, and in teaching or communicating evidence-based health care (15). The resulting list of Key Concepts is an evolving document hosted by

testingtreatments.org, and is reviewed annually to allow for revisions of existing concepts or identification and inclusion of additional concepts.

Please enter Table 1. The Key Concepts

A systematic mapping review conducted as part of the IHC project concluded that the list of Key Concepts has wide interdisciplinary relevance, including in research areas such as use of decision support tools, training in evidence-based healthcare and critical appraisal, promotion of informed consent through improving understanding of trial methods, and school science education (16). Although, the common goal of these research fields is to facilitate informed decision-making, the research is heterogeneous. Partly overlapping and sometimes parallel research areas have been responsible for studies focusing on specific concepts, such as Key Concept 5.1 "weighing the benefits and harms of a treatment", or the Key Concept 2.1 "Treatment comparisons are necessary" (16). Furthermore, we have not been able to identify any previous consensus or conceptualisation of Key Concepts critical to understanding the effects of treatments, nor have we found any instrument that measures understanding of all of the Key Concepts we have identified. Based on the findings of our systematic review, we concluded that the teaching resources we identified, and the procedures and instruments used to map or evaluate people's understanding, covered only a handful of the Key Concepts (16).

In summary, we agreed that there existed a need to develop measurement instruments to assess people's understanding of the Key Concepts. Accordingly, we set out to develop the Claim Evaluation Tools to serve as the primary outcome measures for evaluating the effects of the IHC primary school resources and the IHC podcast series in randomised trials. Although our primary target groups were children and adults in Uganda, we wanted to create a set of tools that would also be relevant in other settings. Four important elements underpinned the development of the Claim Evaluation Tools. These tools should (i) objectively measure people's ability to apply the Key Concepts; (ii) be flexible and easily adaptable to particular populations or purposes; (iii) be rigorously evaluated; and (iv) be freely available for non-commercial use by others interested in mapping or evaluating people's ability to apply some or all of the Key Concepts.

Objective

To describe the development of the Claim Evaluation Tools, a set of objective and flexible tools to measure people's ability to apply Key Concepts needed to assess claims about treatment effects.

Methods

The development of the Claim Evaluation Tools included four processes, using qualitative and quantitative methods, over three years (2013-2016): (i) determining the scope of the Claim Evaluation Tools and development of items; (ii) expert item review and feedback (face validity); (iii) cognitive interviews with end-users - including children, parents, teachers and patient representatives - to achieve relevance, understanding and acceptability; and (iv) piloting and practical administrative tests of the items in different contexts. For clarity, the methods and findings of each of these processes are described separately. However, development was iterative, with the different processes overlapping and feeding into each other. Researchers affiliated with the ICH project in six countries (Uganda, Norway, Rwanda, Kenya, UK and Australia) contributed to the development of the Claim Evaluation Tools. An overview of the development process is presented in Figure 1. The roles and purposes of the different research teams are described below.

Please enter Figure 1. Overview and timeline of the development process

Determining the scope of the Claim Evaluation Tools and the development of items

The Claim Evaluation Tools working group, with members of the IHC group from Norway, UK and Uganda (AA, AO, IC, DS, AN), had principal responsibility for agreeing on content, including the instructions and wording of individual items. The development and evaluations were coordinated by the team in Norway (AA and AO). The scope of the Claim Evaluation Tools was based on the list of Key Concepts (15)(see table 1).

Our vision for the Claim Evaluation Tools was that they should not be a standard fixed questionnaire, but rather a flexible tool including a battery of items, of which some may be more relevant to certain populations or purposes. Multiple-choice items are well suited for assessing application of knowledge, interpretation and judgements. In addition, they help problem-based learning and practical decision making (17). Each of the items we created opened with a scenario leading to a treatment claim and a question, which was followed by a choice of answers. We developed the items using two multiple-

choice formats - single multiple-choice items (addressing one concept), and multiple true-false items (addressing several concepts in the same item). We developed all items with "one-best answer" response options (17), the options being placed on a continuum, with one answer being unambiguously the "best" and the remaining options as "worse". All items were developed in English.

The initial target groups for the Claim Evaluation Tools were fifth grade children (10 to 12 year-olds in the next to last year of primary school) and adults (parents of primary school children) in Uganda. However, throughout the development process, our goal was to create a set of tools that would be relevant in other settings. Accordingly, we used conditions and treatments that we judged likely to be relevant across different country contexts. Where necessary, we explained the conditions and treatments used in the opening scenarios. We also decided to avoid conditions and treatments that might lead the respondents to focus on the specific treatments (about which they might have an opinion or prior knowledge), rather than on the concepts.

Exploring relevance, understanding and acceptability of items

In order to get feedback on the relevance, understanding and acceptability of items, we used purposeful sampling of people with expertise in the Key Concepts, as well as patients and members of the public from both low and high-income countries (18-21).

Item review and feedback by methodologists (face validity)First we circulated the complete set of multiple-choice items to members of the IHC advisory group and asked them to comment on their applicability and face validity as judged against the list of Key Concepts. Each advisory group member was assigned a set of three concepts, with associated items. A feedback form asked them to indicate to what extent they felt each item addressed the relevant Key Concept using the response options "Yes", "No" or "Uncertain", together with any open-ended comments. Any items that were tagged as "No" or "Uncertain" by one or more of those consulted were considered for revision.

On two occasions, we also invited four methodologists associated with the Norwegian research group and with expertise in the concepts to respond to the full set of items. These experts were not involved in the project or the development of the Claim Evaluation Tools. In this element of the evaluation, the response options were randomised and the methodologists were blinded to the correct answers. They

were asked to choose what they judged to be the best answer to each item's question, and were encouraged to provide open-ended comments and flag any problems they identified. Any item in which one or more of the methodologists failed to identify the 'best answer' was considered for potential revision.

We also invited people with expertise in the Key Concepts from all project partner countries to provide feedback on several occasions throughout the development of the tools. In addition to providing general feedback, an important purpose of reviewing the items in these different contexts was to identify any potential culturally inappropriate terminology and examples (conditions and treatments).
For all of this feedback, suggested revisions and areas of improvement were summarised in an Excel worksheet in two categories: (i) comments of a general nature relating to all items, such as choice of terminology or format, and (ii) comments associated with specific items.

Cognitive interviews with end-users on relevance of examples, understanding and acceptability

After the Claim Evaluation Tools working group and the IHC project group agreed on the instrument content, we undertook cognitive interviews with individuals from our potential target groups in Uganda, Australia, UK and Norway (22-24). Country representatives of the IHC project group recruited participants in their own contexts, based on purposeful sampling, in consultation with the Norwegian coordinator (AA). Since Uganda has been the principal focus of our interest, this was always our starting and ending point. In total, four rounds of interviews took place in Uganda. The interviews in Norway, UK and Australia were done to assess relevance within these settings.

The overall objective of these interviews was to obtain feedback from potential end-users on the relevance of the scenarios (such as the conditions and treatments used as examples), and the intelligibility and acceptability of the scenarios, formats and instructions. This was particularly important because the items were to be used for children as well as adults. Throughout this process, we also piloted and user-tested several versions of the items (designs and instructions). Failure to address these issues when developing the items might increase the likelihood of missing responses, "guessing" or other measurement errors. For example, we wanted to minimise the influence of people's cultural background on how they responded to the multiple-choice items. The effects of such confounders are being addressed in the last phase of the development in the psychometric testing and Rasch analysis of

the questionnaire (25). The interviews were intended to help prevent such problems relatively early in the evaluation process.

Interviews were performed iteratively between October 2014 and January 2016, allowing for changes to the items between interviews. All interviews were conducted using a semi-structured interview guide (Appendix 1) inspired by previous research (22-24). As part of the interviews, the participants were given a sample set of the multiple-choice items and asked to respond to these. The interviews addressed questions raised during development of the items about the format of questions or the terminology used in the questions. In response, the interview guide was revised and multiple-choice items changed when relevant.

When conducting the interviews, we used the methods of 'think aloud' and 'verbal probing', two approaches to cognitive interviewing (23). With "think aloud" the respondent is asked to explain how they arrived at their response to each item. Such interviews are less prone to bias because of the more limited role of the interviewer. However, some respondents have difficulty in verbalising their thought processes, and in these circumstances we followed up with "verbal probing", which uses questions that the interviewer asks after the respondent has completed each of the items. Following each item the interviewer began with the "think aloud" method by asking respondents how they arrived at their response before asking more specific questions, as necessary.

We audio recorded interviews when possible, and we aimed to have two people doing the interviews (with one person taking notes and the other person being the lead-interviewer). For practical reasons this was not always possible. Each country representative summarised the key points from the interviews. Suggested revisions and areas of improvement were fed back to the Norwegian coordinator who entered these into the same Excel spreadsheet as the feedback from the methodologists.

Piloting and administrative tests

We conducted five pilots of administering sets of the Claim Evaluation Tools to our target groups. The first pilot (March-April 2015) was an administrative test in a primary school in Uganda. This test was performed with a group of children who had taken part in a pilot of the IHC primary school resources as part of the IHC project, and with a comparison group who had not received training in the Key Concepts

(in total 169 children). In this pilot, we administrated all items addressing 22 of the 32 Key Concepts (see Table 1). The reason for this cut-off was that these 22 concepts were targets of the intervention in the first draft of the IHC resources. Because of the large number of items to be tested, they were divided into four sets or questionnaires. These questionnaires were designed to be similar to the questionnaires to be used in the IHC trials, and would thus give us some feedback on how administrating a set of the Claim Evaluation Tools would work in practice, in a classroom setting. We also wanted to explore potential problems with incorrectly completed responses (through visual inspection of the responses).

The second pilot focused solely on format testing (September to December 2015). Three different sets of formats were tested. The formats were designed based on lessons learned from the feedback from the methodologists, interviews with end-users, and through visual inspection of the data collected in the first pilot. We recruited people in Uganda, Rwanda and Kenya to do this (N=204), using purposeful sampling, including children and adults. The same set of Claim Evaluation Tools was kept constant across the three formats. The outcome of this test was evaluated based on the number of missing or incorrectly completed responses per item.

The third pilot (October to November 2015) and fourth pilot (November to December 2015) were conducted with Ugandan primary school children (in two schools) and their parents. The final pilot (December 2015) took place in Norway and included primary school children in one school. In all of these three pilots, we recruited children and adults who had taken part in the piloting of IHC primary school materials and podcast, and children and adults who had received no such intervention. The first objective of these pilots was to compare the ability of people who had and had not received training to apply the Key Concepts. This provided an indication of the sample-sizes that would be needed for the IHC randomised trials. The second objective of the pilots was to estimate the frequency of missing responses as an indication of problems of understanding the item's instructions. For these purposes, we used only one set of the Claim Evaluation Tools (addressing the 22 basic concepts). The reason for this was that we needed to reduce the number of items to gain statistical power in these small samples. In total, 197 children took part in the Ugandan school pilot, 301 parents took part in the podcast pilot, and 85 children took part in the Norwegian school pilot. The results of these pilots were summarised by calculating mean correct responses to all items addressing the same concept. We also calculated missing responses per item.

Results

Feedback from experts and members of the target groups

Face validity, perceived relevance and fit to the target group

We created 6 to 8 items per Key Concept, predicting that about half of these would be removed through feedback from experts, end-users and through the final psychometric testing and Rasch analysis (25). Thirteen members of the IHC advisory group provided feedback on 135 items. Only one of these items was judged to have addressed the concept inadequately, and a further 20 items were deemed to be party relevant. Feedback from the two blinded assessments of the Claim Evaluation Tools provided by the methodologists supported the items relevance to the Key Concepts.

Another important element of the feedback from the test-run with the methodologists was that the 'distance' between the "best" option and the "worse" options was considered too small, with the result that the items were too difficult. Based on this feedback, we revised the 'distractors' in the 'worse' options to make them more "wrong". The cognitive interviews with members of our target group also suggested that the items were too 'text heavy' and needed to be simplified. In relation to this, low-literacy skill was also raised as a potential barrier by experts and end-users in Uganda. Consequently, we tried hard to make the scenarios as simple as possible without losing key content.

The end-users and the methodologists consulted in each country (Uganda, Kenya, Rwanda, UK, and Australia), also provided comments on terminology, as well as on the examples used in the scenarios that they felt might not be appropriate or would need to be explained. The Claim Evaluation Tools working group considered these comments and revised the items. When we were unable to avoid using certain terms (for example, "research study"), we added explanations. Our rationale was that some terms would present a barrier to understanding the items, but were not considered to be part of the learning objectives associated with the Key Concepts. For some other terms, we used alternatives deemed acceptable by researchers, other experts and members of the target groups in each country (Uganda, Kenya, Rwanda, UK, Australia and Norway). This process involved feeding back all changes to experts and end-users in an iterative process with continuous revisions.

Please enter Figure 2. Example of formats

Preference of format and missing responses

Important objectives of the interviews with end-users were to obtain their preferences on format, to follow the steps of their reasoning when responding to the items and to assess their understanding of the items' instructions. The main message was that people preferred a mix of the simple-multiple choice and multiple true-false formats to make the questionnaire more interesting. The items were otherwise well-received. The general feedback from all the different country settings was that the formats were acceptable, recognisable and similar to multiple-choice formats they had encountered in other settings.

Based on verbal feedback, as well as visual inspection of how people responded to the items in the pilots, two potential ways were identified to prevent missing or incorrectly completed responses. The first was to avoid unnecessary open spaces in the items, because respondents tended to use these to write open-ended answers to the questions. The second was to avoid using check boxes, because respondents would check more than one check-box. These issues are easily dealt with when questionnaires are administrated electronically, but are a problem in paper-administered questionnaires. Examples of incorrectly filled in multiple-choice questions are shown in Figure 3. The design changes used to avoid these problems are shown in Figure 2.

Please enter Figure 3. Examples of incorrectly filled in multiple-choice questions

Pilots and administrative tests

The first school pilot in Uganda (March- April 2015) revealed problems with instructions and formats that resulted in mean missing responses of 20-40% of the items. The revised designs (Figure 2) we tested in the second pilot in Uganda, Rwanda and Kenya (September to December 2015) greatly improved people's responses to the questionnaire, reducing missing or incorrectly completed responses to between <4% of items. Based on this pilot, we made final revisions and decided on the formats to be used in the subsequent pilots.

The third, fourth and fifth pilots conducted in Uganda and Norway (October to December 2015), confirmed the appropriateness of the formats, and missing or incorrectly completed responses were <2%. These pilots also confirmed that respondents took between 30 to 60 minutes to complete a

questionnaire that included demographic questions and a sample of 29 items. The participants' correct responses per Key Concept are shown in Figure 3. The participants who had taken part in piloting of the IHC resources did slightly better than others for most of the Key Concepts (see Figure 4).

Please enter Figure 4. Distribution of correct answers in pilots

Discussion

Developing a new evaluation instrument is not straightforward, and requires rigorous testing using qualitative and quantitative methods (26). There are many ways of doing this. We chose to use a pragmatic and iterative approach, involving feedback from experts and end-users and continuous revisions. This development work was made possible by a multidisciplinary, international collaboration including people from high and low-income countries. Despite differences between countries, enabling people to assess treatment claims in their daily lives is a challenge across all countries. Although the Claim Evaluation Tools have been developed as part of the IHC project, we believe that they will be useful tool for others interested in mapping or evaluation of people's ability to apply Key Concepts in assessing claims about treatment effects.

An international group of people with relevant expertise considered that the items we developed appropriately addressed the Key Concepts we had identified. The items were considered by end-users to be acceptable in the four settings in which we conducted interviews: Uganda, Norway, UK and Australia. Certain terms were identified as problematic, so we either simplified the terminology or added explanations. Based on lessons learned from interviews and pilots, we redesigned formats that had led to missing or incorrectly completed responses, with a resultant fall in the frequency of these problems to less than 2%. Rigorous psychometric testing including Rasch analysis is also part of the development of the Claim Evaluation Tools. This is described in a separate paper which provides information about the reliability of the tools, the difficulty of the items, and other properties of the items as described by the Rasch analysis (25).

Feedback from methodologists and end-users indicated that some items were rather difficult and text-heavy. Literacy was also raised as a potential barrier. In response to these findings, we tried to shorten texts, to avoid unnecessarily difficult terminology, and to add explanations where necessary. This

emphasised the importance of measuring literacy skills when administrating the Claim Evaluation Tools in certain settings, as this might impact how well people perform on the items and act as a potential confounder.

Many of the instruments that have been developed to assess people's critical-appraisal skills have relied on self-report by respondents of their own abilities (subjective measurements). Typical examples are the many health literacy instruments, such as the European Health Literacy Survey (HLS-EU)(27) and instruments used to assess competence in evidence-based medicine (28). Self-assessed abilities can be difficult to interpret, and have been found to have a weak association with objectively measured knowledge and skills (29-31). It can also be argued that such instruments measure the confidence of respondents in their own ability rather than their knowledge or actual ability. Although improved confidence in one's own abilities may be a relevant and important effect of an intervention, our primary objective was to develop an instrument to measure objective knowledge and actual ability to apply the Key Concepts when confronted with claims about treatments effects.

Conclusion

We developed the Claim Evaluation Tools to evaluate people's ability to assess claims about the effects of treatments. As far as we are aware, this is currently the only evaluation instrument designed to address all of the Key Concepts we believe people need to know to assess claims about treatment effects. This work is the result of a multidisciplinary, international collaboration including high and low-income countries. We have used a pragmatic and iterative approach, involving feedback from experts and end-users and continuous revisions. Although the Claim Evaluation Tools have been developed primarily to be used as part of the IHC project in Uganda, we believe they should be useful for others interested in evaluating people's ability to apply the Key Concepts. Feedback from experts and end-users in Uganda, Kenya, Rwanda, Norway, UK and Australia supports our hope that they will be found relevant in other contexts.

The Claim Evaluation Tools is a flexible instrument including a battery of items from which researchers can select those relevant for specific populations or purposes. The Claim Evaluation Tools currently consist of four to six multiple-choice items addressing each of the concepts in the list of Key Concepts. However, we anticipated that the Claim Evaluation Tools will continue to evolve. Maintenance and

revision of the Claim Evaluation Tools will reflect changes in the list of Key Concepts, as well as additions or changes made on the basis of further feedback, pilot testing, cognitive interviews and Rasch analyses with different target groups and in different settings. The Claim Evaluation Tools will be hosted on the Testing Treatments interactive website and managed by the Claim Evaluation Tools working group. On request, all items are freely available for non-commercial use.

Authors' Contributions

AA, ØG, AO wrote the protocol and the IHC group provided comments on the protocol. AA coordinated all of the development and evaluation process with support from AO. AA, DS, AN, IC, AO and MO drafted the items with input from the IHC group. AA, IC and AO were responsible for revising the items iteratively based on the feedback received through the different processes. SR and AA were responsible for the format designs. AA and KO approached the IHC advisory group and other methodologists for feedback. AN, DS, LC, AA, MO, SR, TH and MK conducted the interviews with end-users. AN, DS, KO, LAM, MM, LAM, MK, NS, AMU and AA were involved in pilots and administrative tests in Uganda, Kenya, Rwanda and Norway respectively. AA analysed the data from the pilots. AA authored this manuscript with significant input from the rest of the IHC group.

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Ethical approval

Ethical approval was sought by the IHC project representatives in each country.

Data sharing statement

All data are published as part of this study. All Claim Evaluation Tools are available upon request for non-commercial use.

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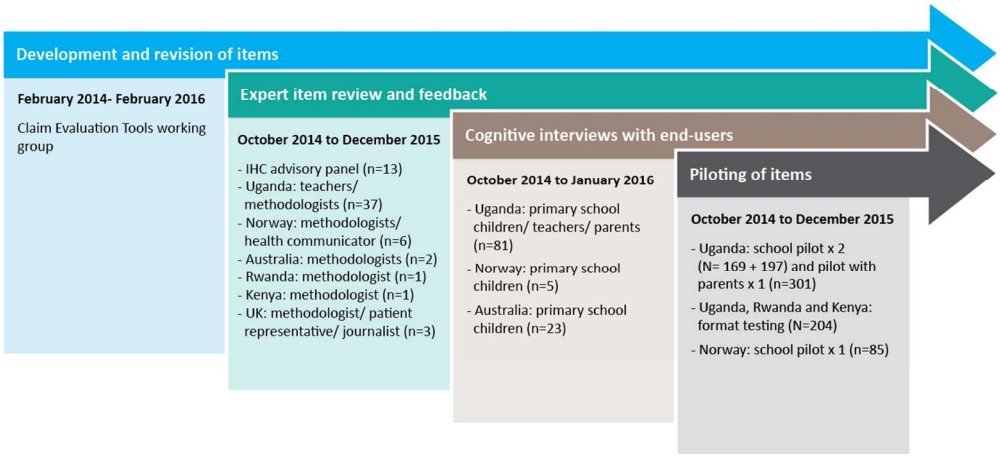


Concept 1.3

Judith wants smoother skin. The younger girls in her school have smoother skin than the older girls. Judith thinks this is because the younger girls use cream on their skin to make the skin smoother.

Question: **Based on this link between using cream and smooth skin, is Judith correct?**

Options:

A) It is not possible to say. It depends on how many younger and older girls there are

B) It is not possible to say. There might be other differences between the younger and older girls

C) Yes, because the younger girls use cream on their skin and they have smoother skin

D) No, Judith should try using the cream herself to see if it works for her

Answer: ☐

Concepts	When you are sick, sometimes people say that something - a <u>treatment</u> - is good for you. It is hard to know whether what they say is true. **Do you agree or disagree with each of the following statements?**		
	For each statement below, use ✓ to mark whether you agree or disagree.		
	Statements:	**Agree**	**Disagree**
1.1	James says that a treatment cannot be helpful and harmful at the same time		
1.2	Peter says that if a treatment works for one person, the treatment will help others too		
1.3	Alice says that if some people try the treatment and feel better, this means that the treatment helps		

Figure 2. Examples of formats: a simple multiple-choice item and a multiple true-false item

George has a stomachache. The last time George had a stomachache was two months ago. That time, he drank some hot milk and after an hour, his stomachache was gone. Therefore, George says hot milk cures stomachaches.

QUESTION:

Is George right?

No

PLEASE CIRCLE THE ANSWER THAT YOU THINK IS THE BEST

A. No, it is only based on George's own experience treating a stomachache with hot milk.

No

B. Not possible to say, the fact that he improved could have happened by chance

Yes

C. Yes, George's own experience is evidence enough for assessing the effects of hot milk for treating a stomachache

No

D. No, it is important to ask what other people think too, not just George

Yes.

Outside the city where Paul lives, there is a mine. The miners often get coughs. For many years, most of the miners have used whiskey mixed in water to reduce the pain from their coughs. Therefore, Paul says that water with a little whiskey is an effective and harmless treatment for a cough, since many people have used it for a long time.

QUESTION:

Do you agree with Paul?

PLEASE CIRCLE THE ANSWER THAT YOU THINK IS THE BEST

A. No, just because whiskey mixed in water has been used by many, does not mean that it is harmless

B. No, just because whiskey mixed in water have been used a lot, does not mean that it is the best treatment

C. Yes, the miners have used whiskey mixed in water to treat their coughs for many years and they would not use the treatment for many years if it were not beneficial and harmless

D. Not possible to say, Paul should try whiskey mixed in water on himself to know for sure that he is correct

. **Andrew has difficulty breathing. He goes to the shop to buy medicine. The shopkeeper gives Andrew tablet and says it will help improve his breathing. Andrew thinks if taking one tablet will help him, then taking two tablets will help him even more. Should Andrew take one or two tablets?** *Mark an X in the box for the best answer (only one)*

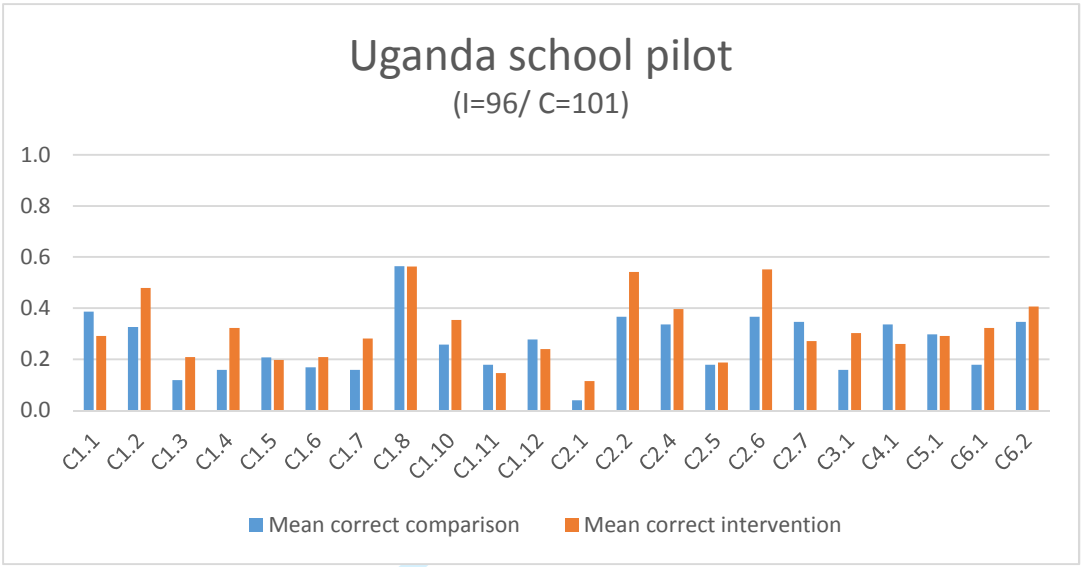
☒ One. Taking two is likely to be harmful and more expensive

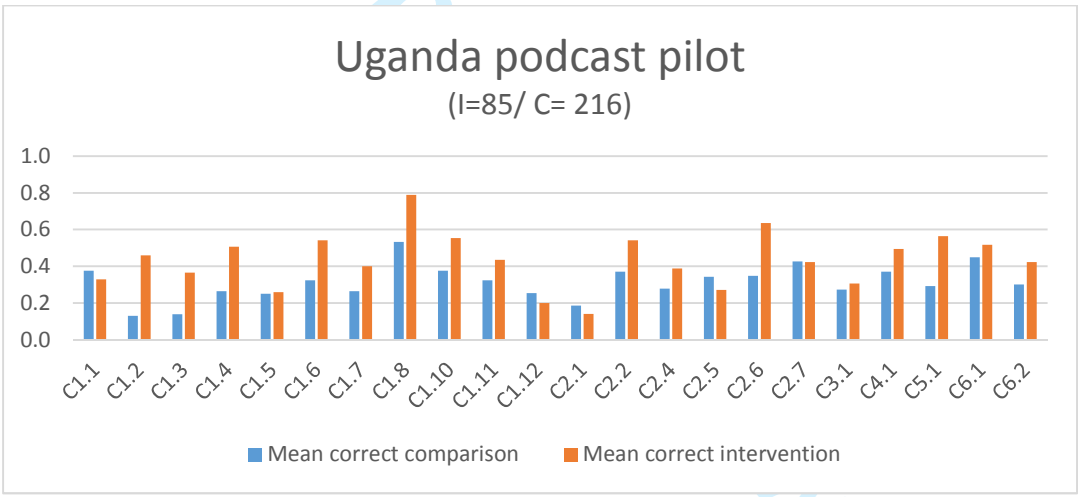
☐ One. Taking more than one will not necessarily be more helpful and may be harmful

☒ One. Andrew should listen to the shopkeeper's advice

☐ Two. Taking more than one will probably help him get better more quickly and is unlikely to be harmful

Figure 3. Examples of incorrectly filled in multiple-choice questions





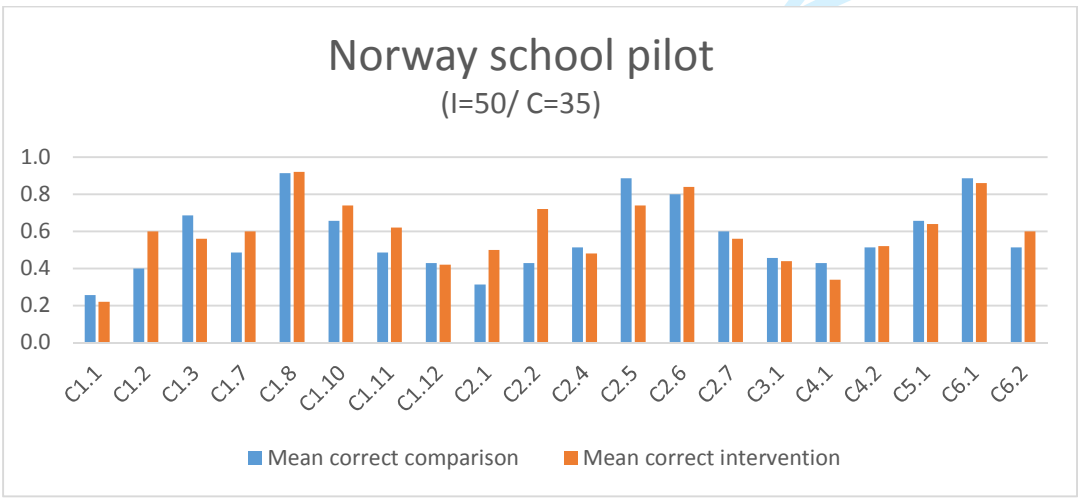


Figure 4. Distribution of correct answers per concept in three pilots

Key Concepts included in IHC intervention pilots	Informed Healthcare Choices Concepts
	1. Recognising the need for fair comparisons of treatments *[Fair treatment comparisons are needed]*
x	1.1 Treatments may be harmful *[Treatments can harm]*
x	1.2 Personal experiences or anecdotes (stories) are an unreliable basis for determining the effects of most treatments *[Anecdotes are not reliable evidence]*
x	1.3 A treatment outcome may be associated with a treatment, but not caused by the treatment *[Association is not necessarily causation]*
x	1.4 Widely used or traditional treatments are not necessarily beneficial or safe [Practice is often not based on evidence]
x	1.5 New, brand-named, or more expensive treatments may not be better than available alternatives *[New treatments are not always better]*
x	1.6 Opinions of experts or authorities do not alone provide a reliable basis for deciding on the benefits and harms of treatments *[Expert opinion is not always right]*
x	1.7 Conflicting interests may result in misleading claims about the effects of treatments *[Be aware of conflicts of interest]*
x	1.8 Increasing the amount of a treatment does not necessarily increase the benefits of a treatment and may cause harm *[More is not necessarily better]*
	1.9 Earlier detection of disease is not necessarily better *[Earlier is not necessarily better]*
x	1.10 Hope can lead to unrealistic expectations about the effects of treatments *[Avoid unrealistic expectations]*
x	1.11 Beliefs about how treatments work are not reliable predictors of the actual effects of treatments *[Theories about treatment can be wrong]*
x	1.12 Large, dramatic effects of treatments are rare *[Dramatic treatment effects are rare]*

	2. Judging whether a comparison of treatments is a fair comparison *[Treatment comparisons should be fair]*
x	2.1 Evaluating the effects of treatments requires appropriate comparisons *[Treatment comparisons are necessary]*
x	2.2 Apart from the treatments being compared, the comparison groups need to be similar (i.e. 'like needs to be compared with like') *[Compare like with like]*
	2.3 People's experiences should be counted in the group to which they were allocated *[Base analyses on allocated treatment]*
x	2.4 People in the groups being compared need to be cared for similarly (apart from the treatments being compared) *[Treat comparison groups similarly]*
x	2.5 If possible, people should not know which of the treatments being compared they are receiving *[Blind participants to their treatments]*
x	2.6 Outcomes should be measured in the same way (fairly) in the treatment groups being compared *[Assess outcome measures fairly]*
x	2.7 It is important to measure outcomes in everyone who was included in the treatment comparison groups *[Follow up everyone included]*
	3. Understanding the role of chance *[Understand the role of chance]*
x	3.1 Small studies in which few outcome events occur are usually not informative and the results may be misleading *[Small studies may be misleading]*
	3.2 The use of p-values to indicate the probability of something having occurred by chance may be misleading; confidence intervals are more informative *[P-values alone can be misleading]*
	3.3 Saying that a difference is statistically significant or that it is not statistically significant can be misleading *['Significance' may be misleading]*
	4. Considering all of the relevant fair comparisons *[Consider all the relevant evidence]*
x	4.1 The results of single tests of treatments can be misleading *[Single studies can be misleading]*

	4.2 Reviews of treatment tests that do not use systematic methods can be misleading *[Unsystematic reviews can mislead]*
	4.3 Well done systematic reviews often reveal a lack of relevant evidence, but they provide the best basis for making judgements about the certainty of the evidence *[Consider how certain the evidence is]*
	5. Understanding the results of fair comparisons of treatments *[Understand the results of comparisons]*
x	5.1 Treatments may have beneficial and harmful effects *[Weigh benefits and harms of treatment]*
	5.2 Relative effects of treatments alone can be misleading *[Relative effects can be misleading]*
	5.3 Average differences between treatments can be misleading *[Average differences can be misleading]*
	6. Judging whether fair comparisons of treatments are relevant *[Judge relevance of fair comparisons]*
x	6.1 Fair comparisons of treatments should measure outcomes that are important *[Outcomes studied may not be relevant]*
x	6.2 Fair comparisons of treatments in animals or highly selected groups of people may not be relevant *[People studied may not be relevant]*
	6.3 The treatments evaluated in fair comparisons may not be relevant or applicable *[Treatments used may not be relevant]*
	6.4 Results for a selected group of people within fair comparisons can be misleading *[Beware of subgroup analyses]*

Table 1. Short list of key concepts people need to understand to assess claims about treatment effects

Example interview guide version 1

1. Introductions and information about purpose
   (The purpose of the interview is *not* to evaluate how participants perform on the questions, but to get feedback on the questions, i.e. comprehension and relevance

2. Steps of reasoning (per item)
   - What was your response?
   - Can you tell me why you choose this response category? (steps of reasoning)

3. Relevance (per item)
   - What did you think of the scenario?
     - Probe:
       - Names
       - Treatment
       - Outcome
       - Other comments

Example interview guide version 2

Content and format of CLAIM

1. Introductions and information about purpose
   (The purpose of the interview is *not* to evaluate how participants perform on the questions, but to get feedback on the questions, i.e. comprehension and relevance

4. Tell me about the test, what did you think about it?
   - First impression?
   - Similarities to other tests or exams?
   - Like/ doesn't like these differences?

5. What did you think about the instructions?
   - The test include different formats (show examples of SMC's and MMC's), what did you think of them?
   - The test also included some questions about behavior and attitudes, what did you think of them?
   - Do you think these questions fit your age group?
   - Was there any information you felt was missing?

6. What about the content of the test, was it easy or not easy for you to answer the questions?
   - What made it easy or not easy?
   - Were there any words you did not understand or otherwise reacted to?

Literacy / understanding of CLAIM questions

7. Ask the respondent to read question 3 (concept 1.2) and question 14 (concept 2.2) from the CLAIM questionnaire that was used.
   - Was it easy or hard to understand that question?
   - What words were hard to understand?
   - What do you think the right answer is?
   - Why?
   - After explaining any words that they did not understand and helping them to read the question and response options, ask them what they think the right answer is.

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Measuring ability to assess claims about treatment effects: The development of the "Claim Evaluation Tools"

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Keywords: evidence based medicine, shared decision making, health literacy, outcome measurement, multiple-choice, patient education

Abstract

Objectives: To describe the development of the Claim Evaluation Tools, a battery of multiple-choice items, to measure people's ability to understand and apply Key Concepts needed to assess claims about treatment effects.

Setting: Methodologists and members of the community in Uganda, Rwanda, Kenya, Norway, United Kingdom and Australia.

Participants: We used purposeful sampling of people with expertise in the Key Concepts, as well as patients and members of the public from both low and high-income countries in the iterative development of the items. This included four processes: (1) determining the scope of the Claim Evaluation Tools and development of items; (2) expert item review and feedback (n=63); (3) cognitive interviews with children and adult end-users (n=109); and (4) piloting and administrative tests (n=956).

Results: The Claim Evaluation Tools currently consists of between four and six multiple-choice items addressing each of the Key Concepts. Each item begins with a scenario intended to be relevant across contexts, and which can be used for children (from 10 years old and above), adult members of the public as well as health professionals. Methodologists and people with expertise in the Key Concepts judged the items to have face validity, and end-users judged them relevant and acceptable in their settings. In response to feedback from methodologists and end-users, we simplified some text, explained terms where needed, and redesigned formats and instructions.

Conclusion:
The Claim Evaluation Tools include a battery of objective and flexible multiple-choice items, from which researchers, teachers and others can select those that are relevant for specific purposes or populations. These evaluation tools are being managed and made freely available for non-commercial use (on request) through the website Testing Treatments interactive (testingtreatments.org).

Strengths and limitations of this study

- To our knowledge, this is the first attempt to develop a set of evaluation tools that objectively measure people's ability to apply key concepts that people need to know to assess claims about treatment effects
- This development was led by researchers in high and low income countries, including feedback from people with methodological expertise and members of the public
- Based on qualitative and quantitative feedback, the Claim Evaluation Tools were found to have face validity and relevance in the studied contexts
- There are many ways of developing evaluation instruments. We chose to use a pragmatic and iterative approach, but the reliability of the items remains to be tested.

Background

There are endless claims about treatments in the mass media, advertisements and everyday personal communication (1-4). Such claims may include strategies to prevent illness, such as changes in health behaviour or screening: therapeutic interventions or public health and system interventions. Many claims are unsubstantiated, and many patients and professionals alike may neither know whether the claims are true or false, nor have the necessary skills or tools to assess their reliability (5-11). As a result, people who believe and act on unvalidated claims may suffer by doing things that can be harmful, and by not doing things that can help. Either way, personal and societal resources for health care will be wasted (12).

The Informed Healthcare Choices (IHC) project aims to support the use of research evidence by patients and the public, policymakers, journalists and health professionals. The multidisciplinary group responsible for the project includes researchers in six countries - Norway, Uganda, Kenya, Rwanda, United Kingdom and Australia. The project is funded by the Research Council of Norway and has been responsible for developing and evaluating resources for two strategies to improve people's ability to assess claims about treatment effects. The first strategy involves the use of resources in primary schools to improve children's ability to assess claims about treatment effects. The second strategy uses podcasts to improve the ability of parents of primary school children to assess claims about treatment effects. We have piloted these resources in Uganda, Kenya, Rwanda and Norway, and the effects of the resources will be tested in randomized trials in Uganda (13, 14).

The IHC project group began by developing a list of key concepts that people need to understand to assess claims about treatment effects (15). This was done by using the second edition of the book "Testing Treatments" as our starting point, and by doing a literature review to identify key concepts and a review of critical appraisal tools for the public, journalists and health professionals (11, 15). The list of Key Concepts (Table 1) which emerged from this process was revised iteratively based on feedback from members of the project team and the IHC advisory group. The latter includes researchers, journalists, teachers and others with expertise in health literacy, and in teaching or communicating evidence-based health care (15). The resulting set list of concepts is an evolving document hosted by testingtreatments.org, and is reviewed annually to allow for revisions of existing concepts or

identification and inclusion of additional concepts. For the remainder of this paper, these will be referred to as Key Concepts.

Key Concepts included in IHC intervention pilots	Informed Healthcare Choices Concepts
	1. Recognising the need for fair comparisons of treatments *[Fair treatment comparisons are needed]*
x	1.1 Treatments may be harmful *[Treatments can harm]*
x	1.2 Personal experiences or anecdotes (stories) are an unreliable basis for determining the effects of most treatments *[Anecdotes are not reliable evidence]*
x	1.3 A treatment outcome may be associated with a treatment, but not caused by the treatment *[Association is not necessarily causation]*
x	1.4 Widely used or traditional treatments are not necessarily beneficial or safe [Practice is often not based on evidence]
x	1.5 New, brand-named, or more expensive treatments may not be better than available alternatives *[New treatments are not always better]*
x	1.6 Opinions of experts or authorities do not alone provide a reliable basis for deciding on the benefits and harms of treatments *[Expert opinion is not always right]*
x	1.7 Conflicting interests may result in misleading claims about the effects of treatments *[Be aware of conflicts of interest]*
x	1.8 Increasing the amount of a treatment does not necessarily increase the benefits of a treatment and may cause harm *[More is not necessarily better]*
	1.9 Earlier detection of disease is not necessarily better *[Earlier is not necessarily better]*
x	1.10 Hope can lead to unrealistic expectations about the effects of treatments *[Avoid unrealistic expectations]*

x	1.11 Beliefs about how treatments work are not reliable predictors of the actual effects of treatments *[Theories about treatment can be wrong]*
x	1.12 Large, dramatic effects of treatments are rare *[Dramatic treatment effects are rare]*
	2. Judging whether a comparison of treatments is a fair comparison *[Treatment comparisons should be fair]*
x	2.1 Evaluating the effects of treatments requires appropriate comparisons *[Treatment comparisons are necessary]*
x	2.2 Apart from the treatments being compared, the comparison groups need to be similar (i.e. 'like needs to be compared with like') *[Compare like with like]*
	2.3 People's experiences should be counted in the group to which they were allocated *[Base analyses on allocated treatment]*
x	2.4 People in the groups being compared need to be cared for similarly (apart from the treatments being compared) *[Treat comparison groups similarly]*
x	2.5 If possible, people should not know which of the treatments being compared they are receiving *[Blind participants to their treatments]*
x	2.6 Outcomes should be measured in the same way (fairly) in the treatment groups being compared *[Assess outcome measures fairly]*
x	2.7 It is important to measure outcomes in everyone who was included in the treatment comparison groups *[Follow up everyone included]*
	3. Understanding the role of chance *[Understand the role of chance]*

x	3.1 Small studies in which few outcome events occur are usually not informative and the results may be misleading *[Small studies may be misleading]*
	3.2 The use of p-values to indicate the probability of something having occurred by chance may be misleading; confidence intervals are more informative *[P-values alone can be misleading]*
	3.3 Saying that a difference is statistically significant or that it is not statistically significant can be misleading *['Significance' may be misleading]*
	4. Considering all of the relevant fair comparisons *[Consider all the relevant evidence]*
x	4.1 The results of single tests of treatments can be misleading *[Single studies can be misleading]*
	4.2 Reviews of treatment tests that do not use systematic methods can be misleading *[Unsystematic reviews can mislead]*
	4.3 Well done systematic reviews often reveal a lack of relevant evidence, but they provide the best basis for making judgements about the certainty of the evidence *[Consider how certain the evidence is]*
	5. Understanding the results of fair comparisons of treatments *[Understand the results of comparisons]*
x	5.1 Treatments may have beneficial and harmful effects *[Weigh benefits and harms of treatment]*
	5.2 Relative effects of treatments alone can be misleading *[Relative effects can be misleading]*
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	6. Judging whether fair comparisons of treatments are relevant *[Judge relevance of fair comparisons]*
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	6.3 The treatments evaluated in fair comparisons may not be relevant or applicable *[Treatments used may not be relevant]*
	6.4 Results for a selected group of people within fair comparisons can be misleading *[Beware of subgroup analyses]*

Table 1. Short list of key concepts people need to understand to assess claims about treatment effects

A systematic mapping review conducted as part of the IHC project concluded that the list of Key Concepts has wide interdisciplinary relevance, including in research areas such as use of decision support tools, training in evidence-based healthcare and critical appraisal, promotion of informed consent through improving understanding of trial methods, and school science education (16). Although, the common goal of these research fields is to facilitate informed decision-making, the research is heterogeneous. Partly overlapping and sometimes parallel research areas have been responsible for studies focusing on specific concepts, such as Key Concept 5.1 "weighing the benefits and harms of a treatment", or the Key Concept 2.1 "Treatment comparisons are necessary" (16). Furthermore, we have not been able to identify any previous consensus or conceptualisation of Key Concepts critical to understanding the effects of treatments, nor have we found any instrument that measures understanding of all of the Key Concepts we have identified. Based on the findings of our systematic review, we concluded that the teaching resources we identified, and the procedures and instruments used to map or evaluate people's understanding, covered only a handful of the Key Concepts (16).

In summary, we agreed that there existed a need to develop measurement instruments to assess people's understanding of the Key Concepts. Accordingly, we set out to develop the Claim Evaluation Tools to serve as the primary outcome measures for evaluating the effects of the IHC primary school resources and the IHC podcast series in randomised trials. Although our primary target groups were children and adults in Uganda, we wanted to create a set of tools that would also be relevant in other

settings. Four important elements underpinned the development of the Claim Evaluation Tools. These tools should (i) objectively measure people's ability to apply the Key Concepts; (ii) be flexible and easily adaptable to particular populations or purposes; (iii) be rigorously evaluated; and (iv) be freely available for non-commercial use by others interested in mapping or evaluating people's ability to apply some or all of the Key Concepts.

Objective

To describe the development of the Claim Evaluation Tools, a set of objective and flexible tools to measure people's ability to apply Key Concepts needed to assess claims about treatment effects.

Methods

The development of the Claim Evaluation Tools included four processes, using qualitative and quantitative methods, over three years (2013-2016): (i) determining the scope of the Claim Evaluation Tools and development of items; (ii) expert item review and feedback (face validity); (iii) cognitive interviews with end-users - including children, parents, teachers and patient representatives - to achieve relevance, understanding and acceptability; and (iv) piloting and practical administrative tests of the items in different contexts. For clarity, the methods and findings of each of these processes are described separately. However, development was iterative, with the different processes overlapping and feeding into each other. Researchers affiliated with the ICH project in six countries (Uganda, Norway, Rwanda, Kenya, UK and Australia) contributed to the development of the Claim Evaluation Tools. An overview of the development process is presented in Figure 1. The roles and purposes of the different research teams are described below.

Please enter Figure 1. Overview and timeline of the development process

Determining the scope of the Claim Evaluation Tools and the development of items

The Claim Evaluation Tools working group, with members of the IHC group from Norway, UK and Uganda (AA, AO, IC, DS, AN), had principal responsibility for agreeing on content, including the instructions and wording of individual items. The development and evaluations were coordinated by the

team in Norway (AA and AO). The scope of the Claim Evaluation Tools was based on the list of Key Concepts (15)(see table 1).

Our vision for the Claim Evaluation Tools was that they should not be a standard fixed questionnaire, but rather a flexible tool including a battery of items, of which some may be more relevant to certain populations or purposes. Multiple-choice items are well suited for assessing application of knowledge, interpretation and judgements. In addition, they help problem-based learning and practical decision making (17). Each of the items we created opened with a scenario leading to a treatment claim and a question, which was followed by a choice of answers. We developed the items using two multiple-choice formats - single multiple-choice items (addressing one concept), and multiple true-false items (addressing several concepts in the same item). We developed all items with "one-best answer" response options (17), the options being placed on a continuum, with one answer being unambiguously the "best" and the remaining options as "worse". All items were developed in English.

The initial target groups for the Claim Evaluation Tools were fifth grade children (10 to 12 year-olds in the next to last year of primary school) and adults (parents of primary school children) in Uganda. However, throughout the development process, our goal was to create a set of tools that would be relevant in other settings. Accordingly, we used conditions and treatments that we judged likely to be relevant across different country contexts. Where necessary, we explained the conditions and treatments used in the opening scenarios. We also decided to avoid conditions and treatments that might lead the respondents to focus on the specific treatments (about which they might have an opinion or prior knowledge), rather than on the concepts.

Exploring relevance, understanding and acceptability of items

In order to get feedback on the relevance, understanding and acceptability of items, we used purposeful sampling of people with expertise in the Key Concepts, as well as patients and members of the public from both low and high-income countries (18-21).

Item review and feedback by methodologists (face validity)First we circulated the complete set of multiple-choice items to members of the IHC advisory group and asked them to comment on their applicability and face validity as judged against the list of Key Concepts. Each advisory group member

was assigned a set of three concepts, with associated items. A feedback form asked them to indicate to what extent they felt each item addressed the relevant Key Concept using the response options "Yes", "No" or "Uncertain", together with any open-ended comments. Any items that were tagged as "No" or "Uncertain" by one or more of those consulted were considered for revision.

On two occasions, we also invited four methodologists associated with the Norwegian research group and with expertise in the concepts to respond to the full set of items. These experts were not involved in the project or the development of the Claim Evaluation Tools. In this element of the evaluation, the response options were randomised and the methodologists were blinded to the correct answers. They were asked to choose what they judged to be the best answer to each item's question, and were encouraged to provide open-ended comments and flag any problems they identified. Any item in which one or more of the methodologists failed to identify the 'best answer' was considered for potential revision.

We also invited people with expertise in the Key Concepts from all project partner countries to provide feedback on several occasions throughout the development of the tools. In addition to providing general feedback, an important purpose of reviewing the items in these different contexts was to identify any potential culturally inappropriate terminology and examples (conditions and treatments).
For all of this feedback, suggested revisions and areas of improvement were summarised in an Excel worksheet in two categories: (i) comments of a general nature relating to all items, such as choice of terminology or format, and (ii) comments associated with specific items.

Cognitive interviews with end-users on relevance of examples, understanding and acceptability

After the Claim Evaluation Tools working group and the IHC project group agreed on the instrument content, we undertook cognitive interviews with individuals from our potential target groups in Uganda, Australia, UK and Norway (22-24). Country representatives of the IHC project group recruited participants in their own contexts, based on purposeful sampling, in consultation with the Norwegian coordinator (AA). Since Uganda has been the principal focus of our interest, this was always our starting and ending point. In total, four rounds of interviews took place in Uganda. The interviews in Norway, UK and Australia were done to assess relevance within these settings.

The overall objective of these interviews was to obtain feedback from potential end-users on the relevance of the scenarios (such as the conditions and treatments used as examples), and the intelligibility and acceptability of the scenarios, formats and instructions. This was particularly important because the items were to be used for children as well as adults. Throughout this process, we also piloted and user-tested several versions of the items (designs and instructions). Failure to address these issues when developing the items might increase the likelihood of missing responses, "guessing" or other measurement errors. For example, we wanted to minimise the influence of people's cultural background on how they responded to the multiple-choice items. The effects of such confounders are being addressed in the last phase of the development in the psychometric testing and Rasch analysis of the questionnaire (25). The interviews were intended to help prevent such problems relatively early in the evaluation process.

Interviews were performed iteratively between October 2014 and January 2016, allowing for changes to the items between interviews. All interviews were conducted using a semi-structured interview guide (Appendix 1) inspired by previous research (22-24). As part of the interviews, the participants were given a sample set of the multiple-choice items and asked to respond to these. The interviews addressed questions raised during development of the items about the format of questions or the terminology used in the questions. In response, the interview guide was revised and multiple-choice items changed when relevant.

When conducting the interviews, we used the methods of 'think aloud' and 'verbal probing', two approaches to cognitive interviewing (23). With "think aloud" the respondent is asked to explain how they arrived at their response to each item. Such interviews are less prone to bias because of the more limited role of the interviewer. However, some respondents have difficulty in verbalising their thought processes, and in these circumstances we followed up with "verbal probing", which uses questions that the interviewer asks after the respondent has completed each of the items. Following each item the interviewer began with the "think aloud" method by asking respondents how they arrived at their response before asking more specific questions, as necessary.

We audio recorded interviews when possible, and we aimed to have two people doing the interviews (with one person taking notes and the other person being the lead-interviewer). For practical reasons

this was not always possible. Each country representative summarised the key points from the interviews. Suggested revisions and areas of improvement were fed back to the Norwegian coordinator who entered these into the same Excel spreadsheet as the feedback from the methodologists.

Piloting and administrative tests

We conducted five pilots of administering sets of the Claim Evaluation Tools to our target groups. The first pilot (March-April 2015) was an administrative test in a primary school in Uganda. This test was performed with a group of children who had taken part in a pilot of the IHC primary school resources as part of the IHC project, and with a comparison group who had not received training in the Key Concepts (in total 169 children). In this pilot, we administrated all items addressing 22 of the 32 Key Concepts (see Table 1). The reason for this cut-off was that these 22 concepts were targets of the intervention in the first draft of the IHC resources. Because of the large number of items to be tested, they were divided into four sets or questionnaires. These questionnaires were designed to be similar to the questionnaires to be used in the IHC trials, and would thus give us some feedback on how administrating a set of the Claim Evaluation Tools would work in practice, in a classroom setting. We also wanted to explore potential problems with incorrectly completed responses (through visual inspection of the responses).

The second pilot focused solely on format testing (September to December 2015). Three different sets of formats were tested. The formats were designed based on lessons learned from the feedback from the methodologists, interviews with end-users, and through visual inspection of the data collected in the first pilot. We recruited people in Uganda, Rwanda and Kenya to do this (N=204), using purposeful sampling, including children and adults. The same set of Claim Evaluation Tools was kept constant across the three formats. The outcome of this test was evaluated based on the number of missing or incorrectly completed responses per item.

The third pilot (October to November 2015) and fourth pilot (November to December 2015) were conducted with Ugandan primary school children (in two schools) and their parents. The final pilot (December 2015) took place in Norway and included primary school children in one school. In all of these three pilots, we recruited children and adults who had taken part in the piloting of IHC primary school materials and podcast, and children and adults who had received no such intervention. The first objective of these pilots was to compare the ability of people who had and had not received training to

apply the Key Concepts. This provided an indication of the sample-sizes that would be needed for the IHC randomised trials. The second objective of the pilots was to estimate the frequency of missing responses as an indication of problems of understanding the item's instructions. For these purposes, we used only one set of the Claim Evaluation Tools (addressing the 22 basic concepts). The reason for this was that we needed to reduce the number of items to gain statistical power in these small samples. In total, 197 children took part in the Ugandan school pilot, 301 parents took part in the podcast pilot, and 85 children took part in the Norwegian school pilot. The results of these pilots were summarised by calculating mean correct responses to all items addressing the same concept. We also calculated missing responses per item.

Results

Feedback from experts and members of the target groups

Face validity, perceived relevance and fit to the target group

We created 6 to 8 items per Key Concept, predicting that about half of these would be removed through feedback from experts, end-users and through the final psychometric testing and Rasch analysis (25). Thirteen members of the IHC advisory group provided feedback on 135 items. Only one of these items was judged to have addressed the concept inadequately, and a further 20 items were deemed to be partly relevant. Feedback from the two blinded assessments of the Claim Evaluation Tools provided by the methodologists supported the items relevance to the Key Concepts.

Another important element of the feedback from the test-run with the methodologists was that the 'distance' between the "best" option and the "worse" options was considered too small, with the result that the items were too difficult. Based on this feedback, we revised the 'distractors' in the 'worse' options to make them more "wrong". The cognitive interviews with members of our target group also suggested that the items were too 'text heavy' and needed to be simplified. In relation to this, low-literacy skill was also raised as a potential barrier by experts and end-users in Uganda. Consequently, we tried hard to make the scenarios as simple as possible without losing key content.

The end-users and the methodologists consulted in each country (Uganda, Kenya, Rwanda, UK, and Australia), also provided comments on terminology, as well as on the examples used in the scenarios that they felt might not be appropriate or would need to be explained. The Claim Evaluation Tools

working group considered these comments and revised the items. When we were unable to avoid using certain terms (for example, “research study”), we added explanations. Our rationale was that some terms would present a barrier to understanding the items, but were not considered to be part of the learning objectives associated with the Key Concepts. For some other terms, we used alternatives deemed acceptable by researchers, other experts and members of the target groups in each country (Uganda, Kenya, Rwanda, UK, Australia and Norway). This process involved feeding back all changes to experts and end-users in an iterative process with continuous revisions.

Please enter Figure 2. Example of formats

Preference of format and missing responses

Important objectives of the interviews with end-users were to obtain their preferences on format, to follow the steps of their reasoning when responding to the items and to assess their understanding of the items’ instructions. The main message was that people preferred a mix of the simple-multiple choice and multiple true-false formats to make the questionnaire more interesting. The items were otherwise well-received. The general feedback from all the different country settings was that the formats were acceptable, recognisable and similar to multiple-choice formats they had encountered in other settings.

Based on verbal feedback, as well as visual inspection of how people responded to the items in the pilots, two potential ways were identified to prevent missing or incorrectly completed responses. The first was to avoid unnecessary open spaces in the items, because respondents tended to use these to write open-ended answers to the questions. The second was to avoid using check boxes, because respondents would check more than one check-box. These issues are easily dealt with when questionnaires are administrated electronically, but are a problem in paper-administered questionnaires. Examples of incorrectly filled in multiple-choice questions are shown in Figure 3. Figure 2 shows the design changes used to avoid these problems.

Please enter Figure 3. Examples of incorrectly filled in multiple-choice questions

Pilots and administrative tests

The first school pilot in Uganda (March- April 2015) revealed problems with instructions and formats that resulted in mean missing responses of 20-40% of the items. The revised designs (Figure 2) we tested in the second pilot in Uganda, Rwanda and Kenya (September to December 2015) greatly improved people's responses to the questionnaire, reducing missing or incorrectly completed responses to between <4% of items. Based on this pilot, we made final revisions and decided on the formats to be used in the subsequent pilots.

The third, fourth and fifth pilots conducted in Uganda and Norway (October to December 2015), confirmed the appropriateness of the formats, and missing or incorrectly completed responses were <2%. These pilots also confirmed that respondents took between 30 to 60 minutes to complete a questionnaire that included demographic questions and a sample of 29 items. The participants' correct responses per Key Concept are shown in Figure 4. The participants who had taken part in piloting of the IHC resources did slightly better than others for most of the Key Concepts.

Please enter Figure 4. Distribution of correct answers in pilots

Discussion

Developing a new evaluation instrument is not straightforward, and requires rigorous testing using qualitative and quantitative methods (26). There are many ways of doing this. We chose to use a pragmatic and iterative approach, involving feedback from experts and end-users and continuous revisions. This development work was made possible by a multidisciplinary, international collaboration including people from high and low-income countries. Despite differences between countries, enabling people to assess treatment claims in their daily lives is a challenge across all countries. The Claim Evaluation Tools were developed to be used in the IHC project's trials, but also to provide a flexible measurement tool for others interested in mapping or evaluation of people's ability to apply Key Concepts in assessing claims about treatment effects. Instead of a "set" instrument, the Claim Evaluation Tools offers the potential to tailor an instrument for specific purposes and target groups. This is useful also for others as the Key Concepts included in interventions may vary, and in this way, the end-users are not forced to respond to unnecessary questions addressing concepts that have not been part of the intervention. The Claim Evaluations Tools will be made available on demand through the website

testingtreatments.org, and we envision that educators, researchers and others can create their own "tests" that fit their needs and contexts.

An international group of people with relevant expertise considered that the items we developed appropriately addressed the Key Concepts we had identified. The items were considered by end-users to be acceptable in the four settings in which we conducted interviews: Uganda, Norway, UK and Australia. Certain terms were identified as problematic, so we either simplified the terminology or added explanations. Based on lessons learned from interviews and pilots, we redesigned formats that had led to missing or incorrectly completed responses, with a resultant fall in the frequency of these problems to less than 2%.

Feedback from methodologists and end-users indicated that some items were rather difficult and text-heavy. Literacy was also raised as a potential barrier. In response to these findings, we tried to shorten texts, to avoid unnecessarily difficult terminology, and to add explanations where necessary. This emphasised the importance of measuring literacy skills when administrating the Claim Evaluation Tools in certain settings, as this might impact how well people perform on the items and act as a potential confounder.

Many of the instruments that have been developed to assess people's critical-appraisal skills have relied on self-report by respondents of their own abilities (subjective measurements). Typical examples are the many health literacy instruments, such as the European Health Literacy Survey (HLS-EU)(27) and instruments used to assess competence in evidence-based medicine (28). Self-assessed abilities can be difficult to interpret, and have been found to have a weak association with objectively measured knowledge and skills (29-31). It can also be argued that such instruments measure the confidence of respondents in their own ability rather than their knowledge or actual ability. Although improved confidence in one's own abilities may be a relevant and important effect of an intervention, our primary objective was to develop an instrument to measure objective knowledge and actual ability to apply the Key Concepts when confronted with claims about treatments effects.

This paper describes the development and initial steps of validation of items addressing all of the 32 Key Concepts including four phases. In the last phase, we also did some pilot testing for which items

referring to 22 of the 32 Key Concepts were included. The objectives of these pilots were several, but for development purposes, we wanted to do practical administrative tests to explore the understanding of formats and timing of Claim Evaluation Tools "sample tests". Which Key Concepts were targeted in these pilots, were judged to be of little importance as the items addressing the different key Concepts use the same formats and are equal in length and language. It is however important to note that this paper does not describe the reliability of the Claim Evaluation Tools. This requires rigorous psychometric testing including Rasch analysis, and is described in a separate paper which also provides information about the difficulty of the items, and other properties of the items as described by the Rasch analysis (25).

Conclusion

We developed the Claim Evaluation Tools to evaluate people's ability to assess claims about the effects of treatments. As far as we are aware, this is currently the only evaluation instrument designed to address all of the Key Concepts we believe people need to know to assess claims about treatment effects. This work is the result of a multidisciplinary, international collaboration including high and low-income countries. We have used a pragmatic and iterative approach, involving feedback from experts and end-users and continuous revisions. Although the Claim Evaluation Tools have been developed primarily to be used as part of the IHC project in Uganda, we believe they should be useful for others interested in evaluating people's ability to apply the Key Concepts. Feedback from experts and end-users in Uganda, Kenya, Rwanda, Norway, UK and Australia supports our hope that they will be found relevant in other contexts.

The Claim Evaluation Tools is a flexible instrument including a battery of items from which researchers can select those relevant for specific populations or purposes. The Claim Evaluation Tools currently consist of four to six multiple-choice items addressing each of the concepts in the list of Key Concepts. However, we anticipated that the Claim Evaluation Tools will continue to evolve. Maintenance and revision of the Claim Evaluation Tools will reflect changes in the list of Key Concepts, as well as additions or changes made on the basis of further feedback, pilot testing, cognitive interviews and Rasch analyses

with different target groups and in different settings. The Claim Evaluation Tools will be hosted on the Testing Treatments interactive website and managed by the Claim Evaluation Tools working group. On request, all items are freely available for non-commercial use.

Authors' Contributions

AA, ØG, AO wrote the protocol and the IHC group provided comments on the protocol. AA coordinated all of the development and evaluation process with support from AO. AA, DS, AN, IC, AO and MO drafted the items with input from the IHC group. AA, IC and AO were responsible for revising the items iteratively based on the feedback received through the different processes. SR and AA were responsible for the format designs. AA and KO approached the IHC advisory group and other methodologists for feedback. AN, DS, LC, AA, MO, SR, TH and MK conducted the interviews with end-users. AN, DS, KO, LAM, MM, LAM, MK, NS, AMU and AA were involved in pilots and administrative tests in Uganda, Kenya, Rwanda and Norway respectively. AA analysed the data from the pilots. AA authored this manuscript with significant input from the rest of the IHC group.

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Ethical approval

Ethical approval was sought by the IHC project representatives in each country.

Data sharing statement

All data are published as part of this study. All Claim Evaluation Tools are available upon request for non-commercial use.

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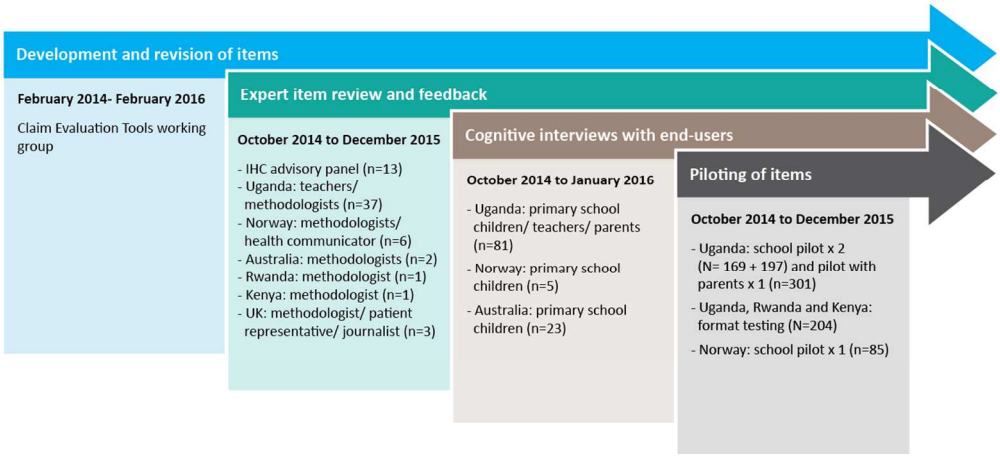

Concept 1.3
Judith wants smoother skin. The younger girls in her school have smoother skin than the older girls. Judith thinks this is because the younger girls use cream on their skin to make the skin smoother.

Question: **Based on this link between using cream and smooth skin, is Judith correct?**

Options:

A) It is not possible to say. It depends on how many younger and older girls there are

B) It is not possible to say. There might be other differences between the younger and older girls

C) Yes, because the younger girls use cream on their skin and they have smoother skin

D) No, Judith should try using the cream herself to see if it works for her

Answer: ☐

Concepts	When you are sick, sometimes people say that something - a treatment - is good for you. It is hard to know whether what they say is true. **Do you agree or disagree with each of the following statements?**		
	For each statement below, use ✓ to mark whether you agree or disagree.		
	Statements:	**Agree**	**Disagree**
1.1	James says that a treatment cannot be helpful and harmful at the same time		
1.2	Peter says that if a treatment works for one person, the treatment will help others too		
1.3	Alice says that if some people try the treatment and feel better, this means that the treatment helps		

173x199mm (300 x 300 DPI)

George has a stomachache. The last time George had a stomachache was two months ago. That time, he drank some hot milk and after an hour, his stomachache was gone. Therefore, George says hot milk cures stomachaches.

QUESTION:

Is George right?

No

PLEASE CIRCLE THE ANSWER THAT YOU THINK IS THE BEST

A. No, it is only based on George's own experience treating a stomachache with hot milk.

No

B. Not possible to say, the fact that he improved could have happened by chance

Yes

C. Yes, George's own experience is evidence enough for assessing the effects of hot milk for treating a stomachache

No

D. No, it is important to ask what other people think too, not just George

Yes.

Outside the city where Paul lives, there is a mine. The miners often get coughs. For many years, most of the miners have used whiskey mixed in water to reduce the pain from their coughs. Therefore, Paul says that water with a little whiskey is an effective and harmless treatment for a cough, since many people have used it for a long time.

QUESTION:

Do you agree with Paul?

PLEASE CIRCLE THE ANSWER THAT YOU THINK IS THE BEST

A. No, just because whiskey mixed in water has been used by many, does not mean that it is harmless

B. No, just because whiskey mixed in water have been used a lot, does not mean that it is the best treatment

C. Yes, the miners have used whiskey mixed in water to treat their coughs for many years and they would not use the treatment for many years if it were not beneficial and harmless

D. Not possible to say, Paul should try whiskey mixed in water on himself to know for sure that he is correct

. **Andrew has difficulty breathing. He goes to the shop to buy medicine. The shopkeeper gives Andrew tablet and says it will help improve his breathing. Andrew thinks if taking one tablet will help him, then taking two tablets will help him even more. Should Andrew take one or two tablets?** ***Mark an X in the box for the best answer (only one)***

☒ **One. Taking two is likely to be harmful and more expensive**

☐ **One. Taking more than one will not necessarily be more helpful and may be harmful**

☒ **One. Andrew should listen to the shopkeeper's advice**

☐ **Two. Taking more than one will probably help him get better more quickly and is unlikely to be harmful**

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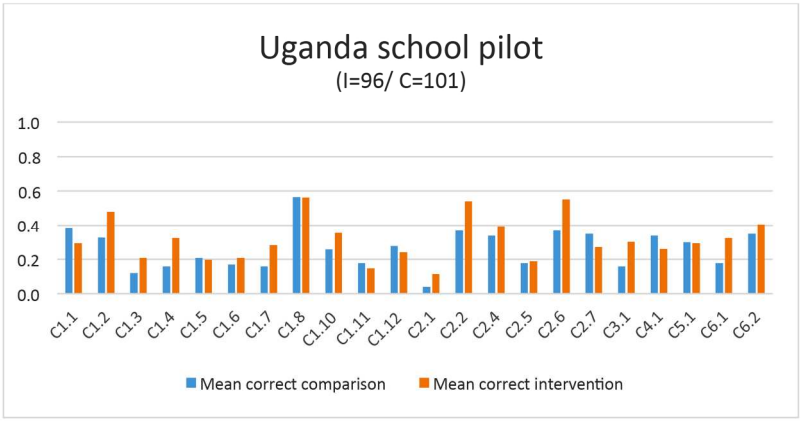

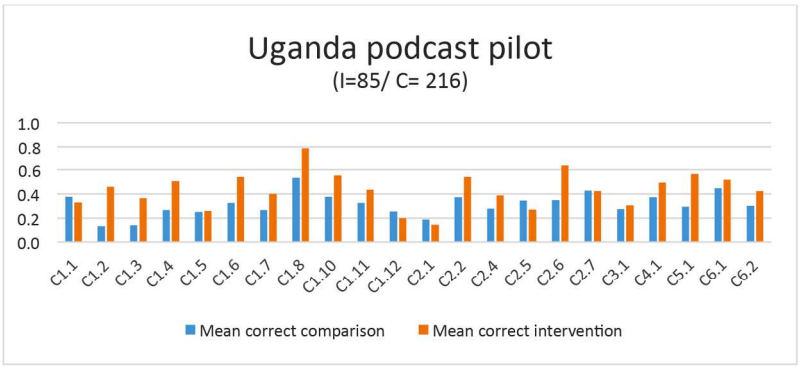

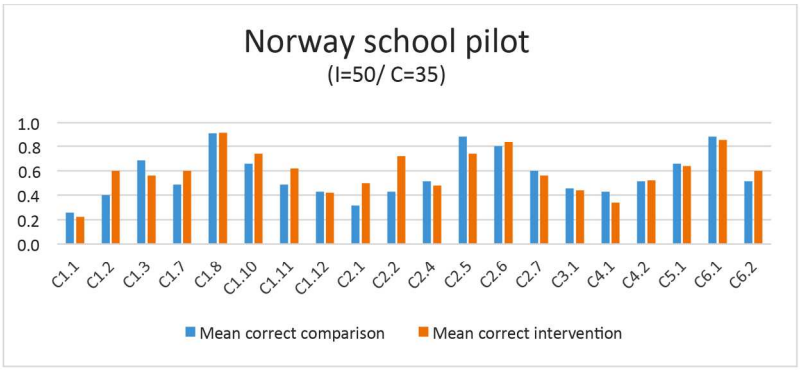

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Example interview guide version 1

1. Introductions and information about purpose
   (The purpose of the interview is *not* to evaluate how participants perform on the questions, but to get feedback on the questions, i.e. comprehension and relevance

2. Steps of reasoning (per item)
   - What was your response?
   - Can you tell me why you choose this response category? (steps of reasoning)

3. Relevance (per item)
   - What did you think of the scenario?
     - Probe:
       - Names
       - Treatment
       - Outcome
       - Other comments

Example interview guide version 2

Content and format of CLAIM

1. Introductions and information about purpose
   (The purpose of the interview is *not* to evaluate how participants perform on the questions, but to get feedback on the questions, i.e. comprehension and relevance

4. Tell me about the test, what did you think about it?
   - First impression?
   - Similarities to other tests or exams?
   - Like/ doesn't like these differences?

5. What did you think about the instructions?
   - The test include different formats (show examples of SMC's and MMC's), what did you think of them?
   - The test also included some questions about behavior and attitudes, what did you think of them?
   - Do you think these questions fit your age group?
   - Was there any information you felt was missing?

6. What about the content of the test, was it easy or not easy for you to answer the questions?
   - What made it easy or not easy?
   - Were there any words you did not understand or otherwise reacted to?

Literacy / understanding of CLAIM questions

7. Ask the respondent to read question 3 (concept 1.2) and question 14 (concept 2.2) from the CLAIM questionnaire that was used.
   - Was it easy or hard to understand that question?
   - What words were hard to understand?
   - What do you think the right answer is?
   - Why?
   - After explaining any words that they did not understand and helping them to read the question and response options, ask them what they think the right answer is.

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Measuring ability to assess claims about treatment effects: The development of the "Claim Evaluation Tools"

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Keywords: evidence based medicine, shared decision making, health literacy, outcome measurement, multiple-choice, patient education

Abstract

Objectives: To describe the development of the Claim Evaluation Tools, a set of flexible items to measure people's ability to assess claims about treatment effects.

Setting: Methodologists and members of the community (including children) in Uganda, Rwanda, Kenya, Norway, United Kingdom and Australia.

Participants: In the iterative development of the items we used purposeful sampling of people with training in research methodology, such as teachers of evidence based medicine, as well as patients and members of the public from both low and high-income countries. Development consisted of four processes: (1) determining the scope of the Claim Evaluation Tools and development of items; (2) expert item review and feedback (n=63); (3) cognitive interviews with children and adult end-users (n=109); and (4) piloting and administrative tests (n=956).

Results: The Claim Evaluation Tools database currently includes a battery of multiple-choice items. Each item begins with a scenario intended to be relevant across contexts, and which can be used for children (from 10 years old and above), adult members of the public, and health professionals. People with expertise in research methods judged the items to have face validity, and end-users judged them relevant and acceptable in their settings. In response to feedback from methodologists and end-users, we simplified some text, explained terms where needed, and redesigned formats and instructions.

Conclusion:
The Claim Evaluation Tools database is a flexible resource from which researchers, teachers and others can design measurement instruments to meet their own requirements. These evaluation tools are being managed and made freely available for non-commercial use (on request) through Testing Treatments *interactive* (testingtreatments.org).

Strengths and limitations of this study

- As far as we are aware, this is the first attempt to develop a set of evaluation tools that objectively measure people's ability to assess treatment claims
- This development resulted from collaboration among researchers in high and low income countries, and included feedback from people with methodological expertise as well as members of the public
- Based on qualitative and quantitative feedback, the Claim Evaluation Tools were found to have face validity and relevance in the contexts studied
- There are many ways of developing evaluation instruments. We chose to use a pragmatic and iterative approach, but the reliability of the items remains to be tested.

Background

There are endless claims about the effects of treatments in the mass media, advertisements and everyday personal communication (1-4). Such claims may include strategies to prevent illness, such as changes in health behaviour or screening; therapeutic interventions; or public health and system interventions. Many claims are unsubstantiated, and patients and professionals alike may neither know whether the claims are true or false, nor have the necessary skills or tools to assess their reliability (5-11). As a result, people who believe and act on unvalidated claims may suffer by doing things that can be harmful, and by not doing things that can help. Either way, personal and societal resources for health care will be wasted (12).

The Informed Health Choices (IHC) project aims to support the use of research evidence by patients and the public, policymakers, journalists and health professionals. The multidisciplinary group responsible for the project includes researchers in six countries - Norway, Uganda, Kenya, Rwanda, United Kingdom and Australia. The project is funded by the Research Council of Norway. It has been responsible for developing educational resources for schoolchildren and their parents in Uganda, with the objective of improving their ability to assess claims about treatment effects (13, 14). Evaluation of the effects of these educational resources is taking place in two randomised trials (the IHC trials) in 2016 and 2017.

As our starting point for developing these educational interventions, the IHC group began by developing a list of key concepts that people need to understand to assess claims about treatment effects (15). The generation of this list was done by using the second edition of the book "Testing Treatments"; by doing a literature review to identify key concepts; and by reviewing critical appraisal tools for the public, journalists and health professionals (11, 15). The list of concepts (Table 1) that emerged from this process was revised iteratively, based on feedback from members of the project team and the IHC advisory group. The latter includes researchers, journalists, teachers and others with expertise in health literacy, and in teaching or communicating evidence-based health care (15). The resulting set list of concepts serves as a syllabus or curriculum from which researchers, teachers and others may develop interventions. It is an evolving document hosted by testingtreatments.org. The list will be subject to annual review to allow for revisions of existing concepts or identification and inclusion of additional concepts. For the remainder of this paper, we will refer to these as Key Concepts.

In our search for appropriate outcome measures for the IHC randomized trials, we conducted a systematic mapping review of interventions and outcome measures used for evaluating understanding of one or more of the Key Concepts (16). Based on the findings of this review, we concluded that the procedures and instruments available covered only a handful of the Key Concepts we had identified, and were not suitable for our purposes (16). Accordingly, we set out to develop the Claim Evaluation Tools to serve as the primary outcome measure of the IHC randomized trials evaluating the effects of the educational resources.

Although our primary target groups were children and adults in Uganda, we wanted to create a set of tools - a database - which would be relevant in other settings. Four important elements underpinned the development of the Claim Evaluation Tools. These tools should (i) measure objectively people's ability to apply the Key Concepts (i.e not rely on self-assessment of own abilities); (ii) be flexible and easily adaptable to particular populations or purposes; (iii) be rigorously evaluated; and (iv) be freely available for non-commercial use by others interested in mapping or evaluating people's ability to apply some or all of the Key Concepts.

Table 1. Short list of Key Concepts that people need to understand to assess claims about treatment effects

Informed Health Choices Concepts
1. Recognising the need for fair comparisons of treatments *[Fair treatment comparisons are needed]*
1.1 Treatments may be harmful *[Treatments can harm]*
1.2 Personal experiences or anecdotes (stories) are an unreliable basis for determining the effects of most treatments *[Anecdotes are not reliable evidence]*
1.3 A treatment outcome may be associated with a treatment, but not caused by the treatment *[Association is not necessarily causation]*
1.4 Widely used or traditional treatments are not necessarily beneficial or safe [Practice is often not based on evidence]

1.5 New, brand-named, or more expensive treatments may not be better than available alternatives *[New treatments are not always better]*
1.6 Opinions of experts or authorities do not alone provide a reliable basis for deciding on the benefits and harms of treatments *[Expert opinion is not always right]*
1.7 Conflicting interests may result in misleading claims about the effects of treatments *[Be aware of conflicts of interest]*
1.8 Increasing the amount of a treatment does not necessarily increase the benefits of a treatment and may cause harm *[More is not necessarily better]*
1.9 Earlier detection of disease is not necessarily better *[Earlier is not necessarily better]*
1.10 Hope can lead to unrealistic expectations about the effects of treatments *[Avoid unrealistic expectations]*
1.11 Beliefs about how treatments work are not reliable predictors of the actual effects of treatments *[Theories about treatment can be wrong]*
1.12 Large, dramatic effects of treatments are rare *[Dramatic treatment effects are rare]*
2. Judging whether a comparison of treatments is a fair comparison *[Treatment comparisons should be fair]*
2.1 Evaluating the effects of treatments requires appropriate comparisons *[Treatment comparisons are necessary]*
2.2 Apart from the treatments being compared, the comparison groups need to be similar (i.e. 'like needs to be compared with like') *[Compare like with like]*
2.3 People's experiences should be counted in the group to which they were allocated *[Base analyses on allocated treatment]*
2.4 People in the groups being compared need to be cared for similarly (apart from the treatments being compared) *[Treat comparison groups similarly]*
2.5 If possible, people should not know which of the treatments being compared they are receiving *[Blind participants to their treatments]*

2.6 Outcomes should be measured in the same way (fairly) in the treatment groups being compared *[Assess outcome measures fairly]*
2.7 It is important to measure outcomes in everyone who was included in the treatment comparison groups *[Follow up everyone included]*
3. Understanding the role of chance *[Understand the role of chance]*
3.1 Small studies in which few outcome events occur are usually not informative and the results may be misleading *[Small studies may be misleading]*
3.2 The use of p-values to indicate the probability of something having occurred by chance may be misleading; confidence intervals are more informative *[P-values alone can be misleading]*
3.3 Saying that a difference is statistically significant or that it is not statistically significant can be misleading *['Significance' may be misleading]*
4. Considering all of the relevant fair comparisons *[Consider all the relevant evidence]*
4.1 The results of single tests of treatments can be misleading *[Single studies can be misleading]*
4.2 Reviews of treatment tests that do not use systematic methods can be misleading *[Unsystematic reviews can mislead]*
4.3 Well done systematic reviews often reveal a lack of relevant evidence, but they provide the best basis for making judgements about the certainty of the evidence *[Consider how certain the evidence is]*
5. Understanding the results of fair comparisons of treatments *[Understand the results of comparisons]*
5.1 Treatments may have beneficial and harmful effects *[Weigh benefits and harms of treatment]*

5.2 Relative effects of treatments alone can be misleading *[Relative effects can be misleading]*
5.3 Average differences between treatments can be misleading *[Average differences can be misleading]*
6. Judging whether fair comparisons of treatments are relevant *[Judge relevance of fair comparisons]*
6.1 Fair comparisons of treatments should measure outcomes that are important *[Outcomes studied may not be relevant]*
6.2 Fair comparisons of treatments in animals or highly selected groups of people may not be relevant *[People studied may not be relevant]*
6.3 The treatments evaluated in fair comparisons may not be relevant or applicable *[Treatments used may not be relevant]*
6.4 Results for a selected group of people within fair comparisons can be misleading *[Beware of subgroup analyses]*

Objective

To describe the development of the Claim Evaluation Tools, a set of flexible tools to measure people's ability to assess claims about treatment effects.

Methods

The development of the Claim Evaluation Tools included four processes, using qualitative and quantitative methods, over three years (2013-2016). These phases were: (i) determining the scope of the Claim Evaluation Tools and development of items; (ii) an expert item review and feedback (face validity); (iii) cognitive interviews with end-users - including children, parents, teachers and patient representatives - to assess relevance, understanding and acceptability; and (iv) piloting and practical administrative tests of the items in different contexts. For clarity, we have described the methods and findings of each of these processes separately. However, development was iterative, with the different processes overlapping and feeding into each other. Researchers affiliated with the IHC project in six countries (Uganda, Norway, Rwanda, Kenya, UK and Australia) contributed to the development of the

Claim Evaluation Tools. An overview of the development process is presented in Figure 1. The roles and purposes of the different research teams are described below.

Please enter Figure 1. Overview and timeline of the development process

Development of items

The Claim Evaluation Tools working group, with members of the IHC group from Norway, UK and Uganda (AA, AO, IC, DS, AN), had principal responsibility for agreeing on content, including the instructions and wording of individual items. The team in Norway (AA and AO) coordinated the development and evaluations. The scope of the Claim Evaluation Tools was based on the list of Key Concepts (15)(see table 1).

Our vision for the Claim Evaluation Tools was that they should not be a standard, fixed questionnaire, but rather a flexible tool-set including a battery of items, of which some may be more or less relevant to certain populations or purposes. For example, a teacher developing a series of lectures targeting five of the concepts in the Key Concept list, could design her own evaluation instrument to test her students by picking items from the database that specifically addressed those Key Concepts.

Multiple-choice items are well suited for assessing application of knowledge, interpretation and judgements. In addition, they help problem-based learning and practical decision making (17). Each of the items we created opened with a scenario leading to a treatment claim and a question, followed by a choice of answers. We developed the items using two multiple-choice formats - single multiple-choice items (addressing one concept), and multiple true-false items (addressing several concepts in the same item). We developed all items with “one-best answer” response options (17), the options being placed on a continuum, with one answer being unambiguously the “best” and the remaining options as “worse”. We developed all items in English.

The initial target groups for the Claim Evaluation Tools were fifth grade children (10 to 12 year-olds in the next to last year of primary school) and adults (parents of primary school children) in Uganda. However, throughout the development process, our goal was to create a set of tools that we hoped would be relevant in other settings. Accordingly, we used conditions and treatments that we judged

likely to be relevant across different country contexts. Where necessary, we explained the conditions and treatments used in the opening scenarios. We also decided to avoid conditions and treatments that might lead the respondents to focus on the specific treatments (about which they might have an opinion or prior knowledge), rather than on the concepts.

Exploring relevance, understanding and acceptability of items

In order to get feedback on the relevance, understanding and acceptability of items, we used purposeful sampling of people with expertise in the Key Concepts, as well as patients and members of the public from both low and high-income countries (18-21).

Item review and feedback by methodologists (face validity)

First, we circulated the complete set of multiple-choice items to members of the IHC advisory group and asked them to comment on their face validity and applicability as judged against the list of Key Concepts. Each advisory group member was assigned a set of three concepts, with associated items. A feedback form asked them to indicate to what extent they felt each item addressed the relevant Key Concept using the response options “Yes”, “No” or “Uncertain”, together with any open-ended comments. Any items that were tagged as “No” or “Uncertain” by one or more of those consulted were considered for revision.

On two occasions, we also invited four methodologists associated with the Norwegian research group and with expertise in the concepts to respond to the full set of items. These experts were not involved in the project or the development of the Claim Evaluation Tools. In this element of the evaluation, the response options were randomised and the methodologists were blinded to the correct answers. They were asked to choose what they judged to be the best answer to each item’s question, and were encouraged to provide open-ended comments and flag any problems they identified. Any item in which one or more of the methodologists failed to identify the ‘best answer’ was considered for potential revision.

We also invited people with expertise in the Key Concepts from all project partner countries to provide feedback on several occasions throughout the development of the tools. In addition to providing general

feedback, an important purpose of reviewing the items in these different contexts was to identify any terminology and examples (conditions and treatments) that might be culturally inappropriate.
For all of this feedback, suggested revisions and areas of improvement were summarised in an Excel worksheet in two categories: (i) comments of a general nature relating to all items, such as choice of terminology or format; and (ii) comments associated with specific items.

Cognitive interviews with end-users on relevance of examples, understanding and acceptability

After the Claim Evaluation Tools working group and the IHC project group agreed on the instrument content, we undertook cognitive interviews with individuals from our potential target groups in Uganda, Australia, UK and Norway (22-24). Country representatives of the IHC project group recruited participants in their own contexts, based on purposeful sampling, in consultation with the Norwegian coordinator (AA). Since Uganda has been the principal focus of our interest, this was always our starting and ending point. In total, four rounds of interviews took place in Uganda. We organised interviews in Norway, UK and Australia to assess relevance within those settings. We used these interviews to obtain feedback from potential end-users on the relevance of the scenarios (such as the conditions and treatments used in the examples), and the intelligibility and acceptability of the scenarios, formats and instructions. This was particularly important because we intended to use the items for testing children as well as adults. Throughout this process, we also piloted and user-tested several versions of the items (designs and instructions). Failure to address these issues when developing the items might increase the likelihood of missing responses, "guessing", or other measurement errors. For example, we wanted to minimise the influence of people's cultural background on how they responded to the multiple-choice items. The effects of such confounders have been addressed in the final phase of development using psychometric testing and Rasch analysis of the questionnaire (25). The interviews were intended to help prevent problems resulting from confounders relatively early in the evaluation process.

Our interviews were done iteratively between October 2014 and January 2016, allowing for changes to the items between interviews. All our interviews used a semi-structured interview guide (Appendix 1) inspired by previous research (22-24). As part of the interviews, participants were given a sample set of the multiple-choice items and asked to respond to these. The interviews addressed questions raised during development of the items about the format of questions or the terminology used in the questions. In response, we revised the interview guide and changed the multiple-choice items when

relevant. When conducting the interviews, we used the methods of 'think aloud' and 'verbal probing', two approaches to cognitive interviewing (23). With "think aloud" the respondent is asked to explain how they arrived at their response to each item. Such interviews are less prone to bias because of the more limited role of the interviewer. However, some respondents have difficulty in verbalising their thought processes, and in these circumstances we followed up with "verbal probing", which uses questions that the interviewer asks after the respondent has completed each of the items. Following each item, the interviewer began with the "think aloud" method by asking respondents how they arrived at their response before asking more specific questions, as necessary. We audio recorded interviews when possible, and we aimed to have two people doing the interviews (with one person taking notes and the other person being the lead-interviewer). For practical reasons this was not always possible. Each country representative summarised the key points from the interviews. Suggested revisions and areas of improvement were fed back to the Norwegian coordinator who entered these into the same Excel spreadsheet, as also the feedback from the methodologists.

Piloting of sample sets of Claim Evaluation Tools

We conducted five small pilots in which we administered sample sets of the Claim Evaluation Tools to our target groups. As previously stated, the Key Concept list serves as a syllabus or curriculum from which researchers, teachers and others may develop interventions. Likewise, we developed the Claim Evaluation Tools so that researchers and others can pick items that are relevant for their purposes. In other words, they can design their own instrument.

The IHC interventions were initially developed to target 22 Key Concepts that were prioritized as most relevant for our target populations in Uganda. We have developed two instruments addressing the 22 Key Concepts targeted by the IHC interventions by selecting relevant items from the Claim Evaluation Tools database. For the pilots reported in this paper we included items that were relevant for the IHC trials, both to test how sample sets of Claim Evaluation Tools would work in a practical setting, but also to obtain an indication of the sample sizes required for the randomized trials.

The first pilot (March-April 2015) was an administrative test in a primary school in Uganda. This involved a group of children who had taken part in a pilot of the IHC primary school resources as part of the IHC project, and a comparison group of children who had not received training in the Key Concepts (in total

169 children). We included all items addressing the 22 Key Concepts. Because of the large number of items to be tested, we divided them into four sample set questionnaires. We designed these questionnaires to be similar to the questionnaires to be used in the IHC trials. This would provide us with some feedback on how administrating a set of the Claim Evaluation Tools would work in practice, in a classroom setting. We also wanted to explore potential problems with incorrectly completed responses (through visual inspection of the responses).

The second pilot (September to December 2015) focused solely on format testing. Three different sets of formats were tested, but with the same items addressing 22 of the 32 Key Concepts kept constant across the three formats. We designed the formats based on lessons learned from the feedback from methodologists, interviews with end-users, and through visual inspection of the data collected in the first pilot. We recruited people in Uganda, Rwanda and Kenya to do this (N=204), using purposeful sampling of children and adults. The outcome of this test was the number of missing or incorrectly completed responses per item.

The third, fourth and fifth pilots had two objectives. The first was to compare the ability of people who had and had not received training to apply the Key Concepts. This provided an indication of the sample sizes that would be needed for the IHC randomised trials. The second objective was to estimate the frequency of missing responses as an indication of problems with understanding the item's instructions. For these purposes, we used one sample set of the Claim Evaluation Tools (addressing the 22 basic concepts). In these pilots, we also observed the time required to complete a sample set of the questionnaire. To fit an evaluation using the Claim Evaluation Tool in a busy school day as part of the IHC intervention, we hoped that it would be possible to complete a sample set questionnaire within an hour.

The third pilot (October to November 2015) and fourth pilot (November to December 2015) were conducted with Ugandan primary school children (in two schools) and their parents. The fifth pilot (December 2015) took place in Norway and included primary school children in one school. In all three of these pilots, we recruited children and parents who had taken part in piloting IHC primary school materials and podcast, respectively, and children and parents who had received no such intervention. In total, 197 children took part in the Ugandan school pilot, 301 parents took part in the podcast pilot, and 85 children took part in the Norwegian school pilot. The results of these pilots were summarised by

calculating mean correct responses to all items addressing the same concept. We also calculated missing responses per item.

Results

We present the results thematically, beginning with the development of items, and the subsequent issues that were explored as part of the development process; judgement of relevance of the items to the Key Concepts (face validity); understanding and perceived difficulty of content; preference and understanding of instructions (formats); timing; and correct responses. An overview of the sources of feedback we used to explore these themes, our main findings and our revisions is shown in table 2.

Table 2. Overview of main findings and decisions about revisions, by theme

Theme	Type of feedback	Findings	Revisions
Relevance of the items to the Key Concepts (face validity)	• Methodologists and people with expertise in the Key Concepts	• Most items were judged as relevant.	• Minor revisions, items that were found to be partly relevant (20) or not relevant (1) was considered by the working group
Understanding and perceived difficulty of content	• Methodologists and people with expertise in the Key Concepts • Cognitive interviews with end-users	• The 'distance' between the "best" option and the "worse" options was considered too small • Low literacy skills in the target audience raised as a concern • Certain terminology identified as problematic	• The worse options made more "wrong" • Reduction of text • Adding explanations of terminology and rewriting of scenarios
Preference and understanding	• Cognitive interviews with end-users	• A mix of the simple-multiple choice and multiple true-false	• Redesign of formats and instructions to

of instructions (formats)	• Piloting of sample sets of the Claim Evaluation Tool (pilots 1 to 5)	formats preferred • Formats acceptable and recognizable • Misunderstandings of instructions; open-answers provided and checking of multiple check-boxes	remove unnecessary open spaces, avoiding use of multiple check-boxes, and the use of grids in multiple true-false options
Timing and correct responses	• Piloting of sample sets of the Claim Evaluation Tool (pilots 3 to 5)	• 30 to 60 minutes to complete a questionnaire that included demographic questions and a sample of 29 items • Participants who had taken part in piloting of the IHC resources did slightly better than others for most of the Key Concepts	• No revisions

Development of items

We developed items using two formats, with several items to address each Key Concept. The single multiple-choice items address only one Key Concept within each item; the multiple true-false items include questions that relate to three or more Key Concepts. The two different formats are shown in figure 2. We created an initial batch of 4-6 items addressing each Key Concept. Because we did not know which formats would be preferred by end-users, or which items would have the best psychometric properties, this allowed us to remove items based on feedback from experts, end-users and through the final psychometric testing and Rasch analysis (25).

Please enter Figure 2. Example of formats

Exploring relevance (face validity)

Judgements about the relevance of items to the Key Concepts was made by methodologists and people with expertise in the Key Concepts. The first phase included feedback from our advisory group: thirteen members provided feedback on 135 items. Only one of these items was judged to have addressed the

concept inadequately; a further 20 items were deemed to be only partly relevant. The relevance of the items was confirmed in the test-run with the Norwegian research group using the four invited methodologists, as well as by people with expertise in the Key Concepts from the project partner countries.

Understanding and perceived difficulty of content

Understanding of formats and acceptability was explored by consulting methodologists and other people with expertise in the Key Concepts, as well as through cognitive interviews with end-users. Although the items were judged to be relevant, an important element of the feedback from the test-run was that the 'distance' between the "best" option and the "worse" options was considered too small, with the result that the judgements required were too difficult. Based on this feedback, we revised the "worse" options to make them more "wrong".

The cognitive interviews with members of our target group also suggested that the items were too 'text heavy', and needed to be simplified. Experts and end-users in Uganda also felt that low literacy might also be a barrier. Consequently, we tried hard to make the scenarios as simple as possible without losing key content.

The end-users and the methodologists consulted in each country (Uganda, Kenya, Rwanda, UK, and Australia), also provided comments on terminology, as well as those scenarios that they felt might not be appropriate or would need to be explained. The Claim Evaluation Tools working group considered these comments and revised the items. When we were unable to avoid using certain terms (for example, "research study"), we added explanations. Our rationale was that some terms would present a barrier to understanding the items, but were not considered to be part of the learning objectives associated with the Key Concepts. For some other terms, we used alternatives deemed acceptable by researchers, other experts and members of the target groups in each country (Uganda, Kenya, Rwanda, UK, Australia and Norway). This process involved feeding back all changes to experts and end-users in an iterative process with continuous revisions.

Preference and understanding of instructions (formats)

An iterative process of cognitive interviews and piloting the items using sample questionnaires informed the design and formats of the instructions. Our interviews with end-users were to obtain their preferences on format, to follow the steps of their reasoning when responding to the items, and to assess their understanding of the items' instructions. The main message was that people preferred a mix of the simple-multiple choice and multiple true-false formats to make the questionnaire more interesting. The items were otherwise well received. The general feedback from all the different country settings was that the formats were acceptable, recognisable and similar to multiple-choice formats they had encountered in other settings.

Based on verbal feedback in the interviews with the end-users, as well as visual inspection of how people responded to the items in the five pilots, we identified two potential problems. The first was that respondents tended to provide open-ended responses to the questions; the second was that people tended to tick more than one check-box. Because of these problems, the mean missing/ incorrectly completed responses in the first school pilot in Uganda (March- April 2015) was 20-40%. Examples of such incorrectly completed multiple-choice items from this first pilot are shown in Figure 3.

Please enter Figure 3. Examples of incorrectly completed multiple-choice questions

We tested revised designs (Figure 2) in the second pilot in Uganda, Rwanda and Kenya (September to December 2015). This greatly improved people's responses to the questionnaire, reducing missing or incorrectly completed responses to less than 4% of the items. Based on this pilot, we made final revisions and decided on the formats to be used in the subsequent pilots.

Figure 2 shows the design changes we used to avoid these problems. These included removing blank spaces, which could be misinterpreted as inviting open (free text) responses; and avoiding use of multiple check boxes for "one-best answer" formats. For the multiple true-false formats, response options using an open grid design, with instructions at the top, resulted in fewer problems.

The third, fourth and fifth pilots, conducted in Uganda and Norway (October to December 2015), confirmed the appropriateness of the formats, and missing or incorrectly completed responses were less than 2%. These pilots also confirmed that respondents took between 30 and 60 minutes to complete a

questionnaire that included demographic questions and a sample of 29 items. The participants' correct responses per Key Concept are shown in Figure 4. This figure, in which correct answers are plotted for each Key Concept per group, shows that participants who had taken part in piloting the IHC resources were slightly more likely than others to give correct answers for most of the Key Concepts.

Please enter Figure 4. Distribution of correct answers in pilots

Discussion

Developing a new evaluation instrument is not straightforward, and requires rigorous testing using qualitative and quantitative methods (26). There are many ways of doing this. We chose to use a pragmatic and iterative approach, involving feedback from experts and end-users and continuous revisions. This development work was possible because we are a multidisciplinary, international collaboration including people from high and low-income countries. Despite differences between countries, enabling people to assess treatment claims in their daily lives is a challenge in all countries.

We developed a battery of multiple-choice items using two formats, with several items addressing each Key Concept. An international group of people with relevant expertise considered that the items we developed addressed the Key Concepts we had identified appropriately, and end-users considered the items to be acceptable in their settings. Methodologists and end-users suggested that some items were too difficult, so we revised the answer options, reduced the amount of text used, and explained terminology if necessary. Based on feedback from the interviews with end-users, the revised formats were well received, but the piloting also identified issues with understanding of instructions. We addressed these problems by further testing and redesign of instructions and formats. This resulted in a reduction of missing or incorrectly completed responses in subsequent pilots. Piloting of sample sets of Claim Evaluation Tools also confirmed that it was possible to complete a questionnaire with 29 items within an hour, and that people who had received training in the Key Concepts did slightly better than those who had not received such training.

The relevance of the items outside the contexts studied as part of this project is unclear. Feedback from end-users in other settings may be different. Researchers or teachers who would like to use the Claim Evaluation Tools in their contexts should consider the relevance of terminology and the examples used,

involving end-users if possible. It should also be noted that the first phases in the development described in this paper did not include any evaluations of the reliability of the items. This requires rigorous psychometric testing including Rasch analysis, and is described in a separate paper (25).

This paper describes the development and initial steps of validation of items addressing all 32 of the Key Concepts, in four phases. However, in the last phase, we also did some pilot testing of items referring specifically to 22 of the 32 Key Concepts. There were several objectives of these pilots, but for development purposes, we wanted to do practical administrative tests to explore the understanding of formats and timing of Claim Evaluation Tools "sample tests". A limitation of these pilots is that people may respond differently to the items addressing the 10 Key Concepts not included, in terms of number of missing responses, incorrectly filled in questions, or in time to completion. We judge this to be of little importance as the items addressing these two "groups" of Key Concepts use the same formats and are similar in length and language.

As our first step in the choice of outcome measurement for the IHC trials, we conducted a systematic mapping review of interventions and outcome measures used for evaluating one or more of the Key Concepts (16). Our findings suggested that research on the Key Concepts is of interdisciplinary interest, and that a variety of assessment tools exists. However, none of the identified tools addressed more than 15 Key Concepts. The most relevant of these were instruments designed to assess competency in evidence-based medicine, The Fresno test by Ramos and colleagues (2003) (27), and an instrument developed by Godwin and colleagues (2003) (28). Assessment tools used in studies targeting patients or consumers included only seven or fewer Key Concepts. The large majority of these generally only touched on one concept - 5.1 "Weigh benefits and harms of treatment" (29). The Claim Evaluation Tools were developed to be used as the primary outcome measurement in the IHC project's randomized trials, but also to provide a flexible measurement tool for others interested in mapping or evaluation of people's ability to apply Key Concepts when assessing claims about treatment effects. Instead of a "set" instrument, the Claim Evaluation Tools offers the potential to tailor an instrument for specific purposes and target groups. This is useful also for others, as the Key Concepts covered in interventions may vary. This flexibility avoids forcing end-users to respond to unnecessary questions addressing concepts that have not been covered in their interventions. The Claim Evaluations Tools will be made available on request through the website testingtreatments.org. We envision that educators, researchers and others

will use them to create their own "tests", fitting their specific needs and contexts. The Claim Evaluation Tools also appear to be unique in that the items have been developed to be used to assess ability in both children and adults, including members of the public as well as health professionals. This offers the opportunity to compare knowledge and application of the Key Resources across populations.

The Claim Evaluation Tools were developed as objective multiple-choice items to measure understanding of the Key Concepts. A limitation of many of the instruments that have been developed to assess people's critical-appraisal skills is that they rely on self-report by respondents (subjective measurements). Typical examples are the many health literacy instruments, such as the European Health Literacy Survey (HLS-EU)(30) and instruments used to assess competence in evidence-based medicine (31). Self-assessed abilities can be difficult to interpret, and have been found to have a weak association with objective measures of knowledge and skills (32-34). Such instruments may be more likely to measure the confidence of respondents in their own ability rather than their knowledge or actual ability. Although improved confidence in one's own ability may be a relevant and important effect of an intervention, it may be a poor indicator of actual knowledge and ability.

Conclusion

We developed the Claim Evaluation Tools to evaluate people's ability to assess claims about the effects of treatments. As far as we are aware, this is currently the only evaluation instrument designed to address most of the Key Concepts we believe people need to know to assess claims about treatment effects. This work is the result of a multidisciplinary, international collaboration including high and low-income countries. We have used a pragmatic and iterative approach, involving feedback from experts and end-users, and continuous revisions. Although the Claim Evaluation Tools have been developed primarily to be used as part of the IHC project in Uganda, we believe they should be useful for others interested in evaluating people's ability to apply Key Concepts when assessing treatment claims. Feedback from experts and end-users in Uganda, Kenya, Rwanda, Norway, UK and Australia supports our hope that they will be found relevant in other contexts.

The Claim Evaluation Tools includes a battery of items from which researchers can select those relevant for specific populations or purposes, and currently includes approximately 190 multiple-choice items. However, we anticipate that the Claim Evaluation Tools will continue to evolve. The Claim Evaluation

Tools will be hosted on the Testing Treatments interactive website (www.testingtreatments.org) and managed by the Claim Evaluation Tools working group. On request, all items will be made freely available for non-commercial use.

Authors' Contributions

AA, ØG, AO wrote the protocol and the IHC group provided comments on the protocol. AA coordinated all of the development and evaluation process with support from AO. AA, DS, AN, IC, AO and MO drafted the items with input from the IHC group. AA, IC and AO were responsible for revising the items iteratively, based on the feedback received through the different processes. SR and AA were responsible for the format designs. AA and KO approached the IHC advisory group and other methodologists for feedback. AN, DS, LC, AA, MO, SR, TH and MK conducted the interviews with end-users. AN, DS, KO, LAM, MM, LAM, MK, NS, AMU and AA were involved in pilots and administrative tests in Uganda, Kenya, Rwanda and Norway respectively. AA analysed the data from the pilots. AA authored this manuscript with significant input from the rest of the IHC group.

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Ethical approval

Ethical approval was sought by the IHC project representatives in each country.

Data sharing statement

All data are published as part of this study. All Claim Evaluation Tools are available upon request for non-commercial use.

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Figure legends

Figure 1. Overview and timeline of the development process

Figure 2. Example of formats

Figure 3. Examples of incorrectly completed multiple-choice questions

Figure 4. Distribution of correct answers in pilots

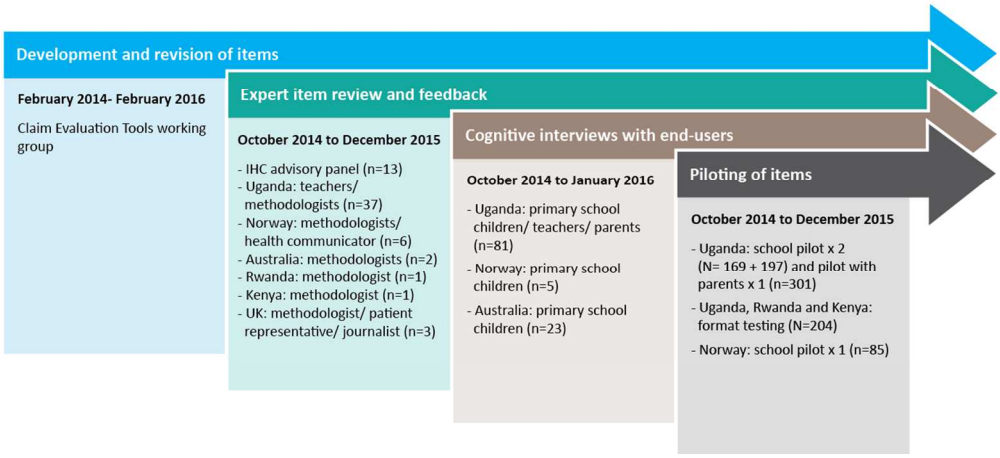


Figure 1

173x78mm (300 x 300 DPI)

Concept 1.3
Judith wants smoother skin. The younger girls in her school have smoother skin than the older girls. Judith thinks this is because the younger girls use cream on their skin to make the skin smoother.

Question: **Based on this link between using cream and smooth skin, is Judith correct?**

Options:

A) It is not possible to say. It depends on how many younger and older girls there are

B) It is not possible to say. There might be other differences between the younger and older girls

C) Yes, because the younger girls use cream on their skin and they have smoother skin

D) No, Judith should try using the cream herself to see if it works for her

Answer: ☐

Concepts	When you are sick, sometimes people say that something - a treatment - is good for you. It is hard to know whether what they say is true. **Do you agree or disagree with each of the following statements?**		
	For each statement below, use ✓ to mark whether you agree or disagree.		
	Statements:	**Agree**	**Disagree**
1.1	James says that a treatment cannot be helpful and harmful at the same time		
1.2	Peter says that if a treatment works for one person, the treatment will help others too		
1.3	Alice says that if some people try the treatment and feel better, this means that the treatment helps		

173x199mm (300 x 300 DPI)

George has a stomachache. The last time George had a stomachache was two months ago. That time, he drank some hot milk and after an hour, his stomachache was gone. Therefore, George says hot milk cures stomachaches.

QUESTION:

Is George right?

No

PLEASE CIRCLE THE ANSWER THAT YOU THINK IS THE BEST

A. No, it is only based on George's own experience treating a stomachache with hot milk.

No

B. Not possible to say, the fact that he improved could have happened by chance

Yes

C. Yes, George's own experience is evidence enough for assessing the effects of hot milk for treating a stomachache

No

D. No, it is important to ask what other people think too, not just George

Yes.

Outside the city where Paul lives, there is a mine. The miners often get coughs. For many years, most of the miners have used whiskey mixed in water to reduce the pain from their coughs. Therefore, Paul says that water with a little whiskey is an effective and harmless treatment for a cough, since many people have used it for a long time.

QUESTION:

Do you agree with Paul?

PLEASE CIRCLE THE ANSWER THAT YOU THINK IS THE BEST

A. No, just because whiskey mixed in water has been used by many, does not mean that it is harmless

B. No, just because whiskey mixed in water have been used a lot, does not mean that it is the best treatment

C. Yes, the miners have used whiskey mixed in water to treat their coughs for many years and they would not use the treatment for many years if it were not beneficial and harmless

D. Not possible to say, Paul should try whiskey mixed in water on himself to know for sure that he is correct

. **Andrew has difficulty breathing. He goes to the shop to buy medicine. The shopkeeper gives Andrew tablet and says it will help improve his breathing. Andrew thinks if taking one tablet will help him, then taking two tablets will help him even more. Should Andrew take one or two tablets?** *Mark an X in the box for the best answer (only one)*

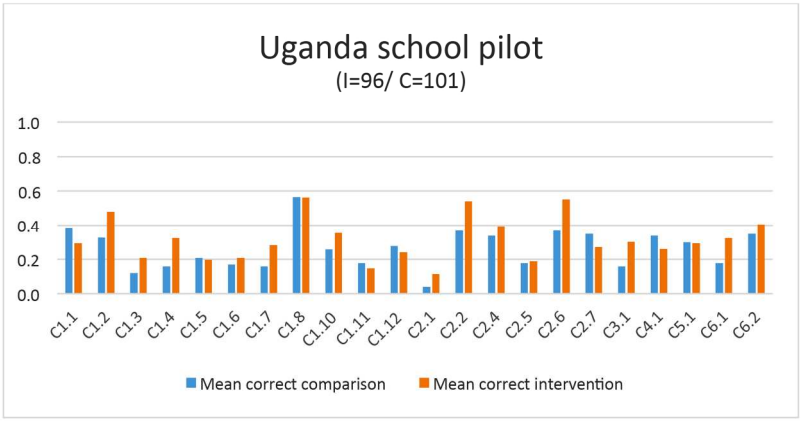
☒ One. Taking two is likely to be harmful and more expensive

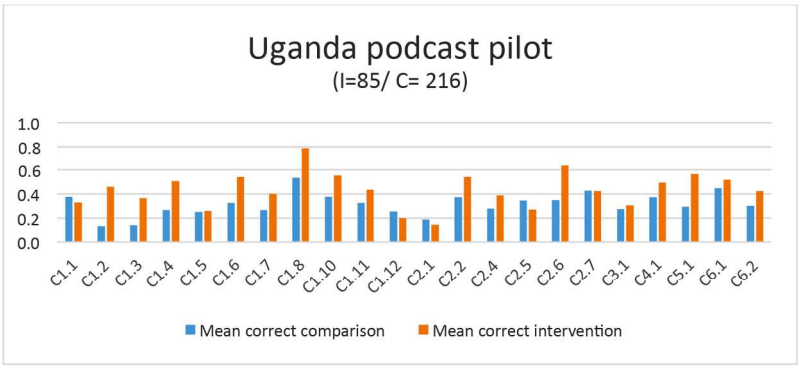
☐ One. Taking more than one will not necessarily be more helpful and may be harmful

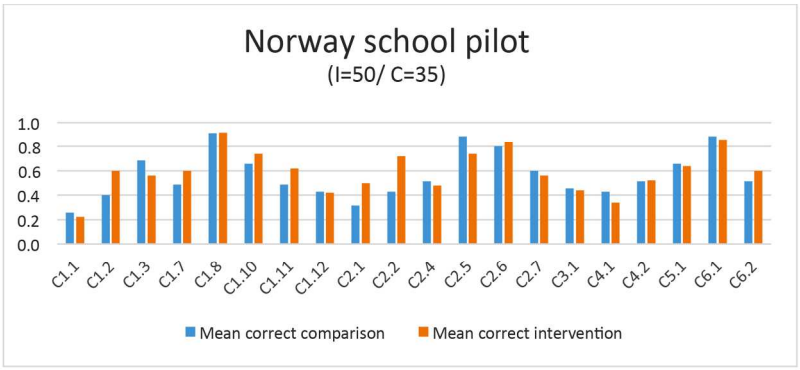
☒ One. Andrew should listen to the shopkeeper's advice

☐ Two. Taking more than one will probably help him get better more quickly and is unlikely to be harmful

82x215mm (300 x 300 DPI)







148x215mm (300 x 300 DPI)

Example interview guide version 1

1. Introductions and information about purpose
   (The purpose of the interview is *not* to evaluate how participants perform on the questions, but to get feedback on the questions, i.e. comprehension and relevance

2. Steps of reasoning (per item)
   - What was your response?
   - Can you tell me why you choose this response category? (steps of reasoning)

3. Relevance (per item)
   - What did you think of the scenario?
     - Probe:
       - Names
       - Treatment
       - Outcome
       - Other comments

Example interview guide version 2

Content and format

1. Introductions and information about purpose
   (The purpose of the interview is *not* to evaluate how participants perform on the questions, but to get feedback on the questions, i.e. comprehension and relevance

4. Tell me about the test, what did you think about it?
   - First impression?
   - Similarities to other tests or exams?
   - Like/ doesn't like these differences?

5. What did you think about the instructions?
   - The test include different formats (show examples of SMC's and MMC's), what did you think of them?
   - The test also included some questions about behavior and attitudes, what did you think of them?
   - Do you think these questions fit your age group?
   - Was there any information you felt was missing?

6. What about the content of the test, was it easy or not easy for you to answer the questions?
   - What made it easy or not easy?
   - Were there any words you did not understand or otherwise reacted to?

Literacy / understanding of the multiple-choice items

7. Ask the respondent to read question 3 (concept 1.2) and question 14 (concept 2.2) from the Claim Evaluations Tools questionnaire that was used.
   - Was it easy or hard to understand that question?
   - What words were hard to understand?
   - What do you think the right answer is?
   - Why?
   - After explaining any words that they did not understand and helping them to read the question and response options, ask them what they think the right answer is.