

PEER REVIEW HISTORY

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ARTICLE DETAILS

TITLE (PROVISIONAL)	Development of a checklist for people communicating evidence-based information about the effects of healthcare interventions: a mixed methods study
AUTHORS	Oxman, Andrew; Glenton, Claire; Flottorp, Signe; Lewin, Simon; Rosenbaum, Sarah; Fretheim, Atle

VERSION 1 – REVIEW

REVIEWER	Roland Brian Büchter Department of Health Information, Institute for Quality and Efficiency in Health Care (IQWiG) I am an employee of IQWiG, which publishes informedhealth.org , a website providing evidence based health information to the public. This site was reviewed in an article authored by the first author of this paper. As this is a piece on methods I have included possible competing interests into my comments, where appropriate.
REVIEW RETURNED	04-Feb-2020

GENERAL COMMENTS	<p>It was a pleasure to review this interesting and valuable paper. I believe that the authors have made a good job of distilling the most important requirements of communicating treatment effects to enable evidence-informed decisions. I find the table in additional file 2 to be particularly helpful, as it also discusses the (often difficult) practical aspects.</p> <p>With that in mind, I have some thoughts and suggestions for minor changes and additions to the manuscript. I have made these from the perspective of someone with a specific research interest in the topic and from the practical perspective of someone who develops evidence-based health information for the German public on a vast number of different topics.</p> <p>For clarity, I have included specific suggestions in italics following my comments.</p> <p>Box 1: Checklist for communicating Effects</p> <p>Item 3: I believe the word “potentially” should be dropped from this recommendation. Asking for “all potentially important benefits and harms” seems unrealistic for a number of reasons, including: the difficulties of gathering and assessing evidence on very rare harms; the added complexity of presenting a very large number of potentially important outcomes; the difficulty of comprehending them from the perspective of the information recipient. Furthermore, “potentially” is an ill-defined term and different outcomes might matter to different groups of people. The authors rightly highlight</p>
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	<p>the importance of involving the target audience and this is arguably the most important step in selecting the outcomes that are important for decision making. The authors also describe the possible downsides very well under “caveats and risk mitigation” in additional file 2. Asking for all “potentially relevant outcomes” might be asking too much from some information providers.</p> <p>(To elaborate: I believe that we should not let the perfect become the enemy of the good and – in making recommendations – should be mindful of honest and patient centred information providers who do their best to deliver good and reliable information but lack the resources to fulfil all the criteria that would be desirable from a methodological perspective such as dedicated and independent patients groups that develop information for their members, but lack the resources or skills to fulfil all criteria in the checklist, to name one example).</p> <p>-> Suggestion for the manuscript: Consider dropping the word “potentially” from item 3.</p> <p>Item 6: When I read “summary of findings table” in this recommendation, I immediately associated this with GRADE SoF tables. The references, however, suggest that the authors are not exclusively referring to these, as they also cite drug fact boxes, for example (which I believe is appropriate). To avoid confusion, I suggest slightly rephrasing the item.</p> <p>-> Suggestion for the manuscript: Consider rephrasing item 6 to avoid confusion, e.g. “Present both numbers and words, and consider including tables summarizing the treatment benefits and harms, for example using GRADE summary of findings tables or drug fact boxes”.</p> <p>Items 4/7: While item 4 addresses the certainty of the evidence, I am missing an explicit statement that the presented effects should be based on fair comparisons – e.g. treatment vs no treatment/placebo/sham or an alternative treatment. Arguably this seems appropriate for benefits and most harms, at least. The authors could consider adding this to item 4 or item 7, e.g.: “Report absolute effects based on fair treatment comparisons such as the number of patients improving with treatment compared to the number of patients improving without treatment, or the absolute difference between these two.” This might not be self-explanatory to all readers and adding such a statement might help prevent dubious, but common uses of absolute “effects” (I often see statements such as “90% of the patients were satisfied with the treatment/improved” based on uncontrolled studies or because the control arms are ignored by the information provider). While comparisons are mentioned in additional file 3, I believe this point might be important enough to be included in the checklist.</p> <p>-> Suggestion for the manuscript: Consider explicitly including a statement that treatment effects should be based on fair comparisons from controlled studies, with few exceptions.</p> <p>Synthesis and comparison to other guidance</p> <p>Regarding the guidance documents on communicating treatment effects that the authors have collected and used to compare their checklist to, I would like to point them to a guideline on “evidence-</p>
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based health information” that was developed by a research group at the University of Hamburg in collaboration with the working group for patient information and involvement of the German Network for Evidence Based Medicine. Many of the chapters of this guideline have been translated into English and can be found here: <https://www.leitlinie-gesundheitsinformation.de/guideline/?lang=en>

I believe this guideline may be of interest to readers of this paper, as the guideline group has made a large effort to systematically review the evidence on various questions related to the communication of treatments effects and graded the evidence for each question using up to date methods for guideline development (transparency note: I have not been involved in developing these guidelines, but I am a member of the German Network for Evidence Based Medicine, I generally agree with most of the recommendations and I have commented on the guideline during an open consultation period).

In summary, the recommendations in the German guideline are in line with the recommendations in the checklist developed for this paper, specifically the recommendation

- to present both numbers and words: https://www.leitlinie-gesundheitsinformation.de/wp-content/uploads/2019/08/Recommendation_Presentation-of-Frequencies_1.pdf
- to use absolute risk formats: https://www.leitlinie-gesundheitsinformation.de/wp-content/uploads/2019/08/Recommendation_Presentation-of-Frequencies_2.pdf
- and the statement that there is the limited evidence for adding visual aids: https://www.leitlinie-gesundheitsinformation.de/wp-content/uploads/2019/08/Recommendation_Using-Graphics_1.pdf

Of note, the developers of this guideline are currently conducting a randomised controlled trial to test whether implementing this guideline with an accompanying training program among providers of health information improves the quality of the health information being developed (<http://www.isrctn.com/ISRCTN96941060>).

-> Suggestion for the manuscript: Consider adding the German guideline for developing evidence-based health information to the discussion. While not all chapters have been translated to English yet, many have been, and these may be of additional interest to readers.

Interestingly, the German guideline makes a weak recommendation against the use of patient stories/narratives, which are considered in the discussion of this paper: https://www.leitlinie-gesundheitsinformation.de/wp-content/uploads/2019/08/Recommendation_Using-Narratives_1.pdf

I personally believe that this recommendation is not specific enough and risks throwing out the baby with the bathwater. While there are very good reasons to avoid using patient stories to communicate treatment effects and some evidence to support this, there are many other reasons for their use (e.g. allowing for peer to peer communication, providing emotional support, reducing stigma, illustrating how different preferences can lead to different decisions, understanding how certain interventions and their outcomes may

affect everyday life and simply because people ask for them). In addition to the review by Fadlallah et al. [61] that the authors cite, I am aware of only one quantitative study which examined the effects of patient stories, albeit not as an add-on to specific treatment information (Giesler et al. 2017, <https://www.jmir.org/2017/10/e3334/>). This RCT set out to examine whether provision of patient stories via the German DIPEX increases self-efficacy for coping with bowel cancer and patient competence using a waiting-list design. The trial faced some methodological challenges, however, and failed to find an effect.

-> Suggestion for the manuscript: I agree with the authors that more research is needed on the use of patient stories. However, their possible advantages and disadvantages depend on their purpose of use and the manuscript is a bit vague and could be differentiated regarding this issue (page 8, lines 23-31). Since the focus of this paper is to provide recommendations on communicating treatment effects, it seems appropriate to caution readers regarding the use of patient stories for this purpose – in contrast to other purposes, where they may be useful as suggested above.

Tables 1 and Figure 2

-> Please check the references in table 1 and figure 1. Several of these do not seem to match the citations in the reference list.

Table 2

In table 2, the authors make suggestions for further research. I was surprised to that see that communicating uncertainty (e.g. risk of bias, lack of sufficient follow-up, applicability) is not included here and wonder whether this is intentional. There is some research on the effects of communicating statistical uncertainty/precision of effect estimates (e.g.

<https://www.ncbi.nlm.nih.gov/pubmed/22858415> and <https://www.ncbi.nlm.nih.gov/pubmed/26823204>). To my knowledge, however, little is known about the effects of communicating other types of uncertainty and how to do this. From my experience, it is usually difficult for people to distinguish between the two concepts of the magnitude of an effect and the certainty or confidence in an effect estimate.

(Transparency note: we have conducted a trial to evaluate the effects of how we communicate uncertainty in our health information and are currently in the process of publishing this; German Clinical Trials Register DRKS00015911).

-> Suggestion for the manuscript: consider adding the research need on how to communicate uncertainty, especially to patients and the public. The Agency for Healthcare Research and Quality has conducted a systematic review on this issue in 2013 (<https://www.ncbi.nlm.nih.gov/books/NBK179104/>), but an up to date review appears timely.

I also believe that it would be helpful to agree on a set of outcomes that should be used in research on communicating treatment effects. I am not sure, whether the authors would agree with this, but if so, they might consider adding this to the list.

	<p>-> Suggestion for the manuscript: consider discussing the need for a review and consensus on appropriate outcomes for studies evaluating different approaches of communicating treatment effects.</p> <p>Flow chart</p> <p>The authors might consider including feedback from content experts in the process for producing evidence-based information. I don't think that this is always required, but depending on the topic and how the team developing the information is composed, it can be helpful (I agree that many experts have strong opinions and their interpretation of the evidence often has to be taken with a pinch of salt, but this need not be the case and they can also provide helpful insights). In my experience, it is also very useful to involve editors to make the language concise and easy to understand, which could also be added as a consideration to the flow chart.</p> <p>-> Suggestion for the manuscript: consider adding feedback from content experts and editors to the flow chart.</p>
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REVIEWER	Sharon Jo Tucker Ohio State University - College of Nursing Columbus, OH USA
REVIEW RETURNED	17-Mar-2020

GENERAL COMMENTS	<p>This manuscript focuses on creation of a checklist that can guide the development and communication of health interventions and their level of evidence for those making decisions about the relevance and appropriateness of implementing select health interventions. This checklist adds to existing published tools and can provide a needed resource. There are some issues needing clarification and revision.</p> <p>1) The aim is not very clear to me including that the checklist (primary outcome) is not listed. It is also a bit confusing. Seems it could read better - perhaps something like this: The aim of this paper is to provide guidance and a checklist for people preparing and communicating evidence-based information on the effects/relevance of interventions for health decision makers (e.g., patients and the public, health professionals, or policymakers).</p> <p>2. Consistent with the aim, I was unclear in reading the paper about specifically who the recommendations are for in the end? Patients will need a very different tool than clinicians, and policy makers, yet these are included as one group. I found this confusing.</p> <p>3. I would have liked to see the study design listed in the abstract and manuscript. The study seems to use a mixed methods approach with a literature review, hybrid Delphi technique or qualitative method, and report of some quantitative data. This omission lacks some rigor.</p> <p>4. The authors acknowledge that they did not conduct a systematic review and yet I was left wondering why not?? This is listed in the limitations of the paper too along with not using a grading system, yet they state in Table 2 that for what is known there is low to moderate evidence. How was this discerned? They also state in Table 2 that there is not enough evidence to make any conclusions. Yet, how do they know they reviewed as much of the evidence as possible by not using a systematic approach? Moreover, there is a risk of cherry picking resources to support the</p>
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	<p>recommendations, rather than be sure all the published evidence is reviewed for making the recommendations.</p> <p>5. The manuscript provides many supplemental resources that are useful. Figure 1 and supplemental file 2 seem very important to supporting the checklist.</p> <p>6. The interactive tool is very nice yet apparently not useful/appropriate for all patients (per the authors). Perhaps more about for whom this would be helpful is needed.</p> <p>7. There are multiple references list, I am assuming to go with the various tables/supplemental files.</p>
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VERSION 1 – AUTHOR RESPONSE

Comments from Reviewer 1 (Roland Brian Büchter, Department of Health Information, Institute for Quality and Efficiency in Health Care (IQWiG))		
5	<p>It was a pleasure to review this interesting and valuable paper. I believe that the authors have made a good job of distilling the most important requirements of communicating treatment effects to enable evidence-informed decisions. I find the table in additional file 2 to be particularly helpful, as it also discusses the (often difficult) practical aspects. With that in mind, I have some thoughts and suggestions for minor changes and additions to the manuscript. I have made these from the perspective of someone with a specific research interest in the topic and from the practical perspective of someone who develops evidence-based health information for the German public on a vast number of different topics.</p>	<p>Thanks for this comment and for such a careful and thoughtful review of our paper.</p>
6	<p>Box 1: Checklist for communicating Effects Item 3: I believe the word “potentially” should be dropped from this recommendation. Asking for “all potentially important benefits and harms” seems unrealistic for a number of reasons, including: the difficulties of gathering and assessing evidence on very rare harms; the added complexity of presenting a very large number of potentially important outcomes; the difficulty of comprehending them from the perspective of the information recipient. Furthermore, “potentially” is an ill-defined term and different outcomes might matter to different groups of people. The authors rightly highlight the importance of involving the target audience and this is arguably the most important step in selecting the outcomes that are important for decision making. The authors also describe the possible downsides very well under “caveats and risk mitigation” in additional</p>	<p>We agree with this point and have changed this to “<i>the most important benefits and harms</i>”.</p>

	<p>file 2. Asking for all “potentially relevant outcomes” might be asking too much from some information providers. (To elaborate: I believe that we should not let the perfect become the enemy of the good and – in making recommendations – should be mindful of honest and patient centred information providers who do their best to deliver good and reliable information but lack the resources to fulfil all the criteria that would be desirable from a methodological perspective such as dedicated and independent patients groups that develop information for their members, but lack the resources or skills to fulfil all criteria in the checklist, to name one example). <i>Suggestion for the manuscript: Consider dropping the word “potentially” from item 3.</i></p>	
7	<p>Item 6: When I read “summary of findings table” in this recommendation, I immediately associated this with GRADE SoF tables. The references, however, suggest that the authors are not exclusively referring to these, as they also cite drug fact boxes, for example (which I believe is appropriate). To avoid confusion, I suggest slightly rephrasing the item. <i>Suggestion for the manuscript: Consider rephrasing item 6 to avoid confusion, e.g. “Present both numbers and words, and consider including tables summarizing the treatment benefits and harms, for example using GRADE summary of findings tables or drug fact boxes”.</i></p>	<p>We have changed this item so that it now reads: 6. Present both numbers and words, and consider using tables to summarise benefits and harms, for instance using GRADE summary of findings tables or similar tables.</p>
8	<p>Items 4/7: While item 4 addresses the certainty of the evidence, I am missing an explicit statement that the presented effects should be based on fair comparisons – e.g. treatment vs no treatment/placebo/sham or an alternative treatment. Arguably this seems appropriate for benefits and most harms, at least. The authors could consider adding this to item 4 or item 7, e.g.: “Report absolute effects based on fair treatment comparisons such as the number of patients improving with treatment compared to the number of patients improving without treatment, or the absolute difference between these two.” This might not be self-explanatory to all readers and adding such a statement might help prevent dubious, but common uses of absolute “effects” (I often see statements such as “90% of the patients were satisfied with the treatment/improved” based on uncontrolled studies or because the control arms are ignored by the information provider). While comparisons are mentioned in additional file 3, I believe this</p>	<p>Having considered this suggestion, we do not agree that this should be added to the checklist. Basing information on systematic reviews of fair comparisons, whenever possible, is an underlying assumption of the checklist, as explained in the Introduction. We have further emphasised this by adding the highlighted text to the last sentence of the Introduction: <i>The aim of this paper is to provide guidance and a checklist to anyone who is preparing and communicating evidence-based information on the effects of interventions (i.e. information based on systematic reviews of fair comparisons) that is intended to inform decisions by patients and the public, health professionals, or policymakers.</i></p> <p>We have also added the highlighted text to the Detailed Guidance (additional file 3) for the first item in the checklist, where this point is addressed again: <i>Unless an intervention is compared to something else, it is not possible to know what would happen without the intervention, so it is difficult to attribute</i></p>

	<p>point might be important enough to be included in the checklist. <i>Suggestion for the manuscript: Consider explicitly including a statement that treatment effects should be based on fair comparisons from controlled studies, with few exceptions.</i></p>	<p><i>outcomes to the intervention. Consequently, it is essential to specify at least two options (the intervention and a comparison intervention, which may be simply not adding the intervention to whatever else is done) whenever presenting information about the effects of interventions. Ideally, you should consider all the relevant options, since people making choices want to know what their options are.</i></p> <p>And we have added the highlighted text to the Detailed Guidance for the 10th item, where this point is again addressed: <i>In order to earn their trust, and for transparency, you should tell them how the information was prepared, what evidence it is based on – and specifically whether the information about the effects of interventions is based on systematic reviews of fair comparisons.</i></p>
9	<p>Synthesis and comparison to other guidance Regarding the guidance documents on communicating treatment effects that the authors have collected and used to compare their checklist to, I would like to point them to a guideline on “evidence-based health information” that was developed by a research group at the University of Hamburg in collaboration with the working group for patient information and involvement of the German Network for Evidence Based Medicine. Many of the chapters of this guideline have been translated into English and can be found here: https://www.leitlinie-gesundheitsinformation.de/guideline/?lang=en I believe this guideline may be of interest to readers of this paper, as the guideline group has made a large effort to systematically review the evidence on various questions related to the communication of treatments effects and graded the evidence for each question using up to date methods for guideline development (transparency note: I have not been involved in developing these guidelines, but I am a member of the German Network for Evidence Based Medicine, I generally agree with most of the recommendations and I have commented on the guideline during an open consultation period). In summary, the recommendations in the German guideline are in line with the recommendations in the checklist developed for this paper, specifically the recommendation</p>	<p>Thank you for pointing this out to us. The authors of that guidance made us aware of these guidelines after we submitted this paper. They were not available in English at the time and, as noted by the reviewer, and on the group’s website: “Guideline report (Is not yet available)”. In keeping with the reviewer’s suggestions, we have made the following changes to the text: We noted limiting non-English language literature as a limitation in the list of “Strengths and limitations” below the abstract:</p> <ul style="list-style-type: none"> • <i>We did not review non-English language literature.</i> <p>We have revised the first paragraph of the Discussion and added a paragraph comparing our guidance to the German guidelines, so it now reads: <i>Although our guidance overlaps with other guidance [38,47-54], for the most part other guidance does not specifically addressing preparation of evidence-based information for decision makers about the effects of interventions. The one exception or which we are aware is the “Guideline for evidence-based health information” prepared by the German Network for Evidence-Based Medicine (DNEbM) [55], which is only partially translated to English as of April 2020. The DNEbM recommendations are consistent with or recommendations to present both numbers and words and report absolute effects. They do not explicitly address our other recommendations. Comparison of our guidance with other guidance is summarised in Table 1.</i></p> <p>In the subsequent paragraph that addresses recommendations regarding visualisations, we have added:</p>

	<ul style="list-style-type: none"> to present both numbers and words: https://www.leitlinie-gesundheitsinformation.de/wp-content/uploads/2019/08/Recommendation_Presentation-of-Frequencies_1.pdf to use absolute risk formats: https://www.leitlinie-gesundheitsinformation.de/wp-content/uploads/2019/08/Recommendation_Presentation-of-Frequencies_2.pdf and the statement that there is the limited evidence for adding visual aids: https://www.leitlinie-gesundheitsinformation.de/wp-content/uploads/2019/08/Recommendation_Using-Graphics_1.pdf <p>Of note, the developers of this guideline are currently conducting a randomised controlled trial to test whether implementing this guideline with an accompanying training program among providers of health information improves the quality of the health information being developed (http://www.isrctn.com/ISRCTN96941060). <i>Suggestion for the manuscript: Consider adding the German guideline for developing evidence-based health information to the discussion. While not all chapters have been translated to English yet, many have been, and these may be of additional interest to readers.</i></p>	<p><i>The DNEbM guidelines [55] recommend that “Graphics may be used to supplement numerical presentations in texts or tables” based on “low quality” evidence. They also recommend that “If graphics are used as a supplement, then either pictograms or bar charts should be used” based on “moderate quality” evidence.</i></p> <p>In the paragraph that addresses interactive presentations, we have added: <i>The DNEbM guidelines [55] suggest “Interactive elements may be used in health information” based on “moderate quality” evidence. Similarly, the . . .</i></p> <p>And we have added the following text to the paragraph that addresses including stories: <i>Lastly, the DNEbM guidelines [55] conclude that “Narratives cannot be recommended” based on “low quality” evidence. In contrast, . . .</i></p>
10	<p>Interestingly, the German guideline makes a weak recommendation against the use of patient stories/narratives, which are considered in the discussion of this paper: https://www.leitlinie-gesundheitsinformation.de/wp-content/uploads/2019/08/Recommendation_Using-Narratives_1.pdf</p> <p>I personally believe that this recommendation is not specific enough and risks throwing out the baby with the bathwater. While there are very good reasons to avoid using patient stories to communicate treatment effects and some evidence to support this, there are many other reasons for their use (e.g. allowing for peer to peer communication, providing emotional support, reducing stigma, illustrating how different preferences can lead to different decisions, understanding how certain interventions and their outcomes may affect everyday life and simply because people ask for them). In addition to the review by Fadlallah et al. [60] that the authors cite, I am aware of only one quantitative study which examined the effects of patient stories, albeit not as an add-on to specific treatment information</p>	<p>We agree with this comment and have edited the text to reflect this: <i>Lastly, the DNEbM guidelines [55] conclude that “Narratives cannot be recommended” based on “low quality” evidence. In contrast, the IPDAS checklist [51,52] recommends including stories of other patients’ experiences and using audio and video to help users understand information. We agree that this may be helpful. However, it is also possible that stories that specifically describe patients’ experiences of treatment effects and side effects can have unintended consequences. For example, people’s perceptions of their own risks of experiencing a benefit or harm could be influenced by whether they identify with the person telling the story or not. We are not aware of evidence from randomised trials comparing information with and without patients’ experiences, audio, or video; or comparing different types of presentations. A recent systematic review on the use of narratives to impact health policymaking did not find any trials [61].</i></p>

	<p>(Giesler et al. 2017, https://www.jmir.org/2017/10/e334/). This RCT set out to examine whether provision of patient stories via the German DIPEX increases self-efficacy for coping with bowel cancer and patient competence using a waiting-list design. The trial faced some methodological challenges, however, and failed to find an effect.</p> <p><i>Suggestion for the manuscript: I agree with the authors that more research is needed on the use of patient stories. However, their possible advantages and disadvantages depend on their purpose of use and the manuscript is a bit vague and could be differentiated regarding this issue (page 8, lines 23-31). Since the focus of this paper is to provide recommendations on communicating treatment effects, it seems appropriate to caution readers regarding the use of patient stories for this purpose – in contrast to other purposes, where they may be useful as suggested above.</i></p>	
11	<p>Tables 1 and Figure 2 <i>Please check the references in table 1 and figure 1. Several of these do not seem to match the citations in the reference list.</i></p>	<p>We have corrected the references in Table 1, Table 2, and Figure 1. Thank you. We also checked the references in the text to ensure that they were correct.</p>
12	<p>Table 2 In table 2, the authors make suggestions for further research. I was surprised to that see that communicating uncertainty (e.g. risk of bias, lack of sufficient follow-up, applicability) is not included here and wonder whether this is intentional. There is some research on the effects of communicating statistical uncertainty/precision of effect estimates (e.g. https://www.ncbi.nlm.nih.gov/pubmed/22858415 and https://www.ncbi.nlm.nih.gov/pubmed/26823204). To my knowledge, however, little is known about the effects of communicating other types of uncertainty and how to do this. From my experience, it is usually difficult for people to distinguish between the two concepts of the magnitude of an effect and the certainty or confidence in an effect estimate. (Transparency note: we have conducted a trial to evaluate the effects of how we communicate uncertainty in our health information and are currently in the process of publishing this; German Clinical Trials Register DRKS00015911). <i>Suggestion for the manuscript: consider adding the research need on how to communicate uncertainty, especially to patients and the public. The Agency for Healthcare Research and Quality has conducted a systematic review on this</i></p>	<p>We recommend that evidence-based information about effects should “Explicitly assess and report the certainty of the evidence.” The basis for this recommendation is provided in Additional file 2 and detailed guidance for this recommendation is provided in Additional file 3. While we agree that head to head comparisons of different ways of doing this are warranted, we have not included this or many other uncertainties that warrant further investigation. The list in Table 2 is not intended to be complete. As stated in the text under Implications for research: <i>We have summarised key uncertainties that we identified while preparing this checklist in Table 2.</i></p> <p>That said, although we did not identify the above as a key uncertainty, we did identify how best to report confidence intervals as a key uncertainty, as noted in the Detailed guidance (Additional file 3) for item 8: <i>Although confidence intervals are more informative than p-values, confidence intervals can also be misinterpreted [3,30]. There are pros and cons to reporting confidence intervals and little evidence to support a recommendation either to include them or exclude them, or how to present and explain them, if they are included. Deciding whether and how to report confidence intervals may depend on the target audience.</i></p> <p>We have added that key uncertainty to Table 2, which is supported by the AHRQ review.</p>

	<p>issue in 2013 (https://www.ncbi.nlm.nih.gov/books/NBK179104/), but an up to date review appears timely.</p>	
13	<p>I also believe that it would be helpful to agree on a set of outcomes that should be used in research on communicating treatment effects. I am not sure, whether the authors would agree with this, but if so, they might consider adding this to the list. <i>Suggestion for the manuscript: consider discussing the need for a review and consensus on appropriate outcomes for studies evaluating different approaches of communicating treatment effects.</i></p>	<p>We agree with this point and have added the following sentence to the text under Implications for research: <i>In addition, there is a need for a methodological review and a consensus on appropriate outcomes for studies evaluating different ways of communicating evidence-based information about the effects of interventions [e.g. 62].</i></p>
14	<p>Flow chart The authors might consider including feedback from content experts in the process for producing evidence-based information. I don't think that this is always required, but depending on the topic and how the team developing the information is composed, it can be helpful (I agree that many experts have strong opinions and their interpretation of the evidence often has to be taken with a pinch of salt, but this need not be the case and they can also provide helpful insights). In my experience, it is also very useful to involve editors to make the language concise and easy to understand, which could also be added as a consideration to the flow chart. <i>Suggestion for the manuscript: consider adding feedback from content experts and editors to the flow chart.</i></p>	<p>We agree and we have added this to the third step in the flow chart:</p> <ul style="list-style-type: none"> Establish an editorial process including, for instance, peer review using content experts, assessment of language quality, and copy editing.
<p>Reviewer 2. Sharon Jo Tucker, Ohio State University - College of Nursing Columbus, OH USA</p>		
15	<p>This manuscript focuses on creation of a checklist that can guide the development and communication of health interventions and their level of evidence for those making decisions about the relevance and appropriateness of implementing select health interventions. This checklist adds to existing published tools and can provide a needed resource. There are some issues needing clarification and revision.</p>	<p>Thank you.</p>
16	<p>1) The aim is not very clear to me including that the checklist (primary outcome) is not listed. It is also a bit confusing. Seems it could read better - perhaps something like this: The aim of this paper is to provide guidance and a checklist for people preparing and communicating evidence-based information on the effects/relevance of interventions for health decision makers (e.g., patients and the public, health professionals, or policymakers).</p>	<p>We have clarified this in the abstract by adding the highlighted text: <i>The aim of this paper is to provide guidance and a checklist to those producing and communicating evidence-based information about the effects of interventions intended to inform decisions about healthcare.</i></p> <p>And at the end of the introduction: <i>The aim of this paper is to provide guidance and a checklist to anyone who is preparing and communicating evidence-based information on the effects of interventions</i></p>

17	<p>Consistent with the aim, I was unclear in reading the paper about specifically who the recommendations are for in the end? Patients will need a very different tool than clinicians, and policy makers, yet these are included as one group. I found this confusing.</p>	<p>The recommendations are for anyone who is communicating evidence-based information about the effects of interventions for any of those audiences:</p> <p><i>The aim of this paper is to provide guidance and a checklist to anyone who is preparing and communicating evidence-based information on the effects of interventions that is intended to inform decisions by patients and the public, health professionals, or policymakers.</i></p> <p>As explained in the introduction, we disagree that very different recommendations are needed for those different audiences.</p>
18	<p>I would have liked to see the study design listed in the abstract and manuscript. The study seems to use a mixed methods approach with a literature review, hybrid Delphi technique or qualitative method, and report of some quantitative data. This omission lacks some rigor.</p>	<p>We agree that this can best be described as a mixed methods study, and we have now referred to it as such in the paper's title.</p>
19	<p>The authors acknowledge that they did not conduct a systematic review and yet I was left wondering why not?? This is listed in the limitations of the paper too along with not using a grading system, yet they state in Table 2 that for what is known there is low to moderate evidence. How was this discerned? They also state in Table 2 that there is not enough evidence to make any conclusions. Yet, how do they know they reviewed as much of the evidence as possible by not using a systematic approach? Moreover, there is a risk of cherry picking resources to support the recommendations, rather than be sure all the published evidence is reviewed for making the recommendations.</p>	<p>We used systematic reviews when they were available. As noted, our approach was pragmatic. The paper would have required conducting multiple systematic reviews, which would require substantial resources and time. While we agree it would be helpful to have more systematic reviews, that was not our aim.</p> <p>We do refer to “low to moderate certainty” in Table 2. However, this is the judgement of the authors of the review that is cited (which includes a GRADE SoF table).</p> <p>We agree that we cannot rule out that we missed relevant evidence. We did not knowingly cherry pick evidence, but we agree readers might reasonably be concerned that we did. That is why we acknowledged not conducting systematic reviews as a limitation. We did search for research, compare our recommendations to the recommendations of others (and the evidence that they found), and seek feedback from experts. As noted, we also reference all our recommendations and describe the basis for each recommendation in additional file 2.</p> <p>We have now highlighted the need for more research, including systematic reviews, in this field under “Implications for research”.</p>
20	<p>The manuscript provides many supplemental resources that are useful. Figure 1 and supplemental file 2 seem very important to supporting the checklist.</p>	<p>Thank you.</p>
21	<p>The interactive tool is very nice yet apparently not useful/appropriate for all patients (per the authors). Perhaps more about for whom this would be helpful is needed.</p>	<p>We did not say and would not conclude that the iSoF is not appropriate for all patients. What we found and say is the following:</p>

		<p><i>“The qualitative data that we collected suggested that participants (people in Scotland with an interest in participating in randomised trials of interventions [60]) had mixed views about their preferences for an interactive versus a static presentation.”</i></p> <p>It is possible to postulate several possible reasons for this finding, but at present there is not evidence, which is why we included this as a question in Table 2.</p>
22	There are multiple references list, I am assuming to go with the various tables/supplemental files.	There is one reference list for the text, tables and figures. Additional file 2 and additional file 3 each have a separate reference list.

VERSION 2 – REVIEW

REVIEWER	Roland Brian Büchter Department of Health Information, Institute for Quality and Efficiency in Health Care (IQWiG), Germany
REVIEW RETURNED	21-Apr-2020

GENERAL COMMENTS	Many thanks for addressing and thoughtfully replying to my comments and adding this helpful paper to the field. Best wishes, RBB
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REVIEWER	Sharon Tucker The Ohio State University Columbus, OH 43212
REVIEW RETURNED	11-May-2020

GENERAL COMMENTS	Appreciate the thoughtful revisions.
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