PEER REVIEW HISTORY

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ARTICLE DETAILS

| TITLE (PROVISIONAL) | The design and user-testing of a question prompt list for attention-deficit/hyperactivity disorder |
|---------------------|-------------------------------------------------------------------------------------------------|
| AUTHORS             | Ahmed, Rana; Raynor, David; McCaffery, Kirsten; Aslani, Parisa                                |

VERSION 1 - REVIEW

| REVIEWER               | Bora Pajo                                                  |
|------------------------|-----------------------------------------------------------|
| Mercyhurst University, Pennsylvania, United States |                                                                |
| REVIEW RETURNED        | 17-Sep-2014                                               |

| GENERAL COMMENTS       | My biggest concern about this study is the fact that it considers ADHD to be an actual disorder or disease. The work described here does not consider the fact that there are no tests, no exams, no x-rays to detect or diagnose ADHD. Also, many researcher question the validity of diagnostication and medicalization of children. I think, if one is trying to reduce parents' confusion about these things, maybe one needs to tell parents that there is no agreement in the research community about ADHD. Some researchers believe this is a disorder of the brain, whereas others believe it is merely an exhibit of differences among children and other social and cultural factors. I think it is unethical to design something like this booklet that will help parents adhere to medications when in fact we don't know the long term effect of those medications on children yet.

In terms of research, the study is well conducted, the language is engaging and professional. I think the statistics are properly conducted. I am concerned about how this booklet addresses the ambiguity of this childhood problem. It may have been important to include this booklet as a supplement in the article.

I guess the entire literature that questions the validity of ADHD is missing from this article. It only gives one perspective on the problem, and I would be skeptical about distributing this booklet to parents when it is only showing the side of researchers who believe that ADHD is a disorder of the brain and children need to be medicated. Denying parents the fact that there are other opinions about these issues, and that there are not real biological markers to detect ADHD for sure, and that we don't know yet the effects of medications on these children in the long term, is unethical to say the least. |
**REVIEWER** | Robyn Sayner, PharmD  
Postdoctoral Research Fellow  
University of North Carolina, USA  
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**REVIEW RETURNED** | 23-Sep-2014  
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**GENERAL COMMENTS** | Thank you for the opportunity to review such an interesting manuscript. This manuscript thoroughly details the process of refining the content and the format of a question prompt list booklet to be used by parents/caregivers of children/adolescents with ADHD using actual input from 20 parents/caregivers of children/adolescents with ADHD.

One minor item to be considered for clarification is found on page 19, line 8 where the authors refer to "point (d) above"; however, it is a little confusing about which point the authors are referring to.

The authors should consider clarifying why the parents' years of formal education was used rather than the parents' level of health literacy. There may be some people who have completed university-level courses who are not able to understand medical literature, or those who have obtained a secondary level of education who are able to understand medical literature.

Also, the authors may consider adding how long the children have been diagnosed with ADHD so that readers can understand how much background knowledge about ADHD parents might already have before reviewing the question prompt list booklet.

Finally, the authors should consider describing how they envision their question prompt list booklet be used in clinical practice. When would this be given to the parents in the current workflow of a pediatric clinic?

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**REVIEWER** | Emma Sciberras  
Murdoch Childrens Research Institute  
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**REVIEW RETURNED** | 26-Sep-2014  
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**GENERAL COMMENTS** | Thank you for the opportunity to review this interesting study. This study aimed to develop a question prompt list (QPL) for parents of children with ADHD. The ultimate goal is that this QPL will be used in clinical consultations to facilitate communication between parent and health-care providers. The study is novel and is based on solid background work. I think this study will be of interest to the readers of this journal. The key strength of this study is that the questions included in the QPL were generated via a Delphi study conducted with parents, clinicians and researchers. The authors reference the paper for this work as being under review. Is there any update on the status of this article?

The main limitation of this study is the relatively small sample size that was used in the testing process (i.e. two groups of 10 parents). Although it is reported that another group was not required given that most issues were resolved after the second group, it raises the possibility that the diversity of parents of children with ADHD that reviewed this booklet was limited.

It needs to be clearer from the outset how parents would be able to
access the QPL in real-life clinical practice. Many of the questions seem particularly important at the time of diagnosis but how would this be facilitated? The discussion does not provide enough of a discussion about the clinical applicability of this resource in real-life clinical practice.

How long ago had the children of the participants been diagnosed with ADHD? I think this is an important factor to consider in the QPL process. The needs of families of newly diagnosed children are likely to be different from the needs of parents who have been dealing with the diagnosis for many years.

A stronger rationale for not proceeding to Round 3 could have been provided. For example, there were still instances in which 1 in 5 families had some difficulties with some content material in Round 2.

I am unclear why the authors chose to include information about the impact of diet on ADHD in the QPL but did not include other more important relating to comorbidities and common medications. I understand the authors’ initial rationale for not providing this information (i.e. the purpose is to encourage parents to ask questions and obtain tailored responses) but the same should apply to diet. The rationale for this decision and potential impact needs to be much clearer i.e. it may influence parents to believe that diet is one of the most important issues in ADHD.

Thank you again for the opportunity to review this interesting work.

VERSION 1 – AUTHOR RESPONSE

Reviewer 1: Bora Pajo

Comment 1
My biggest concern about this study is the fact that it considers ADHD to be an actual disorder or disease. The work described here does not consider the fact that there are no tests, no exams, no x-rays to detect or diagnose ADHD.

Response
The authors wish to thank the reviewer for these insights. We agree that the aetiology of ADHD is an area of ongoing research and inquiry. However, it is not possible to discount the extensive body of literature which provides credence to the existence of ADHD and the benefits associated with approved treatments for the disorder when correctly diagnosed.

In light of this, the researchers have approached the current work from the perspective that:
1. ADHD is a clinically diagnosable condition as stipulated by the Diagnostic and Statistical Manual of Mental Disorders (DSM-V, American Psychiatric Association, 2014) and the International Classification of Diseases (ICD-10, World Health Organisation, 1994)
2. The management of ADHD symptoms with pharmacotherapy is standard clinical practice as emphasised throughout international treatment guidelines:
   (http://www.nhmrc.gov.au/_files_nhmrc/publications/attachments/mh26_adhd_cpp_2012_120903.pdf
   - http://pediatrics.aappublications.org/content/early/2011/10/14/peds.2011-2654 -
   http://www.nice.org.uk/guidance/cg72/chapter/guidance)

The reviewer has also noted that “there are no tests, no exams, no x-rays to detect or diagnose ADHD”. We believe that there are a number of well-documented diagnostic tools used to support DSM-V/ICD-10 criteria during initial assessments for ADHD e.g. Conners’ rating scale http://www.mhs.com/product.aspx?gr=cli&id=overview&prod=conners3 & the Strengths and Difficulties Questionnaire http://bjp.rcpsych.org/content/177/6/534.short
The aim of our work is to develop a tool to empower parents of children diagnosed with ADHD to ask questions in order to find out further information about the diagnosis, treatment and prognosis of the condition and to support their decision making. We have now clarified this purpose in the introduction and discussion of the manuscript, please refer to page 7 and page 23 of the revised manuscript.

Comment 2
Also, many researcher question the validity of diagnostication and medicalization of children. I think, if one is trying to reduce parents' confusion about these things, maybe one needs to tell parents that there is no agreement in the research community about ADHD. Some researchers believe this is a disorder of the brain, whereas others believe it is merely an exhibit of differences among children and other social and cultural factors. I think it is unethical to design something like this booklet that will help parents adhere to medications when in fact we don't know the long term effect of those medications on children yet.

Response
We again acknowledge the reviewer’s comments. Potential for overdiagnosis and medicalization of children is already addressed in the introductory section of the manuscript with appropriate references included- we have highlighted this section in the revised version of the manuscript, please refer to page 4.

We are in agreement with the reviewer that clinicians should have open and transparent discussions with parents about the disorder and its treatments. Whether or not clinicians are already engaging with parents in such discussions is beyond the scope of the current manuscript and would require further investigation. However, we believe the question prompt list booklet we have developed for parents and carers may be one of the first steps in promoting or enhancing these discussions, and an important step towards shared decision making.

We strongly believe that our booklet is not “unethical” when its intended purpose is to encourage parents to express their concerns and preferences during consultations with the clinicians involved in their child’s care by asking appropriate and relevant questions from the QPL booklet. The content of the booklet was previously determined through a Delphi process with clinical experts as well as parents and advocates. The booklet contains questions related to a variety of ADHD-related topics, spanning from identifying and understanding the disorder through to treatment (medicines, psychological and alternative), monitoring the disorder and future expectations. Also, there are a number of questions in the QPL, which are directly related to the controversies surrounding the disorder including questions about diagnosis as well as the short and long-term effects associated with medication use. The full list of QPL topics has now been included in the revised version of the manuscript, please refer to page 7.

We anticipate that the booklet will allow parents to obtain information that is tailored to their specific situation and ultimately make informed (and importantly shared) decisions about treatments. Therefore, if it is deemed that the booklet encourages informed and shared decisions, and for parents who choose pharmacological management, the booklet supports adherence to treatment (if that is the chosen option with their clinician), then we don’t perceive that this will have any ethical implications for families using this booklet.

Although we agree with the reviewer that the long-term effects of the medications used for ADHD are still being researched, we believe that this is a question more suited to examinations of treatment persistence rather than treatment adherence. To reiterate, the intended purpose of the OPL is to increase parents’ knowledge about ADHD and its treatments and to enhance their potential for shared decision making about treatment options. A consequence of this may be that families who choose medication as a treatment option, will be better informed about it and may have better adherence as a consequence.

Comment 3
In terms of research, the study is well conducted, the language is engaging and professional. I think the statistics are properly conducted. I am concerned about how this booklet addresses the ambiguity of this childhood problem. It may have been important to include this booklet as a supplement in the
Response
We were very keen to include a soft copy of the booklet as a supplement to our submitted manuscript. However, the booklet is currently being tested for its suitability during clinical interactions between parents and their child’s paediatricians. Depending on the outcomes of this study, the researchers may need to make some changes to the booklet before its full content can be made publicly available.

Comment 4
I guess the entire literature that questions the validity of ADHD is missing from this article. It only gives one perspective on the problem, and I would be skeptical about distributing this booklet to parents when it is only showing the side of researchers who believe that ADHD is a disorder of the brain and children need to be medicated. Denying parents the fact that there are other opinions about these issues, and that there are not real biological markers to detect ADHD for sure, and that we don't know yet the effects of medications on these children in the long term, is unethical to say the least.

Response
We thank the reviewer for their insights here.

We disagree that “the entire literature” discussing some of the controversies surrounding ADHD is missing from the manuscript. We have made reference to the fact that this remains a contentious area in the literature and provided appropriate references within the introductory section of the manuscript. However, we have now provided further detail about this in the introduction of the manuscript and reinforced this in the discussion - please refer to page 4 and page 26 of the revised manuscript.

The reviewer notes that “I would be skeptical about distributing this booklet to parents when it is only showing the side of researchers who believe that… children need to be medicated”. The authors would like to emphasise that we have made no such statement regarding our stance towards medicating children. The booklet we have developed is based on the findings of a needs analysis conducted by the research team exploring the information needs of parents and carers of children with ADHD and which is referenced within the current manuscript (references 17 & 22). We developed this booklet in response to parents’ expressed needs from this investigation with the sole intention of allowing parents to allay any of their concerns and to make informed decisions about their child’s care - which may very well be decisions NOT to commence pharmacotherapy. In no way does the booklet promote the use of medications nor does it deny parents “the fact that there are other opinions about these treatments”. As per our previous response, there are whole topics dedicated to the use of non-pharmacological and alternative treatments in our booklet.

The authors wish to thank the reviewer for their time in reviewing our manuscript and for their valuable feedback.

Reviewer 2: Robyn Sayner

Comment 1
Thank you for the opportunity to review such an interesting manuscript. This manuscript thoroughly details the process of refining the content and the format of a question prompt list booklet to be used by parents/caregivers of children/adolescents with ADHD using actual input from 20 parents/caregivers of children/adolescents with ADHD.

Response
The authors wish to thank the reviewer for their kind comments.

Comment 2
One minor item to be considered for clarification is found on page 19, line 8 where the authors refer to “point (d) above”; however, it is a little confusing about which point the authors are referring to.

Response
Thank you for highlighting this. Point (d) relates to parents asking about obtaining a second medical
opinion (Question 10 of the user-testing interview). This has now been clarified in-text. Please refer to page 20 of the revised manuscript.

Comment 3
The authors should consider clarifying why the parents' years of formal education was used rather than the parents' level of health literacy. There may be some people who have completed university-level courses who are not able to understand medical literature, or those who have obtained a secondary level of education who are able to understand medical literature.

Response
Based on previous user-testing studies, it is standard practice to recruit participants from a range of educational levels, to ensure that the study sample is from a broad section of the population. Educational level was used as a proxy for literacy levels in this study (rather than health literacy, for the reasons outlined by the reviewer). Although education and health literacy are not synonymous, educational level remains the strongest predictor of health literacy. Screening for health literacy levels as part of study inclusion is a consideration for future modifications of the user testing process. The user testing process is currently limited in this respect. We have now highlighted this as a limitation of the current study - please refer to page 26 of the revised manuscript.

Comment 4
Also, the authors may consider adding how long the children have been diagnosed with ADHD so that readers can understand how much background knowledge about ADHD parents might already have before reviewing the question prompt list booklet.

Response
As noted in the limitations section of the manuscript, we did not specifically enquire about or record the treatment or diagnostic histories of the participants' children nor did we assess their level of ADHD-related knowledge. We believe that the time since diagnosis does not necessarily reflect how much background information/knowledge parents might already have about ADHD. We also believe that for the purposes of this study (where we were user-testing a booklet which principally consists of questions), these assessments were not relevant. The purpose of user testing was to determine the parents' ability to locate, understand and act on the questions listed in the booklet.

Comment 5
Finally, the authors should consider describing how they envision their question prompt list booklet be used in clinical practice. When would this be given to the parents in the current workflow of a pediatric clinic?

Response
Thank you for this suggestion. We anticipate that the question prompt list booklet will be of most value to parents who have been referred for or have recently received an ADHD diagnosis. Greater detail about our vision for the distribution and use of the QPL has now been included in text. Please refer to page 27 of the manuscript.

The authors would like to thank the reviewer for their time and valuable feedback on our manuscript.

Reviewer 3: Emma Sciberras

Comment 1
Thank you for the opportunity to review this interesting study. This study aimed to develop a question prompt list (QPL) for parents of children with ADHD. The ultimate goal is that this QPL will be used in clinical consultations to facilitate communication between parent and health-care providers. The study is novel and is based on solid background work. I think this study will be of interest to the readers of this journal.

Response
The authors wish to thank the reviewer for her generous comments about our manuscript.

Comment 2
The key strength of this study is that the questions included in the QPL were generated via a Delphi study conducted with parents, clinicians and researchers. The authors reference the paper for this work as being under review. Is there any update on the status of this article?

Response
As per our response to the editorial comments, the manuscript related to our Delphi study remains under review at the present time.

Comment 3
The main limitation of this study is the relatively small sample size that was used in the testing process (i.e. two groups of 10 parents). Although it is reported that another group was not required given that most issues were resolved after the second group, it raises the possibility that the diversity of parents of children with ADHD that reviewed this booklet was limited.

Response
The purpose of the user testing method used in the current study was to determine whether users of our QPL would be able to locate, understand and act on key questions in the document. It is important to note that small sample sizes are common in studies applying user testing as a diagnostic tool for document performance. Most deficiencies in a document can be identified after interviewing just 10 potential users. Importantly, as is standard practice in user testing, testing was conducted until the EU targets for document testing were achieved (at the conclusion of the second round of testing). We believe that the small sample recruited here was appropriate for our study aims. The diversity of parents of children with ADHD was captured during the content-development process, our Delphi study and our current testing of the QPL booklet in clinical environments.

Comment 4
It needs to be clearer from the outset how parents would be able to access the QPL in real-life clinical practice. Many of the questions seem particularly important at the time of diagnosis but how would this be facilitated? The discussion does not provide enough of a discussion about the clinical applicability of this resource in real-life clinical practice.

Response
We have now included further detail in the revised version of the manuscript about how we envision the QPL to be used in real-life clinical practice and how parents would be able to access the resource. Please refer to page 27 of the revised manuscript.

Comment 5
How long ago had the children of the participants been diagnosed with ADHD? I think this is an important factor to consider in the QPL process. The needs of families of newly diagnosed children are likely to be different from the needs of parents who have been dealing with the diagnosis for many years.

Response
As noted in the limitations section of the manuscript, we did not specifically enquire about or record the treatment or diagnostic histories of the participants’ children. We did not feel that this information would be relevant in addressing the aims of the current study namely, to determine whether or not potential users of the booklet could locate, understand and act on the questions within it. We believe that time since diagnosis would be a critical factor for parents in deciding which sections of the QPL to use during clinical consultations. The QPL consists of questions that could be used by parents during the developmental lifespan of their child and therefore from the point of diagnosis to when their child no longer requires treatment or is an adult with ADHD, whichever applies. The impact of time since diagnosis is currently being assessed in our study of the acceptability and usefulness of the QPL in the clinical setting (interactions between parents and paediatricians).

Comment 6
A stronger rationale for not proceeding to Round 3 could have been provided. For example, there were still instances in which 1 in 5 families had some difficulties with some content material in Round 2.
Response

There were 2 information points that were located and understood by 8 out of 10 participants at the conclusion of Round 2. The remaining 13 information points were located and understood by all 10 participants. Our decision to conclude testing at this point was based on the fact that these results met the targets set by the EU for medicine leaflet testing. These are the standard targets used in all user-testing studies.

Comment 7

I am unclear why the authors’ chose to include information about the impact of diet on ADHD in the QPL but did not include other more important relating to comorbidities and common medications. I understand the authors’ initial rationale for not providing this information (i.e. the purpose is to encourage parents to ask questions and obtain tailored responses) but the same should apply to diet. The rationale for this decision and potential impact needs to be much clearer i.e. it may influence parents to believe that diet is one of the most important issues in ADHD.

Response

To clarify, the only addition made to the QPL which related to the impact of diet on ADHD was in the form of a question, rather than any detailed information about diet. The question was “How does diet affect ADHD?” and was included under Topic 2, “Understanding ADHD” - we have highlighted this section in Table 2 of the manuscript. This addition was only made after interest in the inclusion of a question related to diet was identified during the user-testing interviews.

The purpose of the QPL we have developed is to encourage parents to ask their child’s clinicians questions that are relevant to their child’s specific needs so as to obtain tailored responses that can be updated over time. For this reason and as summarised by the reviewer, we did not include any sections of information about any ADHD-related topics. Apart from the instructions on how to use the booklet, the content of the QPL consisted only of questions for parents to ask their child’s clinicians. We have added an additional statement to reinforce this fact- please refer to page 7 of the revised manuscript.

Comment 8

Thank you again for the opportunity to review this interesting work.

Response

The authors would like to thank the reviewer for taking the time to review our manuscript and for her valuable feedback and suggestions.

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VERSION 2 – REVIEW

| REVIEWER          | Emma Sciberras  |
|-------------------|-----------------|
| Murdoch Childrens Research Institute, Australia |               |

| REVIEW RETURNED | 23-Nov-2014 |

GENERAL COMMENTS

Thank you for the opportunity to re-review this manuscript. The authors have been very responsive to the reviewers’ comments. In fact, I feel that the altering of the introduction to incorporate reviewer 1’s comments was unnecessary. The purpose of this article is not to examine the validity of the ADHD diagnosis and the way the introduction is now positioned puts some doubt on the validity of the ADHD diagnosis. As I’m sure the authors are aware, ADHD is one of the most widely researched disorders of childhood. Although there is no one cause of ADHD, this does not undermine the validity of the diagnostic category. This is common to most other mental health or even medical conditions, where a number of different risk factors, both biological and environmental, contribute to the development of the condition. I prefer the introduction included in the initial
The additional information describing the purpose of the QPL is very helpful and strengthens the manuscript. Similarly, the additions to the manuscript about the next steps in rolling out the QPL are welcomed and will be of interest to readers.

I have no further suggestions except for recommending that the original version of the introduction be included in this article.

VERSIO\N 2 – AUTHOR RESPONSE

Reviewer Name- Emma Sciberras
Comment:
Thank you for the opportunity to re-review this manuscript. The authors have been very responsive to the reviewers’ comments. In fact, I feel that the altering of the introduction to incorporate reviewer 1’s comments was unnecessary. The purpose of this article is not to examine the validity of the ADHD diagnosis and the way the introduction is now positioned puts some doubt on the validity of the ADHD diagnosis. As I’m sure the authors are aware, ADHD is one of the most widely researched disorders of childhood. Although there is no one cause of ADHD, this does not undermine the validity of the diagnostic category. This is common to most other mental health or even medical conditions, where a number of different risk factors, both biological and environmental, contribute to the development of the condition. I prefer the introduction included in the initial submission of this article.

The additional information describing the purpose of the QPL is very helpful and strengthens the manuscript. Similarly, the additions to the manuscript about the next steps in rolling out the QPL are welcomed and will be of interest to readers.

I have no further suggestions except for recommending that the original version of the introduction be included in this article.

Authors’ response:
The authors would like to thank the reviewer for taking the time to provide us with this feedback. We strongly agree with the reviewer's comments regarding the validity of the diagnosis and the extensive body of research in this area. The changes to the introduction were made in an attempt to address the concerns of reviewer 1 from our initial submission. However we have now reverted back to the original version of the introduction as recommended, and kept some minor additions which increased the clarity of the information. These have been highlighted in the revised version of the manuscript.