PEER REVIEW HISTORY

ARTICLE DETAILS

TITLE (PROVISIONAL)	Decisional needs assessment of patients with complex care needs in primary care: a participatory systematic mixed studies review protocol
AUTHORS	Bujold, Mathieu; Pluye, Pierre; Legare, France; Haggerty, Jeannie; Gore, Genevieve C.; El Sherif, Reem; Poitras, Marie-Eve; Beaulieu, Marie-Claude; Beaulieu, Marie-Dominique; Bush, Paula; Couturier, Yves; Debarges, Beatrice; Gagnon, Justin; Giguère, Anik; Grad, Roland; Granikov, Vera; Goulet, Serge; Hudon, Catherine; Kremer, Bernardo; Kroger, Edeltraut; Kudrina, Irina; Lebouche, Bertrand; Loignon, Christine; Lussier, Marie-Therese; Martello, Cristiano; Nguyen, Quynh; Pratt, R; Rihoux, Benoit; Rosenberg, Ellen; Samson, Isabelle; Senn, Nicolas; Li Tang, David; Tsujimoto, Masashi; Vedel, Isabelle; Ventelou, Bruno; Wensing, Michel

VERSION 1 – REVIEW

REVIEWER	Nananda Col Shared Decision Making Resources, USA I consult widely in the development and testing of decision aids and other interventions to support shared decision making. I have my own contract research and consulting company that develops and tests decision support tools.
REVIEW RETURNED	01-May-2017

GENERAL COMMENTS	The decisional needs assessment proposed at face value, appears to serve an important step. However, the premise of this undertaking needs clarification. The premise appears to be that it is possible to identify the decision needs of patients with complex care needs and to extract a taxonomy of decisional needs from a body of published works that did not necessarily set out to address decisional needs, and that the importance of those needs could then be prioritized by the team of investigators. These two premises do not seem to be supported. If the purpose is to develop a taxonomy of decisional needs, why would one start from this body of published work, much of which may have been motivated by other factors. Starting with published literature, as is proposed, runs a risk of conflating pre-determined outcomes that were identified by investigators/authors of the studies, with the decisional needs of the stakeholders themselves. Thinking about studies of DA, many DA studies tend to draw heavily on previously published works for their needs assessment, or do a poor job of describing their formative work. Many simply use validated instruments and outcomes that were chosen to demonstrate a positive impact of a tool that was already

	developed and/or marketed, so it is not at all clear to me how the proposed work will accomplish the stated objectives. Additionally the proposed work is not entirely clear about who are the stakeholders of interest and how they will be identified and stratified in the study. What is the rationale for limiting the study to primary care settings? Would the decisional needs of patients be different in specialty care settings? The boundaries between specialty care and primary care are somewhat fluid. There seems to be a rather large leap of faith involved between developing a taxonomy and designing an IP-SDM tool. The methods presented on p 13 address simply the logistics of assembling a team, not the design of the tool. Then the paper moves directly in dissemination. This is a significant shortcoming. p.4, lines 9-11. I am confused by the definition of patients with complex care needs, which seems perhaps a bit narrow. What about the person with a single diagnosis but that on its own requires complex care? For example, there are many chronic conditions which in and of themselves create complex care needs. For example, MS, Crohn's disease, TBI, stroke, to name but a few. In describing the evidence about SDM, I think it is important to distinguish between patient decision aids, which were what was specifically studied in the Cochrane review, and SDM. SDM and patient DAs appear to be conflated. (p.7 , lines 15-16, in the statement "A Cochrane systematic review of 110 randomized controlled trials provides strong evidence for the effectiveness of SDM and decision support tools.) Further, decision support tools and DAs are not the same. Perhaps define the terms used and be consistent about their use. It is important to note that most of the DAs included in the Cochrane review of decision aids only targeted patients, bypassing HCPs altogether (hence their name, patient decision aids). As such, the definition offered for SDM in this paper, which mentions HCPs, seems somewhat off and inconsistent with the evidence that is available. The benefits of SDM are somewhat exaggerated. For example, the statement that 'SDM is the most effective decision making process when careful deliberation is needed to.." is not actually supported, to my knowledge. (p 7, lines 31-32). If this has been established, please describe the approaches that SDM has been compared to. Furthermore, as noted above, the evidence pertains to patient decision aids, not to SDM. The focus on decisional conflict is somewhat problematic and confusing, in light of the body of literature showing that more decisional conflict may be beneficial. Perhaps some acknowledgement of those studies, and an explanation about why you focus on this measure. Further, the focus on decisional conflict does not seem to tie into the remaining methods. If you rely on that outcome, you may run into a circular reasoning problem. Many studies relied on decisional conflict early on because it was the first validated measure to assess a good decision. Then as the field grew and other measures emerged, it became perhaps the only measure that one could consistently rely on if one wanted to demonstrate a positive impact of a decision aid (which helped in getting a paper published, a research grant funded, or for companies or foundations that profited from their decision aids, at least in the US). If you use this outcome in your review, you run the risk of confirming the elements included in this measure (a self-fulfilling prophesy). P8, line 21. The word 'Inspired' could be replaced perhaps by 'based upon'? More rationale for the use of MMAT instead of GRADE would be useful. The refs cited as validating all appear in the same journal,

	making me wonder about the robustness of the tool. The dichotomous grading seems inconsistent with GRADE. Why is GRADE itself not used? It can be used to assess non-randomized studies. p.9. Who are the stakeholders? Does it refer to patients or practitioners (as is implied elsewhere?) Will family members/surrogate decision makers be included as well? Third party payers? These stakeholders are not necessarily clearly identified in studies. P 10, lines 33-35. Some explanation of how CCM works and will be operationalized for this study would be helpful. The term 'theory-driven' is sprinkled throughout the paper (e.g., p 10, line 41) without a clear definition of which theory or theories are driving the proposed work.

REVIEWER	Karen Sepucha Massachusetts General Hospital, Harvard Medical School, USA Dr. Sepucha receives salary support as a scientific advisory board member for Healthwise, a not for profit organization that develops patient education material including patient decision aids.
REVIEW RETURNED	17-May-2017

GENERAL COMMENTS	This paper outlines a proposal for developing decision support tool for patients with complex care needs. The team will use mixed methods, including a comprehensive literature review to create a taxonomy of needs, then engage a larger team to prioritize key decisional needs, and finally, create a prototype decision support tool. The project addresses an important and understudied area, and the description of the methods for conducting the systematic review and developing the taxonomy of decisional needs is strong. However, the description of the methods for identifying key needs and the development of the tool is lacking sufficient details. 1. P5: It would be helpful to provide more details of the IP-SDM model. 2. The authors suggest that they will contribute to theory with their results, please clarify how they plan to do this. Are there certain aspects of the model that the authors anticipate adapting or confirming using this population? Are there pre-specified hypotheses that they plan to test with the data collected from their systematic review? 3. P 7 Methods: second paragraph mentions that "team members are knowledge users": please provide some details on how many are on the team, their background/stakeholder group, and the roles and responsibilities. This would be helpful as it appears that the team is really only participating in a half day meeting and the executive team is doing the bulk of the work. In addition, please describe the executive task force – who is in that group, what is the structure and responsibilities. 4. P 8 Eligibility criteria: 4a. The inclusion criteria for the systematic review say populations with at least one of the following...and include "healthcare services overuse, misuse or underuse." This criteria seem too broad and many published studies documenting overuse do not necessarily mean that the population has complex care needs. Please clarify how a study of overuse/misuse/underuse is sufficient for indicating complex care needs? 4b. Why do the authors limit the studies to a primary health care

	setting? It would seem that inter-professional and organizational issues that the authors emphasized were important might be lost if the search is limited to primary care only. Please provide further justification for the limitation of published studies to primary care setting. 5. P11. The authors introduce a demonstration project that involves interviews and focus groups to explore decision needs and states that the systematic review and demo project will be used to validate decisional needs. It would be important to provide details for how these very different sources of information will be combined and in particular, how discrepancies or differences will be addressed in determination of the key decisional needs. 6. P12: There are not sufficient details to understand the development of the decision tool. It is possible that this section could be removed from this paper, or else, it will require considerable additional details to describe the approach to developing a decision support tool and how it is employing 'user-centered design.' To do this well, it will need to be at least as detailed as the methods used to conduct the systematic review. 7. P12: The dissemination plan is confusing – and details about the tool are introduced here that seem to make many assumptions about the results of the taxonomy and determination of key decisional needs (e.g. they have already determined it will be part of a case management intervention and that it will be web-based tool, etc). What if the needs assessment finds a different target or different approach is more important?

VERSION 1 – AUTHOR RESPONSE

REVIEWER: 1

The decisional needs assessment proposed at face value, appears to serve an important step.

RESPONSE

Thank you.

COMMENT R1.1

However, the premise of this undertaking needs clarification. The premise appears to be that it is possible to identify the decision needs of patients with complex care needs and to extract a taxonomy of decisional needs from a body of published works that did not necessarily set out to address decisional needs, and that the importance of those needs could then be prioritized by the team of investigators. These two premises do not seem to be supported.

If the purpose is to develop a taxonomy of decisional needs, why would one start from this body of published work, much of which may have been motivated by other factors. Starting with published literature, as is proposed, runs a risk of conflating pre-determined outcomes that were identified by investigators/authors of the studies, with the decisional needs of the stakeholders themselves. Thinking about studies of DA, many DA studies tend to draw heavily on previously published works

for their needs assessment, or do a poor job of describing their formative work. Many simply use validated instruments and outcomes that were chosen to demonstrate a positive impact of a tool that was already developed and/or marketed, so it is not at all clear to me how the proposed work will accomplish the stated objectives.

RESPONSE TO COMMENT R1.1

Thank you. These issues are addressed in 3 ways (Revised Manuscript Marked Copy).

First, parallel qualitative decisional need assessment

This systematic review is planned and conducted in parallel with a qualitative research study on the same topic (decisional needs assessment) and the same research questions about the patients with complex care needs. This has been clarified in several sections of this manuscript. In the abstract, two sentences have been added (page 3, paragraph 1, last sentence; page 3, paragraph 2, first sentence). In the Introduction section, we deleted the last sentence and added a new one (page 8, paragraph 2, last sentence). In the Methods section, we revised four sentences (page 14, paragraph 2, sentences 1 to 4). In the Discussion section, we revised three sentences (page 15, paragraph 2, sentence 3; page 16, paragraph 3, sentences 1 and 2). Also, the Author contributions section has been revised to list the authors of this systematic review who are also involved in the qualitative decisional need assessment (page 18-19).

Second, participatory research approach, involving researchers and knowledge users

All the stage of this systematic review will use a participatory research approach, carrying out the work in collaboration with not only with researchers, but also with knowledge users (clinicians, patients and managers) from various backgrounds. This collaboration with people experiencing and working with complex care needs situations will reduce the risk of conflating pre-determined outcomes with the decisional needs of the patients with complex care needs. This has been clarified in the following sections of the manuscript. In the Abstract, we revised one sentence (page 2, paragraph 2, last objective). We revised the second point of the Strengths and limitations section (pages 3). We also revise the third objective in the Review question and objectives section (Page 8, paragraph 3, third objective). In the Methods section, we revised fives sentences: (Page 9, paragraph 1, sentences 3; Page 9, paragraph 2, sentences 2, 3, 4, and 5). In the Discussion section, we revised one sentence (Page 16, paragraph 4, sentence 2). Knowledge users are defined in Key terms section (page 18). Finally, we added a table in the Appendix (table 1, page 20) to describe the multidisciplinary expertise of our research team.

Third, decisional needs by type of stakeholder

The results of decisional needs thematic analysis will be categorised according to type of stakeholder. The qualitative data (extracts of the selected studies) will be assigned to ‘attributes’, namely: patients,

family, caregivers, practitioners, others, using specialized software (NVivo). This will allow us to, for example, compare the perceptions that patients have of their decisional needs with the practitioners' ones. We will also assign with other categories of attributes to the data (e.g. types of practitioners). This has been clarified. In the Methods section, four sentences have been added (Page 12, paragraph 3, sentences 1-4) and one revised (Page 12, paragraph 4).

COMMENT R1.2

Additionally the proposed work is not entirely clear about who are the stakeholders of interest

RESPONSE TO COMMENT R1.2

Thank you for asking for this clarification. This has been clarified in the Abstract (page 2, paragraph 1), the Introduction section (page 5, paragraph 1, sentence 5) and Key terms section (page 17). Stakeholders are the patients with complex care needs, their families, their caregiver, their health care practitioners or any other people involved in decisions-making related to their complex care needs (surrogate, significant others, case manager, decision coach, navigator, mediator, interpreter, etc.).

In fact, it is part of the decisional needs assessment to identify all stakeholders. A sentence has been added in the Decisional needs assessment subsection (page 8, paragraph 2, question 5).

COMMENT R1.3

How they will be identified and stratified in the study?

RESPONSE TO COMMENT R1.3

Please see the response to the comment above. See R 1.1 (Third, decisional needs by type of stakeholder)

COMMENT R1.4

What is the rationale for limiting the study to primary care settings?

RESPONSE TO COMMENT R1.4

Thank you. Two sentences and three references have been added in the Introduction to justify our focus on primary care settings (page 5, paragraph 1 and 2, firsts sentences). Primary care plays a key role regarding complex care needs situations. This study emerges from a group of health and social primary care practitioners, patients and researchers who identified the necessity to better understand

PCCNs decisional needs. Moreover, majority of clinical research (at least in Canada) is conducted in secondary or tertiary care. Indeed, this systematic review is timely as it addresses an important issue for our partners and a priority of the Quebec Ministry of Health.

See also response to comment R 1.5

COMMENT R1.5

Would the decisional needs of patients be different in specialty care settings? The boundaries between specialty care and primary care are somewhat fluid.

RESPONSE TO COMMENT R1.5

This has been specified, and a parenthesis added in Eligibility criteria section (page 10, paragraph 4, second criterion). The decision needs of patients with complex care needs are not limited to primary care. This systematic review includes primary care studies and studies on integrated care (dealing with links between primary care and other settings). For example, one type of decisions needs is related to the option to consult a specialist.

The sentence 'primary care patients with complex care needs' may be confusing as these patients use all types of care including the hospital, and has been revised throughout the manuscript, as well as the title. Thus, "primary care" has been removed from the Abstract (page 3, paragraph 2), one sentence in the Strengths and limitations section (page 3, first point), one sentence in the Introduction section (page 8, paragraph 2), two sentences in the Methods section (page 13, paragraph 3; page 14, paragraph 2), and from one sentence in the Discussion (page 15, paragraph 2).

COMMENT R1.6

There seems to be a rather large leap of faith involved between developing a taxonomy and designing an IP-SDM tool. The methods presented on p 13 address simply the logistics of assembling a team, not the design of the tool. Then the paper moves directly in dissemination. This is a significant shortcoming.

RESPONSE TO COMMENT R1.6

Thanks for highlighting this challenge. The Title has been revised ("tool" removed). The Objective 4 (page 8) and the related section (page 14) have been removed. We have also removed the reference to the tool in three sentences in the Abstract (Page 2, paragraph 1, last sentence; Page 3, paragraph 1 & 2), six in the IP-SDM model subsection (page 6, paragraph 2, sentences 2 to 7), two in the Decisional needs assessment subsection (page 8, paragraph 1, last sentence; page 8, paragraph 2, sentence 2), one in the Review question and objectives subsection (page 8, paragraph 3, sentence 2), two in the Methods section (Page 9, paragraph 1, 2), and one in the Discussion section (Page 15, paragraph 2, sentence 2; Page 17, paragraph 2). A legend has also been added to the IP-SDM figure (page 21).

The tool development will be a subsequent step, and part of a provincial ‘Demonstration project’ of the Quebec SPOR SUPPORT Unit (funded by the Canadian Institutes of Health Research, the Quebec Ministry of Health, and the Quebec Research Fund in Health). The tool development will be based on the combination of the results of this systematic review with those of the above-mentioned parallel qualitative research study. We agree there is not enough space in this manuscript to clearly describe the development of the tool, and the manuscript has been revised to simply mention it in the Discussion section (page 16, paragraph 1, sentence 2).

COMMENT R1.7

p.4, lines 9-11. I am confused by the definition of patients with complex care needs, which seems perhaps a bit narrow. What about the person with a single diagnosis but that on its own requires complex care? For example, there are many chronic conditions which in and of themselves create complex care needs. For example, MS, Crohn’s disease, TBI, stroke, to name but a few.

RESPONSE TO COMMENT R1.7

The definition has been clarified. We have revised two sentences in the abstract (page 2, paragraph 1, 2 first sentences). In the first paragraph of the Introduction section (page 5), we have revised three sentences (sentences 2, 4 and 6) and added one (sentences 5). A sentence has been added in the Decisional needs assessment subsection (page 8, paragraph 2, sentence 4). We also have revised the “Patients with complex care needs” eligibility criteria in the Methods section (page 10, paragraph 3).

Typically, patients with complex care needs face interactional issues (patient-practitioner and interprofessional) in interrelated decision-making process involving various stakeholders (themselves, their families, their caregivers, their health care practitioners). Previous pilot research (case series and scoping review) identified possible characteristic of patients with complex care needs. These patients often suffer from combinations of multiple chronic conditions, mental health problems, drug interactions and social vulnerability, which can lead to health care services overuse, underuse or misuse. We agree that a person with a single diagnosis could have complex care needs, while another with multiples chronic conditions may not have such needs. Our criteria take this into account to increase the sensitivity of our comprehensive literature search and selection process.

COMMENT R1.8

In describing the evidence about SDM, I think it is important to distinguish between patient decision aids, which were what was specifically studied in the Cochrane review, and SDM. SDM and patient

DAs appear to be conflated. (p.7, lines 15-16, in the statement “A Cochrane systematic review of 110 randomized controlled trials provides strong evidence for the effectiveness of SDM and decision support tools.) Further, decision support tools and DAs are not the same. Perhaps define the terms used and be consistent about their use. It is important to note that most of the DAs included in the Cochrane review of decision aids only targeted patients, bypassing HCPs altogether (hence their name, patient decision aids). As such, the definition offered for SDM in this paper, which mentions HCPs, seems somewhat off and inconsistent with the evidence that is available.

RESPONSE TO COMMENT R1.8

Thanks for highlighting this distinction. See our response to comment R 1.6 (removal of tool-related sentences).

This review aims to make a theoretical contribution to the Interprofessional Shared Decision Making (IP-SDM) model that extends the SDM beyond the patient-health professional dyad to interprofessional (IP) teams. The explanation of the IP-SDM model has been enhanced (page 7, paragraph 2, sentences 3 to 6) and the expected theoretical contribution of our study to this model have been clarified in the Abstract (page 3, paragraph 2, sentence 2), in the IP-SDM model subsection (page 7, paragraph 2, last sentence); in the Methods section (page 13, paragraph 1, sentence 5) and in the Discussion section (page 15, paragraph 2, sentence 5).

COMMENT R1.9

The benefits of SDM are somewhat exaggerated. For example, the statement that ‘SDM is the most effective decision making process when careful deliberation is needed to..” is not actually supported, to my knowledge. (p 7, lines 31-32). If this has been established, please describe the approaches that SDM has been compared to. Furthermore, as noted above, the evidence pertains to patient decision aids, not to SDM.

RESPONSE TO COMMENT R1.9

The SDM benefits have been nuanced (page 6, paragraph 2).

COMMENT R1.10

The focus on decisional conflict is somewhat problematic and confusing, in light of the body of literature showing that more decisional conflict may be beneficial. Perhaps some acknowledgement of those studies, and an explanation about why you focus on this measure. Further, the focus on decisional conflict does not seem to tie into the remaining methods.

If you rely on that outcome, you may run into a circular reasoning problem. Many studies relied on decisional conflict early on because it was the first validated measure to assess a good decision. Then as the field grew and other measures emerged, it became perhaps the only measure that one

could consistently rely on if one wanted to demonstrate a positive impact of a decision aid (which helped in getting a paper published, a research grant funded, or for companies or foundations that profited from their decision aids, at least in the US). If you use this outcome in your review, you run the risk of confirming the elements included in this measure (a self-fulfilling prophesy).

RESPONSE TO COMMENT R1.10

We agree. In fact, decisional conflicts are only one of the elements of a decisional needs assessment. This has been clarified in six sentences: Abstract (page 2, paragraph 1, sentence 2; and page 3, paragraph 2, sentence 2); Introduction section (page 5, paragraph 1, sentence 4; and paragraph 2, sentence 4); Decisional needs assessment subsection (page 7, paragraph 3, sentences 3 and 4); and Method section (the “Decision needs” eligibility criteria have been revised in page 10, paragraph 2).

COMMENT R1.11

P8, line 21. The word ‘Inspired’ could be replaced perhaps by ‘based upon’?

RESPONSE TO COMMENT R1.11

The word has been replaced (page 10, paragraph 2).

COMMENT R1.12

More rationale for the use of MMAT instead of GRADE would be useful. The refs cited as validating all appear in the same journal, making me wonder about the robustness of the tool. The dichotomous grading seems inconsistent with GRADE. Why is GRADE itself not used? It can be used to assess non-randomized studies.

RESPONSE TO COMMENT R1.12

The sentence mentioning GRADE has been removed (page 11, paragraph 3), and a review of critical appraisal tools has been cited (page 11: Crowe & Sheppard, Journal of Clinical Epidemiology, 2011). In this review, the MMAT is used because it allows for concomitantly appraising the methodological quality of qualitative, quantitative and mixed methods. This is necessary for the present systematic mixed studies review (including studies with diverse research methods). For example, the GRADE cannot be used for appraising the methodological quality of qualitative research and mixed methods (combining qualitative and quantitative methods).

COMMENT R1.13

p.9. Who are the stakeholders? Does it refer to patients or practitioners (as is implied elsewhere?) Will family members/surrogate decision makers be included as well? Third party payers? These stakeholders are not necessarily clearly identified in studies.

RESPONSE TO COMMENT R1.13

Please see the response to the comment R 1.2

COMMENT R1.14

P 10, lines 33-35. Some explanation of how CCM works and will be operationalized for this study would be helpful.

RESPONSE TO COMMENT R1.14

A methodological sentence listing main steps of a CCM analysis has been added (page 13, paragraph 1).

COMMENT R1.15

The term ‘theory-driven’ is sprinkled throughout the paper (e.g., p 10, line 41) without a clear definition of which theory or theories are driving the proposed work.

RESPONSE TO COMMENT R1.15

Please see the response to the comment R 1.8

REVIEWER: 2

This paper outlines a proposal for developing decision support tool for patients with complex care needs. The team will use mixed methods, including a comprehensive literature review to create a taxonomy of needs, then engage a larger team to prioritize key decisional needs, and finally, create a prototype decision support tool. The project addresses an important and understudied area, and the description of the methods for conducting the systematic review and developing the taxonomy of decisional needs is strong.

RESPONSE

Thank you.

COMMENT R 2.1

P5: It would be helpful to provide more details of the IP-SDM model.

RESPONSE TO COMMENT R 2.1

See response to comment R1.8

COMMENT R 2.2

2. The authors suggest that they will contribute to theory with their results, please clarify how they plan to do this. Are there certain aspects of the model that the authors anticipate adapting or confirming using this population? Are there pre-specified hypotheses that they plan to test with the data collected from their systematic review?

RESPONSE TO COMMENT R 2.2

See response to comment R 1.8

COMMENT R 2.3

3. P 7 Methods: second paragraph mentions that “team members are knowledge users”: please provide some details on how many are on the team, their background/stakeholder group, and the roles and responsibilities. This would be helpful as it appears that the team is really only participating in a half day meeting and the executive team is doing the bulk of the work.

RESPONSE TO COMMENT R 2.3

This has been specified. The Author contributions section has been revised (page 18-19, Revised Manuscript Marked Copy) and a table has been added in the Appendix (Table 1, page 20). Six sentences have been revised (page 9, paragraph 3, sentence 5; page 10, paragraph 1, last sentence; page 12, paragraph 2, sentence 3; Page 12, paragraph 3, sentence 2; Page 13, paragraph 3, last sentence; and Page 14, paragraph 1, sentence 2) and two sentences have been added in the Methods section (page 12, paragraph 2, sentence 2; & page 14, paragraph 2, sentence 3).

All team members, including knowledge users, will participate in this study, via the workshops, email, and by commenting the blog and during a half day meeting. Knowledge users and team members are defined in Key terms section (page 18).

COMMENT R 2.4

In addition, please describe the executive task force – who is in that group, what is the structure and responsibilities.

RESPONSE TO COMMENT R 2.4

This has been described in the Author contributions section has been revised (page 18-19) and a table has been added in the Appendix (Table 1, page 20).

COMMENT R 2.5

4. P 8 Eligibility criteria:

4a. The inclusion criteria for the systematic review say populations with at least one of the following...and include ”healthcare services overuse, misuse or underuse.” This criteria seem too broad and many published studies documenting overuse do not necessarily mean that the population has complex care needs. Please clarify how a study of overuse/misuse/underuse is sufficient for indicating complex care needs?

RESPONSE TO COMMENT R 2.5

We did not change the eligibility criteria. Our previous pilot research (case series and scoping review) identified potential characteristics of patients with complex care needs. One of them is possible “health care services overuse, underuse or misuse”. Thus, we use these criteria to increase the sensitivity of our systematic review (comprehensive search). Stated otherwise, we agree that the “healthcare services overuse, misuse or underuse” criteria are broad, but the other selection criteria, particularly the “decisional needs” criterion, will considerably reduce the number of studies when we will reed full-text papers.

COMMENT R 2.6

4b. Why do the authors limit the studies to a primary health care setting? It would seem that inter-professional and organizational issues that the authors emphasized were important might be lost if the search is limited to primary care only. Please provide further justification for the limitation of published studies to primary care setting.

RESPONSE TO COMMENT R 2.6

Thank you. This has been justified. See response to comment R 1.4 and R 1.5

COMMENT R 2.7

5. P11. The authors introduce a demonstration project that involves interviews and focus groups to explore decision needs and states that the systematic review and demo project will be used to validate decisional needs. It would be important to provide details for how these very different sources of information will be combined and in particular, how discrepancies or differences will be addressed in determination of the key decisional needs.

RESPONSE TO COMMENT R 2.7

See response to comment R 1.1.

COMMENT R 2.8

6. P12: There are not sufficient details to understand the development of the decision tool. It is possible that this section could be removed from this paper, or else, it will require considerable additional details to describe the approach to developing a decision support tool and how it is employing 'user-centered design.' To do this well, it will need to be at least as detailed as the methods used to conduct the systematic review.

RESPONSE TO COMMENT R 2.8

See response to comment R 1.6.

COMMENT R 2.9

7. P12: The dissemination plan is confusing – and details about the tool are introduced here that seem to make many assumptions about the results of the taxonomy and determination of key decisional needs (e.g. they have already determined it will be part of a case management intervention and that it will be web-based tool, etc). What if the needs assessment finds a different target or different approach is more important?

RESPONSE TO COMMENT R 2.9

See response to comment R 1.6