PEER REVIEW HISTORY

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ARTICLE DETAILS

TITLE (PROVISIONAL)	Changing Conversations in Primary Care for Patients Living with Chronic Conditions: A Pilot and Feasibility Study of the ICAN Discussion Aid
AUTHORS	Boehmer, Kasey R.; Dobler, Claudia; Thota, Anjali; Branda, Megan; Giblon, Rachel; Behnken, Emma; Organick, Paige; Allen, Summer; Shaw, Kevin; Montori, Victor

VERSION 1 – REVIEW

REVIEWER	Michael McGillion McMaster University, Canada
REVIEW RETURNED	14-Feb-2019

GENERAL COMMENTS	Thank you for the opportunity to review this paper, which I believe will make a substantive contribution with some modifications. There are a few areas for improvement that, if addressed, would serve to strengthen the paper. Items for consideration are as follows: The abstract is balanced. However, it would be a good idea to clearly explain the breakdown of proportions expressed in terms of clinical encounters. For example, p. 5, line 8 to 13 states, "The first 40 clinical encounters were usual care. After the first 40 encounters, clinicians were then trained during a standing meeting or individually on how to use the ICAN Discussion Aid. The remaining 60 clinical encounters were intended to be ICAN encounters". This is later followed by the following text on page 21, Table 4, line, 2: "All Encounters (n=84/ICAN= 45)". I find the breakdown somewhat confusing- further clarity is needed. The abstract should state the duration of data collection/time to follow up. This is missing. 4. Are the methods described sufficiently to allow the study to be repeated? In terms of methods a few points of clarification would help: • The ICAN tool could be described more clearly. There is little to no description of it. • The data collection time points are also unclear, as is the study setting (e.g. MD office, clinic setting?). • There is no clear description of what data was being collected (for patients e.g. obtaining patient/clinician address/ contact to follow up p5. line 3 to allow for follow up survey collection) • Further, it was not stated who consented the clinicians to participate (p.4, line 34) • Also, what was used to screen patients for major barriers to consent (p.4, line 38-43)?

	□ It was not stated who approached participants prior to participation (p.4, line 43). In terms of discussion of the results, it would be useful to explore the potential impact of some topics being discussed less frequently with use of ICAN tool (e.g. family, faith…). For example, is there any potential for less frequent discussions of these topics to negatively impact patients? If so, does the potential benefit of the topics of increased discussion outweigh the potential harms of discussing these other topics less frequently? It would also be useful to reflect on potential reasons why only 45/60 ICAN encounters yielded useable data. For example, 9/13 times the clinicians did not use the ICAN tool; they stated that it was not needed. Exploring the reasons behind clinicians perceiving that the tool was not needed would perhaps provide insights on priority use cases for the ICAN tool. Finally, it would be helpful to address in the limitations section the fact that in terms of the medication adherence data, only two thirds (27/40) of pre-intervention patients had pharmacy records analyzed.

REVIEWER	Claudia Zanini Department of Health Sciences and Health Policy, University of Lucerne, Switzerland Swiss Paraplegic Research, Nottwil, Switzerland
REVIEW RETURNED	08-Apr-2019

GENERAL COMMENTS	Comment for the authors The paper is well written and clearly structured. The pilot test of the ICAN Discussion Aid is methodologically sound and well described. However, the relevance of the study and the added value of the ICAN Discussion Aid for clinical practice remains unclear in the current version of the manuscript. I invite the authors to reflect on the purpose of their instrument and to better explain to the readers how it can contribute to the achievement of specific health outcomes. My main comments are related to the introduction, in particular to the presentation of the ICAN Discussion Aid, and to the discussion section. The improvements in the manuscripts will need to be reflected in the abstract. Introduction • Who was involved in the development of the ICAN Discussion Aid? How was it developed? And more importantly, what is the purpose of the instrument? In my opinion, this is the main flaw of the article: if it is not clear what the purpose of the instrument is, how can we measure its impact and assess the results? If the development of the ICAN Discussion Aid was described in a previous publication, it would be appropriate to refer to it. If its development is not described anywhere, I suggest that the authors dedicate a short paragraph to it. Considering the centrality of the concept of “treatment burden”, I guess that contributing to reducing treatment burden might be the goal of the instrument. However, treatment adherence seems also to play a major role. To better define the desired endpoints, I propose that the authors refer, for instance, to the model developed by Haes and Bensing or to the model by Street et al. (see references and figures below). Discussion

	• Clarifying the goal of the ICAN Discussion Aid and its endpoints can help also in the discussion of the results and in their evaluation. From the results presented, it seems that the instrument has the potential to modify the topics discussed, by taking into consideration topics that are more relevant to the patients and topics in relation to competing priorities (this is also reflected in the proposed title of the manuscript). Why is this valuable per se? Can this be considered as a proximal or intermediate outcome for treatment burden? • The clinicians consider the instrument to be feasible and length of the visit was not impacted. However, they perceived that it worsened the success of the visit. This perception is likely to be an obstacle for clinicians to use the ICAN Discussion Aid in their practice. How will you address this perception? Considering their perception, why shall clinicians use the ICAN Discussion Aid? • Several other instruments have been developed for the medical consultation to improve the communication between clinicians and patients (e.g. treatment decision aids). I invite the authors to discuss the added value of the ICAN Discussion Aid with respect to other instruments. • I believe that in your discussion you could further address one of your findings, namely the fact that clinicians elicited competing priorities using the ICAN Discussion Aid. It is for sure important that patients can voice their topics of choice. However, I believe that it is even more central that clinicians discuss competing priorities, especially in the case of MCC. As shown in previous literature, the need to adhere to treatment recommendations is overruled by the desire to live a full and meaningful life and the fear of a decreased quality of life. This phenomenon, called sometimes “strategic non-compliance”, was observed in several chronic conditions and could hinder adherence to the treatment plan (see for instance: Campbell et al. 2003; Jackson et al 2010; Zanini et al 2018). • In the conclusion, the authors state that the pilot testing was successful. Nonetheless, to foster the implementation of an instrument, its relevance for clinical practice should be proven. For this reason, it is important to show how the instrument has the potential to contribute to the achievement of health outcomes. Some potentially useful references: • Haes, H. de, Bensing, J. Endpoints in medical communication research, proposing a framework of functions and outcomes. Patient Education and Counseling: 2009, 74(3), 287-294

Fig. 2. Functions of medical communication, its goals and outcomes.

	Six function model of medical communication	Goals	Immediate endpoints	Intermediate (and/or surrogate) endpoints
1	Fostering the relationship(s)	Good and effective relationship	e.g., + eye contact + patient participation - physiological stress measure	e.g., + trust + sense of rapport + satisfaction with consultation
2	Gathering information	Adequate diagnosis and/or interpretation of symptoms	e.g., + explorative behavior + expression of patient concerns	e.g., + adequate diagnosis / treatment plan - diagnostic test ordering - medical errors
3	Providing information	Good information provision	e.g., + check understanding / explore prior knowledge - used of jargon	e.g., + recall + understanding
4	Decision making	Decision based on information and preferences	e.g., check decision making preference / patient values + provide information	e.g., - decisional conflict + satisfaction with decision
5	Enabling disease & treatment related behavior	Adequate and feasible disease and treatment related behavior	e.g., address patient motivation and efficacy	e.g., + illness related behavior + treatment adherence + life style ? costs
6	Responding to emotions	Supporting the patient, enhancing the communication and referral where needed	e.g., + clinician explorative skills / silence + patient expression of emotions ? time constraints	e.g., + patient sense of support + treatment of psychopathology

- R.L. Street Jr, G. Makoul, N.K. Arora, R.M. Epstein, How does communication heal? Pathways linking clinician–patient communication to health outcomes, Patient education and counseling 74 (2009) 295-301.

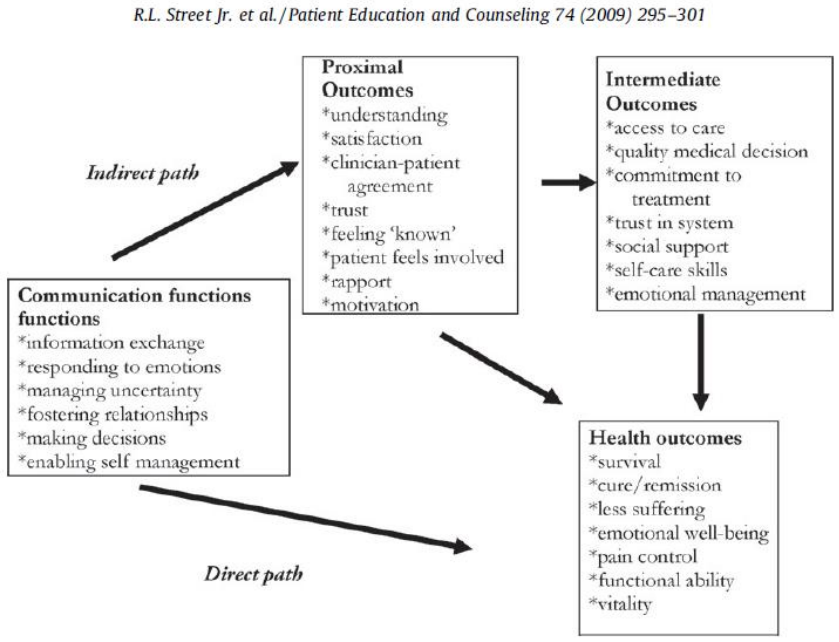

Fig. 1. Direct and indirect pathways from communication to health outcomes.

- Campbell R, Pound P, Pope C, Britten N, Pill R, Morgan M, et al. Evaluating meta-ethnography: a synthesis of qualitative research on lay experiences of diabetes and diabetes care. Soc Sci Med 2003;56(4):671–684.
- Jackson J, Carlson M, Rubayi S, Scott MD, Atkins MS, Blanche EI, et al. Qualitative study of principles pertaining to lifestyle and pressure ulcer risk in adults with spinal cord injury. Disabil Rehabil 2010;32(7):567–578.

	• C. Zanini, M. Brach, N. Lustenberger, A. Scheel-Sailer, H.G. Koch, G. Stucki, S. Rubinelli, Engaging in the prevention of pressure injuries in spinal cord injury: A qualitative study of community-dwelling individuals' different styles of prevention in Switzerland, J Spinal Cord Med 12 (2018) 1-10.

VERSION 1 – AUTHOR RESPONSE

Comment 1: The paper is well written and clearly structured. The pilot test of the ICAN Discussion Aid is methodologically sound and well described. However, the relevance of the study and the added value of the ICAN Discussion Aid for clinical practice remains unclear in the current version of the manuscript. I invite the authors to reflect on the purpose of their instrument and to better explain to the readers how it can contribute to the achievement of specific health outcomes.
My main comments are related to the introduction, in particular to the presentation of the ICAN Discussion Aid, and to the discussion section. The improvements in the manuscripts will need to be reflected in the abstract.

Response: Thank you for your very helpful reviews of this manuscript. We have taken all comments into consideration and revised the manuscript accordingly. In line with your reviews, the bulk of the edits are within the background and discussion sections. For example, we have added the following section to address the potential impact of the ICAN discussion aid:

“To date, the ICAN Discussion Aid remains untested in terms of its impact on the discussion of patient workload, capacity, and treatment burden in the clinical encounter. We hypothesize that if ICAN proves feasible in busy primary care and positively impacts the clinical encounter with greater discussion of patients’ context, it could spark treatment plans that better fit patients’ lives, with downstream impact on patient health outcomes and quality of life.”

Comment 2: Who was involved in the development of the ICAN Discussion Aid? How was it developed? And more importantly, what is the purpose of the instrument? In my opinion, this is the main flaw of the article: if it is not clear what the purpose of the instrument is, how can we measure its impact and assess the results? If the development of the ICAN Discussion Aid was described in a previous publication, it would be appropriate to refer to it. If its development is not described anywhere, I suggest that the authors dedicate a short paragraph to it. Considering the centrality of the concept of “treatment burden”, I guess that contributing to reducing treatment burden might be the goal of the instrument. However, treatment adherence seems also to play a major role. To better define the desired endpoints, I propose that the authors refer, for instance, to the model developed by Haes and Bensing or to the model by Street et al. (see references and figures below).

Response: In our first version, it was unclear that the reference to the development paper was made in the introduction section. We have now called out this reference explicitly. Furthermore, the development of ICAN was grounded in a model already, called the Cumulative Complexity Model. We have thus made this explicit as well in the fourth paragraph of the introduction. Finally, we have stated the way in which we hypothesize the aid can improve patient care and outcomes in the final paragraph of the introduction.

“The ICAN Discussion Aid (Figure 1) was developed to address these problems, with the aim of enabling the discussion of patient workload, capacity, and treatment burden within the time constraints of busy primary care visits.17 The process to develop ICAN is described in full

elsewhere.17 Briefly, it was developed using a robust, iterative user-centered design process, previously used to develop decision aids18 and was grounded in the Cumulative Complexity Model, which states that patients living with chronic illness must enact both patient and life work with limited capacity.19 When workload exceeds patient capacity, it affects patients' abilities to access and use healthcare and enact self-care, in turn effecting their health outcomes.19 In addition to worsening health outcomes, unaddressed workload-capacity imbalance can lead to a vicious cycle of added treatment burden and illness burden.19

To date, the ICAN Discussion Aid remains untested in terms of its impact on the discussion of patient workload, capacity, and treatment burden in the clinical encounter. We hypothesize that if ICAN proves feasible in busy primary care and positively impacts the clinical encounter with greater discussion of patients' context, it could spark treatment plans that better fit patients' lives, with downstream impact on patient health outcomes and quality of life."

Comment 3: Clarifying the goal of the ICAN Discussion Aid and its endpoints can help also in the discussion of the results and in their evaluation. From the results presented, it seems that the instrument has the potential to modify the topics discussed, by taking into consideration topics that are more relevant to the patients and topics in relation to competing priorities (this is also reflected in the proposed title of the manuscript). Why is this valuable per se? Can this be considered as a proximal or intermediate outcome for treatment burden?

Response: This is a good point, as we did not make explicit the reason that the outcome of greater discussion of patient-important topics is ultimately a good outcome. We have now clarified our understanding of how this finding relates to the Cumulative Complexity Model (as described in the introduction) as well as the relationship to Street's model as suggested. This change was made by adding an additional paragraph to the discussion on page 12 – 13 that reads:

"Ultimately, the discussion of topics of greater importance to patients and their competing priorities is important as it could lead to better tailoring of treatment plans to patients' context, improving the workload-capacity balance in managing chronic illness. As mentioned earlier, the Cumulative Complexity Model postulates that workload-capacity balance impacts patients' abilities to access and use healthcare and enact self-care, with downstream impact on their outcomes.19 Furthermore, communication models, such as the one proposed by Street et al. have postulated the pathways from patient-clinician communication to patient outcomes.27 For example, Street's model supports that communication functions supported by ICAN such as managing uncertainty, fostering relationship, and enabling self-management can impact proximal outcomes such as patient trust and "feeling known," with downstream consequences on self-care skills, adherence, and ultimately health outcomes.27"

Comment 4: The clinicians consider the instrument to be feasible and length of the visit was not impacted. However, they perceived that it worsened the success of the visit. This perception is likely to be an obstacle for clinicians to use the ICAN Discussion Aid in their practice. How will you address this perception? Considering their perception, why shall clinicians use the ICAN Discussion Aid?

Response: This is definitely something we have begun to work into our in-person and online trainings in using ICAN, and we have called out the way in which we believe this finding should be interpreted and addressed at the end of the first paragraph on page 14:

"Specifically, this requires attention and clinician exposure in future ICAN trainings to the potentially uncomfortable and off-script conversations that may occur as a result of using the aid, as well as practice in having those conversations first in safe spaces, such as with peers and trainers, prior to real-life clinical encounters."

Comment 5: Several other instruments have been developed for the medical consultation to improve the communication between clinicians and patients (e.g. treatment decision aids). I invite the authors to discuss the added value of the ICAN Discussion Aid with respect to other instruments.
Response: Indeed, ICAN is not intended to replace a treatment decision aid, but provides big-picture information about the patient's situation that may be helpful in considering more specific decisions. We have now discussed this in the first paragraph on page 13:
"ICAN is a general discussion aid for use in chronic illness, intended to provide insight into the personal, social, material, and spiritual aspects of the patient's situation; it can be used in conjunction with the many available decision-specific conversation aids.28 For example, an ICAN conversation may illuminate that a patient finds their overall medication regimen particularly burdensome, and this may spark a treatment-specific conversation about choosing a different treatment in replacement of a current one or inform the decision to add or not add another medication to the list. A good example of the use of ICAN and a treatment decision aid is available on the web.29"
Comment 6: I believe that in your discussion you could further address one of your findings, namely the fact that clinicians elicited competing priorities using the ICAN Discussion Aid. It is for sure important that patients can voice their topics of choice. However, I believe that it is even more central that clinicians discuss competing priorities, especially in the case of MCC. As shown in previous literature, the need to adhere to treatment recommendations is overruled by the desire to live a full and meaningful life and the fear of a decreased quality of life. This phenomenon, called sometimes "strategic non-compliance", was observed in several chronic conditions and could hinder adherence to the treatment plan (see for instance: Campbell et al. 2003; Jackson et al 2010; Zanini et al 2018).
Response: Ultimately, we see ICAN as a way to understand patients' context in high definition, and therefore, create treatment plans that best fit their lives. We have noted now in the first paragraph of page 13 how, in conjunction with treatment-specific decision aids, clinician can fully appreciate patients' values, preferences, and context to co-create treatment plans that allow them to live their fullest lives.
"Used in this way, clinicians may fully understand patients' competing priorities as well as treatment-specific values and preferences, and therefore, be able to co-create with them treatment plans that fit their context and allow them to lead quality lives to the fullest extent."

Comment 7: In the conclusion, the authors state that the pilot testing was successful. Nonetheless, to foster the implementation of an instrument, its relevance for clinical practice should be proven. For this reason, it is important to show how the instrument has the potential to contribute to the achievement of health outcomes.

Response: In conjunction with the edits to the background section and discussion section of the paper, we have added a sentence to the conclusion that points to the further need to determine if ICAN's use leads to better patient workload-capacity balance and if so, whether this translates to better patient health outcomes.

"ICAN deserves further testing to determine if its implementation leads to better workload-capacity balance for patients living with chronic illness and if this translates to improved patient health outcomes."

VERSION 2 – REVIEW

REVIEWER	Michael McGillion McMaster University, Canada
REVIEW RETURNED	16-Jun-2019

GENERAL COMMENTS	Thank you for the opportunity to re-review this manuscript. The authors have adequately addressed much of the feedback

	provided in the earlier review, while some information remains missing. A summary of outstanding items that I believe should be considered is listed below: 1. Abstract & sample description. As mentioned previously, further clarity is needed in explaining the proportion of subjects receiving the intervention and those in the control group. See comment from initial review: The abstract is balanced. However, it would be a good idea to clearly explain the breakdown of proportions expressed in terms of clinical encounters. For example, p. 5, line 8 to 13 states, "The first 40 clinical encounters were usual care. After the first 40 encounters, clinicians were then trained during a standing meeting or individually on how to use the ICAN Discussion Aid. The remaining 60 clinical encounters were intended to be ICAN encounters". This is later followed by the following text on page 21, Table 4, line, 2: "All Encounters (n=84/ICAN= 45)". I find the breakdown somewhat confusing- further clarity is needed. 2. Recruitment and consent. Please describe: a. who consented the clinicians to participate? b. what was used to screen patients for major barriers to consent? c. who approached participants prior to participation? 3. Missing data. Please address: a. What were the potential reasons why only 45/60 ICAN encounters yielded useable data? b. Why did only two thirds (27/40) of pre-intervention patients have pharmacy records analyzed? Overall, the paper is much improved and I see attention to these items as constituting the need for minor revision. Thank you again for the opportunity to re-review the manuscript.

REVIEWER	Claudia Zanini Swiss Praplegic Research, Nottwil, Switzerland & University of Lucerne, Lucerne, Switzerland
REVIEW RETURNED	11-Jun-2019

GENERAL COMMENTS	I would like to thank the authors for having thoughtfully addressed the comments of the reviewers. I believe that with the current contextualization and presentation of the ICAN instrument as well as with the improved discussion of the results, the manuscript is ready for publication.

VERSION 2 – AUTHOR RESPONSE

Reviewer 1:

Comment 1: As mentioned previously, further clarity is needed in explaining the proportion of subjects receiving the intervention and those in the control group.

See comment from initial review:

The abstract is balanced. However, it would be a good idea to clearly explain the breakdown of proportions expressed in terms of clinical encounters. For example, p. 5, line 8 to 13 states, "The first 40 clinical encounters were usual care. After the first 40 encounters, clinicians were then trained during a standing meeting or individually on how to use the ICAN Discussion Aid. The remaining 60 clinical encounters were intended to be ICAN encounters". This is later followed by the following text on page 21, Table 4, line, 2: "All Encounters (n=84/ICAN= 45)". I find the breakdown somewhat confusing- further clarity is needed.

Response: Thank you for pointing this out. Upon further review, this should have stated 39/40 encounters. Hopefully this clears up the numerical confusion. Furthermore, we have also added a missing data section in the discussion section that is now section 4.3. and is copied and pasted below for your review.

Comment 2: 2. Recruitment and consent. Please describe:

a. who consented the clinicians to participate?

Response: We have now included this in section 2.2. “Clinicians were recruited from two clinical sites in the Midwest and were eligible for participation if they regularly saw patients with chronic conditions. Clinicians were consented for participation either at a lunch-hour clinical practice meeting or immediately before their first eligible patient. Clinicians were consented by the principal investigator (KRB) or a trained study coordinator.”

Comment 3: b. what was used to screen patients for major barriers to consent?

We have now included this in section 2.2 as well: “Adult patients were eligible if they had one or more chronic conditions, no major barriers to consent (e.g. cognitive impairment), and were seeing a clinician who had agreed to participate. To assess for barriers to consent, we used the electronic medical record to look for keywords such as language, cognitive function, serious vision/hearing impairment, etc., and also confirmed with the primary care clinician that the patients did not have any of the listed barriers to consent and were appropriate to include in the study. Patients were approached immediately before the encounter with their clinician.”

Comment 4: c. who approached participants prior to participation?

We have now clarified in section 2.2 that a trained study coordination approached patients prior to participation.

Comment 5: 3. Missing data. Please address:

a. What were the potential reasons why only 45/60 ICAN encounters yielded useable data?

We have now included a Missing Data section in the discussion after the strengths and limitations section to clarify this issue and the below issue as well. It reads: “4.3 Missing Data

Detailed missing data information is depicted in Figure 2 and should be considered when interpreting the study’s findings. 39/40 baseline encounters yielded usable data. One survey was unreturned and one encounter’s videographic coding was lost due to technical error. 45/60 follow-up encounters yielded usable data. 15 videos during the intervention period were excluded from analyses because although the clinician had been trained in using ICAN and intended to use it in the encounter, they did not use the tool during the encounter. This occurred for a variety of reasons including that the patient brought up more pressing concerns for that day that made the clinician feel the ICAN tool was no longer appropriate for that encounter or the clinician simply forgot to use the tool. Consent to pharmacy record review was an optional portion of the study, therefore reducing the number of profiles available. For all patients that consented to this optional portion, pharmacy records were requested. However, in some cases, the pharmacy did not return a profile for the patient after two request attempts, whereas in other cases, the patient did not have any active prescriptions at the pharmacy on file for chronic conditions.”

Comment 6: b. Why did only two thirds (27/40) of pre-intervention patients have pharmacy records analyzed?

Please see above.

VERSION 3 – REVIEW

REVIEWER	Michael McGillion McMaster University Ontario, Canada
REVIEW RETURNED	31-Jul-2019

GENERAL COMMENTS	Thank you for thoroughly addressing the recommended revisions from last review. Issues related to participant consent and missing data have been clarified.