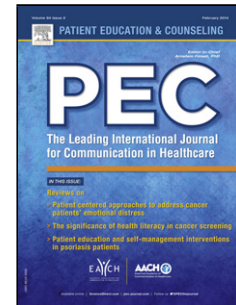


Accepted Manuscript

Title: Development and field testing of a consumer shared decision-making training program for adults with low literacy

Author: Danielle M. Muscat Suzanne. Morony Heather L. Shepherd Sian K. Smith Haryana M. Dhillon Lyndal. Trevena Andrew. Hayen Karen. Luxford Don. Nutbeam Kirsten. McCaffery



PII: S0738-3991(15)30030-6
DOI: <http://dx.doi.org/doi:10.1016/j.pec.2015.07.023>
Reference: PEC 5114

To appear in: *Patient Education and Counseling*

Received date: 23-1-2015
Revised date: 15-7-2015
Accepted date: 20-7-2015

Please cite this article as: Muscat DM, Morony S, Shepherd HL, Smith SK, Dhillon HM, Trevena L, Hayen A, Luxford K, Nutbeam D, McCaffery K, Development and field testing of a consumer shared decision-making training program for adults with low literacy, *Patient Education and Counseling* (2015), <http://dx.doi.org/10.1016/j.pec.2015.07.023>

This is a PDF file of an unedited manuscript that has been accepted for publication. As a service to our customers we are providing this early version of the manuscript. The manuscript will undergo copyediting, typesetting, and review of the resulting proof before it is published in its final form. Please note that during the production process errors may be discovered which could affect the content, and all legal disclaimers that apply to the journal pertain.

Highlights

- We developed a comprehensive consumer SDM training program for adults with low literacy for delivery in education settings.
- The program aims to improve SDM knowledge, skills and self-efficacy.
- Consumer input was fundamental in our iterative development process.

Development and field testing of a consumer shared decision-making training program for adults with low literacy

Danielle M Muscat^{a,b}, Suzanne Morony^{a,b}, Heather L Shepherd^{b,c}, Sian K Smith^d, Haryana M Dhillon^{e,f}, Lyndal Trevena^{a,b}, Andrew Hayen^g, Karen Luxford^h, Don Nutbeamⁱ, Kirsten McCaffery^{a,b,*}

^a *The Screening and Test Evaluation Program (STEP), Sydney School of Public Health, The University of Sydney, NSW, Australia.*

^b *Centre for Medical Psychology and Evidence-based Decision-making (CeMPED), Sydney School of Public Health, The University of Sydney, NSW, Australia*

^c *Psycho-oncology Co-operative Research Group (PoCoG), School of Psychology, The University of Sydney, NSW, Australia.*

^d *Psychosocial Research Group, Prince of Wales Clinical School, Faculty of Medicine, University of New South Wales, NSW, Australia.*

^e *Centre for Medical Psychology and Evidence-based Decision-making (CeMPED), Concord Clinical School, The University of Sydney, NSW, Australia.*

^f *School of Psychology, The University of Sydney, NSW, Australia*

^g *School of Public Health and Community Medicine, University of New South Wales, NSW, Australia.*

^h *Patient-based care, Clinical Excellence Commission, NSW, Australia.*

ⁱ *Office of the Vice Chancellor, University of Southampton, Southampton, UK*

* Corresponding author at: The Screening and Test Evaluation Program (STEP), Sydney School of Public Health, The University of Sydney, NSW, 2006, Australia. Tel.: +61 2 9351 7220; fax: +61 2 9351 5049

Email address: kirsten.mccaffery@sydney.edu.au

Abstract

Objective: Given the scarcity of shared decision-making (SDM) interventions for adults with low literacy, we created a SDM training program tailored to this population to be delivered in adult education settings.

Methods: Formative evaluation during program development included a review of the problem and previous efforts to address it, qualitative interviews with the target population, program planning and field testing.

Results: A comprehensive SDM training program was developed incorporating core SDM elements. The program aimed to improve students' understanding of SDM and to provide them with the necessary skills (understanding probabilistic risks and benefits, personal values and preferences) and self-efficacy to use an existing set of questions (the AskShareKnow questions) as a means to engage in SDM during healthcare interactions.

Conclusions: There is an ethical imperative to develop SDM interventions for adults with lower literacy. Generic training programs delivered direct-to-consumers in adult education settings offer promise in a national and international environment where too few initiatives exist.

Practice implications: Formative evaluation of the program offers practical insights into developing consumer-focused SDM training. The content of the program can be used as a guide for future efforts to engage consumers in SDM.

Keywords: Shared Decision Making; Training; Consumers; Low Literacy; Health Literacy; Patient-centred healthcare; Intervention; Development; AskShareKnow; Question Asking

1. Introduction

Shared decision-making (SDM) occurs when patients and healthcare professionals work together to make decisions about the patient's health based on best available evidence [1,2]. It necessarily involves information exchange and deliberation about test and treatment options and the benefits and harms of those options, as well as consideration of patient preferences and values [3]. As a midpoint between the paternalistic model of care and 'informed choice', SDM is an interpersonal and interdependent process between a clinician or clinical team and patient [4]. Shared decision-making has been identified as an effective method of reaching treatment agreements [5] and may improve affective-cognitive outcomes for patients [6]. Patients who are more informed also have more accurate risk perceptions and improved clinical outcomes [7].

Despite the benefits of SDM, involving consumers in SDM in clinical practice has, to date, had limited success [4]. There have been few attempts to engage consumers in SDM practices and fewer still to make SDM a clinical reality for individuals with low literacy and low education [8]. Adults with low literacy make up a large proportion of the population across Organization for Economic Co-operation and Development (OECD) countries [9-11] and have higher rates of illness and chronic disease [12]. They are less likely to understand the concept of SDM and are less familiar with medical language and the healthcare system [13]. They may also perceive a greater power imbalance between doctor and patient than individuals with higher levels of literacy [14] and may ask physicians fewer medical and lifestyle-related questions during consultations [15]. Patients with low literacy also report less patient-centered communication and less satisfaction with their healthcare providers [16].

Despite the current lack of engagement, there are a number of potential ways to promote SDM for adults with low literacy. Patient-mediated decision tools such as decision aids, option grids and question prompt lists could be designed using low literacy design principles (such as those outlined in the International Patient Decision Aid Standards chapter on addressing health literacy) and trialed for use in this population [8]. Shared decision-making coaching, training or education programs could also be used to support consumers with low levels of literacy to read, understand and use the decision tools for reaching decisions about their health.

We adopted the latter approach and created a SDM training program for consumers with low literacy. This program was to be delivered as two, three-hour lessons within a larger Australian program – based on the UK *Skilled for Health* initiative [17] – to train lower-literate adults in health literacy in adult education settings (See Appendix A for the full program outline). The adult education context is considered an appropriate and under-utilised avenue for improving health literacy among adults with low levels of literacy and numeracy [18,19]. In Australia (and many other OECD countries) adult education programs are widely available and provide a previously untapped infrastructure to deliver education to improve health literacy to adults with lower literacy using trained adult literacy teachers. Our program utilised this existing infrastructure to deliver an educational program to improve health literacy within an existing adult literacy and numeracy program using Functional Contextual Education methods [20]. This approach to adult learning embeds education within topics that are of relevance and interest to adult learners which promotes greater engagement among students [20].

Shared decision-making was included as a core component of the health literacy program in recognition of its importance in contemporary healthcare [3]. Health decision making is required at every level of healthcare [3] and is an important aspect of communicative and critical health

literacy as defined by Nutbeam [21]. Nutbeam's levels of health literacy reflect the different skills required to obtain and use health information in ways that lead to greater autonomy and empowerment in health decision-making [21]. Aligning with the communicative and critical levels in Nutbeam's model, the SDM training program promoted skills to obtain relevant health information, derive meaning and apply information, and share decision-making with healthcare professionals.

Specifically, the SDM training program aimed to (a) increase knowledge of the concept of SDM amongst adults with low literacy; (b) provide learners with the necessary skills to engage in SDM; (c) promote self-efficacy to engage in SDM. The final version of the SDM training program is currently being evaluated in a randomised controlled trial involving 23 adult education colleges throughout New South Wales, Australia. This paper reports the formative evaluation and field testing of the SDM training program prior to its broader application in an adult learning environment.

2. Methods and results

Formative evaluation is a set of activities designed to develop and pre-test program materials and methods to ensure relevance to the target population [22]. There are several stages of activities considered part of formative evaluation, including: Stage 1; reviewing the problem and previous efforts to address it; Stage 2; formative evaluation to understand the target population; Stage 3; program planning; and Stage 4; pre-testing intervention methods and materials [22]. We conducted activities within these stages as part of formative evaluation of the SDM training program.

2.1 Stage 1: Reviewing the problem and previous efforts to address it

2.1.1 Methods

A variety of approaches have been used to support patients and clinicians to achieve SDM including decision aids, option grids, and question prompt list interventions which address specific health issues [23,24,25]. Within the context of a community-based adult education setting, students' ages and health status are varied so promoting SDM by teaching use of decision tools or option grids developed for specific clinical contexts is not appropriate or possible. However generic consumer questions may be a feasible way to engage adult learners in SDM. Generic questions designed to elicit evidence to support clinical decisions can be taught to consumers and can increase the amount of information provided by healthcare professionals [26].

We conducted a review of the literature to identify generic question sets which could be used to promote SDM within the context of a community-based adult education setting. An additional review was conducted to identify existing SDM training courses for consumers.

2.1.2 Results

From the literature, we identified three sets of generic consumer questions; Ask Me 3 [28], Smart Health Choices [27] and AskShareKnow [26]. See Table 1. Whilst the Ask Me 3 questions were designed to promote communication between healthcare providers and patients but not to address SDM, the AskShareKnow and Smart Health Choices questions were designed specifically to promote evidence-based SDM in a variety of clinical encounters. Therefore, the AskShareKnow and Smart Health Choices questions were included in formative evaluation, whilst the Ask Me 3 questions were not.

Neither the AskShareKnow nor the Smart Health Choices generic question sets had been trialed with adults with low literacy or education. However, the AskShareKnow questions have been shown to increase the amount and quality of information about treatment options provided by family physicians. Specifically, the questions increased the presentation and quality of evidence provided to patients related to options, and the occurrence and quality of information which considered patient preferences [26]. The AskShareKnow questions have also been shown to be acceptable to patients and practical to implement within family planning clinics in Australia, with 68% of patients asking at least one of the questions during their consultation after watching a 4-minute video-clip informing them of the questions and the value of sharing information and decision-making [29].

Table 1

AskShareKnow, Smart Health Choices and Ask Me 3 questions.

| AskShareKnow questions [26] | Smart Health Choices questions [27] | Ask Me 3 questions [28] |
|---|---|---|
| a) What are my options? | a) What will happen if I wait and watch? | a) What is my main problem? |
| b) What are the possible benefits and harms of those options? | b) What are my test and treatment options? | b) What do I need to do? |
| c) How likely are each of those benefits and harms to happen to me? | c) What are the benefit and harms of those options? | c) Why is it important for me to do this? |
| | d) How do these benefits and harms weigh up for me? | |
| | e) Do I have enough information to make a choice? | |

Whilst there has been a proliferation of SDM training courses for healthcare professionals since 2007 [30], we were unable to identify any courses specifically designed for consumers. The

SDM training programs created for healthcare professionals have varied widely in terms of language, teaching methods and the clinical specialty of the target audience, and often lack sufficient evaluation data [30].

2.2 Stage 2: Formative evaluation to understand the target population and the community

2.2.1 Methods

Semi-structured qualitative interviews were conducted with adults with low levels of literacy to assess their perception of, and ability to use, either the AskShareKnow or the Smart Health Choices questions.

Students enrolled in adult Language Literacy and Numeracy courses were invited by their teacher to participate in a 30-minute semi-structured interview at their education institution. To be enrolled in these courses, students had been independently assessed by their adult education provider as having low levels of literacy and numeracy. As shown in Figure 1, consenting participants were assigned to receive one of the two sets of SDM questions. All interviews were carried out in English by a researcher trained in qualitative methods (DM), audio-recorded and transcribed verbatim.

-----Figure 1 HERE-----

Interviews were analysed using Framework Analysis which uses a thematic matrix (a matrix with participants as rows and themes as columns) to organise and manage data according to key themes, concepts and categories [31]. The five key steps of the Framework Analysis method were observed: familiarisation with the data; creating a thematic framework; indexing; charting; and mapping and interpretation [31].

2.2.2 Results

As shown in Figure 1, 26 interviews were conducted, 13 with native-English-speakers and 13 with adults from non-English-speaking backgrounds. This language background reflected the typical diversity of students enrolled in Australian adult Language Literacy and Numeracy courses [32], and, as such, of those who would later participate in the SDM training program. Of the 26 participants, the majority were women ($n = 20$), and 12 indicated receiving treatment for existing health conditions. Participants were aged between 18 to 63 years with an average age of 42 years.

Qualitative results are summarised in Box 1, with illustrative quotes. In general, participants seemed to lack confidence and functional literacy skills to discuss health problems in clinical settings. They described their role as a patient as being a passive recipient of care and typically asked questions to seek clarification rather than to be actively involved in the decision-making process.

Although participants from non-English-speaking backgrounds had slightly more difficulty than native-English-speakers, participants from both language groups struggled to read and understand the meaning of several key terms within the AskShareKnow and Smart Health Choices questions. See Box 1. However, students appeared to be able to read and understand the AskShareKnow questions more easily than the Smart Health Choices questions, and once the concepts were explained, students generally appreciated the usefulness of the questions. These results show that there is considerable scope for confusion and misunderstanding in the use of generic consumer questions, and demonstrate the importance of the adult education setting that allows for questions and clarification.

Box 1: Difficulties with the AskShareKnow and Smart Health Choices questions: qualitative interview findings

Difficulties across both AskShareKnow and Smart Health Choices questions

- reading and understanding the word *options*

“...it’s not coming to my brain what is this one. Option is...?” (P403, English-speaker)
- understanding the meaning of *wait and watch*

“Because sometimes when I was waiting in the doctor’s surgery I was waiting for two hours or more.” (P506, NESB)
- reading and understanding the word *harms*

“Yeah, harms is a tricky word. I think arm, like that [*pointing to arm*]...” (P301, NESB)

Difficulties specific to AskShareKnow

- understanding question 3 (*How likely are each of these benefits and harms to happen to me?*)

“What is the length of period that it’s going to... what’s the duration of the medicine or... stuff like that...” (P102, English-speaker)

Difficulties specific to Smart Health Choices

- understanding the meaning of *wait and watch* when it was presented as the first question, without placing it in context as a potential treatment option
- understanding question 4 (*How do the benefits and harms weigh up for me?*)

“What the ‘weigh’... You mean weigh up, more heavy?” (P204, NESB)
- understanding a question-set with an increased number of questions and words

2.3 Stage 3: Program planning and development

2.3.1 *Methods*

Program development was guided by the predetermined aims of the SDM module, stages 1 and 2 of formative evaluation, and the integrative model of SDM developed by Makoul and Clayman [33]. The integrative model outlines nine essential elements of SDM – define/explain problem; present options; discuss pros/cons (benefits/risks/costs); patient values/preferences; discuss patient ability/self-efficacy; doctor knowledge/recommendations; check/clarify understanding; make or explicitly defer decision; arrange follow-up – with discussion of these elements initiated by physicians or patients in clinical encounters [33]. This is a widely used model, with 50 SDM training programs for healthcare professionals having similarly focused on *at least one* of the model's nine essential elements of SDM [30].

We explicitly incorporated 7 of the 9 SDM elements into our SDM program to be taught in a community sample not receiving clinical care. Whilst there was no explicit reference to the last two SDM elements defined by Makoul and Clayman [33] (make or explicitly defer a decision and arrange follow-up), these elements were incorporated within the AskShareKnow questions concerning options and making a decision. See Table 2.

Table 2

Shared decision-making aims and resources.

| Program aims | Essential SDM elements [33] | Program Activities | Resources included in second iteration[†] |
|---|---|--|---|
| To explain the concept of SDM, including: -Right to be involved -Right to express values and preferences | - Define/explain problem - Patient values/preferences | 1. Introduction to SDM | 1. Visual representation of SDM 2. Cloze passage activity 3. Cut-and-paste activity |
| Provide learners with skills to engage in SDM including: -Different management options -Probabilistic information about benefits and harms -Visual representations of outcomes (icon arrays) | - Present options - Discuss pros/cons (benefits/risks/costs) - Doctor knowledge/recommendations | 2. Engaging in SDM by asking questions 3. AskShareKnow questions a) Asking about your options b) Asking about the benefits and harms of options c) Asking about the likelihood of benefits and harms i. Understanding likelihood information ii. Understanding graphical information | 4. Information sheet 5. Clinical examples worksheet 6. Revision worksheet 7. Brainstorm activity I 8. Definition worksheet 9. Clinical examples worksheet II 10. Brainstorm activity II 11. Definition worksheet 12-13. Introducing risk worksheet I-II 14. Clinical examples worksheet III 15-20. Numerical risk worksheet I-V |
| Increase self-efficacy to engage in SDM | - Discuss patient ability/self-efficacy - Check/clarify understanding | 4. Promoting the use of the AskShareKnow questions | 17. Icon array activity sheet 21. Brainstorm activity III 22. AskShareKnow modelling video 23. Role play 24. Seeking more information worksheet 25. Addressing SDM barriers worksheet 26. Revision worksheet |

[†]Contact corresponding author for a copy of the resources

Program development was led by the first author (DM). Learning activities were developed and mapped to the essential SDM elements, and supplementary resources were created.

The first draft of the SDM training program was reviewed by international experts in SDM training (LT and HS) and health literacy (KM), in addition to an independent adult literacy and numeracy expert (KY). As a consequence of feedback received, minor changes were made to the format and content of the program before the pre-testing stage of formative evaluation.

2.3.2 Results

A list of activities and resources included in the final version of the program is provided in Table 2, and 4 selected student resources are shown in Figures 2 and 3.

Introductory activities and resources focused on defining SDM and asserting patients' rights to be involved in decision-making about their health and to express values and preferences. Resources included a visual representation of SDM, and cut-and-paste activity elucidating the potential contributions of patients and healthcare professionals during consultations (See Figure 2).

-----Figure 2 HERE-----

Question-asking was introduced as a means to participate in SDM. Specifically, the AskShareKnow questions were introduced as a tool to facilitate this process because they were found to be easier to understand. Based on qualitative findings outlined in Box 1, each question was defined and interpreted within a range of activities. For the program to meet the language needs and learning style of both native-English-speaking students and those from non-English-

speaking backgrounds, teachers are given the option to choose the type and quantity of activities they feel is appropriate for their cohort. Examples of the information each of the questions may elicit from healthcare providers were also included in various learning activities to facilitate student understanding. Specific emphasis was placed on the third AskShareKnow question (see Table 2), and activities and resources concerning numerical and graphical risk information that could be given in response to this question were included. Such resources included a word bank chart with verbal descriptions of risk (ranging from certain to impossible; see Figure 3) and worksheets asking students to select the percentage or fraction which represented the biggest risk for a patient. Emphasis on promoting student understanding of numerical and graphical risk information aligns with research endorsing the importance of numeracy and graphical literacy in SDM [34]. All students were provided with an AskShareKnow pocket card for future reference.

-----Figure 3 HERE-----

Finally, in an effort to increase learners' self-efficacy to use the AskShareKnow questions, discussion questions addressing potential barriers to SDM faced by adults with low literacy were included in the lesson plan. These questions were open-ended to encourage discussion of barriers to question asking that students perceived to be real and important. Modelling activities (e.g. a modelling video of a patient asking each AskShareKnow question in a hypothetical medical consultation) and cognitive and behavioural rehearsal of learned information (e.g. revision worksheets and pair or small-group role plays) were also included, with teachers again having the choice to include as many revision activities as they considered appropriate for their cohort. Developing self-efficacy increases the likelihood of the training program influencing behaviour [35].

A teaching manual was also developed to facilitate the delivery of the SDM program. The manual included (a) learning outcomes; (b) a guided lesson plan with detailed delivery instructions and suggested discussion questions; (c) student resources including information sheets, activities and diagrams; and (d) answers for the teachers' reference.

2.4 Stage 4: Pre-testing intervention methods and materials

2.4.1 Methods

Teacher training was considered essential to effective program delivery. A full-day teacher training session was conducted for the broader health literacy program and included a 1-hour session dedicated to the SDM module. The SDM training was led by the first author (DM) who defined SDM and discussed the benefits of this approach to clinical communication using available evidence. The SDM teacher training component also included a review of each of the SDM activities and resources, small-group discussions regarding implementation of SDM activities and resources, and time for questions and clarification.

Following teacher training, the first author (DM) observed the delivery of the training program at 2 adult education centers in New South Wales, Australia. This was an unstructured observation in which there were no predetermined notions of the discrete behaviors that would be observed [36]. Chronological field notes were taken including dialogue, the behaviour and interactions of students and teachers, and the structural and organisational features of the adult education centre, as well as personal thoughts and reflections on the content of the training program [36].

2.4.2 Results

In total, 3 teachers and 23 students (17 native-English-speaking students and 6 students from non-English-speaking backgrounds) were observed, for a total of 12 hours of observation. Discussions with participating teachers occurred immediately after observation.

Observational field notes, together with comments made by teachers following field-testing, were coded and analysed using Framework Method to revise the training program. All revisions were approved by the panel of SDM and adult education experts. See Table 3.

There were noticeable differences in terms of pace and choice of activities amongst classes with native-English-speaking students, and those with students from non-English-speaking backgrounds. Students from non-English-speaking backgrounds progressed more slowly through the activities and completed more activities focused on defining key terms, such as benefits and harms. Native-English-speaking students were not impeded by language barriers, and were able to move more quickly through the program. However, the range of activities appeared to cater appropriately for both groups when tailored by teachers to their learning style needs.

Table 3

Major issues identified in the observational review phase and implemented responses.

| Identified issue | Response to identified issue in second iteration |
|---|--|
| 1. Lessons lacked a comprehensive explanation of SDM which placed the three AskShareKnow questions in context. There was little or no explicit acknowledgement of how or why to use the three questions in clinical situations despite references in the lesson plan. | a) Importance of defining SDM clearly emphasised in the lesson plan. b) Cloze-passage activity which defined and contextualised SDM added. c) Information sheet providing context to the AskShareKnow questions added. d) Brainstorm activity about potential use of each question in clinical situations added. e) Discussion questions focusing on use in clinical settings added. |
| 2. The clinical examples we used were confusing for some students. E.g., students had difficulty understanding that obesity and depression were health issues which could be discussed with their GP. Teachers also commented that the clinical example involving different contraceptive methods was inappropriate for older learners and some male students felt uncomfortable. | a) Changed clinical examples in Resources 5, 14 & 15. New clinical examples included skin allergies, heart attack/blood pressure and ear infection. |
| 3. There was inconsistency between groups in the delivery or use of specific resources despite explicit instructions in the guided lesson plan. | a) Explicit instructions <u>were added at the top of all resources in addition to instructions</u> in the guided lesson plan (e.g. Resource 14 “People’s medical history, family history and lifestyle make some benefits and harms more likely. Read through the examples below and answer the questions”). |
| 4. Teachers commented that students lacked the computer skills required to complete some activities. There were also inadequate computing facilities at some campuses to complete computer tasks. | a) Replaced all individual computing tasks with teacher demonstrations. b) Provided links to online resources in a student website for students to access at home. |
| 5. Adult learners required reinforcement to understand and remember new concepts and specific terminology. | a) Additional revision questions added to reinforce content. b) Guided lesson plan explicitly stated the need for reinforcement. |

3. Discussion and conclusion

3.1 Discussion

We created a SDM training program for adults with low literacy to be delivered in an adult education setting. To our knowledge, this program represents the first attempt to train consumers – either with lower or higher levels of literacy or education – to engage in SDM in this context. The program was informed by existing literature and SDM training courses for healthcare professionals, in addition to qualitative interviews with the target population and expert and observational review processes. The final iteration of the SDM training program not only aimed to improve students' understanding of the concept of SDM and skills, but to also empower them to use an existing set of questions to facilitate SDM in healthcare interactions. Whilst the efficacy of the training course is yet to be formally evaluated in a randomised trial, the development process and formative evaluation offer valuable insights regarding the needs of adults with low literacy and an approach to addressing them.

Shared decision-making is gaining prominence in health policy internationally. It is now an explicit policy goal in the United States and United Kingdom, as well as in many healthcare organisations [37-39]. However considerable work still needs to be done to translate SDM policy into practice. Alongside development of interventions that can be readily implemented in clinical contexts [40], we must ensure that patients, particularly those with limited levels of literacy or education, have the necessary skills or are supported to use these interventions when making decisions in real world clinical encounters. Failing to do so may inadvertently exacerbate existing inequalities in health between those with higher and lower level literacy skills.

Training programs delivered direct-to-consumers can address this challenge. The formative evaluation of our SDM program offers important contributions to understanding how such training programs can be comprehensively designed to provide consumers with knowledge and skills needed to engage in SDM. In particular, it has highlighted the importance of using an iterative approach involving consumers and providers. Qualitative interviews with students who closely reflected those who would later participate in the SDM program provided valuable insights into the beliefs and capabilities of adults with low levels of literacy and allowed the training program to address gaps in knowledge and understanding. For example, qualitative reports informed our choice of generic question set (i.e. AskShareKnow), and highlighted the necessity of defining key terms (such as *options* and *harms*). Similarly, discussions with adult education teachers provided practical insights that led to the revision of certain activities and the adoption of more relevant clinical examples for use in the SDM program.

Crucially, the development and field testing of our SDM training program for adults with low literacy included both native-English-speaking consumers and consumers from non-English-speaking backgrounds. These are two different populations with different learning needs, but are both captured within the same student population for basic literacy and numeracy courses in adult education institutions in Australia. Including individuals from both of these populations in the development stages further influenced the design of activities, allowing them to be flexible enough to cater for the needs of both groups. Activities ranged from simple (such as definition exercises) to more complex (such as numeric exercises comparing risks) to allow trained teachers to tailor the program to their cohort. Although it is important to examine differences in learning experiences and outcomes between groups in any program involving linguistically and

culturally diverse populations, our formative evaluation has highlighted the importance of considering such groups differences well prior to this, at the design stage.

If SDM training programs are to be delivered in adult education institutions or other community settings they may need to be developed in a generic manner, providing skills which can be transferred to a variety of clinical contexts and interactions with healthcare providers. We achieved this in different ways in our training program. Most obviously, we presented the AskShareKnow consumer questions as a means to facilitate SDM. As a generic intervention, these questions represent a tangible tool which can be used by all regardless of demographic characteristics, health status or healthcare encounter. We also provided activities and resources to help contextualise SDM and the AskShareKnow questions. Field testing highlighted the need to explain to learners in adult education settings why they were learning about SDM and how and when they could apply acquired knowledge and skills in their own lives. Finally, cognitive and behavioural reinforcement of learned information was incorporated within the training program to facilitate the retention of knowledge and skills, and all students were provided with a pocket card for future reference. Given that consumers' interactions with healthcare providers may be some time in the future, it is important to include such reinforcement and memory aids into training in community settings.

Delivering generic SDM programs in community settings could potentially eliminate reliance on time-poor healthcare professionals and overburdened healthcare systems to train consumers in SDM. Although our program formed part of a broader health literacy program, it could potentially be delivered in isolation in a range of community contexts: no prior knowledge or skills are assumed, the scope and depth of content allows it to stand-alone and the detailed

teaching manual provides a guided lesson plan, all necessary resources, and answers. Training video instruction or a train-the-trainer approach could replace the face-to-face teacher training method employed in our field testing to ensure that facilitating teachers are aware of the theoretical approach and evidence-base for SDM, and are confident delivering SDM content which may be new to them.

Community contexts such as adult education centres may be particularly appropriate for training adults with low literacy and numeracy given that SDM may be particularly challenging for these individuals and additional time may be required for training. Field testing as part of the formative evaluation suggested that 6 hours of instructional time (approximately 2 lessons) was feasible and necessary to address the aims of the module: teaching understanding of the concept of SDM, providing learners with the necessary skills to engage in SDM and promoting self-efficacy to engage in SDM with healthcare professionals. Notably, this time was also devoted to developing numeracy skills to allow students to better understand risks and benefits information, a key component of SDM. Community settings may be key to providing the necessary support for adults with low literacy to use SDM tools and effectively engage in interdependent decision-making processes.

Despite the benefits of delivering SDM training programs in adult education settings, there may be limitations of our approach which was distinctly consumer-focused. As an interdependent process, SDM necessarily involves an interaction between consumers and healthcare professionals. There are barriers – both real and perceived – which prevent clinicians from engaging in SDM [41] that could stand in the way of consumers putting their training into practice in clinical situations. Far from rejecting the importance of consumer-focused SDM initiatives, however, we suggest that providing consumers with appropriate knowledge and skills

is an important step towards demanding a system which is more inclusive of patients in the decision-making process [40]. By equipping consumers with the skills to assert themselves and communicate confidently with healthcare providers, they are better placed to achieve SDM in different clinical encounters.

We also suggest that developers of consumer SDM training seek to align their program's aims and content with existing SDM training programs for healthcare professionals. In our design, we explicitly incorporated essential elements of SDM defined by Makoul and Clayman [33]. Fifty SDM training programs for healthcare professionals have similarly focused on at least one of the model's essential elements [30]. Although this indicates some consistency between the content of the programs, greater emphasis needs to be placed on curriculum alignment between professional and consumer programs to ensure that the SDM skills and knowledge taught to consumers complement those taught to professionals. Consumers and healthcare professionals having a shared understanding of what constitutes SDM and how to achieve it may further support consumers to use SDM skills during healthcare encounters.

3.2 Practice implications

Formative evaluation of the SDM program offers practical insights into developing consumer-focused SDM training. Not only should insights from the formative evaluation of our SDM training program be used in the development of future programs, program developers should also conduct their own evaluation to create programs which are effective for their target population. Moreover, the aims, resources and activities of our SDM training program can be used to guide future efforts to engage consumers in SDM.

3.3 Conclusion

There is a clear ethical and moral imperative to develop and test interventions that promote SDM for adults with lower levels of literacy [42] Training programs delivered in adult education or other community settings offer promise in a national and international environment where too few of these initiatives exist. Future research should seek to refine SDM programs and investigate the barriers and facilitators to implementation in community settings.

Acknowledgements

We are grateful to Dr Keiko Yasukawa (Centre for Research in Learning and Change, University of Technology, Sydney, NSW, Australia) for her invaluable advice in developing the SDM training program and assistance reviewing early iterations.

Role of funding

The Australian Research Council funded the trial through a Linkage grant (no. LP130100480). Kirsten McCaffery is supported by a Career Development Fellowship (no.1029241). Danielle Muscat is supported by a University of Sydney Australian Postgraduate Award. The above funding sources had no involvement in study design; in the collection, analysis and interpretation of data; in the writing of the report; and in the decision to submit the article for publication.

Conflicts of interest: none

References

- [1] Charles C, Gafni A, Whelan T. Shared decision-making in the medical encounter: What does it mean? (or it takes at least two to tango). *Soc Sci & Med* 1997;44:681-92.
- [2] Charles C, Gafni A, Whelan T. Decision-making in the physician–patient encounter: revisiting the shared treatment decision-making model. *Soc Sci & Med*. 1999;49:651-61.
- [3] Hoffmann TC, Légaré F, Simmons MB, McNamara K, McCaffery K, Trevena LJ, Hudson B, Glasziou PP, Del Mar CB. Shared decision making: what do clinicians need to know and why should they bother? *Med J Aust*. 2014;201:35-9.
- [4] Légaré F, Wittteman HO. Shared decision making: examining key elements and barriers to adoption into routine clinical practice. *Health Aff*. 2013;32:276-84.
- [5] Joosten EAG, DeFuentes-Merillas L, de Weert GH, Sensky T, van der Staak CPF, de Jong CAJ. Systematic review of the effects of shared decision-making on patient satisfaction, treatment adherence and health status. *Psychother Psychosom*. 2008;77:219-26.
- [6] Shay LA, Lafata JE. Where is the evidence? A systematic review of shared decision making and patient outcomes, *Med Decis Making*. 2015;35:114-31.
- [7] Stewart MA. Effective physician-patient communication and health outcomes: A review. *Can Med Assoc J*. 1995;152:1423-33.
- [8] McCaffery K, Sheridan S, Nutbeam D, Clayman M, Kelly-Blake K, Rovner M, Rovner D, Smith S, Wolf M. Addressing Health Literacy. In: Volk R, Llewellyn-Thomas H, editors. Update of the International Patient Decision Aids Standards (IPDAS) Collaboration's Background Document. 2012. Chapter J. Available from <http://ipdas.ohri.ca/resources.html>.

- [9] Australian Bureau of Statistics. Adult Literacy and Life Skills Survey, Summary Results, Australia. Report No.: 4228.0.Canberra: ABS; 2006.
- [10] Department for Education and Skills. Skills for Life Survey: A National Needs and Impact Survey of Literacy, Numeracy and ICT Skills. London: Department for Education and Skills; 2003.
- [11] Kutner M, Greenberg E, Baer J. National Assessment of Adult Literacy (NAAL). A first look at the literacy of America's adults in the 21st century; 2006. Available from: <http://nces.ed.gov/naal>
- [12] Dewalt DA, Berkman ND, Sheridan S, Lohr KN, Pignone MP. Literacy and health outcomes: A systematic review of the literature. *J Gen Intern Med.* 2004;19:1228-39.
- [13] McCaffery KJ, Smith SK, Wolf M. The challenge of shared decision making among patients with lower literacy: A framework for research and development. *Med Decis Making.* 2010;30:35-44.
- [14] Smith SK, Dixon A, Trevena L, Nutbeam D, McCaffery K. Exploring patient involvement in healthcare decision making across different education and functional health literacy groups. *Soc Sci & Med.* 2009;69:1805-12.
- [15] Katz M, Jacobson T, Veledar E, Kripalani S. Patient literacy and question-asking behavior during the medical encounter: A mixed-methods analysis. *J Gen Intern Med.* 2007;22:782-6.
- [16] McCaffery KJ, Holmes-Rovner M, Smith SK, Rovner D, Nutbeam D, Clayman ML, Kelly-Blake K, Wolf MS, Sheridan SL. Addressing health literacy in patient decision aids. *BMC Med Inform Decis Mak.* 2013;13 Suppl 2: S10-10.

- [17] The Tavistock Institute and Shared Intelligence. Evaluation of the second phase of the Skilled for Health programme. Available from <http://www.tav institute.org/projects/report-evaluation-of-phase-two-of-the-skilled-for-health-programme/>
- [18] Chervin C, Clift J, Woods L, Krause E, Lee K. Health literacy in adult education: a natural partnership for health equity. *Health Promot Pract*. 2012;13:738-46.
- [19] Diehl SJ. Health literacy education within adult literacy instruction. *New Dir Adult Contin Educ*, 2011;130:29-41.
- [20] Sticht T. The theory behind content-based instruction. Available from: <http://www.ncsall.net/?id=43>.
- [21] Nutbeam D. Health literacy as a public health goal: a challenge for contemporary health education and communication strategies into the 21st century. *Health Promot Int*. 2000;15:259-67.
- [22] Nutbeam D, Bauman A. Evaluation in a nutshell: a practical guide to the evaluation of health promotion programs. Australia: McGraw-Hill; 2006.
- [23] D. Stacey, F. Légaré, N.F. Col, C.L. Bennett, M.J. Barry, K.B. Eden, M. Holmes-Rovner, H. Llewellyn-Thomas, A. Lyddiatt, R. Thomson, L. Trevena, J.H.C. Wu, Decision aids for people facing health treatment or screening decisions. *Cochrane Database of Syst. Rev.* 1 (2014) 1-332 [Art no.: CD001431].
- [24] Elwyn G, Lloyd A, Joseph-Williams N, Cording E, Thomson R, Durand MA, Edwards A. Option grids: Shared decision making made easier. *Patient Educ Couns*. 2013;90:207–12.
- [25] Dimoska A, Tattersall MH, Butow PN, Shepherd H, Kinnersley P. Can a "prompt list" empower cancer patients to ask relevant questions? *Cancer* 2008;113:225-37.

- [26] Shepherd HL, Barratt A, Trevena LJ, McGeechan K, Carey K, Epstein RM, Butow PN, Del Mar CB, Entwistle V, Tattersall MH. Three questions that patients can ask to improve the quality of information physicians give about treatment options: A cross-over trial. *Patient Educ Couns* 2011;84:379-85.
- [27] Irwig L, Irwig J, Trevena L, Sweet M. *Smart health choices: Making sense of health advice*. United Kingdom: Hammersmith Press; 2008.
- [28] National Patient Safety Foundation. Ask Me 3. [cited 2015 Jan 15] Available from: <http://www.npsf.org/?page=askme3>
- [29] Shepherd H, Barratt A, Jones A, Bateson D, Carey K, Trevena L, et al. Can consumers learn to ask three questions to improve shared decision-making?: A feasibility study of the ASK(AskShareKnow) Patient-Clinician Communication Model intervention in a primary health care setting. *Proceedings of the 7th International Shared Decision Making (ISDM) Conference*; 2013 June 16-19; Lima, Peru.
- [30] Légaré F, Politi MC, Drolet R, Desroches S, Stacey D, Bekker H, Team S-C. Training health professionals in shared decision-making: An international environmental scan. *Patient Educ Couns*. 2012;88:159-169.
- [31] Ritchie J, Spencer L, O'Connor W. Carrying out qualitative analysis. In: Ritchie J, Spencer L, editors. *Qualitative research practice: A guide for social science students and researchers*. London: Sage Publications; 2003. p. 219–62.
- [32] New South Wales Department of Education and Communities. TAFE New South Wales Enrolments: Student profile (2007-2011). Available from: <https://www.det.nsw.edu.au/media/downloads/about-us/statistics-and-research/tafe-nsw-statistics-newsletters/student-profile-2011.pdf>

- [33] Makoul G, Clayman ML. An integrative model of shared decision making in medical encounters. *Patient Educ Couns*. 2006;60:301-12.
- [34] Reyna VF, Nelson WL, Han PK, Dieckmann NF. How numeracy influences risk comprehension and medical decision making. *Psychol Bull*. 2009;135:943-73.
- [35] Bandura A. Self-efficacy: Towards a unifying theory of behavioural change. *Psychol Rev*. 1977;84:191-215.
- [36] Mullhall A. In the field: Notes on observation in qualitative research. *J Adv Nurs*. 2003;41:306-13.
- [37] Washington State Legislature, RCW 41.05.033. Shared decision-making demonstration project - preference-sensitive care (2007). Available from:
<http://apps.leg.wa.gov/rcw/default.aspx?cite=41.05.033>
- [38] Patient Protection and Affordable Care Act, H.R. 3590, Sec. 3506 (Jan 05, 2010). Available from: <https://democrats.senate.gov/pdfs/reform/patient-protection-affordable-care-act-as-passed.pdf>
- [39] Department of Health. Equity and excellence: liberating the NHS. Available from:
<https://www.gov.uk/government/publications/equity-and-excellence-liberating-the-nhs-executive-summary>
- [40] Frosch DL, Elwyn G. Don't blame patients, engage them: Transforming health systems to address health literacy. *J Health Commun*. 2014;19:10-14.
- [41] Légaré F, Ratté S, Gravel K, Graham ID. Barriers and facilitators to implementing shared decision-making in clinical practice: Update of a systematic review of health professionals' perceptions. *Patient Educ Couns*. 2008;73:526-35.

- [42] Légaré F, Thompson-Leduc P. Twelve myths about shared decision making. *Patient Educ Couns*. 2014;96:281-86.

Accepted Manuscript

Appendix A

Table 1
Health Literacy program outline

| Day | <i>Being Healthy</i> Teacher Manual 1 | Day | <i>Staying Healthy</i> Teacher Manual 2 |
|-----|--|-----|---|
| 1 | 1.1 Introduction 1.2 Baseline assessment | 2 | 2.1 Getting involved [†] 2.2 Food groups |
| 3 | 3.1 Taking temperature [†] 3.2 Checking medicine labels [†] | 4 | 4.1 Food labels [†] |
| 5 | 5.1 Prescriptions 5.2 Dosage and timing | 6 | 6.1 Nutritional information [†] |
| 7 | 7.1 Health workers 7.2 Telling your doctor what is wrong | 8 | 8.1 Food temperature safety 8.2 Food date safety |
| 9 | 9.1 Asking questions [†] 9.2 Immunisation and health screening | 10 | 10.1 What is a portion? 10.2 Budgeting |
| 11 | 11.1 Talking to your doctor 11.2 Answering your doctor's questions | 12 | 12.1 Understanding a diet 12.2 Drinking enough fluids |
| 13 | 13.1 Completing medical forms 13.2 Emergency services | 14 | 14.1 Heart rate and pulse |
| 15 | 15.1 Advice from pharmacist 15.2 Follow written instructions | 16 | 16.1 Being active 16.2 First aid demonstrations |
| 17 | 17.1 Saving lives | 18 | 18.1 Revision |
| 19 | 19.1 Following emergency instructions | 20 | 20.1 Post assessment |

[†]Core topic

Figure 1
[Click here to download high resolution image](#)

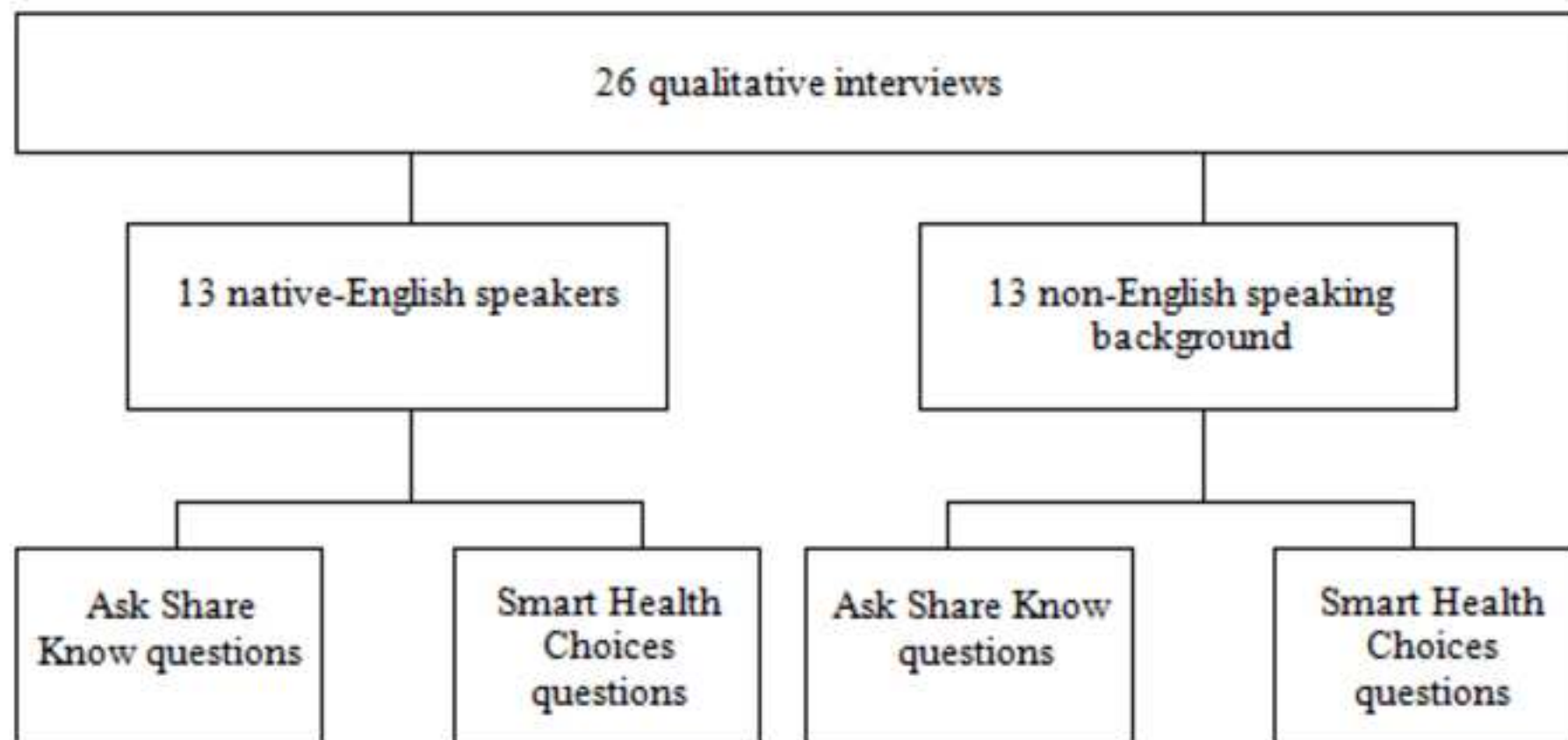


Figure 2
Click here to download high resolution image

SHARED DECISION-MAKING

RESOURCE 2

What is Shared Decision Making?

Shared decision making is when patients and doctors work _____ to make decisions about the patient’s health.

_____ decision making happens when doctors and patients share information and _____ about all of the different things that can be done.

Sharing information _____ doctors and patients make decisions that they are both happy with and can improve the care that patients receive.

It is important that _____ and patients work together to make decisions about health. The doctor should not decide what is best for the patient without talking to them: the patient and the doctor should _____ together.

Word bank:

| | | |
|-------|----------|--------|
| helps | doctors | Shared |
| talk | together | decide |

Discussion Questions

Q1. Have you ever heard of Shared Decision Making before?

Q2. What is good about sharing decisions with your doctor?

SHARED DECISION-MAKING

RESOURCE 3

It is important for the doctor and the patient to share information with each other. Choose which information might be given to the doctor, and which information might be given by the patient.

| DOCTOR | PATIENT |
|--------|---------|
| | |
| | |
| | |
| | |
| | |

| | |
|--|--|
| 1. Diagnose the problem | 5. Express feelings about risks |
| 2. Describe lifestyle (e.g. smoking, exercise, work) | 6. Identify the cause of the condition |
| 3. Suggest treatment options | 7. Explain preference/feelings (e.g. you would prefer to wait and see what happens, or would you prefer to take medicine?) |
| 4. Describe symptoms and history of the condition | 8. Predict what might happen. For example, will the condition get worse? |


Figure 3
[Click here to download high resolution image](#)

SHARED DECISION-MAKING

RESOURCE 5

The examples below have different options for treatment. Read through the examples as a class and talk about the options.


Example 1: You have pain in your ear and a fever for two days.



Take antibiotics

Wait and watch

Example 2: You have an itchy rash on your hands due to a skin allergy for a week.



Avoid touching things that irritate your skin

Weak steroid cream (from the pharmacy)

Stronger prescription steroid cream

Moisture cream from the supermarket

SHARED DECISION-MAKING

RESOURCE 12

Word bank:

Certain

Very Likely

Likely

Possible

Unlikely

Very Unlikely

Impossible

%

%

%