

# BMJ Open Using rapid cycle tests of change to develop the Carers Assistive Technology Experience Questionnaire: a cognitive interview study in the UK

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## ABSTRACT

We describe the use of rapid cycle tests of change to pretest and develop a Carers Assistive Technology Experience Questionnaire for a survey of informal carers of persons with dementia. The Plan-Do-Study-Act (PDSA) cycle is a commonly used improvement process in healthcare settings. We used this method for conducting rapid cycle tests of change through cognitive interviews to pretest the questionnaire. The items for the questionnaire were developed based on an earlier systematic review and qualitative study. PDSA cycles were used incrementally with learning from each cycle used to inform subsequent changes to the questionnaire prior to testing on the next participant.

**Design** Qualitative with use of cognitive interviews through rapid cycle tests of change.

**Setting** UK.

**Results** Nine participants were recruited based on eligibility criteria and purposive sampling. Cognitive interviewing using think aloud and concurrent verbal probing was used to test the comprehension, recall, decision and response choice of participants to the questionnaire. Seven PDSA cycles involving the participants helped identify problems with the questionnaire items, instructions, layout and grouping of items. Participants used a laptop, smartphone and/or tablet computer for testing the electronic version of the questionnaire and one participant also tested the paper version. A cumulative process of presenting items in the questionnaire, anticipating problems with specific items and learning from the unanticipated responses from participants through rapid cycle tests of change allowed rich learning and reflection to progressively improve the questionnaire.

**Conclusion** Using rapid cycle tests of change in the pretesting questionnaire phase of research provided a structure for conducting cognitive interviews. Learning and reflections from the rapid testing and revisions made to the questionnaire helped improve the process of reaching the final version of the questionnaire, that the authors were confident would measure what was intended, rapidly and with less respondent burden.

## INTRODUCTION

Dementia describes a set of symptoms that may include memory loss and difficulties

## Strengths and limitations of this study

- This study recruited participants from across the UK, adopting a purposeful sampling strategy to identify suitable participants with diverse age groups, gender, ethnicity and living arrangements, who could support interpreting and answering items within the questionnaire.
- Use of concurrent think aloud and verbal probing methods during the cognitive interviews allowed for richer interpretation and in-depth understanding of changes needed to the questionnaire.
- The participants were recruited through voluntary participation in research databases and potentially may not be representative.

with thinking, problem solving or language.<sup>1</sup> Caring for a person with dementia can be demanding for carers (family, friends and neighbours) and can affect their mental and physical health and their social lives.<sup>2</sup> Assistive technology (AT) may support carers in caring for persons with dementia in the community; however, very little is known about their experience and use of AT.<sup>3,4</sup> To better understand the use and impact of AT on carers, we developed a survey instrument—Carers Assistive Technology Experience Questionnaire (CATEQ).

In survey research, the data collection tool is typically a structured questionnaire and the measurements obtained are the respondent's answers to survey questions.<sup>5</sup> This type of data collection assumes that all participants understand the questions in a consistent way; the questions are asking for information that participants have and can retrieve and the questions are worded in a way that the participants are able to answer them as intended by the researcher. In order to provide a valid and reliable instrument, the wording, structure and layout of the questionnaire must

make allowance for the nature and characteristics of the participating population.<sup>6</sup>

### Cognitive interviews

Cognitive interviews are commonly used for pretesting survey questions.<sup>5,7</sup> They can provide information on how the questions are understood and answered by typical participants. Cognitive interviews can help detect problems participants may have in understanding survey instructions and items, and in formulating answers.<sup>8</sup> Cognitive interviews can identify problems in item interpretation, memory retrieval, decision processes and response selection.<sup>9</sup> A draft questionnaire with candidate items is developed and cognitive interviewing with participants representing the target population is used to revise the questionnaire. Cognitive interviews also afford the opportunity to detect other problems in questionnaire instructions, design and organisation.<sup>10</sup> They consist of one-to-one interviews in which the respondents describe their thoughts while answering the survey questions and can be done through different methods such as think aloud, verbal probing, confidence rating, card sorting and paraphrasing.<sup>6</sup> Cognitive interviews are usually undertaken in rounds, with several participants interviewed in each round, their responses analysed and changes to the questionnaire only made after each round.<sup>11–13</sup> This process could be burdensome for respondents and researchers and involve higher costs during questionnaire development.

### Plan-Do-Study-Act cycles

The iterative process of learning and revising through cognitive interviews can be viewed as following the steps of action-oriented learning such as Plan-Do-Study-Act (PDSA) cycles.<sup>14,15</sup> PDSA cycles consist of<sup>14,16</sup>:

**Plan:** State the objective of the test, the planned change, make predictions of what will happen and why and develop a plan to test the change

**Do:** Carry out the test/intervention, document problems and unexpected observations, begin analysis of the data

**Study:** Complete the analysis of the data, compare the data to earlier predictions in the plan phase and summarise and reflect on what was learnt

**Act:** Determine what modifications should be made, that is, deciding that the intervention has achieved the required standard and can therefore be implemented more widely or deciding that an entirely new change is required and the current plan should be changed and prepare a plan for the next test

While PDSA cycles are commonly used in clinical care, few clinical research trials have documented its use for implementation<sup>17</sup> and none have used PDSA cycles as a framework for cognitive interviews for pretesting questionnaires. The authors present here one way of developing a questionnaire, based on using rapid cycle tests for change framed within PDSA cycles for conducting cognitive interviews in pretesting questionnaire items to

develop the CATEQ. This is an alternative way of developing and pretesting a questionnaire and highlights how rapid cycle tests for change such as PDSA cycles can be used in questionnaire development.

## METHODS

### Patient and public involvement

This study is part of a larger research project which has a patient and public advisory group that meets twice a year. The group consists of two carers of persons with dementia and a person with dementia (all living in England). This group gave feedback on the initial items and instructions framed as part of the CATEQ and reviewed the final version of CATEQ submitted for ethical approval. This group has also committed to support dissemination of study results to other patient involvement groups and their wider networks.

### Study design

The authors describe the steps followed in designing the questionnaire and conducting the cognitive interviews using PDSA cycles to arrive at the final version of the CATEQ.

### Develop items for the questionnaire

The items of CATEQ were developed on the basis of results from a systematic review<sup>3,18</sup> and a qualitative study<sup>4</sup> and are intended to be administered as an electronic survey. The CATEQ explores themes that carers (family, friends and neighbours) described as relevant for use of AT for dementia care in the community. An iterative process of drafting, evaluation, revision and content checking was followed. Attention was taken to draft the items in the questionnaire to: capture the intended concept of experience using AT and their impact on carers; relevance to all members of the target population irrespective of age, living arrangements and relationship with the person with dementia; the response choices were ordered in a meaningful way; ensure the questions were worded in a manner consistent with best practice style guide by Alzheimer's Society<sup>19</sup>; each item represented a single concept, rather than a multidimensional concept; the content of the items was appropriate for the recall period of the previous 4 weeks; and the items could be answered in a self-administered questionnaire. The questionnaire items were mainly closed questions with multiple-choice answers with some questions being partially closed with 'other' as open-ended text options. The questions were a mixture of behavioural (*What input is required from you for using the assistive technology?*; *How often are you able to solve problems with the assistive technology by yourself?*), opinion (*How helpful is the assistive technology in reducing your stress?*; *How helpful is the assistive technology in giving you more time for yourself?*) and factual questions (*age*; *gender*; *who was involved in the choice of AT?*). The CATEQ included questions to capture demographic information of participants, health-related quality of life and expression of interest in participating in qualitative interviews later. None of the questions except for the consent question at the beginning

of the survey had a forced-choice response (ie, respondents could omit answers to questions). The draft questionnaire had a Likert-like rating scale as response choices. For ease of administering cognitive interviews the initial set of interviews did not include demographic (for participants 1–4) and health-related quality of life (participants 1–6) questions. This questionnaire was labelled draft 0 and minor corrections were made based on comments by the patient and public advisory group for the project and by three clinical and social care experts involved in prescribing AT for use by persons with dementia at home. This modified CATEQ was labelled draft 1 and was used in the first cognitive interview.

### Design cognitive interview process

Cognitive interviews were used to assess participants' comprehension of the items in CATEQ as well as establish that no important items were missing. A semistructured interview guide with think aloud questions, and verbal probing questions, was developed to elicit further information from the participants (box 1). All the cognitive interviews were conducted by VS who is an occupational therapist and is trained in qualitative interviewing and quality improvement methods. Regular time was made for all the authors to meet to discuss progress with the cognitive interviews and modifications to the drafts of CATEQ.

### Recruitment

Participants for the cognitive interviews were recruited through the Join Dementia Research website.<sup>20</sup> Participants were carers of persons with dementia based in the UK willing to be contacted by researchers through this website. The inclusion criteria were: adult carers—family, friends or neighbours—providing at least 10 hours of care (eg, shopping, leisure, personal care, finance) per week to a person with dementia who lives in their own home, with the carer living together with or away from the person with dementia; carers should have used at least one AT device at home in the previous year and be able to communicate in English. Participants were emailed a copy of the participant information sheet (online supplemental file 1) and a purposive sample of participants reflecting variations in gender, age, ethnicity, living arrangements and relationship with persons with dementia were selected. The recruitment commenced in October 2019 and the final interview was completed in February 2020. A target sample size of 7–10 participants was deemed enough to complete cognitive interviews for items in the CATEQ. This was based on previous estimates<sup>13 21 22</sup> but the intention was to continue with cognitive interviews until no further amendments to the CATEQ were necessary.<sup>23</sup>

### Conduct cognitive interviews

#### Data collection

Semistructured interviews were conducted face to face (at the participant's own home/at the researcher's office) taking into consideration the participant's geographical location and preference. The 'think aloud' and verbal

## Box 1 Cognitive interview guide

### Preinterview

Participant to re-receive the information sheet and asked to read it through. Participant will be given a brief introduction to the research that includes a description of assistive technology.

- ▶ Show university card for ID of researcher and introduce self.
- ▶ Participant to be told what will happen during the interview process and reminded that the interview will also be audio recorded.
- ▶ Participant to be told that a transcript will be made from the audio recording.
- ▶ Participant to be told the method of analysis and reminded that they will remain anonymous, and that their data will be confidential.
- ▶ Participant given time to ask questions.
- ▶ Participant will be asked to sign two copies of the consent form, one of which is to be retained by the researcher.

### Instructions

Based on our research, we have the following questions as part of the Carers Assistive Technology Experience Questionnaire. Please look at each page and the questions in this survey. During the interview, we will ask you to speak aloud about what you are thinking as you respond to questions. I am also going to ask you additional questions about individual items in this questionnaire. Remember, the purpose of this interview is to test the questionnaire and not to test you. Are you ready to begin? We will start with the instructions for the survey.

Example verbal probes used to test the questions:

### For Question abc...

1. What to you, is '.....'?
2. Tell me more about '.....'?
3. Can you repeat this question in your own words?
4. What does '.....' mean to you?
5. Would you mind providing some examples about '....'?
6. When you think about '.....' what comes to your mind?

### Overall for the survey...

7. Are there additional questions you believe should be asked?
8. Are there questions you believe should be deleted?
9. Are there questions you believe should be modified?
10. Are there words used in the questions that you think could be changed to make it more understandable to others who help/look after those with dementia?

Do you have any questions for me?

probing methods were used for data collection and involve an interviewer asking the participants how they went about answering a particular survey question.<sup>10</sup> In the think aloud method, the participant is asked to speak all thoughts aloud as he/she answers the question. For verbal probing, the interviewer asks specific questions or probes which are designed to elicit how the participant went about answering the question, for example, how the participants made their choice among the response options or how they interpreted an instruction.<sup>5 6</sup> Participants were shown the electronic version of CATEQ developed using Qualtrics software<sup>24</sup> during the interview on a laptop. Participant 8 also tested the questionnaire on a smart mobile phone. The final participant in addition to the electronic version was also requested to comment on the paper version of CATEQ.<sup>21</sup> The participants were



not known to the interviewer or the other authors prior to recruitment. Trust and easing into the think aloud interview was built by establishing rapport with the participants. The interviewer (VS) explained that the purpose was to make the questionnaire better by identifying items that were difficult to answer. Interviews were undertaken using concurrent think aloud and verbal probing questions and lasted between 55 and 95 min; all interviews were audio recorded along with field notes and a PDSA template (online supplemental file 2). The field notes noted verbal and non-verbal cues from the participants, as well as their perception of the items in CATEQ. Confidentiality of the participants was maintained throughout the process by avoiding references to names of the participant or persons with dementia, cities and other person identifiable information.

### Make decisions to revise questionnaire

#### Data analysis

The PDSA template (online supplemental file 2) was used to document the hypothesis being tested, results of the cognitive interview process, and to make changes to the CATEQ. After discussion among all the authors, the questionnaire items were changed in line with suggestions from the participant and accounting for difficulty encountered by the participant with specific items during the cognitive interview. Changes were made after every cognitive interview instead of waiting for rounds of interviews to finish, which is the process in traditional cognitive interview methods,<sup>13</sup> thereby narrowing the time between data collection, analysis and changes made. The authors also ensured each subsequent participant, in addition to ‘thinking-aloud’ on a focused section of the questionnaire, also commented on the latest iteration of the full questionnaire to determine if the modified version then functioned as intended, without introducing further difficulties in comprehension or changes needed to the questionnaire. Subsequent CATEQ questionnaire drafts were numbered draft 2, draft 3, and so on, which were used contiguously for the progressive set of cognitive interviews.

#### Final test

At the end of questionnaire revision, the final version of CATEQ was tested on three volunteers and the patient and public advisory group to check for time taken to complete the questionnaire, issues with formatting, skip logic and ease of understanding of the instructions before it was deemed ready to be used in a quantitative survey.

## RESULTS

Emails (n=38) for recruitment were sent to potential participants. From the responses received (n=22), 11 carers did not meet the eligibility criteria and nine carers (five women and four men), with varying types of relationship to a person with dementia, took part in interviews (table 1). Every participant had used at least one

**Table 1** Participant characteristics

ID	Age range	Gender	Ethnicity
1	56–70	Female	White British
2	56–70	Male	White British
3	40–55	Female	White British
4	40–55	Male	Asian British
5	71–85	Male	White British
6	56–70	Female	Caribbean British
7	40–55	Male	White British
8	40–55	Female	Mixed White British
9	40–55	Female	Asian British

AT device in the last 12 months. Participants were aged between 42 and 75 years. The authors used PDSA cycles for the cognitive interviews to make iterative changes to the CATEQ. The changes between draft 1 and draft 7 of the questionnaire are given in table 2.

### PDSA 1: testing instructions and questionnaire items

CATEQ draft 1 had instructions for participating in the survey, eligibility criteria and a consent statement. In addition, it had 29 items (21 items in matrix format) about carers’ current experiences and impact of using AT with a person with dementia at home. During PDSA 1, participant 1 was able to comprehend and understand the instructions and commented on the font and layout of the instructions that could be improved. The eligibility criteria and consent statements were easy to understand, and overall participant 1 took less time than anticipated to complete these sections. On verbal probing, participant 1 indicated that most instructions only carried information regarding data protection and use which were standard statements.

*...these are what...err...you’ll find in a product agreement you know...and who reads these through fully? I always click agree, so I can start using the thing, err...you know... like the cookie thing on websites...*

Participant 1 answered the items on the questionnaire and commented that the layout was easy to follow, the questions were easy to understand with the option of ‘other’ where extra information was needed. As part of the think aloud interview for item 1, it was observed that there was some difficulty in sorting through AT devices that participant 1 had used but is no longer currently using, and additional instructions and questionnaire items to provide details of these devices might be helpful. At the end of the PDSA cycle, modifications to the layout and instructions were made by adjusting the font size and paragraph spacing, instructions for current AT were modified and four additional questions on previously used AT and reason for abandonment were added, as well as adding information on the research website at the end of survey message, and the CATEQ draft was labelled draft 2.

**Table 2** Table of changes to CATEQ from draft version 1 to draft version 7

Questionnaire structure	Draft 1 of CATEQ	Draft 7 of CATEQ
1 Instructions		
Line numbers	16	41
Paragraphs	12	12
2 Questions on assistive technology	9	10
Questions on previous assistive technology	0	5
3 Matrix questions on experience and impact	21	20
4 Demographic questions	0	9
5 Health-related quality of life questions	0	15
6 End of survey response line number	1	1+research website details
7 Layout and structure of questionnaire		
Colour scheme	Blue progress bar	Green progress bar
Font size	12	15

CATEQ, Carers Assistive Technology Experience Questionnaire.

### PDSA 2: testing questionnaire items

Cognitive interviews with participants 2 and 3 were carried out separately using the electronic version of draft 2 of CATEQ. Both participants felt the image at the start of the instructions with common AT devices was helpful. The think aloud interviews for the questionnaire items highlighted confusion regarding the cost of AT. The question was framed as: ‘*Can you give the approximate cost (in pounds) associated with the assistive technology currently used, paid for by the person with dementia or by you or another carer (family, friend or neighbour)?*’ Participant 2 had difficulty in separating out initial cost in purchasing the AT with that of ongoing costs for maintenance. Participant 3 also had difficulty with the cost of AT question ‘*Are you concerned about cost of the assistive technology?*’ as the AT they were using was provided by the social care services without a cost to them. Both participants were able to differentiate questions on *anxiety* and *stress* presented as separate questions. On verbal probing, both participants wanted a ‘*does not apply*’ option to matrix questions such as: ‘*How helpful is the assistive technology in giving you additional time for tasks that you have to do?*’ and ‘*How helpful is the assistive technology in maintaining dignity of the person with dementia?*’. These cognitive interviews also gave authors the unsolicited confirmation that the CATEQ could be self-administered.

*...you’ll get more out of me doing this (answering the questions) on a laptop or on the phone than if I were sat in front of you and answering them...these are personal questions and (I) might be feeling guilty answering them honestly if*

*you were in the room, you know what I mean... (Participant 2)*

At the end of this PDSA cycle the questionnaire items were modified to change the wording on items on cost and add a ‘*does not apply*’ option to the Likert-type scale choice for the matrix questions and the new draft of the CATEQ was labelled draft 3.

### PDSA 3: testing questionnaire items and skip logic

Cognitive interview with participant 4 was used to test the questionnaire items including the modified items from draft 2, as well as the layout and format of the electronic version of the questionnaire. The think aloud interview confirmed that the modified questionnaire items on cost were better understood by participant 4. On verbal probing, participant 4 appreciated the option of ‘*does not apply*’ as a choice. Participant 4 on verbal probing also commented that the layout of the questionnaire was easy to understand and suggested a change in colour scheme for the button indicating progress to the next page of the questionnaire:

*...You know this arrow button in the bottom (indicates on screen), it is blue now, but if this were in green, other carers who do your survey would think they are good to go, sort of like...you know...like...like a traffic light system and make good headway with your questionnaire....*

At the end of this PDSA cycle, the colour scheme for the questionnaire was changed and a new version of the CATEQ was labelled draft 4; this version for the next cognitive interview now contained items for capturing demographic data of participants.

### PDSA 4: testing questionnaire items and demographic questions

Cognitive interview with participant 5 concentrated on questionnaire items with a specific focus on the nine demographic questions in CATEQ. Verbal probing and think aloud interview were used to check comprehension, recall and ease of answering demographic questions in the CATEQ. The participant understood the questions readily enough, participant 5 had some hesitation in answering the question on income and on verbal probing disclosed that the participant and the person with dementia pooled their income for household expenses and some of the hesitation was in disclosing this in a survey, even if it was anonymous. At the end of this PDSA cycle, it was decided to reframe the question on income to ‘*family income*’ and add an option of ‘*do not wish to disclose*’ as part of the response options of this question. After modifying the questionnaire items, further modifications to the instructions for survey participants were made on the advice of the ethics committee; this included further detailed instructions on use of data, data protection and contact details of all the study authors. The next version of CATEQ incorporating all these changes was labelled draft 5.



### **PDSA 5: testing modified instructions and questionnaire items**

Participants 6 and 7 participated in cognitive interviews that tested the modified instructions and questionnaire items. Both participants completed the questionnaire items without difficulty and on verbal probing commented that the instructions were long but easy to understand and in any case were not spending too much time on them. On verbal probing, participant 7 also felt the order in which items on stress, anxiety, time for self and effort on caring were presented could be rearranged in the questionnaire and grouped together as they helped the participant think through them better and maintain 'flow of thought'. Participant 6 also recommended testing the questionnaire on participants using a smartphone device, as this might be the way some participants would choose to complete the questionnaire during their commute into work. At the end of this PDSA cycle, questionnaire items were regrouped to facilitate ease of recall; items on health-related quality of life based on the validated 12-item Short Form Survey (SF-12) version 1<sup>25 26</sup> plus three questions on coping with caring and relationship with person with dementia were added to the CATEQ, and this version of the questionnaire was labelled draft 6.

### **PDSA 6: testing items on health-related quality of life and completion of questionnaire using a smartphone**

The next PDSA cycle involved a cognitive interview with participant 8, who tested additional items on the questionnaire from the SF-12. The SF-12 contains items covering physical functioning, social functioning, role functioning (physical and mental), vitality, bodily pain, mental health and general health. The SF-12 generates two summary scores: the physical component score and the mental component score. A higher score indicates better quality of life. As the SF-12 is well validated, the cognitive interview was limited to comprehension of the questions and answer choices as well as layout of the electronic version of the questionnaire with the health-related quality of life question items at the end of the questionnaire. The participant also completed the questionnaire using a smartphone device to check for ease of use and layout of the questionnaire in a smartphone device. The participant completed the questionnaire with ease and had no specific difficulty in comprehension or recall of information required for completion of the questionnaire. The layout of the questionnaire on the smartphone was easy to follow and the questions were presented one after the other and were completed without difficulty. At the end of this cycle, the questionnaire was deemed to be ready for a test to include electronic and paper versions to check ease of completion and minor modifications to instructions, such as to remove references to 'IP address will not be collected' and as skip logic could not be applied for consent to participate in future interviews. The next version of CATEQ was labelled draft 7.

### **PDSA 7: testing electronic and paper versions of the questionnaire**

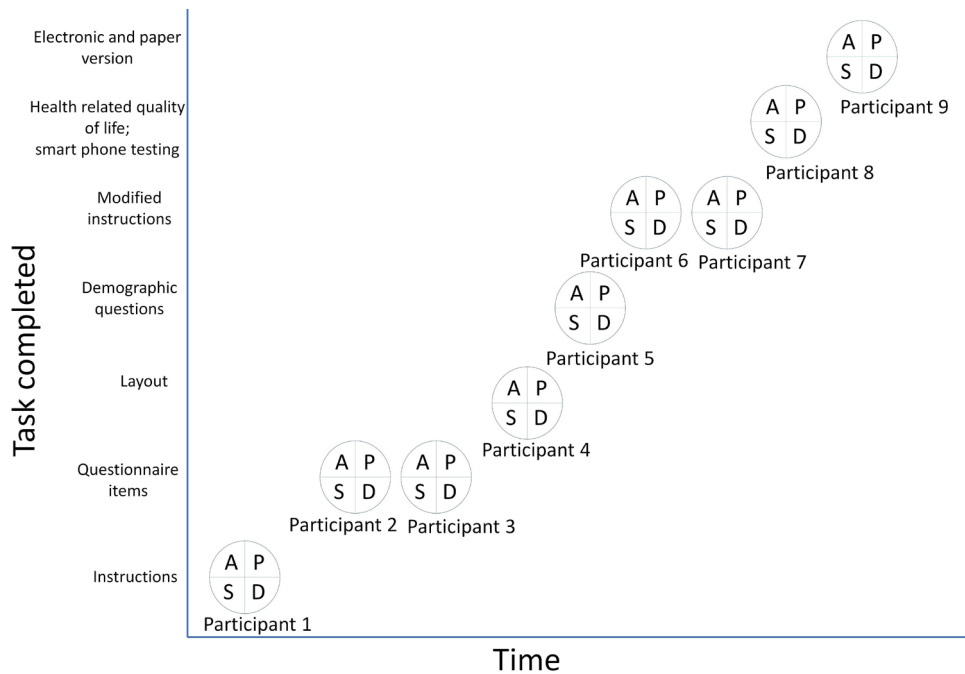
Participant 9 completed the CATEQ initially on a tablet computer and then as a paper version. Time taken to complete the questionnaire without prompts was 19 and 23 min, respectively. The additional time taken to complete the paper version was because participant 9 had to flip back and forth between the pages as the matrix questions asked about three AT devices that were currently used and the participants needed to remind themselves in which order they were answering this question.

At the end of this PDSA cycle, the CATEQ was deemed to be ready to be used in a survey and was prepared for final comments by the patient and public advisory group. Figure 1 gives a visual depiction of the PDSAs and stages of tasks presented to subsequent participants.

## **DISCUSSION**

Cognitive interviews have helped researchers develop better questions and survey instruments and are increasingly being used routinely to pretest questionnaires.<sup>27 28</sup> Our results showed rapid cycle tests of change using PDSA cycles as a format could be used as an alternate way of conducting cognitive interviews. Each cycle tested the changes made to the questionnaire and allowed quick and easy-to-test changes in subsequent versions of the questionnaire without increasing participant burden within the cognitive interview sessions. Cognitive interviews are usually undertaken in rounds, with several participants interviewed and changes to the questionnaire only made after each round.<sup>11 12</sup> Problems in comprehension, recall or response choices to the questionnaire items emerge from the interviews themselves<sup>22</sup> without the interviewer anticipating or having a hypothesis of which items or layout in the questionnaire may require change. Using small tests for change through PDSA cycles, on the other hand, enabled better structuring of questionnaire items with improved ease of comprehension, recall and response choices to items within this questionnaire. Using PDSA cycles as a learning mechanism for cognitive interviews resulted in predicting potential problems (what are we expecting to happen?) with questionnaire items and layout; this allowed the authors to focus on potentially problematic items such as, for example, questions on costs and freeing up carer time. Learning from each cognitive interview was used to inform the modifications that need to be carried out to the questionnaire and changes to the probing questions.<sup>27 29</sup> Making changes to the questionnaire after every cognitive interview as a result became easier to manage, and learning from each cycle of the PDSA was applied to the next.<sup>30 31</sup> Also, over the course of seven PDSA cycles, the think aloud interviews indicated potential problems with a questionnaire item or instruction other than the ones that were considered problematic; this unanticipated learning helped reframe and retest the questionnaire until it was satisfactory. Focusing on different items in the questionnaire and building up





**Figure 1** Plan-Do-Study-Act (PDSA) cycles and tasks involved in the cognitive interviews. Each cycle shows the focused section of the questionnaire that participants were asked to comment on.

the testing helped reduce fatigue among the participants and better insight into item comprehension, language used and layout. Using PDSA cycles enabled rapid tests of change to questionnaire items, which provided information on problems in a question and its possible source(s), as well as information towards the problem’s solution.

#### Advantage of using rapid cycle tests for change

Unlike usual cognitive interviews, the use of rapid cycle tests of change in this questionnaire development allowed the authors to test on as small a scale as possible before building confidence and scaling up to test additional items in the questionnaire and with different devices and a paper version. The authors decided to divide questionnaire items for cognitive interviews during the planning phase into parts—instructions, questionnaire items, demographic data and health-related quality of life questions for pragmatic reasons. Planning to anticipate problems with questionnaire items this way and splitting the tasks into small manageable tests of change and increasing its complexity over the course of the PDSA cycles helped maximise learning opportunities, decrease costs and time taken to complete cognitive interviews and reduce participant fatigue and burden. The PDSA cycles allowed the ability to break things down and focus on making small, measurable changes.<sup>14 31</sup> Testing using a paper version, a laptop and a smartphone helped identify if question wording communicates the objective of the question; and quickly identify problems such as redundancy, missing skip instructions and awkward wording with only a few interviews, instead of waiting for multiple participants in each round of interviews in the typical way cognitive interviews are conducted. PDSAs are a clever learning methodology whose ‘simplicity belies its sophistication’<sup>15</sup>;

the use of iterative (PDSA) cycles for cognitive interviews provided information that would otherwise have been unseen by the interviewer before launch of the survey—for example, questions on AT devices that are no longer being used by carers. The PDSA cycles also helped our learning from unsolicited information such as the questionnaire could be self-administered instead of interviewer administered.

Cognitive interview is one component from a multitude of ways for pretesting a questionnaire, to assess it does collect the information that it is supposed to. Using rapid cycle tests for change through PDSA cycles included planning and a researcher hypothesis of the difficulty of the various questions in the questionnaire; this allowed rapid and iterative pretesting of the questionnaire without having to wait for multiple rounds of cognitive interviews before changes to the questionnaire could be made and retested again. The use of PDSA cycles to inform cognitive interviews in questionnaire development is another use for PDSAs and could be one way of pretesting questionnaires in the future.

#### Strengths and limitations of this study

The authors acknowledge that while cognitive interview methods can be used to evaluate existing questions, and to test proposed revisions to the original questions, they cannot provide quantitative evidence on whether the revised version of the question is better than the original; however, the action in each PDSA cycle built on the learning from the previous cycle and we are confident that the final version of the CATEQ is better than the first draft. The authors also acknowledge that some participants were less articulate than others and could not adequately verbalise their thought processes; however, a



combination of think aloud and verbal probing interviews helped achieve the intended aim for each PDSA cycle of improving instructions and comprehension, recall and answering of items within the questionnaire.

## CONCLUSION

The addition of cognitive interviews as an extra step in the survey development process assures data that are more likely to reflect the actual circumstances being examined. The use of PDSA cycles to frame the process of cognitive interviews would be an alternative way to pretesting questionnaires that minimises risks by using rapid small-scale tests of the changes introduced to layout and items in the questionnaire as well as potentially helping to reduce fatigue and burden to researchers and participants. The PDSA process is widely used and familiar to many involved in healthcare and appears to be an appropriate mechanism for pretesting questionnaires before deploying them in large-scale surveys in healthcare.

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**Contributors** VS, CJ and MP conceived the design of the study. VS completed the cognitive interviews and PDSA cycles. VS, MP and CJ discussed emerging issues and agreed on the final changes to the questionnaire. VS drafted this version of the manuscript with critical revision and input from MP and CJ. All authors have read and given approval for this version. VS is the guarantor of the manuscript.

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**Author note** VS is a postgraduate student registered for his DPhil at the University of Oxford exploring informal carers' experience of assistive technology use in dementia. VS is an Occupational Therapist and is trained in interviews and qualitative research methods as part of his clinical training and Masters in Evidence Based Healthcare course from the University of Oxford. VS is also a quality improvement expert and teaches and develops training packages including PDSA methodology for improving quality of care for patient benefit. MP is an Associate Professor within the Health Services Research Unit (HSRU), Nuffield Department of Population Health, University of Oxford. CJ is Professor of Health Services Research and Director of the HSRU, Nuffield Department of Population Health, University of Oxford. MP and CJ have extensive experience in qualitative research methods and are joint supervisors of VS for the DPhil.

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## Developing the Carers Assistive Technology Experience Questionnaire

### PARTICIPANT INFORMATION SHEET

Ethics Approval Reference: R57703/RE001

#### 1. **What is the purpose of this study?**

Dementia describes a set of symptoms that may include memory loss and difficulties with thinking, problem solving or language. Caring for a person with dementia can be demanding for informal carers (family, friends and neighbours) and can affect their mental and physical health and their social lives. **Assistive Technology (AT)** devices are often electronic. They include talking clocks, electronic medication dispensers, smart gas meters, falls and motion detectors and door exit alarms. While Assistive Technology is usually aimed at helping the person with dementia, these may also have an impact on carers. Due to the thinking and problem-solving difficulties of the person with dementia, the carer may need to be an active user of the Assistive Technology. It is not yet clear what positive or negative effects such technology may have on carers and there is little information on their experience with its use.

#### Purpose of this research:

Using themes from existing research studies and interviews with carers, researchers from the Nuffield Department of Population Health, University of Oxford, have developed a Carers' Assistive Technology Experience Questionnaire for use with informal carers (family, friends and neighbours) who support and help persons with dementia at home.

To refine and understand, if the questions in this questionnaire measure what it is intended for and if carers understand and correctly interpret the questions, we want to carry out *cognitive interviews* with a sample of carers of persons with dementia who have used assistive technology.

The cognitive interviews will explore your interpretation and understanding of the survey questions within this questionnaire to identify errors and problems with the questionnaire before it is used in a survey.

#### 2. **Why have I been invited to take part?**

You have been invited because you are over 18 years of age and a family member/friend/neighbour of a person with dementia.

To participate in the study, you need to be

- Looking after or supporting a person with dementia who has used at least one electronic AT device (such as those described above) at home within the past year.

**3. Do I have to take part?**

No, your participation is voluntary. You can ask questions about the study before deciding whether to take part. If you agree to take part, you may withdraw from the study at any time, without any penalty and without giving a reason. If you choose to withdraw after the interview, the research team will delete any data including personal information and interview recordings and transcripts, and it will not be used in the analysis.

**4. What will happen if I take part in the study?**

By taking part in this interview, you are helping us evaluate how easy or difficult the questions in the Carers Assistive Technology Experience Questionnaire are to understand and answer. If you are happy to take part, you will be asked to answer questions in an informal interview, like a conversation. The interview questions will ask you about your understanding of the survey questions, your views on any missing information from the questionnaire and if the questionnaire is user-friendly and comments on the visual appearance and layout of the questionnaire.

The interview will be audio recorded to allow for us to type up your answers. You will never be identified by any of your personal information.

The interview will take approximately 60-90 minutes and will take place at your home, your place of work, by telephone or at the University of Oxford. The interview location and time will be arranged in discussion with you, to suit your convenience and preference. The interviews will be conducted by Mr Vimal Sriram, a doctoral student at the University of Oxford.

**5. Are there any potential risks in taking part?**

The questions asked during the interview may be personal and occasionally some people feel upset when asked to think about their experiences of looking after a person with dementia. You do not have to answer any question that you would prefer not to answer. If you become upset at any point, the researcher will ask you if you wish to pause or stop the interview. You could then: stop and withdraw your data (the interview recording would be deleted), end the interview and allow the interview recording until that point to be used in the research, or carry on with the interview when you are ready.

The researcher can also provide you with an information sheet which contains a list of organisations who you can get in touch with if you feel the need for further support.

**6. Are there any benefits in taking part?**

You will not receive any direct benefit by taking part in this study. However, the information gained in this research study will improve the survey questionnaire and subsequently provide a better understanding and insight of carers' experiences of using assistive technology.

**7. What happens to my data?**

The **research data** will be stored and examined using University approved software.

Any information that you may have given in the interview that could identify you will be removed from the interview before it is analysed. Confidentiality will be maintained throughout this research study. If you consent to take part in this study, you will be required to sign an informed consent form. To protect your identity, your name will be replaced by a pseudonym in any research reports.



Any identifying information like your name, details or other personal information will not be used or disclosed to anyone outside, to any third party or appear on any transcripts, thesis, publications or on any academic paper.

However, there might be certain circumstances in which it may be necessary to breach this confidentiality and disclose information to a third party. This includes situations when someone provides information during the study that raises serious concern about:

- Intention to harm themselves or other people
- Risk to the health, welfare or safety of vulnerable adults such as someone with dementia
- Disclosure of a criminal offence

The researcher will discuss this issue with you before telling anyone else. The researcher will be obliged to share this evidence with his supervisors, who may advise that further action is taken.

Personal / sensitive information such as your name, age, gender, marital status, employment status, telephone number or address details in case of face-face interviews will be stored confidentially using computer software that does not allow anyone else except the researcher and his supervisors access to your data. All paper forms will be stored in a locked cupboard within the Department of Population Health, University of Oxford. Your personal/sensitive data, including your signed consent forms will be kept separately from audio recordings and transcripts from your interviews. Your answers may be quoted directly in the research publication with information suitably anonymised.

All audio recordings will be erased permanently once they have been transcribed.

All research data and records will be stored for a minimum retention period of 3 years after publication or public release of the work of the research.

**8. Will the research be published?**

The research will be written up as a doctoral thesis. On successful submission of the thesis, it will be deposited both in print and online in the University archives, to facilitate its use in future research. The thesis will be published open access.

Additionally, the research may be published in academic journals and presented in national and international conferences. The University of Oxford is committed to the dissemination of its research for the benefit of society and the economy and, in support of this commitment, has established an online archive of research materials. This archive includes digital copies of student theses successfully submitted as part of a University of Oxford postgraduate degree programme. Holding the archive online gives easy access for researchers to the full text of freely available theses, thereby increasing the likely impact and use of that research.

**9. Who is organising and funding the research?**

This study is being carried out as part of the DPhil (PhD) Programme in Population Health at the Nuffield Department of Population Health, University of Oxford.

**10. Who has reviewed this study?**

This study has been reviewed by, and received ethics clearance through, the University of Oxford Central University Research Ethics Committee (Reference number: R57703/RE001).

**11. Data Protection:**

The University of Oxford is the data controller with respect to your personal data, and as such will determine how your personal data is used in the study. The University will process your personal data for the purpose of the research outlined above. Research is a task that we perform in the public interest. Further information about your rights with respect to your personal data is available from <http://www.admin.ox.ac.uk/councilsec/compliance/gdpr/individualrights/>."

**12. Who do I contact if I have a concern about the study or I wish to complain?**

If you have a concern about any aspect of this study, you can contact me through an email at [vimal.sriram@dph.ox.ac.uk](mailto:vimal.sriram@dph.ox.ac.uk) or by telephone on 01865 743762 or my supervisors Dr Michele Peters ([michele.peters@dph.ox.ac.uk](mailto:michele.peters@dph.ox.ac.uk)) or by telephone on 01865 289428 or Professor Crispin Jenkinson ([crispin.jenkinson@dph.ox.ac.uk](mailto:crispin.jenkinson@dph.ox.ac.uk)) or by telephone on 01865 289441, who will do their best to answer your query. We will acknowledge your concern within 10 working days and give you an indication of how we intend to deal with it. If you remain unhappy or wish to make a formal complaint, please contact the chair of the Research Ethics Committee at the University of Oxford who will seek to resolve the matter in a reasonably expeditious manner:  
Chair, **Medical Sciences Inter-Divisional Research Ethics Committee**; Email: [ethics@medsci.ox.ac.uk](mailto:ethics@medsci.ox.ac.uk);  
Address: Research Services, University of Oxford, Wellington Square, Oxford OX1 2JD

**13. Further Information and Contact Details**

The interviews for this researcher study will be carried out by Mr. Vimal Sriram (Doctoral student) from the Nuffield Department of Population Health, University of Oxford. The researcher will identify himself to you using a University of Oxford student card.



If you would like to discuss the research with someone beforehand (or if you have questions afterwards), please contact:

Mr. Vimal Sriram  
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Health Services Research Unit  
Richard Doll Building, Old Road Campus, Oxford OX3 7LF  
Telephone number: 01865 743762  
E-mail: [vimal.sriram@dph.ox.ac.uk](mailto:vimal.sriram@dph.ox.ac.uk)

**Thank you for taking the time to read this information sheet.**

## CATEQ Cognitive Interview

**Worksheet for Testing Change- PDSA Cycle 1**

**Aim:** To test items in the CATEQ for understandability, response choice and layout

Every goal will require multiple small tests of change

<b>Describe your first (or next) test of change</b>	<b>Person Responsible</b>	<b>When to be done</b>	<b>Where to be done</b>
Complete cognitive interview with participant 1	VS	14.11.2019	Participant 1's home

<b>List the task needed to set up this test of change</b>	<b>Person Responsible</b>	<b>When to be done</b>	<b>Where to be done</b>
<ol style="list-style-type: none"> <li>1. Test comprehension of initial instructions</li> <li>2. Test eligibility criteria listed</li> <li>3. Test layout and format for informed consent statement</li> <li>4. Test layout and instructions of willingness to participate in part 3 interviews</li> <li>5. Test layout and instructions of end of survey statement</li> <li>6. Test items 1-29</li> </ol>	VS	14.11.2019	Participant 1's home.

<b>Predict what will happen when the next test is carried out</b>	<b>Measures to determine if predictions accurate</b>
<ol style="list-style-type: none"> <li>1. Participant 1 will be able to comprehend all initial instructions in the CATEQ (time: 3 minutes) and will agree with layout.</li> <li>2. Participant 1 will agree with the eligibility criteria as listed out (time: 1 minute)</li> <li>3. Participant 1 will agree with layout and format of informed consent statement</li> <li>4. Participant 1 will agree with layout and instructions for the willingness to participate in part 3 interviews</li> </ol>	<ol style="list-style-type: none"> <li>1. Time taken to read through the instructions; Able to understand the instructions on verbal probing.</li> <li>2. Time taken to read through the eligibility criteria; On verbal probing able to answer that the eligibility criteria listed is comprehensible.</li> <li>3. On verbal probing, able to inform layout and format of informed consent statement is simple and easy to answer.</li> <li>4. On verbal probing, able to inform that the layout and instructions for the willingness to participate in part 3 interviews is simple and easy to</li> </ol>



## CATEQ Cognitive Interview

<p>5. Participant 1 will agree with layout and instructions at the end of the survey.</p> <p>6. Participant 1 will be able to comprehend, retrieve and answer questionnaire items 1-23</p>	<p>answer.</p> <p>5. On verbal probing, able to inform that the layout and instructions for the end of survey message is simple and easy to answer.</p> <p>6. On concurrent think-aloud exercise, able answer questions as comprehensible, easy to retrieve answers to. On verbal probing able to inform if response choices of the items are adequate.</p>
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**Do** Describe what actually happened when you ran the test

Completed cognitive interview with audio recording at participant's home with informed consent. Used concurrent verbal probing for instructions, eligibility criteria, consent statement, participation in further interviews and the end of survey statement. Think aloud method used for items 1-29 to record understanding, retrieval of information and answering questions plus verbal probing about response choice for these items.

Time taken to complete each section was noted and verbal prompting and their responses were also noted in field notes using a paper copy of the CATEQ to concurrently record comprehension, retrieval and use of information.

**Study** Describe the measured results and how they compared to the predictions

Total time taken for the interview was 70 minutes.

1. Time taken to complete reading instructions was 90 seconds. Participant 1 indicated that the instructions about the questionnaire and approximate time that it would take to complete the questionnaire was useful. Commented that the font size could be slightly bigger and the instructions could be further spaced to allow for easier reading.
2. Participant 1 understood the eligibility criteria and took 30 seconds to read this through and did not recommend any changes.
3. Participant 1 understood the informed consent statement and did not recommend any changes.
4. Participant 1 understood the instructions for willingness to participate in further interviews section of the CATEQ, recommended using email address and/or telephone number to be added to the instructions.

### CATEQ Cognitive Interview

5. Participant 1 understood and agreed with the layout and final instructions at the end of survey and did not recommend any changes.
6. Think aloud exercise for questions 1-29 – easy to understand instructions and liked the “other” option for free text questions. Participant 1 had difficulty sorting through AT devices no longer being used.

**Act** Describe what modifications to the plan will be made for the next cycle

Make changes to the font and layout of the initial instructions. Add questions and clarify in instructions about AT used in the past and no longer in current use. Test entire CATEQ item list on participant 2.