

Using qualitative data to inform the adaptation of a stroke preparedness health intervention

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ABSTRACT

Qualitative research methods are often used to develop health interventions, but few researchers report how their qualitative data informed intervention development. Improved completeness of reporting may facilitate the development of effective behavior change interventions. Our objective was to describe how we used qualitative data to develop our stroke education intervention consisting of a pamphlet and video. First, we created a questionnaire grounded in the theory of planned behavior to determine reasons people delay in activating emergency medical services and presenting to the hospital after stroke symptom onset. From our questionnaire data, we identified theoretical constructs that affect behavior which informed the active components of our intervention. We then conducted cognitive interviews to determine emergency department patients' understanding of the intervention pamphlet and video. Our cognitive interview data provided insight into how our intervention might produce behavior change. Our hope is that other researchers will similarly reflect upon and report on how they used their qualitative data to develop health interventions.

Introduction

Using qualitative data to develop health interventions

Qualitative data can be useful in all stages of health intervention development including the design, delivery, and evaluation stages. Guidance exists on how to develop complex health interventions (Craig et al., 2008), and an expert consensus panel of intervention developers recommends qualitative methods in addition to quantitative methods in designing complex health interventions (O'-Cathain 2019). Specifically, the panel advises that researchers can take a target population centered approach by performing qualitative interviews of the intended target population to inform intervention development. Another approach suggested by the panel is to partner with stakeholders to co-design the intervention, obtaining stakeholder input through qualitative interviews and surveys. Qualitative data are not only useful in developing *de novo* interventions, but also in adapting existing interventions for a new target population (Duggleby et al., 2020). Despite the use of qualitative research methods by health intervention researchers, there is a dearth of studies

that report in detail how qualitative data were used to inform intervention design (Wigginton et al., 2020).

Often, researchers simply report the outcome of their qualitative studies, but there is methodological value in researchers' reflecting on and reporting how their qualitative data are used to develop interventions (Sandelowski & Leeman, 2012; Wigginton et al., 2020) and how qualitative findings are used to interpret intervention results (Lewin et al., 2009).

There are significant advantages to thorough qualitative methodology reporting. First, this practice can help other health intervention researchers understand how qualitative data can be used to develop interventions and interpret intervention results. Second, researchers might identify the theory-based active components of an intervention through reflecting on their qualitative data.

To achieve improved completeness of intervention reporting, researchers can use existing tools. The CONSORT statement for randomized controlled trials of non-pharmacologic treatments states that researchers should describe the components of their intervention (Boutron et al., 2017). In behavior change intervention research, taxonomies have been developed to facilitate uniform description of the active components of behavior change interventions. Greater specification of the link between theory and selection of the active components of an intervention has also been recommended (Michie et al., 2018). When designing behavior change interventions, tables identifying links between theoretical constructs that affect behavior, called "mechanisms of action" (MoA), and active components of the intervention that enable behavior change, called "behavior change techniques" (BCT), can be used to select the appropriate BCT or identify the underlying MoA (Carey et al., 2019). Reflection on qualitative data may lead to the identification of MoAs, particularly when qualitative research methods are grounded in theory.

In this article, we attempt to overcome shortcomings in reporting the outcome of qualitative research for intervention development by adding to the few existing studies that describe the use of qualitative data in intervention development (Fjeldsoe et al., 2012; Yardley et al., 2015). Specifically, we focus on the use of qualitative data in the design stage of health interventions, reporting on how our qualitative data (i) were used to inform development of a stroke education intervention, (ii) revealed MoAs of our intervention components, (iii) and informed how our intervention might produce positive behavior change.

We begin by describing prior research that supports the need to develop a stroke education intervention. Next, we provide an overview of our qualitative research methods, presenting our qualitative and quantitative data and the ways that qualitative data were used to inform development of our intervention linking MoAs to behavior change techniques. We then describe how our qualitative data informed how our intervention might produce positive behavior change.

Our study consisted of a survey of stroke patients to inform adaptation of our intervention and cognitive interviews of patients to assess their understanding of the adapted intervention materials to determine whether further adaptation was needed. We present the methods and results separately for both parts of the study.

Background on the need for the intervention

Stroke is a leading cause of disability (Katan & Luft, 2018). Tissue plasminogen activator (tPA) is a treatment for stroke that reduces disability and can only be given at the hospital within a limited time after stroke symptom onset (National Institute of Neurological Disorders and Stroke rt-PA Stroke Study Group, 1995). Black Americans are less likely to receive tPA than White Americans (Aparicio, 2015; Boehme, 2014; Faysel, 2019; Hsia et al., 2011a; Johnston, 2001; Nasr et al., 2013), at least partly due to Black Americans' delay in hospital arrival after stroke symptom onset (Hsia et al., 2011b; Lacy et al., 2001; Lichtman et al., 2009; Siegler et al., 2013; Springer et al., 2017). Randomized controlled trials of stroke preparedness interventions for Black Americans that teach stroke symptoms and the importance of activating emergency medical services (hereafter referred to as "calling 911") are few in number and have occurred in settings such as schools and churches (Williams, et al., 2008; Williams, et al. 2019).

The Stroke Ready brief intervention was a randomized controlled trial of a community stroke preparedness intervention among people at a community health center consisting of an oral presentation of a pamphlet on stroke symptoms, stroke treatment, and the importance of calling 911 upon stroke symptom recognition. The brief intervention was found to increase intent to call 911 immediately after the intervention (Robles et al., 2020). Our objective was to adapt the Stroke Ready brief intervention for patients presenting to an emergency department of a predominantly Black American community. Adaptation of the intervention is necessary because of the unique features of the emergency department environment such as its unpredictability, rapid pace, and possible anxiety felt by the patients (Wei & Camargo, 2000). In future research, we plan to test the ability of the adapted intervention to increase stroke symptom recognition and intent to call 911. We chose the emergency department setting to increase the reach of the intervention to Black Americans who are at high risk for stroke and those who are frequent users of the emergency department (Colligan, et al., 2017).²⁹

Intervention materials

The Stroke Ready intervention materials consisted of a pamphlet and a video, both of which describe stroke symptoms, stroke treatment, and the importance of rapid activation of emergency medical services. Both the pamphlet and the video are grounded in the theory of planned

behavior, which is described in detail below. The video is approximately three minutes long and consists of local actors singing about stroke symptoms and the importance of rapid activation of emergency medical services. The video also contains a skit depicting a person who develops stroke symptoms and a witness calling 911 upon stroke symptom recognition. The pamphlet includes a definition of stroke, the consequences of stroke, an explanation of stroke symptoms, how to check for stroke symptoms, the importance of calling 911 when stroke symptoms start, and a description of stroke treatment. The purpose of our study was to adapt the pamphlet and intervention video, as they were originally designed without the input of stroke survivors. We therefore surveyed stroke patients who delayed in hospital arrival after stroke symptom onset to inform adaptation of the intervention materials. This study was approved by the hospital's institutional review board and was conducted in agreement with the Helsinki declaration. Informed participant consent was obtained.

Survey of stroke patients to inform intervention adaptation

Materials and Methods

Setting

The study setting was a stroke inpatient ward of a hospital located in Flint, Michigan. The city of Flint, Michigan has a population of 54% Black Americans, 38% White Americans, and other racial groups in smaller proportions; 51.5% of Flint residents are female, and 12% of the population has a Bachelor's degree or higher education (U.S. Census Bureau, 2021).³⁰

Participants

Participants included in the study were patients hospitalized with stroke who were 18 years of age and older, English speaking, and had arrived at the hospital three hours or more after stroke symptom onset. Patients who awoke with stroke symptoms were excluded.

Survey instrument

We developed a survey instrument (questionnaire) to determine reasons that stroke patients delay in hospital arrival after stroke symptom onset and grounded the questionnaire in the theory of planned behavior. The theory of planned behavior states that a person's intent to engage in a particular behavior is influenced by their attitude toward the behavior, subjective norm/social pressure to perform the behavior, and perceived behavioral control/self-efficacy to perform the behavior (Ajzen, 1991). A person's attitude towards the behavior is influenced by their behavioral beliefs (i.e., expectations about the outcome associated with the behavior). The subjective norm around

a behavior, in turn, is informed by a person's normative beliefs (beliefs about the social expectations around performing the behavior). Finally, perceived behavioral control is shaped by control beliefs regarding how easy or difficult it is to perform the behavior (Figure 1).

The behavior of interest was calling 911 upon stroke symptom onset. We included questions that asked: i) reasons for delay in hospital arrival (in order to determine control beliefs and behavioral beliefs); ii) actions performed upon stroke symptom onset (which may be shaped by one's attitude towards performing the behavior); iii) self-efficacy for stroke symptom recognition and calling 911; and iv) subjective norms about calling 911.

The questionnaire included multiple choice questions with most having the option for the respondent to provide their own answer if none of the options was considered appropriate. Response options were based on data from previous surveys and focus groups assessing reasons for delay after stroke symptom onset conducted in similar communities (Hsia et al., 2011b; Skolarus et al., 2013). Several questions asked respondents to rate their level of agreement with a written statement on a Likert scale. There was one open-ended question (see supplementary file for questionnaire.)

After creating the questionnaire, we performed cognitive interviewing on a convenience sample of stroke survivors to ensure that they understood the questions as intended. Cognitive interviewing is a technique used to study how material is understood and processed by the intended target audience. We used the cognitive interviewing technique of verbal probing, asking participants questions to probe their understanding of the survey questions (Willis, 2005). The convenience sample consisted of stroke survivors attending a session of a stroke survivor support group. Based on the cognitive interviewing, slight modifications were made to the wording of questions to improve comprehensibility. The hospital stroke coordinator distributed the final questionnaire to stroke patients, who self-administered the questionnaire.

Data analysis

Given the types of questions asked on the questionnaire, we used a mixed-methods approach to analyze sur-

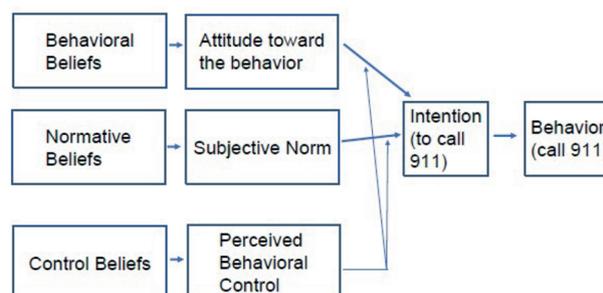


Figure 1. Theory of planned behavior.

vey responses. Quantitative methods were used to describe the proportion of respondents who selected different answer choices and the proportion who provided the same free-text responses. The number of questionnaire respondents (N=19) was too small to permit inferential statistics on the questionnaire data. After identifying the most frequent responses, we used a qualitative approach by using the theory of planned behavior to interpret the responses. Specifically, we categorized responses into the beliefs that comprise the theory of planned behavior. We then used survey responses to inform development of the intervention by linking MoAs to behavior change techniques (Carey, et al., 2019; Figure 2). The following section presents a description of the survey participants, organization of survey responses into the theory of planned behavior, response proportions, and linking of mechanisms of action to behavior change techniques.

Results

We surveyed 19 stroke patients between December 2020 and April 2021. Participants had a mean (\pm standard deviation) age of 57 ± 8 years old. Of the participants, 58% were men, 63% had at least some college education, 63% self-reported their race as Black, 37% self-reported their race as White, and 16% had a self-reported past history of stroke. Percentages indicate the proportion of survey respondents who provided the response.

Theory of planned behavior: Behavioral beliefs

The most frequent beliefs about stroke symptoms that were identified as reasons for waiting to come to the hospital included that the symptoms would go away (73.7%) and that the symptoms were not serious (31.6%). The majority of stroke survivors (57.9%) understood that they would get an ambulance by calling 911. Even though many stroke survivors (57.9%) thought that they would have to pay for the ambulance, very few stroke survivors (15.8%) indicated that the thought of having to pay for an ambulance caused them to delay in calling 911.

Theory of planned behavior: Normative beliefs

The majority of participants (89.5%) held normative beliefs about calling 911, with the opinion that most of their friends or family would call 911 if they had symptoms of stroke. Many stroke survivors (21.1%) thought

that their friends and family would not be able to recognize stroke symptoms or were unsure (31.6%) if their friends and family would recognize stroke symptoms. The majority of stroke survivors (63.2%) called a family member when their stroke symptoms started, and this was the first action after symptom onset in 31.6% of stroke survivors. Many stroke survivors (47.4%) eventually presented to the hospital because family told them to do so.

Theory of planned behavior: Control beliefs

Some participants (31.6%) identified not wanting to miss work as a reason for waiting to call 911. Most participants (63.2%) stated that, considering what they knew prior to coming to the hospital, they would know what to do if someone was having a stroke. The majority of participants (63.2%) also stated that, considering what they knew prior to coming to the hospital, they would have been able to tell a 911 operator why they thought someone was having a stroke.

How survey results informed development of intervention materials: Linking MoAs to BCTs

We adapted the intervention pamphlet based on the questionnaire responses. Adaptation of the video was not needed to address the survey responses.

In modifying the intervention, we directly addressed behavioral beliefs that were identified by stroke survivors as reasons for waiting to come to the hospital—including that the symptoms would go away and that the symptoms were not serious—and, therefore, might influence their attitude towards calling 911. We addressed stroke survivors' attitude towards the behavior of calling 911 by including information about health consequences. We modified the intervention pamphlet to include the sentence *Don't wait for the signs to go away, STROKE IS SERIOUS!*. We also added the sentence *Faster treatment means improved health!* (Table 1). Since stroke survivors expressed knowledge that calling 911 would result in dispatch of an ambulance, we did not reinforce this fact. Instead, we emphasized the message to call 911 and get an ambulance as soon as stroke symptoms start.

While stroke survivors held normative beliefs that their friends or family would call 911 upon stroke symptom onset, many thought that their friends or family would not or might not be able to recognize the signs of



*Identified using Table 1 of Carey et al., 2019

Figure 2. Linking theory to mechanisms of action to behavior change techniques.

stroke. The pamphlet already addressed the lack of knowledge or skills by providing written and pictorial descriptions of stroke signs and how to check for those signs. We added instruction on when to call 911 by stating *Notice just one sign? REACT- Call 911!*. Since many stroke survivors called family when their stroke symptoms started, we provided verbal persuasion about the stroke survivor's capability of calling 911 by stating *Time to call 911! Make it the FIRST thing you do!* (Table 1).

Participants expressed self-efficacy in recognizing stroke symptoms and calling 911. A control belief identified by some stroke survivors included not wanting to miss work which has the potential to influence their attitude toward calling 911. We therefore emphasized the salience of the consequence of not calling 911 by including the reason why rapid stroke treatment is important, specifically *The longer a stroke goes without treatment, more of the brain dies!* We also emphasized throughout the intervention pamphlet that stroke is an emergency and that stroke is treatable (Table 1).

Cognitive interviews and intervention refinement

After having adapted the intervention pamphlet, we interviewed patients presenting to the emergency department of the local hospital to determine whether they understood the content of the intervention pamphlet and video as we intended.

Materials and Methods

Setting

The emergency department of the same local hospital in which questionnaires were administered.

Participants

Eligible emergency department patients were 18 years of age or older, English speaking, likely to be discharged home as determined by the emergency department triage

system, and lacked severe pain or any other condition which would distract from participation.

Data collection

The research coordinator screened the emergency department triage list for patients who met the eligibility criteria described above and enrolled participants after obtaining informed consent. The research coordinator performed cognitive interviews in the emergency department at the patient's bedside.

Participants were asked to read the intervention pamphlet in sections. While participants were reading the pamphlet, the research coordinator noted any challenging words or sentence structures. After each section, the research coordinator asked questions to assess the meaning that the participant had obtained from reading the section. Participants then viewed the intervention video in sections. After each section of the video, the research coordinator asked questions to assess the participant's understanding of the video. (See supplementary file for cognitive interview guides for the initial versions of the pamphlet and video.) Interviews were audio recorded and transcribed.

Results

We enrolled 40 participants between July 2021 and November 2021. Enrolled participants had a mean (\pm standard deviation) age of 47 ± 16 . Of the participants, 40% were men, 57.5% had at least some college education, 37.5% self-reported their race as Black, 50% self-reported their race as White, 12.5% self-reported their race as Other, and 10% had a self-reported history of stroke.

Cognitive interviews and intervention adaptation

After reviewing the interview transcripts, we identified sections of the pamphlet that were misunderstood by many participants. We modified the wording of those sections. The intervention video was edited to remove repetitive messages. We confirmed the acceptability of the modified

Table 1. Link between the mechanism of action to the behavior change technique.

MoA-BCT links (Carey <i>et al.</i> , 2019)		Stroke Intervention	
MoA	BCT	MoA	BCT
Attitude towards the behavior	Information about health consequences	Symptoms will go away; symptoms are not serious	Don't wait for the signs to go away, STROKE IS SERIOUS. Faster treatment means improved health!
Knowledge/skills	Instruction on how to perform the behavior	Friends and family would not or might not be able to recognize stroke symptoms.	Notice just one sign? REACT- Call 911!
Beliefs about capabilities	Verbal persuasion about capability	First action after symptom onset was calling family.	Time to call 911! Make it the FIRST thing you do!
Attitude towards the behavior	Salience of consequences	Do not want to miss work.	The longer a stroke goes without treatment, more of the brain dies!

BCT, Behavior Change Technique; MoA, Mechanism of Action.

pamphlet and video via an additional round of cognitive interviews of 10 new emergency department patients who were also identified by screening the emergency department triage list. We found that participants understood these modified intervention materials as intended.

Intervention materials and possible intervention outcomes

The intent of the interviews was to determine participants' understanding of the intervention pamphlet and video, but we also identified possible mechanisms by which the intervention materials might produce the intended outcome of increasing stroke symptom recognition and intent to call 911.

Evoking personal experiences with stroke

Although we did not ask participants about their prior knowledge or experience with stroke, several participants recounted stories about their personal experience with family members or friends who had had a stroke. Through these stories, participants affirmed their knowledge of stroke symptoms, the impact of stroke, and evaluated their past experiences with stroke symptom recognition and response in light of what was described in the intervention material. For example, when one participant was asked their understanding of the stroke signs presented in the pamphlet, the participant stated "Like I said, I have my mother and my grandmother who have it. I know all the signs." Another participant stated, "If you...like if I saw that the mouth or the face was drooping, I'd be on the phone with 911 instantly...because that's to me the first sign of what I saw my cousin go through." When asked to explain what was meant by the phrase *disability caused by stroke can leave a person unable to do everyday, normal activities*, one participant drew on their personal observation of stroke to describe the impact of stroke and stated, "...normally it changes up a person's living in, like you said, daily activities, because I know a lot of people have strokes, they lose their jobs, and they can't return to work because they're high risk." When one participant was asked their understanding of the pamphlet's explanation of how to check for stroke signs, the participant evaluated their past experience with evaluating and responding to stroke signs:

Because Mom was just like laying on the couch. I would have never thought...or did I pick her arm up? Now I know if I'm around anybody I think's maybe having one, I'll know to raise both their arms. And, and I did get the ambulance. Some of the family didn't think they got there fast enough, of course.... But I think they got there in a reasonable time.

The intervention materials caused the participants to reflect on their own knowledge and experiences with stroke.

Drawing upon a sense of community

The intervention video contained scenes of local landmarks, and participants were asked what thoughts came to mind when seeing them. Some participants linked the local landmarks to the relevance of the intervention for their community. One participant stated, "[it means] that it's [stroke is] happening closer than we think...showing you that it's right here in our community." One participant similarly stated, "When they see that, they think, this is in my neighborhood, or this is in our area." Another participant said, "They really trying to get Flint people to care about, um, strokes." The local landmarks evoked a sense of comfort and community, as one participant remarked, "Ah, I feel a little more comfortable just seeing it from Flint. It's Flint people." Another participant stated, "Oh, home. I'm a Flintstone," and a different participant stated, "Um, that it's kind of like our hometown."

Eliciting emotional responses

Although not specifically asked, some participants expressed their emotional response to the intervention content. When asked their understanding of the phrase *Stroke is common*, some participants voiced fear in response to this fact. According to one participant, "It means that a lot of people have strokes, and it is...it is very...it is very common, yes. Actually, my-my significant other had a mild stroke years ago. It's frightening." Another participant stated, "That's kind of scary, too. I don't think it should be common, but that's life..." Other participants expressed fear when reading the sentence on the intervention pamphlet that stroke causes part of the brain to die.

Discussion

In the sections above, we described how qualitative data informed development of our stroke education intervention. We found that grounding questionnaire items in a behavior change theory facilitated adaptation of our intervention.

Our questionnaire revealed attitudes that may be associated with a delay in calling 911 upon stroke symptom recognition. We addressed these attitudes in the intervention pamphlet by adding information about the health consequences of stroke and about the consequences of not calling 911. Survey participants identified possible shortcomings in knowledge, skills, and capability associated with calling 911 for stroke. We therefore added instruction on when to call 911 and persuasion about their capability of calling 911.

We showed how a behavioral change theory—the theory of planned behavior—was useful in developing our stroke education intervention. Using the theory of planned behavior, we were able to identify behavioral, normative, and control beliefs that influenced the behavior of delay in

going to the hospital upon stroke symptom onset. We adapted our intervention to address those beliefs by identifying the links between MoAs, or theoretical constructs, and active components of the intervention, or BCTs. Linking MoAs to BCTs in the intervention adaptation or design phase can thus contribute to more effective behavioral interventions (Carey et al., 2019; Michie et al., 2018).

Through cognitive interviews that were intended to assess participants' understanding of the intervention materials, we learned that the intervention materials caused some participants to reflect on their personal experience with family members or friends who had a stroke. These participants constructed their own narrative around recognition of stroke signs or response to stroke signs. The use of narratives in health interventions has been shown to positively change attitudes, beliefs, intentions, and behaviors in Black American populations (Ballard et al, 2021; Houston, et al., 2011), which is a finding that has great relevance given the target population of our intervention.

Through our qualitative methodology, we also found that the visual depiction of community landmarks in our intervention video elicited a sense of community belonging—i.e., connectedness between an individual and his/her community (Hystad & Carpiano, 2012)—in some of our participants. A dose-response relationship has been reported between a person's perceived degree of community belonging and health behavior change, such that a stronger sense of community belonging is associated with increased likelihood of undertaking health behavior change (Hystad & Carpiano, 2012). The sense of community belonging evoked by including landmarks in our intervention video might, therefore, be a mechanism through which the intervention can effect positive behavior change.

Conclusions

In this manuscript, we have described how our qualitative data informed development of our behavioral intervention. We showed how grounding data collection instruments in behavior change theory facilitates interpretation of the results and identification of MoAs that can be linked to BCTs to be included in the intervention. We also showed how qualitative data collected for intervention development can provide insight into how the intervention might produce its intended effect. Our hope is that greater reflection and more detailed reporting of how qualitative data are used in intervention development will facilitate the development of effective behavioral interventions.

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