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Cognitive testing to evaluate revisions to the Vaccine Adverse Event Reporting System (VAERS) reporting form

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Abstract

Introduction: The Vaccine Adverse Event Reporting System (VAERS) is the spontaneous (passive) reporting system CDC and FDA use to monitor vaccine safety. We used cognitive testing to evaluate proposed revisions to the current VAERS form.

Methods: We conducted in-person cognitive interviews with 22 volunteers to evaluate proposed revisions in a prototype VAERS 2.0 form (new VAERS form). We analyzed data using thematic analysis.

Results: Repeating themes included preferences for: brevity, simplicity and clarity; features to minimize time requirements and facilitate ease of completion; logical ordering of questions by topic and importance; and visual cues like color-coded highlighting. Interviews identified instances of discordance between the intended meaning questions (from the perspective of CDC and FDA) and interpretation by volunteers.

Conclusions: Cognitive testing yielded useful information to guide further revisions of the VAERS form. Cognitive testing can be an effective tool for public health programs interested in developing surveys and reporting forms.

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Human subjects protection

The Centers for Disease Control and Prevention Human Research Protection Office determined the activity did not qualify as research and Institutional Review Board approval was not required. Consent was obtained from all volunteers.

Conflicts of interest

None of the authors have any conflicts of interest.

Keywords

Vaccine Adverse Event Reporting System (VAERS); Cognitive testing; Thematic analysis; Vaccine safety

1. Introduction

Vaccines undergo rigorous testing for safety and effectiveness prior to licensure [1]. After licensure, the Centers for Disease Control and Prevention (CDC) and US Food and Drug Administration (FDA) jointly monitor safety using the Vaccine Adverse Event Reporting System (VAERS) [2]. VAERS is a national spontaneous (passive) monitoring system for detecting possible safety signals. It relies on individuals to voluntarily report experiences of adverse events (AE) following vaccination. In recent years, 26% of reports have come from healthcare professionals, 11% from patients and parents, 12% from “others” and 51% from vaccine manufacturers (CDC unpublished data). As such, the VAERS reporting form and reporting process must accommodate individual reporters with varying backgrounds and education levels.

The VAERS-1 paper reporting form [3] has been in use since 1990, but little qualitative research has been done to evaluate public perception and understanding of its questions. CDC and FDA have identified data elements on the VAERS-1 form that have limited value for safety monitoring. Furthermore, important data elements are absent (e.g., information on pregnancy), and other existing data elements required language clarification. CDC and FDA are presently updating the VAERS-1 form to revise questions, improve ease of completion, and transition to a computer-based form that can be submitted electronically using the Internet (the new VAERS 2.0 form) [4]. To evaluate proposed revisions, CDC conducted cognitive testing of a prototype VAERS 2.0 form.

2. Methods

Cognitive testing is used to evaluate how people interpret survey questions and to gain insight into cognitive processes used when completing surveys, with the goal of improving quality, accuracy and consistency of data collected [5–9]. CDC conducted cognitive testing of a prototype VAERS 2.0 form with 22 volunteers of varying backgrounds and experiences, including physicians (9), nurses (4), pharmacists (2), medical office staff (1), persons aged 65 years and older (3), and parents of young children (3), from November 2013 through January 2014, in Atlanta, Georgia. Eligibility criteria for volunteers was that they fell into one of the above categories and were willing to complete an in-person interview. Purposive sampling was used based on CDC contacts. Research shows that small sample sizes can provide adequate data – the goal of cognitive testing is to capture repeating themes, which usually emerge quickly [9].

We conducted in-person interviews using Cognitive Interviewing: A “How To” Guide [9] as our reference. One member of the two-person interview team was a behavioral scientist with experience in qualitative research. Pre-identified topics included: (1) initial impression of the revised form, (2) opinions on content, format, design and flow, (3) interpretation of language

(i.e., what information do people think they are being asked to provide and how do they understand response options), (4) how volunteers would complete the form (i.e., cognitive processes involved in formulating and providing responses), and (5) time required to complete the form. We asked volunteers to verbalize thoughts throughout the interview.

We used verbal probing techniques and documented body language and non-verbal communication cues. In addition to taking notes, we digitally recorded interviews. Interviews continued until repeating themes had been identified and new themes or ideas were no longer being expressed; often 45–60 min. Follow-up to clarify outstanding issues was necessary with five volunteers. CDC staff spent approximately 80 h preparing for and conducting interviews. Thematic analysis [10] included inductive (open-ended or non-preconceived) and deductive (pre-identified or pre-conceived) approaches. Based on findings, we made further revisions to the proposed VAERS 2.0 form. The CDC Human Research Protection Office determined the activity did not qualify as research and Institutional Review Board approval was not required. Consent was obtained from all volunteers.

3. Results

Repeating themes from cognitive testing included recommendations to:

1. Shorten and simplify questions and the form overall. Initial impressions of the form were that it was visually cluttered, unnecessarily long, and confusing. We addressed these concerns by removing fine print at the top and bottom of the form (e.g., URL link to the VAERS website and HIPAA privacy rules) and for clarity, we revised or deleted text that did not contribute to understanding the intent of questions. For example, in a question about vaccinations given to pregnant women, we changed instructions from “. . . describe pregnancy history, key dates, and the event. . .” to “. . . describe the event, any pregnancy complications, and estimated due date if known. . .”.
2. Reorder questions in a more logical completion sequence. A repeating theme was that certain questions should be grouped together (e.g., questions about demographics or reporter information) and ordered in a way that made sense. In response, we reordered questions, within space constraints of the form, to the most logical left-to-right, top-to-bottom completion sequence, thereby allowing persons to complete the form with minimal skipping from one section to another.
3. Visually highlight essential questions (i.e., those asking for high value public health and regulatory information such as date and time of vaccination and date and time the AE started). Highlight features were (and would be) helpful, especially when reporters are under time-constraints. This was accomplished through color coding essential questions.
4. Deemphasize non-essential questions by moving them to the end of the form. Moving non-essential questions to the end prevents mental fatigue that occurs when a person is forced to maintain concentration for an extended period of time during form completion. Questions about race and ethnicity were moved to the

end because volunteers felt these questions were less relevant to them when reporting an AE. This was accomplished during the question reordering process.

Cognitive testing revealed different preferences for healthcare professionals compared to laypersons. Healthcare professionals wanted a savable computerized form to allow multiple users to independently work on sections, similar to how paperwork is completed in clinic office settings. Laypersons preferred less clinical terms and medical jargon – the data element “route and site of vaccine administration” was cited as an example. Factors that could influence the amount of time to complete the form varied between healthcare professionals and laypersons. For healthcare professionals, factors were clinic workload and severity of the AE – severe AEs would require more time to report. For laypersons, factors were time it would take to gather health records and to call or visit their healthcare provider. Estimated length of time to complete the form ranged from 5 to 30 min for healthcare professionals and 15 to 20 min for laypersons.

Interpretation of some questions was problematic. For example, physicians interpreted the question asking for “Responsible Physician,” which was meant to identify the best physician to contact if additional clinical information was needed, as implying liability (i.e., risk of being sued). This was not anticipated and resulted in a change in language to “Best doctor/ healthcare professional to contact about the adverse event.” Quotes from interviews are in Table 1.

4. Discussion

Cognitive testing yielded useful information that will help improve efficiency and data quality in VAERS reporting. Importantly, it identified discordance between the intended meaning of some questions (from the perspective of CDC and FDA scientists), and interpretation by healthcare professionals and laypersons. The findings challenged many assumptions. CDC and FDA scientists believed questions were generally clear and concise, and would be easily understood by both healthcare professionals and laypersons. However, testing revealed that some questions were confusing or non-specific, such as the meaning of “responsible physician,” and terms like “route and site” of vaccine administration. We assumed the length of the form and order of questions were satisfactory, but cognitive testing demonstrated that volunteers preferred a shorter, simplified form, with a more logical sequence of information and grouping together of similar data elements like demographics and clinic information.

There were differences in preferences between healthcare professionals and laypersons, with the former wanting a shorter form with focus on essential data elements, and the latter wanting plain language and less medical jargon. Healthcare professionals cited busy schedules and severity of the AE as factors that would influence time to complete the form (i.e., having to retrieve and review patient records). In contrast, laypersons cited factors like having to call or visit a clinic to get specific information, like vaccine lot number and route and site of administration.

Based on findings of the cognitive testing, CDC and FDA made revisions to the proposed VAERS 2.0 form and briefed federal advisory committees on changes [11–13]. The updated

form was also posted on the Federal Register for public comment [4]. Computer-based user testing was conducted with the updated version of the form, including testing on mobile devices like smartphones and tablets, which contributed to an additional round of revisions. Post-implementation cognitive testing with a more representative sample of volunteers will be considered as part of the evaluation process.

A limitation of our cognitive testing was the relatively small purposive sample of volunteers, which might preclude generalizing results to a broader population. However, representative samples are not an absolute requirement for cognitive testing. Rather, it is critically important to identify key repeating themes or problem areas, which often become apparent quickly during the course of interviews [9].

5. Conclusion

Cognitive testing revealed that brevity, simplicity, clarity, and ease of completion were desired traits in the reporting form. Suggestions from volunteer testers led to meaningful changes to the form and demonstrated the value of cognitive testing as a component of survey and questionnaire development. With training and practice, cognitive testing can be an effective tool for any public health program interested in creating or revising surveys and reporting forms.

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Abbreviations:

VAERS	Vaccine Adverse Event Reporting System
AE	adverse event
CDC	Centers for Disease Control and Prevention
FDA	US Food and Drug Administration
HIPAA	Health Insurance Portability and Accountability Act.

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Table 1

Themes and individual quotes from cognitive testing of the proposed VAERS 2.0 form (N = 22 volunteers).

Theme	Healthcare professional	Layperson
Shorten and simplify the form	"...it's going to be one thing to ask a clinic physician or an office based physician to fill out this information but to ask somebody in my area of specialty [Emergency Medicine] to take time to fill out something like this would be nearly impossible..." - Pediatric emergency physician	"...it looks like a tax form...it's uninviting..." - Parent of a young child
Reorder questions in a more logical completion sequence	"...I guess last time [in the VAERS-1] you had the data about the patient first, and the information about the clinic and the person completing the form kind of grouped together...I like them all grouped together" - Pediatrician	"...Number 6 and 7 should be together...race and ethnicity..." - Parent of a young child
Visually highlight essential questions	"...I like that there are certain portions that are highlighted, you know to kind of draw your attention to those aspects, I am assuming those are important..." - Obstetrician/gynecologist	"...I like the highlighted...section titles...those jump out at you obviously, first thing that I would look at..." - Senior (65 +years)
Clarify language to avoid misinterpretation of questions	"...instead of responsible doctor...you may want to put the ordering doctor because responsible has some liability connotations..." - Primary care/internal medicine physician	"...a birth defect, congenital anomaly, I am not sure what they mean by that..." - Senior (65 +years)
Minimize the time required to complete the form	"...maybe 5or10 min [to complete the form] if you have all of the information right here...you have to access the computer to get the address and stuff like that...unless I am really busy and cannot fill it out, I think I will be able to do it by myself" - Nurse	"...Now a layperson wouldn't necessarily have that information...right? Or would they?...maybe you could say enter as much information as possible about the vaccines given...depends on how many vaccines given...15-20 min [to complete the form]" - Senior (65 +years)