the CFER-DS items valid, appropriate in scope, and adequate to the task of encoding details of diagnostic safety events. We also explored users' perceptions of feasibility and potential for adoption by healthcare organizations.

METHODS

Rationale and Overview

Prior studies have evaluated the content and usability of previously developed Common Formats using various qualitative and quantitative methods.[10–13] Qualitative methods, such as interviews and focus groups, have been used to evaluate other safety event reporting systems.[14–16] Structured items should be able to capture the dynamic complexity of diagnostic safety events but also be easily understood by the range of individuals who capture these events. We thus assessed the usability and validity of the CFER-DS by soliciting feedback from quality and safety personnel in U.S. healthcare organizations.

Participants were invited to use the CFER-DS to simulate reporting for a minimum of 5 diagnostic safety events. To protect the privacy and confidentiality of patients and providers, we collected information on user experiences with completion of the CFER-DS but did not collect information about the events themselves. The first author's institution served as the coordinating site and housed the evaluation team who were primarily responsible for developing evaluation procedures, interviewing participants, and collecting and analyzing data. All procedures were approved by the institutional review board at the coordinating institution and conducted between August 2020 and December 2020.

Initial Draft of the CFER-DS

The draft of the CFER-DS adapted items from previously developed Common Formats and from 2 existing frameworks for conceptualizing diagnostic errors, the Safer Dx Framework[17] and the Diagnostic Evaluation and Education Research taxonomy.[4,5] The draft was revised with input from 3 subject matter experts (M.G., G.D.S., H.S.) with extensive experience in measurement and classification of diagnostic errors. The CFER-DS also offers a definition of a diagnostic safety event using concepts proposed in 2 prior diagnostic error definitions (one by the National Academy of Medicine,[1] and the other by Singh[18]), as follows:

Diagnostic safety event: one or both of the following occurred, whether or not the patient was harmed:

•Delayed, wrong, or missed diagnosis: There were one or more missed opportunities to pursue or identify an accurate and timely diagnosis (or other explanation) of the patient's health problem(s) based on the information that existed at the time.
•Diagnosis not communicated to patient: An accurate diagnosis (or other explanation) of the patient's health problem(s) was available, but it was not communicated to the patient (includes the patient's representative or family as applicable).

The test version of the CFER-DS was a paper form with 2 main components: a brief narrative report designed to be completed by a clinician with knowledge of the event and a series of structured items with multiple choice, yes/no answer choices, and/or free-text fields to capture detailed aspects of the event. Only the "form" version of the CFER-DS was subjected to usability testing, so participants experienced it as a questionnaire or survey tool.

Site Recruitment

We recruited a purposive sample of personnel from 8 U.S. healthcare organizations to provide feedback about the usability

of the CFER-DS and potential for implementation. Participants held operational roles in their organizations, had expertise in healthcare quality and safety, and were involved in local and/or national organizational initiatives in quality and safety. Participants were encouraged to consult other team members from the same organization at their discretion.

Procedure

All evaluation procedures were conducted remotely. First, participants attended a teleconference during which they were oriented to the purpose of the project and the data collection procedures. The evaluation team then emailed an electronic copy of the draft CFER-DS to each participant. Participants were asked to complete the CFER-DS to simulate event reporting for 5 cases of diagnostic safety events that were familiar to them (e.g., events that occurred at their organizations, published or hypothetical events) and to email written feedback within approximately 4 weeks. The evaluation team held an interim "office hours" teleconference to answer questions while sites worked with the CFER-DS. Finally, participants engaged in individual postcompletion interviews with the evaluation team to follow up on written feedback and answer additional questions about usability and feasibility.

Data Collection

We developed a semistructured interview guide for postcompletion interviews that included questions about usability; the design, content, and sequence of items; and future implementation prospects. A qualitative methodologist (U.S.) led the postcompletion interviews; other members of the team took notes and occasionally prompted for elaboration or clarification. Interviews were scheduled for 1 hour, and participants were invited to include colleagues from their respective organizations as desired. We also developed a structured usability questionnaire to solicit multiple choice and open-ended feedback on ease of completion, burden, item clarity and flow, overall length, and importance of items. Finally, we invited participants to make comments and suggested revisions directly on a blank electronic copy of the CFER-DS (formatted in Microsoft Word). Thus, our evaluation data comprised participants' written feedback and our team's notes from the interviews and office-hour calls. Participants were reminded to maintain privacy and confidentiality of involved patients and providers, and no protected health information or other case details were disclosed during data collection.

Data Analysis

The interviewer conducted the initial data analysis by reviewing all team members' notes, responses to the usability questionnaire, and participants' annotations to the CFER-DS and creating a spreadsheet to categorize the detailed feedback from each participant (deidentified). The evaluation team met on multiple occasions to review and discuss participant feedback before sharing it with AHRQ. Frequently occurring issues, usability-related themes, and conceptual/definitional issues were captured in writing and are summarized in the following section. Separately, we consulted a psychometrician with expertise in survey design to comment on the design, clarity, and usability of the CFER-DS. The psychometrician was briefed on our methodology and on key themes from participants' feedback.

RESULTS

Participants

Participants were located in the northeastern, southern, midwestern, and western regions of the United States. Participants