## Appendix C. Operations Manual

# The Health Care Safety Hotline: Operations Manual

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# 1. Contents of the Manual

This operations manual describes the main components and functions of the hotline, including instructions for processing, sharing, classifying, and using the event data; detailed scripts; tracking methods; Web tool text; required hardware and software; and information on maintenance and data storage. Section 2 summarizes the required hardware and software. Section 3 presents the functional and non-functional requirements for operation. Section 4 describes the report form and the handling of the toll-free telephone report form, including suggested scripts. Section 5 describes the instructions for processing and sharing reports. Section 6 provides the details on maintenance of the system and data storage.

# 2. Hardware and Software Requirements

This section describes the required hardware and software that are needed to operate the Health Care Safety Hotline, as well as the design assumptions.

### *System Processing Requirements*

The hotline employs a Microsoft Technology platform, including the latest operating system and software. It utilizes Microsoft Windows 64-bit 2008 R2 servers, Microsoft SQL Server 2012 64-bit, and ASP.NET.Architecture.

The hotline employs a well-known Web server architecture, in which a front-end tier (a Web browser) communicates with a back-end tier (a database) through a Web server tier. Table C.1 shows the minimum requirements on a single server.

**Table C.1. System Processing Requirements**

| | |
|---|---|
| Operating system | Microsoft Windows 64-bit 2008 R2 Servers |
| Database | SQL Server 2012 64-bit |
| Web server | IIS 7 |
| Security | SSL Certificate |

The prototype utilizes Hypertext Transfer Protocol Secure (HTTPS), which is a combination of the Hypertext Transfer Protocol and the SSL protocol that provides encrypted communication and secure identification of a network Web server. An SSL certificate was procured by ECRI Institute to establish this secure transfer of data.

### *Supported Browser*

The prototype supports the current and previous version of Internet Explorer.

### *Prototype Design Assumptions*

- The hotline team is able to review data based on role level.
- There are six user types: SuperUser – Administrative; SuperUser – Research; Intake Administrative User; Consumer – Guest; Consumer – Registered; and Post Audit Review.

- The Consumer – Registered is required to provide an e-mail address for registration. An e-mail is sent to the Consumer – Registered containing a link to the site where he or she is able to enter and verify a password and then is allowed to access the prototype.
- A user password must contain a minimum of eight characters and at least one upper-case letter and one number.
- Context-sensitive help will be implemented as pop-ups in module development.
- The application does not require an install package.
- The prototype is hosted at ECRI Institute.
- If another organization wants to subsequently host the application, the minimum hardware and software requirements must be met as defined in Minimum System Requirements.
- The administrative section is a web-based interface.
- The software is maintained by mid- to senior-level developers fluent in C# and the newer Microsoft technologies.
- SQL Server 2012 is used for the system.
- This application is built as a standalone prototype and is not intended to interoperate with other applications.
- The prototype is not intended to be a distributed system that will synchronize data among multiple instances of the application. A data synchronization strategy and distributed data security model were outside the scope of this project.
- There is workflow around the initial entering of the data by the patient, family member, or caregivers to make sure that the skip logic integrity is kept. No specific workflow is kept beyond that point. The users will maintain any business flow operationally.
- Exporting of the information from our SQL Server database into an Excel file occurred during the prototype phase.
- Analysis of the data is handled at the database level. Only simple tabulations of the reported safety occurrence (RSO) data from patient/family/caregiver reports based on the taxonomy categories were developed. (See details under Reporting Function.)

In addition, the prototype was designed to meet the following standards of 508 compliance:

- A text equivalent for non-text elements shall be provided (e.g., via “alt,” “longdesc,” or element content).
- Web pages are designed so that all information conveyed with color is also available without color, for example, from context to markup.
- Redundant text links are provided for active regions of a server-side image map.
- Row and column headers are identified for data tables.
- When a timed response is required, the user is alerted and given sufficient time to indicate more time is required.

For organizations that decide to adopt or create a similar Web site, we recommend a series of usability considerations to make the submission process more streamlined. See Appendix C.1.

## 3. Functional and Non-Functional Requirements for Operation

This section describes the functional and non-functional requirements for the Health Care Safety Hotline, including the reporting.

### *Functional Requirements*

**General Requirements**

The prototype is Web-enabled. Access is controlled based on the role of the user (e.g., public reporter, back-end hotline administrator) and also according to specific data types. The prototype Web interface captures the details of patient-reported safety events from reporters (e.g., patients, families, and caregivers). The main data entity is called a reported safety occurrence (RSO). Data are entered via a report form.

The report form was developed in a modular format and allows for the capture of information from reporters within the following modules:

- Module 1: Introduction – who is reporting a safety concern.
- Module 2: Description of your safety concern – description of the safety concern.
- Module 3: Mistake – details of the mistake.
- Module 4: Negative effect – details of the negative effect.
- Module 5: Contributing factors, changes in care, discovery, and reporting – details of the contributing factors, changes in care, discovery, and reporting of the patient safety concern.
- Module 6: Patient and clinician/facility information – details of the patient and clinician/facility information.

See Appendix C.2 for the Web version of the report form and Appendix C.3 for the phone version.

The prototype is also utilized by back-end administrators (referred to as SuperUser – Administrators), who process the report form after intake and then collect additional information (where possible) from the health care delivery organization. The back-end processing information is also captured in a modular format and allows for the inclusion of the following information from the hotline team within the modules:

- Module 7: Comments/clarifications – additional details/clarifications from the reporter of the RSO.
- Module 8: Administrative script – details of provider supplementation follow-up information with the identified health care organization (Step 6 in Figure C.29)..

See Appendix C.4 for provider supplementation process follow-up questions and administrative script (Module 8).

**Embedded Patient Safety Event Taxonomy**

The prototype allows the display of an embedded patient safety event taxonomy using drill-down (multilevel) menus. The prototype contains two top-level categories; each category has a drill-

down list from which reporters select items to describe the mistake and/or negative effect (subcategories) experienced.

The taxonomy is:

- Mistake:
  – Related to medicine.
  – Related to test, procedure, or surgery.
  – Related to pregnancy or childbirth.
  – Related to a diagnosis or advice from a doctor, nurse, or other health care provider.
  – Related to poor cleanliness or poor hygiene.
  – Related to something else, or more than one mistake.
- Negative effect:
  – Related to medicine.
  – Related to test, procedure, or surgery.
  – Related to pregnancy or childbirth.
  – Related to a diagnosis.
  – Related to advice.
  – Related to unclean or unsanitary care.
  – Related to something else, or more than one negative effect.
- Type of negative effect:
  – Physical
  – Emotional
  – Both.

**Administrative Requirements**

The prototype allows a Web-based administrative interface with the following administrative requirements:

- Only users with the SuperUser – Administrative role are allowed to access the administrative interface.
- The prototype allows SuperUser – Administrative to manage users and their effective role-based permissions.
- Users include: SuperUser – Research, Intake Administrative User, and Post Audit Review.
- The SuperUser – Administrative is not able to manage Consumers – Registered accounts.
- The prototype allows SuperUser – Administrative to manage roles.
  – Managing roles include setting and changing roles for those accounts created (excluding Consumer – Guest, Consumer – Registered).
- The prototype allows the SuperUser – Administrative to set the e-mail notification preference of new RSOs to the following users: SuperUser – Administrative, SuperUser – Research, Intake Administrative User, Post Audit Review.
  – The e-mail preference is set at prototype level for each user and sends a change of status of the RSO.
- The prototype enables a SuperUser – Administrative (for the prototype, the role was assigned by ECRI Institute) to view all the information for the purposes of assisting health care delivery organizations in working through any issues related to the patient- or caregiver-reported safety occurrence.

The prototype distinguishes between reports submitted by patients/families/caregivers and those submitted by intake staff over the phone. The prototype records the User ID of the intake staff in relation to the report he or she submits.

**Business Process/Rules**

The prototype was designed using the following business processes and rules:

- The Patient Safety Act prohibits the impermissible disclosure of patient safety work product, and thus, publicly available data must be rendered non-identifiable in accordance with the Patient Safety Rule.
- The prototype requires all users to read and accept the hotline consent and attestations prior to any significant interaction with the prototype (refer to Section 4 of this Operations Manual).
- The prototype stores each user's acceptance of the agreement by event ID (e.g., patient submitting an event anonymously); the acceptance is stored by a unique identifier. To the extent possible, the prototype makes individuals accept the general terms and conditions only once.
- The report of safety occurrence (RSO) moves to an activity status of "Submitted" when it is initially saved.
- The RSO automatically saves when the user clicks the button to move to the next module.
- "Submit" status is applied when the "Submit" button is clicked after completing modules 1–6. "[Submitted]" is auto-selected after the consumer has submitted the report.
- A prototype-generated RSO # ID is established when submitted.
- The prototype has a time-out feature established at 20 minutes of inactivity and displays a warning at 15 minutes of inactivity, at which point the user will either respond or be logged out of the prototype, thus losing any unsaved information.
- Once a resolution is submitted by the user, the hotline team may alter the status to one of the following five options:
  - Screened:
    - Is selected by the Intake Administrative User/SuperUser – Research after the inclusion/exclusion criteria have been applied.
  - Audited – needs patient/caregiver/other reporter followup.
    - Is selected by the SuperUser – Administrative when clarification of the RSO by the reporter is needed.
  - Audited – needs team decision (free text reviewed and sanitized).
  - Clarified (questions answered by reporter team; ready for matching to provider).
    - Is selected by the SuperUser – Administrative after auditing and clarification of the RSO is completed and all free text fields have been reviewed and de-identified.
  - Finalized:
    - Is selected by the SuperUser - Administrative once the supplementation process is completed.

The details of these processes and the handling of the RSO are detailed in Section 5 of this Operations Manual.

**Operational Requirements**

All systems are kept up-to-date within 3 to 5 days of every security and system update released by the vendor. The prototype retains a full audit trail, with each version of the RSO accessible for review. The audit trail maintains the entire version of the record at each update of the RSO each time it is committed to the database. The prototype shows by whom (user) and when (date and time) an RSO was accessed. Only the SuperUser – Administrative has access to this information.

**Reporting Function**

The following reports are made available for viewing the RSO details only as appropriate after assessment for the potential to de-identify the RSO when the user has requested anonymity. There are functional reports and administrative reports. See Appendix C.5 for the detailed content of both the functional and administrative reports.

- Functional reports:
  - Summary and report by mistake type.
  - Summary and report by negative effect (mistake type, type, location).
  - Summary and report of contributing factors (mistake type, type, location).
  - Summary and report by type of reporter.
  - Summary of patient demographics (gender, age, race, language, insurance).
  - Print RSO to PDF.
- Administrative reports:
  - Summary by "How did you learn about the hotline?"
  - Summary by modality used to submit the report (phone/computer).
  - Export data set – Modules 1–7.
  - Export data set – Module 8: Provider supplementation process information.
  - Web traffic report.

The reports available in the system allow for the data to be filtered based upon certain criteria for additional analysis. The additional filtering criteria include

- Criteria for community and aggregate reports:
  - Date submitted criteria.
  - Mistake type (3.1) criteria.
  - Negative effect (4.2) criteria.
  - Where? (3.2) criteria.
- Criteria for aggregate reports (The following criteria are applicable for both detail and aggregate reporting):
  - Date submitted.
  - Event ID number.
  - RSO status.
  - Community.

### *Non-Functional Requirements*

**Overview of User Community**

The main user community for the Web site consists of patients, families, and/or caregivers and the administrative phone-intake personnel. The prototype's intention is to assist policymakers in understanding the variety, extent, and seriousness of the consumer-reported safety occurrences.

To access the hotline, consumers (patients, families, and other caregivers) are assigned a user role (Consumer – Registered or Consumer – Guest). Users can log in as a guest to provide anonymity, or they may establish a username and password to edit and review established RSOs. The Consumer – Registered user is required to submit an e-mail address, and after e-mail confirmation and password creation, is permitted to access the RSO via a link in an e-mail.

Intake personnel and the hotline analysis team (SuperUser – Administrative, SuperUser – Research, Intake Administrative User, and Post Audit Review) must use their unique passwords and user IDs, which are set up through the same e-mail method as those of the consumers.

There is also an administrative web-based interface to the prototype that is secured by role for internal, non-public use. This interface is restricted to users by role.

**User Profile(s)**

There are several levels of access to the prototype that are controlled by the roles assigned to each user by the Web site administrator. These levels of access are

- Consumer – Registered.
- Consumer – Guest.
- Admin SuperUser – Administrative.
- Admin SuperUser – Research.
- Intake Admin User.
- Post Audit Review.

See Appendix C.6 for an overview of user profiles.

## 4. Report Form

Patients and their caregivers, families, and friends are able to voluntarily report safety observations through a safety report form that can be completed on the Web or by calling a toll-free telephone line.

### *Report Form (Web Tool) Plus Post-Submission Survey*

The report form contains 10 domains of items, described in Table C.2.

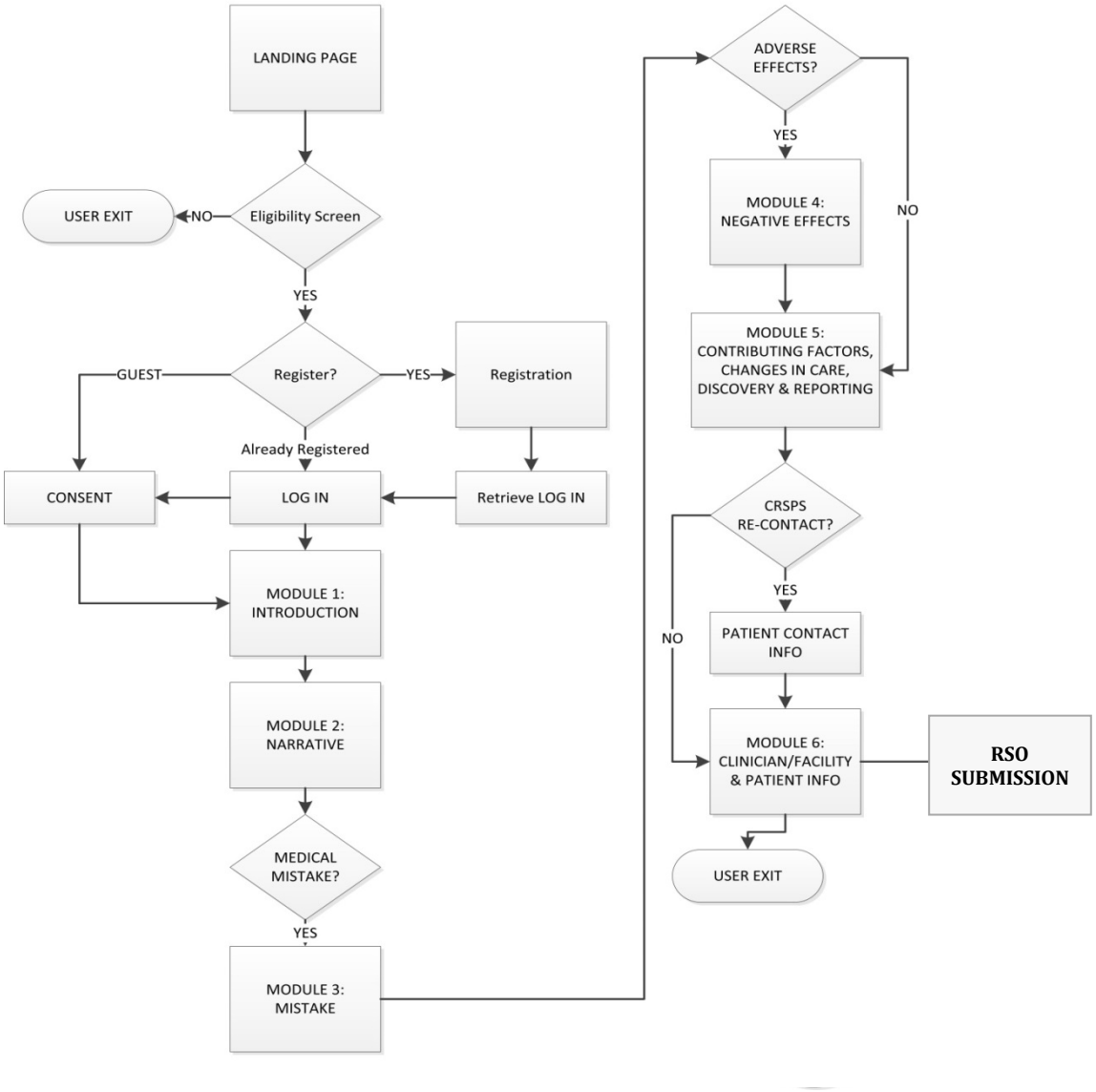
**Table C.2. Hotline Report Form Content by Domain**

| Count | Domain |
|---|---|
| 14 items | Type of safety problem (negative health effect or medical mistake) and whether it involved medications, tests, procedures or surgery, pregnancy, diagnosis, cleanliness, or other health care processes |
| 5 items | Impact on the patient and caregivers (financial, physical, emotional) |
| 2 items | Subsequent care (need for additional medical treatment or new providers) |
| 8 items | Contributing factors |
| 3 items | How the safety issue was discovered |
| 2 items | Prior reporting about the safety issue |
| 2 items | Mitigation efforts |
| 8 items | Descriptive characteristics (e.g., when, where) |
| 12 items | Information about providers |
| 14 items | Information about the patient (and caregiver, if applicable) |

The survey contains 77 items formatted with skip patterns to allow for reporting concerns that are considered medical mistakes, negative effects, or both, followed by demographic questions about the reporter. The reading level of the report form, including the required consent language is seventh grade, ninth month—7.9 on the Flesch-Kincaid reading scale, with 4 percent passive sentences. Without the consent language, the reading level of the report form is seventh grade (7.7 on the Flesch-Kincaid reading scale). Appendix C.2 contains the final Web version of the report form. Appendix C.3 contains the final phone version.

The report form includes a structured set of questions that enable patients, families, and caregivers to report about two types of safety events: negative effects related to health care (e.g., harm, injury, adverse event) and/or suspected medical errors or mistakes, whether or not they are associated with harm or injury. Figure C.1 presents the report form modules and key questions.

**Figure C.1. Flow Chart of Report Form Questions**




The landing page, also referred to as the introduction page, contains an introductory script, along with an overview of the hotline, general instructions, and links to additional reporting resources and FAQs. The OMB Paperwork Reduction Act Statement is also included on the landing page.

The welcome message appears at the very top of the landing page. This message gives a very brief description of the hotline, including definition and purpose:

**Figure C2. Welcome to the Health Care Safety Hotline – Share Your Concerns**

| |
|---|
| The Health Care Safety Hotline comprises a Web site and toll-free number that patients and caregivers can use to report on safety concerns and negative effects of health care. The purpose of collecting this information is to make health care better by making it safe. |

After the welcoming messaging, how it works, how to report, and what to report, script guides walk reporting patients or caregivers briefly through the process of using the hotline (Figures C.3, C.4, and C.5).

**Figure C.3. How It Works**

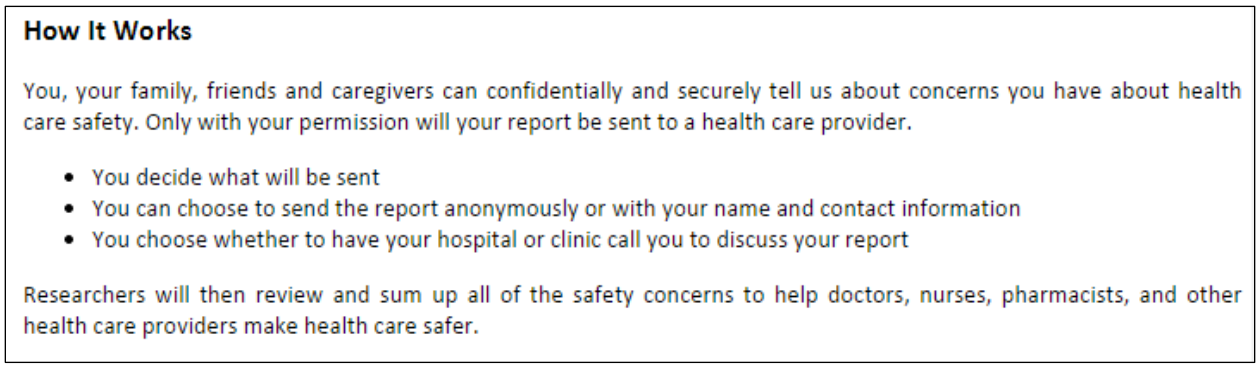



**Figure C.4. How to Report**

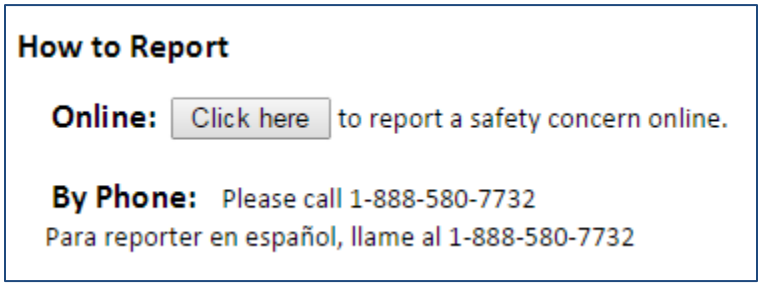
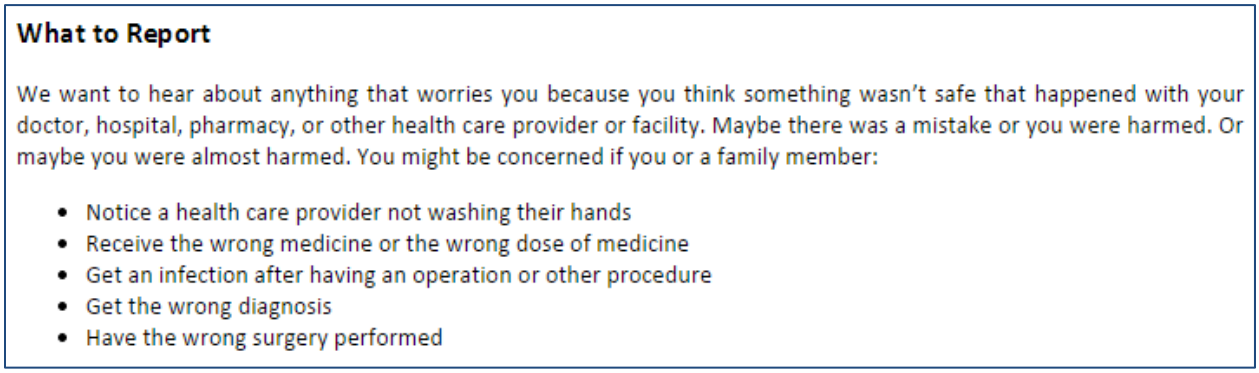


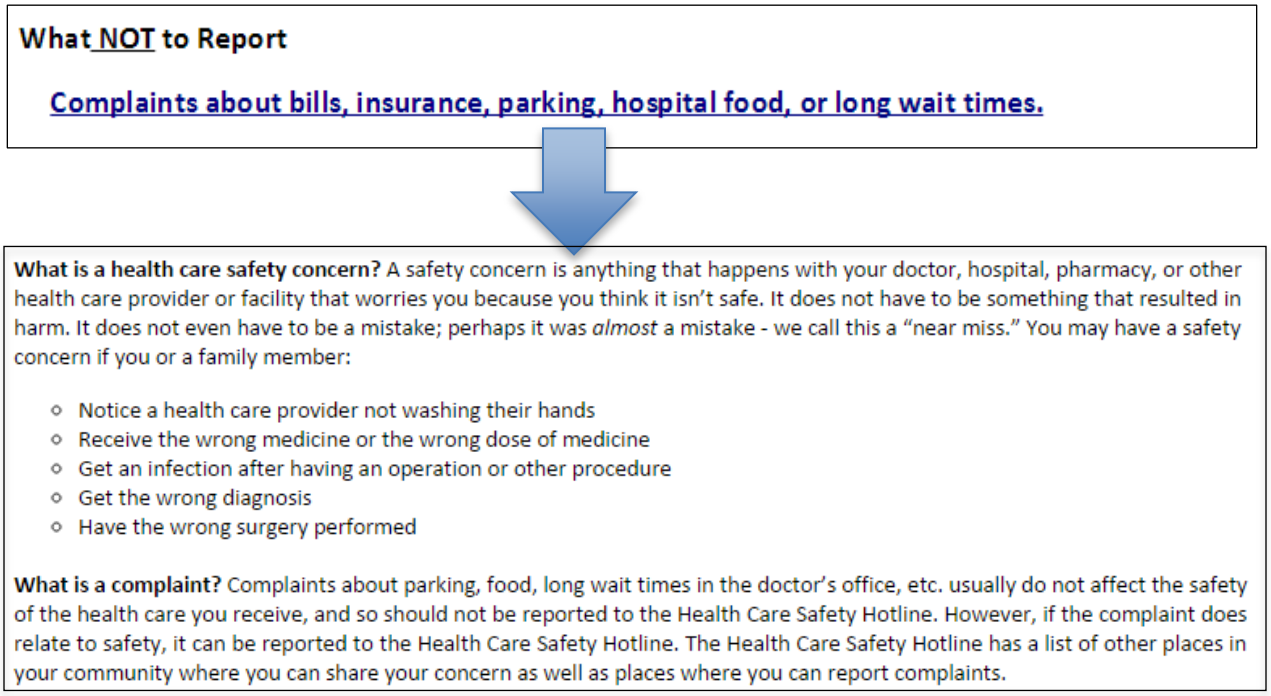

**Figure C.5. What to Report**




Reporting patients or caregivers are also given a brief description of what *not* to report, or what is not appropriate to report to the hotline. The link on the landing page leads to the portion of the FAQs that discusses a reportable health care safety concern compared with a complaint (Figure C.6).

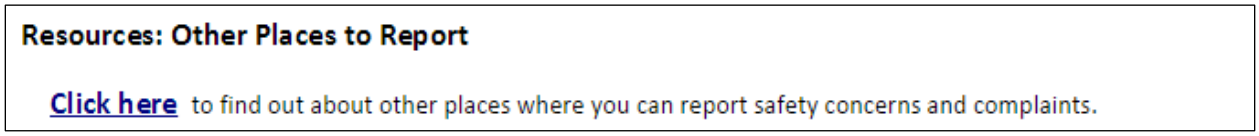
A FAQs list is included as a reference for patients, family members, and caregivers. The FAQs answer a series of questions that the reporter may have and also provide directions to links or 800 numbers where they can get answers to their questions or concerns. Appendix C.7 contains the FAQs.

**Figure C.6. What *Not* to Report**



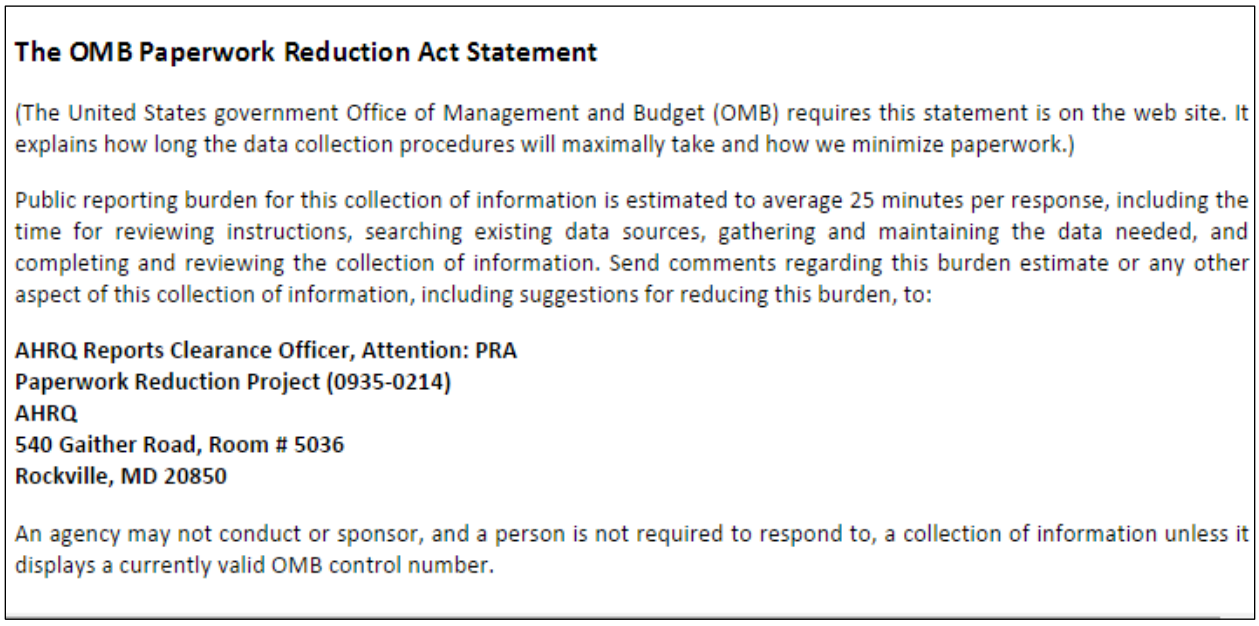

A resources link appears after the series of scripts (Figure C.7). This link opens to a new pop-up site that contains information for reporting complaints, including how to report a complaint and contact information for various reporting agencies. One link identifies local patient advocates from the pilot community, including those from the participating facilities. The site also identifies other systems that are designed for reporting concerns.

**Figure C.7. Resources**




Finally, for the purpose of research and human-subjects protection, the landing page includes the OMB Paperwork Reduction Act Statement (Figure C.8).

**Figure C.8. OMB Paperwork Reduction Act Statement**



**The OMB Paperwork Reduction Act Statement**

(The United States government Office of Management and Budget (OMB) requires this statement is on the web site. It explains how long the data collection procedures will maximally take and how we minimize paperwork.)

Public reporting burden for this collection of information is estimated to average 25 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to:

**AHRQ Reports Clearance Officer, Attention: PRA**
**Paperwork Reduction Project (0935-0214)**
**AHRQ**
**540 Gaither Road, Room # 5036**
**Rockville, MD 20850**

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

To begin a report, patients, or caregivers can either call the hotline's toll-free number or use the Web site URL. Once on the landing page of the Web site, the reporter can start the process by clicking either "Enter a New Event" or "Click Here" (Figure C.9).

**Figure C.9. Entering Events**

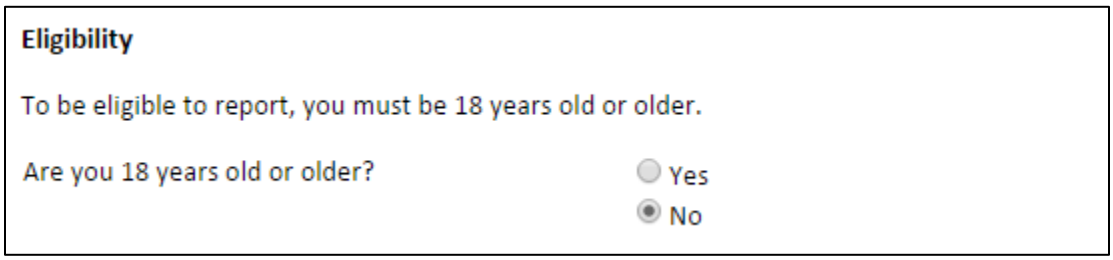
Enter a new event
Report by Telephone: 1-(888) 580-7732

**Online:** Click here to report a safety concern online.

After the landing page, the patient or caregiver is taken through a series of screening and introductory steps.

In the first step, before providing answers questions about the safety concern, the patient or caregiver is screened for age—reporters must be at least 18 years old (Figure C.10).

**Figure C.10. Eligibility**



**Eligibility**

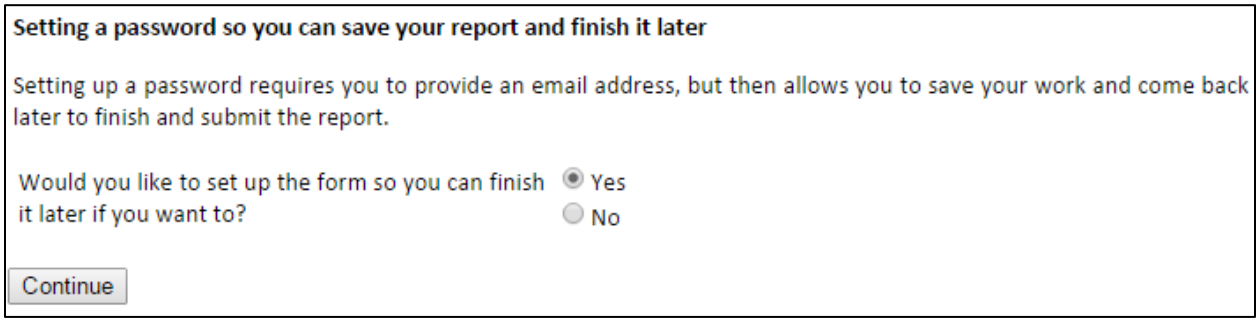
To be eligible to report, you must be 18 years old or older.

Are you 18 years old or older?

- Yes
- No

Next, the reporter is offered the option of registering with a username connected to his or her e-mail address so he or she they can save and return to the report. The reporter can register by using an e-mail address (Figure C.11).

**Figure C.11. Setting a Password**




Next, the reporter is directed to an overview of the hotline that describes the types of safety concerns that should be reported and advises that complaints about services like food or parking should not be reported (Figure C.12). The text briefs the reporter on the length of time it should take to complete the report and discusses options for sharing the report and the steps that will take place if consent is given to do so.

The next section of the Web site reviews the types of information patients or caregivers may need to answer the questions about their safety concerns (e.g., month and year of the concern, where the concern occurred) (Figure C.13).

The reporter then must click “Accept” to indicate that he or she understands the information provided (Figure C.14).

For the patient or caregiver who chooses to enter a report, the report form provides a series of open-ended questions about what happened, when and where it occurred, whether there were negative effects, and the types of negative effects (Figure C.15).

The section also requests the name of the patient, provision of which is optional (Figure C.16).

**Figure C.12. Health Care Safety Hotline Overview**

**The *The Health Care Safety Hotline* allows patients and their families or caregivers to voluntarily report on the safety of their health care. "Safety concerns" include medical mistakes and negative effects. Negative effects can be physical or emotional and they may include infections, drug reactions, or other complications. Safety concerns might come up during a visit to a doctor's office, at a pharmacy, or in the hospital.**

**Complaints about services like food or parking should not be reported here. Please refer to the resources link on the home page for where to report those in your area.**

**It should take about 20-25 minutes to complete a report. You may skip any question by leaving it blank. The more information you provide, the more we can learn from your experience.**

**You will have the option to give permission for the *Health Care Safety Hotline* staff to share your report with any doctor, nurse, or other health care provider (or facility) that was involved in the negative effect. This would alert the facility's staff so they can learn about what went wrong and improve safety. The facility might also need to use or disclose information in your report if it is required or permitted to do so by law.**

**Figure C.13. What Is Needed to Complete a Report**

To complete this form, you will need:

- Month and Year of the concern [NOTE: Concerns that occurred more than ten years ago should not be reported]
- Where the concern occurred, including the facility or provider name(s) and street address, city and state, if you wish to share this information
- Names of medications that were involved (if any)
- Names of the tests, procedures or surgery that were involved (if any)
- Your email address if you would like to leave the web-site and return to it to finish reporting the concern
- Your own contact information if you wish to be contacted to discuss the details of the concern

**Figure C.14. Consent**

**Please read, then accept or decline:**

I have read and understood the information that describes *the Safety Hotline* staff and this web site. I promise that I am 18 years old and that I will give information that is true and complete. I give my permission to *the Safety Hotline* staff team to use my information as long as they do not share my name and other identifying information. I will not share my access to my report (e.g., passwords) with anyone. I understand that I will not be paid for my participation.

I understand my individual answers to the survey questions are strictly confidential and will not be seen by anyone outside *the Safety Hotline* staff team, unless during the reporting process I agree to allow *the Safety Hotline* staff team to share this information. This confidentiality is established by provisions in the AHRQ authorization legislation.

(•) Accept
( ) Decline

Continue

**Figure C.15. Describe Safety Concern**

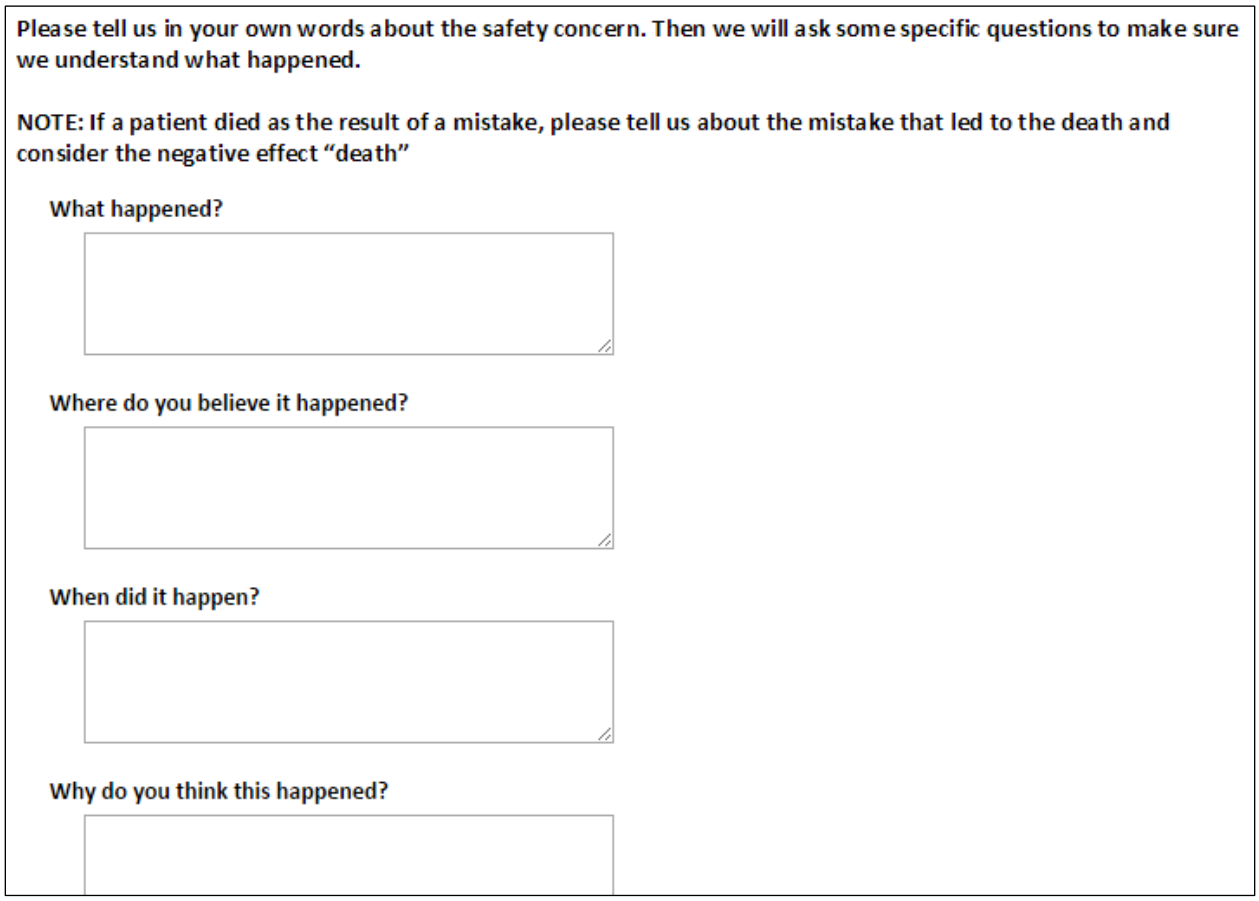
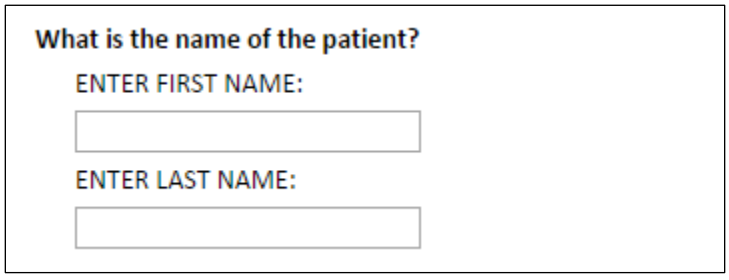
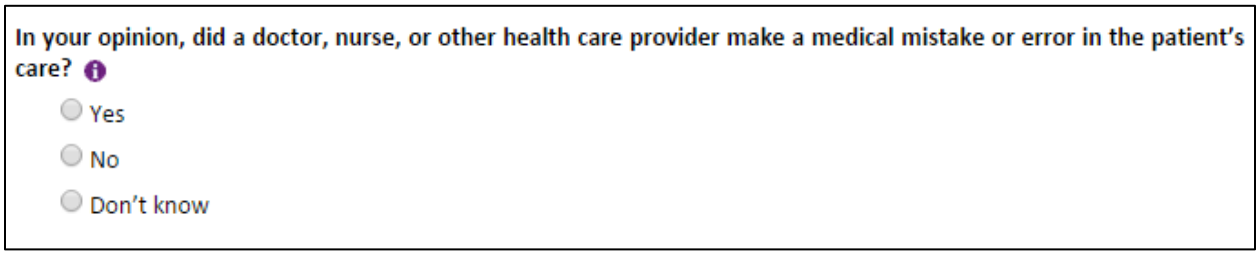



**Figure C.16. Name of Patient**



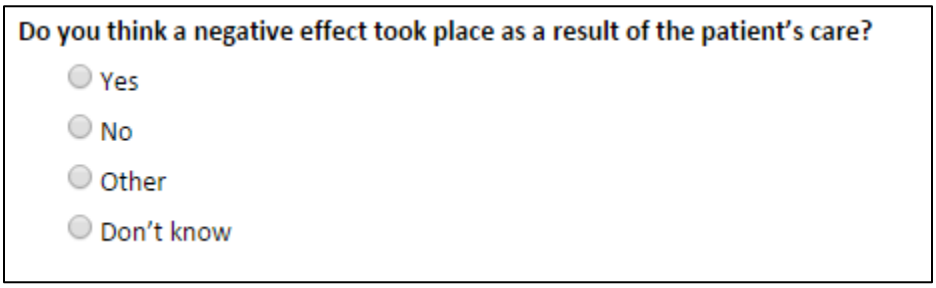

After this open-ended narrative information is collected, the patient or caregiver is asked if either a medical mistake or negative event occurred (Figure C.17). Depending on the nature of the patient safety concern, one or both of these options may apply. Reporting patients or caregivers may also indicate that they do not know.

**Figure C.17. Medical Mistake**




Depending on the selection made by the reporter, additional screens with questions will be prompted. For example, if the patient or caregiver notes that a medical mistake occurred, he or she will then be directed to the section of the report that asks specifically about the medical mistake. Similarly, patients who report the occurrence of a negative effect will be directed to the section of the report that asks specifically about the negative effect (Figure C.18). Patients and caregivers who report the occurrence of a medical mistake will be prompted to answer whether they believe a negative effect also occurred. Those who report that a medical mistake did *not* occur but that a negative effect did will be prompted to answer questions *only* about the negative effect.

**Figure C.18. Negative Effect**



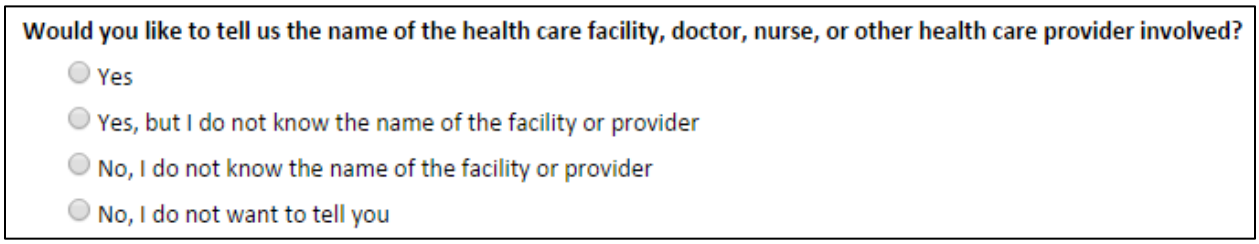

The person making the report is given the option to describe in his or her own words the factors that might have contributed to the safety event and is asked whether each of a limited list of potential factors might have contributed to the event. This limited list includes only those factors that are plausibly directly observable by a patient or caregiver and considered valid and reliable based on prior testing (e.g., communication with providers using constructs that have been tested on prior surveys such as the Consumer Assessment of Healthcare Providers and Systems [CAHPS] survey series) or have been used in other safety reporting instruments.

In both sections of the form (medical mistake or negative effect), patients or caregivers are asked to answer questions related to the nature of the mistake or negative effect and to provide specific details, such as when and where the mistake or negative effect occurred and the results of the occurrence.

Reporters are then offered the opportunity to submit the report to the health care facility, doctor, nurse, or other health care provider involved (Figure C.19). A Yes response results in an additional question series to obtain contact information about the facility or provider. The

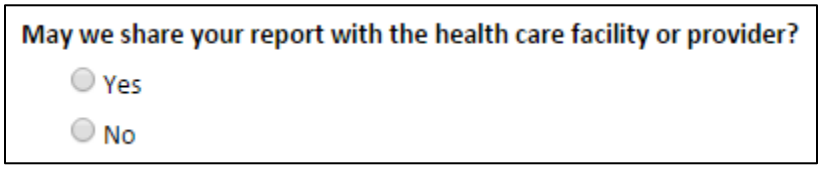
remaining three responses do not prompt these additional questions but skip to asking about consent to share the report.

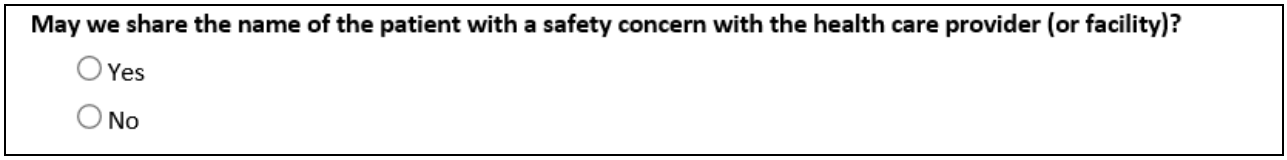
**Figure C.19. Identify the Facility**




Patients or caregivers are asked if they consent to sharing the report with the relevant health care facility or providers and to sharing the patient's name (Figure C.20).

**Figure C.20. Consent to Share**

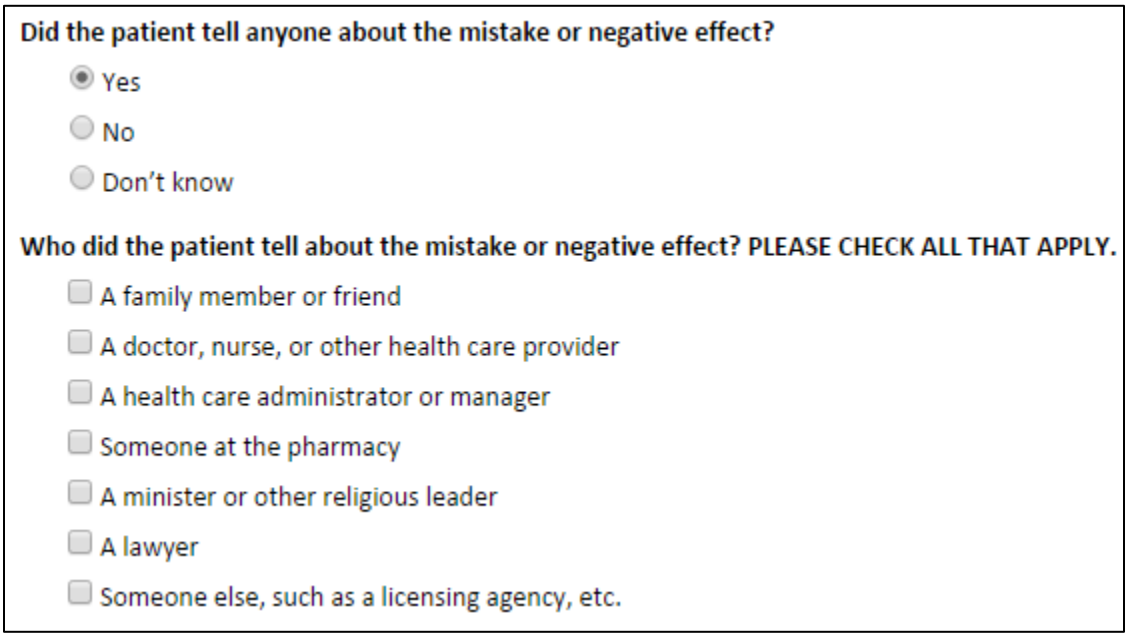



Reporters are also asked to provide consent to link the report with name and contact information.

In addition, the intake portion of the medical mistake or negative event sections on the report form asks whether the patient reported the event to a health professional, manager, or other person (Figure C.21), and it asks whether the event was disclosed to the patient by a health professional.

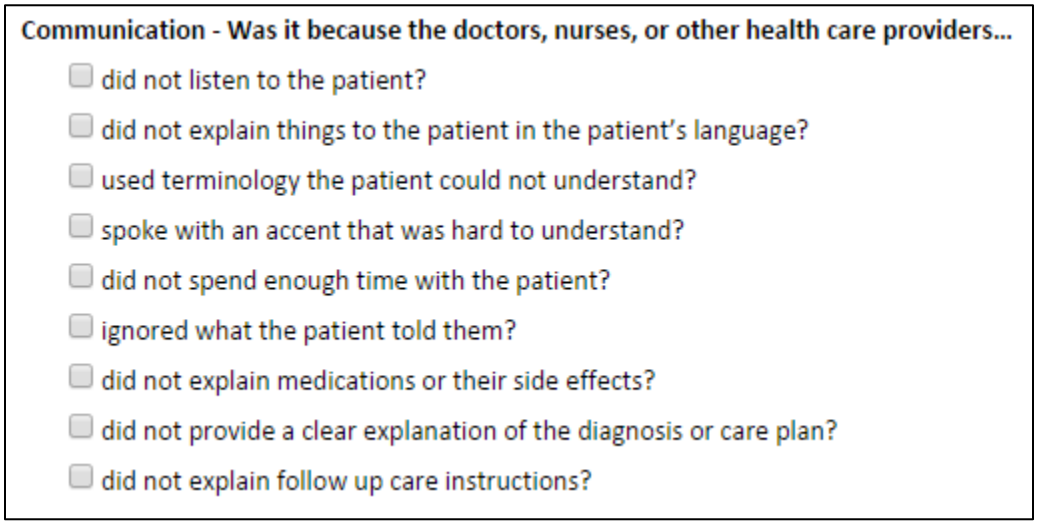
**Figure C.21. Notification of Mistake or Negative Effect**




The form then asks patients or caregivers to answer questions regarding contributing factors, changes in care, and discovery and reporting. In this section, reporters are asked to identify potential contributing factors to the mistake or negative effect and to comment on the outcome, aftermath, or result.

Contributing factors are broken down by section: communication, responsiveness, coordination, access, verification, and other. Each of these sections offers several options that reporting patients or caregivers can choose to describe the factors contributing to the mistake or negative effect. The example in Figure C.22 outlines the communication section for reference.

**Figure C.22. Contributing Factor Example**



The reporter may opt to allow a hotline intake staff person to follow up in order to clarify details about the report (Figures C.23 and C.24). Those who opt in will be contacted by telephone by a hotline staff member, who will clarify information in the initial report and annotate the report accordingly. This service is available in both English and Spanish.

**Figure C.23. Consent to Follow Up**

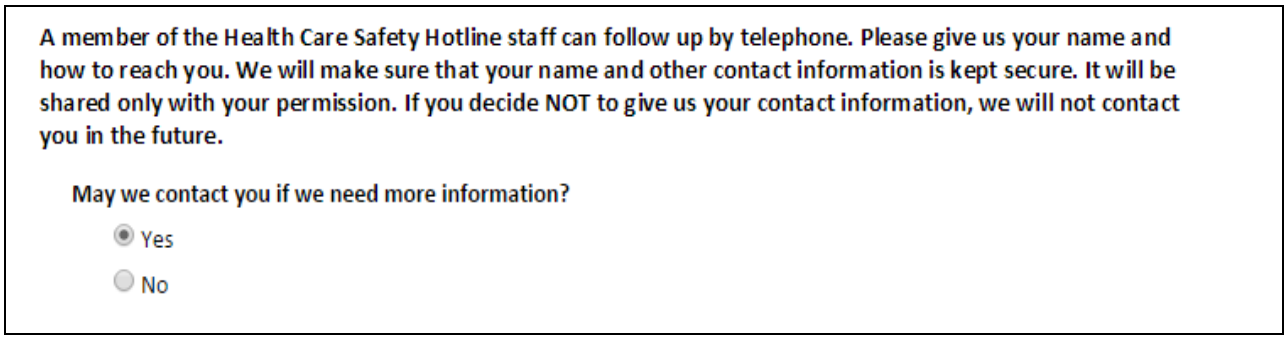
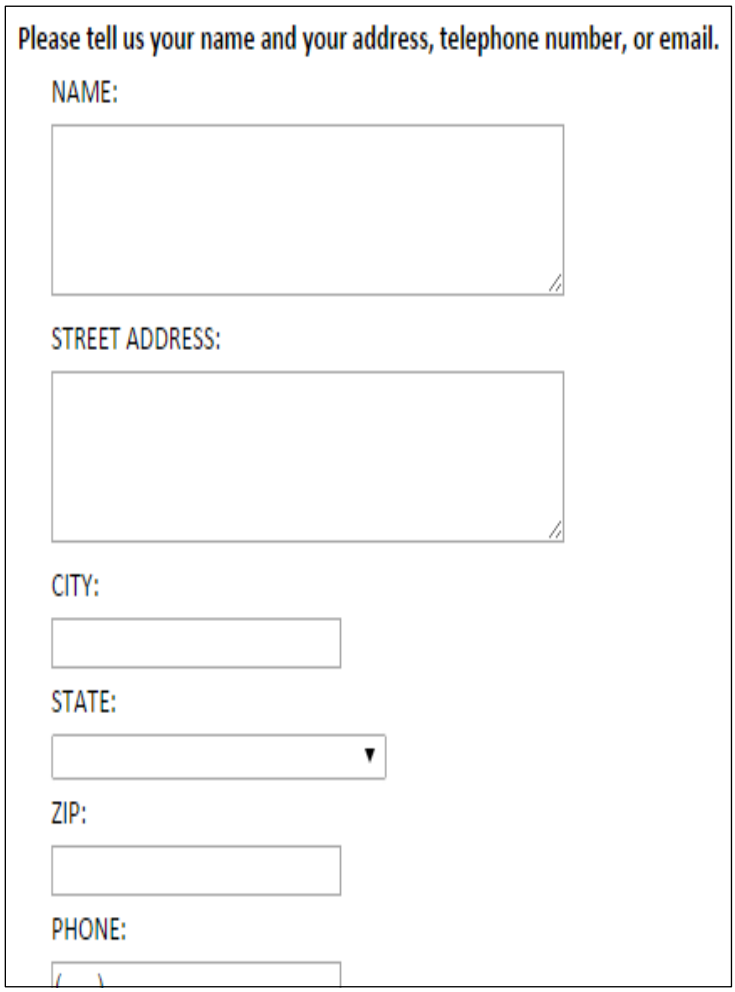


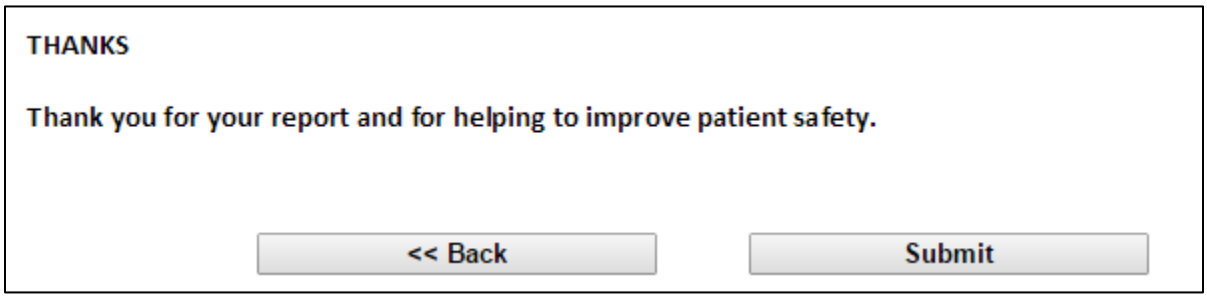

**Figure C.24. Contact Information**



Finally, at the end of the form, a series of questions asks about the demographics of the patient or caregiver: sex, age, race and ethnicity, and type of insurance. Patients or caregivers are also asked how they learned about the hotline.

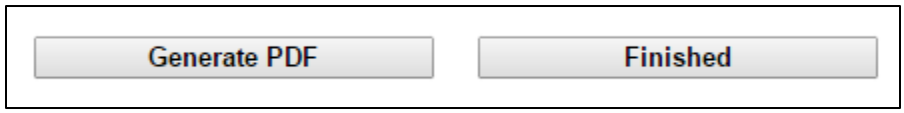
The report is complete only when the reporting patient or caregiver clicks the "Submit" button (Figure C.25).

**Figure C.25. Submission of Report**




Reporters are then directed to an RSO submission review page, which allows them to download a copy of the PDF version of the report and, finally, to officially submit the report by clicking the "Finished" button (Figure C.26).

**Figure C.26. Finishing the Report**




The hotline form also provides a place for reporters to voluntarily rate their experience via a brief, confidential survey (Figure C.27). The survey is reproduced in Appendix C.8.

**Figure C.27. Patient Satisfaction Survey**

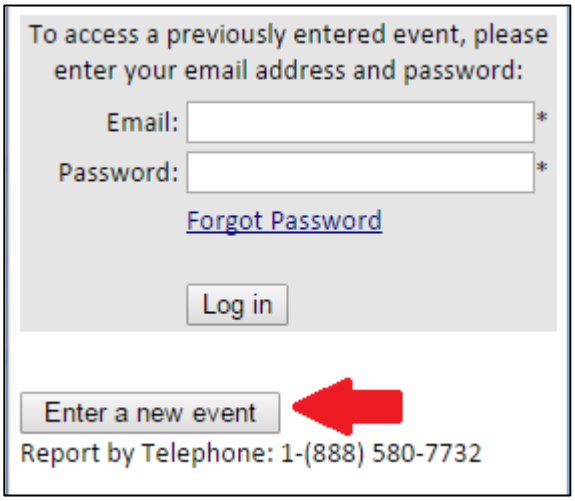

Upon leaving the safety report form page, patients and caregivers are directed back to the landing page.

### *Handling Toll-Free-Number Phone Intake (Including Suggested Scripts)*

Individuals may also access the Health Care Safety Hotline by telephone via the designated toll-free number. A phone-intake administrator will guide consumers through the intake process in either English or Spanish. The phone-intake administrator will start by introducing himself or herself and the hotline. The administrator will then guide the reporter through the hotline prompts by accessing the Web page and entering a new event (Figure C.28). The administrator

has been trained to input the reporter's responses in the first person, as though the reporter were entering the report. A phone script is available to guide the phone-intake administrator through the hotline questions (Appendix C.3).

**Figure C.28. Entering an Event by Phone**



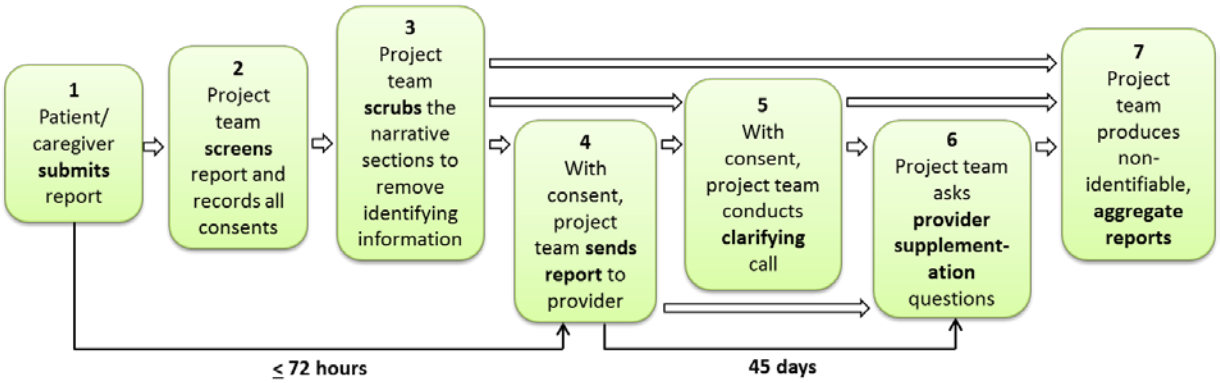

When the phone intake administrator has finished entering the information in the report, and if the patient or caretaker has consented to being contacted to clarify the information, the administrator should advise the reporter that a person may call to ask any clarifying questions that are necessary to better understand the nature and specifics of the report. If the patient or caregiver has consented to sharing the report with the health care organization, the phone-intake administrator will also advise him or her that an individual from the health care organization may call.

Messages that are left on the hotline voicemail are returned and processed as soon as possible. A total of five attempts are made to reach a caller; the attempts are made at different times of the day to maximize the chance of making contact. Because of the confidential nature of the hotline, messages are not left on the caller's voicemail or with individuals other than the caller. If after five attempts the caller cannot be reached, this information is documented on the tracking sheet, and the caller is considered lost to contact.

## 5. Processing and Sharing Reports

The project team collaborated with the health care delivery organization to develop detailed protocols for each step of processing patient and caregiver reports of safety concerns. Figure C.29 shows a high-level overview of the processing steps.

**Figure C.29. Processing and Sharing Reports**




In Step 1 (described in Section 4 of this Operations Manual), the hotline receives information about the safety concern through a series of questions that patients and caregivers can answer on a secure Web site or by calling a toll-free phone number. The patient or caregiver goes through the series of screens described above in order to make a report. Once a report is submitted, a project team member screens the report to confirm that it meets the inclusion criteria.

In Step 2, a project team member reviews the report, noting whether the patient or caregiver consented to receive a followup call and whether permission was granted to share the report with the named provider; if permission is given, the patient or caregiver is asked whether his or her name and contact information can be shared with the provider when a summary is sent. All activities should be included on an Excel tracking spreadsheet (an example is shown in Figure C.30). Appendix C.9 provides details on the Excel tracking sheet.

In Step 3, the team member scrubs the narrative sections provided by the patient or caregiver to safeguard confidentiality, removing identifying information such as names of people and institutions. Answers to questions that explicitly request identifying information, however, are not scrubbed. Complete instructions on how to audit or scrub a report, which prepares it for being shared, can be found in Appendix C.10. The screening and auditing process is to be completed within 72 hours of receipt of the report.

**Figure C.30. Excel Tracking Sheet for Screening and Auditing**

| Rpt_ID | Full_Rpt_ID | Owner | Rpt_date | Rpt_timeET | Notify_ECRI_date | Notify_ECRI_timeE | Notify_MD_date | Notify_MD_timeET | Assigned_MD |
|---|---|---|---|---|---|---|---|---|---|
| 40 | 40_ERROR | | 9/19/2014 | 12:33 | 9/19/2014 | | | | |
| 41 | 41_PI | AB | 10/9/2014 | 8:31 | N/A | N/A | | | |
| 42 | 42_PSI | AB | 10/9/2014 | 8:58 | 10/12/2014 | 2:58 | 10/12/2014 | 4:58 | EF |
| 46 | 46_PSI | CD | 11/13/2014 | 17:16 | 11/14/2014 | 9:00 | 11/14/2014 | 13:30 | GH |
| 47 | 47_PS | CD | 11/13/2014 | 18:21 | 11/14/2014 | 9:00 | 11/14/2014 | 14:15 | EF |
| 48 | 48_PSI | AB | 12/29/2014 | 9:24 | 12/29/2015 | 10:05 | 1/3/2015 | 12:30 | IJ |
| 51 | 51_P | CD | 1/5/2015 | 9:42 | N/A | N/A | 1/5/2015 | 15:30 | EF |

In Step 4, if the patient or caregiver consented to have the report shared with the relevant health care facility or provider, a PDF file of the scrubbed report is uploaded to a secure Web site accessible to the named provider. This is done within 72 hours to minimize delays and enable the health care delivery organization to follow up with the patient or caregiver. Notification to the

relevant health care facility or provider is sent via e-mail with a link to the report on the secure Web site.

In Step 5, hotline staff members review the report for incomplete or inconsistent information that requires clarification from the patient or caregiver. Detailed instructions for making the clarification call are given in Appendix C.11. As part of this process, the hotline staff works with one of the clinicians on the team, who reviews the report to identify any issues or areas that require clarification. If clarification is required by either the doctor, the staff person, or both, a project team member conducts a followup call with the person who made the report. The additional information elicited through the clarifying call is uploaded to the secure Web site if the patient or caregiver has given permission. Appendix C.12 provides more information on the clarification call and gives examples of the types of questions that should be included.

If the report has been clarified (Step 5), a revised version is uploaded to the secure Web site, and the relevant health care organization or provider is notified via email, with a link to the clarified report.

In Step 6, within 45 days of sharing the report with the named provider in Step 4 (to accommodate the 30-day Centers for Medicare & Medicaid Services (CMS) grievance followup period), the project team reaches out to the health care delivery organization or facility with a series of questions about what the organization did with the reported information. These questions are on an administrative intake page linked to each report, referred to as Module 8.

The sharing process is documented by the patient safety organization (PSO) project team on an Excel spreadsheet (Figure C.31), which contains the report ID number, relevant health care organization, date submitted, date sent to the facility/provider, date the clarified report was sent, if applicable, when the followup supplementation call from the PSO staff to the provider about the specific report is due (e.g., 45 days after receipt of the initial report), and when the supplementation process with the relevant health care facility or provider was completed.

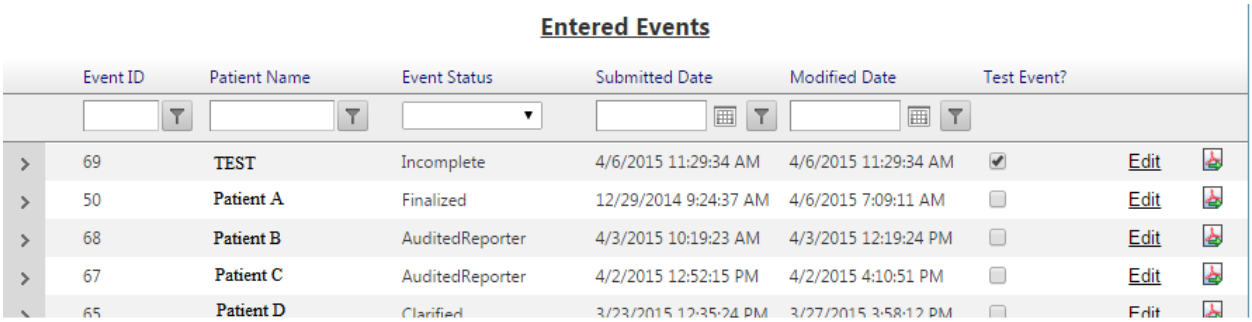
**Figure C.31. Excel Tracking Sheet for Sharing Reports**

| | RSO# | Pilot Site | Submitted | Date Sent | Clarification Sent | Follow-up Due | Follow-up Completed |
|---|---|---|---|---|---|---|---|
| 1 | 13 | 1 | 3/21/2014 | 3/24/2014 | n/a | 5/8/2014 | 5/5/2014 |
| 2 | 15 | 1 | 4/25/2014 | 4/28/2014 | 5/6/2014 | 6/12/2014 | 5/12/2014 |
| 3 | 16 | 2 | 4/29/2014 | 5/1/2014 | 5/8/2014 | 6/15/2014 | 8/7/2014 |
| 4 | 20 | 1 | 6/9/2014 | 6/10/2014 | 7/18/2014 | 7/25/2014 | 8/1/2014 |
| 5 | 21 | 2 | 6/23/2014 | 6/23/2014 | | 8/7/2014 | 8/20/2014 |
| 6 | 22 | 2 | 6/23/2014 | 6/24/2014 | 6/24/2014 | 8/8/2014 | 8/20/2014 |
| 7 | 24 | 1 | 6/25/2014 | 6/28/2014 | 7/18/2014 | 8/12/2014 | 8/26/2014 |

With each report, progress through the seven processing steps (shown in Figure C.29) is tracked on an administrative page linked to the report. The administrative page is viewable by the project team but not by the patient or caregiver who made the report. To access the hotline Web site, administrative users click on the link in the email that refers them to the URL. To access the administrative page that lists the reports, the administrator enters his or her email address and password in the appropriate text fields on the left side of the Web site landing page. Then the

administrator clicks on “View Entered Patient Safety Events.” An example of the Entered Patient Safety Events spreadsheet is shown in Figure C.32.

**Figure C.32. Entered Patient Safety Events**



Entered Events

| Event ID | Patient Name | Event Status | Submitted Date | Modified Date | Test Event? | |
|---|---|---|---|---|---|---|
| 69 | TEST | Incomplete | 4/6/2015 11:29:34 AM | 4/6/2015 11:29:34 AM | ☑ | Edit |
| 50 | Patient A | Finalized | 12/29/2014 9:24:37 AM | 4/6/2015 7:09:11 AM | ☐ | Edit |
| 68 | Patient B | AuditedReporter | 4/3/2015 10:19:23 AM | 4/3/2015 12:19:24 PM | ☐ | Edit |
| 67 | Patient C | AuditedReporter | 4/2/2015 12:52:15 PM | 4/2/2015 4:10:51 PM | ☐ | Edit |
| 65 | Patient D | Clarified | 3/23/2015 12:35:24 PM | 3/27/2015 3:58:12 PM | ☐ | Edit |

In Step 7, for research and summary purposes, the hotline generates non-identifiable aggregated reports on the types of events reported.

After the hotline receives a report and any additional information elicited through the patient or caregiver clarification process is added to it, a clinician reviews the report and classifies the event(s) described according to the AHRQ Common Formats event type, harm scale, and duration of harm. The clinician also comments on the preventability of the event and contributing factors.

### *Instructions for Classifying Events*

After a report is submitted, a clinician on the hotline team classifies the reported event(s). The classification form is shown in Appendix C.13. The clinician first classifies the type of event, using the AHRQ Common Formats, Version 1.2, as either an incident, a near miss, or unsafe conditions. An incident is an event that reaches a patient; that is, an event that exposes a patient to harm, regardless of whether the patient is ultimately harmed. A near miss is an event that does not reach a patient. An unsafe condition is “any circumstance that increases the probability of a patient safety event.”

After classifying the report according to the type of event, the clinician identifies the level of harm associated with the event, again using the AHRQ Common Formats. (This step occurs only if the event is classified as an incident; near misses and unsafe conditions, by definition, do not expose patients to harm.) There are six levels of harm in the Common Formats: unknown, no harm, mild harm, moderate harm, severe harm, and death. The Common Formats provide definitions for each level; for example, mild harm is defined as “minimal symptoms or loss of function, or injury limited to additional treatment, monitoring, and/or increased length of stay.” For events classified as resulting in any level of harm, the clinician indicates the duration of harm: unknown, temporary (less than 1 year), or permanent (1 year or more).

The clinician then provides a short narrative (typically two to three sentences) describing the preventability of the event, drawing on his or her clinical expertise in addition to the patient perspective contained in the report. A patient may believe that a certain aspect of the event was preventable, but when the clinician reviews the report and reflects on relevant clinical

knowledge, he or she may disagree. After describing the event's preventability, the clinician provides a short narrative describing the contributing factors—that is, the factors that contributed to the event. Again, the clinician draws on his or her clinical expertise and selects relevant contributing factors from a structured list—the same list that patients and caregivers use when reporting to the hotline. The list of contributing factors is organized into categories: communication with health care providers, staff responsiveness, care coordination, access, verification, and other.

In many instances, a project team member successfully completes a clarification call with the patient or caregiver who submitted the initial report. After a clarification call occurs, the clinician reviews the completed classification form and evaluates whether it needs to be revised to reflect the new information elicited through the call. If revision is needed, the clinician revises the form.

### *Instructions for Generating Aggregated Reports of Events*

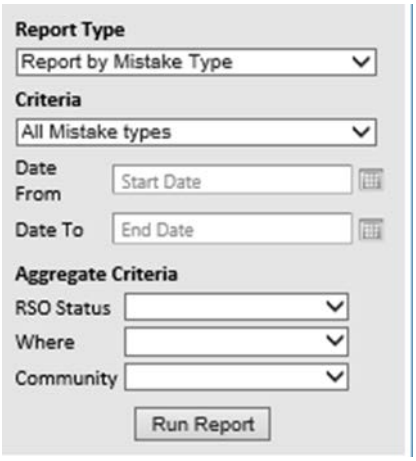
Aggregated reports for all RSOs can be generated in real time via the Web-based system. Aggregated reports include:

- Report by mistake.
- Report by negative effect.
- Report by contributing factors.
- Person reported for.
- Summary patient demographics (gender, age, race, and insurance).
- How the reporter learned about the hotline.
- Modality reported by (phone/computer).

Descriptions of the individual reports are shown in Table C.3.

To conduct the initial analysis of the RSOs, reports can be filtered based upon criteria within the report, such as date range, and aggregate criteria, such as RSO status, where care was provided (i.e., the type of health care facility/provider), and community (Figure C.33).

**Figure C.33. Filtering Options for Reporting Function**



Administrative reports can also be generated for additional analysis. These reports include:

- Export data set – Modules 1–7.
- Export data set – Module 8.
- Evaluation report (Web traffic).

Descriptions of the administrative reports are shown in Table C.4.

**Table C.3. Descriptions of Individual Hotline Reports**

| Type of Report | Description |
|---|---|
| Report by mistake type | This report provides a tabular and pie chart representation of mistake type and mistake subtypes. Based on certain criteria, submission date, and aggregate criteria selected, it displays the count and percentage of each mistake type or mistake subtype. |
| Report by negative effect | This report provides a tabular and pie chart representation of negative effect and physical negative effects. Based on certain criteria, submission date, and aggregate criteria selected, it displays the count and percentage of each negative effect and physical negative effects. |
| Report by contributing factor | This report provides a tabular and pie chart representation of mistake type and contributing factors. Based on certain criteria, submission date, and aggregate criteria selected, it displays the count and percentage of each mistake type and contributing factors. |
| Person reported for | This report provides a tabular and pie chart representation of the person reported for. Based on certain criteria, submission date, and aggregate criteria selected, it displays the count and percentage of events submitted on behalf of a child, spouse/domestic partner/other family member, friend, patient or client, or someone else. |
| Summary patient demographics | This report provides a tabular and pie chart representation of patients' gender, age, race, and insurance. Based on certain criteria, submission date, and aggregate criteria selected**,** it displays the count and percentage of gender, age, race, and insurance. |
| How reporter learned about the hotline? | This report provides a tabular and pie chart representation of the provider Web site, flyer/poster, kiosk, conversation, mail, and other. Based on certain criteria, submission date, and aggregate criteria selected**,** it displays the count and percentage of provider Web site, flyer/poster, kiosk, conversation, mail, and other. |
| Modality reported by (phone/computer) | This report provides a tabular and pie chart representation of events submitted by phone or computer (online). Based on certain criteria, submission date, and aggregate criteria selected**,** it displays the count and percentage of events submitted by phone or computer (online). |

**Table C.4. Descriptions of Administrative Reports**

| Type of Report | Description |
|---|---|
| Export data set – Module 1-7 | This report exports all the questions and answers of modules 1–7 to a CSV file based on the criteria and date range (up to 6 months of data) selected. This report is accessible only by Super User – Administrators. |
| Export data set – Module 8 | This report exports all the provider supplementation information followup questions and answers in Module 8 to a CSV file based on the criteria and date range (up to 6 months of data) selected. This report is accessible only by Super User – Administrators. |
| Evaluation report (Web traffic) | This report exports all the Web traffic data to a CSV file based on the date range (up to 1 month of data) selected. This report is accessible only by Super User – Administrators. |

## 6. Maintenance of the System and Data Storage

### *Change Management*

During the pilot project, we used a formal change management process for any application changes, feature additions, and bug fixes. Documentation was very important, so we used a Microsoft Team Foundation Server to track all changes, including requirements and code check-ins. User stories, test cases, tasks, bugs, conversations, and code were all associated together to keep track of them for documentation purposes.

### *Backups*

ECRI's backups were performed on a daily basis and written to disk. We then put these data on weekly tapes and sent them to Iron Mountain. The tapes were cycled back to ECRI on a monthly basis and stored in an internal locked vault. The disaster recovery (DR) site was built and tested to handle all of the applications in case of a failure at the main facility. All ECRI data are replicated instantaneously to the DR site within the storage area network (SAN), which allows a very quick turnaround time. The recovery point objective (RPO) is 30 minutes, and the recovery time objective (RTO) can occur in less than 12 hours.

### *Disaster Recovery*

ECRI's data center has two HVAC and two UPS backup systems. The facility has two generators as backup sources for power and a redundant Internet connection. In addition to this, it has a DR site, which is a Tier II equivalent facility with N+1 capability with redundancies built in. There is one SAN in the data center and another at the DR site. Data are replicated between the two SANs every 30 to 60 minutes, which is less than 4 hours RPO.

ECRI's DR site is housed at a separate geographical location about 56 miles away from the primary site and is on a separate power and Internet grid. The RTO is less than 12 hours, and the RPO is less than 4 hours. In the event of a disaster that cannot be handled by the redundancies in the main facility, ECRI is able to switch to the DR site.

### *Encryption*

Data transfer is encrypted through Secure Socket Layer (SSL), using at least 128-bit encryption. The prototype uses FIPS Compliant Servers and Transparent Data Encryption (TDE) on all Protected Health Information SQL Servers.

### *Security*

Access to the application is managed by ASP.NET Forms Authentication, using ASP.NET Application Services, which are built-in Web services that provide access to features such as forms authentication, roles, and profile properties:

1. Authentication service. This service allows users to log on to an application. It accepts user credentials and returns an authentication ticket.
2. Roles service. This service determines the application-related roles for an authenticated user, based on information that is made available by an ASP.NET roles provider, which determines the user's permissions to edit and view RSOs information.

### *Profile Service*

This service provides per-user information as a user profile that is stored on the server.

### *Knowledge Transfer*

All programming source code and prototype documentation is to be transferred to AHRQ at the end of the contract period.

# Appendix C.1. Web Strategy and Communications Team Technical Review of the Health Care Safety Hotline Web Site

Monica Hertzman, Lee Floyd, Deanna Lee
RAND Corporation

The technical comments provided in this appendix focus on what the user sees or experiences when submitting a patient safety concern via the July 2015 version of the hotline Web site. We approached this review with an eye toward usability and accessibility best practices, among other issues. In testing the site, we used Chrome and ChromeVox (a screen reader). Testing in other browsers (Safari, Firefox, IE) may result in additional areas that could benefit from review.

If another organization (health care organization, State regulatory agency, university, etc.) decides to adopt or create a similar Web site, we recommend the usability considerations described here to streamline the report submission process. Several usability suggestions pertain to the process of creating an account or using it after having logged in and are relevant to nearly all online forms, not only the one on the hotline Web site (see the discussion in Chapter IV in the hotline report).

As noted in Chapter IV of the report, we recommend against using accounts unless it is absolutely necessary (e.g., if the organization anticipates that many users will return to the form). If a login/account creation process is included on a site, the link to enter a new event should be more prominent than the login form for accessing an existing event. Similarly, the option for setting up a password should be presented only after the estimated completion time and/or the list of required information is provided. If a user does choose to create an account, password restrictions (length, required characters) should be shown as visible text, and error messages should be written in plain language (e.g., "Please use at least one special character" rather than "Non-alphanumeric characters in 'newPassword' needs to be greater than or equal to '1'."). Then, after submitting the form to create an account, the user should remain on a page that presents a "success" message rather than being sent back to the home page. Ideally, the message should include the email address entered, making it easy to log in at that point. If a user has logged in and is entering a new event, the form should omit certain questions that were answered when the user created an account, e.g., the user's e-mail and the fact that the user is over 18 years of age (a requirement for creating the account).

The following suggestions are also relevant for all Web forms and are worth considering regardless of account/login status. First, unless required for compliance, timing out a session should be avoided. If the timeout must be retained, the user should see a warning message a few minutes prior to the timeout. Second, it is important to use the right size/type of input field for each question and to carefully consider what restrictions are used. For example, the phone number field should just be a plain input; the JavaScript that is in place on the hotline Web site form restricts use to entering only numbers, which prevents the user from using the delete key to fix mistakes. Also, the name field in the contact information section might be better as an input, and "What could have been done?" might be better as a text area. Third, when coding pop-up messages, consider how the user will react. Exclamation points and all caps in error messages could be perceived as scolding and could increase user frustration (e.g., "The password MUST contain at least one capital letter, one number and one special character!"). Use of a polite tone,

punctuation, and sentence case is preferred. Fourth, as the user goes from one page to another, it is useful to make that transition obvious. When a significant portion of the page stays the same, it may not be clear what has changed. Rather than repeat introductory text from one page to another, offer a link or toggle (defaulting to closed) to the repeated content. Also, use unique headlines and titles on each page. Fifth, it is best to minimize the risk that the user will click off the form before completing it. Unless all transitions automatically save changes, nonlinear navigation through the form (e.g., back buttons and left column links) should be avoided.

Although there are myriad interpretations of Section 508 compliance, we recommend using a tool such as Chrome Vox to test sites; we often find that improving a site for the visually impaired will also improve it for sighted users. For example, forms should allow keyboard submission using the return/enter key; this helps people using screen readers and also helps regular users who prefer to tab through forms. Forms should be coded such that making a selection (via radio buttons or checkboxes) lets the user proceed to the next field. We noticed that in some cases, the hotline Web site's forms would return users to the top of the page rather than to the next field. This means that users who have visual impairments must re-read the entire page to return to the question, and that sighted users must scroll back down to the next form field. Finally, information icons that provide additional context for questions should be coded so as to be accessible to screen readers as well as sighted users; while less common today, some people do browse Web sites with image displays turned off for security reasons.

Several other considerations are also helpful for both usability and accessibility. For example, using "Click here" as the link text is fine, but offering descriptive text is more useful for regular visitors as well as screen readers. Similarly, links ("href" code) should contain paths to actual pages, rather than to one-click attributes. If pop-up or other functionality is desired, JavaScript events can be attached. This allows default browser behavior to work as expected and ensures that the site will be usable by a larger number of users. Finally, modern Web sites can be coded to respond to the available space in the browser window. This technique, called responsive Web design, makes it easier for users on mobile devices to use the site and is also frequently useful for people who have visual impairments, as elements of the page may be easily skipped when using screen readers.

The following additional suggestions are listed in order of Web site access and use (i.e., what the user sees or experiences when submitting a concern), rather than in order of importance.

- Input buttons <input type="submit"> should be used only for submitting forms. For links, use anchor tags <a>, which can be styled to look like buttons.
- In the quick links, the "Complaints about bills and insurance" link does not link to a particular FAQ.
- Since the user will need to receive the email to continue, a single email address field is sufficient.
- Form elements (input, select, text area) should have associated labels. Some questions use other tags (e.g., Enter the city, Enter the State).
- Save/submit/continue buttons should be aligned under the other form elements on each screen.
- In the post-submission survey, the text area is too large.

- The filter options on the entered-events list seem too robust for an individual user; perhaps they could be added only if the number of records is greater than n (e.g., 10).
- Display pagination only if items span more than one page
- The generated PDFs appear blank in Preview on OSX.
- Nearly all Web users are comfortable with the concept of scrolling; there is no need to add messaging about it on the form pages.

## Appendix C.2. Survey Report Form – Web Version

**SECTION 1: INTRODUCTION**

**The *Health Care Safety Hotline* allows patients and their families or caregivers to voluntarily report on the safety of their health care. "Safety concerns" include medical mistakes and negative effects. Negative effects can be physical or emotional and they may include infections, drug reactions, or other complications. Safety concerns might come up during a visit to a doctor's office, at a pharmacy, or in the hospital.**

**Complaints about services like food or parking should not be reported here. Please refer to the resources link on the home page for where to report those in your area.**

**It should take about 20–25 minutes to complete a report. You may skip any question by leaving it blank. The more information you provide, the more we can learn from your experience.**

**You will have the option to give permission for the Health Care Safety staff to share your report with any doctor, nurse, or other health care provider (or facility) that was involved in the negative effect. This would alert the facility's staff so they can learn about what went wrong and improve safety.**

To complete this form, you will need:

- Month and year of the concern [NOTE: Concerns that occurred more than 10 years ago should not be reported]
- Where the concern occurred, including the facility or provider name(s) and street address, city and state, if you wish to share this information
- Names of medications that were involved (if any)
- Names of the tests, procedures, or survey that were involved (if any)
- Your e-mail address if you would like to leave the Web site and return to it to finish reporting the concern
- Your own contact information if you wish to be contacted to discuss the details of the concern



**1.1 Who is the patient with a safety concern?**

□$_A$ Me
□$_B$ A child

□C A spouse, domestic partner or other family member (for example, a grandparent, aunt, etc.)
□D A friend
□E A patient or client
□F Someone else → [DISPLAY AS TEXT BOX: Who is the patient?]

**1.1.1 In what city and state did the safety concern occur?**

Enter the city:
Enter the state:

## SECTION 2: DESCRIPTION OF YOUR SAFETY CONCERN

**2.1 Please tell us in your own words about the safety concern.** Then we will ask some specific questions to make sure we understand what happened.

**2.1a. What happened?**

NOTE: If you believe a patient died as the result of a mistake, please tell us about the mistake and record the negative effect as "death."

**2.1b. Where do you believe it happened?**

**2.1c. When did it happen?**

**2.1d. Why do you think this happened?**

**2.2 What is the name of the patient?**
ENTER FIRST NAME:
ENTER LAST NAME:

**Now we will ask some questions to make sure we understand what happened.**

**2.3 In your opinion, did a doctor, nurse, or other health care provider make a medical mistake or error in the patient's care?**

**POP-UP:** A medical mistake or error is something that was done (or not done) by a health care provider that would be considered incorrect at the time it happened. Sometimes medical mistakes can result in harm or injury to the patient, but not every time.

□A Yes → GO TO 3.1
□B No → GO TO 2.3.1
□C Don't know → GO TO 2.3.1

****When people are harmed or injured as a result of medical care, we call this a negative effect. Negative effects can be physical or emotional and they may include infections, drug reactions, or other complications.**

**2.3.1 Do you think a negative effect took place as a result of the patient's care?**
□A Yes → GO TO 4.1
□B No → GO TO 2.3.1.1
□C Other → [DISPLAY AS TEXT BOX: Please describe ]
→ GO TO 2.3.1.1
□D Don't know → GO TO 2.3.1.1

**2.3.1.1 You told us that a mistake did not take place (or that you don't know) and that a negative effect did not take place (or that you don't know). Is this correct?**
□A Yes → GO TO 6.0
□B No → GO TO 6.0
□C Don't know → GO TO 6.0

## SECTION 3: MISTAKE

**3.1 Did the medical mistake or error involve any of the following? Please choose the one answer that fits best.**
□A A mistake related to a medicine
[POP-UP: Medicines can include prescription or non-prescription medication, herbs, dietary supplements, vaccines, contrast dye or other injected medicines] → GO TO 3.1.1.1

□B A mistake related to a test, procedure, or surgery
[POP-UP: This includes tests that involve taking samples of skin or tissue, inserting tubes to examine internal parts of your body, or other tests involving blood, urine, or X-rays.] → GO TO 3.1.2.1

□C A mistake related to pregnancy or childbirth
[POP-UP: This includes errors in diagnostic testing during pregnancy and errors during labor and delivery] → GO TO 3.2

□D A mistake related to a diagnosis or advice from a doctor, nurse, or other health care provider → GO TO 3.1.3.1

□E A mistake related to poor cleanliness or poor hygiene → GO TO 3.2

□F Something else, or more than one mistake [GO TO 3.1f1]

**3.1.f1 In your opinion, what was the mistake? [FREE TEXT BOX]**

**3.1.1.1 As best as you can, please name or describe the medicine. [FREE TEXT BOX]**

**3.1.1.2 Was it a prescription medicine?**
[POP-UP: Don't include over-the-counter medicines that you can buy without a prescription from a doctor or nurse.]
□A Yes
□B No
□C Don't know

**3.1.1.3 Did the mistake with medicine involve any of the following? Please <u>choose the one answer</u> that fits best.**
□A Wrong medicine→ GO TO 3.2
□B Wrong dose→ GO TO 3.2
□C Something else→ [GO TO 3.1.1.3-OTHER: What did the mistake involve? FREE TEXT BOX, ALLOW 50. GO TO 3.2]

**3.1.2.1 As best as you can, please name or describe the test, procedure, or surgery. [FREE TEXT BOX]**

**3.1.2.2 Did the mistake with a test, procedure, or surgery involve any of the following? PLEASE CHECK ALL THAT APPLY.**

□A Wrong patient [POP-UP: The patient was not correctly identified.]
□B Wrong test, procedure, or surgery [POP-UP: The wrong type of test, procedure, or surgery was done.]
□C Wrong part of the body [POP-UP: The test, procedure, or surgery was on the wrong part of the body.]
□D A mistake was made <u>during</u> the test, procedure, or surgery
□E The test, procedure, or surgery was delayed
□F The test results were lost and the patient did not receive them
□G The patient developed an infection
□H A problem with anesthesia
□I Something else→ What did the mistake involve?

→ GO TO 3.2 ONCE ITEMS CHECKED

**3.1.3.1 In your opinion, what was the mistake with the diagnosis or medical advice? [FREE TEXT BOX]**

**3.2 Where did the mistake happen? Please <u>choose the one answer</u> that fits best.**
□A In a doctor's office or a clinic
□B In a pharmacy
□C In the emergency department
□D In a hospital
□E At home
□F Don't know
□G Somewhere else

**3.3 Would you like to tell us the name of the health care facility, doctor, nurse, or other health care provider involved?**

□A Yes
□B Yes, but I do not know the name the facility or provider → GO TO 3.4
□C No, I do not know the name of the facility or provider → GO TO 3.4
□D No, I do not want to tell you → GO TO 3.4

**3.3.1 Please write the name and address of the health care facility or provider involved.**

NAME OF HEALTH CARE FACILITY/PROVIDER:
STREET ADDRESS:
CITY:
STATE:

**3.3.2 Was a second health care facility or provider involved?**

□A Yes
□B No→ GO TO 3.3.5

**3.3.3 Would you like to tell us the name of the second health care facility or provider involved?**

□A Yes
□B Yes, but I do not know the name and address of the facility or provider → GO TO 3.3.5
□C No, I do not know the name of the facility or provider → GO TO 3.3.5
□D No, I do not want to tell you → GO TO 3.3.5

**3.3.4 Please write the name and address of the second health care facility or provider involved.**

NAME OF HEALTH CARE FACILITY/PROVIDER:
STREET ADDRESS:
CITY:
STATE:

**You have the option to give permission for the Health Care Safety Hotline staff to share your report with any doctor, nurse, or other health care provider (or facility) that was involved in the mistake. This would alert the facility's staff so they can learn about what went wrong and improve safety.**

**3.3.5 May we share your report with the health care provider or facility?**
□A Yes
□B No

**3.4 In what month and year did the mistake happen? (Your best estimate is fine.)**

ENTER MONTH:
ENTER YEAR:

**3.5 Did a doctor, nurse, or other health care provider tell you the mistake happened?**
□A Yes→GO TO 3.6
□B No [FREE TEXT BOX: How did you find out that the mistake happened

**Sometimes medical mistakes affect patients financially. For example, patients may have to miss work, pay for extra tests or procedures, or take additional trips to a health care facility.**

**3.6 Did the mistake affect the patient financially?**
□A Yes
□B No
□C Don't know

**When people are harmed or injured as a result of medical care, we call this a negative effect. Negative effects can be physical or emotional and they may include infections, drug reactions, or other complications.**

**3.7 Did the patient experience any negative effects as a result of the mistake or error?**
□A Yes
□B No → GO TO 5.1
□C Don't know → GO TO 5.1

**Table 3-4**
**SECTION 4: NEGATIVE EFFECT**

**4.1 Did the negative effect involve any of the following? Please choose the one answer that fits best.**
□A A negative effect related to a medicine
□B A negative effect related to a test, procedure, or surgery
□C A negative effect related to pregnancy or childbirth
□D A negative effect related to a diagnosis
□E A negative effect related to medical advice
□F Unclean or unsanitary care
□G Something else or more than one negative effect

**4.2 What kind of negative effect did the patient experience?**
□A Physical

□B Emotional → GO TO 4.4
□C Both

**4.3 What kind of <u>physical</u> negative effect did the patient experience? PLEASE CHECK ALL THAT APPLY.**
□A Dizziness
□B Sick to the stomach (nausea)
□C Infection
□D Pain
□E A fall that caused an injury
□F Open sores on skin
□G A sexual problem
□H Blood clot
□I Uncontrolled bleeding
□J Breathing difficulty
□K Numbness or weakness
□L Injury to teeth
□M Injury to an eye
□N Burn
□O Heart attack or stroke
□p Continuing symptoms
□q Worsening of a health problem
□r Patient died
□s Other physical effect→ [Please describe]
□T The negative effect was not physical

**4.4 Where did the negative effect first happen? Please <u>choose the one answer</u> that fits best.**
□A In a doctor's office or a clinic
□B In a pharmacy
□C In the emergency department
□D In a hospital
□E At home
□F Somewhere else→ [Where did this first happen?]
□G Don't know

**4.5 Would you like to tell us the name of the health care facility, doctor, nurse, or other health care provider involved?**
□**A** Yes
□**B** Yes, but I do not know the name of the facility or provider → GO TO 4.6
□**C** No, I do not know the name of the facility or provider → GO TO 4.6
□**D** No, I do not want to tell you → GO TO 4.6

**4.5.1 Please write the name and address of the health care facility or provider involved.**

NAME OF HEALTH CARE FACILITY/PROVIDER:

STREET ADDRESS:
CITY:
STATE:

**4.5.2 Was a second health care facility or provider involved?**
□**A** Yes
□**B** No→ GO TO 4.5.5

**4.5.3 Would you like to tell us the name of the second health care facility or provider involved?**
□**A** Yes
□**B** Yes, but I do not know the name of the facility or provider → GO TO 4.5.5
□**C** No, I do not know the name of the facility or provider → GO TO 4.5.5
□**D** No, I do not want to tell you → GO TO 4.5.5

**4.5.4 Please write the name and address of the second health care facility or provider involved.**

NAME OF HEALTH CARE FACILITY/PROVIDER:
STREET ADDRESS:
CITY:
STATE:

**You have the option to give permission for the Health Care Safety Hotline staff to share your report with any health care facility, doctor, nurse, or other provider that was involved in the negative effect. This would alert the facility's staff so they can learn about what went wrong and improve safety.**

**4.5.5 May we share your report with the health care facility or provider?**
□**A** Yes
□**B** No

**4.6 In what month and year did the negative effect happen? (Your best estimate is fine.)**

ENTER MONTH:
YEAR:

**4.7 Did the patient get additional medical testing or treatment because of the negative effect?**
□A Yes
□B No
□C Don't know

**4.8 How did the patient find out that the negative effect happened? Please <u>choose the one answer</u> that fits best.**
□A The patient noticed it.
□B A doctor, nurse, or other health professional noticed it.
□C A friend or family member noticed it and told the patient.

□D A doctor, nurse, or other health care provider told the patient about it.
□E An administrator or manager told the patient about it
□F The patient found out in some other way. → [How did patient find out?]
□G The patient never knew about it.

**4.9 Did a doctor, nurse, or other health care provider make any special effort to help the patient handle the negative effect?**
□A Yes
□B No → GO TO 4.9
□C Don't know → GO TO 4.9

**4.9.1 How helpful were they?**
□A Extremely helpful
□B Very helpful
□C Somewhat helpful
□D Slightly helpful
□E Not at all helpful

**4.10 Did the negative effect cause the patient to miss work, school, or other regular activities?**
□A Yes
□B No
□C Don't know

**Sometimes patients experience negative <u>financial</u> effects. For example, patients may have to miss work, pay for extra testing or treatment, or take additional trips to a health care facility.**

**4.11 Did the negative effect cause <u>financial</u> problems for the patient?**
□A Yes
□B No
□C Don't know

**<u>Table 3-5</u>**
**<u>SECTION 5: CONTRIBUTING FACTORS, CHANGES IN CARE, DISCOVERY, & REPORTING</u>**

**Now we will ask some questions about why the mistake or negative effect happened, and what the patient did afterward.**

**5.1 In your opinion, could anything have been done differently to prevent this mistake or negative effect from happening?**
□A Yes→ [What could have been done?]
□B No
□C Don't know

**5.2 Why do you think this mistake or negative effect happened?**

**5.3 In your opinion, did any of the following lead to the mistake or negative effect? PLEASE CHECK ALL THAT APPLY.**

**Communication with doctors, nurses or other health care providers**

**5.3.1** Was it because the doctors, nurses, or other health care providers…
□A did not listen to the patient?
□B did not explain things to the patient in the patient's language?
□C used terminology the patient could not understand?
□D did not spend enough time with the patient?
□E spoke with an accent that was hard to understand?
□F ignored what the patient told them?
□G did not explain medications or their side effects?
□H did not explain follow-up care instructions?

**Responsiveness**

**5.3.2** Was it because of not getting…
□A help as soon as the patient needed it?
□B a referral as soon as the patient needed it?
□C an appointment as soon as the patient needed it?
□D care as soon as the patient needed it?

**Coordination**

**5.3.3** Was it because…
□A the doctors, nurses, or other health care providers were not aware of care that took place someplace else?
□B of the lack of follow-up by the doctors, nurses, or other health care providers?
□C doctors, nurses, or other health care providers did not seem to work well together as a team?

**Access**

**5.3.4** Was it because the patient…
□A was not able to get in to see a specialist for care?
□B was not able to get the tests or treatments that the patient believed necessary?
□C was not able to get the tests or treatments that a provider believed necessary?
□D did not get help or advice they needed?

**Verification**

**5.3.5** Was it because someone did not…
□A correctly identify the patient?
□B have the most recent and up-to-date information about the patient?

**Other**

**5.3.6** Was it because the patient…
□A couldn't afford the care the patient believed necessary?
□B couldn't afford the care a provider believed necessary?
□C had no insurance to pay for the care the patient believed necessary?
□C had no insurance to pay for the care a provider believed necessary?
□D Something else? → [What do you believe led to the mistake or negative effect?]

**5.4 Did this mistake or negative effect cause the patient to switch to a different doctor, nurse, or other health care provider or transfer to a different medical facility? PLEASE CHECK ALL THAT APPLY.**

□A Yes – Switched to a different health care provider
□B Yes – Transferred to a different hospital
□C Yes – Transferred to a different pharmacy
□D Yes – Other→ [What was the switch?]
□E No – There was no change

**5.5 Did the patient tell anyone about the mistake or negative effect?**
□A Yes
□B No → GO TO 6.1
□C Don't know → GO TO 6.1

**5.5.1 Who did the patient tell about the mistake or negative effect? PLEASE CHECK ALL THAT APPLY.**
**PROGRAMMER NOTE: ALL CHECKED ITEMS GET CODE OF "1"; ALL THAT ARE NOT CHECKED GET CODE OF "0"**
□A A family member or friend
□B A doctor, nurse, or other health care provider
□C A health care administrator or manager
□D Someone at the pharmacy
□E A minister or other religious leader
□F A lawyer
□G Someone else, such as a licensing agency, etc. → GO TO 5.5.1other

**5.5.1Other Who did the patient tell?**

**Table 3-6**
**SECTION 6: CLINICIAN/FACILITY & PATIENT INFORMATION**

**6.0 Would you like to tell us the name and address of the health care doctor, nurse, or other health care provider (or the health care facility) involved?**
□**A** Yes
□**B** Yes, but I do not know the name and address of the provider → GO TO 6.0.5
□**C** No, I do not know the name and address of the provider → GO TO 6.0.5
□**D** No, I do not want to tell you → GO TO 6.0.5

**6.0.1 Please write the name and address of the health care facility or provider involved.**

NAME OF HEALTH CARE FACILITY/PROVIDER:
STREET ADDRESS:
CITY:
STATE:

**6.0.2 Was a second health care facility or provider involved?**
□**A** Yes
□**B** No→ GO TO 6.0.5

**6.0.3 Would you like to tell us the name of the second health care facility or provider involved?**
□**A** Yes
□**B** Yes, but I do not know the name of the facility or provider → GO TO 6.0.5
□**C** No, I do not know the name of the facility or provider → GO TO 6.0.5
□**D** No, I do not want to tell you → GO TO 6.0.5

**6.0.4 Please write the name and address of the second health care facility or provider involved.**

NAME OF HEALTH CARE FACILITY/PROVIDER:
STREET ADDRESS:
CITY:
STATE:

**You have the option to give permission for the Health Care Safety Hotline staff to share your report with any health care facility, doctor, nurse, or other provider that was involved. This would alert the facility's staff so they can learn about what went wrong and improve safety.**

**6.0.5 May we share your report with the health care facility or provider?**
□**A** Yes
□**B** No

**6.1 May we contact you if we need more information**

□A Yes
□B No → GO TO 6.2

**6.1.1 Please tell us your name and your address, telephone number or e-mail.**

Name:
Street Address:
City:
State:
Zip:
Phone:

This is my
□A Home number
□B Work number
□C Cell number
E-mail:

**6.1.2 Is it better to reach you on weekdays or weekends? PLEASE CHECK ALL THAT APPLY**

□A Weekday
□B Weekend

**6.1.3 What is the best time of day to reach you? PLEASE CHECK ALL THAT APPLY**

□A Morning
□B Afternoon
□C Evening

**6.1.4 When we contact the doctor, nurse, or other health care provider (or facility) to share your report, may we include your name and contact information? This will help the provider or facility match your report with their records.**

□A Yes
□B No

**Our last questions will help us to understand whether some people are more likely than others to experience medical mistakes and negative effects.**

**6.2 What is the patient's sex?**

□A Male
□B Female

**6.3 At the time of the mistake or negative effect, approximately how old was the patient?**

Age of patient at time of mistake or negative effect: Years

Note: If the patient was a child and less than 1 year, enter 1 year.

**6.4 Is the patient Hispanic, Latino/a, or Spanish origin? (One or more categories may be selected)**

□A No
□B Yes, Mexican, Mexican American, Chicano/a
□C Yes, Puerto Rican
□D Yes, Cuban
□E Yes, another Hispanic, Latino, or Spanish origin

**6.5 What is the patient's race? (One or more categories may be selected)**

□A White
□B Black or African American
□C American Indian or Alaska Native
□D Asian Indian
□E Chinese
□F Filipino
□G Japanese
□H Korean
□I Vietnamese
□J Other Asian
□K Native Hawaiian
□L Guamanian or Chamorro
□M Samoan
□N Other Pacific Islander

**6.6 What type of health insurance did the patient have at the time of the mistake or negative effect? Please <u>choose the one answer</u> that fits best.**

□A Private insurance through an employer
□B Private insurance that the patient bought
□C Medicare
□D Medicaid (including Medicaid managed care plans)
□E Tricare (for active military personnel and their families)
□F Veterans care
□G Other → 6.7eTYPE
□H Not insured (please select this only if you have not picked any other answer)
□I Don't know
□J I do not wish to disclose this information

**6.6eTYPE What other type of health insurance did patient have?**

**6.8 How did you learn about the Health Care Safety Hotline? Please <u>choose the one answer</u> that fits best.**

□A Web site
□B Flyer or poster at a hospital
□C Admission or discharge paperwork
□D Doctor, nurse, or other health care provider
□E Other [How did you learn about the Safety Hotline? [FREE TEXT BOX. ALLOW 100]

**>THANKS<**
**Thank you for your report and for helping to improve patient safety.**

## Appendix C.3. Survey Report Form Document – Phone Version

*>INTRO<*
*Hello, you have reached the Health Care Safety Hotline.*

*My name is [**XXX**]. I will be talking with you about your health care safety concern. First I will go over a few instructions with you.*

*>AGE<*
*To provide a report, you must be older than 18.* ***Are you 18 years or older?***

____ YES→ *PROCEED*
____ NO → *THANK and EXIT*

*>INTRO2<*
*Thank you for providing that information.*

*This interview will take about 20–25 minutes. We will ask you questions about the experiences you or your family members have had with health care. We will ask if you have ever had an experience where you think a mistake was made or where you had concerns about your safety. There are no right or wrong answers. If there are any questions you don't want to answer, tell me and we will just go on to the next one. You do not have to participate. You may change your mind and stop at any time, even after we start.*

*The Health Care Safety Hotline allows patients and their families* **or caregivers** *to voluntarily report on the safety of their health care. Hotline staff will use the information that you and others give us to understand patients' concerns. Hotline staff are researchers from the RAND Corporation and the ECRI Institute. We will only tell doctors, hospitals, and pharmacists a compilation of what we learn; no individual reports are shared. We hope they will make changes and that health care will be safer.*

*The information you give us is completely private. We will not use your name or your address or your phone number. Nobody will see your answers except people on the Health Care Safety Hotline team unless you say it is OK to share it. In some cases, my supervisor might listen to this call to make sure that I am doing a good job.*

*We will write a report about what we learn from the data collected in the Health Care Safety Hotline. We will give the report to doctors, hospitals, and pharmacists so they can do a better*

*job and make health care safer. But we will combine all the answers we get from lots of people. Nobody will know the names of the people who helped us, and nobody will be able to tell who said what.*

*The Health Care Safety Hotline was paid for by an agency that is part of the United States government. The agency is called the Agency for Health Care Research and Quality. It has strict laws about protecting patients' privacy.*

*You will not receive any payment or any other direct benefits for your help. But by sharing your story, you can help make health care safer for the people in your town and in towns all across the United States.*

*>PHONE<*
*Would you mind giving me your phone number? If our phone call gets disconnected, I will call you right back.*

**ENTER TELEPHONE NUMBER: ( _____) _____ - _____**

- ***Ask:***
    - *Do you have any questions?* [***If so, refer to FAQs list***]
    - *Do you understand everything I said or is there anything I should go over again?*
    - *May I use a tape recorder as we talk so I will remember what you tell me exactly right?*

____ *YES → START RECORDING Thanks. I'll start recording now.*
____ *NO → Thanks. I will take notes only but not record our conversation.*

*I am ready to ask you questions about your health care safety concern. Are you ready to begin?*

To complete the questions, you will need

- Month and year of the concern [NOTE: Concerns that occurred more than ten years ago should not be reported]
- Where the concern occurred, including the facility or provider name(s) and street address, city and state, if you wish to share this information
- Names of medications that were involved (if any)
- Names of the tests, procedures, or survey that were involved (if any)
- Your own contact information if you wish to be contacted by the Safety Hotline staff to discuss the details of the concern

*Do you know this information? Or would you like a minute to grab any documents.* [WAIT IF NECESSARY}
{When they are back on the line} Ask again*: Thank you. Are you ready to begin?*

**1.1 Who is the patient with a safety concern?**
□A Me
□B A child
□C A spouse, domestic partner or other family member (for example, a grandparent, aunt, etc.)
□D A friend
□E A patient or client
□F Someone else → [DISPLAY AS TEXT BOX: Who is the patient?]

**1.1.2 In what city and state did the safety concern occur?**

Enter the city:
Enter the state:

## SECTION 2: DESCRIPTION OF YOUR SAFETY CONCERN

**2.1 Please tell us in your own words about the safety concern.** Then we will ask some specific questions to make sure we understand what happened.

**2.1a. What happened?**

NOTE: If you believe a patient died as the result of a mistake, please tell us about the mistake and record the negative effect as "death."

**2.1b. Where do you believe it happened?**

**2.1c. When did it happen?**

**2.1d. Why do you think this happened?**

**2.2 What is the name of the patient?**
ENTER FIRST NAME:
ENTER LAST NAME:

**Now we will ask some questions to make sure we understand what happened.**

**2.3 In your opinion, did a doctor, nurse, or other health care provider make a medical mistake or error in the patient's care?**

POP-UP: A medical mistake or error is something that was done (or not done) by a health care provider that would be considered incorrect at the time it happened. Sometimes medical mistakes can result in harm or injury to the patient, but not every time.

□A Yes → GO TO 3.1
□B No → GO TO 2.3.1
□C Don't know → GO TO 2.3.1

**When people are harmed or injured as a result of medical care, we call this a negative effect. Negative effects can be physical or emotional and they may include infections, drug reactions, or other complications.**

**2.3.1 Do you think a negative effect took place as a result of the patient's care?**
□A Yes → GO TO 4.1
□B No → GO TO 2.3.1.1
□C Other → [DISPLAY AS TEXT BOX: Please describe ]
→ GO TO 2.3.1.1
□D Don't know → GO TO 2.3.1.1

**2.3.1.1 You told us that a mistake did not take place (or that you don't know) and that a negative effect did not take place (or that you don't know). Is this correct?**
□A Yes → GO TO 6.0
□B No → GO TO 6.0
□C Don't know → GO TO 6.0

## SECTION 3: MISTAKE

**3.1 Did the medical mistake or error involve any of the following? Please choose the one answer that fits best.**
□A A mistake related to a medicine
[POP-UP: Medicines can include prescription or non-prescription medication, herbs, dietary supplements, vaccines, contrast dye or other injected medicines] → GO TO 3.1.1.1

□B A mistake related to a test, procedure, or surgery
[POP-UP: This includes tests that involve taking samples of skin or tissue, inserting tubes to examine internal parts of your body, or other tests involving blood, urine, or X-rays.] → GO TO 3.1.2.1

□C A mistake related to pregnancy or childbirth
[POP-UP: This includes errors in diagnostic testing during pregnancy and errors during labor and delivery] → GO TO 3.2

□D A mistake related to a diagnosis or advice from a doctor, nurse, or other health care provider → GO TO 3.1.3.1

□E A mistake related to poor cleanliness or poor hygiene → GO TO 3.2

□F Something else, or more than one mistake [GO TO 3.1f1]

**3.1.f1 In your opinion, what was the mistake? [FREE TEXT BOX]**

**3.1.1.1 As best as you can, please name or describe the medicine. [FREE TEXT BOX]**

**3.1.1.2 Was it a prescription medicine?**
[POP-UP: Don't include over-the-counter medicines that you can buy without a prescription from a doctor or nurse.]
□A Yes
□B No
□C Don't know

**3.1.1.3 Did the mistake with medicine involve any of the following? Please <u>choose the one answer</u> that fits best.**
□A Wrong medicine→ GO TO 3.2
□B Wrong dose→ GO TO 3.2
□C Something else→ [GO TO 3.1.1.3-OTHER: What did the mistake involve? FREE TEXT BOX, ALLOW 50. GO TO 3.2]

**3.1.2.1 As best as you can, please name or describe the test, procedure, or surgery. [FREE TEXT BOX]**

**3.1.2.2 Did the mistake with a test, procedure, or surgery involve any of the following? PLEASE CHECK ALL THAT APPLY.**

□A Wrong patient [POP-UP: The patient was not correctly identified.]
□B Wrong test, procedure, or surgery [POP-UP: The wrong type of test, procedure, or surgery was done.]
□C Wrong part of the body [POP-UP: The test, procedure, or surgery was on the wrong part of the body.]
□D A mistake was made <u>during</u> the test, procedure, or surgery
□E The test, procedure, or surgery was delayed
□F The test results were lost and the patient did not receive them
□G The patient developed an infection
□H A problem with anesthesia
□I Something else→ What did the mistake involve?

→ GO TO 3.2 ONCE ITEMS CHECKED

**3.1.3.1 In your opinion, what was the mistake with the diagnosis or medical advice? [FREE TEXT BOX]**

**3.2 Where did the mistake happen? Please <u>choose the one answer</u> that fits best.**

□A In a doctor's office or a clinic
□B In a pharmacy
□C In the emergency department
□D In a hospital
□E At home
□F Don't know
□G Somewhere else

**3.3 Would you like to tell us the name of the health care facility, doctor, nurse, or other health care provider involved?**

□A Yes
□B Yes, but I do not know the name the facility or provider → GO TO 3.4
□C No, I do not know the name of the facility or provider → GO TO 3.4
□D No, I do not want to tell you → GO TO 3.4

**3.3.1 Please write the name and address of the health care facility or provider involved.**

NAME OF HEALTH CARE FACILITY/PROVIDER:
STREET ADDRESS:
CITY:
STATE:

**3.3.2 Was a second health care facility or provider involved?**

□A Yes
□B No→ GO TO 3.3.5

**3.3.3 Would you like to tell us the name of the second health care facility or provider involved?**

□A Yes
□B Yes, but I do not know the name and address of the facility or provider → GO TO 3.3.5
□C No, I do not know the name of the facility or provider → GO TO 3.3.5
□D No, I do not want to tell you → GO TO 3.3.5

**3.3.4 Please write the name and address of the second health care facility or provider involved.**

NAME OF HEALTH CARE FACILITY/PROVIDER:
STREET ADDRESS:
CITY:
STATE:

**You have the option to give permission for the Health Care Safety Hotline staff to share your report with any health care facility, doctor, nurse, or other provider that was involved in the mistake. This would alert the facility's staff so they can learn about what went wrong and improve safety.**

**3.3.5 May we share your report with the health care facility or provider?**
□A Yes
□B No

**3.4 In what month and year did the mistake happen? (Your best estimate is fine.)**

ENTER MONTH:
ENTER YEAR:

**3.5 Did a doctor, nurse, or other health care provider tell you the mistake happened?**
□A Yes→GO TO 3.6
□B No [FREE TEXT BOX: How did you find out that the mistake happened

**Sometimes medical mistakes affect patients financially. For example, patients may have to miss work, pay for extra tests or procedures, or take additional trips to a health care facility.**

**3.6 Did the mistake affect the patient financially?**
□A Yes
□B No
□C Don't know

**When people are harmed or injured as a result of medical care, we call this a negative effect. Negative effects can be physical or emotional and they may include infections, drug reactions, or other complications.**

**3.7 Did the patient experience any negative effects as a result of the mistake or error?**
□A Yes
□B No → GO TO 5.1
□C Don't know → GO TO 5.1

## SECTION 4: NEGATIVE EFFECT

**4.1 Did the negative effect involve any of the following? Please choose the one answer that fits best.**
□A A negative effect related to a medicine
□B A negative effect related to a test, procedure, or surgery
□C A negative effect related to pregnancy or childbirth
□D A negative effect related to a diagnosis
□E A negative effect related to medical advice
□F Unclean or unsanitary care
□G Something else or more than one negative effect

**4.2 What kind of negative effect did the patient experience?**
□A Physical
□B Emotional → GO TO 4.4

□C Both

**4.3 What kind of <u>physical</u> negative effect did the patient experience? PLEASE CHECK ALL THAT APPLY.**

□A Dizziness
□B Sick to the stomach (nausea)
□C Infection
□D Pain
□E A fall that caused an injury
□F Open sores on skin
□G A sexual problem
□H Blood clot
□I Uncontrolled bleeding
□J Breathing difficulty
□K Numbness or weakness
□L Injury to teeth
□M Injury to an eye
□N Burn
□O Heart attack or stroke
□p Continuing symptoms
□q Worsening of a health problem
□r Patient died
□s Other physical effect→ [Please describe]
□T The negative effect was not physical.

**4.4 Where did the negative effect first happen? Please <u>choose the one answer</u> that fits best.**

□A In a doctor's office or a clinic
□B In a pharmacy
□C In the emergency department
□D In a hospital
□E At home
□F Somewhere else→ [Where did this first happen?]
□G Don't know

**4.5 Would you like to tell us the name of the health care facility, doctor, nurse, or other health care provider involved?**

□**A** Yes
□**B** Yes, but I do not know the name of the facility or provider → GO TO 4.6
□**C** No, I do not know the name of the facility or provider → GO TO 4.6
□**D** No, I do not want to tell you → GO TO 4.6

**4.5.1 Please write the name and address of the health care facility or provider involved.**

NAME OF HEALTH CARE FACILITY/PROVIDER:
STREET ADDRESS:
CITY:

STATE:

**4.5.2 Was a second health care facility or provider involved? PROGRAMMER NOTE: SELECT "1"**
□**A** Yes
□**B** No→ GO TO 4.5.5

**4.5.3 Would you like to tell us the name of the second health care facility or provider involved?**
□**A** Yes
□**B** Yes, but I do not know the name of the facility or provider → GO TO 4.5.5
□**C** No, I do not know the name of the facility or provider → GO TO 4.5.5
□**D** No, I do not want to tell you → GO TO 4.5.5

**4.5.4 Please write the name and address of the second health care facility or provider involved. [FREE TEXT BOX]**

NAME OF HEALTH CARE FACILITY/PROVIDER:
STREET ADDRESS:
CITY:
STATE:

**You have the option to give permission for the Health Care Safety Hotline staff to share your report with any health care facility, doctor, nurse, or other provider that was involved in the negative effect. This would alert the facility's staff so they can learn about what went wrong and improve safety.**

**4.5.5 May we share your report with the health care facility or provider?**
□**A** Yes
□**B** No

**4.6 In what month and year did the negative effect happen? (Your best estimate is fine.)**

ENTER MONTH:
YEAR:

**4.7 Did the patient get additional medical testing or treatment because of the negative effect?**
□A Yes
□B No
□C Don't know

**4.8 How did the patient find out that the negative effect happened? Please <u>choose the one answer</u> that fits best.**
□A The patient noticed it.
□B A doctor, nurse, or other health professional noticed it.

□C A friend or family member noticed it and told the patient.
□D A doctor, nurse, or other health care provider told the patient about it.
□E An administrator or manager told the patient about it
□F The patient found out in some other way. → [How did patient find out?]
□G The patient never knew about it.

**4.9 Did a doctor, nurse, or other health care provider make any special effort to help the patient handle the negative effect?**
□A Yes
□B No → GO TO 4.9
□C Don't know → GO TO 4.9

**4.9.1 How helpful were they?**
□A Extremely helpful
□B Very helpful
□C Somewhat helpful
□D Slightly helpful
□E Not at all helpful

**4.10 Did the negative effect cause the patient to miss work, school, or other regular activities?**
□A Yes
□B No
□C Don't know

**Sometimes patients experience negative financial effects. For example, patients may have to miss work, pay for extra testing or treatment, or take additional trips to a health care facility.**

**4.11 Did the negative effect cause financial problems for the patient?**
□A Yes
□B No
□C Don't know

**Table 3-5**
**SECTION 5: CONTRIBUTING FACTORS, CHANGES IN CARE, DISCOVERY, & REPORTING**

**Now we will ask some questions about why the mistake or negative effect happened, and what the patient did afterward.**

**5.1 In your opinion, could anything have been done differently to prevent this mistake or negative effect from happening?**
□A Yes→ [What could have been done?]
□B No

□C Don’t know

**5.2 Why do you think this mistake or negative effect happened?**

**5.3 In your opinion, did any of the following lead to the mistake or negative effect? PLEASE CHECK ALL THAT APPLY.**

**Communication with doctors, nurses or other health care providers**

**5.3.1** Was it because the doctors, nurses, or other health care providers…
□A did not listen to the patient?
□B did not explain things to the patient in the patient’s language?
□C used terminology the patient could not understand?
□D did not spend enough time with the patient?
□E spoke with an accent that was hard to understand?
□F ignored what the patient told them?
□G did not explain medications or their side effects?
□H did not explain follow up care instructions?

**Responsiveness**

**5.3.2** Was it because of not getting…
□A help as soon as the patient needed it?
□B a referral as soon as the patient needed it?
□C an appointment as soon as the patient needed it?
□D care as soon as the patient needed it?

**Coordination**

**5.3.3** Was it because…
□A the doctors, nurses, or other health care providers were not aware of care that took place someplace else?
□B of the lack of follow-up by the doctors, nurses, or other health care providers?
□C doctors, nurses, or other health care providers did not seem to work well together as a team?

**Access**

**5.3.4** Was it because the patient…
□A was not able to get in to see a specialist for care?
□B was not able to get the tests or treatments that the patient believed necessary?
□C was not able to get the tests or treatments that a provider believed necessary?
□D did not get help or advice they needed?

**Verification**

**5.3.5** Was it because someone did not…

□A correctly identify the patient?
□B have the most recent and up-to-date information about the patient?

**Other**

**5.3.6** Was it because the patient…
□A couldn't afford the care the patient believed necessary?
□B couldn't afford the care a provider believed necessary?
□C had no insurance to pay for the care the patient believed necessary?
□C had no insurance to pay for the care a provider believed necessary?
□D Something else? → [What do you believe led to the mistake or negative effect?]

**5.4 Did this mistake or negative effect cause the patient to switch to a different doctor, nurse, or other health care provider or transfer to a different medical facility? PLEASE CHECK ALL THAT APPLY.**

□A Yes – Switched to a different health care provider
□B Yes – Transferred to a different hospital
□C Yes – Transferred to a different pharmacy
□D Yes – Other→ [What was the switch?]
□E No – There was no change

**5.5 Did the patient tell anyone about the mistake or negative effect?**
□A Yes
□B No → GO TO 6.1
□C Don't know → GO TO 6.1

**5.5.1 Who did the patient tell about the mistake or negative effect? PLEASE CHECK ALL THAT APPLY.**
**PROGRAMMER NOTE: ALL CHECKED ITEMS GET CODE OF "1"; ALL THAT ARE NOT CHECKED GET CODE OF "0"**
□A A family member or friend
□B A doctor, nurse, or other health care provider
□C A health care administrator or manager
□D Someone at the pharmacy
□E A minister or other religious leader
□F A lawyer
□G Someone else, such as a licensing agency, etc. → GO TO 5.5.1other

**5.5.1other Who did the patient tell?**

**<u>SECTION 6: CLINICIAN/FACILITY & PATIENT INFORMATION</u>**

**6.0 Would you like to tell us the name and address of the doctor, nurse, or other health care provider (or the health care facility) involved?**

□**A** Yes
□**B** Yes, but I do not know the name and address of the provider → GO TO 6.0.5
□**C** No, I do not know the name and address of the provider → GO TO 6.0.5
□**D** No, I do not want to tell you → GO TO 6.0.5

**6.0.1 Please write the name and address of the health care facility or provider involved.**

NAME OF HEALTH CARE FACILITY/PROVIDER:
STREET ADDRESS:
CITY:
STATE:

**6.0.2 Was a second health care facility or provider involved?**
□**A** Yes
□**B** No→ GO TO 6.0.5

**6.0.3 Would you like to tell us the name of the second health care facility or provider involved?**
□**A** Yes
□**B** Yes, but I do not know the name of the facility or provider → GO TO 6.0.5
□**C** No, I do not know the name of the facility or provider → GO TO 6.0.5
□**D** No, I do not want to tell you → GO TO 6.0.5

**6.0.4 Please write the name and address of the second health care facility or provider involved.**

NAME OF HEALTH CARE FACILITY/PROVIDER:
STREET ADDRESS:
CITY:
STATE:

**You have the option to give permission for the Health Care Safety Hotline staff to share your report with any health care facility, doctor, nurse, or other provider that was involved. This would alert the facility's staff so they can learn about what went wrong and improve safety.**

**6.0.5 May we share your report with the health care facility or provider?**
□**A** Yes
□**B** No

**6.1 May we contact you if we need more information**
□A Yes
□B No → GO TO 6.2

**6.1.1 Please tell us your name and your address, telephone number or e-mail.**

Name:

Street Address:
City:
State:
Zip:
Phone:

This is my
□A Home number
□B Work number
□C Cell number

E-mail:

**6.1.2 Is it better to reach you on weekdays or weekends? PLEASE CHECK ALL THAT APPLY**

□A Weekday
□B Weekend

**6.1.3 What is the best time of day to reach you? PLEASE CHECK ALL THAT APPLY**

□A Morning
□B Afternoon
□C Evening

**6.1.4 When we contact the doctor, nurse, or other health care provider (or facility) to share your report, may we include your name and contact information? This will help the provider or facility match your report with their records.**

□A Yes
□B No

**Our last questions will help us to understand whether some people are more likely than others to experience medical mistakes and negative effects.**

**6.2 What is the patient's sex?**

□A Male
□B Female

**6.3 At the time of the mistake or negative effect, approximately how old was the patient?**

Age of patient at time of mistake or negative effect: Years

Note: If the patient was a child and less than 1 year, enter 1 year.

**6.4 Is the patient Hispanic, Latino/a, or Spanish origin? (One or more categories may be selected)**

□A No
□B Yes, Mexican, Mexican American, Chicano/a
□C Yes, Puerto Rican

□D Yes, Cuban
□E Yes, another Hispanic, Latino, or Spanish origin

**6.5 What is the patient's race? (One or more categories may be selected)**
□A White
□B Black or African American
□C American Indian or Alaska Native
□D Asian Indian
□E Chinese
□F Filipino
□G Japanese
□H Korean
□I Vietnamese
□J Other Asian
□K Native Hawaiian
□L Guamanian or Chamorro
□M Samoan
□N Other Pacific Islander

**6.6 What type of health insurance did the patient have at the time of the mistake or negative effect? Please <u>choose the one answer</u> that fits best.**
□A Private insurance through an employer
□B Private insurance that the patient bought
□C Medicare
□D Medicaid (including Medicaid managed care plans)
□E Tricare (for active military personnel and their families)
□F Veterans care
□G Other → 6.7eTYPE
□H Not insured (Please select this only if you have not picked any other answer)
□I Don't know
□J I do not wish to disclose this information.

**6.6eTYPE What other type of health insurance did patient have?**

**6.8 How did you learn about the Health Care Safety Hotline? Please <u>choose the one answer</u> that fits best.**
□A Web site
□B Flyer or poster at a hospital
□C Admission or discharge paperwork
□D Doctor, nurse, or other health care provider
E Other □ [How did you learn about the Safety Hotline?

## <u>SECTION 7: BARRIERS TO REPORTING/ USABILITY</u>

**7.0 You could have reported by phone or the web. Why did you choose to call in?**

**7.1 Did you attempt to report this concern using the web?**

□A Yes, but I did not answer any of the questions; instead I called the toll-free number. → END
□B Yes, but I only answered some of the questions and then quit to call this toll-free number. → **GO TO 7.1**
□C No. I only called the toll-free number → END

**7.2 When filling out the questions on the web, what problems did you encounter: CHECK ALL THAT APPLY**

□A The Web form took too long
□B The Web form hotline information was not clear
□C On the Web, it was hard to find the information I needed
□D The organization of the information on the hotline screens was not clear
□E The hotline did not have all the functions and capabilities that I needed it to have
□F On the Web, I was not able to explain "in my own words" what happened
□G On the Web, I was often frustrated when answering the hotline questions
□H Many of the questions asked for unnecessary information

**7.3 What changes could be made to the Health Care Safety Hotline to better allow you to report a safety concern? [OPEN ENDED]**

**END:**
**>THANKS<**
**Thank you for your report and for helping to improve patient safety.**

## Appendix C.4. Provider Supplementation Process: Provider Followup Questions and Administrative Script

The following is the administrative intake page that is linked to each report, referred to as Module 8. It is a checklist of Steps 2 through 6 in the processing of a report, as outlined in Figure C.30. Second, it contains questions (8.1 through 8.8) that gather information during a followup phone call with the health care delivery organization/provider. The information captured in these questions documents the actions taken by the health care delivery organization. Specifically, Question 8.4 identifies and documents whether the health care delivery organization found a matching incident report in their incident reporting system that is from the same patient, family member, or caregiver about the same incident that was submitted to the hotline.

**Module 8 – Processing Checklist**

**8.0 RSO Status**

☐ Screened **GO TO → 8.0.1 ---- Clickable by SuperUser – Research AND SuperUser – Administrative**

☐ Audited – Needs reporter/patient follow-up (free text reviewed and sanitized)
**GO TO → 8.1.0 ----- Clickable by Intake Admin User AND SuperUser – Administrative**

☐ Audited – Needs team decision (free text reviewed and sanitized)
**GO TO → 8.1.0 ----- Clickable by Intake Admin User AND SuperUser – Administrative**

☐ Clarified (questions answered by reporter team; ready for matching to provider)
**GO TO → 8.1.0 ----- Clickable by Intake Admin User AND SuperUser – Administrative**

☐ Finalized (ready for patient safety concern classification by team)

**8.0.1** Exclusion reason:
☐ Age
☐ Grievance
☐ Service complaint
☐ Other

**8.1.0 Community**
a. Not applicable
b. Community 1
c. Community 2

**Module 8: Questions 8.1 – 8.8. Administrative Script When Matching Consumer Submission with Incident Reporting System**

**8.1.1 Was patient's report edited based on followup with patient/consumer?**
a. Yes.
b. No, we spoke to the reporter and there were no changes.
c. No, we were <u>not able to contact</u> the reporter.

d. No, we did not have permission to contact the reporter.

**8.1.2 Patient, family, or caregivers/consumer gave permission to speak to the facility**

a. Yes
b. No (if no, do not proceed)

**8.2 Was the health care facility (HCF) aware of the patient safety concern?**

a. Yes
b. No
c. Uncertain

**8.3 Was the patient safety concern reported internally within the health care facility as a patient safety event?**

a. Yes
b. No
c. Uncertain (e.g., no match found)

**8.4 Was the patient safety concern reported within the PSO as a patient safety event?**

a. Yes
b. No
c. Uncertain (e.g., no match found)

**8.5 Who reported the event or unsafe condition?**

a. Health care professional (if selected, go to 7.4.1)

**8.4.1. What is the type of health care professional?**

a. Doctor, dentist (including student)
b. Nurse, nurse practitioner, physician assistant (including student or trainee)
c. Pharmacist, pharmacy technician (including student)
d. Allied health personnel, paramedic
e. Health care worker, including liaison officer, patient transport/retrieval personnel, assistant/orderly, clerical/administrative personnel, domestic/hotel service personnel, interpreter/translator, technical/laboratory personnel, pastoral care personnel, or biomedical engineer
f. Emergency service personnel, including police officer, firefighter, or other emergency service officer
g. Patient/relative/volunteer/caregiver/home assistant
h. Anonymous or unknown

**8.6 Was a root cause analysis (RCA) completed?**

a. Yes
b. No
c. Unknown

**8.7 Are any contributing factors to the event known?**

a. Yes (if yes, go to 8.6.1)
b. No

c. Unknown

**8.7.1 What factor(s) contributed to the event? CHECK ALL THAT APPLY:**

☐ **Team coordination factors**

a. Communication: supervisor to staff
b. Communication: staff to patient
c. Communication: among staff or team members
d. Clinical supervision
e. Managerial supervision
f. Scheduling conflicts
g. Heavy workload
h. Shift change

☐ **Staff/individual factors**

a. Adherence to policy, protocols, or orders
b. Cognitive factors
c. Competence (qualifications, experience)
d. Familiarity with environment
e. Familiarity with policy and procedure
f. Fatigue
g. Health issues
h. Inattention
i. Long work hours
j. Stress
k. Training

☐ **Operating environment factors**

a. Biohazards and sharps management
b. Equipment/device availability
c. Equipment/device design
d. Equipment/device function
e. Equipment/device maintenance
f. Housekeeping
g. Physical surroundings (e.g., lighting, noise)
h. Unlocked/unsecured area
i. Interruptions (human)

☐ **Workflow/task factors**

a. Bed capacity
b. Delay in response to code
c. Delay in discharges
d. Staffing ratios
e. Transport delays
f. Consent error/not completed
g. Completion of patient/resident assessment
h. Data legibility
i. Data availability
j. Data accuracy

k. Management of test results
l. Order/requisition difficulties

☐ **Patient/resident factors**

a. Agitated/aggressive
b. Confused/disoriented
c. Impaired hearing or speech
d. Language barrier
e. Refusal of care or non-compliance
f. Unresponsive

☐ **Management/organization factors**

a. Clarity of policy/procedure
b. Culture of safety management
c. Empowerment (e.g., any health care provider can call a code)
d. Presence of policy/procedure
e. Resource constraints (financial or human)

☐ Other

a. Please Specify

**8.8 Lessons Learned? [OPEN TEXT BOX]**

## Appendix C.5. Content of Functional and Administrative Reports

Table C5.1 lists the functional and administrative reports generated by the hotline.

**Table C5.1. List of Reports Generated by the Hotline**

| Module | Report | Aggregate and/or Community |
|---|---|---|
| Mistake | Summary & report by mistake type | Aggregate and community |
| Negative effect | Summary & report by negative effect (mistake type, type, location) | Aggregate and community |
| Contributing factors, changes in care, discovery and reporting | Summary & report of contributing factors (mistake type, type, location) | Aggregate and community |
| Patient & clinician/facility information | Summary & report by type of reporter | Aggregate and community |
| Patient & clinician/facility information | Summary patient demographics (gender, age, race, language, insurance) | Aggregate and community |
| Administrative | Summary by how reporter learned about the hotline | Aggregate and community |
| Administrative | Summary by modality used (phone/computer) | Aggregate and community |
| Administrative | Export data set – Module 1–7 | All fields (Modules 1–7) |
| Administrative | Export data set – Module 8 | All fields (Module 8) |
| Administrative | Web traffic report | All metrics |
| Administrative | Print RSO to PDF | All completed questions and answers |

The detailed content of each of these reports is shown in Tables C5.2–C5.12.

**Table C5.2. Report 1, Report by Mistake Type**

| Report Properties | Comments |
|---|---|
| Style | Pie chart, tabular |
| Data source | Aggregate and community |
| Criteria | Submission date, mistake type (3.1), mistake subtype(s) (3.1.1.3, 3.1.2.2, 3.1.3.1) |
| Aggregate criteria | RSO status (8.1), where (3.2), RSO ID#, community (8.1) |
| Data series - pie chart | Mistake type (3.1)<br>Mistake types: a.) medicine, b.) test / procedure / surgery, c.) pregnancy or childbirth, d.) diagnosis or advice, e.) other/more than one mistake |
| Data label - pie chart | Series name and percentage |
| Row data - tabular | Same as data series – pie chart |
| Column data - tabular | Number, percentage |

**Table C5.3. Report 2, Report by Negative Effect**

| Report Properties | Comments |
|---|---|
| Style | Pie chart, tabular |
| Data source | Aggregate and community |
| Criteria | Submission date, negative effects (4.2), physical negative effect (4.2.1). |
| Aggregate criteria | RSO status (8.1), where (3.2), RSO id#, community (8.1) |
| Data series - bar chart | Negative effect (4.2)<br>Negative effect: a.) physical, b.) emotional, c.) both<br>Physical negative effect: a.) dizziness, b.) sick to the stomach (nausea), c.) infection, d.) pain, e.) a fall that caused an injury, f.) open sores on skin, g.) a sexual problem, h.) blood clot, i.) uncontrolled bleeding, j.) breathing difficulty, k.) numbness or weakness, l.) injury to teeth, m.) injury to an eye, n.) burn, o.) heart attack or stroke, p.) other, q.) the negative effect was not physical. |
| Data label - bar chart | Series name and percentage |
| Row data - tabular | Same as data series – bar chart |
| Column data - tabular | Number, percentage |

**Table C5.4. Report 3, Report by Contributing Factor**

| Report Properties | Comments |
|---|---|
| Style | Pie chart, tabular |
| Data source | Aggregate and community |
| Criteria | Submission date, mistake type, contributing factors (5.1), CF processes |
| Aggregate criteria | RSO status (8.1), where (3.2), RSO ID#, community (8.1) |
| Data series - pie chart | Contributing factors (5.1)<br>Contributing factors: communication (a-d), staffing and overwork (e-f), coordination of care (g-i), access (j-k), other (l) |
| Data label - pie chart | Series name and percentage |
| Row data - tabular | Same as data series – pie chart |
| Column data - tabular | Number, percentage |

**Table C5.5. Report 4, Report on Person Reported For**

| Report Properties | Comments |
|---|---|
| Style | Pie chart, tabular |
| Data source | Aggregate and community |
| Criteria | Submission date |
| Aggregate criteria | RSO status (8.1), where (3.2), RSO ID #, community (8.1) |
| Data series - pie chart | Reported by |
| Data label - pie chart | Reported by (1.1)<br>Reported by (a-l) a.) me, b.) child, c.) spouse/domestic partner/other family member, d.) friend, e.) patient or client, f.) someone else |
| Row data - tabular | Same as data series – pie chart |
| Column data - tabular | Number, percentage |

**Table C5.6. Report 5, Summary of Patient Demographics**

| Report Properties | Comments |
|---|---|
| Style | Pie chart, tabular |
| Data source | Aggregate and community |
| Criteria | Submission date |
| Aggregate criteria | RSO status (8.1), where (3.2), RSO ID#, community (8.1) |
| Data series - pie chart | Patient information |
| Data label - pie chart | Demographics:<br>gender (6.2), age (6.3), race (6.4, 6.5), insurance (6.7) |
| Row data - tabular | Same as data series – pie chart |
| Column data - tabular | Number, percentage |

**Table C5.7. Report 6, How Reporter Learned About Hotline**

| Report Properties | Comments |
|---|---|
| Style | Pie chart, tabular |
| Data source | Aggregate and community |
| Criteria | Submission date |
| Aggregate criteria | RSO status (8.1), where (3.2), RSO ID#, community (8.1) |
| Data series - pie chart | How |
| Data label - pie chart | How (6.9)<br>How: (a-f) a.) Web site, b.) flyer/poster c.) admission or discharge paperwork d.) doctor, nurse or other health care provider, e.) other |
| Row data - tabular | Same as data series – pie chart |
| Column data - tabular | Number, percentage |

**Table C5.8. Report 7, Report of Modality Used (Phone/Computer)**

| Report Properties | Comments |
|---|---|
| Style | Pie chart, tabular |
| Data source | Aggregate and community |
| Criteria | Submission date |
| Aggregate criteria | RSO status (8.1), where (3.2), RSO ID#, community (8.1) |
| Data series - pie chart | Phone/computer (fields??) |
| Data label - pie chart | Modality: a.) phone, b.) computer |
| Row data - tabular | Same as data series – pie chart |
| Column data - tabular | Number, percentage |

**Table C5.9. Report 8, Report of Export Data Set – Modules 1–7**

| Report Properties | Comments |
|---|---|
| Style | Export to .csv using ID codes |
| Data source | Aggregate and community |
| Criteria | Status: all (saved, submitted, screened, audited, finalized)<br>RSO ID#<br>Latest RSO version<br>Will export question names – answer names as columns<br>Will export answer names if user selected |
| Aggregate criteria | All |
| Data series - | All fields (Modules 1–7) |

**Table C5.10. Report 9, Report of Export Data Set – Module 8**

| Report Properties | Comments |
|---|---|
| Style | Export to .csv using ID codes |
| Data source | Aggregate and community |
| Criteria | Status: all (saved, submitted, screened, audited, finalized)<br>RSO ID #<br>Latest RSO version<br>Will export question names – answer names as columns<br>Will export answer names if user selected |
| Aggregate criteria | All |
| Data series | All fields (Module 8) |

**Table C5.11. Report 10, Report That Prints Out the RSO to a PDF File**

| Report Properties | Comments |
|---|---|
| Style | PDF |
| Data source | Only questions and answers completed |
| Criteria | Status: submitted |
| Consumers | Modules 1–6 only |
| SuperUsers - administrative | All modules (1–8) |
| SuperUsers - research | Modules 1–7 only |
| Intake administrative user | Modules 1–6 only |

**Table C5.12. Report 11, Evaluation Report (Web Traffic)**

| Report Properties | Comments |
|---|---|
| Style | Export to .csv using ID codes |
| Data source | Aggregate |
| Criteria | e-mail address, user role, page clicked, date, time, IP address |
| Aggregate criteria | All |
| Data series | All fields |

## Appendix C.6. Overview of User Profiles

Access to the Web-based system is based on user profiles. The user profile determines which modules/reports a user can access. There are six user profiles:

- SuperUser – Administrative.
- SuperUser – Research.
- Intake Administrative User.
- Consumer – Guest.
- Consumer – Registered.
- Post-Audit Review.

Table C6 provides the user profiles by privilege.

**Table C6. User Profiles by Privilege**

| Privilege | Consumer - (Registered / Guest) | Admin SuperUser - Adminis-trative | Admin Super-User - Research | Intake Admin User | Post Audit Review |
|---|---|---|---|---|---|
| Submit a new event (Modules 1–6) | Allow | Deny | Deny | Allow | Deny |
| Complete (Modules 7–8) | Deny | Allow | Allow (except status: finalize) | Allow (except status: finalize) | Deny |
| Edit existing event (saved RSOs only) | Allow (registered only) | Allow | Deny | Allow | Deny |
| Edit existing event (submitted RSOs only) | Deny | Allow | Deny | Allow | Deny |
| View and run reports (Modules 1–7 & 10) | Deny | Allow | Allow | Deny | Allow |
| View and run reports (Modules 8–9) | Deny | Allow | Deny | Deny | Deny |
| View aggregate/community type data | Deny | Allow | Allow | Deny | Deny |
| View RSO | Allow | Allow | Allow | Allow | Deny |
| Print RSO | Allow | Allow | Allow | Allow | Deny |
| Screen RSO (inclusion/exclusion criteria) | Deny | Allow | Allow | Allow | Deny |
| Audit RSO (edit/de-identify) | Deny | Allow | Deny | Deny | Deny |
| Finalize RSO | Deny | Allow | Deny | Deny | Deny |
| Flag test event | Deny | Allow | Deny | Deny | Deny |

## Appendix C.7. Frequently Asked Questions (FAQs)

The FAQs section of the Health Care Safety Hotline provides information to patients and caregivers about the hotline, including background and procedural information, as well as information on privacy and security.

### *Frequently Asked Questions (FAQs) About the Health Care Safety Hotline*

**Here are some questions that other people have asked about the Health Care Safety Hotline. The answers might help you understand the hotline.**

- What is the Health Care Safety Hotline for?
- What is a health care safety concern?
- What is a complaint?
- Who is developing the Health Care Safety Hotline?
- How are people recruited or how do they find out about the Health Care Safety Hotline?
- Why should I participate?
- What will I get if I report to the Health Care Safety Hotline?
- What are the risks of reporting a concern through the Health Care Safety Hotline?
- Do I have to participate?
- What happens to my doctor, nurse, hospital, or pharmacy if I submit a Health Care Safety Hotline report about my safety concern involving them?
- How will you protect my privacy?
- Why are you recording the reports made by phone?
- Will my report be secure when submitted over the Internet?
- How do I share a safety concern through the Health Care Safety Hotline?
- Who can I call if I have problems submitting the form online?
- Will I be able to print my form or save it on my computer?
- Can I submit other documents using this online reporting form?
- How will I know that my report has been received?
- What if I want more information?
- What if I want to tell a different organization about my health care safety concerns?

**What is the Health Care Safety Hotline for?** The purpose of Health Care Safety Hotline is to make health care better by making it safer. Researchers are testing a tool for patients and their caregivers to make reports about the safety of their care. Here is how it works: You and other patients and caregivers will tell us about any health care safety concerns you have. Researchers will then look at the safety concerns you report to see how doctors, nurses, pharmacists, and other health care providers need to make changes that will make health care safer. Also, we give you the opportunity to share your report directly with your provider if you would like to do so.

**What is a health care safety concern?** A health safety concern is anything that happens with your doctor, hospital, pharmacy, or other health care provider or facility that worries you because you think it isn't safe. It does not have to be something that resulted in harm. It does not even have to be a mistake; perhaps it was almost a mistake—we call this a "near miss." You may have a safety concern if you or a family member:

- Notice a health care provider not washing his or her hands.
- Receive the wrong medicine or the wrong dose of medicine.
- Get an infection after having an operation or other procedure.
- Get the wrong diagnosis.
- Have the wrong surgery performed.

**What is a complaint?** Complaints about parking, food, long wait times in the doctor's office, etc., usually do not affect the safety of the health care you receive, so they should not be reported to the Health Care Safety Hotline. However, if the complaint does relate to safety, it can be reported to the Health Care Safety Hotline. The Health Care Safety Hotline has a list of other places in your community where you can share your concerns, as well as places where you can report complaints.

**Who is developing the Health Care Safety Hotline?** Several organizations that want to make health care better are working together to create and test the Health Care Safety Hotline. They are the RAND Corporation, ECRI Institute, Tufts Medical Center, and Brigham and Women's Hospital. The Federal Government through the Agency for Healthcare Research and Quality (AHRQ) is paying for development of the Health Care Safety Hotline.

**How are people recruited or how do they find out about the Health Care Safety Hotline?** The doctors, nurses, hospitals, and pharmacies in your community want to make health care safer. They are helping us advertise the Health Care Safety Hotline by providing brochures, talking with patients, and communicating information about the Health Care Safety Hotline in other ways. The Health Care Safety Hotline has a secure Web site, and a toll-free telephone number is available. Information you submit to the Health Care Safety Hotline is kept private unless you give permission for it to be shared. You may enter your name, but you do not need to. Doctors, nurses, hospitals, and pharmacies will never know if you participate unless you want to tell them.

**Why should I participate?** You can share your experiences and help make health care safer for people in your community. We need to hear from many people. We need to hear about many health care experiences and concerns.

**What will I get if I report to the Health Care Safety Hotline?** You will not be paid if you choose to report information. Your report will not be sent to a health care provider unless you give us permission. You decide what will be sent and when it will be sent. If you want to send a report, you can request that it be sent anonymously or sent with your name and contact information. If you include your name and contact information, someone from the hospital or clinic may call you to discuss your report. Providers can use the reports to learn about many different types of safety concerns and will have a chance to do better. All issues are written about together; no one individual story, mistake, or name is listed. Your story may help to make health care safer.

**What are the risks of reporting a concern through the Health Care Safety Hotline?** Your health and your family's health will not be at risk if you participate. The participating health care

providers and facilities have rules that protect people who report concerns. Participation will not affect your health care or your health insurance. The Health Care Safety Hotline team will keep everything private unless you give permission for your information to be shared with a provider. If you choose to have your information shared with a health care provider or facility, you should review it and make sure you're comfortable having it shared. We also suggest that you fill out the report or talk to us on the phone in a place where you have privacy.

**Do I have to participate?** No. You do not have to participate. If you do choose to participate, you can stop providing information at any time. Some of the questions might make you feel upset. You do not have to answer all the questions.

**What happens to my doctor, nurse, hospital or pharmacy if I submit a Health Care Safety Hotline report about my safety concern involving them?** Providers that participate have a policy that they will use this information to improve safety and will not embarrass or punish your care providers. All of the health care concerns will be part of the written report that will go to doctors, nurses, hospitals, and pharmacies. They will learn about all of the types of mistakes and have a chance to do better. In the written report, all issues are written about together; no one individual story, mistake, or name is listed. Your story may help to make health care safer. If you agreed to share your report with a provider, then we will send it to that provider; if you did not agree to share your report, then your doctor, nurse, hospital, or pharmacy will receive only an overall report.

**How will you protect my privacy?** All of the reports are kept in locked file cabinets or on computers that are protected with passwords. Only a few people on the research team have access to the files and computers. If you agreed to share your report with a provider, then we will contact that provider. The Federal agency that supports the research has strict laws about patient privacy. We cannot use the information for another project unless we obtain your permission first. If you have questions about privacy, please call this telephone number: 1-800-XXX-XXXX.

**Why are you recording the reports made by phone?** If you talk to us by telephone, we will record the call to make sure that we capture everything you say correctly. The research team will listen to the recording and type the information into a computer. Then they will destroy the recording.

**Will my report be secure when submitted over the Internet?** If you fill out the form on your computer and send it to us, the report will go through a special Internet connection to make sure the report stays private. The information will be encrypted through Secure Socket Layer (SSL) using at least 128-bit encryption. We can tell you more about this and answer other questions at the toll-free number 1-888-XXX-XXXX.

**How do I share a safety concern through the Health Care Safety Hotline?** You can complete the Health Care Safety Hotline form on your computer and then send it through the Internet. Once you're on the home page for the Health Care Safety Hotline Web site, you click "Click here." There are instructions at the beginning of the form. Other instructions will pop up on your computer screen as you go through the form. Or you can call the toll-free telephone number 1-

888-XXX-XXXX to leave a message saying you would like to provide your information by phone. A staff person will then call you back and can guide you through the form in either English or Spanish.

**Who can I call if I have problems submitting the form online?** If you have questions or have problems submitting the form, please call the help-line telephone number 1-866-247-3004 to leave a message. A staff person will then call you back and can help you in English or Spanish.

**Will I be able to print my form or save it on my computer?** Yes. When you send the form to us through the Internet, you can choose to look at your report, print it, and save it as a PDF document on your computer. If you have Adobe Reader, you can view and print the report. If you have Adobe Acrobat, you can also save it.

**Can I submit other documents using this online reporting form?** No. When you send the report to us through the Internet, you cannot attach and submit other documents. If you have text in another document that you want to include, you might be able to copy the text and paste it into the form.

**How will I know that my report has been received?** You will see a message on your computer screen telling you that we have received your report. If you do not see this message, call us at the toll-free telephone number 1-888-XXX-XXXX and we can check to see if your report has been received.

**What if I want more information?** If you want to know more, call _____ at _____. Her phone number is 1-800-XXX-XXXX.

**What if I want to tell a different organization about my health care safety concerns?** Other groups also are working to make health care safer for patients. The Health Care Safety Hotline has a list of other places in your community where you can share your concern. If you have trouble locating the list, please call _____ at the _____. Her phone number is 1-800-XXX-XXXX. She can provide you with the list.

## Appendix C.8. Post-Submission Survey

This appendix presents an example of the post-submission survey for individuals who use the Web to report to the Health Care Safety Hotline.

### Final Post-Submission Survey

Thank you for using the Health Care Safety Hotline.

Please rate your experience with the hotline. Participation is voluntary and confidential. This will take less than 5 minutes.

Q1. It was easy to use the hotline

Strongly Agree Strongly Disagree Not Applicable

1……...2……3……4……5……6……7 NA

Q2. I was able to report the important details of my safety concern.

Q3. Reporting a safety concern did not take too long.

For questions Q4, Q5, and Q6, we ask your opinion about the information within the Health Care Safety Hotline, such as instructions, frequently asked questions, and definitions of terms.

Q4. The hotline information is clear.

Q5. It was easy to find the information I needed.

Q6. The organization of the information on the hotline screens is clear.

Q7. The hotline has all the functions and capabilities that I need it to have.

Q8. The hotline helped me to explain “in my own words” what happened.

Q9. I was often frustrated when answering the hotline questions.

Q10. Many of the questions asked for unnecessary information.

Q11. Overall, I am satisfied with the hotline.

Q12. I would recommend that others use the hotline if they have a safety concern.

Q13: What changes could be made to the Health Care Safety Hotline to better allow you to report a safety concern?

## Appendix C.9. Script and Instructions for Step 2 – Tracking Date, Time, and Consents via Excel Tracking Sheet

This appendix describes how to utilize the Excel spreadsheet, shown in the Instructions for Back-End Screening and Auditing of Reports (Including Excel Spreadsheets) section of the report, to track the date, time, and consents of submitted reports.

**Step 2 (Outlined in Figure C.30): Track Date, Time, and Consents**

1. Record the report ID in column A of the tracking spreadsheet. This number is in the e-mail alert (RSO) and the table of entered events on the Web site (Event ID).
2. Access the report by clicking "Edit" (to enter into the report itself) or the Adobe image (to view a PDF of the report). Record the full report ID in column B of the tracking spreadsheet using one of the following extensions:
    a. IF consent to receive **P**hone call[1] = yes

AND consent to **S**hare report with provider[2] = yes
AND consent to include name and contact **I**nformation[3] = yes
THEN add extension: "_PSI"

    b. IF consent to receive **P**hone call = yes

AND consent to **S**hare report with provider = yes
AND consent to include name and contact **I**nformation = no
THEN add extension: "_PS"

    c. IF consent to receive **P**hone call = yes

AND consent to **S**hare report with provider = no
THEN add extension: "_P"

    d. IF consent to receive **P**hone call = no

AND consent to **S**hare report with provider = yes
AND consent to include name and contact **I**nformation = yes
THEN add extension: "_SI"

    e. IF consent to receive **P**hone call = no

AND consent to **S**hare report with provider = yes
AND consent to include name and contact **I**nformation = no
THEN add extension: "_S"

    f. IF consent to receive **P**hone call = no

AND consent to **S**hare report with provider = no

---

[1] Q6.1: "May we contact you if we need more information?"

[2] Q3.3.5 or Q4.5.5: "May we share your report with the health care provider (or facility) you identified?"

[3] Q6.1.4: "When we contact the doctor, nurse, or other health care provider (or facility) to share your report, may we include your name and contact information?"

THEN add extension: "_N"

3. Record your initials in column C.
4. Record the date and time the report was received by the e-mail listserv in columns D and E. The time should be in military time and the Eastern time zone.
5. **If the patient/caregiver consented to share the report with the provider**, then add 66 hours to the date and time in which the report was received. Record this date and time in columns F and G.
    a. **If the patient/caregiver did <u>not</u> consent to share the report with the provider**, then enter "NA" in columns F and G.
6. **If the patient/caregiver consented to receive a clarification phone call**, then add 68 hours to the date and time in which the report was received. Record this date and time in columns H and I.
    a. **If the patient/caregiver did <u>not</u> consent to receive a clarification phone call**, then enter "NA" in columns H and I.
7. Access the report by clicking on "Edit," go to the Administrative Script module, and click "Screened." Click "Submit" at the bottom of the page.

## Appendix C.10. Script and Instructions for Step 3 – Auditing and Scrubbing the Report

This appendix describes exactly how to audit or scrub a report.

### Step 3 (Outlined in Figure C.30): Audit (Scrub) the Report

1. Beginning with the Introduction module of the report, review all open text fields for references to names, including names of delivery organizations, facilities, clinicians, staff, patients, and caregivers. "Scrub" all names; that is, replace the names with "XXXX."
    a. **If the patient/caregiver consented to share the report with the provider**, then do not scrub the names in questions Q2.1b,[4] Q3.3.1,[5] or Q4.5.1[6] and Q3.3.4[7] or Q4.5.4.[8]
    b. **If the report was made by a patient, and the patient consented to include his or her name and contact information with the report**, then do not scrub Q2.2[9] and Q6.1.1.[10]
    c. **If the report was made by a caregiver, and the caregiver consented to include his or her name and contact information with the report**, then do not scrub Q6.1.1. **DO, HOWEVER, SCRUB Q2.2**. Consent to share the patient name (Q2.2) can be requested during the clarification call, if the caregiver consented to such a call.
    d. If Q2.2 is being scrubbed, then record this information in the relevant columns of the tracking spreadsheet.
    e. If Q6.1.1 is being scrubbed, then record this information in the relevant columns of the tracking spreadsheet.
    f. In the tracking spreadsheet, record "scrubbed" in the column corresponding to each question that has been scrubbed.
    g. Go to the "Administrative Script" module and click "Submit" at the bottom of the page to save the scrubbing.
2. Go to the Administrative Script module of the report and click "Audited – Needs reporter/patient follow-up." Click "Submit" at the bottom of the page.
3. **If the patient/caregiver consented to share the report with the provider**, then send the following e-mail to ____ by the date and time in columns F and G:

---

[4] Q2.1b: "Where do you believe it happened?"

[5] Q3.3.1: "Please write the name and address of the health care provider (or facility) involved in the mistake."

[6] Q4.5.1: "Please write the name and address of the health care provider (or facility) involved in the negative effect."

[7] Q3.3.4: "Please write the name and address of the second health care provider (or facility) involved in the mistake."

[8] Q4.5.4: "Please write the name and address of the second health care provider (or facility) involved in the negative effect."

[9] Q2.2: "What is the name of the patient?"

[10] Q6.1.1: "Please tell us your name and your address, telephone number, or e-mail."

“Hi [_____ team member name],

The Health Care Safety Hotline received RSO [number] on [month day] at [time] Eastern. I reviewed the report and scrubbed [number of text fields] text fields that contained names.

The report is ready to be shared with the relevant health care organization.

Please let me know if you have any questions.

Thanks,
[Your name]”

4. In the tracking spreadsheet, record “999” in the column that corresponds to each question that the patient/caregiver did not answer but should have answered, given the skip patterns.
5. If the patient/caregiver appears to have “broken off” the survey (i.e., did not answer several questions at the end of the survey), then record “yes” in the relevant column of the tracking spreadsheet.
6. **If the patient/caregiver did <u>not</u> consent to receive a clarification call**, then go to the Administrative Script module of the report and click “Audited – Needs Team Decision (Free Text Reviewed and Sanitized).” Click “Submit” at the bottom of the page. Go to Stage 4 below.

## Appendix C.11. Script and Instructions for Stage 3 – Clarification Call

This appendix describes exactly how to clarify a report.

1. **If the patient/caregiver consented to receive a clarification call**, then save HCSH_Clarification_Script_RSOXX.doc with the relevant RSO number in the file name.
2. Read the full report and identify any inconsistencies or issues needing clarification.
    a. In the clarification script, highlight questions needing clarification. Add probes below the questions and highlight the probes.
    b. Highlight any questions that the patient/caregiver did not answer but should have answered, given the skip patterns.
    c. If the patient/caregiver appears to have "broken off" the survey (i.e., did not answer several questions at the end of the survey), then highlight the Section 7 questions.
    d. If the report was made by a caregiver, then highlight Q2.2 and add the following probe: "We have that you would like us to share your report with the health care provider or facility that you identified, and that you would like us to include your name and contact. If we also include the patient's name, it will be easier for the provider or facility to identify the problem. May we share the patient's name?"
3. Complete section 1 of the classification form (HCSH_Classification_Form_v5.docx) and record a team clinician's name (Michael Smith or Eric Newman) in question 1 of section 2. Select the clinician who is next in the cycle. In the tracking spreadsheet, record the clinician's name in column J.

4. Send the following e-mail to the assigned clinician by the date and time in columns H and I:

> Hi [clinician name],
>
> The Health Care Safety Hotline received a report on [month day] at [time] Eastern. We would like you to review the report, add probes to the clarification call script, and return the clarification call script and classification form to me by no later than [48 hours after e-mail is sent] so that we can complete the clarification call on time. Please let me know if this deadline is not doable with your schedule.
>
> Please do the following by [48 hours after e-mail is sent]:
> 1. Review the report (1st attachment)
> 2. Highlight questions and add probes to the clarification call script, starting on page 5 (2nd attachment). Please be especially thoughtful about any probes that may be needed to classify the type, harm/severity, duration of harm, preventability, and contributing factors. You'll see that I have taken a first pass at highlighting questions and adding probes.
> 3. E-mail the revised clarification call script to me.
>
> Please let me know if you have questions.
>
> Thanks,
> [Your name]

5. In column K of the tracking spreadsheet, record the date that you sent the e-mail to the assigned clinician.
6. When the clinician returns the revised clarification call script and the classification form, record the date in column L of the tracking spreadsheet.
7. In column M of the tracking spreadsheet, record the initials of the person who will be completing the clarification call. Most of the time, you will complete the clarification calls for the reports that you process.

8. Make five attempts to complete the clarification call. Use column N for notes about each attempt. The last attempt should take place no later than 10 days after the report was received by the e-mail listserv (see columns D and E).
    a. If the patient/caregiver is reached and agrees to complete the clarification call:
        i. Walk the patient/caregiver through the clarification call script. Enter the patient/caregiver's responses into the script. Audio record the call and password-protect the audio recording.
        ii. Record the questions and answers in the Comments/Clarifications module of the report. Go to the Administrative Script module and click "Audited – Needs Team Decision (Free Text Reviewed and Sanitized)" and "Clarified (Questions answered by reporter team; Ready for matching to provider)." Click "Submit" at the bottom of the page.
        iii. Enter the date of the clarification call in column O of the tracking spreadsheet.
        iv. Record "clarified" in the relevant columns of the tracking spreadsheet.
        v. Send the following e-mail to _____:

> Hi [_____ team member name],
>
> I completed the clarification call for RSO [number] and have recorded notes from the clarification call in the Comments/Clarification module of the report.
>
> The updated report is ready to be shared with the relevant health care organization.
>
> Please let me know if you have any questions.
>
> Thanks,
> [Your name]

    b. If the clarification call does not take place, then go to the Administrative Script module of the report and click "Audited – Needs Team Decision (Free Text Reviewed and Sanitized)." Click "Submit" at the bottom of the page.
9. Record the disposition of the attempts to complete the clarification call in column P.

## Appendix C.12. Clarification Call Instructions and Script Samples

A clarification call with the reporting patient or caregiver may be necessary to provide the most accurate and complete information in the report. The purpose of this call is to ensure that all the facts within the report are clear and easy to understand when the report is passed on to the health care organization for review. The clarification call may also gather any other necessary information or consent to process the report.

When the report is initially received and processed, it should be reviewed for clarity and consistency. Questions related to the specifics of the report should be noted and added to a clarification call script. Any questions added to the clarification script are highlighted in yellow.

Clarification questions can be broad, especially when more information about the event itself is necessary (see Figure C12.1). In Figure C12.1 the example clarification questions are highlighted in yellow.

**Figure C.12.1. Examples of Broad Clarification Questions**

**2.1** **We have the following information about the safety concern.** [READ WHAT WAS IN THE TEXT BOX]

*12.1* *Could you please clarify in your own words:*
*What happened?*
*Where do you believe it happened?*
*When did it happen?*
*Why do you think this happened?*

*Q: Can you tell me a little more about the event itself?*

*Q: Can you describe your symptoms at the clinic? When did they start? When did they improve?*

*Q: What actions would have been sufficient in maintaining a safe environment for you?*

Clarification questions may also be very specific, especially when the focus of the report is much more narrow (see Figure C.12.2).

**Figure C.12.2. Example of a Narrower Clarification Question**

**2.1** **We have the following information about the safety concern.** [READ WHAT WAS IN THE TEXT BOX]

*12.1* *Could you please clarify in your own words:*
*What happened?*
*Where do you believe it happened?*
*When did it happen?*
*Why do you think this happened?*

*Q: Do you know the name of the specific medication?*

*Q: Approximately what time was the medication given?*

An individual with a medical background should review all clarification questions. This helps to ensure that the questions being asked of the reporting patient or caregiver will clarify confusing or unclear aspects of the report as it pertains to patient safety and appropriate care. In Figure C12.2 the example clarification questions are highlighted in yellow.

When the administrator has reviewed all clarification questions with the reporter, answers to the questions, as well as the questions themselves, should be added back into the RSO in the Comments/Clarification section.

## Appendix C.13. Classification Form

The Health Care Safety Hotline classification form provides insight into the incident after the report has been completed. The classification form attempts to categorize the type of reported incident, assigning a level of harm, preventability, contributing factors, and incident type. This form should be filled out by the reviewing physician.

### Health Care Safety Hotline
### Classification of Reported Safety Occurrence (RSO)

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**1. BASIC INFORMATION ABOUT RSO**
(TO BE COMPLETED BY THE PERSON WHO "SCREENED AND SCRUBBED" THE RSO)

Reported safety occurrence (RSO) #: ____
Date/time RSO submitted to HCSH Web site: _____
Name of person who "screened and scrubbed" RSO: _____
Date person who "screened and scrubbed" RSO e-mailed classification request to person who conducted the initial classification: _____

---

**2. INITIAL CLASSIFICATION (BEFORE CLARIFICATION CALL)**
(TO BE COMPLETED BY THE PERSON WHO IS CONDUCTING THE INITIAL CLASSIFICATION)
**Directions: Please use the information provided in the RSO, as well as your own clinical knowledge, in completing the initial classification.**

Name of person who is conducting initial classification: _____

AHRQ Common Formats Event Type (Version 1.2):

___ **Incident**: A patient safety event that reached a patient and resulted in either no harm (no-harm incident) or harm (harm incident). The concept "reached a patient" encompasses any action by a health care practitioner or worker or health care circumstance that exposes a patient to harm.
Example: If a nurse gives a patient an incorrect medication to take and the patient recognizes it as such and refuses to take it, an incident has occurred.

___ **Near miss:** An event that did not reach a patient. **[SKIP TO QUESTION #6]**
Examples: Discovery of a dispensing error by a nurse as part of the process of administering the medication to a patient (which if not discovered would have become an

incident); discovery of a mislabeled specimen in a laboratory (which if not discovered might subsequently have resulted in an incident).

___ **Unsafe condition**: Any circumstance that increases the probability of a patient safety event; includes a defective or deficient input to or environment of a care process that increases the risk of an unsafe act, care process failure or error, or patient safety event. An unsafe condition does not involve an identifiable patient. **[SKIP TO QUESTION #6]** For example, an out-of-date medicine on a shelf represents an unsafe condition. The medicine might be given to a patient, but the identity of such patient is unknown at the time of discovery. The attempt to administer the out-of-date medicine to a patient would represent either a near miss (if not administered) or an incident (if administered).

AHRQ Common Formats Harm Scale (Version 1.2)

___ **Death**: Dead at time of assessment.

___ **Severe harm**: Bodily or psychological injury (including pain or disfigurement) that interferes significantly with functional ability or quality of life.

___ **Moderate harm**: Bodily or psychological injury adversely affecting functional ability or quality of life, but not at the level of severe harm.

___ **Mild harm**: Minimal symptoms or loss of function, or injury limited to additional treatment, monitoring, and/or increased length of stay.

___ **No harm**: Event reached patient, but no harm was evident. **[SKIP TO QUESTION #6]**

___ **Unknown**

AHRQ Common Formats Duration of Harm (Version 1.2)

___ **Permanent** (one year or greater)

___ **Temporary** (less than one year)

___ **Unknown**

Preventability: _____
_____
_____
_____

Contributing factors: _____
_____
_____
_____.

**In addition to the narrative above, please also select any contributing factors below.**

***Communication with doctors, nurses or other health care providers***

Was it because the doctors, nurses, or other health care providers…

___A did not listen to the patient?
___B did not explain things to the patient in the patient's language?
___C used terminology the patient could not understand?
___D spoke with an accent that was hard to understand?
___E did not spend enough time with the patient?
___F ignored what the patient told them?
___G did not explain medications or their side effects?
___H did not provide a clear explanation of the diagnosis or care plan?
___I did not explain follow-up care instructions?

***Responsiveness of staff***

Was it because of not getting…

___A help as soon as the patient needed it?
___B a referral as soon as the patient needed it?
___C an appointment as soon as the patient needed it?
___D care as soon as the patient needed it?

***Coordination of care***

Was it because…

___A the doctors, nurses, or other health care providers were not aware of care that took place someplace else?
___B of the lack of follow-up by the doctors, nurses, or other health care providers?
___C doctors, nurses, or other health care providers did not seem to work well together as a team?

***Access***

Was it because the patient…
___A was not able to get in to see a specialist for care?
___B was not able to get the tests or treatments that the patient believed necessary?
___C was not able to get the tests or treatments that a provider believed necessary?
___D did not get help or advice he or she needed?

***Verification***
Was it because someone did not…
___A correctly identify the patient?
___B have the most recent and up-to-date information about the patient?

***Other***
Was it because the patient…
___A couldn't afford the care the patient believed necessary?
___B couldn't afford the care a provider believed necessary?
___C had no insurance to pay for the care the patient believed necessary?

---

**3. FINAL CLASSIFICATION (AFTER CLARIFICATION CALL)**
(TO BE COMPLETED BY THE PERSON WHO CONDUCTED THE INITIAL CLASSIFICATION)

**Directions: Please use the information provided in the RSO (including the information gained from the clarification call), as well as your own clinical knowledge, in completing the final classification.**

IF YOU DO NOT RECOMMEND ANY CHANGES TO THE INITIAL CLASSIFICATION, PLEASE MARK AN 'X' HERE: __

AHRQ Common Formats Event Type (Version 1.2):

___ **Incident**: A patient safety event that reached a patient and resulted in either no harm (no-harm incident) or harm (harm incident). The concept "reached a patient" encompasses any action by a health care practitioner or worker or health care circumstance that exposes a patient to harm.
Example: If a nurse gives a patient an incorrect medication to take and the patient recognizes it as such and refuses to take it, an incident has occurred.

___ **Near miss:** An event that did not reach a patient. **[SKIP TO QUESTION #6]**

Examples: Discovery of a dispensing error by a nurse as part of the process of administering the medication to a patient (which if not discovered would have become an incident); discovery of a mislabeled specimen in a laboratory (which if not discovered might subsequently have resulted in an incident).

___ **Unsafe condition**: Any circumstance that increases the probability of a patient safety event; includes a defective or deficient input to or environment of a care process that increases the risk of an unsafe act, care process failure or error, or patient safety event. An unsafe condition does not involve an identifiable patient. **[SKIP TO QUESTION #6]** For example, an out-of-date medicine on a shelf represents an unsafe condition. The medicine might be given to a patient, but the identity of such patient is unknown at the time of discovery. The attempt to administer the out-of-date medicine to a patient would represent either a near miss (if not administered) or an incident (if administered).For example, an out-of-date medicine on a shelf represents an unsafe condition. It might be given to a patient, but the identity of such patient is unknown at the time of discovery. The attempt to administer the out-of-date medicine to a patient would represent either a near miss (if not administered) or an incident (if administered).

AHRQ Common Formats Harm Scale (Version 1.2)

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___ **Severe harm**: Bodily or psychological injury (including pain or disfigurement) that interferes significantly with functional ability or quality of life.

___ **Moderate harm**: Bodily or psychological injury adversely affecting functional ability or quality of life, but not at the level of severe harm.

___ **Mild harm**: Minimal symptoms or loss of function, or injury limited to additional treatment, monitoring, and/or increased length of stay.

___ **No harm**: Event reached patient, but no harm was evident. **[SKIP TO QUESTION #6]**

___ **Unknown**

AHRQ Common Formats Duration of Harm (Version 1.2)

___ **Permanent** (one year or greater)

___ **Temporary** (less than one year)

___ **Unknown**

Preventability: _____

_____

_____

_____

Contributing factors: _____

_____

_____

_____

**In addition to the narrative above, please also select any contributing factors below.**

***Communication with doctors, nurses or other health care providers***

Was it because the doctors, nurses, or other health care providers…

___A did not listen to the patient?

___B did not explain things to the patient in the patient's language?

___C used terminology the patient could not understand?

___D spoke with an accent that was hard to understand?

___E did not spend enough time with the patient?

___F ignored what the patient told them?

___G did not explain medications or their side effects?

___H did not provide a clear explanation of the diagnosis or care plan?

___I did not explain follow-up care instructions?

***Responsiveness of staff***

Was it because of not getting…

___A help as soon as the patient needed it?

___B a referral as soon as the patient needed it?

___C an appointment as soon as the patient needed it?

___D care as soon as the patient needed it?

***Coordination of care***

Was it because…

___A the doctors, nurses, or other health care providers were not aware of care that took place someplace else?

___B of the lack of follow-up by the doctors, nurses, or other health care providers?

___C doctors, nurses, or other health care providers did not seem to work well together as a team?

***Access***

Was it because the patient…

___A was not able to get in to see a specialist for care?

___B was not able to get the tests or treatments that the patient believed necessary?

___C was not able to get the tests or treatments that a provider believed necessary?

___D did not get help or advice he or she needed?

***Verification***

Was it because someone did not…

___A correctly identify the patient?

___B have the most recent and up-to-date information about the patient?

***Other***

Was it because the patient…

___A couldn't afford the care the patient believed necessary?

___B couldn't afford the care a provider believed necessary?

___C had no insurance to pay for the care the patient believed necessary?