CARES Quality Assurance

The CARES quality assurance process is one of the strengths of the registry, as a number of measures are taken to ensure the integrity and cleanliness of the data. These measures include standardized training of all CARES users, built-in software logic, an automated audit algorithm ensuring data validation across the entire registry and a bi-annual assessment of population coverage, survival data and case ascertainment.

Training

In an effort to reduce the number of data entry errors, EMS and hospital personnel receive extensive training on the CARES data elements. This training includes a one-on-one session with a CARES Program Associate prior to being granted access to the software with a unique username and password. EMS and hospital users are also provided with a detailed CARES data dictionary, a list of frequently miscoded data elements, user guides and other tools to further support training of participants.

Software Logic

Logic is incorporated into the software to minimize the number of incomplete fields and implausible data entries. A list of these items is found in Appendix A.

Automated Audit

In order to provide consistent data validation across the registry, each CARES record is reviewed for completeness and accuracy through an audit algorithm. Automated audits occur on a monthly basis, after a 2-month lag in data entry (for example, January records are reviewed in March) to allow for the entry of hospital outcomes. Once the record is processed through the algorithm, data entry errors are "flagged" for review by EMS and hospital users (as appropriate) and CARES staff. Examples of frequently miscoded elements can be found in Appendix B. The automated audit covers both required and supplemental fields. For supplemental fields, the audit can be customized to those data elements that the individual agency chooses to collect.

Once any data entry errors are resolved and the record is complete and accurate, the record is "scrubbed" by removing patient identifiers such as name and date of birth. In addition to the automated data validation, each EMS agency is asked to confirm their non-traumatic call volume to ensure that we are capturing all arrests in a defined geographic area. The volume of OHCA per month is compared with historic monthly volumes; when a substantial drop in the number of events occurs, the EMS contact is notified to determine if the variation was real or the result of a lag in the data-entry process.

CARES staff also review outstanding hospital outcomes on a quarterly basis. Hospitals with a large number of old or outstanding records are identified and contacted to prompt outcome entry. This helps prevent a back-log of records, and ensures that EMS agencies are able to run up-to-date, accurate reports. Occasionally, hospitals may have difficulty locating the outcome for a patient transported to their facility. In these cases, CARES staff provides the EMS and hospital user with a "lost to follow-up" protocol to minimize the number of outstanding hospital outcomes.

Finally, aggregate data is analyzed on a regular basis to look for agency-specific anomalies. CARES staff utilize site-by-site comparison tables to look for outliers, and also compare each agency's data with the national average.

As the registry expands at the state-level, CARES staff works closely with state Program Coordinators to conduct training on all quality assurance measures. State coordinators receive extensive training on EMS and hospital web demos, as well as the CARES audit process.

Bi-Annual Assessment

In addition, CARES conducts an assessment twice a year of agency contact information, population coverage, survival data and case ascertainment. CARES staff and state coordinators provide each EMS agency's geographic coverage, census population and start date via a standardized Excel template. This information is then linked with survival data and record volume, by etiology, to identify outliers across the entire registry. In the event that an outlier is identified, CARES staff or the state coordinator works closely with the EMS agency to identify any issues in the data collection process and resolve as needed.

APPENDIX A. Direct Data Entry Software Logic

- Blank required fields are flagged when an EMS or hospital user saves a record.

- Date of Arrest and Date of Birth cannot be a future date.

- If "Other" is selected as the arrest location or presumed arrest etiology, the EMS user is prompted to specify the location or etiology in a free text field.

- If an arrest is entered as unwitnessed, but after the arrival of a 911 Responder, the user is prompted that this is conflicting information.

- If a user indicates that resuscitation was not attempted by a 911 Responder, but CPR, defibrillation, or transport occurred, they are prompted that this is conflicting information.

- If a question is not applicable, it grays out so it cannot be answered. For example, if "Who Initiated CPR = Responding EMS", "Type of Bystander CPR Provided" is grayed out.

- If a shockable rhythm is indicated, but no defibrillation occurred, the user is prompted that this is conflicting information.

- If discharge location and CPC score conflict (i.e. patient is discharged home in a coma), the hospital user is asked to clarify in the comments box.

APPENDIX B. Frequently Miscoded Data Elements

- Check for duplicate records.

- Check for blank fields.

- Confirm questionable ages (>100).

- If End of Event is coded "Pronounced in the ED" or "Ongoing Resuscitation in ED", Destination Hospital should be selected.

- If End of Event is coded "Pronounced in the Field" or "Effort ceased due to DNR", Destination Hospital should be blank.

- If "Other" is selected as the location type, confirm that the free text field does not correspond with one of the other answer choices.

- If an arrest occurs after the arrival of a 911 Responder, it cannot be unwitnessed.

- "Resuscitation attempted by a 911 Responder" should be "Yes" if any of the following occurred: CPR by a 911 professional, defibrillation by anyone, and/or transport by a 911 Responder.

- If Who Initiated CPR is "Not Applicable", confirm with EMS agency that CPR was not performed.

- If arrest was after arrival of 911 Responder, it is unlikely that a lay person initiated CPR, applied an AED, or defibrillated the patient.

- If Responding EMS initiated CPR, it is unlikely that a First Responder would apply an AED and/or defibrillate the patient.

- The AED/Defibrillation section is checked for conflicting information regarding AED application prior to EMS arrival and defibrillation of the patient. For example, if "Was an AED applied prior to EMS arrival" is answered "Yes, with defibrillation", "Who First Defibrillated the Patient" should not be "Not Applicable" or "Responding EMS Personnel".

- If EMS was first to place a device on the patient, first arrest rhythm should not be "unknown shockable" or "unknown unshockable", as EMS likely has recording ability.

- If the patient was found in a shockable rhythm, lack of defibrillation is confirmed.

- If End of Event is "Pronounced in the Field", Sustained ROSC should not be coded as "Yes, pulse at end of EMS care".