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Data Capture and Analysis of Signs and Symptoms in a Chemically Exposed Population

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Abstract

This manuscript provides a practical case study to demonstrate data collection from paper-based medical records so that the occurrence of specific signs/symptoms indicative of a chemical exposure can be studied.

Keywords

Triage; chemical exposure; mass casualty

The requirement that healthcare providers adopt meaningful use of electronic medical records (EMR) (U.S. Department of Health and Human Services [DHHS], 2010) can be helpful to improve clinical care and advance research. However, such technological advances should not encourage the medical community to discount the many decades of extant medical records that have been collected with standardized paper-based methods. Many clinical lessons could be learned if informatics tools are utilized to help researchers study such historical paper-based records that have yet to be imported into any standardized EMR. Towards those ends, chart abstraction tools have been developed successfully to study important clinical issues, such as maternal death (Eftekhar-Vaghefi, Foroodnia, & Nakhaee, 2013), surgical intervention (Boatright et al., 2013), and heart failure mortality (Lee et al., 2012). However, making sense of the abstracted information is sometimes a challenge.

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One way to overcome the challenge of working with unstructured abstracted EMR data is through the development and use of novel informatics data algorithms. Informatics algorithms have been used to develop clinical best practices (Beitz & van Rijswijk, 2012), an emergency department early warning system (Nannan Panday, Minderhoud, Alam, & Nanayakkara, 2017), an asthma clinical assessment (Dexheimer et al., 2014), and deliriumdiagnostic tools (Kuhn et al., 2014). However, few studies have tried to improve triage of mass casualty incidents (MCIs) by using abstracted EMR data and informatics algorithms (Griffiths, Estipona, & Waterson, 2011). Additional research is needed to help leverage the wealth of information in archived paper medical records for use in triage studies and public health preparedness.

Acute chemical exposures occur daily across the USA (Culley et al., 2017). The difference between life and death may be contingent on the rapid identification of a chemical agent before appropriate triage/treatment can be performed, especially in MCIs. Many communities do not have the resources to respond to MCIs. All hospitals should be prepared for MCls and the associated surge into the ED, even for chemical events. Hospital preparedness has improved significantly in recent years, yet much work is still needed (Kim, 2016).

South Carolina experienced a tragic MCI in 2005 that severely taxed local resources. In the early morning hours of January 5, 2005, two trains collided in Graniteville, SC, releasing an estimated 42–60 tons of chlorine gas into the environment. This resulted in the death of nine people and sent hundreds to local community hospitals (Craig, Culley, Tavakoli, & Svendsen, 2013; Culley & Svendsen, 2014; Culley, Svendsen, Craig, & Tavakoli, 2014; Van Sickle et al., 2009).

The objective herein is to demonstrate how to execute data mapping and interpretation from abstracted archival medical records such that the occurrence of signs/symptoms can be studied within a population exposed to a chemical MCI. The research team used clinical data from the primary hospital impacted by the 2005 Graniteville chlorine disaster to accomplish this goal.

Methods

Study Population

Prior research based on the Graniteville incident indicated that there were no informatics tools available to rapidly detect chemical exposures from presenting symptoms and to quickly identify the most critical patients during a patient surge into a hospital emergency department (Craig et al., 2013; Culley & Svendsen, 2014; Culley et al., 2014; Van Sickle et al., 2009). The team previously found that:

1. Limited hospital data were available for study
2. Key data elements were often missing from the clinical records for many patients (Craig et al., 2013).

At the time of the Graniteville incident, medical records for the patients treated in the emergency department at the Regional Medical Center indicated that multiple paper forms (about 25) were used for data capture.

The standard clinical forms used during the incident were cumbersome and inefficient for quickly processing patients during a surge. The clinicians were rightly focused on saving patients' lives and not completing paperwork. Many patient records held copious notes within the margins and free-text fields rather than completed check boxes and data fields. Such unstructured data require sophisticated strategies to extract useful data for subsequent research.

Clinical Datasets

Data for 198 Graniteville patients seen in the emergency department following the chlorine incident were abstracted from the hospital records at the Regional Medical Center closest to the disaster and most impacted by the immediate surge of patients. The dataset included 146 patients treated during the 2005 chlorine exposure surge as well as 52 patients that received treatment not related to the exposure.

Data Abstraction Overview

The goal of the data abstraction process was to safely archive and protect the clinical data for future research with an easy to use interface for abstractors to record the data electronically. Medical coders from a regional medical center completed the data abstraction using a Health Insurance Portability and Accountability Act (HIPAA) compliant internet-based data system. The abstractors excluded patient identifiers and utilized a unique patient ID for each patient when entering the data into the database.

Human Subjects Protection

The Office of Research Compliance at the University of South Carolina reviewed the study and determined the study to be exempt from the Protection of Human Subjects Regulations. The academic research team was only provided de-identified clinical data.

Database Design

Research Electronic Data Capture (REDCap), an open source application, was chosen for data collection (Harris et al., 2009). REDCap is a mature, secure, internet-based application for building and managing online research surveys and databases. While REDCap can be used to collect virtually any type of data, it is specifically geared to support data capture for research studies, especially those including human subjects because it is encrypted and HIPAA compliant. REDCap can be accessed by a web browser and provides the ability to:

- Map clinical forms to REDCap forms
- Store and backup the data
- Manage user access
- Hide or remove patient identifiers
- Eliminate the need for paper copies or electronic spreadsheets

Furthermore, REDCap has integrated reporting, import/export features, and the ability to perform simple statistics. The export feature allows the user to save the project in the format expected by leading statistical software packages for further analysis, such as SAS®9.4 software (SAS Institute Incorporated, 2013).

To simplify the abstraction process for this study, internet-based forms were created using REDCap to match the format and flow of the clinical paper forms used during the actual disaster. Furthermore, the internet-based form names corresponded to the clinical form name, the field labels and data type were matched as closely as possible. For example, if the clinical form had check boxes, the electronic version would have check boxes with the same choices. Short text field types were used for a short-written response; note field types were used for longer responses that appeared in a nurse or physician note. A section for additional information was provided on all electronic forms allowing the abstractor to place information found in the margins of the paper versions. Figure Figure 1 includes an example of one of the original paper forms while Figure 2 shows a portion of the same form created using REDCap matched to the sections from the original paper form (see Figures Figure 1 and 2).

The Graniteville clinical database design efforts used the following steps:

1. Gather unique set of paper forms used for all included patients
2. Create REDCap project for the development of clinical forms
3. Develop REDCap forms to match paper clinical forms
4. Finalize REDCap forms and their order
5. Manage REDCap users and roles
6. Test REDCap project forms
7. Place REDCap project in production
8. Abstract de-identified clinical data (medical records staff from the Regional Medical Center)
9. Continually monitor the data abstraction process for any issues or problems
10. Immediately resolve any issues or problems with the research team
11. Analyze abstracted clinical data
12. Map clinical data to chemical exposure signs/symptoms tools

Data Testing and Collection

After the REDCap forms were created, medical coders from the Regional Medical Center tested the internet-based forms by extracting information from the paper clinical forms and then entering the data into the REDCap forms. REDCap modifications were made as needed to improve form layout, help text, and field type. Project settings were set to mimic the order of paper forms observed in the medical record files. Once testing was complete, the REDCap project was placed in a production status. At this point, the medical coders completed the forms for 198 patients. During data entry, the research team monitored the data for quality allowing the coders the opportunity to correct errors in a timely manner.

Data Mapping

One goal for the subsequent analysis of these data was to identify any features, patterns, and parameters that enable the most sensitive and reliable patient triage during a chemical inhalation MCI. A first step was to record if specific signs/symptoms that could be assessed as indicators of chemical exposure were present or not. The signs/symptoms evaluated were identified by the Wireless Information System for Emergency Responders (WISER) (U.S. National Library of Medicine, 2015)and/or Chemical Hazards Emergency Medical Management Intelligent Syndromes Tool (CHEMM-IST) (DHHS,2015) developed by the National Library of Medicine. WISER and CHEMM-IST are systems designed to assist emergency responders during hazardous material incidents in their patient assessment and triage following chemical exposure events. Therefore, the team mapped the abstracted clinical data to the 93 signs/symptoms used by the WISER and CHEMM-IST tools. WISER includes 79 signs/symptoms and CHEMM-IST includes 14 possible signs/symptoms.

Findings

Simple descriptive data analysis using REDCap reporting capabilities was performed to investigate if specific signs/symptoms were present or not within the clinical data. The team initially found that many of the expected items of interest (the signs/symptoms) were stored in "note" fields and not in the discrete data field(s) on the clinical data forms. To mitigate this challenge, software developed by the research team (Culley et al., 2017) was used to extract the data from the freeform text fields and transform them into a single set of Y/N answers identifying if a victim had a specific sign or symptom. Database tables were used to map the many REDCap data fields into the expected response for WISER and CHEMM-IST. After the team was satisfied that the mapping was complete and accurate, the software created a spreadsheet for WISER and for CHEMM-IST that contained the results of the data mapping and linkage rules. The data were imported into the REDCap project for future analysis and reporting. The team used the following data rules:

> Rule 1: If any REDCap field indicated the sign/symptom was present, then the final sign/symptom would be "Yes."
>
> Rule 2: The sign/symptom must be present on the day of the event.

The following example is included to explain how the mapping process was implemented and to demonstrate the decisions the team made regarding mapping observed data to the CHEMM-IST and WISER signs/symptoms. Two database mapping tables were used to generate the sign/symptom import files. The first mapping table defined the relationship between the REDCap fields and the CHEMM-IST or WISER sign/symptom. For example, the REDCap column for the appearance of skin was mapped to the CHEMM-IST question "Irritated or Burning Skin?" and to the WISER symptom "Skin: skin burns/burning." The second table mapped the recorded REDCap value to the CHEMM-IST or WISER sign/symptom decision. This particular REDCap column for the appearance of skin had a REDCap recorded response of 1 for Normal or 2 for Abnormal. The second mapping table had multiple rows for each REDCap value (i.e., 1, 2) mapped to the CHEMM-IST or WISER sign/symptom assessment. For example, a Normal REDCap value for skin appearance was mapped to the CHEMM-IST "Irritated or Burning Skin?" symptom and WISER "Skin: skin burns/burning" symptom as 0 for "No," while an Abnormal REDCap value for skin appearance was mapped to CHEMM-IST "Irritated or Burning Skin?" as 2 for "Can't Assess" and not mapped to the WISER "Skin: skin burns/burning" sign/symptom. In all decisions, the team chose the conservative option and made no assumptions. Fortunately, most signs/symptoms could be pulled from multiple REDCap forms.

Data Algorithm Validation

To validate the mapping algorithm, the team mapped four victims manually using all abstracted information. The results of the mapping algorithm were then compared with the four manually mapped victims. When the algorithm results matched the manually entered values, the team was satisfied that the data mapping was ready for import. The match of the manually entered sign/symptom choices was in 100% agreement with the algorithm, meaning the algorithm selection of Y/N/Can't Assess or null (i.e., no information) matched exactly to the manually entered choices. WISER and CHEMM-IST assessment values for each victim were then imported into the REDCap project and placed into a single form for later analysis with the statistical software package, SAS® software. Figure 3 contains all 14 of the CHEMM-IST signs/symptoms and state of alertness and seven of the 79 WISER signs/symptoms from the REDCap form (see Figure 3). The form displays the imported data created with the mapping process and allows the research team to easily view and correct any of the imported items without changing any abstracted data. For example, the team discovered a few REDCap fields were mapped for CHEMM-IST that should have been mapped to WISER. Using the reporting tools, the team could easily obtain a list of the patients who had values for the specific columns and make corrections as needed.

Results

Abstracted Database

Data for 198 Graniteville patients were successfully captured using REDCap and summarized in the effort to develop a new chemical exposure triage algorithm for use by emergency department personnel. Table1 shows the counts for the resulting CHEMM-IST signs/symptoms (see Table 1). Out of 198 cases, the team found 10 cases where nothing was recorded for any of the REDCap fields that contained the state of alertness, seven where the state of alertness was "Altered," two where the state of alertness was "Anxious," 176 where state of alertness was "Awake," and three where the victim was "Unconscious." CHEMM-IST has three categories for the assessment: "Yes" where the sign/symptom was found, "No" where the sign/symptom was clearly not found, and "Can't Assess" where there was information related to the sign/symptom but not enough to clearly state "Yes" or "No." When there was no information at all related to the sign/symptom, the assessment was mapped to null for no information.

Similarly, Table 2 shows the counts for 17 of the 79 WISER signs/symptoms (see Table2). WISER had binomial responses of Yes where the sign or symptom was found or No where the sign or symptom was clearly not found. The heading No Information means there were no data to indicate a Yes or No evaluation for the presence or absence of the sign or symptom.

Discussion

Using REDCap as the data capture tool for the Regional Medical Center paper forms worked well. The reporting tools in REDCap allowed the team to easily explore the data. The dashboard view allowed a visual identification of the forms that were used most often. Having the data in an electronic form allowed the team to develop and use tools and software outside of REDCap to create the import files for WISER and CHEMM-IST signs/symptoms. The team took advantage of REDCap roles to protect the abstracted data from modification, while allowing modification to forms created for team use. The data was successfully used in development of a triage algorithm that serves as the basis for the triage logic in a mobile application (Culley et al., 2018). The mobile application, intended for use by emergency department personnel, incorporates the new triage algorithm and allows for evaluation of collected data across patients to quickly identify a surge of patients and to make triage recommendations based on the identified class of a chemical.

Public Health/Clinical Significance

During large-scale MCIs, many hospitals and first responders continue to use paper-based forms as a back-up plan if computers are not available or to expedite the collection of data. Developing methods to abstract unstructured data from historical paper-based records as well as from forms used during public health emergencies is the first step in developing new informatics tools with the potential to revolutionize the process by which public health personnel/emergency department clinicians manage the triage and care of victims of chemical incidents.

Conclusions

REDCap proved to be an excellent data capture tool for data abstraction and protection of historical extant medical records that were collected with standardized, but sometimes unstructured and cumbersome, paper-based methods. The mapping method was configurable, repeatable, and accurate in development of derived information. Many clinical lessons can be learned if informatics tools are employed to help researchers abstract the information available in these unstructured formats. Additional research is needed to help leverage the wealth of information in archived paper medical record data for use in triage studies and public health preparedness.

Acknowledgments

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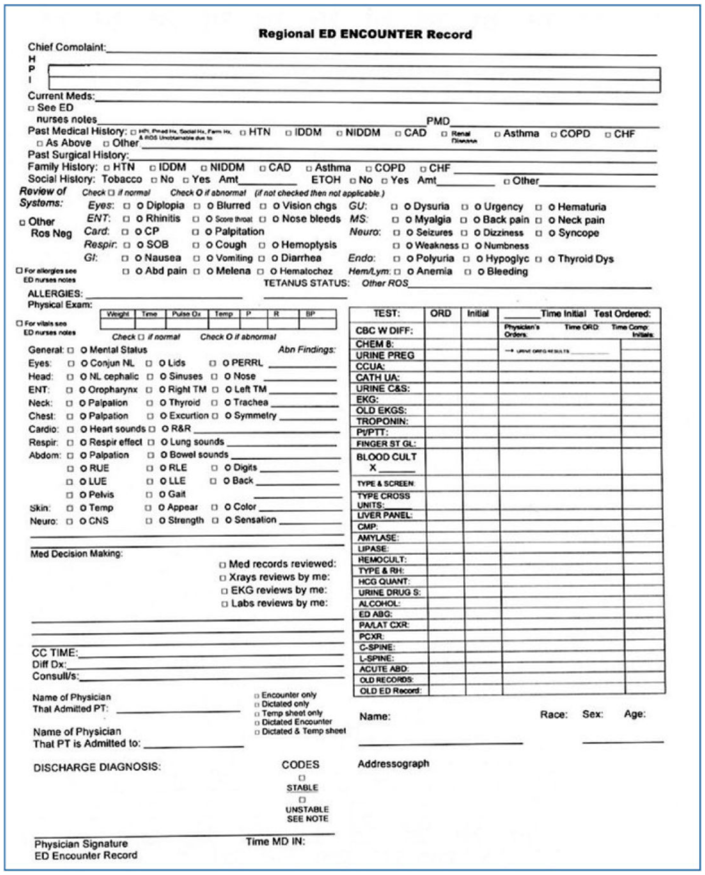


Regional ED ENCOUNTER Record

Chief Complaint:
H
P
I
Current Meds:
□ See ED nurses notes PMD
Past Medical History: □ HTN □ IDDM □ NIDDM □ CAD □ Renal Disease □ Asthma □ COPD □ CHF
□ As Above □ Other
Past Surgical History:
Family History: □ HTN □ IDDM □ NIDDM □ CAD □ Asthma □ COPD □ CHF
Social History: Tobacco □ No □ Yes Amt ETOH □ No □ Yes Amt □ Other
Review of Systems: Check □ if normal Check O if abnormal (if not checked then not applicable.)
□ Other Ros Neg
Eyes: □ O Diplopia □ O Blurred □ O Vision chgs
ENT: □ O Rhinitis □ O Sore throat □ O Nose bleeds
Card: □ O CP □ O Palpitation
Respir: □ O SOB □ O Cough □ O Hemoptysis
GI: □ O Nausea □ O Vomiting □ O Diarrhea □ O Abd pain □ O Melena □ O Hematochez
GU: □ O Dysuria □ O Urgency □ O Hematuria
MS: □ O Myalgia □ O Back pain □ O Neck pain
Neuro: □ O Seizures □ O Dizziness □ O Syncope □ O Weakness □ O Numbness
Endo: □ O Polyuria □ O Hypoglyc □ O Thyroid Dys
Hem/Lym: □ O Anemia □ O Bleeding
□ For allergies see ED nurses notes
ALLERGIES: TETANUS STATUS: Other ROS
Physical Exam:
□ For vitals see ED nurses notes

Weight	Time	Pulse Ox	Temp	P	R	BP

Check □ if normal Check O if abnormal Abn Findings:
General: □ O Mental Status
Eyes: □ O Conjun NL □ O Lids □ O PERRL
Head: □ O NL cephalic □ O Sinuses □ O Nose
ENT: □ O Oropharynx □ O Right TM □ O Left TM
Neck: □ O Palpation □ O Thyroid □ O Trachea
Chest: □ O Palpation □ O Excurtion □ O Symmetry
Cardio: □ O Heart sounds □ O R&R
Respir: □ O Respir effect □ O Lung sounds
Abdom: □ O Palpation □ O Bowel sounds □ O RUE □ O RLE □ O Digits □ O LUE □ O LLE □ O Back □ O Pelvis □ O Gait
Skin: □ O Temp □ O Appear □ O Color
Neuro: □ O CNS □ O Strength □ O Sensation

TEST:	ORD	Initial	Time Initial	Test Ordered:
CBC W DIFF:				
CHEM 8:				
URINE PREG				
CCUA:				
CATH UA:				
URINE C&S:				
EKG:				
OLD EKGS:				
TROPONIN:				
PT/PTT:				
FINGER ST GL:				
BLOOD CULT X				
TYPE & SCREEN				
TYPE CROSS UNITS:				
LIVER PANEL:				
CMP:				
AMYLASE:				
LIPASE:				
HEMOCULT:				
TYPE & RH:				
HCG QUANT:				
URINE DRUG S:				
ALCOHOL:				
ED ABG:				
PA/LAT CXR:				
PCXR:				
C-SPINE:				
L-SPINE:				
ACUTE ABD:				
OLD RECORDS:				
OLD ED Record:				

Med Decision Making:
□ Med records reviewed:
□ Xrays reviews by me:
□ EKG reviews by me:
□ Labs reviews by me:
CC TIME:
Diff Dx:
Consult/s:
Name of Physician That Admitted PT:
□ Encounter only □ Dictated only □ Temp sheet only □ Dictated Encounter □ Dictated & Temp sheet
Name of Physician That PT is Admitted to:
Name: Race: Sex: Age:
DISCHARGE DIAGNOSIS: CODES □ STABLE □ UNSTABLE SEE NOTE
Addressograph
Physician Signature Time MD IN:
ED Encounter Record

Figure1.

The (ED) Emergency Encounter Form Used by a Regional Medical Center Emergency Department During the 2005 Graniteville Disaster

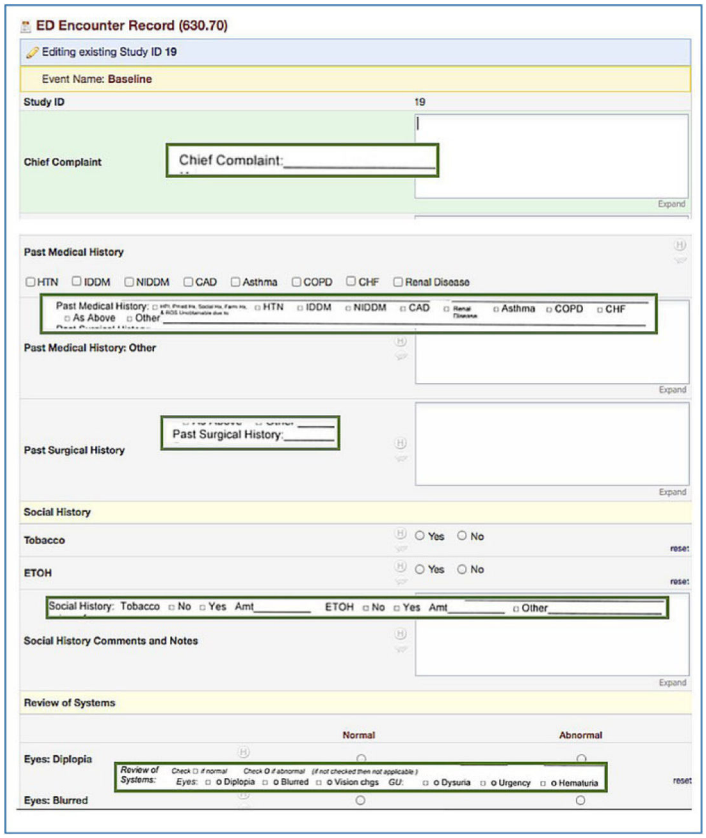
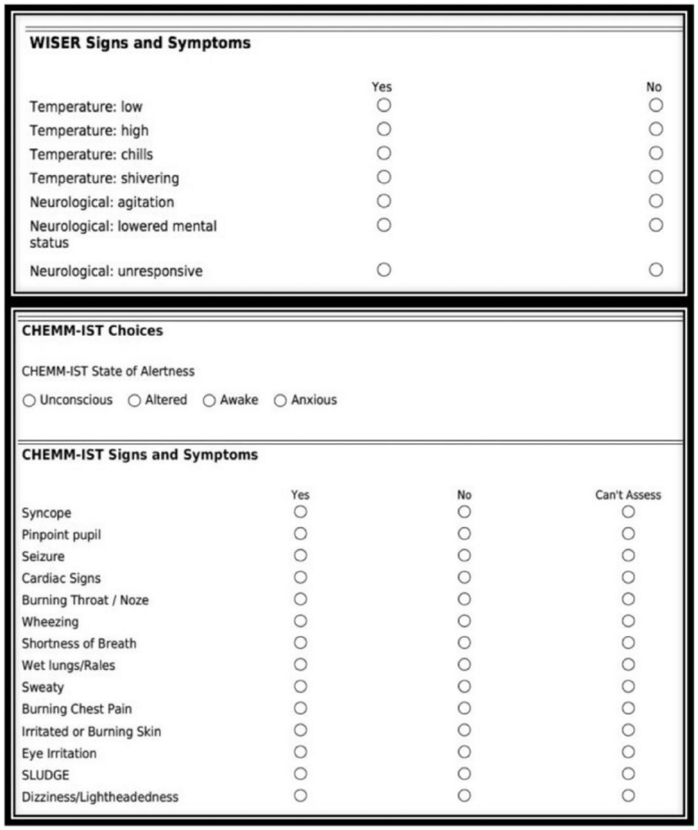


Figure 2.
A Portion of the ED Encounter Form Developed Using REDCap with Corresponding Sections from the Original Paper Form Outline with a Dark Green Box



WISER Signs and Symptoms

	Yes	No
Temperature: low	○	○
Temperature: high	○	○
Temperature: chills	○	○
Temperature: shivering	○	○
Neurological: agitation	○	○
Neurological: lowered mental status	○	○
Neurological: unresponsive	○	○

CHEMM-IST Choices

CHEMM-IST State of Alertness

○ Unconscious ○ Altered ○ Awake ○ Anxious

CHEMM-IST Signs and Symptoms

	Yes	No	Can't Assess
Syncope	○	○	○
Pinpoint pupil	○	○	○
Seizure	○	○	○
Cardiac Signs	○	○	○
Burning Throat / Noze	○	○	○
Wheezing	○	○	○
Shortness of Breath	○	○	○
Wet lungs/Rales	○	○	○
Sweaty	○	○	○
Burning Chest Pain	○	○	○
Irritated or Burning Skin	○	○	○
Eye Irritation	○	○	○
SLUDGE	○	○	○
Dizziness/Lightheadedness	○	○	○

Figure 3.

Seven of the 79 WISER Signs/Symptoms and All 14 CHEMM-IST Signs/Symptoms and State of Alertness

Table 1.

CHEMM-IST Assessment Summary for Graniteville Patients

		CHEMM-IST Assessment				
CHEMM-IST Sign/Symptom	**Altered**	**Anxious**	**Awake**	**Unconsciou**	**No information**	**Total**
State of Alertness	7	2	176	3	10	198
		CHEMM-IST Assessment				
CHEMM-IST Sign/Symptom		**Can't Assess**	**No**	**Yes**	**No Information**	**Total**
Burning Chest Pain		53	78	20	47	198
Burning Throat or Nose		19	124	29	26	198
Cardiac Signs *		7	158	32	1	198
Dizziness or Light Headedness		1	67	12	118	198
Eye Irritation		11	119	52	16	198
Irritated or Burning Skin		13	134	12	39	198
Pinpoint Pupil		4	144		50	198
Seizure		9	73	2	114	198
SLUDGE **			1		197	198
Shortness of Breath			96	94	8	198
Sweaty		1	164	5	28	198
Syncope		6	29	1	162	198
Wet lungs or Rales		28	127	22	21	198
Wheezing		5	111	62	20	198

* Cardiac Signs: Cardiac signs are arrhythmias, bradycardia and/or hypotension.

** SLUDGE: A mnemonic for signs/symptoms of exposure to nerve agents and some chemical exposures that include: **S**alivation, **L**acrimation, **U**rination, **D**efecation, **G**astrointestinal upset, **E**mesis.

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Table 2.

Portion of the WISER Assessment Summary for Graniteville Patients

	WISER Assessment			
WISER Sign/Symptom	**No**	**Yes**	**No Information**	**Total**
Cardiovascular arrhythmia	163	6	29	198
Cardiovascular bradycardia	185	11	2	198
Cardiovascular chest pain	73	66	59	198
Cardiovascular hypotension	83	100	15	198
Cardiovascular hypotension or shock	172	13	13	198
Cardiovascular hypoxia or cyanosis	159	27	12	198
Cardiovascular tachycardia	128	68	2	198
Ears - hearing loss	7		191	198
Ears - tinnitus	4	1	193	198
Eyes - constricted pupils	155		43	198
Eyes - dilated pupils	155		43	198
Eyes impaired vision	85	7	106	198
Eyes - irritation or redness	120	52	26	198
Eyes - light sensitivity	5	1	192	198
Eyes - eye swelling	14		184	198
Eyes - tearing	18	4	176	198
Eyes - vision loss	8		190	198