Large-Scale Disclosure Toolkit

Communicating Large-Scale Adverse Events
Developed through VA HSR&D grant proposal SDR 11-440

VA HEALTH CARE Defining EXCELLENCE in the 21st Century

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Veterans Health Administration

Introduction

Audience

This Toolkit is intended to assist facility leaders when disclosing large-scale adverse events to patients. Large-scale adverse event disclosure is complex and requires quick execution. In a multi-year research project, we interviewed leaders, employees, patients, and family members at nine facilities where recent large-scale adverse events were disclosed to identify key lessons learned[1]. **When reflecting on past events, many leaders and employees felt that they needed resources to help with this difficult communication; this Toolkit helps to address that need**. The Toolkit begins with steps facilities can take to prepare for a large-scale adverse event ***before*** it occurs. The Toolkit then describes the disclosure team leaders each facility director will appoint, and the roles each team needs to play throughout the disclosure process. Each disclosure team has goals to meet, action items to follow, and training materials and resources to assist them. While this toolkit was created initially for use within the Veterans Health Administration, its contents are applicable to any healthcare system.

> *"Most facilities haven't done anything like this before and they need the support." – Employee*

Stakeholders

There are many stakeholders in large-scale adverse event disclosures. Closest to and most affected by the adverse event are the patients who received the disclosure, their families, and the employees of the facility where the event occurred. There are additional stakeholders to consider as illustrated in the figure below. Elected officials, patient advocacy groups (in VA, these are called Veteran Service Organizations (VSOs)), media, and other healthcare systems are stakeholders. Finally, the larger community, including other patients who were not affected by the adverse event but who seek care at the facility where disclosures were made, are stakeholders in this process. Each of these stakeholders will be looking for messages about what happened. Their proximity to the event will help you prioritize communication with these stakeholders.

Stakeholder/Audience Relationship to the Adverse Event*

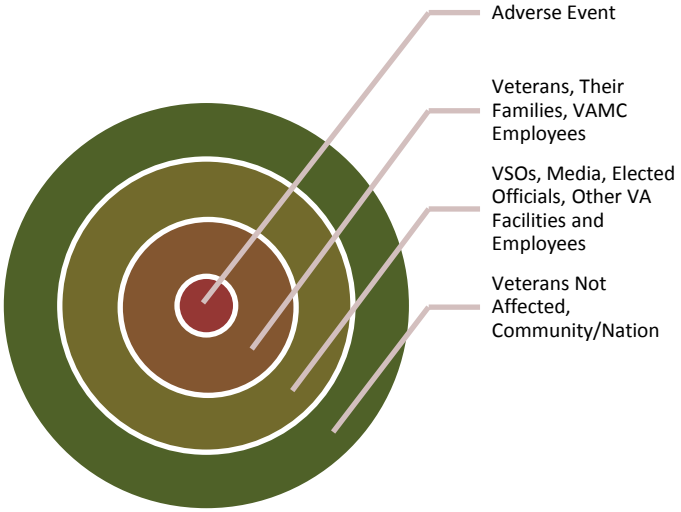

**Figure adapted from Crisis and Emergency Risk Communication (CERC) materials*[3]

Why be prepared?

Large-scale adverse events can affect patients' trust in any healthcare system. Preparing to communicate openly with patients can help retain trust during difficult times and show our values in action. A healthcare system's values define our culture and strengthen our dedication to those we serve. In the VA, we call this mission and values "I CARE": Integrity, Commitment, Advocacy, Respect, and Excellence.[2]

Many facilities are focused on institutional disclosure and have not planned their large-scale disclosure process. When an event does occur, facilities are often under-prepared. There are preparatory steps facilities can take before an event occurs. Take a look at the Pre-Crisis section of the Toolkit now and start helping your facility to prepare. If a large-scale adverse event does occur at your facility, you will be ready to act quickly. The remaining sections of the Toolkit will be implemented after an event has been identified.

> *"We've just bashed our head against the wall so many times with this and it's just silly that, you know, we, that there isn't a central clearinghouse of information - a set of, you know, recommendations everyone can follow." –Employee*

There are many challenges you will face during a large-scale adverse event disclosure. You may be concerned that patients will be very upset when notified even if the risk of harm is low. We discussed this issue with Veterans involved in several low risk events and they felt it was important that the VA was open and honest with them about the large-scale adverse event, even if they were upset or angry at first. Disclosure can be a way for facilities to strengthen trust with their patients. You may also worry that you do not have the resources available to quickly execute a disclosure to so many patients. **Help is available!** This Toolkit will help you evaluate what you need to begin this disclosure process. The Toolkit authors are a resource to provide assistance. Please find our contact information in the Appendix.

Toolkit Overview

The Centers for Disease Control and Prevention (CDC) developed the Crisis and Emergency Risk Communication (CERC)[3] model to help identify key messages that should be in place when communicating with your audience about risk. The CERC Model has five stages of communication: Pre-Crisis, Initial Event, Maintenance, Resolution, and Evaluation (see CERC Z Card). This Toolkit is organized by these five stages. Each stage includes goals for the stage, key topics, action items, and resources. The Pre-Crisis section should be reviewed and needed action items should be implemented **before** a large-scale adverse event occurs.

Each section of this Toolkit is informed by evidence collected from a series of four studies undertaken to determine how to disclose adverse events to Veterans in a way that strengthens their trust and confidence in the VA while minimizing their anxiety and distress during disclosure. More information on these studies, funded by the Department of Veterans Affairs,

Health Services Research and Development Service, can be found in the Appendix. The Toolkit also references the VA's Clinical Episode Review Team (CERT)[4] as well as the VHA Look-Back Program Operations Manual: Patient Notification/Disclosure, Clinical Look-Back, and Epidemiologic Investigation of Large-Scale Adverse Events Involving Potential Exposure to Infectious Diseases[4].

Communication Goals During Pre-Crisis Through Evaluation Stages

Pre-Crisis

- Provide an open and honest flow of information to the public.
- Emphasize that there is a process in place.

Initial Event

- Don't over-reassure.
- Acknowledge uncertainty.
- Emphasize that a process is in place to learn more.
- Be consistent in providing messages.

Maintenance

- Acknowledge fears.
- Express wishes.
- Give people things to do.
- Acknowledge shared misery.
- Give anticipatory guidance (foreshadow).
- Address the "what if" questions, when appropriate.
- Be a role model and ask more of people.

Resolution

- Be regretful, not defensive.
- Express wishes.

Evaluation

- Communicate what worked and what were the challenges.

Adapted from CERC Materials[3]

Pre-Crisis

Goals:

- Preparation for possible event
- Understand the key messages needed during disclosures
- Form alliances with stakeholders
- Establish effective communication strategies and patient-centered culture

Action Items:

☐ Use the measures you currently collect on patient and employee satisfaction to look for potential problematic areas.

Who: Facility leadership

☐ Evaluate current communications practices and leadership style and commitment to healthcare system values throughout the organization.

Who: Facility leadership

☐ Determine who would be best to focus work on the large-scale adverse event and who will assist in completing regular duties while that person leads the disclosure.

Who: Facility leadership

☐ Network with key stakeholders, and establish ongoing communication to reinforce relationships

Who: Facility leadership, Facility Public Relations, External Stakeholder Communication Team

☐ Identify facility disclosure team leads (5 teams: identification/programming, internal communication, patient communication, external stakeholder communication, testing clinics)

Who: Facility leadership

☐ Distribute Toolkit to team leads, train teams on best practices and check-in on a yearly basis for sustainability

Who: Toolkit authors and facility leadership

☐ Complete the SQL trainings as needed to assist with lookback process

Who: Identification/programming team lead

☐ Review the tested patient communications materials in the appendix.

Who: Patient communication team

☐ Review Issue Brief template

Who: Facility leadership

Tools & Resources:

- Issue Brief outline and sample

- Communication language (letters, phone scripts)
- CERC Online Training and CERC Manual
- Action Item Checklist
- VHA Disclosure of Adverse Events to Patients Directive

Topics:

Prevention & Early Identification: Use of Current Data

Before a large-scale adverse event occurs, facility leaders can focus on a few key areas as preventive and early identification steps. First, communicate the importance to employees of reporting all actual and potential events that negatively impact patient care. Employees should know that they are expected to report these types of events and should be informed about the facility's reporting process for these. If employees feel supported in identifying adverse events, these events may be identified earlier and subsequently fewer patients may be affected[5]. This focus helps creates a culture of safety.

> *Michael Leonard, Physician Leader for Patient Safety at Kaiser Permanente in Colorado, offers a simple definition of a culture of safety: "No one is ever hesitant to speak up regarding the well-being of a patient [psychological safety], and everyone has a high degree of confidence that their concern will be heard respectfully and be acted upon."*

Use the measures you currently collect on patient and employee satisfaction to look for potential problematic areas. One facility director we spoke to reported that the service where the large-scale adverse event occurred had lower ratings on the All Employee Survey (an annual VA survey to assess organizational climate, culture and psychological safety) than other service areas. This could be a sign that employees aren't receiving enough support, need more effective training, or there are other issues. Patient satisfaction surveys may also identify areas that may be facing strain and are at risk for potential errors. In addition, staffing data may provide additional information, such as services with high employee turnover may be areas to watch closely. For example, high turnover in Sterile Supply Processing staff means that potentially less experienced staff is performing key sterilization processes. These processes can be complex, and missing steps in the process is one key cause of some large-scale adverse events.

Action Item: VA employees can access the All Employee Survey data by contacting VHA National Center for Organization Development (NCOD): vhancod@va.gov (513) 247-4680

Communications Patterns

Internal communications patterns throughout the organization are important when you face a challenging event like a large-scale disclosure. When there are strong formal communications

channels throughout all levels of the organization, reliance on rumors and gossip can be reduced.

Action Item: Take some time to evaluate your current communications practices by answering the following questions:

- How are timely events and issues at your facility communicated to employees? How have you evaluated the effectiveness of this communication?
- How is email used to reach specific groups and the full staff of the facility? Are there staff who do not regularly use email and if there are, how is information delivered to them in a timely fashion?
- How quickly are updates made to your facility's intranet?
- Are supervisors asked to follow-up with their staff to answer questions following big announcements?
- What other ways do you communicate with staff and receive feedback?

If employees feel that communication is strong before an event takes place, they will be more confident in the communications they receive during an event and less likely to look for information elsewhere.

> *"And there were a lot of different stories. The communication was not clear. I think everyone was uh, basically running for the hills so to speak uh, and the people that did know about it wouldn't really communicate about it. The people that didn't know about it relied on rumors." - Employee*

Real Life Example: One facility director takes regular communication seriously and provides regular weekly email updates to all staff. When he is traveling, he lets everyone know where he will be and also lets them know what he would like them to work on while he is away. Staff have responded positively to these regular emails from leadership and expressed confidence that this leader would be open with them during a large-scale adverse event.

Leadership Engagement

Leadership engagement goes hand in hand with culture and communications. Many leaders talk about having an "open door policy" where employees are welcome to come and discuss issues. This type of engagement can encourage reporting of errors and also promote open feedback during difficult times. Executive walk rounds or Leadership WalkRounds are also methods that can help with leadership engagement. The Maintenance section has more information on these methods.

> *"And emails are sometimes overrated and you know what we could do, you know we have this um, this front line the, e- executive office say, 'Let's get out and make friends.'*

They need to know who the medical center director is. And don't just show up when it's a bad time." -Facility leadership

Action Item: Leaders should evaluate their current leadership style and engagement strategies. If needed, make changes to solicit regular feedback from employees.

Patient-Centered Culture

Many of the leaders and employees we talked with discussed the importance of focusing on the Veteran first. When large-scale adverse events occur, stress is high and the facility may get a lot of attention from the media and elected officials. Strive to maintain a focus on the patient and make sure your actions are serving patients. This work on creating a culture where patients are our main priority starts now and continues through each stage of the disclosure process.

Action Item: Have leaders and employees committed to your hospital's mission and values. For example, in the VA this is referred to as I CARE:
Integrity, Commitment, Advocacy, Respect, and Excellence. You can test this by asking employees for examples of these values in action and formally recognizing employees who display these values in their work.

Real Life Example: Many facilities have created an I CARE award to recognize employees who go above and beyond in their commitment to putting Veterans first. This award provides concrete examples of actions that show VA values in practice.

Changing Roles

When a large-scale adverse event occurs, leadership roles may need to change temporarily. For example, the facility Director may need to devote his/her time solely to overseeing the disclosure process. If this is the case, the Associate Director should be prepared to take over standard responsibilities of the Director during this time.

Action Item: In the Pre-Crisis phase, determine who would be best to assume the director's role during the disclosure process while the director works closely with the disclosure team leaders.

Relationship development: Media, Patient Advocacy Groups, Other External Stakeholders

Stakeholder relationship development is an ongoing process. Before an adverse event occurs, facility leaders and public relations staff should be working to develop and maintain relationships with the media, patient advocacy group or key external stakeholders.

Public Affairs staff may already have relationships with the media. Evaluate your relationships and see where you might improve communications. Public Affairs staff should be sending copies of press releases to all local reporters covering patient issues and submitting article pitches on local healthcare system issues. These pitches may be about the positive impact of a hospital program, new construction updates, leadership awards and so forth. Public Affairs staff should also prioritize responding to inquiries from reporters quickly. Many reporters have tight deadlines and will appreciate swift responses for comment. This practice of timely communication will be essential when communicating with many different stakeholders during a large-scale adverse event. Strive to develop internal and external relationships that will facilitate timely internal vetting and external delivery of communications.

During the Pre-Crisis phase, careful attention should also be paid to relationships with key external stakeholders. Maintaining open dialogue with these groups can be of assistance when an event occurs. You will have a pattern of regular, open communication that can be maintained during large-scale adverse event communications.

Action Item: Facility leadership should evaluate current relationships and seek to make improvements by setting regular meetings to discuss important issues and briefing these groups before the hospital makes any big public announcements.

Real Life Example: One leader talked about all of the work the facility has done to build relationships before a large-scale adverse event occurred: "We have chamber meetings, I attend monthly breakfasts, we have congressional briefings every six months. Any time I'm in DC, I meet with our congressmen. I know the editor at our local paper, my PR person knows the writers. Do all this beforehand. The VA has new opportunities for marketing. We need money for local marketing. Right now, we are working with VSOs to develop local articles because some of our doctors have made a top 100 physicians list. If you have ongoing relationships with media, you can limit coverage when something negative happens."

Large-scale adverse event response team formation and training

Interviews with leaders and employees involved in past disclosures helped us identify the five key teams that are needed during the large-scale adverse event disclosure process:

1. Identification/programming (see also Initial Event, page 16)
2. Internal communication (see also Initial Event, page 18)
3. Patient communication (see also Initial Event, page 20)
4. External stakeholder communication (see also Initial Event, page 25)
5. Follow-up clinics for assessment and referral (see also Initial Event, page 28)

The Initial Event phase of this Toolkit will provide more detail on the steps each of these teams must take.

Action Item: In the Pre-Crisis phase it is important to identify a lead for each of these five teams. You may wish to have one person responsible for multiple teams. For example, you can have someone with communications experience be responsible for the internal communication and external stakeholder communication teams. It may be helpful to look for individuals who have responsibilities in other emergency preparedness or Incident Command System functions for your organization and see if leading one of these teams fits well with their responsibilities. Professionals, who regularly communicate with patients, such as nurses and social workers, may be ideal patient communication team leads. You will also want to make sure you have a physician with clinical skills included in this group to help deal with questions regarding the clinical impact of the event.

The Pre-Crisis stage is the ideal time to think through a couple of different large-scale adverse event scenarios with your team leads and discuss how you would respond to all stakeholders involved. Read the scenario about colonoscopy equipment in the appendix and think through the action items your team would need to execute. Use this time to identify your strengths and weaknesses. Work to addresses weakness now.

Action Item: Team leaders should be given a copy of this Toolkit before an adverse event occurs. Yearly trainings in preparedness for large-scale adverse events may be available to team leaders. Check this website for up-to-date information about trainings.

Action Item: The Identification/Programming team should complete any needed SQL trainings to make sure they are prepared to conduct the lookback. These trainings may be available internally or externally.

Preparing Messages

When Veterans were interviewed following past large-scale adverse event disclosures, they had many suggestions for how they felt they should have been told about the event:

1. Patients prefer to receive a phone call before a letter. The phone call provides an opportunity to get more information, discuss the level of risk in more detail, and set up a testing appointment if needed.
2. Patients prefer regular mail letters instead of certified letters.
3. Patients would like a direct opening paragraph about what happened instead of language about the healthcare systems' commitment to quality and safety.
4. An apology should be included in all communications.
5. Communications should include detail about what happened. If the event is regarding improperly cleaned equipment, for example, provide detail on what elements of the cleaning did not take place. Was one step missed or was the equipment not cleaned at all? Detail helps the patient to think through the level of risk. Be sure to provide detail on what is known but do not speculate as to causality. Don't get ahead of the facts.
6. Talk about what follow-up is being done at the facility so that this event does not happen again.

7. Provide a phone number for follow-up questions. Make sure those staffing the number have adequate information to share and can make follow-up clinic appointments as needed.
8. Provide information about what the patient can do (such as blood borne pathogen testing, if needed with necessary detail).

Following interviews with patients, the Toolkit team developed and tested new communications methods and language. These telephone scripts and letters are included in the appendix. Please use these materials as a template and add in your facility's specific information as needed.

Action Item: Review the tested Veteran communications materials in the appendix. These can be tailored for any patient population.

Issue Brief Planning

Preparing an Issue Brief is one of the first things facility leadership will do when a large-scale adverse event is discovered. Familiarize yourself with the components of the Issue Brief now so you will be prepared for this important first step.

Action Item: Review the Issue Brief template and example in the appendix now and make sure your facility is prepared to quickly gather the required information.

Initial Event

Goals:

- Rapidly communicate: reassurance, healthcare system action taken, personal response activities
- Move quickly to plan for disclosure, aiming for under 75 days from discovery to notification.[1]

Action Items:

☐ Submit an Issue Brief
Who: Facility leadership

☐ Determine which patients are part of the cohort
Who: Identification/programming team

☐ Team preparation for communication and testing
Who: Internal communication, patient communication, external stakeholder communication, follow-up clinic teams

☐ Communicate with employees
Who: Internal communication team

☐ Communicate with patients
Who: Patient communication team

☐ Communicate with other stakeholders
Who: External stakeholder communication team

☐ Communicate with the media
Who: External stakeholder communication team, facility leadership

☐ Track Veterans
Who: Identification/programming team

☐ Continue communication within the healthcare system
Who: Internal communication team, leadership from facility and healthcare system

Tools & Resources:

- Tools for tracking patients
- CDC's basic tenets of emergency risk communication checklist
- CDC guide for message development and message planning templates
- Tips from leaders who have gone through crisis and risk communication
- Website examples
- How to respond to negative social media comments
- The 5 C's of Crisis Communication

- 7 rules to remember when a crisis strikes
- VHA Look-Back Program Operations Manual (Accessible by VA employees only)
- Sample communications plan, letters, and phone scripts

Topics:

Working with a Healthcare System's Executive Leadership Team

As this toolkit was first created for the Veterans Health Administration, we focused our efforts on how local VA facilities could work with regional (i.e., VISN) and central (i.e., Veterans Affairs Central Office) on disclosure planning. The examples we provide here may be adapted and tailored for any integrated healthcare system, and may be modified for smaller organizations.

The process for working with the VISN and Central Office on a potential large-scale adverse event in VA has multiple steps. First, the facility will notify the VISN and 10N about the potential event and develop an Issue Brief. An Issue Brief template and example are included in this Toolkit. Facility Directors must work quickly with their staff, including heads of the service affected and infectious disease experts (as needed) to provide detail on the event. The Issue Brief must be developed and submitted quickly. Detail should include any deviations from standard operating procedures, how the event was discovered, and how many Veterans are likely affected. This Issue Brief will be a living document which will be updated as the disclosure progresses.

Then, the Clinical Episode Review Team (CERT)[4] conducts a coordinated triage process for a review of each potential adverse event that may require large-scale disclosure. The triage process involves preliminary investigation of the facts, preliminary assessment of risks and development of a plan to determine the need for disclosure. This may be readily apparent due to the nature of the adverse event and evidence of patient harm, or may require additional review by a subject matter expert (SME) Review Panel or the clinical review board (CRB).

Developing a Communications Plan

Once it has been determined that there should be a disclosure, there are several steps that must be taken. After consultation with legal counsel, healthcare system leadership, communications officers, and the local facility work together on a communications plan. The communications plan will include any communications materials that will be shared with patients (disclosure letter, call scripts, FAQs) and other stakeholders. This plan will also include the timing of communications to all stakeholders. After the communications plan has been approved, the disclosure can take place.

Large-Scale Adverse Event Team Responsibilities

Each of the five teams has a role in the communications plan and disclosure process. Timing is important in disclosure. There are many tasks to complete, including complex tasks like patient

identification. A media content analysis revealed that events that took under 75 days from discovery of the event to patient disclosure had fewer mentions of secrecy and slow response.[1] Veterans who were interviewed expressed concern about delays in notification.[1] Teams should take time to make sure that work is complete and accurate before disclosing, while also working efficiently to reduce delays in contacting patients.

Key activities for the Initial Event stage are listed below. Detailed information follows. There may be more than one team working on an activity but one team should be designed as the primary team responsible.

Key Initial Event Activities	Primary Team	Secondary Teams
Patient identification	Identification/Programming	
Internal reporting	Internal Communication	Identification/Programming, Patient Communication, Follow-Up Clinic
Patient communication material development and initial notification	Patient Communication	Internal Communication, Follow-Up Clinic
Establish hotline	Patient Communication	Follow-Up Clinic
Establish follow-up clinic	Follow-Up Clinic	Patient Communication
Notify all facility employees	Internal Communication	
Notify media	External Stakeholder Communication	
Notify key external stakeholders	External Stakeholder Communication	
Notify patients of test results	Patient Communication	Follow-Up Clinic

Identification/Programming Team Responsibilities:

> *"We built tools that helped facilitate telephone triage. It was a note that got pulled up that could help in comforting people in the right way. It was a progress note. It was coordinated really well. We also created a dashboard that management and [VA leadership] could look at daily. It had numbers on how many contacted, scheduled, refused, labs, tracked letters." -VA Regional employee*

Reporting

This team will determine the process and format of routine local reporting. In addition, your healthcare system will require reporting at various points in the disclosure process. This team should work to create reporting procedures that will serve both local and national needs. A few things to consider when designing reporting:

- Where possible, electronic tools that facilitate data collection should be employed. Given the significant variation in the way information is recorded in the EMR, it may not be always possible to use electronic data extraction but where it is feasible, it can greatly facilitate reporting.
- Keep reporting frequency at a manageable level. Reporting requirements and process should be established early.
- Generate a shared site for disclosure information. Due to the large number of people involved, an organized, shared site (e.g., SharePoint) with access granted to key people helps improve communication and access to information.

Identifying Affected Patients & Continued Tracking of Patients

The specific strategies used to identify patients affected by a large-scale adverse event disclosure and to determine their status will depend on the clinical scenario involved. In most programs the knowledge and skills of multiple team members including both clinicians and support staff will be necessary. It is important to agree on a process for identifying Veterans before beginning the look back. The facility should consult with their hospital leadership and subject matter experts as need before finalizing the process.

Developing precise metrics is an essential step in this process. Efficiency and expediency can be optimized by the following:

- **Establish what information/data will be required to identify affected Veterans and confirm their current status.** Clinical information will be required to determine whether a Veteran was exposed to a potential risk and demographic information will be necessary to conduct notification. This includes the date range and procedures/events identified as exposure risk. Efficiency may be increased if both clinical and demographic information is collected simultaneously. For each Veteran identified, a review of the clinical data should be performed to verify that the patient should be included in the disclosure.

- **Optimize use of the electronic medical records (EMR).** EMR provide an indispensable tool to expedite patient identification. Local implementation will likely require involvement of clinical support and technical staff, to assure that all affected patients are identified.

- **Review of alternate data sources may be necessary.** Recognize that there may be variation in local documentation practice and/or that documentation procedures have changed over time, and provide alternatives to automated EMR queries. For example, some clinics may maintain a log book which can augment information available elsewhere. This should not be seen as encouraging use of nonstandard processes, rather as using all available data sources. Depending on the time frame involved, it may be necessary to review information that precedes full implementation of EMR. In such cases, record retrieval and manual review may be necessary, and importantly, timelines may need to be adjusted to allow for these activities or staffing levels temporarily adjusted. Additionally, an independent review of EMR and alternate data sources used to compile the affected patient list should be performed to help ensure that all exposed patients are identified at the outset. The reviewer's role will be to assess the sources used to identify potentially exposed patients and help identify additional sources of information that may have been overlooked.

- **Considerations for families of a deceased patient.** Facilities may find it useful to review publicly available information to identify patients whose death has not previously been documented in the healthcare system prior to beginning notification. One example used is the review of Social Security death information for patients not seen anywhere in healthcare system for over a year.

- **Create summaries of record reviews to limit duplication and aid in care delivery and reporting.** Review of clinical data may be required to determine if the patient is affected. For patients who are affected, some clinical data may also be required to provide care. To increase efficiency by reducing the need for repeated reviews, a tracking template may be helpful. Electronic versions of such tools can be useful but only if they are user-friendly and the time and resources required for developing and deploying the tool are reasonable and do not delay disclosure. In some cases, it will be reasonable to use a hard copy tool for use by staff as they conduct reviews of individual patients. For the data collected during this process to be useful, it must be accessible to the staff members who see the patient; this can be achieved by entering pertinent data on an electronic note template.

- **For large-scale programs it may be useful to establish a program specific stop code which does not generate a co-pay.** This also allows for tracking of workload resource utilization. In the VA, consider that some Veterans may request reimbursement for travel and determine what will or will not be provided prior to the start of patient notification and assure that any necessary administrative direction and procedures are in place. Note: This may apply to the Follow-up Clinic team as well.

"If you know CPRS then you know there are many ways of skinning a cat. Garbage in, garbage out. We did a lot of record reviewing. We did a double review and we worked weekend after weekend to find them. We also did chart reviews which is an intense process." –Facility employee

Internal Communication Team Responsibilities:

"Someone always knows dirt and can always leak information so you can't control that. So you need to act quickly. Get the message to each employee quickly so they know what to say when they get approached. Arm them with the facts." –Facility employee

The Internal Communication Team will need to communicate with all levels of the healthcare system, from leadership to front line employees.

Communication with operational and clinical leaders will continue throughout the disclosure process. This team will be responsible for providing regular updates to healthcare system leadership. This may include use of a shared site like SharePoint as outlined in the previous section. This team will need to coordinate with the Identification/Programming Team, the Patient Communication Team, and the Follow-Up Clinic Team to report on things like number of patients in the disclosure group, how many Veterans have been contacted, how many have been tested, etc.

The Internal Communication team will develop a plan for how and when facility employees receive information about the disclosure. This plan will be part of the large communications plan. Communication with employees should:

- Include a means to communicate with every level of employee at the facility.
- Include detail about the event, level of risk, and follow-up needs of patients.
- Provide information about what employees should do if they are contacted by the media or elected officials about the event.
- Provide resources for employees who experience any distress.
- Provide timely information so that employees receive information before media coverage begins. Timing should also allow employees to prepare for patient questions.

Effective Internal Communication Processes:
All employees should have enough information to answer questions from patients and be able to direct patients to resources (e.g. the testing clinic).

Email can be an effective means of communicating quickly with all employees. Email allows employees to refer back to the information as needed. Email also ensures that all employees have the same information. Town hall meetings, for example, cannot be attended by all employees.

There should be a process in place for gathering employee questions and feedback. One way to engage employees is to have supervisors discuss the event with their team following email

communication. Supervisors can then meet with leaders to discuss any concerns. Executive walk rounds may also be useful (see: Maintenance phase).

Real Life Example: Some Veterans need follow-up services after a disclosure. One facility had to organize follow-up specialty care appointments for a Veterans affected by an event. The employee coordinating that follow-up suggested making scheduling for these Veterans a priority. However, she found that many employees did not know about the large-scale adverse event and didn't realize the importance of coordinated follow-up care for these Veterans. She stressed that employees should know that these Veterans were affected by this event and provide critical customer service to help repair trust in VA.

Impact on employees:

The disclosure process will have a significant impact on employees. Employees may experience a range of emotions. Some will feel embarrassment or anger about the error. Others will feel stress from managing disclosure responsibilities and regular responsibilities. Seeing negative media coverage and feeling concern for Veterans can have a big impact on employees. Employees- including leaders- may also be concerned about job stability.

> *"I saw a news report that the director lost his job. Monday morning, it was like a 100% change. People throughout felt they could be out at any time." –Facility staff*

The employee assistance programs can be a resource for staff during disclosures. Talk with these programs prior to disclosure to make sure they are prepared to assist employees. Employee emotional responses and support needs will vary according to their role related to the event or disclosure process. Some employees may prefer to receive support through existing facility-level experts. These individuals may include chaplains, social workers, risk managers, mental health providers, and other similarly trained professionals. Other employees may prefer support from peers. Peer support programs have been used effectively by allowing an employee to confidentially discuss their feelings with someone they see as a trusted peer.

> *"I had an enormous amount of anxiety… I was overwhelmed." –Facility staff comments on the personal impact of disclosing the large-scale adverse event to Veterans.*

The internal communication team should communicate with employees about the availability of employee supportive services. In addition, you may need to develop a method to provide feedback to leadership anonymously so that changes can be put in place to further support employees.

Real Life Example: One facility saw the impact on employees and there was concern that some may be hesitant to report future errors. To address this, they presented a special award to the employee who reported the error. Other facilities have formally recognized employees who were part of the disclosure team for their efforts. *"It was very demoralizing for the staff. They felt they had done something wrong, that they were being criticized. Managers need to emphasize that they are doing the right thing by reporting errors. We gave a special contribution award for a past event to the staff member who reported the issue- we wanted to encourage reporting." –Leadership*

Patient Communication Team Responsibilities:

> *"I was nervous making that first call. Um, the v-veteran that I called first was a female veteran and it, her reaction was very dramatic. She was, like, [voice gets higher] oh my God! I can't tell you how much this phone call means to me. I have been trying for years to get somebody to listen to me that, ya know, I knew that there was something wrong and I just f-, ya know, it was basically I feel so validated. Ya know, thank you for calling." –Facility employee*

Patient communication is a critical part of the disclosure process. The Patient Communication team must coordinate with the Follow-Up Clinics for Assessment and Referral Team to make sure all arrangements for patients are coordinated. During the Initial Event stage, you need to rapidly communicate with patients and the public[2]:

1. **Reassurance** that issues are being addressed and preventative measures are being put into place to prevent further errors. Preventing recurrences is an important issue to patients.
2. **Understanding of management response(s).** Providing detailed information on what leadership is doing to address the issues.
3. **Personal response activities:** What can patients do in response to the event and how they should contact the healthcare system. This may require testing or follow-up care.

> *"The contact was really confusing for patients. They weren't given specifics and these gentlemen were people who could have understood specifics. One had no clue as to the extent of his risk."- Employee*

Veterans and family members who were part of past disclosures shared their thoughts on communications. Best practices should include:

Careful consideration and selection of staff who will engage with patients. These staff should be proven communicators like social workers or nurses. These staff will need detailed

information about the event in order to answer patient questions. It is helpful to provide scripts and frequently asked questions to employees who engage with patients as part of disclosure.

There must be standardization of what is communicated so that all patients receive a consistent message. However, there should also be flexibility in communication to meet the needs of the individual patients. Some patients will need more information than others. A script with bullet points would be helpful, but not read line by line to the patient. How much do you enjoy presentations when the presenter reads to you? It appears rote without real conviction and without any feeling. Patient receiving a message of possible harm must feel you're caring. When drafting language, disclosure letters in particular, consider the following guidelines:

- Apologize for the error. Start the communication with the patient with an authentic apology[6]:
    - Acknowledge what happened
    - Expression of sympathy
    - Offer of accommodation

  In your first words to the patient, you must be clear on why you are calling/writing, accept responsibility for what happened if appropriate, express your sympathy, and offer them help. The reassurance to the patient that further harm will be mitigated is important but can sound empty if said before a real apology.

- Clearly identify why you are contacting the patient. Instead of beginning a letter with "Our healthcare system is committed to providing quality care…" say "We are contacting you today because there was an issue with colonoscopy equipment that may have affected your care."
- Avoid using jargon.
- Provide as much detail about the error as possible. Many patients in past disclosures asked for detail about the event to help them understand the level of risk.
- Let the patient know what is being done to prevent future errors.
- Provide detail on what follow-up care is needed or available and how they can access that care.
- Provide a number to call where patients can speak to informed, compassionate individuals who can appropriately respond to questions and link patients to appropriate testing and care in a timely manner.

Allow the patient to be tested at their closest facility. Travel for many patients can be difficult. Consider having testing or follow-up care available at community care settings so that patients will not have to travel extensively to return to the facility where the event occurred. Some patients may have moved and will need assistance scheduling follow-up care at a different facility out of state. Using the remote data function in the EMR, a facility can determine where such patients are currently receiving care or last received care. In addition, some patients may be residing out of the country. Plans should be made for those patients to receive testing at an

alternate location. Finally, some patients will choose not to be tested and that choice should be respected.

Patients should be contacted by phone first. Telephone interactions are best handled by staff with well-developed communication skills and who are knowledgeable about the issue and show genuine compassion. A sample call script that includes expected questions and potential responses can be useful, though the notifying staff member should avoid simply reading and instead engage in a respectful and responsive conversation with the affected patient.

> *"I liked getting the phone call because it kept me from being shocked, like shocked about getting AIDS or something. They reassured me, they said just come down and we'll check it out." –Veteran patient*

Use first class mail with return service. Following a phone call, notification letters should be sent via first class mail with return and address service requested. Local mailroom staff should be made aware of this program so that all returned letters are expeditiously provided back to the office conducting the disclosure. Use of a unique mail routing in the return address will facilitate this process.

Communication with patients via email should be done with caution, if at all. Email has not been used as a mechanism for patient notification, and any use of email to or from patients must be done in accordance with current policies, including privacy regulations. Ongoing development of electronic communication tools (e.g., secure messaging within the patient electronic health portal) may permit this type of communication in the future.

Plan a notification schedule. Once disclosure has begun, delivery of required notification to all affected patients should be done in a short period of time to reduce concern among the overall population about whether or not they are affected. If the number of Veterans requiring notification is large (i.e., hundreds to thousands), several factors need to be considered, including:

- Staff available to conduct notification;
- Workload on mailroom staff; and
- Effect on clinical system of a large number of notified patients responding at the same time.

Tracking notification attempts and returned letters. Phone and/or mail notification should be documented in the EMR, including the date the call was made or the letter was mailed. For returned letters, the date returned and subsequent notification attempts should likewise be documented. You will also need to work with the Identification/Programming team to develop and update a database outside of EMR to record and track patient activities. This practice will help in reporting on total number of patients contacted, tested, etc.

Determine how many attempts to contact are sufficient. Some patients may not respond despite repeated attempts to contact them, even if notification letters are not returned. This

team should specify what a facility must do to attempt notification, such as how many letters must be sent and during what time frame. It must be noted that failure to respond within a requested time frame does not mean that a veteran forfeits entitlement to any disclosure related care. For example, the following is a set of rules for determining non-response:

1) The point of contact at the facility will make two separate telephone attempts to contact the patient. (The telephone calls must be made on two separate days);
2) The patient is sent a notification letter;
3) If patient fails to contact the hotline two weeks after delivery of letter or come in for testing/follow-up, then
4) A final phone call attempt will be made. If the patient does not respond within one week of the last call, he/she will be deemed to be non-responsive.

Document notification attempts in the EMR. Notification attempts need to be documented in the EMR. If a standardized letter is used it is not necessary to include a scan of the actual letter, but to simply document that the letter was sent. You may want to coordinate with the Identification/Programming team to standardized note template for this process.

Assist patients in understanding their legal rights. Some patients may have questions relating to rights, entitlements, or other legal issues. While it is important to inform patients that they may file a claim for compensation, healthcare system employees should not make comment on the potential resolution of claims. Your facility risk manager can provide further guidance. In the Veterans Health Administration, it is appropriate to refer Veterans with questions to Veterans Benefits Administration (VBA) representatives and/or a Veterans Service Organization. During previous disclosures, several facilities reported that it was helpful to provide local VSO representatives with a briefing on the program and secure their permission to serve as referral resources for Veterans with legal questions.

Risk managers should be part of any conversations with patients about rights or possible benefits. If a patient has legal representation and representation is present at a meeting, then, within the Veterans Health Administration, VA attorneys should also be present. VA attorneys cannot speak directly with represented patients. Thus the VA attorneys should not attend a disclosure, even in listening mode only, if the patient has retained an attorney and their attorney is not at the meeting. It is important to avoid even the appearance of impropriety. Attendance at disclosures by VA attorneys may be helpful for future resolution of legal claims arising from the disclosure.

The Federal Tort Claims Act can provide additional information:
http://www.va.gov/OGC/FTCA.asp

> *"We've been very clear that we can comment on the process with patients but can offer no opinions on whether they will consider the claim…" -Facility Director*

Consider how a phone call or letter might need to be altered if you decide to contact the family member of a deceased patient. If you decide to contact family members of a deceased patient, create alternative language or communications processes to use. It is possible that notification attempts will identify previously unrecorded deaths, and such information should be forwarded to the appropriate office (e.g., Decedent Affairs) for documentation.

Plan for the notification of test results. For events where blood borne pathogen testing is required or available, the Patient Communication team must develop a plan for notifying patients of the results. Patients need to be notified of positive screening results, even if there is no evidence of chronic disease. A positive screening test may indicate previous exposure with spontaneous viral clearance which is of significance. As soon as can be arranged, set up appointments to disclose positive results to patients and coordinate their follow-up care. Notifications of positive test results are best performed face-to-face by a clinician who can answer questions. These notifications should include:

- Clear presentation of test results and their interpretation.
- An understandable description of test interpretation and referral for appropriate medical evaluation and clinical care.
- What the patient can do to prevent the spread of infection to others and if applicable, provide recommendations for partner testing.
- What the test results may mean with regard to the exposure for which the patient is being followed. Examples:
    - Patient is positive for infection X but has a history of being positive for infection X in the past so the infection is not associated with the exposure.
    - Patient is positive for infection X and has no history of prior testing so it is possible that the patient acquired the infection prior to the procedure but we do not know for sure at this point. Additional testing and epidemiologic study is being performed to help determine this.
    - Patient is positive for infection X and was negative for infection X when previously tested. We will further investigate the possibility that the infection was acquired recently and may/may not be associated with the care received at the facility.
- A chance for the Veteran to ask questions related to their infection/diagnosis.
- A Progress note for each disclosure visit should be placed in the medical record and needs to include accurate documentation of test results and whether or not patient had any questions/concerns.

In the Veterans Health Administration, if the patient has obtained legal counsel, the VA District counsel's office must be notified prior to the disclosure. This should be documented in the disclosure progress note.

External Stakeholder Communication Team Responsibilities:

> *"I would have involved stakeholders earlier. Give them a heads up. You might not have all the answers but you can say to them, this is what we know so far and we'll follow through. Give them lots of updates." –Facility Leadership*

A large part of VA disclosure communications involves external stakeholders, thus this section is focus on VA external stakeholders, yet materials may be adapted for other healthcare system external communication efforts. For the VA, elected officials, VSOs, and the media are three key external stakeholder groups. Reflecting back on past events, VA employees and members of these external stakeholder groups asked to be notified about large-scale adverse events early. They also recommended frequent follow-up briefings so that stakeholders had current information on the disclosure process. Sharing information openly can help increase trust. Communication begins in the initial event stage but will continue in the following stages. Use the message planning template and message development worksheet to plan out your messages to each of these groups. Healthcare systems not affiliated with the VA may also wish to use these templates and worksheets to create their messages for their external stakeholders as well, such as universities, the media, board of directors, and so forth.

Veteran Service Organizations

VSOs can be helpful is relaying information to Veterans. VSOs may also be able to assist Veterans in submitting claims related to the event, if needed. Meet with VSO representatives and provide them with detail about the event and follow-up care without identifying patients. Leave adequate time in these meetings for questions and answers. VSOs may ask questions like:

- How many Veterans are affected?
- Where will testing/follow-up care take place?
- How have you addressed the problem? Who is responsible for this?
- Are there other issues we should know about?
- How will this affected Veteran care in the future?
- When will you share more information?

Continued meetings and sharing of information is important as the event unfolds.

Real Life Example: One Facility Director made presentations to local VSOs following a large-scale adverse event. He demonstrated the equipment that was part of the improper sterilization event and left plenty of time for questions and answers. This type of presentation, he felt, helped clear up misunderstandings from media coverage. *"The media reaction, it was hysteria. I didn't think we could say anything to the papers that would help. They were focused on you messed up instead of on patient safety. So I met with the Veteran Council, along with infectious diseases and brought the [equipment] with me to show them…The group was pleased with the presentation. So we then went to VFWs, the American Legion, etc. to present this. It helped the Veteran community understand." –Facility Leadership*

Elected Officials

Elected officials have requested early and ongoing communication. Communication should be focused on what their constituents need to know. For example, look at the three messages that begin the Veteran Communication team section: Reassurance, Understanding of Management Response, and Personal Response Activities. Elected Officials may ask questions like:

- How many Veterans are affected?
- What should my constituents do (both Veterans affected and not affected by the event)?
- How soon will we know testing results?
- Is this an issue for other facilities?
- How are you addressing the cause of the event? Who was responsible? What changes have already been put into place and what changes still need to happen?

  "The Hill view is this—what are the 5 words I need to say to my constituents? They don't want the 500 words to explain to their constituents." –Congressional staffer

Media

Reporters will expect quick responses from the VA regarding these events. A media content analysis of past large-scale adverse events revealed that events that took fewer than 75 days from discovery of the event to disclosure had fewer mentions of slow response and secrecy in media reports. The media focused on messages of reassurance that preventative measures are being put into place and discussions of cause.

It is not enough to just issue a press release. Continued communication is essential. Identify a spokesperson to address media questions. This spokesperson should have media training and be comfortable answering complex questions about the event. It can be helpful to role play potential reporter questions and responses before talking with the media.

Recommendations for spokespersons include:

Adapted from CERC materials[3]

You can deflect rumors quickly with facts. It can be frustrating when the media asks for information or comments and you do not have the answer. You can respond to these requests by letting the media know that you will work to get the answer for them and provide them with a realistic timeframe on when that information will be available.

Finally, there are some messages that the media will not cover in their reports. Past media analysis showed that reporters are less likely to include apology and personal response activities in their stories. To make sure Veterans, stakeholders, and the public hear these messages, you can seek out alternative ways of delivering messages like your website and social media sites.

Follow-Up Clinics for Assessment and Referral Team Responsibilities:

If your event will need blood borne pathogen testing or follow-up assessment and care, the Follow-Up Team will need to organize resources to address this need.

Phone-in service/Call Centers. Facilities have reported successful use of call centers to manage response from affected patients. In some locations there may be existing access to telephone

care or nurse information lines. Other developed new call centers dedicated to the event. With either strategy, it is essential that staff at the call centers are fully briefed on the program and provided with specific instructions for referral of callers. If a phone line goes to voicemail, responses to messages should be prompt and on-going. Think about how you will phase out use of the phone line as well. Many patients will hold on to their notification letter and use the phone line for follow-up questions months later. Consider having the number redirect to a point person after a few weeks.

Some patients will call the main facility phone line even if notification letters include other instructions. Telephone staff must be briefed on how to respond to such calls.

Testing Clinics and Walk-in Service. Many patients respond to a notification letter in person. This may occur either during a previously scheduled appointment or as a walk-in. Walk-in patients may present to either an urgent care center, clinics with which they have an existing relationship, to information desk staff, or call local telephone center staff directly. All facility staff– including clinical and support staff – must be briefed on how to respond to such situations. Designation of specific staff to serve as the referral resource is helpful and it is essential to disseminate the name and contact information of such staff throughout the facility.

In the past, facilities have had great success developing temporary testing centers for affected patients. These testing centers are set up quickly to handle blood borne pathogens testing of large numbers of patients, both walk in service and by appointment. First, you will need to identify space sufficient for the testing center. Next, develop a process that patients will go through when they arrive. Many facilities first show a video with an overview of the event and affected equipment. An in-person presentation with a healthcare system representative who can answer questions can be even more successful. Patients should have a chance to ask a nurse or provider questions one on one before they are tested. Counselors, social workers, and chaplains should also be available to support both Veterans and employees. Finally, a high-level leader should always be present in the testing center to meet with patients who are highly upset or angry. Leaders also can also provide support to staff.

> *"I didn't see leadership in the clinic at all. I think (the Director) should have been down there and should have been making apologies to Veterans." –Employee*

A few things to consider when planning the testing center:

- Is the space easy to find, accessible for everyone, with adequate parking nearby or a shuttle service?
- Do you have adequate staffing to prevent long wait times?
- Are staff members proven communicators? Have you provided staff with enough training and information to effectively communicate with patients?
- Are you prepared to test the spouses and significant others of patients? If not, have information available on alternative testing sites that they may use.

- How long will it take to get testing results and how will patients be notified? Make sure realistic expectations are set with patients.
- How will you handle patients who are very upset/angry in the testing center?
- Do patients have to go to the dedicated testing center or can they have a blood draw done during a regularly scheduled appointment?

Laboratory Testing

The Lookback Manual[5] discusses strategies for providing laboratory testing to Veteran patients, and is applicable for use in other healthcare systems as well.

Documentation inside the Medical Record

Work with the Identification/Programming team to develop standardized notes for the EMR. The notes can be used for testing and follow-up purposes. The Programming team may also be helpful in developing codes that eliminate copays for testing.

Maintenance

Goals:

- Ongoing communication of: Ongoing risks, Understanding of background issue, Feedback on misunderstandings/rumors

Action Items:

☐ Regular communication to different groups (follow-up care needed, how many have been tested, what changes have been made to the service where error occurred, etc.)
Who: Internal Communication team, Patient Communication team, External Stakeholder communication team

☐ Feedback to staff, recognition of employee work and impact on staff
Who: Internal Communication team

☐ Hold forum for patients to discuss their concerns about the error and the communication process
Who: Facility leadership, Patient Communication team

☐ Solicit feedback from employees
Who: Facility leadership, Internal Communication team

Tools & Resources:

- Example blog post from meningitis event
- Peer Support Program Elements

Topics:

Internal Communication, Patient Communication, and External Stakeholder Communication Teams

How to continue communicating to patients, employees and other stakeholders
Communication does not end at the initial disclosure. Stakeholders will continue to have questions. You can promote trust by answering questions openly and honestly. Ongoing communication should include regular updates about:

- Any ongoing risks
- Clearing up any misunderstandings or rumors
- Providing more background on the adverse event
- Providing updates on testing rates

- Providing updates on preventative measures that have been put into place

Websites and social media postings are great ways to provide regular updates to the public. These updates should also be sent directly to media contacts and VSO representatives. Finally, don't forget to keep employees updated so that they can pass information along to Veterans who ask about follow-up.

Real Life Example: Hospitals who have experienced large-scale adverse event disclosures in the past have used dedicated areas of their websites to provide ongoing information about disclosure, testing, and follow-up. Two examples are provided in appendix. Updates can also be shared over Twitter, Facebook, and blog posts (see the CDC meningitis example) both by the facility directly and by partnerships with local VSOs.

Holding an open forum for patients

Following the disclosure of a large-scale adverse event, patients may want an opportunity to voice their concerns to leadership. An open forum is one way to make sure patients feel like they are heard. An open forum should be planned carefully to encourage participation. Make sure the forum is well advertised to patients who are part of the disclosure cohort. Invite external stakeholders to take part.

This type of forum is focused on getting feedback from patients. Leaders can make opening remarks and let attendees know that their feedback is welcome. You should also have a clinician present to answer any questions on health impact. However, the majority of the time should be focused on letting patients speak. After a patient has spoken, leaders may wish to ask clarifying questions or reiterate what was said. At the close of the forum, leaders should let participants know how issues will be followed up on and how they will communicate lessons learned and improvements with the public.

Anticipating patients' concerns

Sometimes you will encounter an open forum participant who is very upset or who is talking for an extended time. One way to address concerns and move on to additional speakers would be to ask this person if he or she can meet with leadership privately for extended discussions. For example, you could say "It sounds like you have a lot of concerns and suggestions that I am interested in hearing more about. Could you write down your contact information for me and we can work to set up a follow-up meeting to discuss what you've said in more detail?" Your goal is to make sure that all patients feel heard and know that their trust is important to you. You do not need to offer solutions immediately, but you should have a plan for follow-up communication. Although it is difficult, try not to get too defensive or argue with participants. This forum is just the start of open dialogue and relationship repair.

For more tips on town hall meetings or open forums, take a look at the CERC By Leaders For Leaders guide.

Getting employee feedback

Several leaders expressed ideas about how they engage their facility staff to update them on hospital news, including updates during large-scale adverse event disclosures. Some of these ideas involved email blasts and town hall meetings. Many healthcare system leaders are now using blog posts to share information and get feedback in the comments section. Using rounds is another option. Evidence in the literature mostly supports the ideas of executive walk rounds (EWRs) or Leadership WalkRounds ™ as a method to improve employee attitudes toward safety and to engage staff in problem-solving about systems issues. EWRs have been shown to have a positive effect on the safety attitudes of providers who participate in the EWR sessions[7] but these walk rounds require significant organizational motivation, project management and leadership engagement[8].

One type of EWR, the Leveraging Frontline Experience (LFLE), developed in the private sector, was adapted for VA medical centers and successfully implemented and studied at one VAMC in the US Northeast.[10] Take a look at these model steps and determine if they might work for your facility:

- Senior managers participate in scheduled work-system observations, spending at least 30 minutes per visit on a unit, during all shifts.
- Senior managers conduct safety forum meetings with staff in each work unit, focusing on issues identified during observations and new issues raised at these forums.
- Suggestion boxes for anonymous comments are placed on each unit.
- Senior managers meet with the unit manager to discuss what was learned and to plan follow-up on specific problems.
- Problems are prioritized on a safety risk scale and frequency of occurrence on a scale. Based on scores, these leaders propose solutions and identify individuals or groups of individuals to take responsibility for each issue.
- Managers communicate with unit staff through emails and notices on bulletin boards that their safety concerns are being addressed and updates on when changes could be expected.

Recognizing Employees

Leaders and employees with experience in past disclosures of large-scale adverse events discussed the importance of recognizing employee efforts. This can be a stressful time for employees. Recognition of employee contributions is important. Some facilities developed special awards for individual employees. Others gave pins to all employees who were part of disclosure teams.

> *"We actually got pins afterwards that say special care. We supported each other." – Facility employee*

Resolution

Goals:

- Inform about recovery efforts
- Facilitate open discussion
- Improve/create public understanding of new risks
- Promote capabilities of the organization

Action Items:

☐ Hold forum for patients to discuss their concerns about the error and the communication process, if needed

Who: Facility leadership, Patient Communication team

☐ Ask for employee feedback on their concerns and lessons learned

Who: Facility leadership, Internal Communication team

☐ Continue communication with stakeholders

Who: External Communication team

Tools & Resources:

- Strategies for getting feedback from stakeholders post event
- Damage Control Commandments
- VHA Look-Back Program Operations Manual: Epidemiologic Investigation (accessible by VA employees only)

Topics:

Patient Communication, Internal Communication, and External Stakeholder Communication Teams

Informing stakeholders about recovery efforts

Communication with stakeholders, most notably patients, will continue in the resolution stage. This stage will focus informing about recovery efforts. Continue to facilitate opportunities for open discussion through open forums with patients, external stakeholders, and/or employees as needed. It is important to talk to stakeholders about:

- What changes have been made to address the adverse event.

- Ask stakeholders if there are other changes they would like to see including changes that address the cause of the event and changes to the disclosure communication process.
- Discuss process for monitoring and reporting safety issues in the future.

Seek feedback through social media and one-on-one meetings with advocates. This feedback will provide critical information for evaluation and planning for future events in the Pre-Crisis Stage.

Reputation damage control

Repairing your reputation following a large-scale adverse event disclosure is an ongoing process. You can measure reputation through the level of stakeholder trust or mistrust. Speed of response, avoiding missteps during the disclosure, and asking for forgiveness when mistakes occur can go help in building trust during a crisis. Hopefully, you've communicated well to stakeholders from the initial event on and they have detailed information about what happened and how you are working to resolve issues. Providing ongoing, transparent communication will go a long way in improving reputation. At this point in the disclosure process, you can also start communicating the capabilities of the organization and stressing new patient safety measures that have been put into place.

Promote capabilities of the organization

One healthcare system, through their investigation of a large-scale adverse event involving insulin pen reuse that occurred at their site, found that warning statements indicating that insulin pens were for single use on a single patient were only present on the outside of boxes containing 10 insulin pens each. The facility found that nurses would often take 2-3 insulin pens out of the box at one time and would store them in a locked cabinet in a nursing station. The individual insulin pens did not carry this warning on the packaging. After the disclosure of this adverse event, the facility director contacted the manufacturer of the insulin pens to describe this problem with packaging. The individual insulin pens now carry a warning about individual, one-time use, in addition to the warning statement that is present on the box of 10 pens. Subsequent meetings with elected officials, VSOs (key external stakeholders) and the media involved discussing how the facility was able to create positive change following such a large-scale adverse event.

Evaluation

Goals:

- Evaluate responses
- Document lessons learned
- Improve crisis communication
- Create linkages to Pre-Crisis

Action Items:

☐ Formally document lessons learned, including insights gained from open forums
Who: Facility leadership

☐ Discuss lessons learned with Central Office
Who: Facility and healthcare system leadership

☐ Implement any steps necessary to prepare for a future large-scale adverse event
Who: Facility leadership, healthcare system leadership

Tools & Resources:

- Tool for facilities to share lessons learned after a large-scale adverse event

Topics:

Documenting lessons learned and implementing improvements for future large-scale adverse events

Formally documenting lessons learned will assist the facility and your healthcare system as a whole in learning from your event. The outline for documentation can be used as a guide for this process. You can use the feedback you collected from stakeholders, employees and leaders in previous stages to formalize the lessons learned. You can also save any tools that were used and proved to be helpful in planning and execution.

Share your lessons learned with team leaders at your facility so that they can prepare for a future event. Consider sharing your lessons learned with healthcare system board of directors?? as well.

We invite you to share your lessons learned in order to continue to improve this Toolkit. You can submit your suggestions by email to Dr. Gavin West, at Gavin.West@va.gov

Appendix

SCALE Study Information

VA HSR&D SDR 11-440

Veteran and Staff Perceptions of VHA Large-scale Adverse Event Communications
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Funding Period: June 2012 - September 2015

BACKGROUND/RATIONALE:
Large-scale adverse events (LSAE) are unanticipated outcomes resulting directly from medical care involving three or more patients. Currently, the health care system struggles to determine the best way to communicate with patients during LSAEs especially as more information emerges. Our study seeks to identify optimal communication strategies to minimize risk of harm and unintended consequences following disclosure. We will use the Crisis and Emergency Risk Communication model developed by the CDC to guide our study objectives and methodology.

OBJECTIVE(S):
Our four-part study involving qualitative and quantitative methodologies addresses three key short-term objectives: (1) explore the effect of LSAEs on Veterans', families', and staff perceptions of VA services, risk to self, and emotional responses to notification; (2) determine the impact of past notification procedures on unintended outcomes, such as Veterans' and staff anxiety and distress, trust in the VA, and changes in VA healthcare utilizations; (3) empirically test the effectiveness of different models of notification based on evidence collected. Our long-term objective is to develop a LSAE notification toolkit that can be distributed by the VHA's Principal Deputy Under Secretary for Health and the Office of Public Health to medical center leadership for use in future LSAE notifications.

METHODS:
Study Part One involves a directed content analysis of media reports and notification letters for six past VA LSAEs and four non-VA events, to create strategies for how the VA can work with media and elected officials once a LSAE occurs. Study Part Two involves interviews with Veterans, their families, staff and leadership at nine facilities that have disclosed LSAEs in the past three years (97 total interviews), to determine what communication went well and what needs improvement for the future. Study Part Three examines the unintended consequences of adverse event notification by analyzing VA and Medicare cost and healthcare utilization data sets from past LSAEs. This part of the study examines whether Veterans stayed in the VHA system following disclosure, whether they sought non-VA care, whether costs decreased or increased, and the time it took for any changes to return to baseline. Study Part Four will involve creating large-scale disclosure vignettes depicting different infection risk levels, and

different types of LSAEs which will vary by the notification medium. An estimated 740 Veterans will participate in this study via an internet-based survey. We will experimentally manipulate variables to determine the optimal responses to questions about perceptions of risk of harm, trust in VA, self-efficacy for action and distress levels. These findings will culminate in the development of a LSAE toolkit.

FINDINGS/RESULTS:
Study One and Study Three have completed data analysis. The media content analysis, Study One, found 148 unique media reports resulted from the six VA events. Some components of effective communication (discussion of cause, reassurance, self-efficacy) were more often present than others (apology, lessons learned). References to "promoting secrecy" and "slow response" appeared most often in media coverage when time from event discovery to patient notification was over 75 days. Elected officials were quoted often (n=115) with comments that were predominantly negative in tone (83%). Hospital officials' comments (n=165) were predominantly neutral (92%), and focused on information sharing.

Study Three examined five past LSAEs. Receipt of an LSAE notification was associated with an adjusted odds of 49.7 (95% CI 41.2 - 60.0), 103.8 (95% CI 78.1 - 137.9) and 88.4 (95% CI 70.4 - 110.0), for HCV, HIV and HBV testing, respectively. Compared to whites, African Americans were significantly less likely to return to VHA for follow-up testing. LSAEs were also associated with changes in subsequent utilization patterns. Patients exposed to a dental LSAE reduced their use of preventive and restorative dental care over the subsequent year, but they eventually came back to VHA for healthcare services by 18 months post-exposure.

We are currently analyzing data from Study Two interviews and Study Four is underway.

IMPACT:
Currently, VA LSAE disclosures take place without the help of evidence to guide decisions about how to disclose breaches of infection control practices, and without knowledge of how best to communicate this information in a way that minimizes harm to patients and maximizes their trust in the VA. Further, the impact on VHA employees of this breach in infection control practice and the resulting communication with Veterans and their families is unknown. This study will help the VHA better understand what aspects of this communication can be improved to minimize confusion and distress by those involved.

Action Item Checklist

Pre-Crisis:

	Use the measures you currently collect on patient and employee satisfaction to look for potential problematic areas.	Who: Facility leadership
	Evaluate current communications practices and leadership style and commitment to I CARE values throughout the organization.	Who: Facility leadership
	Determine who would be best to focus work on the large-scale adverse event and who will assist in completing regular duties while that person leads the disclosure.	Who: Facility Leadership
	Network with key stakeholders, and establish ongoing communication to reinforce relationships	Who: Facility leadership, Facility Public Relations, External Stakeholder Communication Team
	Identify facility disclosure team leads (5 teams: identification/programming, internal communication, patient communication, external stakeholder communication, testing clinics)	Who: Facility leadership
	Distribute Toolkit to team leads, train teams on best practices and check in on a yearly basis for sustainability	Who: Toolkit authors and facility leadership
	Review the tested patient communications materials in the appendix.	Who: Patient communication team
	Review Issue Brief template	Who: Facility leadership

Initial Event:

	Submit an Issue Brief	Who: Facility leadership
	Determine which patients are part of the cohort	Who: Identification/programming team
	Team preparation for communication and testing	Who: Internal communication, Patient communication, external stakeholder communication, follow-up clinic teams
	Communicate with employees	Who: Internal communication team
	Communicate with patients	Who: Patient communication team
	Communicate with other stakeholders	Who: External stakeholder communication team

	Communicate with the media	Who: External stakeholder communication team, facility leadership
	Track patients	Who: Identification/programming team
	Continue communication within the healthcare system	Who: Internal communication team, leadership from facility, healthcare system

Maintenance:

	Regular communication to different groups (follow-up care needed, how many have been tested, what changes have been made to the service where error occurred, etc.)	Who: Internal Communication team, Patient Communication team, External Stakeholder communication team
	Feedback to staff and recognition of employee work	Who: Internal Communication team
	Hold forum for patients to discuss their concerns about the error and the communication process	Who: Facility leadership, Patient Communication team
	Solicit feedback from employees	Who: Facility leadership, Internal Communication team

Resolution:

	Hold forum for patients to discuss their concerns about the error and the communication process	Who: Facility leadership, Patient Communication team
	Ask for employee feedback on their concerns and lessons learned	Who: Facility leadership, Internal Communication team
	Continue communication with stakeholders	Who: External Communication team

Evaluation:

	Formally document lessons learned, including insights gained from open forums	Who: Facility leadership
	Discuss lessons learned with healthcare system and facility leadership	Who: Facility and healthcare system leadership
	Implement any steps necessary to prepare for a future large-scale adverse event	Who: Facility leadership, healthcare system leadership

Pre-Crisis Scenario for Discussion

Read through this scenario and discuss how you would prepare for communication of the large-scale adverse event described. Make note of any needs that are identified as you discuss.

During a review, you discover that the sterile processing unit has been using methods to sterilize colonoscopy equipment that does not meet manufacturer's guidelines. This reprocessing issue affects procedures that were performed between January 15th and February 28th 2018 at your facility.

Colonoscopy equipment is supposed to go through a multiple step cleaning process between patients. Two of those steps were incomplete. A team of experts has reviewed the issues and testing for infectious diseases, like HIV and hepatitis B and C, is recommended for patients who had colonoscopies during this time.

How will you prepare to identify, notify and test patients about this large-scale adverse event? How will you inform other stakeholders like VSOs, elected officials, and the media?

Issue Brief Template

[Healthcare System] ISSUE BRIEF
Facility Y

Issue Title:

Date of Report:

Brief Statement of Issue and Status:

Actions, Progress, and Resolution to Date:

Background information:

Concurrent investigations:

Data:

Contact for Further Information:

Issue Brief Example

[Healthcare System]ISSUE BRIEF

Facility X

Issue Title: Former contract employee associated with 2012 Hepatitis C outbreak in New Hampshire

Date of Report: July 9, 20XX, July 17, 20XX, July 19, 20XX, July 20, 20XX, July 27, 20XX, July 31, 20XX, August 1, 20XX, August 2, 20XX, August 3, 20XX, August 6, 20XX, August 7, 20XX

Brief Statement of Issue and Status: On July 5, 20XX, a request was received from the X Department of Health and Mental Hygiene (DHMH) to the Infection Control Coordinator for the X facility to review work records and patient records of a contract radiology employee who is currently associated with an outbreak of Hepatitis C in a New Hampshire (NH) hospital. The individual, a radiographer, worked at the X facility as a contract employee from March through November 20XX. It was reported that an outbreak of Hepatitis C in patients treated in a cardiac catheterization lab in a New Hampshire (Exeter Hospital) is under investigation by the New Hospital State Department of Health.

A criminal case of this radiographer is currently under investigation for drug diversion. To date, twenty-six patients have been identified as probably contracting Hepatitis C from this radiographer in New Hampshire. The radiographer had been employed in hospitals in several other states. He had been a contract employee through Advance Med, Inc. working at the X VA between March and November 20XX.

On July 5, 20XX, DHMH requested that the VA review records to identify when the radiologist worked at the X facility, what patients he may have cared for, and any access to drugs for sedation, such as narcotics.

On July 6, 20XX, a conference call was held with representatives from DHMH, the Assistant Attorney General of X, and the X facility Hospital Epidemiologist and the Infection Control Coordinator. It was reinforced in the meeting that an open criminal investigation was underway and information should not be shared to jeopardize the case. Additionally information included that the U.S. Public Health Service-Centers for Disease Control and Prevention has been assisting in the NH investigation. The radiographer is not cooperating with the investigation.

Actions, Progress, and Resolution to Date:

X Facility has confirmed that the radiographer worked at the VA during the time period of March through November 2008. He only worked while supervisory staff were on duty and did not cover any on-call periods. Staff are working to identify the specific times and dates when the radiographer would have worked, and the cases the radiographer participated in including names of patients and any opportunities he may have had to divert drugs.

A FBI agent contacted the X Director on July 9, 20XX, at 9:00 a.m. about the case and indicated that the FBI is conducting an investigation. They will be subpoenaing for records. The X Director turned over the FBI subpoena request to VA Regional Council.

It is not yet known if Institutional Disclosure will be necessary; that decision will be made after the case has been thoroughly investigated.

July 17, 20XX - Update: Below are the answers to the questions received from the VACO Office of Clinical Public Health:

Background information

- **What was the technician in question's (TIQ) MO? What drug was the TIQ diverting?**
  According to the conference calls with the Department of Health and Mental Hygiene, (DHMH), TIQ was using narcotics, specifically Fentaynl.
- **What are the practices at the hospital that may have allowed this employee access to syringes filled with "painkillers" and then using them on patients? Were these "opportunities" also present in X?**
  At the X VA Medical Center (VAMC), a list of cases on which TIQ was a member of the procedure team has been prepared. TIQ would have been acting as a technician during procedures, drugs are prepared and handled by a nurse or physician since this is not a technician role. The Radiology Service has a medication storage and distribution system (machine) since before 20XX. The machine requires a sign-on code before access to the medication is given. Sign-on codes are only available to those authorized to administer medications. This provides for security and easy tracking of medications removed from the machine as the person, date, time and drug dispensed is recorded.

Concurrent investigations

Ongoing results of investigations done by Exeter Hospital and outside agencies such as New Hampshire Department of Public Health, CDC and other agencies.

The facility has been in communication with the Assistant Director of the X Department of Health and Mental Hygiene (DHMH). The facility was informed on Monday, July 9, 20XX, that the FBI was investigating the case.

- **VA's investigation.**
  The Radiology Service has conducted an investigation to verify dates of assignment by the contractor to Radiology at Baltimore VAMC. Also, a detailed search was performed to ascertain which patient exams TIQ participated and dates associated with each exam.

Data

- **Process/procedural documents from Exeter that describe their management of controlled substances in the cardiac cath lab and from the X VAMC.**

The employee has not worked in the Cath Lab at the X VAMC. The Exeter Medical Center in NH has not shared any documents with the VA. Any information would be shared by the State Health Department.

- **A listing of specific job duties and work assignments (by time period) within the VA during the employee's tenure there as a contract employee.** Specific job duties included assisting radiologist and IR nurse with Interventional procedures, preparing room and x-ray equipment for exams, preparing sterile trays, pulling proper implants, and maintaining and scheduling patients. The list of patients who came in contact with the radiographer has been prepared by Radiology Service and is attached as a separate attachment in the Excel spreadsheet. The TIQ had received orientation to his position and spent 100% time working in Interventional radiology while in the Imaging service.
  - **What patients did the TIQ work with?**
    TIQ performed multiple Interventional procedures: PICC lines, drains, biopsies, venous run-offs, and angiograms.
  - **TIQ work schedule?**
    TIQ worked Monday thru Friday with no call duties. His predominant shift was 8:00 a.m. - 4:30 p.m.
  - **Access to other areas where controlled substances may be accessible?**
    TIQ did not have direct access to locked drug cart located in IR (radiology), but did work in the area.
  - **List of patient's cared for during the tenure of the TIQ (note: it may also be of use to have similar data on patients seen during time windows before and after the TIQ's tenure)** A list of patients containing exams participation and contact was formulated and forwarded to XVAMC ID and is provided to the Office of Clinical Public Health as a separate Excel attachment.
    - **Procedure(s) performed**: Details of procedure, exams, and patients are recorded in the separate Excel document attachment
    - **Procedure dates**: Procedure dates are recorded in the separate Excel document attached
- **Were other provider's in the TIQ's work area known to be positive for HCV (or other blood borne pathogens) around the time of the TIQ's tenure?** VA employees are not routinely tested.

July 19, 20XX-Update: The radiographer was arrested in Massachusetts for illegal possession and tampering of drugs. The DHMH Epidemiologist contacted the VAMHCS Epidemiologist at 2:30 p.m. with the news of the arrest. The arrest of the radiographer was noted on the internet news this afternoon.

The Hepatitis C genotype 1B has been identified in the radiographer; first positive known test in June 2010.

August 6, 20XX – Update:
Number of Certified Letters: 35

Number of regular mail letters sent to the same Veterans receiving Certified Letters: 35
Number of return receipts received: Zero
Total number called: 51
Number Contacted and Notified: 35
Number Tested: 13

August 7, 20XX – Update:
Total number of Veterans called via telephone: 51
Of the 51 called, number successfully contacted and notified via phone: 35
Of the 51 called, number not successfully contacted and not notified via phone: 16

Number of Certified Letters: 35
Number of regular mail letters sent to the same Veterans receiving Certified Letters: 35
Number of return receipts received: Zero

Number Tested: 13

Contact for Further Information: X, Chief of Staff, at xxx-xxx-xxxx.

Communicating with Patients and the Public *Avoiding pitfalls and communication traps*		
Topic	**Do…**	**Don't…**
SCIENTIFIC TERMS OR ACRONYMS	Use clear communication. Define all technical terms and acronyms.	Use language that may not be understood by even a portion of your audience.
NEGATIVE ALLEGATIONS	Refute the allegation without repeating it.	Repeat or refer to the negative allegation.
TEMPERAMENT	Remain calm. Use a question or allegation as a springboard to say something positive.	Let your feelings interfere with your ability to communicate positively.
CLARITY	Ask whether you have made yourself clear	Assume you have been understood.
ABSTRACTIONS	Use examples or analogies to establish a common understanding.	Assume that people understand the complexity of HAIs.
PROMISES	Promise only what you can deliver. Set and follow strict deadlines.	Make promises you can't keep or fail to follow through on promises made.
RISK	Give your best estimation, based on the science, on the risk (especially associated with infection control lapses).	State absolutes or expect the lay public to understand risk numbers.
BLAME	Take responsibility for your share of the problem; use empathy.	Try to shift blame or responsibility to others.
NUMBERS	Emphasize performance, trends, and achievements. Explain what you are going to do to improve, especially if the numbers are bad.	Turn the conversation into an attack on the accuracy of the numbers, the system, or place blame elsewhere.
Reference: http://www.atsdr.cdc.gov/risk/riskprimer/vision.html		

Outline for documenting lessons learned:

Leadership:
- What went well:
- What needs work for the future:

Internal Communication Team
- What went well:
- What needs work for the future:
- What materials/tools do you want to save for the future:

Patient Communication Team
- What went well:
- What needs work for the future:
- What materials/tools do you want to save for the future:

External Stakeholder Communication Team
- What went well:
- What needs work for the future:
- What materials/tools do you want to save for the future:

Identification/Programming Team
- What went well:
- What needs work for the future:
- What materials/tools do you want to save for the future:

Testing Clinic Team
- What went well:
- What needs work for the future:
- What materials/tools do you want to save for the future:

Look-back Program progress note templates

Note: These were created specifically for the Veterans Health Administration. Other healthcare systems can tailor these to their own EMR systems

These note templates may be used to document activities related to the VA Look-back Program. The form will assist the clinician and/or coordinator in completing the clinical chart review, standardize information collected on each veteran, and provide any reader (local or remote) standardized documentation for the look-back process. As additional information becomes available the local facility should copy and paste the previous version of the note into a new note and add any new information so that all currently available information is located in the latest.

Veteran Name and demographic information – pulled in from VistA as usual
Date: automatically assigned (today's date)
Title: Documentation of activities related to the Look-back Program

This progress note is used to document activities related to (Name equipment or procedure here).

1. Information regarding procedures done at this facility on this veteran using XX (name equipment here)
    a. Date procedure # 1:
    b. Date procedure # 2:
    c. Date procedure # 3:

2. Laboratory testing done <u>prior and closest to</u> the earliest of the above procedure dates:
    a. **Hepatitis B**: Not done ___
    Done on (date) : (mm/dd/yyyy) _____
    Hepatitis B serostatus (Positive or Negative) _____
    b. **Hepatitis C**: Not done ___
    Done on (date) : (mm/dd/yyyy) _____
    Hepatitis C serostatus (Positive or Negative) _____
    c. **HIV**: Not done ___
    Done on (date) : (mm/dd/yyyy) _____
    HIV serostatus (Positive or Negative) _____

3. Laboratory testing done <u>after</u> the latest of the above procedures (not as part of the Look-back Program):
    a. **Hepatitis B** Not done ___
    Done on (date) : (mm/dd/yyyy) _____
    Hepatitis B confirmed serostatus (Positive or Negative) _____

b. **Hepatitis C**: Not done ___
Done on (date) : (mm/dd/yyyy) _____
Hepatitis C confirmed serostatus (Positive or Negative) _____
c. **HIV**: Not done ___
Done on (date) : (mm/dd/yyyy) _____
HIV confirmed serostatus (Positive or Negative) _____

4. Date notification letter about the Look-back Program mailed or otherwise delivered to veteran: (mm/dd/yyyy): _____

5. Date notification letter returned to sender as undeliverable: (mm/dd/yyyy): _____

a. Efforts made to locate current contact information for veteran:

b. Date letter sent to updated address or otherwise delivered to veteran: (mm/dd/yyyy) _____

6. Date Veteran contacted VA in response to letter: (mm/dd/yyyy) _____

a. Veteran was provided opportunity to ask questions Yes ____ No_____

b. Veteran wishes to come in for clinical evaluation Yes ____ No_____

c. Veteran given appointment for clinical evaluation Yes ____ No_____
If YES, date, time, location:

d. Veteran declines to come to VA for further clinical evaluation Yes ____ No____

e. Comments: (include date with each entry)

7. Look-back completion
a. Reason for Look-back completion (enter effective by date)

i. Veteran deemed non-contactable (minimum 90 days following mailing of notification letter).
(mm/dd/yyyy): _____
ii. Veteran contacted VA and declined further evaluation at VA.
(mm/dd/yyyy): _____
iii. Veteran contacted VA and did not attend scheduled appointments (minimum 90 days following mailing of notification letter).
(mm/dd/yyyy): _____

iv. Veteran contacted VA, attended at least one appointment, and decided not to undergo further testing.
(mm/dd/yyyy): _____

v. Veteran contacted VA, attended at least one appointment, and received further testing.
(mm/dd/yyyy): _____

1. Date and result of lab testing.
    a. Hepatitis B: _____
    b. Hepatitis C _____
    c. HIV _____

8. Additional comments (note date with each entry)

Examples of STL Progress Note Templates

- Initial notification note
- Results interpretation note
- Administrative note

Standardized reporting tool

	Number of Cumulative Cases by Reporting Milestone				
TOTAL NUMBER OF UNIQUE VETERANS	Week 1	Week 2	Week 3	Week 4	Week 5*
To be reviewed					
With evidence of HBV infection *before* the procedure***					
With evidence of HCV infection *before* the procedure***					
With evidence of HIV infection *before* the procedure***					
With CPRS reviews completed					
With first letter sent					
With first letter returned as undeliverable					
With first letter undeliverable, address updated and second letter sent					
Determined to be non-contactable					
Who contacted VA in response to notification (within 90 days of most recent letter)					
Who had a VA appointment scheduled					
Who declined testing					
Had blood testing completed including any confirmatory testing					
Had blood testing results reported back to them					
With *new* HBV diagnosis after procedure date***					
With *new* HCV diagnosis after procedure date***					
With *new* HIV diagnosis after procedure date**					

Summary CPRS progress note completed					
Case completed					

*Completed weekly until finished.
**If the veteran had multiple procedures performed, report diagnoses before and after the first procedure.

Individual Veteran Look Back Program Tracking Tool

1. Identification:

Veteran Name (first, middle initial, last)	Date of Birth	Last 4

2. According to CPRS, is the veteran currently alive? (circle one)YES NO NOT SURE

If NO, what was the date of death: _____

Place all cases with NO responses on hold pending processing of other living cases.

3. Was the veteran seen at *any* VA facility in the past 12 months?(circle one)YES NO

4. Is the veteran receiving Primary Care at this facility? (circle one) YES NO

a. If NO, where are they receiving Primary Care?

i. Facility Name: _____
ii. Primary Care Provider: _____
iii. Contact number for Primary Care Provider:_____

b. If NO, what is their current contact information?
Address: _____
_____

Phone: _____

5. When is the veteran's next primary care appointment? _____
Indicate "DK" for don't know if not known or not currently in VA care.
(If someone had an appointment soon, you may want to directly educate the primary care provider so that she or he may give the veteran the notification letter and educate him during that visit).

6. Key Actions and Dates:

Action or Event		Date (mm/dd/yy)	
Procedure Date(s)*			
CPRS review completed	Yes or No		
		Date	Comments

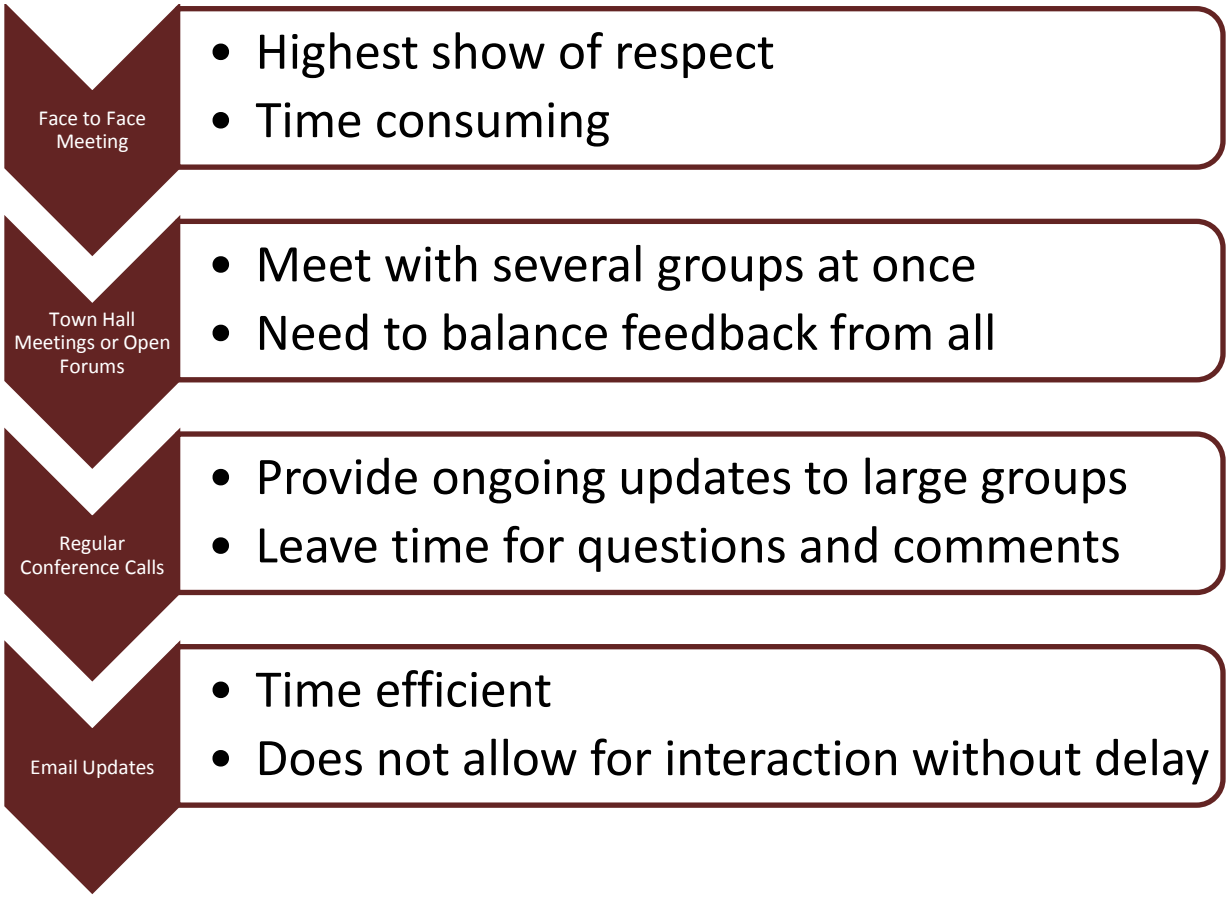
First letter Sent	Yes or No		
First letter returned as undeliverable	Yes or No		
First letter undeliverable, address updated and second letter sent	Yes or No		
Veteran determined to be non-contactable	Yes or No		
If veteran determined to be non-contactable, you can mark case completed below.			
Section below applies only to veterans who respond within 90 days of mailing date			
Veteran responded within 90 days			
Declined testing	Yes or No		
Appointment scheduled	Yes or No		
Blood testing completed (including any necessary confirmatory testing)	Yes or No		
Blood testing results reported to veteran	Yes or No		
Final Look-back Program progress note completed	Yes or No		
Case Completed	Yes or No		

*If the veteran had multiple biopsies performed, report on all dates that meet the look-back criteria. If the veteran had more than three such biopsies, add an additional page.

Website Examples:


Exeter Health Resources Affiliated System of Care
EXETER HOSPITAL
an exeter health resource | The Art of Wellness
Careers
Make a Donation
Contact Us
For Employees & Physicians
About Us
Our Services
For Patients & Visitors
News & Health Library
Our Locations
SEARCH
Uncle Don | Broke His Hip
Mom | Broke Her Collar Bone
You | Are Breaking The Pattern
LEARN MORE
Welcome to Exeter Hospital
Exeter Hospital is a 100-bed tax exempt, community-based hospital and one of five affiliates of Exeter Health Resources. At each of the affiliated companies, we are committed to providing health care services that are innovative, progressive, and focused on quality and the well-being of patients.
News
Events
Network of Caring
Collaborations
Hepatitis C - June 14 Updates
Hospital CEO Apologizes For Hepatitis Outbreak
Hepatitis C - June 13 Updates
Hepatitis C - June 9 Updates
Hepatitis C - June 6 Updates
Hepatitis C - June 4 Updates
Exeter Hospital Reopens Cardiac Cath Lab
Quick Links
Advance Care Planning
Careers
Contact Us
Financial Assistance
Find a Class
Make a Difference
Newcomer Concierge Service
Project Healthcare (Epping)
Sign Up for E-Newsletter
Find a Provider
Like Us on Facebook
Our Key Services
View All
Cancer Care
The most comprehensive in-patient and outpatient services on the Seacoast.
Learn about this service >
Orthopaedics
Total Joint Replacement with a unique, individual and personalized treatment approach.
Learn about this service >
The Center for Breast Health

Strategies for Getting Feedback from Stakeholders:



Patient Communications Materials

Note: This language has been tested with over 1,000 Veterans. Highlighted language should be updated for your event. For best results, do not make major changes to other text.

Sample Facebook Post for high risk event:

The VA continuously monitors the care we provide Veterans and notifies patients of any concerns related to their care. We have identified an issue with colonoscopy procedures that were performed between January 15th and February 28th 2014 at the Eastville VA Medical Center.

Colonoscopy equipment goes through a multiple step cleaning process between patients. Two of those steps were incomplete. A team of experts has reviewed the issues and testing for infectious diseases, like HIV and hepatitis B and C, is recommended for patients who had colonoscopies during this time. All Veterans who may have been affected will soon receive a phone call from the VA medical center. These Veterans will be offered appointments for testing free of charge.

If you are a Veteran and have any questions or concerns about this issue, please call us at (123) 456-7890. We sincerely apologize for this error and any anxiety it may cause our Veterans.

Sample Facebook Post for low risk event:

The VA continuously monitors the care we provide Veterans and notifies patients of any concerns related to their care. We have identified an issue with colonoscopy procedures that were performed between January 15th and February 28th 2014 at the Eastville VAMC Medical Center.

Colonoscopy equipment goes through a multiple step cleaning process between patients. One of those steps was incomplete. A team of experts has reviewed the issues and we are confident that the level of risk for infectious disease, like HIV and hepatitis B and C, is very low. However, we are calling all Veterans who may have been affected and offering them appointments for optional testing, free of charge, at VA.

If you are a Veteran and have any questions or concerns about this issue, please call us at (123) 456-7890. We sincerely apologize for this error and any anxiety it may cause our Veterans.

Sample Veteran letter for high risk event:

Dear Mr. Jones:

We are writing to you today about an unfortunate event. We discovered the colonoscopy procedure you had at the Eastville VA Medical Center may not have been the quality we sought to provide.

The colonoscopies we are concerned about were performed between January 15th and February 28th 2014. Normally, the colonoscopy equipment goes through a multiple step

cleaning process between each patient. During a hospital review, we discovered that two of those steps were not completed during some procedures.

Cleaning that is not complete could lead to infection. VA staff and clinical experts have reviewed the care given to all patients who had colonoscopies during this time to determine if any patients were exposed to harmful or potentially harmful infectious diseases. As a result, the Eastville VA would like to request that you come in for testing for infections like HIV, hepatitis B and hepatitis C. The VA is providing testing at no charge to you.

It is important for you to be tested because people with infectious diseases do not always have symptoms. In an effort to make the screening as convenient as possible, we have created a special clinic at the Eastville VA for patients like you to undergo blood tests to rule out HIV and hepatitis. We scheduled a testing appointment for you:

Tuesday April 30, 2014 at 2PM in room 100 of Building 1 on the Eastville VA campus.

If this time does not work for you, please call (123) 456-7890 and we will reschedule it for you. Your visit will give us an opportunity to answer any questions you have and to discuss any follow-up care needed. Once your blood is drawn, test results could take up to 10 days. We will notify you of the results by mail or phone call.

There are some precautions you should take before you receive your test results. You should not donate blood, share razors, or tooth brushes. You should practice safe sex, which includes the use of a condom. You should not drink alcohol or take Tylenol products because they could be harmful to you if you have one of these diseases.

We understand that this may be an upsetting situation for you and your family and we have staff ready to provide assistance. VA staff are in the process of reaching out to Veterans by phone. If you have not yet received a phone call, please know that we are making efforts to get in touch with you as soon as possible. If you prefer, you can call us directly at our dedicated communication center: (123) 456-7890, from 8:00 a.m. to 8:00 p.m. ET Monday through Friday. A team of our Eastville VA Medical Center nurses will be answering phone calls. Please be assured we are committed to answering your questions. We are also working closely with the Centers for Disease Control and Prevention to make sure our methods of cleaning equipment and training staff are the best they can be.

We realize that you turn to the VA to get better. We sincerely apologize for performing your colonoscopy procedure with an instrument that was not properly cleaned. We accept responsibility for this mistake and are taking steps to prevent it from happening again. This event is unacceptable to us as well, and we want to work with you to correct the situation and ensure your safety and well-being.

Sincerely,

John Smith
Eastville VA Medical Center Director

If you would like more information about the cleaning process and what happened, please visit our website (insert url here) or call us at the number listed above.

Sample Veteran letter for low risk event:

Dear Mr. Jones:

We are writing to you today about an unfortunate event. We discovered the colonoscopy procedure you had at the Eastville VA Medical Center may not have been the quality we sought to provide.

The colonoscopies we are concerned about were performed between January 15th and February 28th 2014. Normally, the colonoscopy equipment goes through a multiple step cleaning process between each patient. During a hospital review, we discovered that one of those steps was incomplete during some procedures.

Cleaning that is not complete could lead to infection. VA staff and clinical experts have reviewed the care given to all patients who had colonoscopies during this time to determine if any patients were exposed to harmful or potentially harmful infectious diseases. We are confident that the risk of infectious diseases is **very low**. For your own reassurance you may wish to be tested for infections like HIV and hepatitis B or C. Testing is not required, however, we are making optional testing available to you in order to alleviate any concerns you may have. The VA is providing testing at no charge to you. A representative from the Eastville VA will be in touch by phone and you will have the option of scheduling testing at that time. You can also reach us at the number below.

We understand that this may be an upsetting situation for you and your family and we have staff ready to provide assistance. VA staff are in the process of reaching out to Veterans by phone. If you have not yet received a phone call, please know that we are making an effort to get in touch with you as soon as possible. If you prefer, **you can call us directly at our dedicated communication center: (123) 456-7890, from 8:00 a.m. to 8:00 p.m. ET Monday through Friday.** A team of our Eastville VA Medical Center nurses will be answering phone calls. We are committed to answering your questions. We are also working closely with the Centers for Disease Control and Prevention to make sure our methods of cleaning equipment and training staff are the best they can be.

We realize that you turn to the VA to get better. We sincerely apologize for performing your colonoscopy procedure with an instrument that was not properly cleaned. We accept responsibility for this mistake and are taking steps to prevent it from happening again. This event is unacceptable to us as well, and we want to work with you to correct the situation and ensure your safety and well-being.

Sincerely,

John Smith
Eastville VA Medical Center Director

If you would like more information about the cleaning process and what happened, please visit our website (insert url) or call us at the number listed above.

Key Information to provide during a phone call:

- Start by clearly stating who you are and why you are calling.
- Provide details about the event to help the patient understand the level of risk.
- Apologize for the event.
- State whether follow-up care (like testing for HIV or HCV) is needed (recommended) or available (optional).
- Provide details for how patients can receive follow up care.
- If testing or follow-up is needed, provide information about co pay costs being waived and expected wait time for testing results.
- Provide contact information for follow-up questions.
- Ask if the patient has any questions.
- If a patient is very upset, offer to have a facility leader talk to the patient and listen to concerns.

A sample telephone conversation is provided below:

Your name is Mr. Jones. You are 52 years old and routinely use your local VA medical center, the Eastville VA, for medical care. Your regular doctor, Dr. R, has recommended that you have a colonoscopy, a test recommended for all patients your age. It is a cancer screening procedure that requires your doctor to check your colon for suspicious growths by looking through a camera attached to a medical device that is inserted in your colon while you are under general anesthesia. You agree to have the colonoscopy procedure. The procedure is performed a week later at the Eastville VA Medical Center by VA staff. Afterwards, Dr. R contacts you to let you know that "everything is fine and there is no follow-up care needed."

A month and a half after your colonoscopy, you receive a phone call from Dr. R explaining that there was an issue with your colonoscopy. Dr. R explains that the colonoscopy equipment wasn't cleaned properly by the staff. The cleaning process is a multiple step system and one of those steps was not completed.

He apologizes on behalf of the Eastville VA Medical Center for the error and any anxiety it may cause you. Your doctor tells you that the risk of exposure to viral diseases like HIV, hepatitis B, and hepatitis C is "very low." However, optional testing is available at no cost to you to alleviate any concerns you may have. Testing results should be ready within ten days. He explains that the use of this equipment could lead to infections if one patient comes into contact with the same equipment used on patient with an infectious disease. Your doctor lets you know that the risk is low enough that the VA isn't requiring testing. Dr. R explains that the VA will provide you with testing and any follow-up care that is needed. He gives you a special phone number at the Eastville VA Medical Center set up specifically for Veterans to call with questions about this event. He encourages you to call if you have any additional questions about what happened or are ready to set up a testing appointment. Finally, he lets you know that "You should receive a follow-up letter from the Eastville VA soon with the information we discussed today."

Peer Support Program Elements [11-13]

1 Acknowledge impact on employees

2 Identify trained professionals and trusted peers

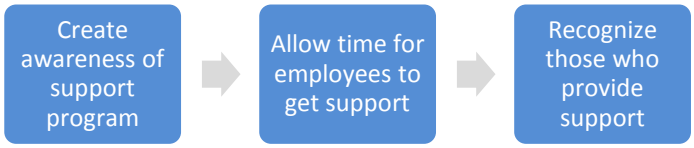
Employees must view the identified individuals as trusted confidents.

Peer support must maintain confidentiality of employee concerns.

Supervisors must be supportive, but cannot serve as peers.

Employees must view the individual selected as their peer or equal.

3 Encourage staff and peer support



Message Planning Template

Audience	Key Message	Supporting Facts	Communication Channel
Example: General Public	[Healthcare system] has identified an issue with insulin pen use at the X facility. 500 patients are being contacted about the error. [Healthcare system] has put preventative measures in place at all facilities to prevent future issues.	• Needles for insulin pens were not reused; the outer part of the pen was used for more than one patient. • Patients affected have very low risk for exposure to blood borne pathogens like HIV and hepatitis C. • If you have questions about the event or your care, please contact the hotline at 800-555-5555.	• [Healthcare system] website, Facebook • Press release to newspaper, local TV
External Stakeholders			
Media			

Message Development for Communication

First, consider the following:

Audience:	Purpose of Message:	Method of delivery:
• Relationship to event • Demographics (age, language, education, culture) • Level of outrage (based on risk principles)	• Give facts/update • Rally to action • Clarify event status • Address rumors • Satisfy media requests	• Print media release • Web release • Through spokesperson (TV or in-person appearance) • Radio • Other (e.g., recorded phone message)

Six Basic Emergency Message Components:

1. Expression of empathy: _____
2. Clarifying facts/Call for Action:

Who

_____

What

_____

Where

_____

When

_____

Why

_____

How

_____

3. What we do not know: _____
4. Process to get answers: _____
5. Statement of commitment: _____
6. Referrals: _____

For more information

_____

Next scheduled update

_____

Finally, check your message for the following:

- Positive action steps
- Honest/open tone
- Applied risk communication principles
- Test for clarity
- Use simple words, short sentences
- Avoid jargon
- Avoid judgmental phrases
- Avoid humor
- Avoid extreme speculation

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