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

Office of Public Health and Environmental Hazards

VA HEALTH CARE | Defining EXCELLENCE in the 21st Century

Department of Veterans Affairs

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PREFACE

As individual members of the health care team, we each bear the responsibility to assure that the services we deliver be safe and effective. As a health care delivery system, VHA must establish diagnostic and therapeutic procedures and processes that assure safety and effectiveness and respond to any indication of risk to patients or staff members. For both individual providers of care and the system as a whole, one of the most difficult situations we encounter is the possibility that a patient experienced a health risk in the course of receiving care. The response to such a situation reflects the core values and ethical principles of the organization.

Based in large part on the experience of implementing past notification programs and extensive epidemiological investigations, VHA undertook review and update of its policy (VHA Directive 2008-002) regarding disclosure of adverse events to patients. With the goal of providing clear direction and practical support to the field, the Office of Public Health and Environmental Hazards has prepared this resource manual. It will be disseminated across the system to guide future patient notification programs and epidemiological investigations of such events.

As the largest integrated health care system in the nation, VHA is in a position to provide leadership and share its experience with the larger health care community. While this document is primarily intended to serve as a resource for VHA, many of the lessons learned, and certainly the underlying spirit of transparency and responsiveness in operations, will be of value to the larger community. We commend the work of VHA employees who have carried out previous look-backs and epidemiological investigations and offer the valuable lessons learned to our colleagues.

National coordination of VHA's response to disclosure of adverse events, the formal look-back and public health investigations is a collective response from across VA and VHA offices including:

VA Office of General Counsel
VA Office of Legislative Affairs
VA Office of Public and Intergovernmental Affairs
VHA Chief Business Office
VHA National Center for Ethics in Health Care
VHA National Center for Patient Safety
VHA Office of Communications
VHA Office of Nursing Services
VHA Office of Patient Care Services, Infectious Disease Program Office
VHA Office of Quality and Performance
VHA Deputy Under Secretary for Health for Operations and Management
VHA Deputy Undersecretary for Health for Clinical and Organizational Support
VHA Office of Public Health and Environmental Hazards (OPHEH)

At each of the facilities implementing a look-back program, the Director and Chief of Staff shall assign responsibility to specific staff members to oversee implementation.

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INTRODUCTION

Despite ongoing efforts to make health care as safe as possible, the process of delivering care carries an inherent risk that patients may be exposed to potentially harmful situations. Any health care system that aspires to transparency must acknowledge this fact, and it is in the best interest of patients and the health care systems to proactively establish a system to respond when such situations are identified. Response must be in a manner that is effective, efficient, timely and sensitive to the needs of affected patients and caregivers.

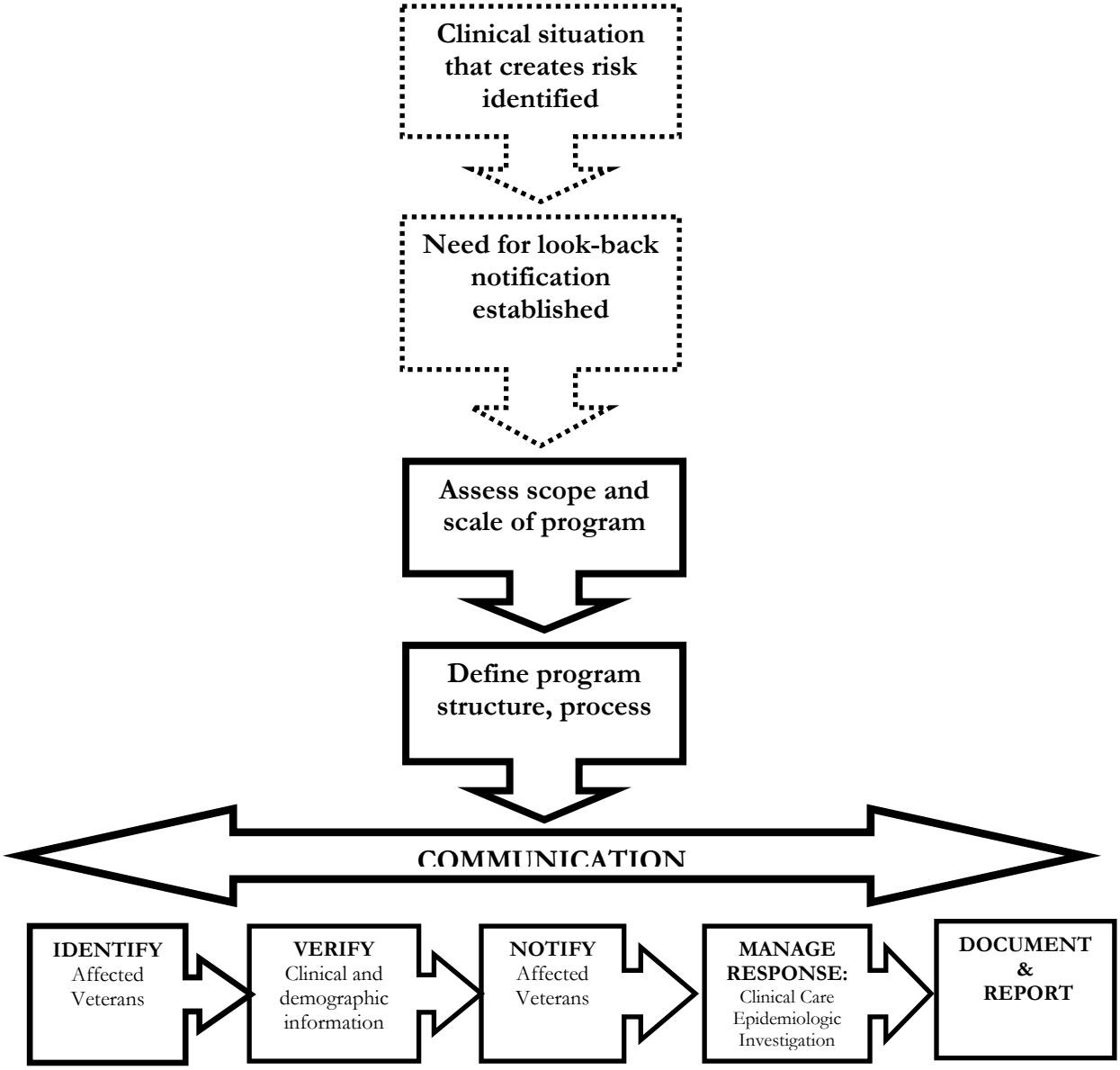
Situations in which a potential exposure to risk occurs during care delivery may be identified through a number of sources, from routine patient safety rounds to standard reporting systems to ad hoc reports from individual staff members. The content of this document has as its starting point the time immediately following an organizational decision that patient notification is warranted, and does not replace or amend directives, policies or procedures related to determining the need for such a program. As used in this document, a look-back program is an organized effort whose objective is to identify patients with evidence of exposure to potential risk during past clinical procedures in order to notify affected patients, offer them appropriate care and document what has been done. One aspect of this manual focuses on operational aspects of implementing a look-back program.

The second aspect of this manual focuses on what is needed at the facility and within VHA in order for an epidemiological investigation to occur. A team of epidemiologists from the Office of Public Health and Environmental Hazards will conduct an epidemiologic investigation into the likelihood that the adverse event was related to any new diagnosis that was identified during the look-back.

The scope of patient notification may vary from a single patient or site to the entire system, but essential components will remain the same regardless of the scope. This document is organized according to the major operational aspects of a look-back/patient notification program and an epidemiological investigation. The manual includes strategies that were identified as useful during previous look-back investigations.

VHA is the largest single health care system in the country and enjoys availability of one of the world's most comprehensive electronic medical record systems and while there are few, if any, systems that operate on the same scale, these lessons learned may offer direction and support to any health care system undertaking a patient look-back and notification process.

This manual focuses on activities that begin once the need to implement a look-back notification program has been established. The important activities antecedent to the determination that a program is necessary are represented by dotted line boxes in the graphic below and are not covered in this document. As depicted, communication is an essential component across the entire program.


Clinical situation that creates risk identified
Need for look-back notification established
Assess scope and scale of program
Define program structure, process
COMMUNICATION
IDENTIFY Affected Veterans
VERIFY Clinical and demographic information
NOTIFY Affected Veterans
MANAGE RESPONSE: Clinical Care Epidemiologic Investigation
DOCUMENT & REPORT

This document is arranged in modules corresponding to the major essential aspects of initiating and implementing a Look-Back and Patient Notification program including:

A. Core leadership and program management
B. Identifying affected patients
C. Notification process
D. Managing response
E. Laboratory testing
F. Clinical disclosure and care
G. Documentation and reporting
H. Epidemiologic investigation
I. Communication

Each **section** starts with a few **key questions** relevant to that area followed by a series of concise summary statements on various operational aspects involved in that aspect of a look-back program. Approaches to various issues are standardized wherever possible to improve portability in larger programs and designed to encourage thought and discussion about its applicability at any administrative level. Because the various aspects of a look-back program must work well together there may be some instances of overlap between sections, most notably comments related to communication which appear throughout the document. The **target audience** includes national program offices, Veterans Integrated Service Network (VISN), and local facility staff involved with designing, implementing, and completing a look-back program. Terminology used throughout the document pertains to VHA with naming conventions such as "service" or "program office" interchanged given the broad target audience. Covering these key administrative levels with any level of granularity would greatly diminish the overall utility of this document. Documents and templates employed during past national look-back programs are included as attachments; readers should note that these are provided as examples and are not intended for use in all programs. Additional support and guidance will be provided by the offices listed in Section A, Core Leadership and Program Management.

A. Core Leadership and Program Management

This section discusses essential activities involved in establishing the structure of a look-back notification program following determination that one will be required. The core objective of this phase is the development and deployment of program requirements, guidance, and supportive tools. While this document focuses on planning for a large scale program that involves multiple sites, many of the issues will also pertain to smaller scale programs.

Key questions that drive activities at this phase are:

- **What offices/expertise needs to be represented on the leadership team in core or supporting roles?**
- **Who is best suited to fill key roles and serve as group leader?**
- **What is the likely extent of the situation?**
- **What information will need to be disseminated and collected?**
- **What communication strategies will be required to disseminate and to collect information?**
- **What resources are required, which of these exist, which need to be developed?**
- **What information will be necessary to identify patients requiring notification?**

VHA provides direction to system components regarding the process to follow in determining the need to notify patients of potential adverse outcomes in VHA Directive 2008-002. Discussion of that process is beyond the scope of this document, which considers operational issues that pertain once the determination has been made that look-back/patient notification/epidemiologic investigation will be required. Experience with previous look-backs provided multiple lessons to guide organization and implementation of a look-back program. The scale of a look-back/notification/epidemiologic investigation program will influence the exact form and format required for successful implementation, but the topics and processes discussed in this document will largely apply whether the scope is national, VISN level, or at the local level. Regardless of scale, the initial step involves designating a group to provide overall leadership and coordination. The following discussion refers to organizational functions rather than specific titles or positions. The person(s) best suited to represent an office or organizational function may vary depending on numerous factors, including the specific clinical issue involved, previous experience, individual training and skills, and availability/competing demands. At the operational level, the best person for membership on a coordinating group is likely to be someone with current practical experience rather than an administrative position.

1. **Assemble a coordinating group**. Designate a lead office and representation from offices and organizational entities whose expertise will be required, likely including but not limited to:

a. Deputy Undersecretary for Health for Clinical and Organizational Support (10A)
b. Deputy Under Secretary for Health for Operations and Management (10N)
c. Office of Public Health and Environmental Hazards (13)
d. Office of Quality and Performance (OQP)
e. National Center for Patient Safety
f. Patient Care Services, including subspecialty services as appropriate
g. Infectious Diseases Program Office (IDPO)
h. Office of Information and Technology (OI&T)
i. Public Affairs/Communications
j. Office of General Counsel (OGC)
k. VISN and Facility Leadership
l. Office of Congressional and Legislative affairs
m. National Center for Ethics in Health Care

For programs which are national in scope this group will provide consultation, support and direction to facilities implementing the program and will provide ongoing updates to VHA/VA leadership. For programs which are of smaller geographic scope, a similar group should be assembled with members from the appropriate organizational level (e.g., VISN).

The coordinating group will need to meet (teleconference is acceptable) on a regular schedule with frequency decreasing as implementation progresses. Membership needs may change as the program matures and some offices may not be required to attend all meetings, but should remain available ad hoc to address emerging issues.

Meeting notes should be action oriented and document decisions made, actions taken and next steps with assignment of responsibility and due date. Meeting notes should be circulated to group members as soon as possible following meetings. In the initial organizational phase frequent meetings will likely be required; as the program matures less frequent meetings will be required but periodic updates should continue.

2. **Designate a Program Lead.** The program leader will oversee and be responsible for all program activities. Depending on the program, this may or may not require a clinical staff member. The lead should rely on the expertise available on the coordinating team, subcommittees, or other entities (i.e., National program office staff for field support). Where multiple facilities are involved with regional or national communications, the Program Lead serves as the point of contact for sending information to and receiving information from participating facilities.

3. **Determine the nature of the adverse event and any risk to patients.** Identify in as much detail as possible the clinical scenario/situation deemed to have precipitated the risk in order to allow facilities to do the most thorough patient identification process. It may help to employ the concept of "inclusion criteria"

when generating guidance for the field – i.e., specifying which clinical or other characteristics indicate a patient may be affected.

a. Provide a succinct explanation of the potential risk. Determine whether and to what extent a risk exists.
b. If specific clinical procedures are involved, list them and include any associated current procedural terminology (CPT) codes. If the date range is large, be sure to include any codes that may have been in use in the past.
c. If equipment is involved, include the supplier, brand name, and model numbers that were in use during the period at issue so the facility material management staff can determine if it is or has been in use and during what period. In some cases, the equipment in question may be required to be quarantined and/or stored for inspection or further testing by the manufacturer or by the epidemiologic investigative team.
d. In scenarios involving processes (e.g., procedures for reprocessing equipment) identify in as much detail as possible the specific steps which when taken or omitted create the risk. During this process include information from staff who previously worked in the area as they may offer important historical information.
e. When requesting information from the field, utilize the simplest format possible – i.e., a questionnaire with "Yes" or "No" responses is preferable to a questionnaire that provides a series of open ended questions but be sure to provide space for additional comments to obtain information not previously recognized as pertinent.
f. Recognize that some clinical scenarios may require consultation and/or discussion beyond what is possible using formatted questionnaires. Site visits may be required to understand the processes or equipment that was used.

4. **Provide a gross assessment of scale.** An important initial task for the coordinating group is to perform a rapid assessment of the probable scale of the program. Identification of individual patients that might be affected is not required, but an informed good faith estimate of the number of patients and facilities affected is sufficient. This is necessary to guide planning, implementation, and estimation of required resources.

5. **Determine with as much specificity as possible what data/information will be required.** When deciding what information will be necessary, be cognizant of the reporting burden on facilities. When requesting information, formulate the question as precisely as possible but also provide a brief rationale for the request; facilities may be able to identify alternate data or data sources that would be less burdensome. If clinical data will be required, obtain expert consultation.

6. **Form subcommittees to expedite and streamline process.** In scenarios involving potentially complex scenarios, it may be advisable for the coordinating group to utilize subcommittees that are tasked to research and report back with recommendations on specific operational issues. Such subgroups would typically

function in a time-limited fashion, though program implementation may raise issues that will require ongoing attention and effort outside the parameters of the look-back program. Likewise, as the program evolves it may become necessary to reconfigure the membership of the coordinating group to assure that organizational representation and operational expertise are provided. Similarly, some individuals may bring expertise required for only a limited part of the overall program and should be excused from ongoing participation when their expertise is no longer required.

7. **Standardize methods of communication for the coordinating team.** Use communication methods that provide ongoing documentation, such as email for disseminating and collecting information. Teleconferences can be a useful tool, especially to monitor and respond to emerging issues, but should be followed by distribution of summary notes to those involved in managing or implementing the program. Each document should include the date the document was generated; in word processing programs this can be accomplished using the footer function.

8. **Create and distribute process overview documentation.** To the greatest extent feasible, construct and disseminate a single document with a comprehensive overview of the program including requirements and expectations of facilities as well as required reporting forms, optional tools and helpful information. Facilities previously performing look-backs identified this as a major contributor to program success. Attachment 1, "BK Lookback Information Packet" provides an example used following a large-scale exposure incident involving prostate biopsy equipment. Consider deployment of a web based system (secure intranet, i.e., SharePoint) with controlled access for information dissemination and collection if it can be implemented in a timely fashion and ongoing maintenance is assured.

9. **Identify Point of Contact (and alternate) for communication with and within the coordinating group.** Designate a point of contact (POC) and an alternate to facilitate communication and coordination as the program is being deployed. The POC serves to facilitate communication and does not necessarily require a clinical background, but will function best if he or she is in a position to understand the operational structure and nature of the issues which precipitated the program. The POC may or may not be the same individual as the coordinating team leader as skills may differ. In the event that they are not the same person, communication between these two individuals is paramount to the success of the program.

10. **Establish a communications network with facilities/VISNs.** At each facility and/or VISN involved in the look-back, the Facility Director or Chief of Staff should designate a primary point of contact (POC) and an alternate. A roster of designated facility/VISN POCs should be assembled and updated as needed and should be provided to all facilities. Frequent change in POC staff can cause major problems with the program as communications lines fail.

11. **Structure response for optimal efficiency.** Specify a realistic timeline/deadline for response to all queries. This rule applies to requests from the coordinating group to the field as well as to subcommittees and vice versa. Short turn-around times must be justified by urgency in the need to know and tempered by the capability of the system to meet the deadline.

12. **Provide clear instruction on what information is to be collected and why**. When establishing key actions required for program implementation, clearly identify the reason/objective but recognize that regional variation in organizational structure and/or local culture may affect the exact manner in which something is done. Likewise, provide tools and options for local use.

13. **Standardize data collection.** Determine what information will need to be collected on an ongoing basis and provide a clear description to the performing facilities on what is to be reported and how it will be done. Detailed instructions should be provided for each "data element" in order to standardize data collection regardless of who is conducting the work.

14. **Assess and prepare for impact on Clinical Services.** The specific clinical scenario will determine what clinical services should be provided. Anticipate that clinical or subject matter experts at the site may be required to handle some aspects of clinical notification or investigation, and who will then require accommodation and time away from normal scheduled duties. Direction to the field should be as specific as possible in terms of identifying the minimum diagnostic tests, procedures, or services which should be offered to affected patients. Individual clinicians may deem additional services to be required on a case-by-case basis. In some scenarios services may be required beyond a single visit. For example, during the BK look-back program some affected Veterans required follow up evaluation due to the six month seroconversion period. Models for managing the impact are provided throughout this document.

15. **Assess and plan for potential fiscal impact to affected Veterans.** Services – clinic appointments, laboratory, or other diagnostic testing, any indicated treatment - related to a look-back program should be provided at no cost to affected patients. For large scale programs it may be useful to establish a program specific stop code which does not generate a co-pay, as was done during previous look-back programs. This also allows for tracking of workload resource utilization. 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.

16. **Consider that the unexpected will happen and be flexible.** It is important to understand that despite the best and most exhaustive planning, there is always the possibility that unanticipated situations will emerge. External events, competing priorities, or new information may require program modification. There is an

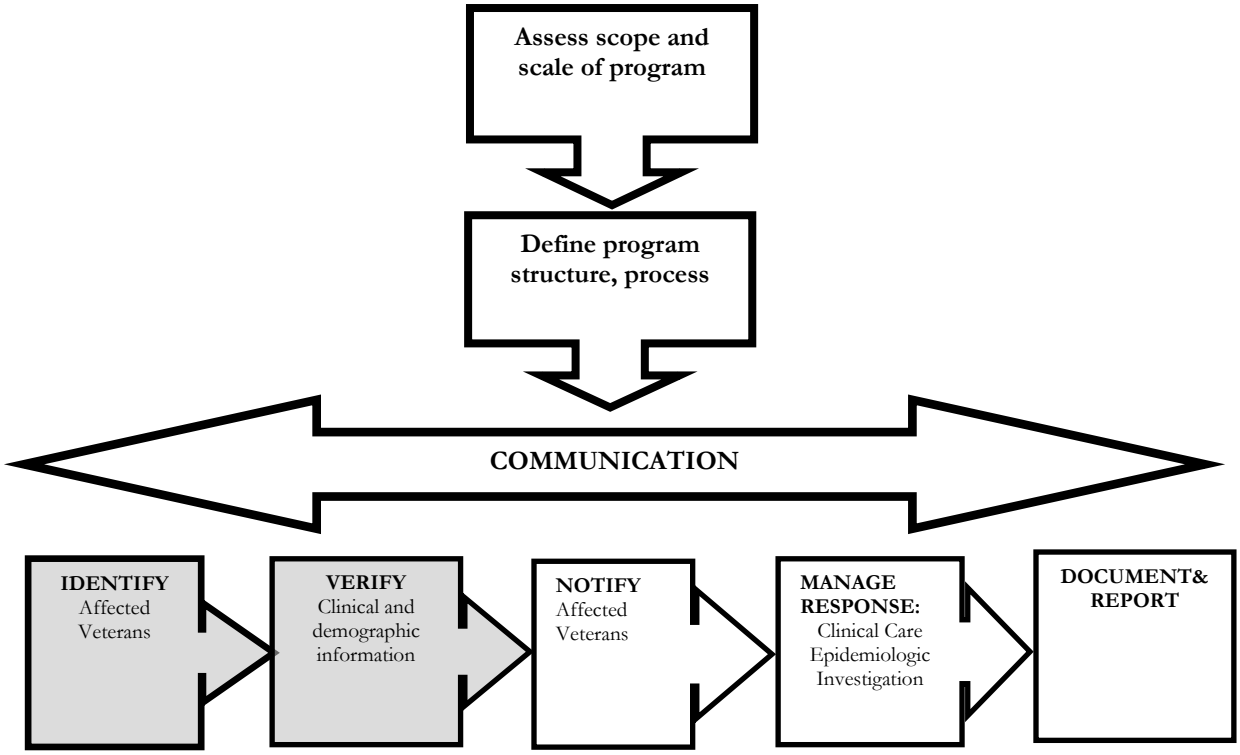
inescapably iterative aspect to program management and the coordinating team needs to remain responsive to developing needs, maintaining a balance between the beneficial aspects of standardization and the risk of stifling creativity and responsive care.

B. Identifying Affected Patients and Verifying Status

This section discusses activities involved with identifying patients who are affected by a look-back notification program. The core objective of this phase of the program is to utilize available data to identify individual patients who received services that are included in the specifications for the look-back notification program.

Key questions to be addressed in this phase of a look-back program include:

1. **What information will be required to identify affected patients?**
2. **Where does required information reside and how can it most efficiently be accessed?**
3. **How can information be collected, stored and shared to reduce duplication of effort in later phases of the program?**



Identifying Affected Patients

The specific strategies used to identify patients affected by a look-back notification program 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. Efficiency and expediency can be optimized by the following:

1. **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 indentified 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 look-back. Attachments 3 and 4 provide examples of forms that may be helpful in this process.

2. **Optimize use of the electronic medical records (EMR).** EMR provide an indispensable tool to expedite patient identification. Develop and distribute step by step instructions for using electronic search strategies. Local implementation will likely require involvement of clinical support and technical staff, to assure that all affected patients are identified. As the program continues, a facility may devise a novel strategy that may be useful at other sites; sharing across sites is to be encouraged and facilitated.

3. **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. Attachment 12 can assist in identifying and recording EMR and alternate data sources available. 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 the Clinical look-back team identify additional sources of information that may have been overlooked.

4. **Limit duplication where possible.** To minimize unnecessary repetition, provide a tool for facility teams to use as a central repository of look-back specific

information. A sample spreadsheet file named "Look-Back Tracker Sheet" is attached (Attachment 3). As with most tools, use should be optional, as some facilities may have local expertise to develop and use an alternative (e.g., using a database program). If a web based reporting system is used, it will be necessary to standardize how specific data elements are tracked, and this needs to be communicated to the field. This type of document is not incorporated into the medical record, and is considered protected information under public law governing patient safety and quality operations, so access should be limited to staff with a need to know and who need to use the information in program implementation. Staff should be cautioned on proper document use when using certain shared resources (e.g. the same file on a shared drive).

5. **Limit emotional impact on families of a deceased Veteran.** For programs in which survivors of deceased Veterans are exempt from notification, facilities may find it useful to review publicly available information to identify Veterans whose death has not previously been documented in the VHA system prior to beginning notification. One example used in the BK look-back program was review of Social Security death information for Veterans not seen anywhere in VHA for over a year. Such review should not cause undue delay in initiation of patient notification. 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.

6. **Identify where the Veteran should receive follow up care.** Facilities may identify patients who received care that qualifies them for inclusion in the look-back notification program but who currently receive care at another VA facility. Using the remote data function in the EMR (CPRS, VistAWeb), a facility can determine where such patients are currently receiving care or last received care.

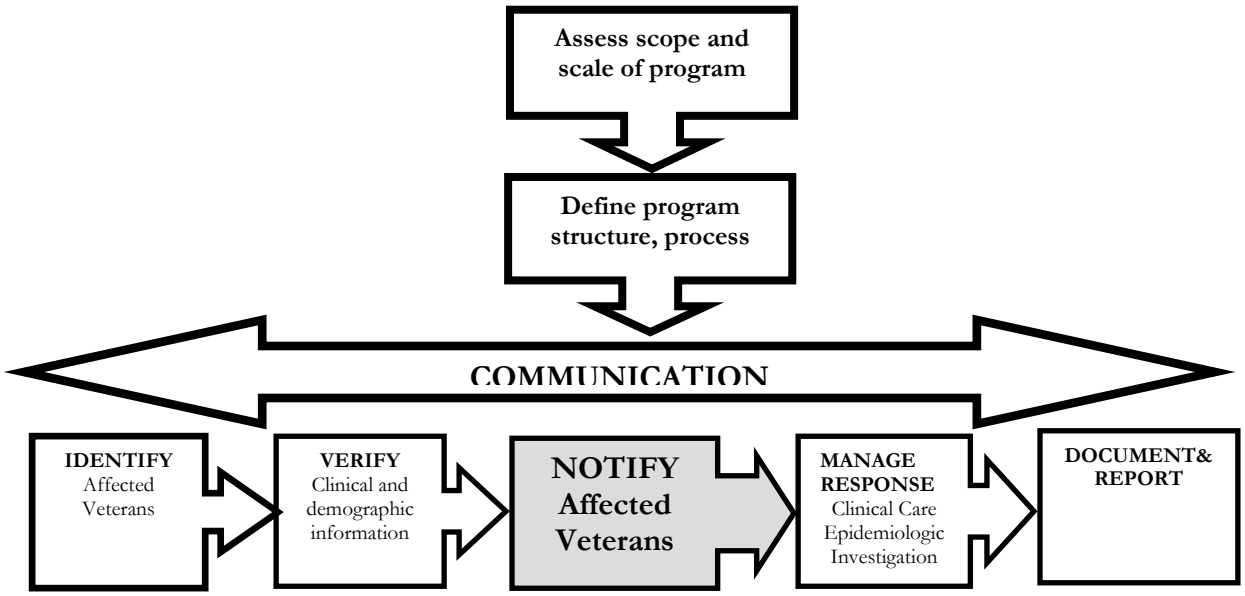
7. **Create summaries of record reviews to limit duplication and aid in care delivery and reporting.** Review of clinical data may be required to determine if the patient is affected. For patients who are affected, some clinical data may also be required to provide care. To increase efficiency by reducing 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 program implementation. 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. An example of a tool that can be used to review individual patient data which was developed for the BK Look-Back is presented in Attachments 1 and 3 in the same document illustrates an electronic note template. Local Office of Information Technology (O&IT) staff should be involved with implementation of such tools to assure that they are deployed in a way that will work in the local environment.

C. Notification Process

This section discusses topics pertinent to the process of communicating to patients that they may have been exposed to some risk in the process of receiving health care services and to advise them of mechanisms to seek care related to that risk exposure. The core objective of this phase of a look-back notification program is to assure that affected patients receive this information in a clear and sensitive fashion that allows them to make informed decisions and avoids creating undue anxiety. It is also important that to provide the Veterans with a contact number to be used in the event that they have questions. The Veterans must be provided with an opportunity to speak with an informed and compassionate individual who can respond to questions and link Veterans to appropriate services.

Key questions to be addressed in this phase include:

1. **What is the optimal method to notify affected Veterans?**
2. **What can be done to minimize risk of causing undue alarm while providing full disclosure?**



Notification Process

The organization retains responsibility to perform and document notification and must elect processes that are reasonable and likely to communicate essential information to patients while minimizing potential for undue anxiety. The process of notifying patients that they have had exposure to some risk is fraught with the potential for negative outcomes and requires insight, foresight, and sound planning. While a decision to require patient notification and what must or must not be included in the disclosure may be made centrally, the exact mechanisms employed to notify patients is best determined at the local level and a degree of flexibility should be permitted as long as basic requirements are met. For example, while a decision that written notification via a letter is a requirement, a facility should retain the option to precede such a letter with telephone notification. Whatever mechanisms may be used to notify affected Veterans, there must be standardization of what is communicated so that all Veterans receive a consistent message. In addition, it is imperative that Veterans have a number to call where they can speak to informed compassionate individuals who can appropriately respond to questions and link Veterans to appropriate testing and care in a timely manner. For notification programs that cover large geographic areas, it is important to consider regional variations in culture, including language. Such discussions and decisions regarding the specific content must be made in a timely manner and not delay the process of patient notification. Other key considerations include:

1. **Obtain legal review of notification language.** Legal review and consultation on content of notification letters is essential, but recommendations from such review should allow for local variation and preferences. The tone and exact content of notification letters is probably best determined at the local/regional level. A description of required elements and/or a sample letter can help local teams craft their own versions (which should also undergo Office of General Counsel (OGC) review before use). A single standardized notification letter is likely to be inferior to one developed with the local insight and input, but it is important that all Veterans receive consistent information across the entire VHA system. See Attachment 7 for an example.

2. **Evaluate option to speak (via telephone) with affected individuals.** Initial contact via telephone can be a helpful strategy but does not replace the need for written notification. Staff members placing such calls must be thoroughly briefed on what information is to be communicated and what should not be said (e.g., well intended but false reassurance.) Any telephone contacts must be documented following standard procedures. 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 veteran.

3. **Provide veterans with complete facility contact information.** Letters sent notifying patients of the potential exposure risk should include clear instructions on how to obtain additional information or care, including telephone numbers, times of availability and, where possible, referral to specific individuals. Given that some affected Veterans may have relocated to another area, the letter should include instructions on how to seek care at the VA facility most convenient to them as well as instructions on how to locate that facility. It is often helpful to include internet resources but it is also important to remember that not all affected patients will have access to or skill using such resources. Notification letters should include access to a toll free telephone number.

4. **Use first class mail with return service/certified mail.** Unless otherwise directed, 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 notification. Use of a unique mail routing in the return address will facilitate this process.

5. **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 My Health***e***Vet) may permit this type of communication in the future.

6. **Plan a notification schedule.** Once notification has begun, delivery of required notification to all affected Veterans 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:
    a) Staff available to conduct notification;
    b) Workload on mailroom staff; and
    c) Effect on clinical system of a large number of notified Veterans responding at the same time.

    In past look-back programs some facilities with large numbers of affected Veterans "batched" letters for mailing over a two week period to help manage call volume.

7. **Tracking notification attempts and returned letters.** As discussed elsewhere in this document, 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. For overall management of the look-back program, there should be a central roster team where such information is recorded, allowing quick assessment of progress with notification as well as response rates. Program guidance should include direction on managing returned letters. Some facilities in the past have scanned images of

returned letters for attachment to the EMR but this has been the exception rather than the rule.

8. **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. Program guidance needs to include specific direction on 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 timeframe does not mean that a veteran forfeits entitlement to any look-back related care. For example, the following is a set of rules for determining non-response:

1) Patient contacted by Facility Director, via certified mail;

2) If patient fails to contact the 800 number 2 weeks after delivery of certified letter, then

3) 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); and

4) If the patient does not respond within one week of the last call, he/she will be deemed to be non-responsive.

9. **Capture and record updated information**. During the notification process, it is possible that staff will learn that a veteran is deceased. Staff should document that information in the EMR and forward the information to the appropriate office so that it can be entered in the proper section of the record. Staff will also need to be prepared to respond to questions from surviving family members and must be briefed on what is permissible to disclose.

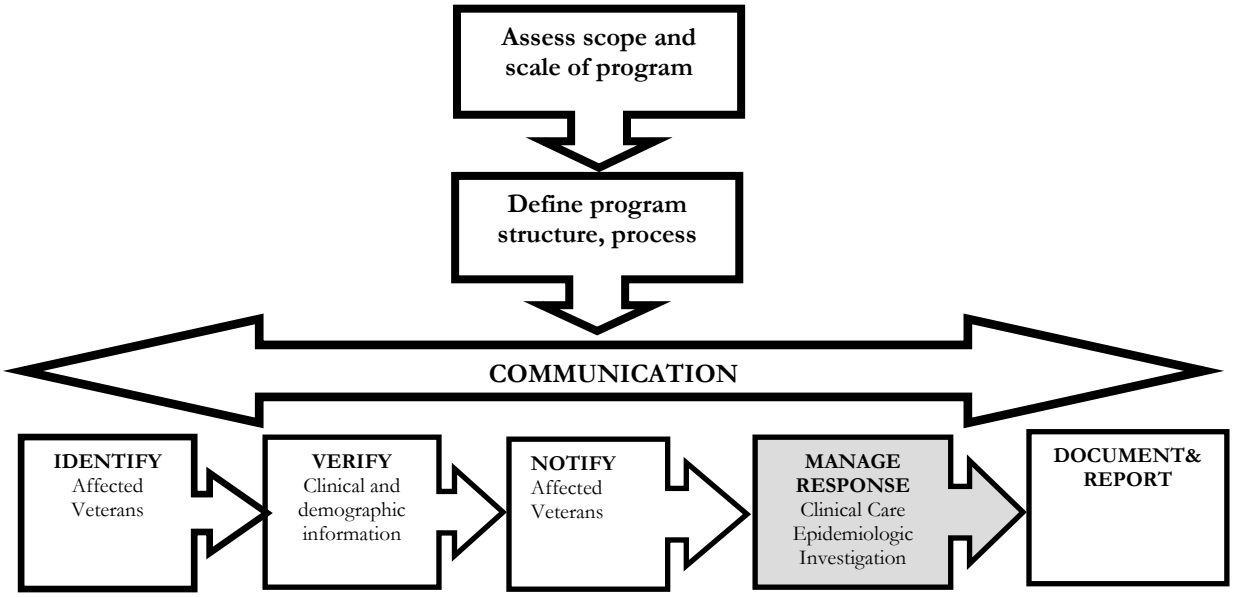
10. **Document notification attempts in the EMR.** Notification attempts need to be documented in the EMR. If a standardized letter is used it is not necessary to include a scan of the actual letter, but to simply document that the letter was sent. As discussed elsewhere, this aspect of the overall look-back notification program may be documented using a standardized note template in the EMR.

D. Managing Response

This section discusses strategies for providing services to Veterans that respond to notification that they are affected by a look-back notification program. The core objective of this program phase is to provide responsive, sensitive, and clinically sound care to affected Veterans in a timely manner. It is essential to remember that some affected Veterans may no longer reside near or receive care at the notifying facility, and response plans must include strategies for such Veterans to obtain care at the facility of their choice. Seeking care related to the program may be perceived as an added burden and facilities may need to employ novel strategies such as evening or weekend clinics in response to this perception. In addition, initiation of a look-back notification program is likely to generate attention among families of affected Veterans, the community, and the media. Plans must be established to respond to these groups.

Key questions that will need to be addressed in this program phase include:

1. **What systems and processes will be required to efficiently provide information, referrals, and care to responding Veterans?**
2. **What will be the likely workload impact and how can resources be deployed most effectively?**
3. **What training will be required across the organization to assure that affected Veterans receive timely, accurate, consistent, and coordinated response when they respond to notification?**
4. **What will be done for responding Veterans who do not reside in the service area, or refuse to be seen in the facility where the event occurred?**
5. **What will be the likely response of family members of deceased Veterans?**



Managing Response

Strategies for meeting the needs of Veterans who respond to notification must be part of the initial planning and response processes should be established before notification begins. The exact clinical scenario will determine which services should be offered, but in all instances, Veterans are likely to seek additional information at a minimum. The size of the affected population will, to some extent, drive the need for special arrangements (e.g., establishing new clinics or reserving appointment slots in existing clinics) to handle patient response. For programs involving only relatively small numbers, it may be reasonable to provide services in established clinics. Other strategies may be required for programs involving larger numbers of affected Veterans.

In all cases, it must be recognized that affected Veterans may respond to notification with a range of emotions from minimization to anger. Once notification has been initiated, information about the adverse event is likely to spread in the larger community via mechanisms ranging from discussions among patients in a waiting room to possible media interest. Facilities must be prepared to respond to affected Veterans (and potentially to their family members); Veterans not affected but have concerns, and public media.

1. **Walk-in service.** Some patients may 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 likely to have contact with such patients – 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. If the designated staff person will not be available (e.g. on leave) there should be a designated alternate.

2. **Phone-in service.**
    a. **Call Centers.** Some facilities have reported successful use of call centers to manage response from affected Veterans. In some locations there may be existing access to telephone care or nurse information lines. If this strategy is to be used it is essential that staff at the call centers are fully briefed on the program and provided with specific instructions for referral of callers. Ideally, Veterans who reach a call center will be immediately transferred to a staff member (could be facility subject matter experts (SME) or triaged to VHA Program Office SME) who will be able to assist them, answer their questions, and/or arrange an appointment).

    b. **Primary Care Clinics and other staff.** Staff members who receive calls from notified Veterans need to be prepared to respond to common questions. Although provided with a general, toll-free number, many Veterans will prefer to directly contact their primary care provider. All clinic staff should be made aware of the program. While individual callers deserve responses to their specific questions, it can be helpful to provide a sample call script for staff receiving calls to be better prepared to respond to anticipated questions. Attachment 5 provides an example of a call

script; this was rated as highly useful in a past look-back by field staff who implemented the program.

c. **Facility telephone operators.** 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.

3. **Manage the responders who are not affected.** Once notification has been initiated, discussions (e.g. while sitting in a clinic waiting room) and/or media coverage may lead to inquiries from Veterans who may or may not be affected. Such calls should be referred to the designated staff member(s) who can access a roster of affected patients to determine if the patient should be included. Such conversations should be documented in the medical record, and do not take the place of notification using the standard procedures adopted for the look-back program.

4. Manage inquiries from the media. All staff should be directed to immediately refer any inquiry from the media to the facility Public Affairs office. No staff member in any position should engage in any discussion with representatives of the media without first consulting Public Affairs. All staff must know who staffs their Public Affairs office and how to contact them. Public Affairs must work closely with administration and clinical experts in order to provide accurate response to inquiries. While the fact that even one veteran experiences some risk exposure is not good news, the fact that the system employs procedures to identify such situations and undertakes efforts to inform affected patients and provide appropriate care is a positive.

5. **Assess and Reassess optimal care delivery models**. It may be necessary to devise novel strategies to provide care in a timely manner. Depending on the specific clinical scenario involved, care may be delivered in the setting of an existing primary or specialty care appointment or other strategies may be required. If look-back program related care is to be delivered in the framework of existing clinic appointments, it will be important to consider the potential impact of increased workload both in terms of more patients seeking appointments and more time required to address patient concerns during each encounter.

   One strategy that worked well during one previous look-back program was group visits. These are planned appointments with prepared presentations coupled with time for questions and answers as well as individual private consultation. A slide set template distributed for local adaptation that has been highly rated by facilities is presented in Attachment 10.

6. Identify and mitigate efficiency barriers.

a. **Wait times**. It is highly advisable to optimize the patient experience of receiving program related care, including reducing waits and delays, by modifying standard practices where possible.

b. **Alternative scheduling**. Some patients may express concern about having to alter their usual schedule (e.g., missing work or planned events) in order to receive look-back related care. Some facilities have employed evening and weekend clinics

dedicated to providing appointments for affected Veterans, with varying success in different areas.

c. Use of alternative facilities (within VA) in the event patients wish to be seen at a facility other than where the look-back is taking place.

7. **Plan for responses to family members.**
   a. **Is the family at risk?** Depending on the specific clinical scenario, Veterans may express concern about potential impact of their clinical risk exposure on other people, including but not limited to their family members. Some may inquire whether such individuals can receive care through the VA. Local staff should be prepared to respond to such questions after obtaining legal guidance. It can be helpful to prepare in advance and have available a list of other resources where non-VA care may be obtained if necessary (e.g., local health department.)

   b. **Responding to direct inquiries by the family.** It is possible that someone other than the affected veteran may contact a facility with requests for specific information about the veteran and his or her clinical status. Such requests must be handled in full compliance with applicable privacy and confidentiality laws and policies, and in general no information may be released without the specific authorization of the patient involved. Questions should be directed to the facility privacy officer.

8. **Assist Veterans in understanding their legal rights.** Some Veterans may have questions relating to rights, entitlements, or other legal issues. It is important for clinicians to make it clear that while they will do everything possible to provide appropriate clinical services they may not act as a resource for legal information. It is appropriate for clinicians to refer Veterans with such questions to Veterans Benefits Administration (VBA) representatives and/or a Veterans Service Organization. During previous look-back programs several facilities reported that it was helpful to provide local Veterans Services Organization (VSO) representatives with a briefing on the program and secure their permission to serve as referral resources for Veterans with legal questions.

9. **Plan response coordination for affected Veterans currently outside your facility service area.** Affected Veterans may currently reside outside the service area of the notifying facility; it is essential that regardless of the geographic scope of a specific program, all VA facilities are briefed and prepared to handle affected Veterans who present for care. During a look-back program a distinction should be made between those facilities that are required to notify patients about care provided at that facility (referred to as a "performing facility") and other facilities (termed "consulting facilities") where affected Veterans might turn upon receipt of notification. To facilitate communication and prompt, accurate care to affected Veterans in a large scale disclosure, a roster of POC's could be disseminated via email to all VHA facilities.

E. Laboratory Testing

This section discusses strategies for providing laboratory testing to Veterans that respond to notification that they are affected by a look-back notification program. The core objective of this program phase is to obtain blood samples from affected Veterans in a timely manner. It is imperative that appropriate clinical and epidemiological laboratory testing is done upfront on Veterans who are identified as part of a look-back cohort. Every look-back investigation should create and disseminate a uniform protocol for testing, documenting results, and storing additional blood samples. This protocol should be followed by all facilities as well as satellite clinics involved in the investigation. OPHEH will work with all facilities who are taking part in a look-back investigation to assure the appropriate testing algorithm is in place (see Attachment 13).

If blood or other specimen testing is required as part of a look-back investigation, patients should be verbally consented for the immediate and possible future testing for infections of interest related to the look-back investigation. Documentation of disclosure and verbal consent should be part of the initial look-back progress note (see Attachment 8, for progress note templates). **Additional blood or sample material should be collected and properly stored at the VA medical center (VAMC), reference laboratory, or a commercial laboratory until the conclusion of the look-back, as decided by OPHEH (**refer to Attachment 18 for sample collection SOP). Facilities should work with OPHEH to insure appropriate collection and storage of additional blood and specimen samples for future testing. Depending on the specific situation and facility laboratory capabilities, the following options should be considered:

1. Look-back VAMC capable of performing appropriate screening tests: All samples collected at the particular VAMC are processed and clearly labeled. Additional samples are frozen and stored on-site; screening viral diagnostic tests are performed on-site; and confirmatory or molecular viral tests (i.e. viral load assays) are performed on-site, at their VISN reference laboratory, or a commercial laboratory.

2. Look-back VAMC not capable of performing screening tests but sends screening tests to VA referral laboratory: All samples collected at the particular VAMC are processed and clearly labeled. Additional samples are frozen and stored on-site. These samples are overnight shipped on ice to a VA referral laboratory for screening viral diagnostic tests and confirmatory or molecular viral tests (i.e. viral load assays). One VA or VISN referral laboratory (i.e., West Haven, Bronx, Palo Alto, etc.) would serve as the testing laboratory for all look-back samples. Additional samples will be clearly labeled and stored for future testing such as molecular fingerprinting assays.

3. Look-back VAMC not capable of performing screening tests but sends screening tests to contract commercial laboratory: All samples are collected at the particular VAMC are processed and clearly labeled. Additional samples are frozen and stored. Under contract, these samples are sent to a commercial reference laboratory that will process and perform screening viral diagnostic tests and confirmatory or molecular viral tests (i.e. viral load assays) as well as store additional frozen samples. Additional samples will be clearly labeled and stored for future testing such as molecular fingerprinting assays.

4. Look-back VAMC is no longer the primary VA for the affected Veteran (or Veteran chooses to be seen at another VAMC): Allow Veteran to have samples drawn at any VAMC or contract laboratories for screening viral diagnostic tests. If any of these tests are positive, the Veteran would report to the VAMC for clinical evaluation and counseling and at that time additional blood would be obtained and either option 1, 2, or 3 would be activated for confirmatory, molecular viral tests as well as storing frozen samples for future testing such as molecular fingerprinting assays.

F. Clinical Disclosure and Care

Roles and Responsibilities of a Clinical Look-Back Team: A Clinical Look-Back Team is highly recommended to evaluate and interpret all positive screening results and disclose positive screening and confirmatory results to patients in a timely manner. OPHEH is available for consultation, but OPHEH does not need to confirm positive results prior to clinical disclosure.

1. The Clinical Look-Back Team should consist of the following facility staff: Infectious Diseases physician, Gastroenterology/Hepatology physician, Chief of Staff/Nurse Executive or designee, and/or other qualified clinical providers designated to review all positive screening tests, disclose test results to look-back patients and coordinate follow-up clinical care. The chart review of positive screening results and conducting disclosure visits is time intensive and the efforts necessary to ensure an accurate and timely disclosure process should be taken into consideration and may require temporary alterations of the team members other clinical duties.
2. The Clinical Look-Back Team should meet ad hoc to review all positive test results and consult with OPHEH as needed. As soon as can be arranged, set up appointments to disclose positive results to patients. Positive disclosures are best performed face-to-face rather than by mail. Team members should document the disclosure meeting with a progress note in the patient's medical record. An example of a disclosure progress note is presented in Attachment 8.
3. The Clinical Look-Back team should ensure that a follow-up clinical plan for care is in place (coordination of care with Primary Care Provider, Infectious Diseases, and/or Gastroenterology/Hepatology).
4. The Clinical Look-Back team should review all patients with negative test results for any virus and determine if the patient's procedure was less than 6 months before first look-back screening tests were performed. Patients falling within the 6 month window need to be marked for retesting after 6 months. For example, a patient is exposed in March 2010 and first tested in June 2010; one or more tests negative. Patient should be re-tested in October 2010.

Notification of Test Results

Positive screening results need to be disclosed to patients, 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 in a look-back investigation. As soon as can be arranged, set up appointments to disclose positive results to patients and coordinate their follow-up care. Positive disclosures are best performed face-to-face. Positive disclosures should include:

1. Clear presentation of test results and their interpretation.
    a. An understandable description of test interpretation and referral for appropriate medical evaluation and clinical care.
    b. What the Veteran can do to prevent the spread of infection to others and if applicable, provide recommendations for partner testing.
    c. What the test results may mean with regard to the exposure for which the patient is being followed. Examples:

i. 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.
ii. 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.
iii. 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.

d. A chance for the Veteran to ask questions related to their infection/diagnosis.

2. 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 (see note template in Attachment 8).

3. Coordination of clinical care: The Look-Back team member disclosing positive results should recommend and facilitate appropriate follow-up care for the identified infection/disease and coordination of care with the patient's VA primary care provider. This should be documented in the disclosure progress note (see note template in Attachment 8).

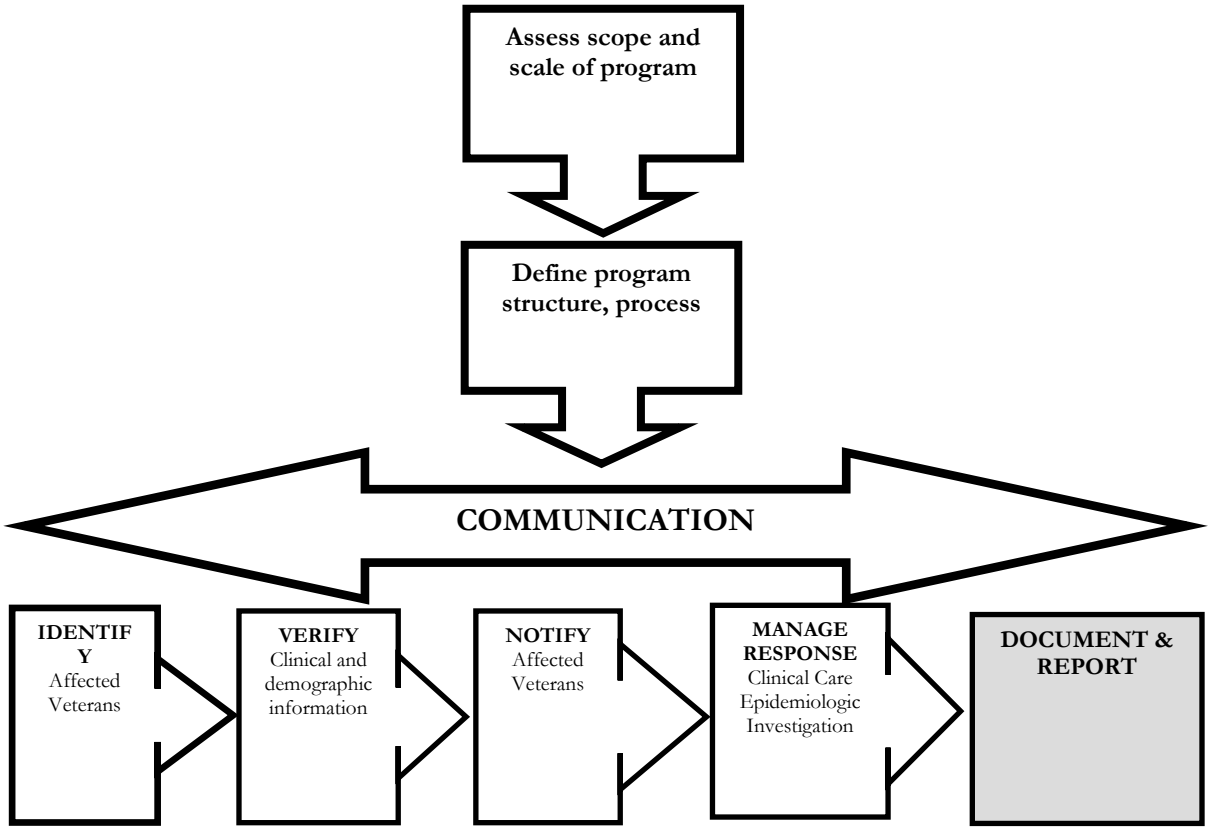
4. In some cases, patients may have obtained legal counsel. In these cases, clinical disclosure may need to occur with the patient's legal counsel present. In such cases, VA regional counsel or Office of General Counsel (OGC) should be consulted prior to the disclosure if the clinical team is aware that the patient is represented by legal counsel. This should be documented in the disclosure progress note.

G. Documentation and Reporting

Management of both individual patients and the entire look-back investigation relies on adequate documentation of both program related services delivered to individual patients and overall program activities. In addition to internal VA offices, it is possible that external federal entities may request or require reporting on the look-back process, progress and/or outcomes.

Key questions that pertain to documentation and reporting include:

1. **What should be recorded in the individual patient medical record with regard to the look-back investigation?**
2. **What aggregate data needs to be collected and documented at the local, VISN, and national level and how are aggregated data collected?**
3. **What standardized reporting mechanism can be established?**
4. **What procedures should be employed to manage reporting to internal and external entities?**
5. **What data is needed to be shared with OPHEH in order for an epidemiologic investigation to occur?**



Documentation and reporting

In addition to documentation of patient specific information in the medical record, it will be necessary to document and report aggregate data related to the look-back investigation process as well as the outcomes. All medical record documentation must be done in accordance with current regulation, policies, and procedures. Clinical care is documented at the individual patient level using the standard EMR; various functionalities in the EMR can facilitate documentation and help assure that all necessary information is available to support decision making. Documentation of the investigation activities may occur at both individual and aggregate levels and outside the EMR. Standard process for documentation of investigation activities may not exist and need to be created, with some aspects customized according to the specific nature of the clinical scenario involved in the look-back investigation. OPHEH is available for consultation regarding the creation of these processes. Any documentation that includes personally identifying information about patients must be maintained in accordance with applicable privacy laws, regulations, and policies.

Look-Back investigation reports guide ongoing organizational oversight and management of the investigation as well as provide the basis for potential policy and procedure revision. In addition, entities external to VA (Congress, Veteran service organizations) will expect and request reporting on the look-back progress and outcomes. Any external reporting would need to be managed in accordance with applicable VA policy and procedure.

This module presents the two parts of documentation – that which is required for the medical record and that which can/should be stored external to the EMR. An overview of reporting follows the section on documentation.

DOCUMENTATION INSIDE THE MEDICAL RECORD

1. Creation of progress notes in the medical record. Use note templates provided in Attachment 8. Use of a standard patient level note template for documentation of information and health care service delivery is helpful. The exact structure will be determined by the clinical nature of the look-back but elements would include documentation of:

a. Historical clinical information needed to support decision making about what care and/or services are indicated;
b. Patient notification, including date and method used (e.g., certified mail, verbal disclosure);
c. Patient response to notification, including date, method of response, disposition (e.g., appointment scheduled, appointment declined), as well as questions asked/answered;
d. Contact with another facility where the patient sought look-back related care, including date, contact name, and information exchanged.
e. Look-back related visits, including what (if any) diagnostic testing was offered and appropriate documentation of verbal consent;
f. Delivery of results of any look-back related testing to the patient; and
g. Closure of the active case for look-back purposes.

Standard templates become even more important when multiple facilities are involved, especially in cases where the affected Veteran is receiving care for the look-back related issue at a site other than the one who identified the risk related event. Attachment 8 is an example of such a standard template. OPHEH is available for consultative advice on the template content as well as the layout of the progress note.

2. Take advantage of available automation. Wherever possible, employ automatic import of data to avoid the need for duplicate entry. Templates should be constructed in a manner that reduces the need for duplicative documentation. Standard templates can be constructed within the EMR to allow automatic import of some existing information, such as demographic information and laboratory test results. It is imperative that the imported, copied, or templated information is confirmed to be accurate by the provider writing the note.

3. Document with an eye to later retrieval. Approaches that allow successive authors to add new information as it becomes available to an existing note (e.g., "parent-child" notes or use of addendum functionality) can make accessing look-back related information easier and less time consuming.

4. Customize note process as expertise exists. Notes newly created to support look-back implementation must be easy to use. Program leadership can specify the minimum content for a standard note but the exact process/layout used may best be determined at the local level.

5. Use clear naming conventions. Templates and progress notes created for use in a look-back investigation should be titled in a distinctive way to allow easy selection at the point of use. All notes related to the look-back investigation should be labeled in a similar identifiable manner.

6. Explore other EMR functionality. Use of the EMR functionalities such as creation of health factors that can be used to generate aggregate reports or drive electronic care prompts (e. g., clinical reminders) may be useful. The utility of such approaches relies on the availability of staff with pertinent skills and experience with using such functionalities as well as adequate training for clinical staff to understand and use such tools.

DOCUMENTATION OUTSIDE THE MEDICAL RECORD

1. **Follow VHA policy related to privacy and security.** Any and all look-back investigation related documents that contain patient identifiers or protected health information must be maintained according to pertinent law, regulation, policy, and procedure with regard to creation, maintenance, access control, and storage.

2. **Use electronic tools for process tracking.** During the process of patient identification and notification it may be necessary to create a roster of affected patients along with demographic and clinical data at the patient level. Use of electronic tools (e.g., spreadsheet or database programs) can facilitate these processes and reduce the need for repeated review of individual records. The attached "Look-Back Tracker sheet" (Attachment 11) provides an

example of such a document. Such tools can be offered by OPHEH for use or adaptation at the local level. In addition, individual facilities should be encouraged to share their own innovative approaches with OPHEH as well as others involved in the look-back investigation.

3. **Treat all information as if it was to be in the official EMR.** While records generated for use in patient safety or quality management activities are designated under federal law as neither subject to legal discovery processes nor subject to Freedom of Information Act (FOIA) disclosure, all staff must maintain the same standards of professionalism, accuracy, and completeness that they would when entering a note into the standard medical record. In general, a Litigation Hold Memorandum will be issued, requiring all documents pertaining to the event and investigation be preserved (see Attachment 14, Litigation Hold Memorandum). All emails should be filed in one location, all electronic documents should be stored on folders labeled as "XXX Look-Back Investigation," and all papers related to a given investigation should be compiled into clearly labeled files that are stored in a locked cabinet.

REPORTING

At the local level, the team charged with the look-back investigation implementation is probably best positioned to determine the form and format of routine local reporting. Such decisions must take into consideration the reporting requirements established by the VISN and VHA national leadership. As early as possible in the investigation, the top level leadership should determine what information will be required at various points in the look-back investigation, what data will best reflect these required measures, and what mechanism will best allow efficient collection of aggregated data. There should be a standardized template for national reporting.

1. **Use electronic methods for 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.

2. **Modify reporting requirements only if absolutely necessary.** As look-back implementation progresses, it may become apparent that additional or different data is required. Significant resources may be required to collect and report additional data, with the potential to divert such resources from the immediate task of providing appropriate care to affected Veterans. Program leadership should limit reporting requirements to what is necessary for look-back investigation operation.

3. **Keep reporting frequency at a manageable level.** Reporting requirements and process should be established early. VHA leadership will likely require ongoing updates on the look-back investigation operation. The frequency, content, and format of such reports should be determined by the exact clinical and organizational scenario. Regular and frequent communication with leadership is important in insuring a timely and successful look-back investigation.

4. **Keep ad hoc queries limited, standardized, and manageable.** Look-back investigations are very likely to elicit requests for reporting from external entities including members of Congress, representatives of Veteran service organizations, and the media. Communication with such entities at all levels should be coordinated to assure consistency and responsiveness. During previous look-back investigations, the national leadership group included representation from the Office of Communications who successfully coordinated dissemination of information to and worked closely with VISN and facility Public Affairs officers and staff. Congressional communication needs to be managed in coordination with the Office of Congressional and Legislative Affairs and in accordance with applicable policy, protocol, and procedure.

5. **Adjust reporting schedules as feasible.** Routine reporting may need to be fairly frequent at the beginning of the look-back investigation, but as it progresses there may come a point where large changes in the information contained on periodic reports are not likely over short periods. Adjustment of reporting frequency is advisable in this scenario in order to reduce the burden on facilities.

6. **Share information.** Throughout the look-back investigation, feedback to performing sites can help facilities evaluate their progress in relation to other sites involved in the look-back if applicable.

7. **Generate a shared site for look-back investigation information.** Due to the large number of people involved in a look-back investigation, an organized, shared site (e.g., SharePoint) with access granted to key people involved in the investigation helps improve communication and access to information.

H. Epidemiologic Investigation

DEFINITION OF TERMS

Lookback: The process of notifying a group of individuals of a possible exposure to one or more blood borne viruses as a result of an adverse event while receiving medical care. A lookback generally includes identification of an affected/exposed group of individuals, notification (disclosure), and an offering of clinical laboratory testing to determine the patient's infectious status.

Epidemiologic Investigation: The process, following a lookback investigation, of evaluating the laboratory testing data with the intention of ascertaining whether or not infection transmission may have occurred as a result of the exposure event. A lookback is not necessarily always followed by an epidemiologic investigation. An epidemiologic investigation is only recommended when there is a reasonable chance that the available data will provide enough basis to determine the likelihood of infection transmission having occurred.

Exposure cohort: a group of individuals identified as having been potentially exposed to one or more diseases or procedures believed to increase risk of exposure to one or more diseases (in this case, blood borne infections).

Cases: patients with newly identified positive results for one or more of the three tests for blood borne viral infection (HBV surface antigen, HCV antibody, HIV antibody). Cases may include patients for whom viral testing has never been performed, or patients whose previously negative tests results were too far in the past to pinpoint date of infection. *Note: unless a patient tested negative immediately BEFORE the exposure, and had evidence of acute illness AFTER exposure, association of infection with exposure cannot be assumed.*

Proximates: patients known previously to have been infected with a blood borne virus, and whose dental procedure was performed prior to a case patient's such that a potential epidemiologic linkage can be established. Case/proximate pairings will be followed-up with additional testing to establish likelihood of patient-to-patient transmission having occurred. The following information is reviewed to identify proximates:

1) Procedure records to identify patients whose procedure was performed during the time frame prior to a case patient's during which transmission could reasonably have occurred;
2) Any lab testing for HBV, HCV, and HIV completed for these patients;
    a. patient must be positive for the same virus as case,
    b. If patient was positive for same virus, was there a history of positive test results, or was this a newly identified case,
    c. Sufficient viral load must be present in patient's blood in order to perform genetic fingerprint testing

Genetic fingerprint testing (DNA analysis): case/proximate pairings (described under Proximates above) are sent to a reference laboratory where samples of blood from each patient are run through a process to isolate the genetic material (DNA) within the virus particles contained within each patient's blood. An analysis of the DNA "fingerprint" (unique sequence

of DNA base pairs) of these viruses can help determine the likelihood that viral infection transmission may have occurred from the proximate patient to the case.

Key question pertaining to Epidemiologic Investigation**:**

How does the Epidemiologic Investigation differ from the Clinical Assessment and Disclosure process?

The epidemiologic investigation is a separate but parallel process with the clinical assessment and disclosure. The epidemiologic investigation should not hinder the progress of patient testing and clinical disclosures, but at the same time, it is imperative that the facility work closely with the OPHEH investigative team from the onset to ensure that the proper testing and data necessary for the epidemiologic investigation is collected and made available.

While the goal of the clinical assessment and disclosure is to determine whether patients are actively infected and if so, that they receive appropriate care, the goal of the epidemiologic investigation is to determine the likelihood that infection transmission occurred as a result of the exposure event(s) in question. These are similar, but slightly different objectives which should be recognized. For example, a look-back patient with no prior history of Hepatitis C virus (HCV) infection may be found to have a positive HCV screening test but a negative HCV viral load. From the standpoint of the clinical assessment and disclosure, the patient is not actively infected and would not be considered a "new positive" by the Clinical Look-Back team or require additional follow-up care. However, from an epidemiologic perspective, it is not clear whether this patient had a false positive screening test or if the patient was exposed and subsequently cleared their infection (resulting in a negative viral load). In this example, the patient would require a confirmatory HCV recombinant immunoblot assay (RIBA) test and if positive, would be considered a "new positive" by the OPHEH investigative team and examined further as a possible infection transmission event, despite the fact that the patient is not actively infected. This example illustrates the importance of close communication and collaboration between the OPHEH investigative and clinical look-back teams in evaluating case patient status.

Conducting the epidemiological investigation:

Facility responsibilities:

1. Review laboratory/clinical records to determine the baseline facility prevalence or seroprevalence rates for each blood-borne pathogen being tested for (i.e. HIV, HBV, and HCV). This will provide investigators with a rough estimate of how many positive results to expect based upon the overall baseline facility rates.

2. Consult with the OPHEH investigative team to determine the testing protocol for the look-back. Use an agreed upon testing algorithm to ensure that the appropriate testing and specimen storage is conducted for each patient (see Attachment 13 for an example).

3. Arrangements must be made to ensure that blood is stored for all Veterans who present for possible future look-back testing both within and outside the VA system. The facility must obtain verbal consent for this and document in the Veterans medical record (VA Informed

Consent for Clinical Treatments and Procedures Handbook 1004.01). The facility should work with the laboratory director to plan for the anticipated storage space needed.

The clinical look-back team should maintain a master spreadsheet for the epidemiological investigation (see Attachment 11 for an example). The look-back team/leadership will ensure that OPHEH and others involved in the investigation have access to a SharePoint site containing this spreadsheet. This spreadsheet is to include a linelist of all Veterans exposed, including all exposure visit dates during risk period, billing codes, screening test dates, and test results with notation of which patients have or do not have stored plasma available for further testing.

OPHEH responsibilities:

1. OPHEH investigators will perform detailed chart reviews using VistA Web or CAPRI for all exposed patients with test results positive for any blood-borne pathogens. Laboratory and clinical data will be reviewed to determine the pre-exposure serologic status for blood-borne pathogens. An extensive review of the EMR will be conducted for each identified individual, including all recent and prior pathogen testing and other relevant laboratory results (e.g. liver function tests); medical histories and risk factors for blood-borne viral infections (including but not limited to known sexual partner with HIV, HCV or HBV, intravenous drug use, transfusions, unprotected intercourse, history of sexually transmitted disease, sexual contact with sex workers). EMRs and procedure logs/records will be used to record procedure/visit date(s); and available details from the procedure(s) (including time, instrumentation, biopsies performed, etc.). Records from all VA facilities visited by case patients will be reviewed, provided that electronic documentation is available as well as any Department of Defense (DoD) and civilian medical records in the EMR. Patient information will be collected and recorded in an electronic database created specifically for the investigation and maintained securely according to all VA security regulations.

2. The purpose of the OPHEH epidemiologic review is to determine the likely timeframe during which patients may have acquired infection, based upon a number of factors such as dates/ results of previous testing, and patient behavioral risk factors. These analyses will result in three lists of patients: 1) those with newly identified infection with one or more blood-borne virus ("case patients"), 2) those infected with blood-borne virus prior to the exposure incident (i.e. known positives that could be potential source patients referred to as "proximate patients"), and 3) those not infected with any of the 3 blood borne viruses. Case patients are those individuals considered to have a possible case of viral transmission from their procedure/visit if they had a positive look-back serologic test result for HBV, HCV, or HIV infection, had undergone their procedure/visit at the facility during the exposure time period and had a no pre-exposure or negative pre-exposure serologic test results available. Potential source patients ("proximate patients") are those individuals with positive pre-exposure serologic test result(s) for one or more virus available or patients who were known to be chronically infected with HBV, HCV, or HIV who underwent their procedure/visit shortly prior to a case patient (generally the same day or the day prior depending on the exposure event).

3. After identifying patients with newly identified infection, and those known to have been with previously infected, OPHEH will identify potential proximate patient and case patient matches. A proximate/case match consists of a patient with newly identified infection paired with one or more patients with known previous infection whose procedure/visit occurred during a defined time-frame before the case patient's procedure/visit, and therefore could potentially serve as the source of infection. Any proximate/case matches will result in virus from both patients undergoing a genetic fingerprinting analysis (generally performed at a reference center, such as the Centers for Disease Control and Prevention) to determine whether or not they are alike, in which case infection transmission would be considered a more likely possibility. Any genetic fingerprint testing required will be coordinated by OPHEH. Fingerprinting test results should be shared with the Veteran during a face to face disclosure meeting similar to what was described above in the Clinical Disclosure and Care section. Given the complex nature of explaining the findings of the epidemiologic investigation and genetic fingerprinting analysis, OPHEH staff may be best suited to conduct these disclosure meetings and will work with the facility to arrange and schedule these visits.

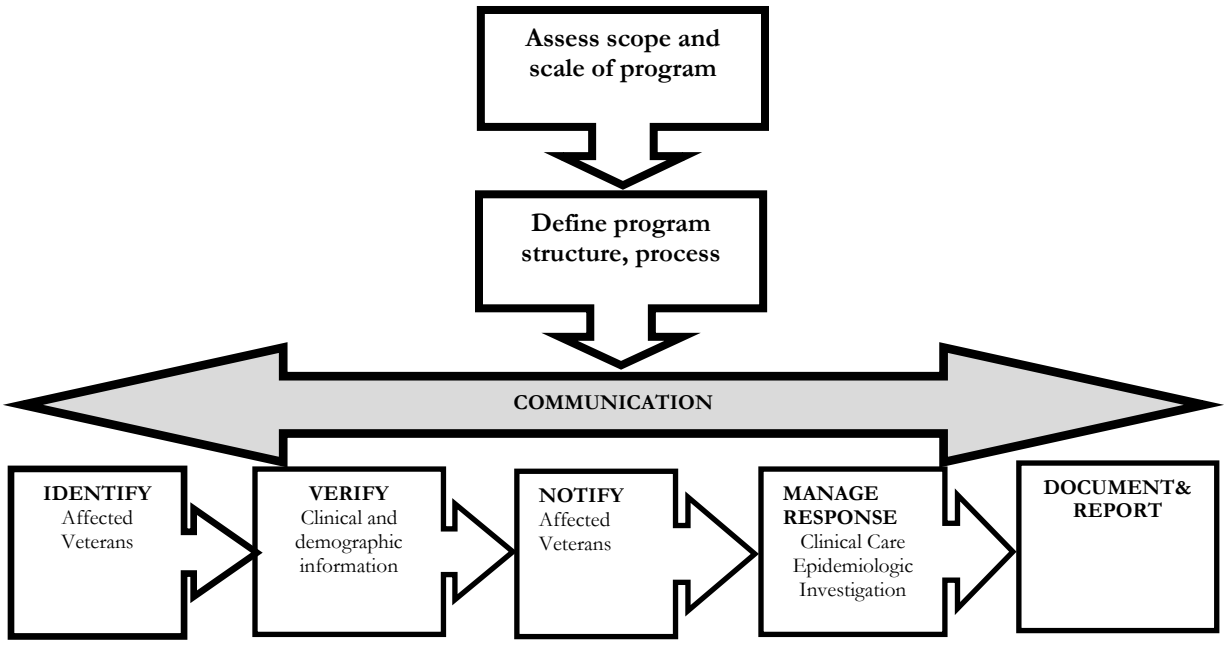
4. OPHEH will provide a final summary of the epidemiologic analysis, which will carry out VA's duty to the Veterans exposed in determining the likelihood of their having acquired infection from the exposure incident. Information on the feasibility of infection transmission in the scenario that occurred will also provide valuable knowledge to VA and non-VA healthcare professionals and public health practitioners.

I. Communication

Successful implementation of any multi-site program depends on effective and efficient communication strategies throughout the program, from inception through final reporting. At various points effective communication will likely require multiple methods including interactive (phone calls, meetings, teleconference or web meetings), active (e-mail dissemination) and passive (web posting, manuals) methods. This section focuses on mechanisms for successful communication between and among Veterans Administration Central Office (VACO), VISN, and facility leadership and OPHEH and key members of the facility look-back team. Communication with entities external to VA (e.g., Congress, veteran service organizations) may also be required and will be guided by existing VA policy and procedure.

Key questions that pertain to communication issues include:

1. **What is the best approach to assure effective dissemination of information?**
2. **What are the optimal strategies to assure collection of required information?**
3. **To what extent can communication be standardized?**
4. **What communication method is best to efficiently achieve specific objectives?**
5. **How do VHA regulations, policies, and procedures regarding privacy and confidentiality affect communication methods?**



From initiation through closure, mechanisms are required for reliable and accessible information exchange between program leadership and the field staff implementing the program. Successful strategies will address variation in time zones, communication preferences, local/regional culture, and accessibility to and skill using specific methods for information exchange. The volume of information and direction of exchange will likely change as the program develops. Initial flow will be from leadership to the field but over time more information will originate from performing sites. This module focuses on communications between the program office, VISN, and the field staff and is presented as specific lessons learned about effective communication during the national look-back investigations.

Communications should be handled as both scheduled events and on an ad hoc basis. Scheduled communications, including conference calls or written communication, help to maintain contact and coordination, provide new information and follow up on outstanding issues, and as a mechanism for sharing ideas and processes. Ad hoc communications provide the means to address and document emerging issues.

1. Telephone contact with the facility. At the time of program initiation, telephone contact (followed by email or written documentation) is the preferred method of communication to inform the facility that they will be required to implement the look-back notification program. This call should be directed to the VISN director, Facility Director, and Chief of Staff, and should include a brief description of what will be expected along with information about who to contact for additional information. For programs that involve multiple VISNs, an efficient strategy would be to assign a VISN level point of contact to receive this information and forward (within a designated time frame) this information to participating facilities.

2. Electronic distribution of a comprehensive package of information at the time of program initiation was seen as very helpful by sites in past look-back investigations.

3. Establishment of a SharePoint site or other form of electronic collaborative tool is an effective method for conveying information that offers the following benefits:

a. Allows recipients to read messages and access information at their convenience;
b. Assures that the same information is available to all involved; and
c. Creates a place where documents and other tools can be shared in electronic format for use at the receiving facility.

4. Email correspondence is also an effective tool, but it must be used with some caveats.

a. Group email messages should include a boilerplate header that informs the addressee why they are receiving the message and instructs them on what to do if they are not the appropriate person to receive it, including notification of the sender.
b. If it is important to know whether a message was received it should be sent with a return receipt requested. The receipt should be for "message read" and not just delivery, as a message can be delivered but remain unopened.
c. Email messages may not identify specific patients or contain other protected health information unless appropriate encryption is used.
d. There is always the possibility that an email message may be lost or go astray during transmission.

e. All email messages pertaining to the look-back should be stored in a specified folder and retained for future reference. In the case of a Litigation Hold (see Attachment 14), this is a required step.

5. Feedback to the site/facility level is helpful, as to what is working or not working in the look-back investigation process.

6. Standardized forms are useful for routine reporting if the forms are clear and succinct as possible. Initial distribution should include a review of the form's purpose and structure, including explicit instructions for data sources to be used or calculations. Distribution in electronic format is helpful. An example of a reporting form used for a previous look-back program appears as Attachment 11.

7. Construct and maintain a roster of point of contact (POCs) at all facilities. Communication is greatly enhanced by availability of a roster of designated points of contact at each facility. Because patients may present at virtually any facility within the entire system, there needs to be a POC at every facility. That POC is not necessarily involved in clinical care but must be familiar with the overall program and be able to appropriately direct calls and information requests.

8. Periodic conference calls are helpful, especially early in program implementation. Calls may be used to disseminate new information. Some facilities may not be able to make a given call, so additional means of information dissemination should be employed. Circulation via email of summary notes soon after such calls meets this need.

9. Scheduled communications (conference calls, group emails, etc.) should occur as frequently as needed. As the program matures there will likely be less need for such calls and the interval may be extended. When calls are scheduled, it is helpful to send a reminder one to three days in advance.

10. Streamline review processes. Communication, including report submission, between program leadership/management and staff implementing the program at the local level need to be clear and unfettered. While local reporting structures and review authority for formal reports must be respected, in the setting of such a focused, time limited effort, the number of levels of review should be minimized as much as possible.

11. Web based communication has been identified as something that would be useful. While not suitable for handling sensitive patient information, the web provides an efficient mode for facilities to submit periodic data and reports. Templated reporting pages can be constructed using readily available standard technology. This could also allow for automated data aggregation, basic analysis, and reporting.

12. Media communication should be carried out through a designated POC. All communication with media representatives must be cleared through appropriate Public Affairs staff.

13. Congressional inquiries should be directed to the VA Office Congressional and Legislative Affairs.

14. Public statements and information may be posted on an internet website after clearance from the look-back POC and routing through Public Affairs.

15. Communication with Public Health Authorities (Local, State, and Federal (CDC) should be coordinated with OPHEH.

16. Publication in journals: As is often the case, knowledge gained though investigations of this type can be utilized by the medical/public health community at large, and should be shared where possible through submission for publication in relevant journals.

ATTACHMENTS

The following materials were developed for use during previous look-back programs are provided as examples/templates and may be adapted as needed.

Example Look Back Program (from BK Look-Back Information Packet) – initial instructions distributed to facilities at the beginning of the program

Example Look Back Flowchart

Individual Veteran Look Back Program Tracking Tool

Standardized Reporting Form and Laboratory Results Spreadsheet

Sample Script for Telephone Contact with Veterans Affected by the Look-back

Essential Topics to Discuss During Clinical Evaluation with Exposed Veterans

Sample Notification Letter

Look Back Program Progress Note Templates

Sample of FAQ sheet

Slide Set Template for Group Visits

Clinical Data Worksheet

Identification Strategies Worksheet

Testing algorithm

Litigation Hold Memorandum

Consent for viral genetic fingerprint testing

Pre- and Post-testing progress note templates

Laboratory Reporting Template

Specimen Collection, Processing, and Shipping SOP

Attachment 1
Example Look Back Program (from BK Look-Back Information Packet) – initial instructions distributed to facilities at the beginning of the look back program

The attached was electronically distributed as a .pdf file to all facilities required to implement a look-back notification program. It served as the basic guide and reference as a facility began their program, outlining goals, objectives, required and suggested actions to be taken. In post program evaluations facility teams rated this document as very helpful, citing especially the provision of a comprehensive program overview and practical information about potential approaches to the required tasks.

Example of Veteran Look-back Program
Patient Safety Alert AL06-011
B-K Transrectal Ultrasound Transducer Assembly Models 8808 and 8551

A. Program Components: This packet contains materials and instructions for completing the Look-back Program related to the Patient Safety Alert for the B-K Transrectal Ultrasound Transducer Assembly, Models 8808 and 8551 (AL06-011, dated April 3, 2006). This packet was developed by staff at the VHA's Center for Quality Management in Public Health (CQMPH) and contains tracking forms, a progress note template, questions and answer script, and educational material for the clinician seeing the veteran.

In brief, the B-K look-back program involves:

- identification of veterans who received biopsies that put them at risk of exposure to infection with Hepatitis B or C or HIV
- review of the clinical medical record
- notification of veterans who were identified as at risk by the VA facilities that performed these biopsies
- provision of laboratory testing to these veterans
- tracking, documenting and reporting for the Look-back Program.

Facilities are to use all available sources of information to identify veterans at risk and their current contact information. The notification letter will encourage the veteran to contact the facility for more information and provide information on how to reach a clinician at that facility who will answer the veteran's questions. If the veteran desires laboratory testing, this clinician will set up an appointment for the veteran so these tests can be ordered. A local staff member will be assigned the following duties: (1) tracking the processing of each veteran, (2) checking for the presence of appropriate CPRS progress notes documenting the process for each veteran, and (3) reporting aggregate information on processing and testing to the National Program Office (at CQMPH).

B. Program Steps: The following provides a summary of the steps contained in this look-back program.

Step One – Assemble Look-back Program

a. Identify program coordinator.

b. Identify staff member(s) or consultant(s) who will assist the coordinator with specific activities such as identifying veterans via a search of procedure records, mailing veteran notification letters, serving as a clinician contact at each medical center and CBOC where a veteran may come in to discuss this patient safety alert, and clinical auditing of charts of veterans (if any) at risk who are diagnosed with Hepatitis B or C or HIV after the biopsy. If there are a large number of medical records to review to identify patients at risk, sites may want to start the program with a larger staff and then reduce staff size once patients have been notified and the numbers of veterans contacting their facilities have tapered off.

c. IRM staff will need to install and make available the standard B-K Look-back Program progress note template.

d. Identify staff and establish policy for who will respond to inquiries from outside VA. Distribute this procedure to all staff with patient contact as soon as possible.

Step Two – Identify veterans on whom the equipment was used

a. Identify affected veterans by name and date of biopsy. First, determine the time period for when the reprocessing procedures for the B-K Transrectal Ultrasound Transducer Assembly models 8808 or 8551 did not meet the minimum criteria for reprocessing as outlined in the document "Criteria for Determining Need for Patient Notification" distributed on April 3, 2006. For this time period, identify all patients who had a transrectal prostate biopsy (not a transrectal ultrasound alone) procedure that involved the use of either of these instruments. These veterans are to ones to be included in this look-back program.

b. Complete tracking information for each identified veteran and establish a procedure to maintain all pertinent information in a centralized manner, either in hard copy or on an automated system.

Step Three – Determine current status and contact information for veterans identified as at risk

a. Determine veteran's current contact information, current source of VA care, and vital status.

b. Prioritize list of veterans to be contacted according to vital status.

Step Four – Inform veteran at risk using official Dear Veteran letter. (The official veteran notification letter was previously provided.)

a. Establish designated telephone number(s) for affected veterans to contact the VA for more information; consider a toll free number for large catchment areas.

b. Identify a limited number of specific VA staff members whom the veteran should contact and identify times when these staff members are available.

c. Assure that designated staff members are available to respond to calls and educated on policies and procedures for responding to veteran inquiries.

d. Label envelopes with Look-back program coordinator name (or designee) and routing number (mail code) to expedite return processing.

e. Label envelopes with "RETURN SERVICE REQUESTED" to improve the chance of having undeliverable mail returned.

Step Five – Mail notification letters and process cases in which letters are returned as undeliverable

a. Notify local VA mailroom of notification mailing and request that returned letters are promptly routed back to the coordinator (or designee).

b. For letters returned as undeliverable, attempt to obtain current address (e.g., by contacting next of kin).

c. If updated address information is available, re-send notification letter to this updated address and update address information in the VA system.

d. If unable to obtain valid current address for a given veteran, document that in his record.

Step Six – Respond to veteran inquiries about the Look-back Program and Patient Safety Alert

a. Designate staff member(s) who will speak/meet with veterans who respond to notification and train them on use of the B-K Look-back Program progress note.
b. Disseminate information about Look-back procedures and designated staff members to units within the VA facility that may receive inquiries from notified veterans or others (e.g., telephone operators, scheduling operators, Tele Care staff, primary care staff, long term care staff, CBOC staff, staff where procedure was done). Disseminate communication plan for queries from outside VA.
c. Establish procedure to respond to veterans who seek follow-up during routine primary care appointments or specialty care where the veteran is made aware of the issue prior to a notification letter being sent (e.g., heard about it from someone in the waiting room, read it in the paper). Document interactions using the B-K Look-back progress note template.
d. If possible, develop a standardized routine for referral for testing at time of visit without need for additional return visit.

Step Seven – Care for veteran during visit to VA facility

a. Insure that clinician seeing the veteran understands the content of the patient safety alert and the issues involved with this look-back program.
b. Take steps to standardize the visit process: standardize lab test ordering by using order sets, use the progress note template provided, and review of HIV testing and counseling processes (e.g., if hard copy consent forms are being used, are they located where clinicians can easily access them?).
c. Educate the veteran on the patient safety alert and answer questions he (and others he approves to listen in) may have
d. Discuss any historical hepatitis B, hepatitis C, and HIV testing of the veteran relative to the biopsy date.
e. If veteran wishes to be tested, provide pretest counseling for HIV and obtained consent for this test.
f. If veteran decides not to be tested, document this decision using the B-K Look-back Program progress note template.
g. For veterans who had documented hepatitis B, hepatitis C, or HIV *prior* to the biopsy date, educate them on the possibility of re-exposure and/or reinfection.
h. For veterans who had a diagnosis of hepatitis B, hepatitis C, or HIV made after the biopsy date, review with the patient any information available that may help determine a time of seroconversion. Also, review with the veteran risk factors associated with infection and answer questions they may have regarding whether they obtained this infection from the biopsy procedure.
i. For patients who decide they want to be tested, order labs including HIV antibody test, hepatitis C antibody test, hepatitis B core antibody, and hepatitis B surface antigen.
j. Clearly explain next steps (e.g., blood draw, when results will be available) and follow

up plan for reporting result.

k. Provide contact names and numbers for VA staff if needed.

l. Document visit using B-K Look-back Program progress note with designated local B-K Look-back coordinator named as expected co-signer.

Step Eight – Complete documentation and national reporting

a. Assure that all attempts to contact veterans and all interactions with the veteran have been documented

a. Use the standard B-K Look-back template to document and track efforts to contact the veteran and results of those efforts.

b. Encounter at which veteran meets with a clinician to discuss his situation may be documented in the comments section of the B-K Look-back Program progress note template or may be included as part of a note documenting another encounter. If the latter, the designated local B-K Look-back coordinator should be named as a co-signer.

b. Complete and submit weekly aggregate data report to CQMPH.

C. Responsible Staff

Each facility should assemble a team of staff or consultants led by the designated coordinator and tailored to the B-K Look-back Program activities planned at that facility. The team may require assistance from the following VA services:

a. DSS or other staff that can query electronic files to identify veterans who had procedures that potentially place them at risk.

b. Staff from SPD should be involved as required.

c. Administrative staff to help with preparing and mailing letters, tracking returned mail, and national reporting

d. Clinical person(s) for completing chart audits. At noted above, if a large number of veterans are to be notified, then a larger team of clinicians should initiate the look-back process to review cases as expeditiously as possible.

e. First contact staff including telephone care staff, primary care providers, and clinic nurses whom veterans may call or visit after they receive the notification letter. This group will require education and training on how the local Look-back Program functions. In addition, be aware of workload issues for these staff; if there are a large number of veterans notified under this program, take steps to provide adequate staff to respond promptly to inquiries (e.g., ensure telephone coverage).

f. Hepatitis B, C and HIV content experts. In the event you discover a person who has a positive test for hepatitis B, hepatitis C, or HIV, you should work closely with your local clinical expert(s) to perform an appropriate clinical review.

D. Case Identification

Each facility must determine the most accurate means to identify veterans who underwent a prostate biopsy with the specific B-K devices when suspect reprocessing protocols, as outlined in Veteran Safety Alert AL06-011, were or may have been in use *and* thus may have been placed at risk for infection secondary to reprocessing practices. Two CPT codes exist for prostate biopsy; 55700 and 55705 and the ICD-9CM procedure code for inpatient procedure is 60.11. Since clinicians may have historically used other codes, the service(s) using this device (likely Urology) should be queried about what CPT codes have been used, including ones used in the past but not currently employed. Care Management reports may be helpful to identify these veterans. At facilities where the reprocessing of devices is tracked to specific veterans, ledger books or logs can be used to assemble a list of veterans to be notified. Facilities should use a conservative approach; that is, they should assume that the suspect reprocessing procedure was used if the facility is unable to distinguish when changes were made in reprocessing protocols.

E. Case Review Definition and Process

Understanding each case will be important in determining if a veteran should be notified of a risk of exposure and if so, at which VA facility is that veteran likely to request testing and in preparing for answering veterans questions. Prior to a facility sending a notification letters to a veteran, his case should be reviewed for the following information:

1. Vital and Clinical Status.
    a. If the veteran has died since the biopsy procedure was performed, please place the case on hold pending the processing of all living cases. Procedures regarding veterans who have died will follow in the next few weeks.[1]
    b. If the veteran is living, review records for hepatitis B, hepatitis C, and HIV testing prior to and in the period following the biopsy so that you are aware of any relevant medical information. Document this information in the B-K Look-back Program progress note so that is will be available to your staff when veterans call or visit the VA. Veterans known positive for any of these infections prior to the biopsy may wonder why they are receiving the notification letter; however, do not modify the veteran letter to remove mention of any diagnoses prior to the biopsy date. All veterans should receive the same official letter with only minor modifications (addressee name, biopsy date, contact number, and contact name). For people with a new diagnosis of hepatitis B, hepatitis C, or HIV following the biopsy procedure, each facility should discuss an appropriate plan to meet with the veteran to discuss any relationship between the biopsy procedure and the positive test. No identifying information regarding a possible source patient may be released. It may be valuable to discuss available pertinent clinical information, such as HIV viral load levels in the possible source veteran at the time of the potential exposure, but no information that could lead to the identification of the possible source veteran may be released. Use the B-K Look-back Program progress note template to document pertinent information.
2. Current VA care site. Veterans may have moved or transferred care to another VA since the biopsy was performed. The facility where the potential exposure occurred retains responsibility to contact the veteran and must do so in coordination with the

VA facility where the veteran is currently receiving care or likely to seek care. Where veterans are receiving care at a new care site, a plan should be worked out with that veteran to be seen at the closest VA facility. The facility where the potential exposure occurred should contact the current facility to inform them of the patient safety alert and of the identity of the affected veteran and to obtain a clinician contact name and number to be given to the veteran. These two facilities should discuss communication strategies for this case and responsibilities for the site where the exposure occurred and for where the veteran is currently receiving care. Check all available records including remote data in CPRS for the following information;

a. Most recent VA care facility
b. Current address
c. Current phone number(s)
d. Current primary care provider name and contact information

[1] For patients who have had multiple prostate biopsies performed with the devices outlined in the Patient Alert, the first date that a device was used that placed the veteran at risk is considered the first biopsy date.

Facilities are free to use other methods (e.g., Microsoft Excel®) to collect this information. You will need information on the current status of efforts to contact each veteran (as well as other information) to prepare the periodic aggregated data reports that are required as part of this Look-back Program.

F. Program Elements to Improve Consistency and Accuracy

The following suggested elements may improve your ability to conduct a highly effective Look-back Program.

1. **Initial Contact**. Look-back processes work well when patients are provided with one telephone number to call and the names of several providers to contact. This approach permits patient education by a knowledgeable, qualified staff thereby limiting patient misinformation. At the same time, this approach prevents delays in response that may arise if only a single provider is assigned responsibility for patient education and that provider is otherwise engaged when a veteran calls.
   After an initial discussion with the provider named in the notification letter, the veteran may immediately call or request to be referred to their VA primary care provider or the clinician who performed the biopsy procedure. Facilities should determine how to respond to these requests prior to dissemination of the notification letter. Also, some veterans may indicate that they need additional time to decide how they wish to proceed (e.g., to discuss with a spouse) and will need to be given specific information about what to do when they reach a decision.

2. **Privacy and Identity Authentication**. When a call is received pertaining to the Look-back Program, prior to engaging in any clinical discussion, verify that the caller is indeed a veteran who was sent a notification letter. Typical authentication procedures involve asking the caller to provide information that typically would be known only to the

veteran, such as SSN, date of birth, period of military service, date of last VA appointment, PCP name, etc. In cases where a spouse or other person calls (in the absence of the veteran) requesting information about a veteran, no information can be released without written authorization from the veteran concerned. If a caller has established his identity as a notified veteran and asks if another person may listen in on the call, VA staff should inform the veteran that doing so is at his option.

3. **Education of the Primary Care Provider**. Many veterans will want to discuss this patient safety alert with their primary care provider. VA staff members who are primary care providers should be made aware of the Look-back Program and provided with information and support to respond to expectable veteran questions and concerns. Although a veteran may want to only interact with their primary care provider, that provider should notify the local look-back coordinator of interactions with the patients. One way to accomplish this communication is through the use of adding a co-signer to a progress note. Some veterans may inquire as to whether the device used for their procedure was used on any veterans known to be infected with hepatitis B or C or HIV. Providers may *not* release any identifying information about any veteran to another veteran without specific written authorization from that other veteran. Providers may discuss pertinent clinical information but not anything that could be used to identify the source veteran. During encounters with a potentially exposed veteran the provider should not have information about other veterans present, including displayed on the computer screen.

4. **Access to Care**. Priority should be given to seeing veterans as soon as possible at their nearest VA. Appointments with the staff member(s) designated to see such veterans should be available with as short a wait time as possible. Beware of selecting first available appointment slots as these may be months in the future. Overbooking procedures may be required and should be handled in coordination with local providers. When utilizing outlying clinics, education of additional providers may be required. The veteran will need to be seen by a VA clinician for HIV testing; thus, a veteran cannot be directly sent to blood draw. Any VA provider qualified to order an HIV test is also qualified to obtain an HIV test. Information about HIV testing in VA can be found at http://www.hiv.va.gov/vahiv?page=prtop02-00-rr

5. **Laboratory Test Ordering**. By creating a quick order set for Hepatitis B, Hepatitis C, and HIV testing, facilities can limit erroneous omission of necessary tests and expedite the ordering process.

6. **Progress Note Template**. Activities and information specific to the B-K Look-back Program are to be documented in the standard B-K Look-back Program progress note. Discussion with an affected veteran may occur during clinic visits for other reasons and be documented in that visit note.

7. **Veterans under Care at another VA**. There will likely be cases in which a notified veteran has transferred his care to a VA facility other than the one at which the biopsy was performed. Following the Case Review Definition and Process described listed

above; the facility at which the biopsy was performed will collect information on the VA facility at which a notified veteran is currently receiving care and make that facility aware that a veteran may be contacting them for follow up.

8. **Planning for the Unexpected**. Prepare staff for what may seem to be unexpected inquiries or reactions to this situation. For example, veterans will talk with each other in the waiting room and rumors may start. As part of your Look-back Program, provide all clinical staff with information about how to respond to questions. Also, veterans with or without pre-existing mental health issues could experience anxiety or mood disturbance in response to being informed of potential exposure. Have a plan for immediate referral to mental health providers in such cases, and assure that such mental health providers are fully informed about the facts surrounding the issue and established response procedures.

G. Local Documentation and National Reporting Process.

1. **Progress Note Documentation.**

a. To consistently track activities related to this program we are providing the B-K Look-back Program note template. All facilities required to contact veterans for this program will use this template to record activities related to contacting veterans.

b. Guidelines for essential topics to be covered during clinician discussions with affected veterans. Documentation of these topics being discussed may be incorporated into a general clinic note or may, as a local option, be recorded in a separate, possibly templated, note.

2. **National Reporting Process**: Reporting of summary information to the CQMPH will be carried out on a scheduled basis. Only one report per week should be provided by a single reporting station (facility/healthcare system). For example, if procedures were carried out at multiple sites within a healthcare center, then only one report should be submitted by the main facility.

The information required for national reporting is listed in the table below. One week after the receipt of this notice, each facility should report the number of veterans to be reviewed to CQMPH. Each week thereafter, the facility should submit update cumulative numbers. The data to report include:

- Total number of unique veterans to be reviewed
- CPRS or other review completed
- Hepatitis B known at time of biopsy
- Hepatitis C known at time of biopsy
- HIV diagnosis known at time of biopsy
- Number alive
- Number dead
- First notification letter sent
- First letter returned as undelivered

- First letter returned as undelivered, address updated and second letter sent
- First letter returned as undelivered, unable to update address
- Veteran contacted VA
- Veteran declined testing
- Appointment scheduled
- Blood testing completed
- Blood testing results reported to veteran
- New Hepatitis B diagnosis after biopsy
- New Hepatitis C diagnosis after biopsy
- New HIV diagnosis after biopsy
- Summary CPRS progress note completed
- Case Completed

In addition, there is a one-time request for the following information:

- the period of time covered by your look-back program (e.g. June 1998 through April 2006)
- the total number of veterans to be contacted by year of biopsy (first year ever for those with multiple biopsies)
- copies of your local reprocessing guide used *prior* to the Patient Safety Alert as well as the current process for the B-K device(s) in use at your facility.

The facility should allow up to 90 days to contact a veteran using mail and/or other methods. Once a case is beyond 90 days from the date of the last notification and the veteran has not responded, the case is to be considered closed for purposes of this Look-back Program. In such cases, all attempts to contact the veteran should be documented in CPRS using the standard B-K Look-back Program progress note.

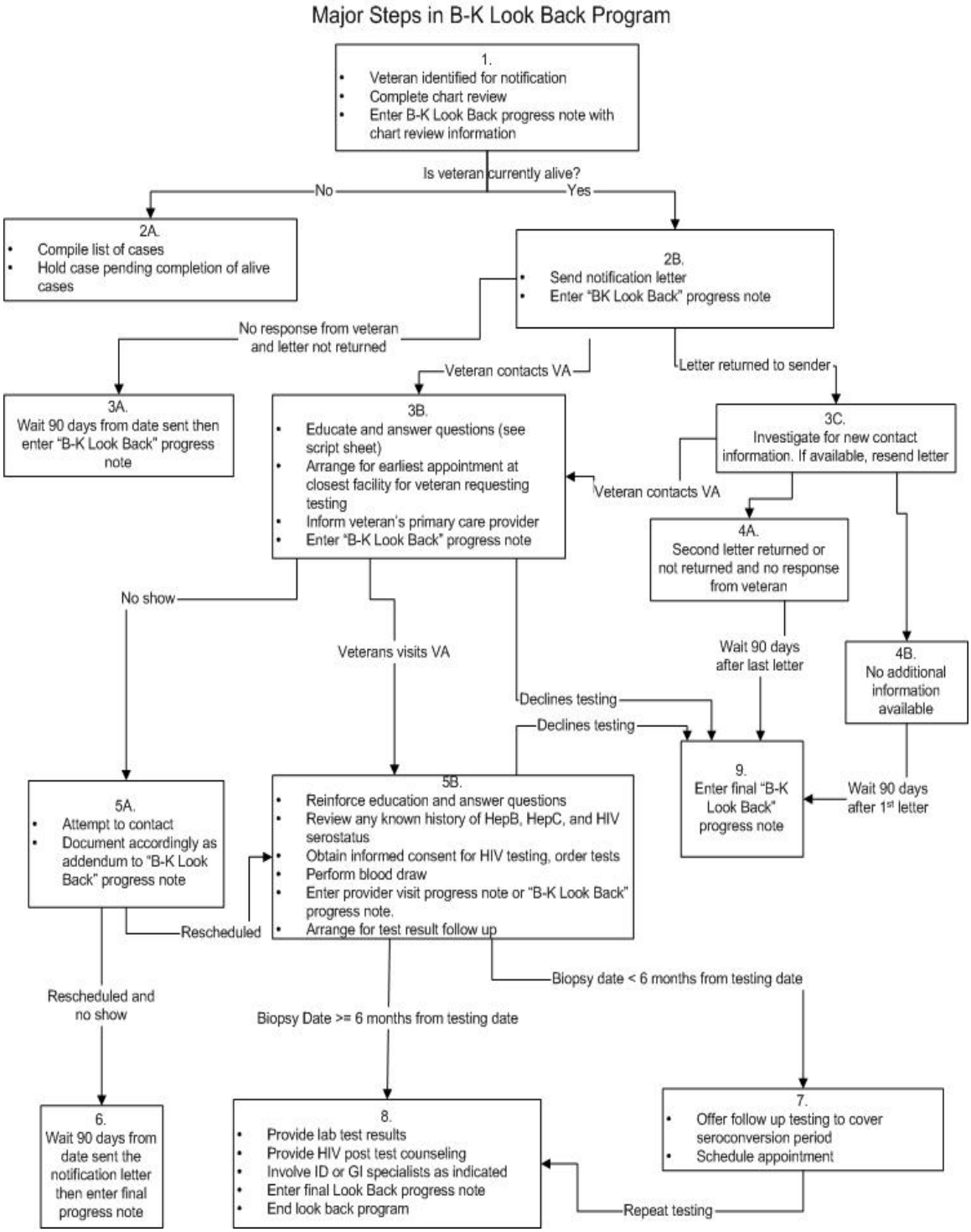
National reporting to CQMPH is due on a weekly basis starting Friday, April 21st.
All information reported will be summarized and shared back with the field as part of a quality improvement initiative.

H. Contact Information.

For questions regarding these procedures please contact the Office of Public Health Surveillance & Research at (650) 849-0365. Please notify the OPHSR staff member answering the phone that the call is regarding the "XX Patient Safety Alert" and you will be routed to the appropriate staff member.

Attachment 2

Example Look Back Flowchart – Major steps in look back process



Attachment 3

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.

Attachment 4
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.

Attachment 5

Sample Script for Telephone Contact with Veterans Affected by the Look-back

NOTES:
1. This document presents possible responses to anticipated questions from affected veterans. While responses should be tailored to the specific veteran and situation and not simply read from this script, this is provided as a sample. As much as possible, persons skilled in speaking with patients should be utilized in the Call center.
2. Veteran emotional responses will vary. Veterans with elevated anxiety levels are likely to be unable to follow complex conversations. Information should be provided in a brief and simple manner with frequent checks to assure the veteran understood what was said.
3. Avoid arguing and never dismiss the veteran's feelings. If a veteran seems agitated to the point that he is unable to hear what you are saying, don't press the issue. Acknowledge that the veteran may be understandably upset, suggest that maybe a better approach would be to schedule the veteran for an appointment to have his questions answered in person or to set up a time when you can call back.
4. Veterans who ask specific questions usually want a specific answer. Provide as much accurate information as is possible and appropriate. If a veteran asks a question the staff member is unable to answer the best response is to acknowledge the inability to provide an answer coupled with a commitment to get the necessary information if it can be determined and call back.
5. In some instances a call may come in from someone other than the veteran to whom the notification letter was addressed. VA regulations prohibit discussing any patient's information with any other person (even if that person is a spouse) unless the patient has specifically authorized doing so by completing a written release of information. Given the nature of the conditions of concern in this look-back effort, there may well be concern on the part of some callers regarding their own potential risk. The first two questions below illustrate approaches to such scenarios.

QUESTIONS AND ANSWERS

Q. I got this letter saying that I may have got an infection. What does this mean?

A. Let me give you information about what this means and then I will be glad to answer any questions you might have. *(Briefly explain the circumstances surrounding the exposure incident)*As a result, there is very small chance that veterans who had a procedure with this equipment were exposed to an infection. This does not mean that you have any infection, but it does mean that you *may* have been exposed. It is VA's policy to inform veterans of all medical information that may affect their health. We are carrying out this program to identify veterans who had procedures with this equipment in order to inform them of the small chance of exposure, provide clinical evaluation, and recommend lab testing.

Q. What kind of infection are we talking about?

A. The infections we are most concerned about are two kinds of hepatitis and human immunodeficiency virus, or HIV.

Q. You mean I could have AIDS and not know it?

A. The chance that you got infected is very small but we want to do everything we can to be sure. It is possible that a person can have HIV and not be aware of it which is one of the reasons why we are offering testing.

Q. So what do I have to do to find out if I got one of these infections?

A. There are simple blood tests that can help us tell if you have one of these infections. You will need to come in for an appointment so that we can answer any more questions you may have and do the paperwork to have these tests done. We have a system set up to make this as easy as possible for you, which is…..(inform veteran of procedures).

Q. Sounds to me like somebody screwed up and now I have to pay the price. If I got one of these infections what will VA do for me?

A. We are notifying you because we want to take good care of you. The chance that you got an infection is very small, but even if you did it does not affect your ability to get care through the VA. We are sorry to have to bother you, but want to do everything we can to take good care of you.

Q. You mean that the VA uses equipment on me that was also used on people with diseases like hepatitis and AIDS?

A. Some medical equipment is disinfected or sterilized and used on multiple veterans. The specific equipment involved here is the kind that is disinfected or sterilized for re-use. VA follows strict procedures for how equipment is disinfected and sterilized and also monitors for patient safety. We identified this issue during routine safety monitoring.

Q. What kinds of germs could be transmitted to me if the device was not cleaned correctly?

A. Bacteria could have been transmitted, but any bacterial infection would probably be gone by now. What we want to be sure of is that you were not infected with a virus. The viruses that we want to test for are hepatitis B, hepatitis C virus and HIV. We have no reason to think that you have been exposed to these viruses but think it is worth checking.

Q. What's the point of coming in for a test? What's in it for me? I have to take time off from my job. Are you going to reimburse me for time off?

A. Although we think that the risk is low that you have been infected with anything, we think that it is worth it to check to be sure. If you test and the test results are negative for any of these infections, you may feel more comfortable. If you cannot take time off from work to get the blood tests we will schedule a time to meet your needs.

Q. So was this equipment used on a veteran with AIDS or not?

A. We do not know the HIV or hepatitis status for all the patients who had a procedure like you. Many people have never been testing for these infections and it is also possible that

someone knew that he had HIV but did not tell us. These are reasons why we are notifying you. The risk is very small, but we want to do everything we can to be sure you are OK.

Q. So what am I supposed to do if I got one of these infections?

A. It's normal and understandable that you would think about that. Right now, though, the important thing is to do the tests might be necessary to determine if you were infected. I want to reassure you that though the chances of you getting one of these infections from your biopsy procedure is very small, even if you did VA would continue to take care of you.

Q. So do I need to use a condom when I have sex now?

A. If you do use condoms you should continue to do so. If you don't currently use condoms you may choose to do so until you have discussed your situation with your provider. Though the chances of your having been infected during your procedure are small, using condoms would reduce the risk that you might give something to your partner.

Q. I heard about this problem with VA procedures. I had a procedure at another VA and I am worried. What do I do?

A. (This question may come from veterans who overhear conversations in the waiting room, read press releases, or by other means. The veteran may have had one or more procedures at one or more VA facilities. Ask the veteran where they had the procedure(s). Determine if that facility name is on the list of facilities involved with this Look-back program. If the facility is not on the list, then assure the patient that they are not part of the notification process. If they did have the procedure at one of the Look-back sites, then offer to contact that facility to clarify his particular case. The veteran may have had a procedure at a Look-back site with a device that is not part of this Look-back investigation. In such a case, he would not receive a letter from that facility.

Q. Am I going to have to pay anything for this appointment?

A. There will not be any additional charges or co-pay. If you would like to discuss this with your VA health care provider during an appointment you already have scheduled, the usual co-pay would apply but there would be no additional charges. If you would like to set up an appointment just to discuss this issue and possibly get some tests done, there will be no co-pay or other charges for that appointment.

Q. I had one of these procedures done at another VA, too. What should I do? Am I going to have to go back there?

A. Every VA in the country is involved with this patient safety program and has reviewed records to identify veterans who need to be notified. If the procedure you had is involved in this program you should get a letter from that VA, but there is no reason you would have to go back to that VA. You can get the attention you need right here where it is more convenient, and the provider you see can check the records from that other VA.

Q. How will I get these test results and how long will I have to wait?

A. It generally takes (*check with your lab for turnaround time. Remember that if an initial antibody test returns as positive an additional confirmatory test will be required, and allow for this in determining what time frame you will give to patients*) for the tests to be completed. At the time of the appointment where you get the blood drawn for these tests your VA provider will tell you when and how you will get the results.

Q. This letter arrived for my (husband, partner, friend, relative, etc.) and I opened it. Is this some kind of emergency that I should call him right away and have him call somebody?

A. No, this is not an emergency, but we do want to be sure that he gets this information. Did we send the letter to the correct address? If not, is there a better address to use?

Q. I read this letter and it says my (husband, partner, etc.) might have AIDS or hepatitis. Do I need to worry that he might give it to me?

A. First of all, let me say that the letter does not say that anyone has a specific infection. Because of privacy regulations I am not able to discuss specific information about any patient, even your (husband, partner, etc.) without the written permission of that patient, but I do understand your concern, and suggest that the best thing to do is to ask your (husband, partner, etc.) to call us at the number provided in the letter. You may want to discuss your concerns with your (husband, partner, etc) before he makes that call so he can get answers to any questions you might have.

Q. What would you do in my situation?

A. I suspect I would be concerned and would want to be tested, but that decision is entirely up to you. Whatever you decide to do, VA will continue to provide you with health care.

Attachment 6

Essential topics to discuss during clinical evaluation with exposed Veterans

Background: The Look-back program identifies veterans with a remote but actual risk of exposure to infection with hepatitis B virus (HBV), hepatitis C virus (HCV) and/or HIV. While the risk is remote, VA is adopting a proactive policy in notifying veterans with potential exposure and providing them with the opportunity to obtain clinical evaluation. Some affected veterans will likely opt to discuss the issue with the VA provider they are already seeing, while others may not have a regular provider or no longer be in care through VA. The following information is provided to assist VA clinicians in evaluating affected veterans.

Affected veterans are those who had a XX procedure using a specific device. The risk derives from potential exposure to pathogens if re-processing practices were used that could fail to remove proteinaceous material from the equipment. All VA facilities have reviewed their policies, procedures and practices relative to this equipment. Using a very conservative approach (i.e., if it cannot be documented that effective re-processing practices were in place assume exposure risk) a list of affected veterans was produced.

The organisms of concern in the Look-back program are HBV, HCV, and HIV viruses. It is theoretically possible that other bacterial organisms could have been transmitted, but symptoms of such infection would likely have presented and been treated or resolved without treatment. The focus of an encounter to discuss a veteran's risk should be to provide accurate information that is as specific and complete as possible, to answer questions and provide information the veteran needs to understand his situation, and to offer any additional clinical evaluation that may be appropriate.

Discussion and clinical evaluation of affected veterans may occur in an encounter specifically for that purpose or as part of an encounter for a broader purpose (e.g., primary care follow up, annual exam, etc.) but regardless of the type of encounter the following are essential topics to discuss and document.

1. Specific reasons the veteran was selected for the Look-back program
    a. Date(s) of procedures
    b. Location where the procedures were performed

2. Specific information about the veteran's general medical condition and hepatitis B and C and HIV serostatus prior to and after the procedure(s)

3. Veteran's expressed concerns and/or questions along with provider responses.

4. Testing for hepatitis B, C and HIV, in accordance with the VHA Informed Consent Handbook 1004-01

5. If the veteran chooses to be tested, documentation of instructions given to veteran regarding how and when he will learn the results of the testing.

6. If the veteran chooses to be tested and the procedure was performed within the past 6 month, the patient should be notified that repeat testing will need to be performed.

7. Documentation of any other pertinent topics discussed and/or referrals made.

Attachment 7
Sample Notification Letter

Date: December XX, 2010

Dear Veteran:

The Department of Veterans Affairs (VA) makes every effort to provide safe, quality care and to inform you of any possible concerns related to your care. During a recent VA review of the XXX VA Medical Center XXX Clinic, it was found that some infection control procedures were not consistently followed in a limited setting of the clinic. This created some possibility that patients undergoing certain invasive dental procedures could have been exposed to bloodborne viruses.

When this issue was brought to the attention of medical center leaders, immediate action was taken. As a precautionary measure, all dental services at the medical center were temporarily suspended. Before dental services were resumed, infection control procedures were thoroughly evaluated, intensive infection control education was provided for staff, and VA leadership was assured that safe, high quality care would be provided. We have also been consulting with the Centers for Disease Control and Prevention on this situation.

You are receiving this letter because our records indicate that you had a certain type of procedure at the XXXVA Medical Center. Although the risk of bloodborne virus transmission is believed to be extremely low, our policy is to evaluate all Veterans who may have been potentially impacted by this situation. We want to emphasize that receiving this letter does not mean you were exposed to or infected with a bloodborne virus, but to ensure your best health, we are recommending that you come in and be tested-- of course at no cost to you – to determine if you are infected with one of these viruses (hepatitis B, hepatitis C, or HIV). These tests require having a small amount of blood taken from your vein. You can have this done at the XXXVA Medical Center or we can help arrange the testing at a VA facility most convenient to you. If you are found to have been exposed to and infected with one of these viruses, we will take care of you according to the highest standards.

All of us at the XXXVA Medical Center understand that this is alarming information and may be frightening. We want to assure you that we will assist you in every way possible. We have established a dedicated communication center and you may call the toll-free number at 1-877-, Monday-Friday, 8 a.m. to 7 p.m. (EST). Knowledgeable staff will be available to answer questions and assist you with scheduling an appointment for your blood test and getting the results.

We realize that you turn to XXXVA Medical Center for the highest level of care. This event is unacceptable to us, and we are trying to be as proactive as possible to ensure the safety and well-being of our patients, as well as a course of action to prevent this from happening in the future.

Sincerely,

Medical Center Director

Attachment 8

Look-back Program progress note templates

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

STL Lookback Note examples.docx

Attachment 9
Sample FAQ Sheet

The following FAQ sheet was assembled from questions that arose during other Look-back program implementation. Content reflects a compilation of questions and issues that emerged during implementation that were not covered in the original Look-back Information Packet or required clarification. It was distributed to sites in electronic format. In post program evaluation facility teams reported that it was helpful to have this single reference document.

Look-back FAQ

This document is intended to provide responses to common questions related to the Look-back program. The links below will take you to the section of the document dealing with specific topics.

Veteran Identification and Notification

How do we identify which veterans are involved with the Look-back program?
Each facility must determine the most accurate means to identify veterans who underwent a procedure with the specific devices when suspect reprocessing protocols, were or may have been in use and thus may have been placed a veteran at risk for infection secondary to reprocessing practices. CPT codes exist for XX procedure; and the ICD-9CM procedure code for inpatient procedure is XX. Since coding practices may have varied and clinicians may have historically used other codes, the service(s) performing the procedure or using this device should be queried

about what CPT codes have been used, including ones used in the past but not currently employed. Review of pathology records and/or Care Management reports may be helpful to identify these veterans. At facilities where the reprocessing of devices is tracked to specific veterans, ledger books or logs, or appointment manager software can be used to assemble a list of veterans to be notified. Facilities should use a conservative approach; that is, they should assume that the suspect reprocessing procedure was used if the facility is unable to distinguish when changes were made in reprocessing protocols. In addition, reprocessing procedures may have been carried out in a clinic setting and in SPD at various times over the Look-back Period and you may find that appropriate procedures were being carried out some of the time.

How should we notify the veteran?
Each veteran should received at minimum an initial letter from your facility using the official Dear Veteran letter which is not to be modified from its approved format nor appended to a cover letter. For facilities that need to contact hundreds of veterans or more, we suggest staggering the batch release of letters in order to handle the expected telephone call volume (e.g. 500 letters a day sent out every 3rd day). Some facilities have made their initial contact by telephone and some have used certified mail to confirm that the veteran received the letter. Again, these practices are not required under this program.

We want to make sure that we don't send letters to deceased veterans. How can we update or check our local death information?
Each facility is responsible for updating their local files in CPRS with the most current death information. Each day, updated death information is created by staff at the Health Eligibility Center (HEC) and is available to facilities to load in their local system. There is a manual process for cases where local information and national information are in conflict. If you are concerned that your local information is not up to date, whoever is responsible for running the update program can run "IVM DEMOGRAPH UPLOAD" and see when the list was last updated. Making sure that the uploading and adjudication process is up to date will lower the chance of sending a letter to a deceased veteran. However, there may still be deaths that the VHA is unaware of meaning that someone who is deceased may receive a letter.

Financial

Can we pay travel for veterans to attend appointments?
Travel is not payable for attending Look-back related appointments unless the veteran involved is otherwise entitled to travel.

How do we make sure Look-back veterans are not charged a co-pay for appointments related to this program?
There are two non-charge clinic stop codes that have been established and need to be set up in your system. Use these codes to schedule veterans for appointments related to Look-back. Link all laboratory tests performed under the Look-back Program to this appointment. Though these codes are set up as non-charge, workload credit will still be captured.

Name/ Description	Stop code Pair	Effective Date	Definition	Category of Change
XX Procedure Follow-up **Group**	394301	12-1-10	Records group session for education on the XX procedure Look-back. Includes clinical, ancillary and administrative services. This credit pair is specifically for patients identified as a participant in the XX Look-back.	1

Name/ Description	Stop code Pair	Effective Date	Definition	Category of Change
XX Procedure Follow-up **Individual**	310301	12-1-10	Records individual patient visit for evaluation, consultation and/or follow-up treatment provided. Includes clinical, ancillary and administrative services. This credit pair is specifically for patients identified as a participant in the XX Look-back.	1

Suppose a veteran has issues related to Look-back addressed during a regularly scheduled primary or specialty care visit – would there be a co-pay for that visit?
Usual co-pay would apply for the primary care visit, but nothing additional just because the Look-back evaluation was done during the visit.

Suppose a veteran has a positive result on a lab test and comes in for counseling and additional testing – is there a co pay for those visits?
If the visit is strictly to provide care related to the Look-back program (e.g., to draw confirmatory lab tests) there should be no co-pay. In order to make this process as convenient and least intrusive for affected veterans, your facility may want to consider automatically running confirmatory tests for any positive antibody test. This is sometimes called reflex testing; discuss with your local clinicians and or lab staff.

We are not a site performing the procedure but veterans are coming to our facility because they now live in our area. If they are not already in our system, do they have to go through an eligibility check before they can be seen?
Any veteran who received a notification letter is eligible to be seen for care related to the Look-back program. Veterans who present for care who are not already in your system should receive expedited processing so they can be seen in the shortest possible time. If an affected veteran does not meet current criteria to be eligible for VA care, they should still be seen for care related to this program.

If an affected veteran has a spouse or partner that he wants tested, will VA pay for that?
VA cannot pay for testing of family members or other partners. It is suggested that each facility keep a referral list that provides information about places where testing is available at low or no cost (e.g., local health departments).

How do we capture workload for this program?
By using the Look-back program clinic stop codes for group or individual sessions; standard workload measures will be captured. We encourage you to document what and how much/many other resources were used to create and implement your program. You may want to measure call volume to a call center or program staff, time for clinical records review, consultant time, laboratory time (or test cost), and other items that aren't easily identifiable through traditional workload capture.

Clinical Review and Documentation

In doing clinical reviews, do we need to look at remote data?
Yes, you need to look at all available data.

Do we have to use the Look-back Note Template? Why?
Yes. The template provides a single place where pertinent information can be accessed, including by consulting facilities that will be seeing patients who had their procedure performed at your facility.

Can we add to the Look-back Note template?
You can feel free to make additions as long as the basic content is not changed.

Suppose a veteran already has primary care or other progress note in which the clinician discusses and documents issues related to the Look-back program – do we still need to use the Look-back Note Template?
Yes. We suggest that you educate primary care or other providers who see affected veterans about Look-back template. In this situation they may wish to include their discussion about Look-back related issues in their general progress note, but the pertinent information still needs to be recorded on the Look-back template.

Whose job is it to make sure the information in the template is up to date?
That's a local decision. We recommend that as few people as possible maintain it so that there is consistency.

Can we edit the Patient Notification Letter?
No. The Patient Notification letter has been reviewed and approved by 10N, Ethics, and General Counsel and is to be used as disseminated, with only information regarding the name and contact information for the local facility. It is also not permitted to use a cover letter.

What lab tests should be reviewed to determine patient status prior to and after the procedure relative to the three target viral infections?
The procedure/algorithm used for classifying patients for the purpose of organizing a Look-back program may be different than what might be done in making clinical decisions about individual patient care. The purpose is to determine patient status relative to exposure to any of the three target viral conditions. For purposes of this program use the following to classify patients:

Pre-procedure status:

- A positive result for Hepatitis B virus (HBV) tests for HBV core antibody or HBV DNA should be considered evidence of past or current infection; document receipt of HBV vaccine.
- A positive result on Hepatitis C virus (HCV) RNA qualitative or quantitative, or HCV RIBA should be considered evidence of positivity. A positive HCV antibody result by itself may not be sufficient for clinical decision-making on an individual patient, but if

that is the ONLY HCV related test available for a patient it should be so noted and counted as positive.

- A positive Human Immunodeficiency Virus (HIV) EIA test result alone is not sufficient to diagnose HIV infection, but as the testing algorithm calls for automatically performing a HIV-1 Western Blot (WB) on repeatedly positive EIA, confirmatory WB should be available. In the rare case that only a positive ELISA is available, count the patient as positive, noting the record that no confirmatory test was done. If WB result is indeterminate and no additional test result is available, count as positive (*for purposes of Look-back classification, not for clinical decision making about individual patient care*).

Post procedure status (if multiple procedures were performed, document status after each):

- A positive result on any test for HBV should be considered evidence of positivity. If the patient received HBV immunization that should be noted, and in such cases the presence of only HBsAb would be deemed due to the vaccination.
- A positive result on a HCV RNA qualitative or quantitative or RIBA should be considered evidence of positivity. A positive HCV EIA antibody result should be confirmed with additional testing per the look-back protocol. If only a positive HCV antibody test result is available, count as positive for purposes of classification for this Look-back program.
- A positive HIV EIA should be confirmed with HIV-1Western Blot testing. Indeterminate WB results should be followed by HIV-1 RNA testing and/or repeat in 6 months. For classification purposes, if only an indeterminate WB result is indeterminate and no additional test result is available, count as positive.

Working with other VA facilities to see your Look-back patients

What do I tell an affected veteran who calls in response to a letter but now lives somewhere else?

Tell the veteran that he can go to the VA facility that is most convenient for him, and that you will help arrange an appointment for him. If you are not sure which VA facility is closest, look at the facility locator online at http://www2.va.gov/directory/guide/home.asp?isFlash=1.

How do I coordinate with other VA facilities that see affected veterans who had their procedure at our facility?

A list of Look-back point of contact (POC) at every VA facility has been disseminated to all Look-back POC's. Your first call should be to the designated POC. How you communicate will depend on a number of factors, including time zone issues. VA privacy and cyber security regulations require sending patient information via Outlook email using approved VA encryption procedures. It is also appropriate to communicate with a POC by phone. For example, it is perfectly fine to send an Outlook message stating "I need to speak with you regarding a patient involved in the Look-back program and set up an appointment for the veteran at your facility. Please contact me at (123) 456-7890, ext 1-7319 at your earliest convenience."
NOTE: If you use VistA Mail you may include patient information in the body of your message but not in the title. Be aware, though, that fewer and fewer VA staff use VistA Mail, so do not send messages to someone unless you first verify that they use the system.

How will the consulting facility know what to tell our patients?
Facilities that see your patients will depend on your having the Look-back Note Template up to date in your system. They will use remote data view to access the information they need in order to provide care for individual patients.

How will we know the status of affected veterans who seek follow up at another facility?
Consulting facilities are instructed to contact the performing facility and report that the veteran is seeking care and the results of any lab tests.

Clinical Management of Affected Veterans

What lab tests should be used to evaluate individual patient status when they come in for follow up care?
Individual patient assessment will be driven by the specific clinical circumstances pertinent to that patient, and facilities should utilize their local medical staff for specific guidance. If antibody tests that require additional confirmatory testing (e.g., HCV antibody test) are used, there should be a system in place to automatically perform the confirmatory testing without requiring the veteran to make an additional visit to the facility.
In general, evaluation of patients who present for follow up would include consideration of their pre- and post-procedure status:

A. Evidence of infection prior to the procedure
    a. Inform patient that lab tests indicate that he was exposed prior to the procedure
    b. If not already in care for this exposure, refer for such care
    c. (Possibly) order appropriate lab tests to assess current status and facilitate ongoing care; specific tests to be ordered determined in consultation with your local medical staff
B. No evidence of infection prior to procedure – no current evidence of infection
    a. Tests performed at least 6 (six) months after procedure
        i. Inform veteran that tests indicate that infection did not occur during the procedure
        ii. Explain that seroconversion usually occurs within 6 months, no further testing will be performed unless symptoms emerge that would indicate the need for additional testing
    b. Tests performed less than 6 (six) months after procedure
        i. Inform patient that current results are negative, but that seroconversion can take up to 6 months
        ii. Schedule repeat antibody testing at a date at least 6 months after procedure –OR- perform virus nucleic acid based testing
C. No evidence of infection prior to procedure – current evidence of infection
    a. Inform patient that test results indicate that infection occurred at some point after the last pre-procedure test
    b. Discuss with veteran any risk factors that may be pertinent now or in the past, and discuss risk reduction strategies

c. Inform veteran that it is not clinically possible at this time to absolutely confirm that the infection was acquired during the procedure but that VA will provide care regardless
d. Refer for appropriate medical follow up
e. If veteran inquires about testing for spouse/partner, inform that VA is not legally authorized to do this and provide referral to local resource such as health department

Suppose a veteran attends an individual or group session and decides he does not want to be tested – what do we do?
Any veteran is free to decline testing for one or more of the target conditions. This should be documented in the notes, and the veteran should be reminded that he is free to come back at a later date and request testing.

Does VA require specific pre-test counseling for HIV testing? Can this be done over the phone?
No, but patients must be informed that HIV testing is being recommended, and the patient has the right to opt-out of this testing. This can be done by phone, and documented in the look-back note.

What about delivering results of lab tests? Can we do this over the phone or by mail, or must it also be done in person?
The issue is balancing appropriate care with concern for simplifying the process for affected veterans, minimizing demand on VA staff and resources, and complying with governing law and regulations. The major concern involves accommodating the prohibition against sending the results of HIV testing via mail. Because affected veterans may opt for testing for any or all of the three target viral infections and may have a mix of positive and negative results, it can get complex. One rational approach to using the mail for results notification would be as follows:

a. Negative result on all tests: send letter stating that all Look-back testing results are negative
b. Positive for HBV or HCV, but negative for HIV: send letter stating that Look-back tests results includes positive result for HBV, HCV or both, but no mention of HIV.
c. Positive HIV result (with or without any other positive result) – send letter stating that results of Look-back tests are available, request that veteran call to schedule an appointment to obtain results, with no mention of specific tests.

Some sites have indicated that they plan to have veterans with any positive result receive a letter requesting that they come in for follow up; this is perfectly acceptable. Other sites have asked about delivery of test results over the phone, again with most concern directed to HIV results. It has always been VA policy to deliver HIV test results in person if at all possible, but there may be instances in which it is not feasible (e.g., veteran lives a great distance away and is unwilling or unable to travel to the facility for results). In such instances it is permissible for the provider to deliver test results if the following conditions can be met:

a. The provider is able to verify that the person to whom he is speaking is in fact the affected veteran; and
b. The provider's clinical judgment is that it is safe to deliver the result over the phone (e.g., patient state of mind and potential emotional response)

Additional information about HIV testing in the VA is posted at
http://www.hiv.va.gov/vahiv?page=prtop02-00-rr

What about the requirement for HIV post-test counseling – will letter notification satisfy this requirement?
If the HIV test result is positive, the letter will not deliver the specific test result but will instruct the affected veteran to schedule a follow up appointment at which time post test counseling will be provided. If the HIV test result is negative, it is sufficient to include in the notification letter a recommendation that the patient discuss the test results at his next regular appointment.

What do we do about veterans who test positive for one of the target conditions and require further care?
Any veteran who developed an infection as a result of the procedure will be entitled to ongoing care whether or not otherwise meeting eligibility requirements. Specific administrative details remain to be defined, but any such veterans should be provided with all necessary care. Operationally, this would be treated like service-connected condition.

What do we say to veterans who have legal questions?
As VA clinicians and administrators we are not qualified nor is it ethical to provide legal advice to affected veterans. VA Office of General Counsel (OGC) has provided some guidance (see below), and veterans with legal questions should be referred to their local Veterans Service Organization (VSO). Facilities should include their VSO's in planning for management of affected veterans so they are aware of the program and how it operates.

What does VA Office of General Counsel (OGC) recommend that facilities tell the patient about his/her ability to file a tort claim?
Prior to meeting with patients and family members to explain the event that triggered the look-back, the facility director and other officials should meet with the Regional Counsel to discuss the issues involved, as outlined in VHA Directive 2008-002 pertaining to Disclosure of Adverse Events to patients. (http://vaww1.va.gov/vhapublications/ViewPublication.asp?pub_ID=1637) It would be appropriate to tell the veteran and family members about the remedy under the Federal Tort Claims Act where an injury is caused by negligence of Government employees. If a contractor was responsible for disinfecting and sterilizing equipment, that information should be shared. It would also be reasonable to provide the name of the equipment manufacturer. The details of the information should be the result of collaboration with the VA Regional Counsel.

Can the patient also file for compensation? Should VHA notify the patient of that right?
VA OGC has informed that the patient may also apply for VA benefits including compensation under 38 U.S.C. [section] 1151 for disability or death due to medical or surgical treatment. Advice about benefits should explain that a type of VA benefit exists that provides compensation for some ill effects of treatment and that those benefits have an offset provision. Regional Counsels have at their disposal a "brochure" that was created for them to provide to VHA officials who are disclosing adverse events, with the intent that it be given to the patients/families after the oral disclosure, to help them remember what they have been told about FTCA and section 1151 remedies. This information can be customized so that it includes local contact information.

Consulting Facility issues

NOTE: Sites that are required to do the Look-back program and notify affected veterans are referred to as "performing facilities". Sites that are not required to do a Look-back may still see veterans who have moved into their area since the time of the procedure; these are referred to as "consulting facilities".

We did not have to notify any of our veterans about the Look-back program, but we are having veterans contact our facility in response to a notification letter they received from another facility. What do we need to do?

Because veterans may have moved since the time when they had their procedure, they may no longer live near the VA facility that performed the procedure. We want it to be as easy as possible for affected veterans to get care, and they will be directed to seek that care at the closest VA facility. If you see such veterans you will need to:

A. Assure any affected veteran who calls that he will be seen at your facility; schedule the veteran as soon as possible.
B. Be sure that the Look-back Note template is installed at your facility and available in CPRS.
C. At the time of this initial contact, determine whether the veteran has been seen at your facility and is loaded into your CPRS. If not, contact your business office to get this done.
D. Use CPRS Remote Data function to collect the information necessary to provide care to the veteran. In the progress notes for the facility that performed the procedure, look for the Look-back note template. This document will contain important clinical information necessary to provide care to affected veterans.
E. When you see a veteran who had his procedure at another facility, contact the Look-back Point of Contact at that facility to inform them that the veteran has been seen at your facility.

We are receiving calls from veterans who have not received a notification letter but have seen information in the media or otherwise heard about the Look-back program and are concerned. What do we tell these veterans?

As information becomes available through the media and word of mouth it is very possible some veterans who are not affected by this Look-back program will express concern. It is also possible that an affected veteran did not receive notification because the Performing facility does not have current contact information. Responses to such veterans should include a review of the following facts:

- VA has conducted a system wide review in all facilities
- Risk was identified only during specific time periods and at a limited number of facilities
- All veterans identified as at risk are being notified and all VA facilities are working together to provide appropriate care to affected veterans
- Whether the Look-back program affects the veteran is based on the location and date of his procedure. (Refer to the list of Look-back POC's – sites in bold are Performing facilities)
    - If the veteran had his procedure at a VA that is <u>not</u> a Performing Facility, inform him that he is not affected and no additional evaluation is required. If

he is having specific symptoms and does not have an appointment scheduled, offer to make an appointment or provide instructions on how he can do so.

- If the veteran did have his procedure at a Performing Facility, verify the date the procedure was performed and inform him that you will consult with that facility to determine whether or not he is affected. Verify that you have current contact information (address and telephone). Contact the Look-back POC at that facility to determine if the veteran had his procedure during a time period covered by the Look-back program. If yes, provide the Performing facility with current contact information so they can immediately send a notification letter. If the procedure was not done during the Look-back period, contact the veteran and inform him that he is not affected.

What if we can't find sufficient information to counsel an affected veteran?
The person coordinating the local Look-back team should review the pertinent information before the scheduled appointment. If important information is missing and not available using Remote data views in CPRS, contact the Look-back POC at the facility where the procedure was performed.

If we are a consulting facility seeing veterans who had their procedure elsewhere, do we have to notify the veteran about results of any lab tests done as part of the Look-back?
The facility that provides the counseling and any lab testing is responsible to notify the affected veteran of test results. Results should also be communicated back to the performing facility.

How do we document care provided to an affected veteran?
The Look-back Note template needs to be completed for each affected veteran in order to track activities related to this Look-back program. Additional progress notes may be appropriate, based on the judgment of the clinician seeing the patient.

Is it true that we cannot use Microsoft Outlook to exchange patient information?
No. VA confidentiality and privacy regulations allow for the use of Outlook for communicating messages that contains patient identifiable information as long as approved encryption technology is used. It is also permissible to use Outlook for message such as "We have been contacted by a veteran who received a Look-back Notification letter from your facility. Please call me at (123) 456-5789 ext 9731 to discuss." It is permissible to send patient identifying information in VistA Mail (as long as no name or SSN appears in the message subject line), but many VA staff no longer use VistA mail so you should confirm that the intended recipient does use it before sending a message.

Policy Issues

Are we required to contact JCAHO about this program?
According to the VHA's Office of Quality and Performance, the Look-back Program does not currently rise to the level of JCAHO reporting. We will let you know if that changes. We do know that in the past JCAHO has contacted facilities in response to media reporting, so you may want to be prepared for this in case it does happen.

Are we required to notify our Local Health Department?
Veterans and other who see media reports may contact their health department. It is not required that facilities notify the local health department about the Look-back program, but doing so could certainly be helpful in terms of maintaining a good working relationship, and the health department can help route inquiries to the appropriate person at the VA facility. We suggest you involve your local Public Affairs office.

Attachment 10
Slide set template for group visits

In order to increase access to care for responding veterans during the Look-back program the option of group visits was used. At the request of facility teams program leadership prepared and distributed a slide set template for adaptation and use at each facility. In post program evaluation this was rated as a very helpful resource.

This slide set is an EXAMPLE intended for adaptation and customization at the local level. It is not designed to be used "as is" but rather must have changes and edits to reflect the specific policies and practices being followed at each facility.

Before using this slide set:

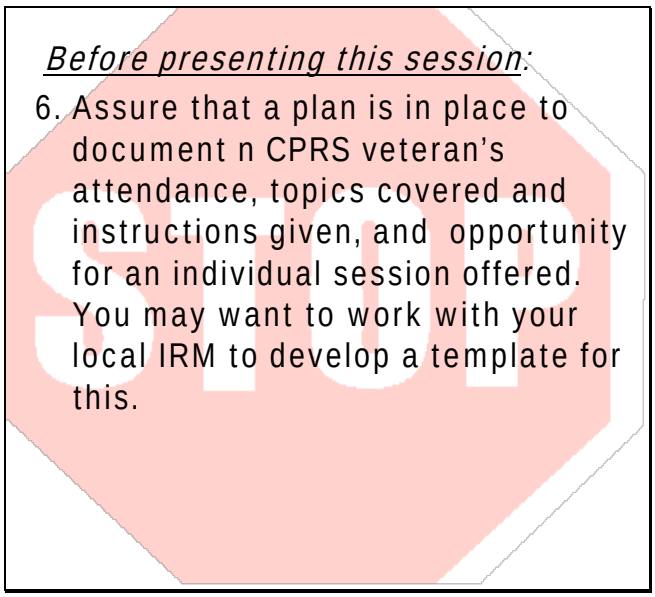
1. Review the entire slide set and insert local information where indicated
2. Make any changes to slide content and script notes required by local procedures
3. Use the "Save as" option, give the file a name indicating it has been customized

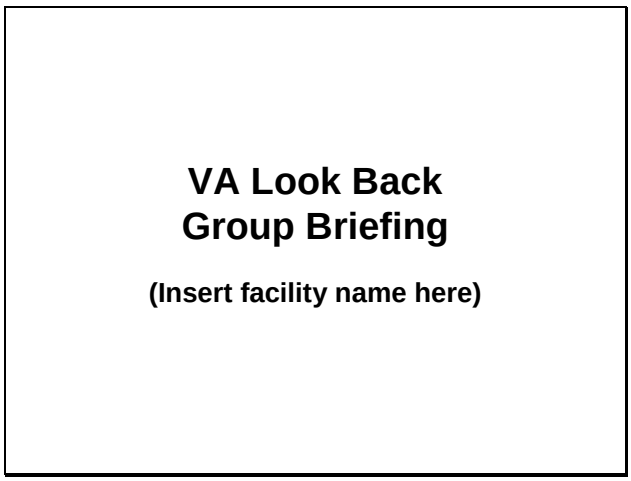
Before presenting this session:

1. Coordinate with lab and pharmacy to assure that what is said is current and accurate. Information on condoms is available at VA pharmacies
2. Verify that you know who is attending and that the clinical information required to provide individual counseling is available

Before presenting this session:

3. Assure that the required clinic stop codes are installed at the facility and used for the group and any individual sessions
4. Confirm plans (space, staff) to provide individual sessions immediately after the group session if desired by a veteran
5. Verify lab ordering and phlebotomy procedures





Purpose: Welcome participants, promote a smooth session by assuring participants that the information they want will be provided and that they will have a chance to ask questions, establish "ground rules".

Sample script:

Hello and welcome. My name is (_NAME__) and I am a (__TITLE__) here at (__FACILITY NAME__). In this group session we will talk about the VA patient safety program that brought you here and give you the chance to ask any questions you might have. Before we get started, there are a few things we need to cover about this session.

1. We want everyone to feel free to say or ask anything during this session and make sure everyone has a chance to be heard. To do that, we ask that only one person speak at a time and that you do not have side discussions with each other during this session. We will have time for questions at the end of our session, but if you have a question that cannot wait please let us know by raising your hand.
2. Nothing you say or ask here will change your entitlement to receive care from the VA.
3. Please turn off or put on vibrate any cell phones or pagers.
4. We will talk about medical equipment and procedures today. Some of the topics we discuss may be things that you have not discussed in a group before regarding medical equipment and body parts but it is important I discuss these things so that you understand this situation.

What we will discuss

- **Why you are here**
- **What brought you here**
- **The facts as we know them**
- **Your concerns and options**
- **Q&A**

Purpose: Provides participant with an overview of what will be covered during the session. Help manage session flow by letting participants know what will be discussed
Sample script:
During our time together we will talk about why you are here, the clinical issues and facts involved, your options and any other concerns you might want to bring up in the group. We will share with you the medical facts related to this program and some common concerns we have heard from veterans. We will do our best to answer any questions you have, and if we cannot answer a question today we will find the answer and get back to you.

Why you are here

Our Purpose is to provide affected veterans with information about a patient safety issue

Information provided in this group will pertain to everyone, and you will have the chance to discuss your individual questions in private

Purpose: Provide overview of the BK Look-back program
Sample script:
You are here today because the VA notified you that you may have been put at risk for exposure to some infections. We will review the specific details about this situation, and tell you why VA decided to do this notification. If there is something that you want to discuss further you can feel free to ask here or wait for a private discussion after this session.
During our time together as a group we will discuss information that may pertain to just about anyone in the group. After this group session each of you will have the opportunity for a private, one-on-one session to discuss any personal concerns or issues you might have. You can feel free to make notes if you would like to do so.

What brought you here -1

The VA Patient Safety Program (PSP) routinely monitors policies and practices in VA facilities

During a routine safety review at one VA facility it was found that a device used for XX procedure might transmit germs if specific cleaning techniques are not used

Purpose: Provide detail on how the Look-back program arose
Sample script:
VA operates a national Patient Safety program with staff at every VA facility. Patient Safety staff monitor all aspects of how VA delivers care.
The equipment that this program concerns is called a XX, and it is used for XX procedure. The equipment is cleaned using multiple steps. During a routine patient safety review at XX facility it was found that appropriate procedures for use and cleaning was not done, and could be a risk of transmitting germs. It was decided to alert all VA's about this and to check with every VA to see how VA staff were using and cleaning this equipment.

What brought you here - 2

VA decided to check and see what cleaning techniques were being used at all VA facilities that used this device

Every VA looked through its records to determine when the device was in use and how it was cleaned between patients.

Purpose: Explain the steps used and rationale for the Look-back program
Sample script:
VA checked with every facility in the country to find out which facilities were using this piece of equipment or had used it in the past. A national coordinating team was put together to run this program. The team had each facility that used this equipment provide documentation of what specific cleaning procedures were in use. If a facility did not have specific documentation of each step of the cleaning process or if the brushing step was missing that facility was directed to change their procedures immediately to include the brushing step, and to begin a "Look-back" procedure. The "Look-back" program involves all affected facilities reviewing all available information to identify any veteran who had a procedure using this equipment.

What brought you here - 3

If a facility could not confirm that all necessary cleaning techniques were used at all times, VA decided that veterans who had a procedure at that facility should be notified of the potential risk and offered an option for follow up care

Purpose: Explain the steps used and rationale for the Look-back program
Sample script:
For any veteran who had a procedure using this equipment during a time when the facility could not document that their cleaning procedures included using a brush, the VA facility was required to send a letter (or, in some cases, make a phone call) notifying the veteran about the issue and advising them of their options to seek care at the VA. For veterans who have moved and no longer live near the VA where they had the procedure performed, their closest VA would provide care. For most if not all of the folks in this group today, receiving this notification letter is the reason for being here today.

Next we are going to review the medical facts involved with this issue, but before we do let's see what questions you might have about the Look-back program, how it came about and operates.

[Pause to see what questions participants have. If participants ask questions that will be covered in the next section, tell them that rather than jumping ahead.]

The facts: viral infections

If a virus was passed symptoms could take a long time to show up

The viruses we are concerned about are hepatitis B, hepatitis C and human immunodeficiency virus (HIV)

Though the risk of transmission is very low, VA wants to let affected veterans know about their risk

Purpose: Provide clinical information about potential risk to allow affected veterans to make informed choice about testing.
Sample Script:
The viral infections we are concerned about would not usually cause symptoms for a while. The viruses we are most concerned about in relation to the procedure are hepatitis B virus, hepatitis C virus, and human immunodeficiency virus, or HIV. Hepatitis B and C can cause damage to the liver. HIV causes damage to the immune system and it is the cause of Acquired Immunodeficiency Syndrome, or AIDS. Though the risk of transmission of these viruses during your prostate biopsy is very low, it is VA policy to inform you anytime we know there is any risk at all.

The facts: how to tell if you are infected

There are blood tests that can be done to see if you have any of these viruses

VA will provide these tests to you at no charge along with any necessary follow up care

Whether or not you take any of these tests, and whatever the result, your eligibility for VA care will not change

Purpose: Provide information to allow affected veterans to make informed choice about testing.
Sample script:
The way to tell if you are infected with one of these viruses is to take a blood test that looks for evidence of the virus in your body. If you decide you want to be tested VA will provide all necessary tests without any charges or co-payment. Whether or not to have one or more of these tests is entirely up to you, and whatever you decide will not affect your eligibility for care from the VA.

Testing for hepatitis B and C can be done with a simple visit to the lab to have your blood drawn once the order is put into the system. For HIV testing, VA has special rules that must be followed, including your providing verbal consent to have the test performed before the order is put into the system.

(NOTE: You may choose to review the required elements of pre-test counseling, but remember that even if this is done each veteran must be offered the opportunity for a private, on-to-one discussion with a provider before signing the informed consent. A veteran may decline such a private session, but it must be offered.)

If you do decide to get tested, we will draw the necessary blood today. You will not be charged a co-pay for that visit. It will take approximately [***insert expected turnaround time at your facility, including time for confirmatory testing if needed***] for the results to be available. If you already have an appointment with a VA provider around that time you may choose to get the results of your test during that appointment. Otherwise, we will get in contact with you when the test results are ready. Before you leave today please verify that the contact information we have for you is current.
[NOTE: Do <u>not</u> say anything that would suggest that the way a veteran gets test results will depend on the result – e.g., a letter if negative and a phone call if positive.]

Common concerns

How good are the tests?

Could this have affected the results of my procedure? Do I need to have it done over?

Purpose: Provide information to allow affected veterans to make informed choice about testing
Sample Script:
Now let's spend a few minute talking about some common concerns.
It can take up to six months for the test to become positive. So as long as it has been at least six months since your procedure the test should be considered reliable. If you were infected less than six months you still might test positive, but to be sure there are some other tests that might be used.

You also might wonder if this would affect the result of your procedure, and the answer is that it does not. Even with the remote chance that you were exposed to one of these bacteria or viruses during your procedure, it would not affect the result. There would be no need to have the procedure repeated.

Common concerns

If I decide not to get tested now, can I still get tested later if I change my mind?

Was the equipment used for my procedure also used on somebody who had one of these infections?

Purpose: Provide information to allow affected veterans to make informed choice about testing and respond to potential concerns
Sample script:
It is entirely up to you whether or not you get tested. Even if you decide not to get tested today, you can come back later and have the testing done at no charge or co-pay.

It is possible that a person who had a procedure had one of these viruses but did not tell us. There is no way to confirm that, that is why we are notifying all patients.

Common concerns

If I got one of these infections, could I pass it to other people?

Should I be taking some kind of precautions?

Purpose: Provide information to allow affected veterans to make informed choice about testing.
Sample Script:
Another question relates to the chances of your passing on one of these viruses to someone else. These viruses are not transmitted by routine, non-intimate contact such as shaking hands or hugging, nor does coughing or sneezing spread them. They can be spread through close personal contact such as sex or sharing needles used for injecting any kind of drug (whether leally obtained or not), placing tattoos or doing body piercing. Of course, if you are not infected this is not a concern, but if you were to find out that you were infected a part of your care would be explaining how you can avoid passing the virus to others.

While you are waiting for test results the safest thing would be to use condoms for any sexual activity. If you would like to get some condoms today we can put in an order and you may pick them up at the pharmacy with no co-pay **(NOTE: Please verify that you pharmacy has condoms in stock and no co-pay is required**) You should never share needles, regardless of what your test result shows.

Common concerns

Suppose I was infected with one of these viruses - do I have the right to sue somebody? Could somebody sue me if I passed it on to them?

Purpose: Address concern about legal rights
Sample script:
Any legal rights you have are not affected by your decision to have this test done or not done. The purpose of this session is to give you the clinical information you need to decide about getting tested. As mentioned earlier, whatever you decide to do about testing will not affect you eligibility for VA care. We are not lawyers and cannot give you any legal advice, but would suggest that for further information you discuss this with your veteran's service organization or VSO. Representatives of [***insert name of VSO's at your facility***] are located in room [***insert room number***]
(NOTE: If there is no VSO representative on site at your facility you may want to have available information about where their offices are located. Check with your Public Affairs office for assistance with this.)

Q & A

What other questions do you have about anything related to this Look Back program?

Purpose: Allow opportunity for additional questions
Sample script:
That's everything that we have to present today, and now we want to be sure you have a chance to ask any other questions you might have. Remember that we cannot discuss personal medical information in this group, and you will have the chance for a private discussion with provider.

[Respond to any questions that participants may have. When all questions have been asked, proceed to private sessions. May also offer participants the opportunity to have their private session now if they have no additional questions]

Thank you for coming

Thanks for taking the time to come in today. We hope this has helped.

While VA is proud to have a Patient Safety Program that finds and responds to this kind of situations, we regret and sincerely apologize for any worry or inconvenience.

Purpose: Provide closure, express thanks to participants and offer apology.
Sample Script:
Thanks for being here, we hope it was helpful. While this issue creates potential concerns for you, VA is proud to have a Patient Safety program and remains committed to keeping all our patients informed about anything that could affect their health and well being. We recognize the effort you took to be here today, and we apologize for the inconvenience as well as any worry you may have experienced about this issue. We want you to feel confident that VA will always do the right thing on your behalf and continue to feel confident and trust the care you receive through VA.

Next Steps

- **If you wish to have a private discussion**
  - **Ask any questions specific to your condition or medical history**
  - **Sign consent if you wish to have HIV test done**
  - **Have blood drawn if you wish to be tested**
- **If you do not wish a private discussion**
  - **Sign consent if you wish to have HIV test done**
  - **Have blood drawn if you wish to be tested**

We will contact you when test results are ready

Purpose: To inform the veteran on what will be the next steps in the process at your facility, proceed to testing.
Sample script:
Now we want to provide you with the opportunity for a private discussion with a VA health care provider. Standing by to meet with you are [**introduce by name and title staff members who will provide one-to-one discussions**]. If you have already decided that you wish to have testing done and do not want to have a private discussion, **[insert instructions on how participants will provide the HIV testing, confirm that appropriate lab orders are in the system and proceed to phlebotomy. You may want to consider having phlebotomy available in or near the location of the group session to enhance participant convenience.]**

Thanks again for being here. If you think of any additional questions after you leave today you can contact [***insert name and contact information; consider having printed handout available that includes resources for clinical questions, emotional support, VSO, Patient Advocate***].

Attachment 11
Clinical Data Worksheet

Link to Site and OPHSR Clinical Data Worksheet


Lookback_ReviewVariables.xlsx


OPHSR template.xlsx

Attachment 12
Identification Strategies Worksheet

Identification of affected patients can be facilitated through automated medical record queries. This tool helps shape the content of such queries.

Look-back Worksheet – PATIENT IDENTIFICATION STRATEGIES (to be modified)

1. Use codes in EMR to identify patients

Procedure(s) involved:

Description	CPT Code(s)	ICD-9 Code(s) (diagnosis or procedure)

2. Other potential sources – e.g., log books maintained in clinics or other departments, appointment lists, procedure logs, billing records, etc.

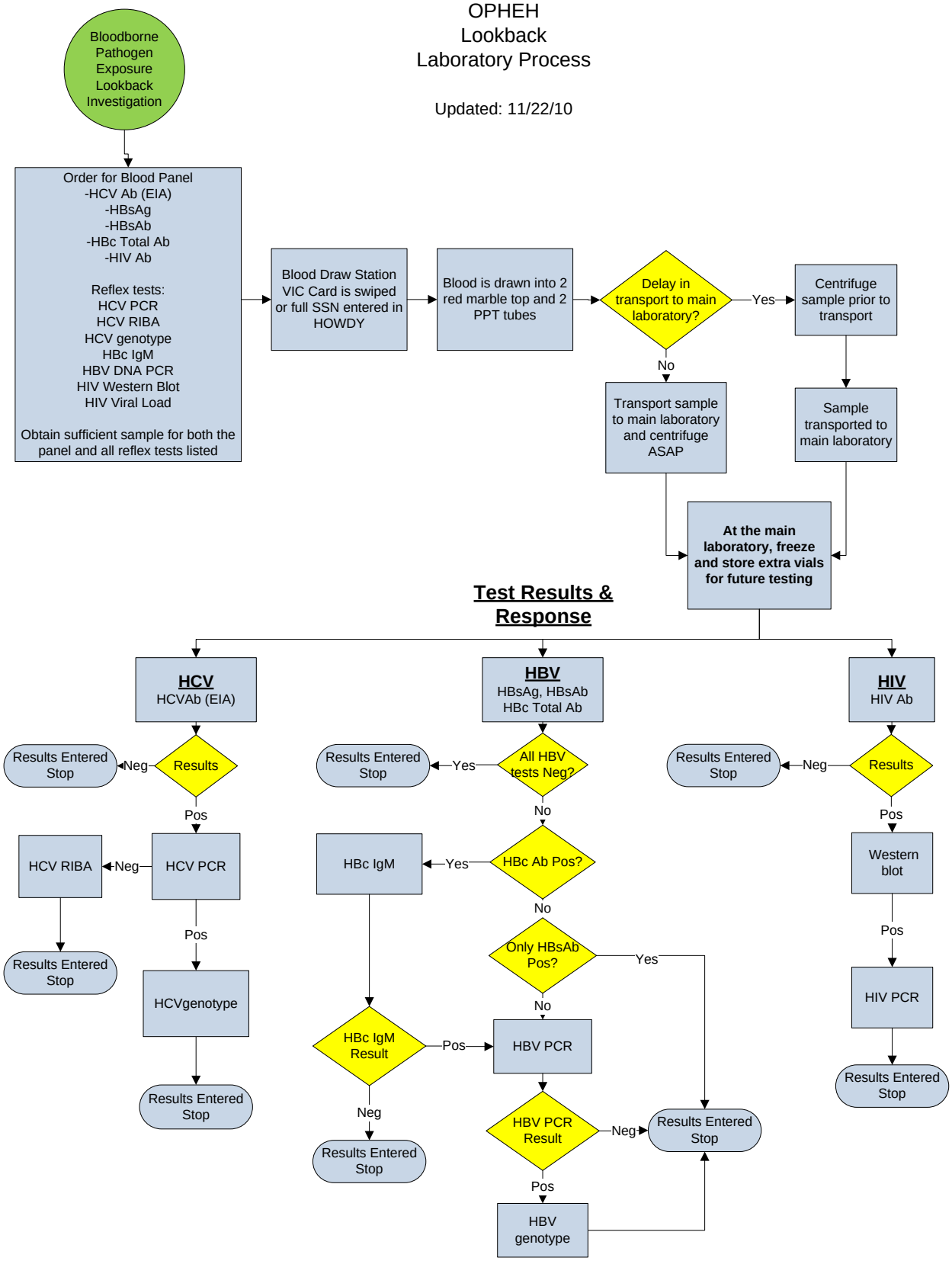
Location / Content	Who maintains it?	What info is needed?

Attachment 13
Testing Algorithm

This tool was employed to help facilities select the appropriate screening and confirmatory tests for blood-borne viruses.

OPHEH
Lookback
Laboratory Process

Updated: 11/22/10



Attachment 14
Litigation Hold Memorandum

Litigation Hold Procedures

Purpose -This policy serves to inform all Department of Veterans Affairs (VA) employees in the offices listed above that they have a legal obligation to preserve information relevant to the disclosures related to the XX Look-back. Relevant information will include information related to XX equipment within the timeframe of 200X to 20XX. This memorandum explains what to do if you have relevant information, describes how it is to be preserved, and provides instructions on how to preserve relevant information if you change jobs within VA or leave VA service. We anticipate that claims under the Federal Tort Claims Act will be filed by veterans who received the notification and that ultimately litigation may be filed.

Legal Duties of All Employees, Contractors, and Volunteers - VA is under a legal obligation to preserve all records and information relevant to this litigation or potential litigation wherever located in the Department. All VA employees, contractors, and volunteers possessing information relevant to this potential litigation have a legal duty to preserve such information.

Failure to preserve records and information described in this memorandum could result in sanctions against VA and you personally in the litigation. The paragraphs below provide instructions for preserving such information.

Managers' Responsibilities - Leaders of all offices are responsible for the following:

- Ensuring that employees, contractors, and volunteers under their supervision are aware of the requirements of this litigation hold (including technical personnel responsible for operating systems that store electronic information).
- Designating a point of contact to assist the Office of the General Counsel as needed in coordinating with their administration, facility, or office and collecting responsive information from persons under their supervision.

Individuals' Responsibilities for Preserving Relevant Information -
Individuals are responsible for complying with the following instructions:

- Do not discard, delete, or destroy the information. If any relevant information is scheduled for destruction, you must delay destruction until all related lawsuits are resolved.
- If you are uncertain whether information is covered by this litigation hold, preserve the information until you have consulted with the Office of the General Counsel attorney listed in paragraph 12.
- Preserve the relevant information within your possession until further notice. If the Office of the General Counsel needs to collect the relevant information in your possession, we will notify you of the methods and time requirements for compiling and transmitting the information.

Sources of Information - The preservation requirement applies to all relevant records, including information on computer systems and removable/portable electronic media, paper records, hand-written notes, telephone message records or logs, e-mail, voicemail, word-processing documents, drafts, spreadsheets, databases, calendars, contact manager information, Internet usage files, network access information, and relevant backup tapes and indices for those tapes. VA must preserve relevant records even if they may be privileged or protected from disclosure.

Preserving Paper Documents, Records, and Files

- If relevant information is contained in a record or file such as a claims file or medical record, retain the record in its original format.
- If relevant information is not contained in a record or file *(e.g.* loose documents) create a file labeled "XX Disclosures 2010," chronologically file all such documents in the folder, and retain it for the duration of all related lawsuits.

Preserving Electronic Documents

- Retain all relevant electronic documents in their original format. For example, if a document was created using Microsoft Word, you must preserve it in Word in the electronic, not printed, format.

Preserving E-mails

Retain in Outlook all e-mails relevant to the XX Disclosures 2010 you have sent or received, creating a folder in Outlook and transferring the relevant e-mails to that folder.

Transfer Jobs Within VA or Leave VA Service

Before transferring jobs within VA or leaving VA, you must identify to your supervisor any relevant paper and electronic information in your possession.
If you do not have relevant information, no further action is necessary. If you have any relevant information, you must do the following:

Paper Documents

Relevant paper documents stay with the position and are retained according to the instructions in Paragraph 7 above.
If you created a "St. Louis Dental Disclosures 2010" folder with loose documents, give it to your supervisor.
Supervisors will provide replacements with the loose documents folder and instructions concerning the litigation hold or, if the position is not filled, will retain such documents for the duration of litigation.

Electronic Documents

If you have relevant electronic information (including e-mails) on your computer's hard drive or file server and you leave VA service, or you move to a new work station without access to your old file server, you must:
Work with local Office of Information & Technology (OI&T) staff to save all relevant information to a file server in a folder identified as "XX Disclosures 2010" - [Last Name, First Name]." Preserve relevant e-mails as "PST" files.

"XX Disclosures 2010 [Last Name, First Name]:
+ Responsive Documents
+ Responsive Emails"

If you are a VA OI&T employee and have questions regarding the technical aspects of this memo, send your questions via email to FieldOperationsRequests@va.gov or contact Kendall Krebs, OI&T Field Operations, at (512) 326-6735.
If you have questions concerning your legal obligation to preserve information relevant to disclosures related to the Dental Clinic at John Cochran VAMC, contact Mary Bell, Office of the General Counsel, at (202) 461-4908.

Attachment 15
Consent Packet for Viral Genetic testing
(For use only in the event that blood samples were not saved in the lookback process)

CONSENT FOR HEPATITIS C VIRUS GENETIC "FINGERPRINT" TESTING (12/2/09)

BACKGROUND:

This testing is being requested as part of a public health investigation involving Veterans who underwent endoscopic procedures with endoscopes that may or may not have been properly cleaned. The investigation is being carried out by public health experts from the U.S. Department of Veterans Affairs (VA). Genetic fingerprint testing is a test that creates a detailed picture of the genetic make-up of your hepatitis C virus. We can use these detailed pictures (or fingerprints) to compare one virus to another and help us determine whether the virus from one person is related to the virus of another. The testing described below is provided free of charge. This testing is not research.

PURPOSE:

The purpose of this testing is to understand how likely it is that hepatitis C virus could have been transmitted from one patient to another during an endoscopy procedure where the endoscope may not have been cleaned correctly. The results of this test will not improve your medical condition or provide any medical benefit to you. This information may benefit other Veterans by providing information that can help us better understand how hepatitis C viruses can be spread in health care settings.

PROCEDURES:

If you agree to participate, we will collect approximately 1-2 tablespoons of blood or less. Your blood sample will be sent to a specialty laboratory at the U.S. Centers for Disease Control and Prevention (CDC) to determine the genetic fingerprint of the hepatitis C virus with which you are infected. Your blood sample will not be identified by name; instead a unique identifier will be used. CDC will report the results of the test to the Chief Consultant, Public Health Strategic Health Care Group; a record of the test results will also be placed in your medical record.

When the CDC has completed the genetic fingerprinting, if you have indicated that you wish to be notified of results, the VA Public Health Strategic Health Care Group (PHSHG) will mail you a letter indicating the genetic fingerprint of the virus you have and its percentage match to the comparison sample taken from another patient (whose identity will not be disclosed to you in any fashion at any time). The letter will provide a contact telephone number for a PHSHG representative you can call if you have any questions about the information provided to you. A copy of this letter will be retained by PHSHG in the records of the investigation. It will also be placed in your medical record. If you have not indicated that you wish to receive a letter with this information, but you decide later that you would, you may contact the PHSHG at 877-309-3735 and this information will be provided.

Once this public health investigation is completed, VA intends to summarize the findings and submit them for publication in a medical journal so that other public health experts can learn from this experience. You will NOT be identified by personally identifiable information in any reports or publications related to this event. Also, within 3 months following publication of these results in a medical journal, any blood samples that were drawn specifically for the purpose of hepatitis C virus genetic fingerprint testing, including the samples held by CDC, will be destroyed.

RISKS:

The risks include the risk of having your blood drawn. The problems that can happen with blood drawing include: pain at the blood draw site, bruising, feeling lightheaded or dizzy, and rarely, infection. Other possible risks of knowing results include anxiety and other psychological distress. If the testing shows that there are similarities between your hepatitis C virus and another patient's virus, this might suggest that another patient got the virus from you, or that you got the virus from another patient. Some patients would not want to know this information or would not want other people to know this information. If the testing shows that there are similarities between your virus and another patient's virus, this might negatively affect how you feel about the care that you receive from VA. If the testing shows that there is not much similarity between your virus and any other patient's virus, this might decrease your chances of receiving compensation either from VA or from a court of law. If there is not much similarity, this might cause you to worry about where you got the virus since it is not likely that you got it from the endoscopy.

BENEFITS:

You will not receive a health benefit from this test as this test will not be used to treat your hepatitis C virus disease. The results of this test are being used to understand the patterns of spread of hepatitis C virus among people receiving endoscopies in health care settings. The results of your test can be used to provide evidence of a transmission link between your hepatitis C virus and another patient's virus. But

they cannot prove a definitive link between your hepatitis C virus and another patient's hepatitis C virus. If the testing shows that there are similarities between your hepatitis C virus and another patient's virus, this might suggest that another patient got the virus from you or that you got the virus from another patient. Some patients would like to have this information. If the testing shows that there is not much similarity between your virus and another patient's virus, this might positively affect how you feel about the care that you receive from VA. If the testing shows that there is similarity between your virus and another patient's virus, this might increase your chances of receiving compensation either from VA or from a court of law.

YOUR RIGHTS:

You have the right to have any questions you have answered clearly and to your satisfaction. You have the right to decide whether or not you want to provide a blood sample; your participation is entirely voluntary. Should you decide not to have this testing done, you will still receive care and any benefits to which you would otherwise be entitled. If you do agree to be tested, the results of your hepatitis C virus genetic fingerprint will be placed in your medical record. You have a right to receive the results of the test, including a copy of the genetic fingerprint of your hepatitis C virus and its percentage match to a comparison sample taken from another patient. You also have the right not to receive this information. You have no right to personally identifiable information regarding any other patient.

The results of the test could be used in any legal proceedings regarding this public health investigation and might help or harm any legal claims, depending on the nature of the findings. If you want more information about the legal ramifications before agreeing to the test, you should consult a lawyer.

ADDITIONAL INFORMATION: If you would like additional information about this test, please contact the PHSHG representative whose name and phone number appear below. If you have questions about treatment of your hepatitis C infection, you should contact your primary care provider.

PHSHG REPRESENTATIVE NAME:_____

PHSHG REPRESENTATIVE CONTACT:_____

RESULTS NOTIFICATION: If you would like to receive a copy of the results of your hepatitis C virus fingerprint as well as its percentage match to a comparison sample taken from another patient, please indicated below and provide your current postal mailing address.

_____YES, I would like to receive a copy of the results of my hepatitis C genetic fingerprint and its percentage match to a comparison patient.

If "YES", please provide your current postal mailing address below:

_____
_____
_____
_____

_____NO, I do not want to receive a copy of the results of my hepatitis C genetic fingerprint and its percentage match to a comparison patient

I have read the information on this consent form, I understand what it says and I agree to provide a blood sample so that my hepatitis C virus can be tested to determine its genetic fingerprint.

PATIENT NAME (please print):_____

PATIENT SIGNATURE: _____

DATE: _____

Letter to Patient from Facility Director

DEPARTMENT OF VETERANS AFFAIRS
Veterans Health Administration
Washington DC 20420

Dear Mr./Ms.

As you know the XXXXVA Medical Center has recently contacted a number of Veterans because of the possibility that patients may have been exposed to an infection because of endoscopes that may not have been suitably cleaned.

Our records indicate that you have tested positive for hepatitis C virus. In our efforts to learn as much as we can about the spread of viruses in health care settings, we would like to test a sample of your blood to determine the exact genetic make-up of your hepatitis C virus. The "genetic fingerprint" of your hepatitis C virus will be compared to the genetic fingerprint of other patients who had endoscopies around the same time as yours to determine how closely related these viruses are to one another.

The risks and benefits of this test are described in the enclosed consent form. Whether you choose to have the test is up to you; you are not required to help us out with this investigation. Results suggesting a link between your hepatitis C virus and another patient's virus may support a claim that the virus was transmitted during endoscopy. Likewise, results suggesting no link between your hepatitis C virus and another patient's virus may weaken a claim that the virus was transmitted during your procedure.

If you are considering filing a claim related to your hepatitis C infection, you may wish to seek legal advice outside of the VA. If you have hired a lawyer to assist you on a claim related to your hepatitis C, we encourage you to discuss this letter with him or her.

Please read the enclosed consent form. If you have questions you can call the following toll free number to reach a subject matter expert who can provide confidential answers and help you schedule an appointment: 877-309-3735. Please note that there will be no co-payment or cost associated with the appointment or testing related to this issue. When you come in for the scheduled appointment a designated representative of the VA Office of Public Health will review the consent form with you and answer any questions you might have. If you agree to have your blood drawn for this test, you can sign the consent form and the VA representative will arrange for it to be put in your medical record.

Thank you for taking the time to read this letter. If you are willing to provide a sample of blood for this testing or if you have any questions, please call the following number to schedule an appointment: 877-309-3735.

Sincerely,

Facility Director

Attachment 16
Pre-Post Testing Progress Note Templates

Pre-test Note: Case Patient Version
LOCAL TITLE: CLINICAL AND INSTITUTIONAL ADVERSE EVENTS REPORTING
STANDARD TITLE: COMMUNICATION OF ADVERSE EVENT
DATE OF NOTE: FEB 1, 2010@00:00 **ENTRY DATE:** FEB 1, 2010@00:00
AUTHOR: XX **EXP COSIGNER:** XX
URGENCY: Routine **STATUS:** COMPLETED
Name and Title of Attending Physician making the disclosure:
Dr. XX, Staff member and Physician in the VA Office of Public Health & Environmental Hazards
Name and Title of other VA employees witnessing the disclosure:
XX Risk Manager, XX Attending Physician, XX Regional Counsel
List names and relationships of those present who are not listed above (including patient, designated surrogate and family or friends):
XX veteran patient, Mrs. XX wife, Mr. XX patient counsel
The patient consents to disclosure of private health information to those present.

DISCUSSION OF THE ADVERSE EVENT
A discussion of the adverse event was completed. The patient was advised in person that an endoscope that was used to perform a procedure on him was possibly not cleaned entirely to manufacturer's specification, and that testing performed on the patient after the procedure showed the presence of HCV infection. This event was explained to the patient and documented in the note titled "Endoscopy Look-back Note" (or whatever) on xx/xx/xx. It was further explained today that the VA is attempting to determine whether infection with HCV could have occurred as a result of this procedure. In order to make this determination, a sample of blood containing HCV was taken, after obtaining the patient's informed consent, and sent to the Centers for Disease Control and Prevention in Atlanta, GA., where it will be examined by scientists and compared to the HCV viral strain from a patient already known to have HCV infection who had a similar endoscopic procedure on the same day. He appeared to understand and accept the explanation and had any questions answered.. He had no problems following the blood draw. He has an appointment to see Dr. XX for results on 3-XX-2010. The results are not currently available.

CORRECTIVE ACTIONS TAKEN
List Actions
The process is still under investigation.

OFFER OF ASSISTANCE
Concern for the patient's welfare was expressed by the VA staff. The patient was advised that if further findings are made that we would advise him of them.
The patient/surrogate's concerns were noted and discussed. (List concerns)
The patient did not appear to have any concerns at the present time.
/es/ XX, XX, MD
STAFF PHYSICIAN,
Signed:

Pre-test Note: Proximate Patient Version
LOCAL TITLE: CLINICAL AND INSTITUTIONAL ADVERSE EVENTS REPORTING
STANDARD TITLE: COMMUNICATION OF ADVERSE EVENT
DATE OF NOTE: FEB 1, 2010@00:00 **ENTRY DATE:** FEB 1, 2010@00:00
AUTHOR: XX **EXP COSIGNER:** XX
URGENCY: Routine **STATUS:** COMPLETED
Name and Title of Attending Physician making the disclosure:
Dr. XX, Staff member and Physician in the VA Office of Public Health & Environmental Hazards
Name and Title of other VA employees witnessing the disclosure:
XX Risk Manager, XX Attending Physician, XX Regional Counsel
List names and relationships of those present who are not listed above (including patient, designated surrogate and family or friends):
XX veteran patient, Mrs. XX wife, Mr. XX patient counsel
The patient consents to disclosure of private health information to those present.

DISCUSSION OF THE ADVERSE EVENT
A discussion of the adverse event was completed. The patient was advised in person that an endoscope that was used to perform a procedure on him was possibly not cleaned entirely to manufacturer's specification, and that testing performed on the patient after the procedure showed the presence of HCV infection. This event was explained to the patient and documented in the note titled “Endoscopy Look-back Note” (or whatever) on xx/xx/xx. At this time, it was determined that the patient’s HCV infection was present prior to the endoscopy procedure. However, it was further explained today that the VA is attempting to determine whether another patient’s infection with HCV could have occurred as a result of his procedure on the same day. In order to make this determination, a sample of blood containing HCV was taken, after obtaining the patient’s informed consent, and sent to the Centers for Disease Control and Prevention in Atlanta, GA., where it will be examined by scientists and compared to the HCV viral strain from a patient who had a similar endoscopic procedure on the same day, and for whom we are attempting to determine whether infection transmission may have been related to the endoscopy procedure. He appeared to understand and accept the explanation and had any questions answered. He had no problems following the blood draw. He has an appointment to see Dr. XX for results on 3-XX-2010. The results are not currently available.

CORRECTIVE ACTIONS TAKEN
List Actions
The process is still under investigation.

OFFER OF ASSISTANCE
Concern for the patient's welfare was expressed by the VA staff. The patient was advised that if further findings are made that we would advise him of them.
The patient/surrogate's concerns were noted and discussed. (List concerns)
The patient did not appear to have any concerns at the present time.
/es/ XX, XX, MD
STAFF PHYSICIAN,
Signed:

Post-test Note: Case Patient Version
LOCAL TITLE: CLINICAL AND INSTITUTIONAL ADVERSE EVENTS REPORTING
STANDARD TITLE: COMMUNICATION OF ADVERSE EVENT
DATE OF NOTE: FEB 1, 2010@00:00 **ENTRY DATE:** FEB 1, 2010@00:00
AUTHOR: XX **EXP COSIGNER:** XX
URGENCY: Routine **STATUS:** COMPLETED
Name and Title of Attending Physician making the disclosure:
Dr. XX, Staff member and Physician in the VA Office of Public Health & Environmental Hazards
Name and Title of other VA employees witnessing the disclosure:
XX Risk Manager, XX Attending Physician, XX Regional Counsel
List names and relationships of those present who are not listed above (including patient, designated surrogate and family or friends):
XX veteran patient, Mrs. XX wife, Mr. XX patient counsel
The patient consents to disclosure of private health information to those present.

DISCUSSION OF THE ADVERSE EVENT
A discussion of the adverse event was completed as follow-up to the discussion begun on xx/xx/xx and documented in the note titled "CLINICAL AND INSTITUTIONAL ADVERSE EVENTS REPORTING". The patient was advised again in person about the issues surrounding his endoscopic procedure and that he has HCV infection. Molecular testing of HCV isolates from the patient and another patient whose procedure preceded his was conducted by scientists at the Centers for Disease Control and Prevention in Atlanta, GA. These results, dated xx/xx/xx and scanned within the electronic record, and were reviewed with the patient. Per final results analysis, the degree of genetic relatedness between the two HCV isolates supports/does not support the possibility of infection transmission having occurred between the two patients.
He appeared to understand and accept the explanation of these results and had no questions. He has an appointment to see Dr. XX for follow-up of his HCV infection on 3-XX-2010.

CORRECTIVE ACTIONS TAKEN
List Actions
The process is still under investigation.

OFFER OF ASSISTANCE
Concern for the patient's welfare was expressed by the VA staff. The patient was advised that if further findings are made that we would advise him of them.
The patient/surrogate's concerns were noted and discussed. (List concerns)
The patient did not appear to have any concerns at the present time.
/es/ XX, XX, MD
STAFF PHYSICIAN,
Signed:

Post-test Note: Proximate Patient Version
LOCAL TITLE: CLINICAL AND INSTITUTIONAL ADVERSE EVENTS REPORTING
STANDARD TITLE: COMMUNICATION OF ADVERSE EVENT
DATE OF NOTE: FEB 1, 2010@00:00 **ENTRY DATE:** FEB 1, 2010@00:00
AUTHOR: XX **EXP COSIGNER:** XX
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Name and Title of Attending Physician making the disclosure:
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Name and Title of other VA employees witnessing the disclosure:
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List names and relationships of those present who are not listed above (including patient, designated surrogate and family or friends):
XX veteran patient, Mrs. XX wife, Mr. XX patient counsel
The patient consents to disclosure of private health information to those present.

DISCUSSION OF THE ADVERSE EVENT
A discussion of the adverse event was completed as follow-up to the discussion begun on xx/xx/xx and documented in the note titled "CLINICAL AND INSTITUTIONAL ADVERSE EVENTS REPORTING". The patient was advised again in person about the issues surrounding his endoscopic procedure. Molecular testing of HCV isolates from the patient and another patient whose procedure followed his was conducted by scientists at the Centers for Disease Control and Prevention in Atlanta, GA. These results, dated xx/xx/xx and scanned within the electronic record, and were reviewed with the patient. Per final results analysis, the degree of genetic relatedness between the two HCV isolates supports/does not support the possibility of infection transmission having occurred between the two patients.
He appeared to understand and accept the explanation of these results and had no questions. He has an appointment to see Dr. XX for follow-up of his HCV infection on 3-XX-2010.

CORRECTIVE ACTIONS TAKEN
List Actions
The process is still under investigation.

OFFER OF ASSISTANCE
Concern for the patient's welfare was expressed by the VA staff. The patient was advised that if further findings are made that we would advise him of them.
The patient/surrogate's concerns were noted and discussed. (List concerns)
The patient did not appear to have any concerns at the present time.
/es/ XX, XX, MD
STAFF PHYSICIAN,
Signed:

Attachment 17
Laboratory Report Template for Viral Genetic Fingerprint Testing

CPRS HCV Fingerprinting Laboratory Report

Hepatitis C Virus (HCV) Genetic Fingerprinting VistA/CPRS Report
Specimen: Serum
Accession: MOL-P 09 xxxx
Provider: Holodniy, Mark
Collected: December 1, 2010 1220
Report Released Date/Time: December 2,, 2010@1822

Similarity Score: XX%
This score indicates the relatedness of the patient's HCV E2 gene sequence to another patient's HCV E2 gene sequence.

Patient's HCV E2 gene Sequence Report

Patient XX Consensus Sequence*
_____E1_____ _____E2_____ VFAILLLVAGVDATTHTTGAQAGRATLGITDFFTVGPQQK The E1E2 AA sequence is shown from positions 372 to 412.

*The consensus sequence is a representative nucleotide or amino acid sequence in which each nucleotide or amino acid is the one which occurs most frequently in nature at that site in the different viral sequences in a given patient.

Evaluation: This test uses an in house assay developed by and performed at the Centers for Disease Control & Prevention (CDC), utilizing hepatitis C virus envelop 2 (E2) gene PCR and sequencing. The assay is intended for use in detecting HCV E2 genomic mutations that can aid in determining similarities and differences between different HCV viral strains. This test is intended for use only in documented HCV infections. Test results should not be used for the diagnosis or treatment of HCV infection. This test was developed and its performance characteristics determined by the CDC. It has not been cleared or approved by the U.S. Food and Drug Administration.

Attachment 18
Specimen Collection, Processing, and Shipping SOP

VA Look-back:
BLOOD BORNE VIRUS SPECIMEN COLLECTION, PROCESSING & SHIPPING

Specimen Tube Labels

The VA Public Health Strategic Health Care Group, Office of Public Health Surveillance & Research (OPHSR) will provide pre-printed labels for specimen identification. See examples below:

Vacutainer Tube

VAENDO
PPT Tube (pearl top)
Site: 640 Pt. ID: 00-01-101
Collection Date: _____
Collection Time: _____

Cryovial

VAENDO
Cryovial (R1)
Site: 640 Pt. ID: 00-01-101
Collection Date: _____
Collection Time: _____

*These labels will already be affixed to the vacutainer tube and cryovials, and include the site number and a coded patient number. Laboratory staff must fill in the date and actual time the sample is collected. Ensure that the label is appropriate for the visit day.

Specimen: BLOOD (to be spun to plasma)

Sample type: Blood Sample
Tube size: 5.0 ml
Tube Type: PPT Vacutainer (BD brand)
Stopper color: (Pearl Top Tube)

HCV RNA Specimen Collection

1. Verify that you have the correct tube for the HCV RNA by PCR (Pearl Top Tube) and that it is correctly labeled with the coded patient number, date, and time of draw.
2. Obtain 5 mL of intravenous blood in each of **2** PPT vacutainer tubes using the method below:
• Venipuncture technique: if possible, use either a vacutainer system to perform venipuncture (blood is collected from site directly into tube). If using a needle and syringe draw, take care transferring the blood from the draw syringe to the vacutainer tube. Use a larger bore needle to insert into vacutainer to prevent cell hemolysis. Do not pop the top off of the vacutainer to transfer the specimen.
3. Transfer specimen to lab immediately for processing. This specimen must be processed within 2 hours of collection.
4. Ensure the blood specimen is centrifuged within 30-60 minutes after drawing the sample. Place the sample on wet ice if a longer transfer period is required.

Blood Specimen Processing for HCV RNA (sequencing)

1. Spin the blood sample in an ambient temperature centrifuge at 3000RPM for 10 minutes.
2. Ensure that each of the five plasma aliquot cryo-storage tube labels is already labeled with the site and coded patient number.
3. Divide the plasma into five equal aliquots. Transfer 1.0 ml of the plasma into each of the five previously labeled plasma cryo-storage tubes using the provided sterile graduated transfer pipettes. Place and hand-tighten lids. Retain all of the plasma collected and use additional cryo-storage tubes as necessary.
4. Record the collection date and time on each of the cryovial labels.
5. Immediately transfer the plasma samples to a -80°C freezer. Each patient should have their samples held in their individual sample box provided by the OPHSR. The box will be labeled on the outside with the coded patient number.
6. Complete the sample tracking log (see appendix 1) and record the patient's name, SSN, station number, unique coded patient number, date of collection, and number of aliquots of plasma obtained. This sample tracking record **must** be retained at your VA Medical Center in a locked, secured area **(specify area at Medical Center).**

Plasma Specimen Storage

Plasma aliquots should be stored in a -80°C freezer. Each patient will have their own specimen storage box. Please store the samples segregated by patient in their specimen box until time for shipment. Batched specimens will be sent organized in the individual patient boxes. You will be given shipping instructions by OPHSR at the time of shipment regarding how many of the individual patient aliquots to ship at any one time. The first aliquot samples shipped will be transferred to the second storage box provided by OPHSR and shipped to the CDC lab in this second storage box.

Packing Plasma Specimens for Shipping - Diagnostic Specimens

A diagnostic specimen is any human or animal material being transported for research, diagnosis, investigational activities, disease treatment or prevention BUT excluding life infected animals. Those known or suspected of containing Category A pathogens must be shipped as infectious substances.

A. **Primary Receptacle/Packaging**

- Primary receptacle(s) must be water tight. Seal screw top containers with parafilm or something similar.
- Wrap multiple containers individually to prevent breakage.
- Primary containers cannot contain more than 1L (liquids) or 4 kg (solids).

Everything in the primary container, including transport media, is considered the diagnostic specimen.

B. Secondary Packaging (usually a plastic or metal cylinder and a cardboard box)

- Use enough absorbent material to absorb the entire contents of all primary containers in case of leakage or damage.
- Secondary packaging must meet IATA packaging requirements for diagnostic specimens including 1.2 meter (3.9 feet) drop test procedure.
- Secondary packaging must be watertight (liquids) or sift proof (solids). Follow the package manufacturer or other authorized party's packing instructions included with the secondary packaging.
- Secondary packaging must be at least 100 mm (4 inches) in the smallest overall external dimension.
- Must be large enough for all markings, labels, and shipping documents (e.g., air waybill).

C. Outer Packaging

- An overpack is used if the secondary packaging is not large enough for all the labels, markings, and documents OR if cold packs or dry ice is used.
- The outer packaging must not contain more than 4L or 4kg.
- Both dry ice and wet ice must be placed outside of the secondary packaging.

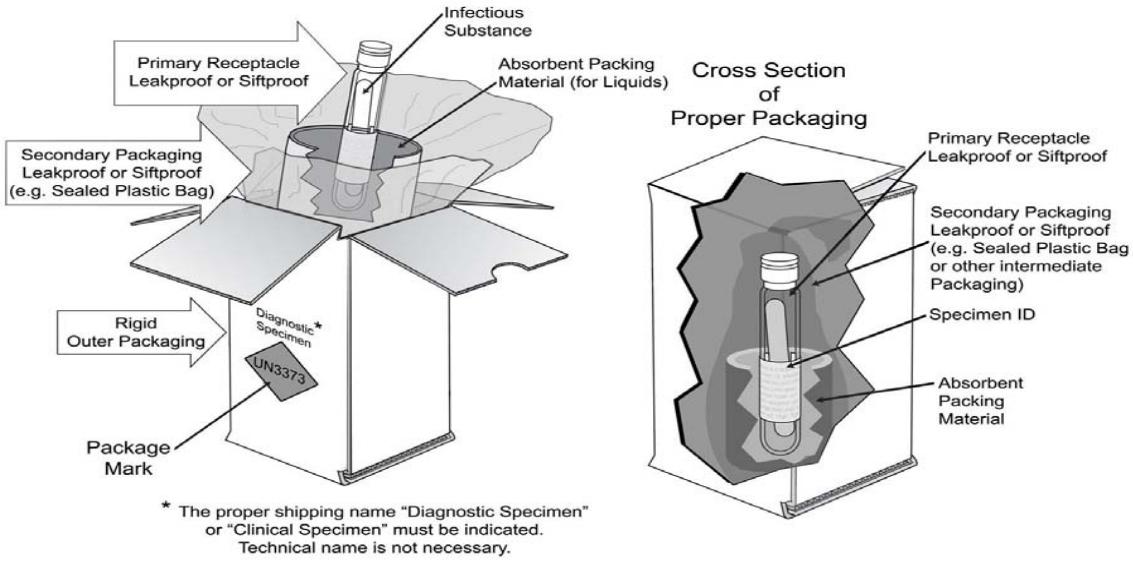
• Dry ice: packaging must permit the release of carbon dioxide gas and not allow a buildup of pressure that could rupture the packaging.
• Wet ice: the packaging must be leak-proof.
• Each package and the air waybill must be marked with the following text **(exact wording)**

DIAGNOSTIC SPECIMENS UN 3373

• An itemized list of contents must be enclosed between the secondary packaging and the outer packaging. Place in a sealed plastic bag to protect from moisture.
• If overpack is used, package must be marked "Overpack". All secondary package markings must be on the overpack.
• The name, address, and telephone number of the responsible person must be on the package and the air waybill.
• You must put the words "DIAGNOSTIC SPECIMENS" or "CLINICAL SPECIMENS" and "UN 3373" in the "Nature and Quantity of Goods" box on the air waybill.
• A Shippers Declaration for Dangerous Goods is NOT required – even if Dry ice is included

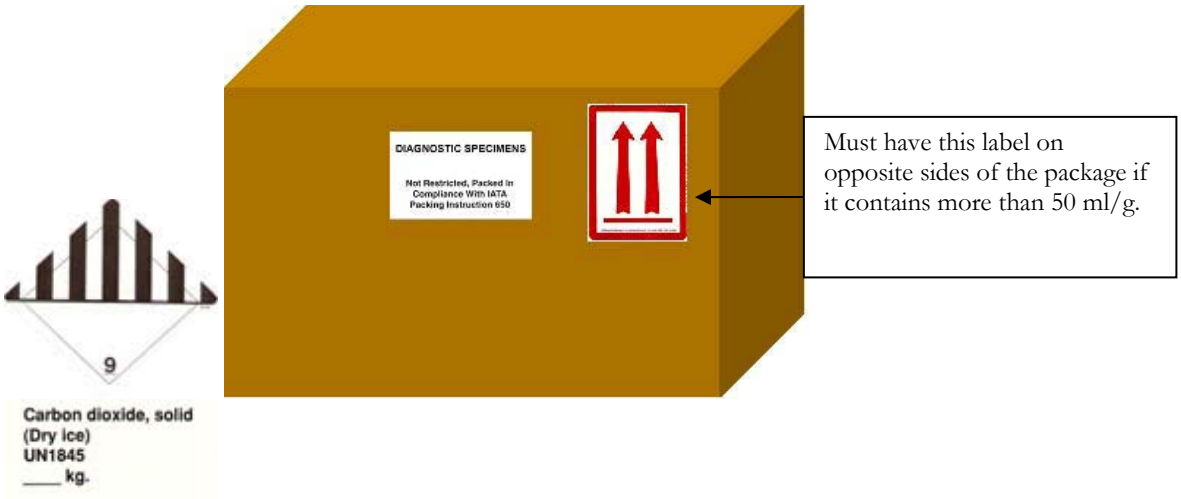
D. Packing and Labeling of Diagnostic Specimens

Packing and Labeling of Category B Infectious Substances



E. Example of outer packaging (overpack) for diagnostic specimens

Add this label and marking if your specimens are packed in dry ice.



Please ship plasma specimens <u>Monday through Wednesday ONLY</u>.

SHIP ON ADEQUATE AMOUNT OF DRY ICE

These specimens will be shipped directly to the CDC laboratory via Federal Express. **DO NOT send all aliquots from a particular patient in the same shipment.** Please send only **3** aliquots and retain **2** aliquots at your facility. Retained aliquots will be kept at your facility if additional aliquots are required for analysis by the CDC and/or if there is a shipping failure. These stored aliquots will be retained for an additional 3 months after all analyses are completed. Instructions to destroy and document destruction of these samples will be provided by OPHSR staff at that time.

The samples must be shipped on dry ice, in compliance with diagnostic specimen shipping regulations. Fill out a shipping manifest form (see attached appendix 2), make a copy of this form to be kept at the VA facility (to be retained with the sample tracking log as above), and an additional copy must be placed in the shipping box prior to closure. Use the shipping materials and follow the instructions provided to you by Federal Express. Should you have any questions regarding this process, call Federal Express Customer Service. They can help you with anything you may need. If all else fails, call the VA Office of Public Health Surveillance & Research.

Federal Express Customer Service: 1-800-463-3339 (24 hours, 7 days/week, 365 days/year)

Hepatitis Reference Laboratory Address:

TBD

SOP Appendix 1: Sample Tracking Record (To be retained at the VA Medical Center)

SPECIMEN COLLECTION & TRACKING RECORD

Please retain this form at your VA Medical Center. DO NOT SEND IN SHIPPING BOX

Check boxes to indicate number of aliquots made

Name	SSN	Station#	Subj. ID	Collection Date	Plasma Aliquots				
					1	2	3	4	5

SOP Appendix 2: Sample Shipping Manifest Form

Federal Express Tracking No:_____

SPECIMEN SHIPPING & TRACKING RECORD							
Please send along with Notification of Sample Shipment form. *Check box to indicate sample included in shipment*							
Subj. Station #	Subj. ID	Visit Date	Plasma Aliquots				
			1	2	3	4	5