SCREENING AND EVALUATION PROTOCOL FOR VETERANS WITH EMBEDDED FRAGMENTS WHO SERVED IN IRAQ AND/OR AFGHANISTAN POST-SEPTEMBER 11, 2001

1. REASON FOR ISSUE: This Veterans Health Administration (VHA) directive outlines the procedures for screening and clinical surveillance of Veterans with embedded fragments who served in Iraq and/or Afghanistan post September 11, 2001, and replaces VHA Directive 2010-029, Screening and Evaluation of Operation Enduring Freedom (OEF) and Operation Iraqi Freedom (OIF) Veterans with Embedded Fragments.

2. SUMMARY OF CONTENT: This VHA directive expands upon the prior directive (VHA Directive 2010-029) to discuss not only the screening process for identifying Veterans but also the protocol for conducting further clinical evaluation, including urine biomonitoring, fragment analyses, imaging and consultation.

3. RELATED ISSUES: None.

4. RESPONSIBLE OFFICE: The Chief Consultant, Post-Deployment Health Services (10P4Q), within the Office of Patient Care Services is responsible for the contents of this directive. Questions about Toxic Embedded Fragment Surveillance Center (TEFSC) examinations and results should be addressed to the Baltimore Depleted Uranium / TEFSC Program at 1-800-815-7533. General questions about protocol may be addressed to Post-Deployment Health Services at 202-461-1020.


6. RECERTIFICATION: This VHA directive is scheduled for recertification on or before the last working day of April 2022. This VHA directive will continue to serve as national VHA policy until it is recertified or rescinded.

Poonam Alaigh, M.D.
Acting Under Secretary for Health

DISTRIBUTION: Emailed to the VHA Publications Distribution List on April 11, 2017.
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PROTOCOL FOR TOXIC EMBEDDED FRAGMENTS SCREENING AND MONITORING ...........................................................................................................A-1
1. PURPOSE

This Veterans Health Administration (VHA) directive outlines the procedures for screening and surveillance of Veterans with embedded fragments, who served in Iraq and/or Afghanistan after September 11, 2001. 


2. BACKGROUND

a. One of the most common injuries from combat in Iraq and Afghanistan is traumatic injury from contact with improvised explosive devices (IED), which may result in wound contamination with toxic metals, plastics, and composite materials. Studies have shown that embedded fragments are not inert in the body and that material from the fragment can be slowly absorbed over time, having the potential to result in local and systemic adverse health effects. In 2009, the Department of Defense estimated that approximately 40,000 Service members who served in Iraq and Afghanistan may have embedded fragment wounds as the result of small arms fire or a blast or explosion caused by an IED, rocket propelled grenade (RPG), landmine, or grenade.

b. In 2007, the Presidential Task Force on Returning Global War of Terror Heroes recommended that VHA establish an embedded fragment surveillance center and registry to allow the Department of Veterans Affairs (VA) to identify and provide clinical surveillance to Veterans with retained fragments. In response, the Toxic Embedded Fragment Surveillance Center (TEFSC) and registry were established at the Baltimore VA Medical Center to follow Veterans nationwide. The TEFSC developed a screening tool to assist in identifying Iraq and Afghanistan Veterans who have embedded fragments, and a medical surveillance protocol for evaluation of those identified as having, or likely to have, embedded fragments.

3. DEFINITIONS

a. Embedded fragment. A piece of metal or other material, such as plastic, that stays in the body after an injury. Another common term used for this material is shrapnel.

b. Toxic embedded fragment. An embedded fragment that may be made out of a material that might be harmful.

4. POLICY

It is VHA policy that each VA medical facility must offer screening to all enrolled Veterans who served in Iraq and Afghanistan for embedded fragments and follow the TEFSC protocol for clinical surveillance. (See Appendix A.)
5. RESPONSIBILITIES

a. **Under Secretary for Health.** The Under Secretary for Health, or designee, is responsible for ensuring overall VHA compliance with this directive.

b. **Chief Consultant, VHA Central Office Post-Deployment Health Services.** The Chief Consultant, VHA Central Office Post-Deployment Health Services, has the responsibility to:

   1. Develop, coordinate, and monitor VHA activities relating to medical issues associated with service in Iraq and Afghanistan.

   2. Maintain separate listings of the Environmental Health Clinicians and Environmental Health Coordinators within Environmental Agents Service (EAS) and publish them on the internet and intranet Web sites at http://www.publichealth.va.gov/exposures/ and http://vawww.publichealth.va.gov/exposures/ respectively. **NOTE:** The second site is an internal VA Web site and is not available to the public.

c. **Director, Post-9/11 Era Environmental Health Program, Post-Deployment Health Services.** The Director, Post-9/11 Era Environmental Health Program, Post-Deployment Health Services, has programmatic oversight of the toxic embedded fragments screening program.

d. **Director, Baltimore VA Medical Center.** The Director of the Baltimore VA Medical Center is responsible for providing dedicated staff, space and other necessary resources for the operation of the Toxic Embedded Fragment Surveillance Center.

e. **VA Medical Facility Director.** Each VA medical facility Director, or designee, must:

   1. Ensure that local VA health care providers and other staff implement the policies and procedures required in this directive.

   2. Ensure that the Iraq and Afghanistan Post-Deployment Screen Clinical Reminder, Evaluation of Embedded Fragment Clinical Reminder, and Screen for Embedded Fragments Clinical Reminder are uploaded at the medical facility.

   3. Identify a person (or persons) responsible for completing the Evaluation of Embedded Fragment Clinical Reminder. This staff person may be a nurse, social worker, Transition and Care Management Program Manager or Case Manager Clinical Coordinator, Environmental Health Coordinator, mental health specialist, primary health care provider or an appropriate VHA staff person.

   4. Identify the person (or persons) who will serve as the point of contact for the TEFSC program.
f. **Director, Toxic Embedded Fragment Surveillance Center.** The TEFSC Director must ensure that TEFSC staff members:

(1) Arrange for the testing of urine and fragment samples submitted to the TEFSC program.

(2) Send, by letter, the urine biological monitoring results directly to the Veteran, with a copy to the VA referring health care provider.

(3) Develop and update as necessary the national Evaluation of Embedded Fragments Clinical Reminder and Screen for Embedded Fragments Clinical Reminder.

(4) Track and ensure urine and fragment analysis results are captured in the TEFSC registry.

(5) Develop medical and surgical guidelines for Veterans with embedded fragments.

(6) Provide consultation to the VA health care providers for complex cases involving embedded fragments.

(7) Provide in-patient evaluation at the Baltimore VA Medical Center, when necessary, for complex cases.

(8) Conduct population level surveillance for Veterans with embedded fragments.

(9) Provide periodic program reports to the VA medical facility Directors.

g. **Facility Staff Member Completing the Clinical Reminders.** The facility staff member completing the clinical reminders must:

(1) Complete the Evaluation of Embedded Fragments Clinical Reminder or Screen for Embedded Fragment Clinical Reminder, if activated within the Computerized Patient Record System (CPRS), by recording the Veteran’s responses to the questions and entering the name and phone number of the person identified as the point of contact for the facility if not already pre-populated.

(2) Inform the Veteran of the message that appears on the screen at the completion of the Clinical Reminder screen and of the Veteran’s inclusion in the registry.

h. **Facility Staff Member Serving as Point of Contact.** The facility staff member serving as point of contact must coordinate with appropriate facility staff in order to ensure that:

(1) Veterans receive information about the TEFSC program and registry.

(2) Fragment collection and urine biological monitoring kits obtained from the TEFSC program are properly distributed and collected.
(3) Instructions, which are included in the urine biological monitoring kits, are reviewed with each Veteran.

(4) Veterans with a disability that prevents them from being able to read, understand, and complete program forms or follow Urine Collection Instructions (e.g., those who are blind, visually impaired, cognitively impaired, etc.) receive assistance with understanding and completing the forms and following the collection protocol by consulting with mental health, blind rehabilitation specialists or other therapists/specialists in the medical center, or a Veteran’s caregiver. If the patient is judged to lack decision-making capacity to provide informed consent for the proposed protocol, the responsible practitioner must identify an appropriate surrogate decision maker according to VHA Handbook 1004.01, Informed Consent for Clinical Treatments and Procedures.

(5) Veterans (or a caregiver on the Veteran’s behalf) complete an exposure questionnaire and a VA staff member reviews for completeness.

(6) Fragments and urine specimen samples as well as the exposure questionnaire are returned to TEFSC per the instructions provided in the kits.

(7) Assist TEFSC staff in contacting the Veteran and the Veteran’s health care provider when needed.

i. **Primary Health Care Providers.** The Veteran’s primary health care provider must:

   (1) Review screening results and consult with TEFSC, as needed.

   (2) Discuss the TEFSC protocol, urine biomonitoring and fragment analyses, with identified Veterans who screen positive for embedded fragments and work with the Veteran to complete the protocol as warranted.

   (3) Encourage all Veterans who have or possibly have a retained fragment to receive ‘baseline’ imaging (x-rays) of body area(s) where fragment(s) is located or suspected for upload into the VA electronic medical record and assist TEFSC in obtaining a copy of the image when requested.

   (4) Review biological monitoring and fragment analysis results and recommended follow-up activities in letters received from TEFSC with the Veteran.

   (5) Ensure that TEFSC is contacted to obtain a fragment collection kit if a Veteran presents with a fragment that was spontaneously expelled or if a fragment is to be removed in surgery.
6. REFERENCES


1. SCREENING

   a. A national clinical reminder, the Iraq and Afghanistan Post-Deployment Screen Clinical Reminder, must be completed for all Iraq and Afghanistan Veterans who served after 9/11/2001. The Clinical Reminder includes a question that asks if the Veteran has or suspects they have retained fragments as a result of injuries received while serving in the area of conflict. The injuries can be the result of small arms fire or a blast or explosion by an improvised explosive device (IED), rocket propelled grenade (RPG), landmine, grenade, or enemy or friendly fire.

   b. If an embedded fragment is present or suspected as indicated by a “yes” response on the Iraq and Afghanistan Post-Deployment Screen, the Evaluation of Embedded Fragments Clinical Reminder will become active in Computerized Patient Record System (CPRS) and must be completed. This second clinical reminder should be completed by a health care provider or any Department of Veterans Affairs (VA) staff member deemed appropriate by the medical facility Director.

   c. The Evaluation of Embedded Fragments Clinical Reminder asks if the injury was from a bullet or from a blast or explosion. If the Veteran responds affirmatively to either question, subsequent questions ask if fragments and/or bullet(s) were removed during surgery, remain in the body, and/or were documented by radiograph.

   d. The Evaluation of Embedded Fragments Clinical Reminder also asks for the name, phone number, and email address of a facility staff member who will serve as the primary point of contact for the Toxic Embedded Fragment Surveillance Center (TEFSC). This individual shall be a facility staff person who can help coordinate the recommended follow-up activities and assist TEFSC in reaching the Veteran and contacting the Veteran’s primary health care provider. This staff person may be a nurse, social worker, Transition and Care Management Program Manager or Case Manager Clinical Coordinator, environmental health coordinator, mental health specialist, primary health care provider or any other individual the medical facility Director deems appropriate. NOTE: VA medical facilities may modify their clinical reminder configuration to pre-populate the local point of contact fields.

   e. Once the Evaluation of Embedded Fragments Clinical Reminder is complete, the individual completing the reminder will automatically receive a short message acknowledging the likelihood that the Veteran has a retained fragment along with contact information for the TEFSC. This message is entered as a progress note in CPRS. In addition, the data will be automatically captured in the Embedded Fragment Registry. The individual conducting the screening shall inform the Veteran of the message that appears on the screen and the Veteran’s inclusion in the registry.

   f. At the time of initial screening, a staff member completing the Evaluation of Embedded Fragments Clinical Reminder (if consistent with the staff member’s scope of
practice) may work with Veterans identified as highest risk to submit a urine sample. These activities are discussed in more detail in section 2 below.

g. TEFSC staff will routinely provide the VA medical facility point of contact the list of Veterans for which a urine collection is recommended and a sample letter that local facilities can use to inform Veterans of the Embedded Fragment Registry and services offered by the TEFSC. The point of contact shall coordinate with other local VA staff to inform Veterans of the available services and recommended follow-up which may include fragment analysis, biological monitoring (analyzing urine for concentrations of various metal and nonmetal components found in fragments), imaging and/or clinical consultation. **NOTE:** These activities are discussed in more detail in below, Sections 2-5.

h. If the Veteran has completed the Iraq and Afghanistan Post-Deployment Screen Clinical Reminder prior to the addition of the embedded fragment screening question, the Screen for Embedded Fragment Clinical Reminder will automatically become active in CPRS and shall be completed. This reminder contains the embedded fragment question included in the Iraq and Afghanistan Post-Deployment Screen Clinical Reminder and all information collected in the Evaluation of Embedded Fragments Clinical Reminder.

2. BIOLOGICAL MONITORING

a. If urine biological monitoring is recommended, urine collection kits provided by TEFSC must be used. VA medical facilities can request these kits in advance or for a specific Veteran. Kits will be mailed to the facility point of contact. The kit includes materials as well as instructions for the collection and return shipping of the urine specimen, on VA Form 10-0464b, TEFSC Urine Collection Instructions for the VA Medical Center. It also includes a brief exposure questionnaire to be completed by the Veteran (VA Form 10-0464, Toxic Embedded Fragment Surveillance Center Exposure Questionnaire). The local VA medical facility is responsible for ensuring that the Veteran receives the kit and understands how to collect the urine specimen according to the instructions provided. Veterans are instructed to return the specimen and questionnaire to their local facility. Veterans with a disability that prevents them from being able to read, understand, or follow the directions included in the forms may require assistance with completing the forms and following the protocol for collection. In these cases, local facility staff should consult mental health, Blind Rehabilitation Specialist, or other therapists/specialists in the medical facility, or a Veteran’s caregiver, to ensure that the forms and specimen collection can be completed appropriately. If the patient is judged to lack decision-making capacity to provide informed consent for the proposed protocol, the responsible practitioner must identify an appropriate surrogate decision maker according to VHA Handbook 1004.01, Informed Consent for Clinical Treatments and Procedures. The local facility shall send the specimen utilizing overnight delivery to the Baltimore VA Medical Center. Samples must be shipped in accordance with Department of Transportation (DOT) and International Air Transportation Association (IATA) regulations and instructions provided by TEFSC. The local VA medical facility must also notify the TEFSC of the
tracking number captured on the TEFSC checklist (VA Form 10-0464b). The local VA medical facility will securely fax a copy of the completed questionnaire and checklist to the TEFSC (410-605-7943).

b. The Baltimore VA Medical Center Laboratory will measure the creatinine concentration and then send the remainder of the specimen to a specified laboratory for additional analysis. This additional analysis will include testing the urine specimen for metals (i.e., aluminum, arsenic, cadmium, chromium, cobalt, copper, iron, manganese, molybdenum, nickel, lead, uranium, tungsten, and zinc) and other chemicals as appropriate based on fragment content data.

c. TEFSC staff will communicate the biological monitoring results directly to the Veteran by letter, with a copy to the Veteran’s VA health care provider for inclusion into the Veteran’s consolidated health record (CHR) and CPRS.

d. Follow-up actions for any Veteran with biological monitoring results outside the normal range will be individualized based on discussion between the Veteran’s VA health care provider and TEFSC staff.

e. Employees who handle filled urine collection kits shall use Universal Precautions in accordance with the Bloodborne Pathogens Standard (29 CFR 1910.1030) during any procedure where spillage of the specimen is possible.

3. FRAGMENT ANALYSIS

a. If a fragment is removed during surgery or if the Veteran presents with a fragment that was spontaneously expelled, a local VA staff member shall contact TEFSC to have the fragment chemically analyzed. TEFSC staff will arrange for a fragment collection kit to be sent to the Veteran’s local facility. The local facility will return the fragment to the TEFSC following DOT and IATA shipping regulations and instructions provided with the kit (VA Form 10-0464a, Toxic Embedded Fragment Surveillance Center Fragment Collection Form/Checklist). TEFSC staff will send the fragment to an appropriate laboratory for chemical analysis.

b. If a fragment is removed during surgery, it should immediately be placed into the specimen collection container. Any pathological specimen attached to the fragment should remain with the fragment. TEFSC will work with an appropriate laboratory to evaluate the tissue for pathology and other fragment-related changes.

c. If a fragment kit is not readily available, the fragment should be placed in a sterile specimen container with formalin until a fragment collection kit can be obtained from TEFSC. The formalin must cover the entire fragment.

d. TEFSC staff will communicate the fragment analysis results and tissue analysis results directly to the Veteran by letter, with a copy to the Veteran’s VA health care provider for inclusion into the Veteran’s CHR and CPRS.
e. Employees who handle spontaneously expelled or surgically removed fragments shall use Universal Precautions in accordance with the Bloodborne Pathogens Standard (29 CFR 1910.1030).

4. IMAGING

a. Based on a recommendation from TEFSC clinicians, local VA healthcare providers shall work with Veterans who have or possibly have a retained fragment to obtain images (x-rays) of body areas where fragment(s) are located or suspected. These images should be included in the VA electronic medical record to serve as a baseline as they will be very helpful for comparing future x-ray images to determine fragment related changes over time.

b. Local VA healthcare providers shall assist TEFSC staff in obtaining electronic copies of the images for review by the TEFSC staff as requested.

5. CLINICAL CONSULTATION

a. If clinical consultation is recommended by TEFSC staff or requested by the VA healthcare provider (contact TEFSC via 1-800-815-7533), TEFSC staff will arrange for a teleconference with the health care provider to discuss the case and determine if a telemedicine or inpatient evaluation is recommended. A preliminary clinical note describing the teleconference will be prepared by the TEFSC physician and a copy will be sent to the health care provider for inclusion into the Veteran’s CHR and CPRS.

b. If a telemedicine evaluation is indicated, TEFSC staff will make arrangements for the VA health care provider, TEFSC staff, and the Veteran to participate. Once completed, the TEFSC physician will prepare the clinical report, and a copy of the report will be sent to the Veteran and the VA health care provider for inclusion into the Veteran’s CHR and CPRS.

c. For complex cases, an inpatient evaluation may be recommended. If this is indicated, TEFSC staff will work with the Veteran and the Veteran’s VA health care provider to make arrangements for the Veteran to travel to the Baltimore VAMC where the clinical evaluation will be conducted by the TEFSC physicians. Once completed, a TEFSC physician will prepare the clinical report and a copy of the report will be sent to the Veteran and the Veteran’s VA health care provider for inclusion into the Veteran’s CHR and CPRS.