

# Chapter 26

## LESSONS LEARNED FROM SELF-SELECTED REGISTRIES (AGENT ORANGE)

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## INTRODUCTION

During the Vietnam War, the US military sprayed noncommercial herbicides, such as the phenoxy herbicide blend Agent Orange, to gain a tactical advantage by defoliating jungle that provided enemy cover. Veterans and others returning from Vietnam have attributed a wide range of illnesses to exposure to Agent Orange and

the dioxin it contained. In April 1970, Congress held the first of many hearings on herbicide health effects. In 1978, the US Department of Veterans Affairs (VA) created the Agent Orange Registry for Vietnam veterans who were concerned about possible adverse health effects from exposure.

## HISTORY OF THE AGENT ORANGE REGISTRY

Agent Orange is the main “tactical” (noncommercial) herbicide the US Air Force sprayed as part of Operation Ranch Hand (1962–1971) during the Vietnam War to destroy food crops and enemy cover.<sup>1,2</sup> Although a number of different herbicides blends were used, Agent Orange comprised the majority. Agent Orange got its name from the color of the stripe on its storage drum. Its active ingredients were a 50:50 mixture of two phenoxy herbicides: 2,4-dichlorophenoxyacetic acid and 2,4,5-trichlorophenoxyacetic acid. Both were common weed killers during the 1950s–1970s, and 2,4-dichlorophenoxyacetic acid is still in use today. The US Department of Defense (DoD) suspended Operation Ranch Hand in early 1971 after Agent Orange was found to be contaminated with 2,3,7,8-tetrachlorodibenzo-*p*-dioxin (TCDD), an unintentional dioxin byproduct of the manufacturing process. Evidence emerged that dioxin caused birth defects in laboratory mice.<sup>3</sup> Returning Vietnam veterans and others have attributed a wide range of illnesses, including birth defects among their children, to exposure to Agent Orange and the dioxin it contained. In April 1970, Congress held the first of many hearings on herbicide health effects. In 1978, the VA created the Agent Orange Registry for Vietnam veterans who were concerned about possible adverse health effects from exposure to Agent Orange during the war. According to Han Kang, PhD (former Director of the Environmental Epidemiology Service, Washington, DC), the VA also initiated this registry as a means to increase access for Vietnam veterans to the VA healthcare system.

In 1994, the Institute of Medicine (IOM) issued its first report titled *Veterans and Agent Orange: Health Effects of Herbicides Used in Vietnam*. This report reviewed the scientific and medical literature regarding the health effects of exposure to Agent Orange and other herbicides used in Vietnam. Reports have been completed every 2 years hence, and the most current update was released on December 3, 2013 (titled *Veterans and Agent Orange: Update 2012*).<sup>4</sup> The VA also asked IOM to determine the level of association between specific health outcomes and exposure to herbicides, including the TCDD contaminant in Agent Orange. Many of the studies reviewed by IOM looked at Agent Orange or its

components because it constituted the majority of what was sprayed in Vietnam; the science linking TCDD to adverse health outcomes is well known. The IOM also reviewed the chemicals in herbicides other than Agent Orange, including picloram (Agent White) and cacodylic acid (Agent Blue). Cacodylic acid contains an organic form of arsenic that is a known carcinogen (based on animal studies). The variation in tumor formation caused by arsenic among different animal species is thought to be strongly influenced by genetic differences. The 1994 report identified five diseases with sufficient evidence of an association between the disease and exposure to herbicides or TCDD:

1. chloracne,
2. Hodgkin's disease,
3. non-Hodgkin's lymphoma,
4. porphyria cutanea tarda, and
5. soft-tissue sarcoma.

The report also identified three diseases with limited or suggestive evidence:

1. multiple myeloma,
2. prostate cancer, and
3. respiratory cancers.

When the 2008 update was published, an additional seven diseases or conditions were added to the category of limited/suggestive evidence:

1. amyloid light-chain amyloidosis,
2. chronic B-cell leukemia,
3. hypertension,
4. ischemic heart disease,
5. Parkinson's disease,
6. peripheral neuropathy, and
7. type 2 diabetes mellitus.

Reliable measures of Agent Orange exposure are not available. The VA defined any veteran as “exposed” for the

purpose of VA healthcare benefits and disability compensation if they served any length of time in Vietnam.

The Secretary of the VA considers the IOM's findings when determining which health conditions will be presumed as related to Agent Orange exposure ("presumptive" diseases) for the purpose of disability compensation. As of December 22, 2012, the VA considers the following 14 diseases as presumptive for being linked to Agent Orange exposure<sup>1</sup>:

1. amyloid light-chain amyloidosis,
2. chloracne,
3. chronic B-cell leukemias,
4. early-onset peripheral neuropathy,
5. Hodgkin's disease,
6. ischemic heart disease,
7. multiple myeloma,
8. non-Hodgkin's lymphoma,
9. Parkinson's disease,
10. porphyria cutanea tarda,
11. prostate cancer,
12. respiratory cancers,
13. soft-tissue sarcomas, and
14. type 2 diabetes mellitus.

## AGENT ORANGE REGISTRY PROGRAM AND ELIGIBILITY

The program offers a medical evaluation available at most VA healthcare facilities. The registry examination provides an opportunity for veterans to obtain a physical examination, discuss their exposure concerns with a knowledgeable healthcare provider, ask questions, and learn about benefits for which they may be eligible.

The Agent Orange Registry is a computerized record of these examinations. Clinicians performing the registry examination follow a comprehensive protocol described in the *Veterans Health Administration Handbook 1302.01*.<sup>5</sup>

Regarding eligibility, any veteran—male or female—who had active military service in the Republic of Vietnam between 1962 and 1975, and who expresses a concern relating to exposure to herbicides may participate in the registry and receive a free examination. Eligible veterans who want to participate in this program are instructed to contact their nearest VA medical facility for an appoint-

ment. There is no minimum period of service in Vietnam. Initially, veterans who did not serve in Vietnam were not eligible for the Agent Orange Registry Health Examination even if they could have been exposed to herbicides elsewhere during military service. Beginning in early 2011, veterans who served along the Korean Demilitarized Zone between 1968 and 1971 are also eligible. Additional groups of veterans who are eligible include those who served in certain units in Thailand, and those who were involved in the testing, transporting, or spraying of herbicides for military purposes. Although children of Vietnam or Korean Demilitarized Zone veterans with spina bifida are eligible for certain VA benefits because of an association with herbicide exposure, spouses of veterans are not eligible for this examination. Veterans do not need to enroll in VA healthcare to receive a registry examination because the examination is free.

## AGENT ORANGE REGISTRY HEALTH EXAMINATION

Data collection begins prior to the examination with veteran demographics and other information recorded on an Agent Orange Registry Health Examination worksheet. The veteran is encouraged to share concerns about his/her exposures during the examination. Educational materials, such as the most current *Agent Orange Review Newsletter*, are provided. In general, the examining clinician evaluates each veteran's military history and other relevant exposure history, signs, and symptoms. Then, an appropriate examination is performed. In the past, baseline laboratory tests were recommended, but this is no longer the case. There are no specific diagnostic tests or treatments generally recommended specifically for Vietnam veterans or others who served in areas where military herbicides were used. Guidance for clinicians regarding the physical examination is to focus on systems that have been found to have an as-

sociation with herbicide or TCDD exposure (which may include the skin, lymph nodes, respiratory system, cardiovascular system, hematological system, bone, endocrine, peripheral nerves, and prostate). The examination is documented in the VA's electronic health record (Computerized Patient Record System; CPRS). Worksheet data are entered in a separate online database that is not connected to the medical record. Longstanding VA policy requires that this information be provided to the veteran in a face-to-face discussion with the clinician and that a follow-up letter summarizing the results of the registry examination be mailed to the veteran within 2 weeks. If health problems are detected during the examination, veterans are encouraged to enroll for VA healthcare if they have not already done so or to follow-up with their private provider. Veterans may receive a follow-up evaluation if necessary.

## VETERANS AFFAIRS ENVIRONMENTAL HEALTH CLINICIANS AND COORDINATORS

Each VA medical center has an assigned Environmental Health Clinician who is responsible for the conduct of Agent Orange Registry Health Examinations (as well as for other special registry and deployment-related environmental and occupational health issues). Each VA medical center

also has an Environmental Health Coordinator who is responsible for coordinating Agent Orange Registry Health Examinations (ie, scheduling appointments, providing educational materials, collecting nonclinical data, ensuring that follow-up letters are completed, and managing data entry).

## AGENT ORANGE REGISTRY DATA

The Agent Orange Registry program is not a research program. Because of the self-selected nature of the veterans who present for the voluntary examination program, as well as the lack of any controls, the registry is no substitute for a properly designed epidemiological study. However, data from the Agent Orange Registry database can be helpful to track patterns of veterans

completing these examinations. The registry can also be utilized to answer queries about the number of veterans who reported exposure outside of Vietnam or other data of interest. Even if all of the veterans completing registry examinations were not exposed to military herbicides, the database can serve as a list of veterans who have concerns about exposure.

## VETERANS' UTILIZATION OF THE AGENT ORANGE REGISTRY HEALTH EXAMINATION

Table 26-1 shows the number of veterans who received Agent Orange Registry Health Examinations since the program started in 1978. As of September 30, 2012, a total of 573,088 veterans have completed an evaluation.<sup>6</sup> Assuming there were approximately 2.7 million Vietnam veterans, this means that about 21% have had an Agent Orange registry evaluation.<sup>7</sup>

It is important to note that even though the program is more than 3 decades old, many veterans are still contacting the VA each week for their initial Agent Orange Registry Health Examination. A query of registry data through early 2012 showed that approximately 98% of the registry participants identified their exposure location as Vietnam. Exposure data are based on self-reports from veterans and have not been verified by the DoD Manpower Data Center (Washington, DC) or the National Personnel Records Center (St Louis, MO). A number

**TABLE 26-1**  
**AGENT ORANGE REGISTRY EVALUATIONS**  
**(SEPTEMBER 30, 2013)**

Evaluations	No.
Initial	573,088
Follow-up	65,758
<b>Total (Initial + Follow-up)</b>	<b>638,846</b>

of the registry participants identified sites that had not been identified by the DoD as a location where Agent Orange was sprayed, tested, or stored (eg, Okinawa, Guam, and Alabama).

## OUTREACH TO VETERANS

Participation in the Agent Orange Registry offers an opportunity for the veteran to discuss his/her exposure concerns and provide information about research studies, VA healthcare, and other benefits. Veterans who complete an Agent Orange Registry Health Examination are automatically added to the mailing list for the *Agent Orange Review*, a hard-copy newsletter with updates on IOM studies and other

research and veteran benefits. Recipients are encouraged to share information in the newsletter with other veterans.

The VA also provides newsletters to all of its healthcare facilities and veterans centers for distribution to veterans and the VA staff. The VA Office of Public Health posts current and archived *Agent Orange Review* newsletters on its website.<sup>8</sup>

## LESSONS LEARNED

Numerous limitations have been identified for the Agent Orange Registry. A key one is that as a self-registry, veterans report exposure to Agent Orange without verification that they meet eligibility criteria for having served in an area that DoD identified as a location where Agent Orange was sprayed, stored, or tested. For veterans who do not receive care through the VA healthcare system, it may not be possible for the clinician performing the examination to validate the symptoms or diagnoses that veterans report.

Not all veterans potentially exposed to Agent Orange are aware of the registry. The VA has estimates for the number of veterans who served in Vietnam, but does not possess a master list of all veterans who were potentially exposed. Therefore, the VA relies on veterans to self-identify.

An ongoing area of substantial confusion for veterans is that the registry examination is not a Compensation and Pension Examination for disability compensation. Some veterans mistakenly believe that completing a registry examination will initiate a disability claim, provide medical treatment, or open the door to other benefits.

For the VA staff, Agent Orange Registry Health Examinations can be quite burdensome. Multiple steps are involved in the registry examination process and require two staff members to complete the following:

- scheduling the examination and collecting information via the worksheet prior to it (usually done by the Environmental Health Coordinator);
- documenting medical information on the worksheet during the examination, as well as entering the physical examination into CPRS (usually done by the Environmental Health Clinician); and
- entering worksheet data into the registry database, which is separate from CPRS and requires a username and password, and issuing the follow-up letter (both tasks are usually done by the Environmental Health Coordinator).

Training of Environmental Health Coordinators and Environmental Health Clinicians on the registry process may vary from facility to facility. Often, these staff have multiple, varied responsibilities, and the clinicians and coordinators are not always co-located in the same facility. Environmental Health Coordinators may lack understanding about eligibility criteria and scheduling guidelines. Some facilities have long waits (greater than the recommended 30 days) for registry appointments. For clinicians, a number of facilities have created a built-

in Agent Orange Registry template to help guide them through the examination, whereas others may record the examination on a generic physical examination paper form to scan into CPRS later.

Delays of data entry and omission may occur for several reasons. First, registry staff often shoulder a variety of responsibilities and thus may have competing time priorities. Second, the dual-data entry that is necessary because of the database being separate from the electronic health record means that some veterans' data may get entered incompletely, late, or not at all. The VA staff may also not understand the importance of entering the data (eg, that the database is used to monitor trends). Examples include providing newsletters with Agent Orange updates to veterans and being a source of information for responding to congressional or veterans service organization inquiries regarding veterans characteristics in the database. The only way to identify a discrepancy between registry examinations conducted and entries in the registry database would be through a manual process.

The quality, consistency, and usability of registry data are limited by many factors. Quality is limited by the unverified self-reported data. A substantial barrier to consistency exists because many of the data fields take free-form text versus categorical data, which also limits their use for epidemiological studies.

Timeliness is another issue. The lag time between herbicide exposure and completion of the registry examination is 7 years at the least and more than 30 years for veterans currently pursuing a registry examination. Decrements in recall, lack of exposure data, and the unavailability of electronic service records during most of the Vietnam War era limit the validity of information entered into the registry database.

The utility of any database depends on the quality and completeness of the data being entered. As previously described, the Agent Orange Registry has substantial challenges in both regards, restricting meaningful analyses. The ability to evaluate and draw conclusions from the registry is also made more difficult because of the immense size of the database (with over half a million veterans and counting), and many data fields accepting open-ended responses. User-friendly procedures and data entry are important. Less is often more, meaning that the more data requested, the greater the workload and a higher likelihood for incomplete or missing data.

Integration of the Agent Orange Registry Health Examination into the VA's electronic health record would have several advantages to the current system; it could

assist eligibility determination, verify self-reported data for veterans who receive their healthcare through the VA, and eliminate the need for dual-data entry. This in turn would improve data timeliness, quality, and consistency. Incorporation into the electronic health record also opens the door for clinicians or other VA staff to run their own data queries on veterans who have completed registry examinations, which enhances the meaningfulness of capturing the data. Having procedures for registry examinations that are different from other examinations steepens the learning curve, impairs clinical workflow,

diminishes the ability to identify VA-wide best practices, and makes it more difficult for facilities to adopt them.

The VA will explore integration of registry examinations and data into the electronic health record as resources become available. Another area that could be investigated would be an evaluation of the health benefits and any harm for veterans who receive Agent Orange Registry Health Examinations. The VA has not conducted such an assessment to date, but it would be important to consider before embarking on changes to the current registry process.

## SUMMARY

The VA initiated the Agent Orange Registry Health Examination program to respond to veterans' health concerns about possible exposure to Agent Orange and to improve the access of Vietnam veterans to the VA services. More than 30 years later, the registry program is still active, and the number of veterans completing registry examinations continues to grow. The main limitations of the Agent Orange Registry from a research perspective are that veterans self-select to participate, and exposure and health data are not confirmed.

The Agent Orange Registry benefits veterans by providing a free evaluation that includes a physical examination, discussion of their exposure concerns with a clinician, and a means for outreach to these veterans by providing updates about relevant health studies and veteran benefits. Integration into the electronic health record could streamline the registry examination process for veterans, improve morale and productivity for clinic staff, increase the quality of examinations, and yield usable data for researchers.

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