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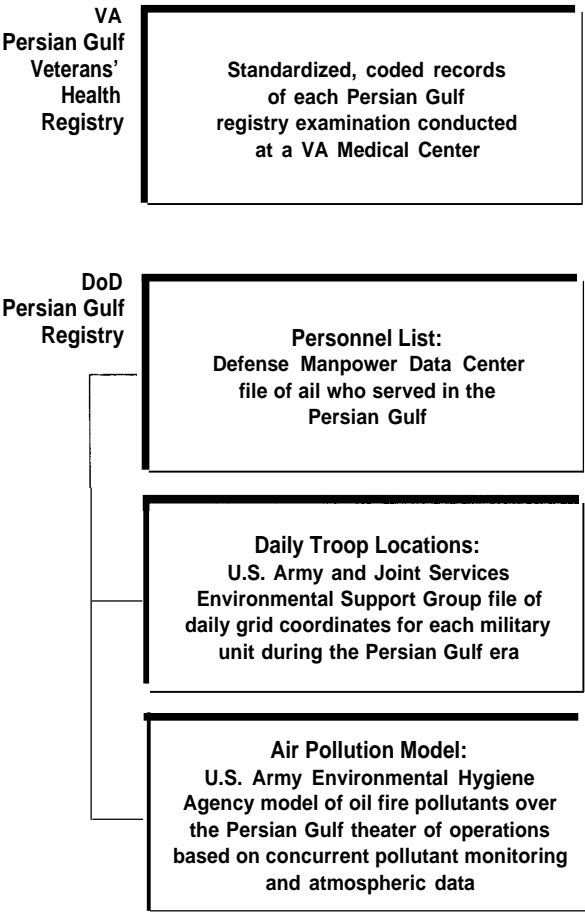
Summary

When Congress directed the U.S. Department of Veterans Affairs (VA) to create a registry for health examinations of Persian Gulf veterans, the greatest potential hazard appeared to be smoke pouring from hundreds of oil wells that had been set on fire by the Iraqis. The U.S. Department of Defense (DoD) list of Desert Storm/Desert Shield participants and the locations of their units in relation to oil fire smoke--the other piece to this registry complex (see figure) --also was driven singularly by concern about the effect of the fires on veterans' health, not only in the short run, but for years afterward. In addition to its role in providing comprehensive medical examinations to concerned Persian Gulf veterans, the VA registry was conceived as a means to identify "sentinel" conditions possibly consequent to Persian Gulf service. Because the registry 'comprises veterans who either have health problems or are particularly concerned about their health--not a representative sample of veterans--analyses of the registry data cannot, themselves, provide clear evidence of a link between Persian Gulf exposures and any specific medical condition. But conditions seen in registry participants could provoke suspicion of a link, which could then be investigated in a formal epidemiologic study.

The law mandating creation of the VA registry also mandated this Office of Technology Assessment (OTA) assessment and, in the long term, set up an arrangement for review of the registry data by the Institute of Medicine's Medical Follow-Up Agency (MFUA). It is MFUA that will have the difficult task of recommending when in-depth studies should be considered.

Once completed, the registry complex may be used in various ways to consider possible health damage from the oil fire smoke. DoD will be able to answer questions from individual veterans about their level of exposure using daily company locations and modeled data on air pollutants. The DoD registry also could be used to identify cohorts of individuals with relatively high and relatively low exposure to oil fire pollutants, should it be desirable to do so for the purposes of an in-depth study. The emphasis on oil fires as the exposure around which the registries are constructed, however, means that they will be much less useful for exploring other potential hazards, except those with known geographic

FIGURE: The Persian Gulf Registry “Complex”



distributions or those that may be unique to certain units or military occupations.

The limitation of the registries, which have been conceived in accordance with congressional mandates, are worth noting. In the VA registry, only relatively rare or unusual conditions, or more common conditions occurring at extremely high rates, will stand out against background rates. In-depth studies of factors other than oil fire smoke, other strictly geographic variables, or possibly those associated with military occupations, will not be facilitated by the DoD registry. Information on exposures other than oil fires would have to be collected on an ad hoc basis, and may not be possible to document. Already, concerns about inoculations, depleted uranium, vehicle paint, diesel fumes, and chemical warfare agents, to name a few, have surfaced. Whether or not these represent real threats, they must, at the very least, be acknowledged and considered for further evaluation. It should be stressed that data from the VA registry can provide only descriptive information about that self-selected population. While the registry population can and should be compared with a similar group not enrolled in the registry, that comparison cannot tell us about a relationship between serving in the Persian Gulf and the occurrence of health conditions.

Some near-term activities that could improve the quality and overall utility of the VA registry are discussed in the body of this background paper and include:

- VA making changes in the collection of medical history and exposure information for the Persian Gulf War Veterans Health Registry;
- VA and DoD standardizing terminology used in their respective registries;
- supplementing the existing coordination and cooperation between DoD and VA to enhance compatibility of the registries by appointing a single Advisory Board to oversee both activities;
- DoD assembling qualitative information about the Persian Gulf conflict, including the distribution of other "exposures" and the specific activities of military units; and

DoD and VA each cataloging and describing other health-related information available for Persian Gulf veterans from before, during, and after their tours of duty.

OTA'S MANDATE TO ASSESS THE PERSIAN GULF REGISTRIES

OTA's mandate for this report comes from Public Law 102-585, which charged the Director of OTA with assessing "the potential utility" of the DoD and VA registries for "scientific study and assessment of the intermediate and long-term health consequences of military service in the Persian Gulf;" the extent to which the registries meet the requirements of the law; the extent to which the data are being collected and stored appropriately; how useful they would be for scientific studies; and related operational questions. The law calls for separate OTA reports on the VA and DoD registries.

This first report focuses on the VA "Persian Gulf War Veterans Health Registry," which is referred to here as the "examination registry." The second report, due in February 1994, will report on DoD's "Persian Gulf Registry," which is actually the combination of three unique pieces: 1) a list of all individuals who served in the Persian Gulf, 2) daily locations for each unit (probably at the company level) during the Persian Gulf era, and 3) daily oil fire smoke pollutant levels modeled for the Persian Gulf theater of operations during the period when the wells were burning. The registries have distinct and separate functions, but they also must be compatible so that information from the personnel registry can be retrieved easily for individuals in the VA registry. For this reason, we refer to the VA and DoD activities together as a "registry complex." The interrelated nature of VA's and DoD's work necessitated OTA beginning to examine DoD's efforts in order to evaluate VA's registry properly. The result is that some of the conclusions in this report apply both to DoD and VA, and some to DoD alone. The second report may also refer back to VA activities.

A small group of experts in epidemiology, statistics, medicine, and toxicology assisted OTA with this evaluation at a July 29, 1993 workshop. The Institute of Medicine (IOM) also was represented by the

Director and staff members of Medical Follow-up Agency (MFUA) and a consultant statistician. The morning consisted of presentations from the DoD and VA offices engaged in registry activities. DoD also briefed the group on several studies bearing on Persian Gulf veterans' health that they have been carrying out, which have already produced useful information and which should continue to do so. The workshop participant list is attached as Appendix B.

CURRENT STATUS OF THE VA EXAMINATION REGISTRY

VA began offering a Persian Gulf medical examination in early 1993, consisting of a brief medical history, some questions about exposure to oil fire smoke in the Persian Gulf, a complete physical and general laboratory tests and optional special tests (e.g., for lung function) and referrals. The examination is available at all VA medical centers. Two physicians at each center, the designated "environmental physician" and specified alternate, are charged with conducting the examinations. Three referral centers have been established, in Washington, DC, Houston, and West Los Angeles, for cases not diagnosable at the local centers. The Houston site has a special focus on multiple chemical sensitivity, and leishmaniasis cases are being seen in Washington, DC.

Examination results are recorded in the veteran's medical record and selected information is entered on a 2-page registry form that is sent by the VA medical center at which the examination takes place directly to a central processing center in Texas where the data are keyed into the registry file. The VA reports that this basic arrangement is similar to the agent orange and ionizing radiation registries.

Early on, the VA developed an addendum to the examination to elicit a more detailed medical history, mental status, history of exposures and experiences in the Persian Gulf, and various other pieces of information. The ad-

dendum is being administered to only a sample of veterans in a pilot trial. The VA intends to assess the usefulness of the addendum with the help of an existing "blue ribbon panel" or a successor to it, a permanent advisory committee that has not yet been appointed.

As of June 30, 1993, about 8,000 Persian Gulf examinations had been conducted and about 6,000 had been recorded in the electronic database.

VA has encouraged Persian Gulf veterans to take advantage of the examination in a number of ways. Posters have been placed in all VA medical centers, mobile displays have been sent to various places, the veterans' service organizations have been notified, and a Persian Gulf newsletter has been produced. Letters have been sent to all veterans or their survivors who have been compensated for Persian Gulf-related problems, notifying them of their eligibility for the registry (presumably, the existing medical records for these individuals would be used in place of a new examination). VA workers have been instructed to offer the special examination to Persian Gulf veterans who come to medical centers for treatment or other services. Information on Persian Gulf veterans can be included in the registry only with their consent, however (except for deceased veterans, who may be included without consent of their next-of-kin, according to VA).

COMMENTS ON THE VA REGISTRY EXAMINATION PROTOCOL

An important function of the VA examination is to provide veterans with a comprehensive medical checkup and to investigate particular complaints. The protocol in use seems to fulfill this need. However, striking the right balance for collecting information that will be useful as a surveillance tool over the long

term is more difficult. A useful guidepost for deciding about what to include or exclude is the desire to keep the registry simple and avoid collecting data that are not justifiable given the limitations of the sample. Information related to health status should be collected as precisely as possible, but effort collecting information on exposures, for which no control group is available, would be wasted.

Some specific problems related to the examination protocol and the coding sheets, particularly for their surveillance value, are identified in Appendix A of this report. This section discusses general concerns with these items.

Medical and Personal History

The current protocol is somewhat weak on medical and personal history, which is covered in great detail in the addendum. The addition of some history questions is justified (e.g., smoking history and civilian occupational history), but there may be too many in the addendum. Resolution of this issue requires a vision of what the information will be used for, beyond any immediate use in dealing with the veteran's medical problems. Even if it may be of immediate use, it may not be of long-term value, so may not need to be a permanent part of the registry (presumably, much more information is generated during the examination and recorded on the medical record than is actually coded).

Health Status Information

The value of the registry to detect sentinel health conditions depends entirely on the medical information captured in the system, but the coding form places strict limits on how much of this information will enter the registry. There is room to write in and code only three complaints and three diagnoses. Even a simple recording of the number of complaints a veteran has is limited to five (an entry of "5" denotes five or more complaints). People reporting with what

has been termed the "mystery illness" may have more than five complaints, and this information would be lost. Nor are there instructions in the Coding Manual to guide a physician about how to choose which three complaints to write out. VA should consider making sure that all relevant medical status information is captured in the registry and that the amount of this important information is not limited arbitrarily (i.e., all complaints and diagnoses should be written out and coded). The basic form need not be made unduly long if a form can be added for people with many complaints. Losing this information is not acceptable.

Exposure Information

An attempt is made in the current examination protocol to collect information about exposure to oil fires using six questions (e.g., "I was enveloped in smoke," and "I ate food or drink that could have been contaminated by oil or smoke"). Answers are graded from "definitely yes" to "definitely no." A number of questions about other experiences and exposures during Desert Shield/Desert Storm service are in the addendum. Other than asking veterans what they think might be the cause of their conditions, and possibly what other exposures or experiences in the Gulf are worrisome, there is reason to question whether any of this self-reported exposure information will prove to be of value. Unless it can be justified in terms of potential surveillance use, VA should consider dropping it and limiting any other exposure questions from the addendum. If these questions are kept, the wording should be

reviewed for clarity (e.g., a veteran might answer "yes" if he or she was heavily exposed to passive cigarette smoke),

Standardization

Given that this examination is being offered at all 171 VA medical centers around the country, a general concern is the problem of standardization. VA does provide training for environmental physicians using the protocol, but the written instructions may not be sufficient to ensure an understanding of what is expected. The examples described above related to medical status (no instruction on how to select which complaints and diagnoses to code) and exposure (no instruction on how to elicit why the veteran thinks he or she might be ill) illustrate the potential problems that might arise if physicians at different centers are inclined to make different choices.

Protocol Revision Process

VA has indicated that it will seek the advice of an advisory group to evaluate the addendum and agree on a final protocol. This would be a very useful approach. The advisory group must be chosen carefully for this particular task, however, including sufficient medical and epidemiologic expertise to evaluate each item critically, both in terms of the validity of the question and of the potential value of the information collected. Information on exposures and the various psychological questions on the addendum are of particular concern. The issue of standardization among centers also should be considered. As discussed in the section below concerning coordination between VA and DoD, it is important that each item, particularly those relating to military experience and demographics, be reviewed with DoD input for consistency with the data in their personnel registry. A decision also must be made about whether to go back to those veterans (either in person or by mail or telephone) who already have been examined to seek additional information.

¹The "mystery illness" denotes a variable group of symptoms reported by members of the 123rd Army Reserve Command after their return from the Persian Gulf. The "outbreak" was investigated thoroughly by the Walter Reed Army Institute of Research and reported on in a June 15, 1992 report.

STRENGTHS AND LIMITATIONS OF THE REGISTRY COMPLEX

Strengths

One factor that distinguishes this registry from others that rely on self-referrals is that the reference population--all Persian Gulf veterans--is known. A Defense Manpower Data Center (DMDC) electronic file lists all those who served in the Gulf, including reservists and those still on active duty, and contains a set of demographic and military information about each. It should be possible to compare the registry population with a sample (or possibly the entire) population from the DMDC file to find out how different or similar they are. This could be useful to MFUA in its judgments about the medical conditions reported.

Limitations

While the registry complex can serve a useful purpose, the limits of what can be achieved are substantial. First and foremost, it cannot be used to determine cause-and-effect relationships. It never will be possible using the registry to say that any particular condition is caused by a particular exposure or event that happened in the Persian Gulf. At best, it will play the role of case reports in medicine, alerting VA and MFUA that veterans believe they may be suffering effects of Persian Gulf service. It is probably safe to say that for many conditions, no suggestive link will be found. For others, a decision will have to be made whether to pursue a potential link through focused epidemiologic studies, considering both the strength of the suspicion and the feasibility of acquiring the necessary exposure information.

People reporting to the registry will not be representative of the population of Gulf veterans, a point of which Congress was aware when it mandated creation of the registry. Veterans presenting for the examination are either suffering from a condition or concerned for other reasons about their health. This much is obvious. But it should also be pointed out,

based on experience with other registries, that the makeup of the registry population may well be influenced by external factors, including stories in the news about particular problems being experienced by veterans. So even what appears to be an unusual number of cases (in proportion to the total registry population) with a particular diagnosis or symptom may not represent an excess in the veteran population as a whole. A question on the registry form asking what prompted the veteran to seek an examination might be helpful in understanding the distribution of conditions reported. The difficult task is sorting out the conditions that may actually be linked to Persian Gulf service from the unlikely ones.

CONCERNS ABOUT COORDINATION OF VA AND DOD ACTIVITIES

Coordination between VA and DoD is taking place, but it may not be sufficient to ensure that, at a practical level, the registry complex can be most effective. Coordination activities should take place among the people responsible for the tasks involved, but a joint VA/DoD permanent oversight group with responsibility for both registries may also be needed.

Three main areas could benefit from increased coordination: 1) ensuring that both veterans and those on active duty have the opportunity to enter the registry; 2) ensuring consistency in the personal identifying information in the two registries so that they can be linked easily; and 3) ensuring consistency of data elements between the two systems where appropriate and eliminating redundant information from the VA registry. These three topics are discussed briefly below.

According to the law, active duty military personnel who served in the Persian Gulf should have the option of entry into the registry. Thus far, very few individuals on active duty have been included, and this lack appears to be due in part

to lack of facilitating administrative arrangements. The number of people on active duty who would avail themselves of this opportunity may be small, but their option should not be foreclosed. In addition, it would be useful for information on inpatients (either active duty or retired) with Persian Gulf service who are treated at DoD hospitals to be available for review by VA and MFUA, if it is possible for DoD to provide this. Some agreement between DoD and VA may be required for this to happen.

A number of items on the VA coding sheet correspond to information on the DoD file. To the extent possible, the items should be collected in a consistent fashion. For example, the codes for race/ethnicity on the VA form are different from those used by the services, and do not allow the range of choices that might be desirable. The personal identifiers (mainly name and Social Security number) may be recorded appropriately for cross-matching the VA and DoD files for individuals, but it is not clear that there has been consultation on this. In addition, military unit is recorded differently in the VA and DoD registries. The VA registry form asks for the veteran's unit by name (e.g., Company C, 1st Battalion, 4th Army), while the DMDC database classifies the units using an alphanumeric code that is unrelated to the names. Translating one to the other is not a complicated task, but it is not obvious where it will take place or who will do it, should it be necessary.

This information would serve as a better cross-check if it were consistent. (The Office of Management and Budget has issued a directive with standards for collecting race and ethnicity information, which might be used for this purpose.) Other information, such as military history, is available from the DoD personnel registry, taken directly from each individual's personnel file. It may not be necessary for the veteran to recount this on the VA form. It probably would be beneficial for each item on the VA form to be reviewed with DoD to assure consistency and to evaluate whether it needs to be

collected at all. If there is a question about possible errors in the DoD file, VA could arrange with DoD for a printout of the DoD file to be sent to each veteran in the registry for corroboration after the examination.

OTHER EXPOSURES OF INTEREST

Discussion and concern about exposures other than oil fire smoke already are apparent. They have been brought up at congressional hearings and in print; included are depleted uranium, inoculations, an anti-nerve gas compound (pyridostigmine), exposure to petrochemicals in other ways (e.g., diesel fumes from tent heaters), pesticides, microwaves, infectious agents (e.g., leishmaniasis, malaria), chemical warfare agents (though there was no known use), a special paint, and others. Additional concerns are bound to surface in the coming years. Unlike oil fire exposure, where exposure estimates will be based on recorded information, finding out about many other exposures may depend on personal recollection.

Qualitative History of Persian Gulf for Exposures

It is not possible, nor would it necessarily be desirable, to gather individual, detailed data on a large number of exposures or experiences that occurred in the Persian Gulf, just in case they become important later on. The general environment and the military activities were complex and data on the occurrence and distribution of exposures are generally not easy to get. Some basic information about unit movements and activities and about the range of activities of individuals could be gathered now--in the form of a "qualitative history"--and could serve as a reference later on. If this is to be undertaken, it should be done soon. At least some of the information needed is "labile" and will become more and more difficult to ferret out and verify with the passage of time.

Items that should be covered in such a report include:

- *Unit-by-unit descriptions of locations and activities.* Base locations will be available from the DoD registry, but the daily activities will not. It could become important to know when units engaged in combat and how heavy the fighting was. Some idea of the amount of ammunition used might be helpful, for instance. In addition, it would be useful to know how much dispersion there was within a unit on a given day. While it will not be possible to quantify this or to describe it on a day-by-day basis, but at least a relative sense of dispersion by type of unit or location would be useful. It could be important to know this if a geographically described exposure is being considered, given that locations for individuals in the DoD database are represented by their unit (probably company) locations only.
- *Descriptions of the range of activities by military occupational specialty (MOS).* While MOS defines an individual's activities to some extent, it is not adequate to describe the range of activities and exposures of any individual. With specific exposures in mind (e.g., degreasers, diesel fuel), it would be helpful to know what people actually did in the Persian Gulf.

Getting the information for this report would involve a combination of research in military records, possibly other government documents, probably personal interviews with key individuals, and sample surveys of veterans to elicit their personal experiences and exposures. One caution is that individuals, particularly in military situations, may not know about many exposures (e.g., if insecticide is sprayed one day and troops enter the location the next, they will not necessarily know the spraying had been carried out). It is important, to ensure credibility, that a mechanism be developed to allow input and review from a representative group of veterans before the report is issued. In addition, the report should

be written so that it is readily understandable by individuals not schooled in military operations.

OTHER SOURCES OF INFORMATION ON HEALTH PROBLEMS OF PERSIAN GULF VETERANS

It has become clear that potentially useful information on current health problems of Persian Gulf veterans, whether or not they are attributable to their service, resides in places other than the VA registry. It will be important for MFUA to be aware of this information and to have access to it for their periodic reviews. This includes new health records, information already recorded in the veteran's DoD or VA files, and results of ongoing VA and DoD studies of Persian Gulf veterans.

Some sources have been brought to OTA's attention. For instance, discharge diagnoses are recorded for inpatients treated at VA hospitals and Persian Gulf veterans are specifically identified in that patient treatment file. In an analysis provided to OTA, VA researchers listed the distribution of all major diagnostic categories for Persian Gulf veterans and a similar-sized group of Persian Gulf-era veterans (who had not served in the Gulf).

The deaths of most veterans are reported to VA and logged in a system that records all compensation claims. Copies of death certificates usually are submitted, and these could be available for review. While relatively few deaths would be expected in this young population, they would represent the most serious conditions.

There may also be valuable information in DoD personnel and medical records and laboratories (e.g., induction physicals and psychological testing, stored serum samples). It is important to researchers for the design of future studies, should they become necessary, to know just what sources of data exist for these individuals.

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A description of these sources including data from before, during, and after Persian Gulf service could be made available from DoD and VA to Congress and to MFUA. If carried out, each data source should be identified and described, including a list of all available data elements. In addition, for each source, an estimate of the completeness of coverage for Persian Gulf veterans and other Gulf-era veterans should be made. Issues related to confidentiality or other issues of access to the records also should be covered in the reports. In addition, updates of relevant ongoing studies should be made available to MFUA.

CONCLUSIONS

A good start has been made on all facets of the registry complex. Changes made at this stage could improve the usefulness of the information gathered in the VA examination registry and lay a better foundation for co

ordination among the pieces of the registry complex once they are complete. Specific OTA conclusions include the following:

1. VA should focus immediately on revising the examination protocol.
2. Terminology used by VA and DoD should be brought into conformity, where appropriate.
3. A joint oversight body for the VA and DoD registries and their related activities should be appointed, which would enhance existing coordination and cooperation.
4. Information on exposures and other experiences of Desert Shield/Desert Storm should be assembled by DoD in a qualitative history for the Persian Gulf theater of operations.
5. DoD and VA should assemble annotated inventories of all sources of relevant health and demographic data, other than the registries, for Persian Gulf veterans.