

Presentation 15 – Lea Steele

2007 RAC Report

Discussion of Recommendations

Lea Steele, Ph.D.
July 18-19,2007

☆☆☆ **RAC-GWVI**

2007 RAC Report: Recommendations

- **Comments, changes since last discussion**
- **Additional recommendations**
- **Timeline**

☆☆☆ **RAC-GWVI**

2007 RAC Report: 5 Sections

1. Overview of the issue, population research, prognosis and treatments
2. “Causes” of Gulf War illness: summary and synthesis of info on GW-related exposures
3. “Nature” of Gulf War illness
4. Federal Gulf War research programs and spending
5. Research priorities and recommendations



RAC-GWVI

Report: Comments, changes since last discussion

- ***Executive summary***, emphasis, take-home points
 - *Gulf War illness: a serious condition that affects a lot of people*
 - *Comprehensive review of extensive research provides consistent picture*
 - *Questions are answerable*



RAC-GWVI

Report: Additional Recommendations

- Need for continuing longitudinal studies ??
- Determine if chemical exposures after the war precipitate, exacerbate veterans' condition(s)?



RAC-GWVI

Report: Additional Recommendations

Possible Recommendations:

- That VA continue to conduct follow-up studies of Gulf War veterans from their national sample to monitor the onset and progression of Gulf War illness and other conditions affecting Gulf War veterans.
?? At regular intervals? 5 year intervals?
- That epidemiologic studies of Gulf War veterans collect data on onset and/or exacerbation of Gulf War illness and other conditions in relation to exposure to hazardous substances subsequent to Gulf War service.
?? Name specific types of exposures? (e.g. pesticides, solvents)?



RAC-GWVI

Report: Additional Recommendations

- Recommendations re: IOM “Gulf War and Health” series
 - Reports mandated in 1998 by Congress in PL105-277, PL105-368
 - To advise Secretary of VA on decisions concerning benefits compensation, VA was directed to contract with IOM (or other appropriate scientific organization) to:

“review and evaluate the available scientific evidence regarding associations between illnesses and exposure to toxic agents, environmental or wartime hazards, or preventive medicines or vaccines associated with Gulf War service.”



RAC-GWVI

Additional Recommendations IOM “Gulf War and Health” series of reports

“Gulf War and Health” series

- Now includes six volumes, hundreds of findings
- Methodology for preparing reports based on IOM series that reviewed evidence re: Agent Orange and diseases in Vietnam veterans



RAC-GWVI

Additional Recommendations IOM "Gulf War and Health" series of reports

Goal of the process is to assign the level of evidence linking individual exposures with individual diseases

1. "Sufficient evidence of causal relationship"
2. "Sufficient evidence of an association"
3. "Limited/suggestive evidence of association"
4. "Inadequate/insufficient evidence of association"
5. "Limited/suggestive evidence of no association"



RAC-GWVI

Additional Recommendations IOM "Gulf War and Health" series of reports

Charge to VA/IOM, as directed by Congress (PL 105-277, PL-368)

Sec. 1603 c) Identify Agents and Illnesses

- A. Identify hazardous substances to which Gulf War military personnel were exposed
- B. Identify illnesses (including diagnosed and undiagnosed illnesses) that occur at higher prevalence in Gulf War veterans



RAC-GWVI

Additional Recommendations IOM "Gulf War and Health" series of reports

Approach directed by Congress (PL 105-277, PL-368)

Sec. 1603 e) Determination of Assoc Between Agents and Illnesses

- A. Determine if there is a statistical association between the exposure and the illness**
- B. Determine if there is an increased risk of illness in human or animal populations exposed to the hazardous substance**
- C. Determine if there is a plausible biological mechanism or other evidence of a causal relationship between exposure and illness**



RAC-GWVI

Additional Recommendations IOM "Gulf War and Health" series of reports

Approach used by IOM in preparing reports

- Generated numerous conclusions determining strength of evidence re: associations between individual exposures and many diagnosed medical conditions**
- Determinations re: levels of evidence rely exclusively on human studies (primarily occupational studies)**
- Almost no information re: exposures in relation to conditions that do (or might) affect Gulf War veterans at excess rates: GWI, ALS, symptom complexes, migraines, seizures, etc**



RAC-GWVI

Additional Recommendations IOM "Gulf War and Health" series of reports

Goal of the process is to assign the level of evidence linking individual exposures with individual diseases

1. "Sufficient evidence of causal relationship"
2. "Sufficient evidence of an association"
3. "Limited/suggestive evidence of association"
4. "Inadequate/insufficient evidence of association"
5. "Limited/suggestive evidence of no association"



RAC-GWVI

Additional Recommendations IOM "Gulf War and Health" series of reports

Findings from Vols 1 – 3 (DU, PB, Sarin & Vaccines, Solvents & Pesticides, Fuel Combustion)

231 conclusions: 134 related to cancers (all types: e.g., childhood cancers, breast cancer, leukemia)

- * 3 findings indicating "sufficient evidence of causal relationship"
 - *Benzene and aplastic anemia*
 - *Benzene and acute leukemia*
 - *Sarin and acute cholinergic syndrome*
- * 6 findings indicating "sufficient evidence of an association"
- * 22 findings indicating "limited/suggestive evidence of association"



RAC-GWVI

Additional Recommendations IOM "Gulf War and Health" series of reports

Major Problems

- Lengthy reports with lots of findings, but few directly relevant to health problems associated with Gulf War service
- Findings based on human studies only
- Selective reporting of available studies

Statute not followed: reports largely peripheral to the purpose for which they were mandated

- Problems due to restrictions in the approach used, studies considered (occupational studies of dx diseases)



RAC-GWVI

Additional Recommendations IOM "Gulf War and Health" series of reports

Examples

- Updated sarin report requested by Sec. Principi due to new info from animal studies; but panel did not consider animal studies in drawing conclusions
- Reports do not consider findings from epidemiologic studies of Gulf War veterans re: associations of GWI w/ exposures
- Prevalence of "multisymptom illness" reported from one selected study



RAC-GWVI

IOM “Gulf War and Health” series of reports Possible Recommendations:

The Institute of Medicine’s “Gulf War and Health” series of reports, as commissioned by VA, have not adhered to requirements set forth by Congress in mandating the reports. As a result, they have not comprehensively addressed key questions regarding Gulf War-related health conditions in relation to Gulf War exposures.

The Committee therefore recommends:



RAC-GWVI

IOM “Gulf War and Health” series of reports Possible Recommendations:

- > That VA, in commissioning reports mandated by Congress in PL 105-277 and 105-368, substantially change the approach used for reviewing scientific information and preparing the reports. As directed by Congress, conclusions should be based on findings from the full range of human and animal studies that provide information on effects of Gulf War-related exposures, as well as both diagnosed and undiagnosed illnesses affecting Gulf War veterans.
- > That VA contract with the Institute of Medicine, or other appropriate scientific organization, to redo previously completed Gulf War and Health reports to adhere to requirements set forth by Congress
- > That responsibility for contracting reports mandated by PL 105-277 and PL 105-368 be reassigned from VA’s Office of Public Health and Environmental Hazards to VA’s Office of Research and Development.



RAC-GWVI

2007 RAC Report

- Comments, changes since last discussion
- Additional recommendations
- **Timeline**

