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POINT PAPER

ANALYSIS OF SERVICE CONNECTION FOR RADIATION-INDUCED SKIN CANCER IN VETERAN COMPENSATION CLAIMS

BACKGROUND

This paper was generated in response to the Veterans' Advisory Board on Dose Reconstruction (VBDR) request of January 2006 to the Department of Veterans Affairs (VA) and the Defense Threat Reduction Agency (DTRA) to present a cost/benefit analysis for presumptive service connection in compensation claims for skin cancer by military participants of the U.S. atmospheric nuclear testing program and occupation forces (or prisoners of war) in Hiroshima and Nagasaki, Japan.

Under Title 38, Code of Federal Regulations (CFR), Part 3.311, a dose must be estimated or reconstructed for all VA radiation-related compensation claims involving skin cancer, and DTRA is tasked with providing this radiation dose assessment (RDA) to VA. As a result of the National Research Council (NRC) review of DTRA's dose reconstruction program in 2003, VA has returned over 1,200 previously-completed RDAs to DTRA for re-evaluation. Many of these involve skin cancer and require a revised RDA. The current backlog of VA non-presumptive claims (which includes reassessments and new cases received since the 2003 NRC report) requiring an RDA is 1,417. This includes 789 pending skin cancer cases, 53% of which are reassessments that require a revised RDA. The attached chart provides a breakdown of pending skin cancer cases at DTRA.

NOTE: The costs, case projections, and data interpretations contained herein are estimates.

DISCUSSION

Skin Dose Reconstruction and Uncertainty

- In its January 2006 report to VBDR, the Dose Reconstruction Subcommittee (SC1) noted that skin dose estimations are uncertain. It may be equally appropriate to state that the uncertainties associated with dermal contamination (and the resulting dose estimations) could be higher than for other exposure modes and pathways.
- While the uncertainties involved in skin dose reconstruction have yet to be formally evaluated by DTRA, they are considered to be potentially significant and tend to increase the upper bound dose. The DTRA upper bound dose is a 95th percentile estimate (i.e., the dose at which there is less than a 5% chance that the estimated dose is lower than the actual dose). As the upper bound dose increases, so does the probability that it will approach or exceed the relevant screening dose. This is especially valid for basal cell carcinoma (BCC) and malignant melanoma (MM), which have relatively low screening doses.

Screening doses

- Screening doses correspond to a probability of causation (PC) of 50% at the 99% credibility limit, at which it is usually assumed "at least as likely as not" that the claimant's cancer was caused by radiation exposure.
- Screening doses for white (non-Hispanic) males were originally reported in the 2003 NRC report as 10 rem for BCC and MM, and 475 rem for squamous cell carcinoma (SCC). The vast majority of claims for skin cancer fall within this racial subcategory, and the skin dose associated with a given PC is highest for this racial subcategory.
- While the PC values in the 2003 NRC report assumed chronic exposure to beta radiation, VA currently evaluates skin cancer PC assuming acute exposure to beta radiation (and gamma, if significant). The assumption of acute exposure generally results in a higher estimate of cancer risk and PC, which is more favorable to the claimant. It should also be noted that the screening doses for BCC and MM are dependent on age at exposure (increasing from approximately 6 rem for exposure at age 18 to nearly 90 rem for exposure at age 40+). In contrast, screening doses for SCC are independent of age at exposure.
- Considering the assumption of acute exposure, screening doses for BCC/MM and SCC in white (non-Hispanic) males, assuming an age at exposure of 20 years and a time since exposure when cancer was diagnosed of 15 years or greater, have been recalculated using the Interactive RadioEpidemiological Program (IREP) to be 8 rem and 300 rem, respectively. These values, along with screening doses for other ages at exposure and screening doses for many other cancer types, will be published in a DTRA technical report that is currently awaiting peer review.

BCC and MM

- Considering the low screening dose for BCC/MM and the potentially significant uncertainty of skin dose estimates, a higher percentage of BCC and MM claims are likely to be successful (compared with other diseases) because the dose associated with 50% PC at the 99% credibility limit is equaled or exceeded. A review of 369 skin RDAs completed since the 2003 NRC report indicates that 54 of 268 upper bound skin doses (20%) generated for BCC and MM claims exceeded the 8-rem screening dose described above.
- Of the 268 completed BCC/MM cases noted above, 113 were Hiroshima/Nagasaki cases (where the potential for skin contamination was greatly reduced). Within this subgroup, only four upper bound skin doses (3.5%) exceeded the 8-rem screening dose. It follows that 50 of 155 non-Hiroshima/Nagasaki upper bound skin doses (32%) generated for BCC/MM exceeded the screening dose.
- Because screening doses for BCC and MM are age-dependent (the 8-rem screening dose assumes a latency period of ≥15 years and an age at exposure of 20), the latency period and age at exposure must be considered on a case-specific basis to validate the 8-rem estimate above.
- While privacy concerns deterred the Veterans Health Administration (VHA) from providing case-specific medical opinion data for the 369 skin cancer cases completed since the 2003 NRC report, VHA did provide a listing of 292 skin cancer medical opinions during the period between 2003 (month unknown) and April 2006. The summary of medical opinions is a useful indicator of the percentage of

upper bound skin doses that exceeded the applicable screening dose. DTRA analysis of VHA medical opinion data (below) is approximate, as DTRA did not formulate the data.

- Analysis of the data indicates that for 24% of BCC cases (22 of 92) and 36% of MM cases (9 of 25) the applicable VHA physician issued favorable medical opinions (i.e., that radiation exposure is as least as likely as not to have caused the cancer). Of the BCC cases, 42% (40 of 95) involved upper bound skin doses of ≤1 rem and 73% were ≤5 rem. Of the MM cases, 32% involved upper bound skin doses of ≤1 rem and 64% were ≤5 rem. Of the BCC cases that received favorable medical opinions, 55% exceeded 37 rem and 82% exceeded 14 rem. Of the MM cases that received favorable medical opinions, 56% exceeded 37 rem and all exceeded 9 rem.
- The percentage of favorable medical opinions provided by VHA is consistent with the percentage of DTRA upper bound skin doses that exceed the assumed BCC/MM screening dose (8 rem) for the range of ages and time periods in question.

SCC

- Compared with BCC/MM and other cancers, SCC is considered to be weakly radiogenic (as suggested by the high screening dose). In fact, just 3 of 144 upper bound skin doses (2.1%) generated for SCC claims since the 2003 NRC report have exceeded the 300-rem screening dose described above. Of the 144 completed SCC cases, 68 were Hiroshima/Nagasaki cases and none of the associated upper bound doses exceeded the SCC screening dose.
- According to the VHA medical opinion data, 3.7% of SCC cases (2 of 54) received a favorable medical opinion. Therefore, the percentage of favorable medical opinions provided by VHA is consistent with the percentage of DTRA upper bound skin doses that exceed the assumed SCC screening dose (300 rem) for the range of ages and latency periods in question.

Undetermined skin cancer types

- The type of skin cancer was undetermined in seven of the 369 completed skin RDAs. In all seven cases, the upper bound skin dose exceeded the 8-rem screening dose for BCC and MM. One of the seven upper bound doses exceeded the 300-rem screening dose for SCC.
- According to the VHA medical opinion data, 3.0% of unspecified skin cancer cases (4 of 133) received a favorable medical opinion; 47% (62 of 130) involved upper bound skin doses of ≤1 rem and 87% (111 of 128) were ≤5 rem. The minor difference in sample size is attributable to the fact that some cases involved several cancers, and VHA medical opinion data report a range of upper bound doses provided (without specifying how they apply to the skin cancers in question). Of the four cases that received favorable medical opinions, three upper bound skin doses exceeded 84 rem and two exceeded 140 rem.
- Because so many medical opinions involved multiple skin cancer types (which are unspecified in the VHA data), a comparison with the percentage of upper bound skin doses exceeding a specified screening dose cannot be performed with confidence.

Skin Doses at Hiroshima and Nagasaki

- The 15 kiloton Hiroshima bomb detonated 600 meters above the ground. The 21 kiloton Nagasaki bomb detonated 503 meters above the ground. Due to the height of the bursts, acute injuries to the Japanese from fallout were completely absent. The first U.S. occupation troops arrived in the vicinity of Hiroshima about 60 days after the bombing. The main body of occupation troops entered Nagasaki about 45 days after the bombing. The mission of the occupation troops was to establish control of the area, ensure compliance with surrender terms, and demilitarize the Japanese war machine. The mission did not include the cleanup or any radiological decontamination of Hiroshima, Nagasaki, any other areas, or the rebuilding of Japan.
- Radioactive fallout from nuclear weapons consists of a variety of radionuclides that decay with various half-lives. For early fallout, for every sevenfold increase in time after the explosion, the dose rate decreases by a factor of ten. Consequently, the effects of radioactive fallout on U.S. forces in Japan after the Hiroshima and Nagasaki detonations proved minimal. Since fallout is the principal pathway leading to skin dose for the NTPR program, calculated skin doses for U.S. forces in Japan following the Hiroshima and Nagasaki detonations are generally minimal.
- In comparison, fallout from some of the U.S. atmospheric nuclear weapons tests was substantial. For example, the Bravo shot of Operation Castle, which was a 15 megaton thermonuclear device detonated at surface level on Bikini Atoll on March 1, 1954, resulted in significant radioactive contamination over an area of more than 7,000 square miles.

Backlog status and costs

- As of April 2006, the average time that a pending skin cancer case has been at DTRA is 708 days; this does not include time required for initial processing at VA. The oldest case has been pending at DTRA for 1,266 days. The average level of effort required for DTRA to complete a skin RDA since the 2003 NRC review (including historical research, scenario development, veteran outreach, RDA preparation, and administrative activities) is approximately 98 person-hours.
- SCC-related cases comprise 30% of the pending skin RDA backlog.
- As a result of the 2003 NRC review, the costs associated with modified DTRA procedures rose dramatically from approximately $5,000 to as much as $27,000 per RDA (applies to all cases, not just skin cancer). DTRA completed 221 skin RDAs in 2004 and 2005, at an approximate cost of $4.1 million (averaging $18,500 per RDA).
- The current DTRA cost per non-Hiroshima/Nagasaki skin RDA claims ranges from approximately $9,000 to $15,000 (based on complexity). Thus, the projected DTRA cost to generate an RDA for all 626 pending non-Hiroshima/Nagasaki skin cancer cases (that do not involve another non-presumptive disease) is approximately $5.6 million to $9.4 million.
- The projected annual DTRA cost to perform future skin RDAs (based on an average incoming rate of 160 new skin cancer cases per year and a cost of $9,000 to $15,000 per case) is approximately $1.4 to $2.4 million.

- VA medical and compensation costs in 2004 and 2005 for service-connected skin cancers have been unofficially estimated to be less than $1 million. Consequently, the cost of performing skin RDAs during the same time period ($4.1 million) likely exceeds the cost of any benefits provided to the veteran.

Claims processing

- Claims for the 21 cancers falling under 38 CFR 3.309 do not require an RDA because radiation exposure is presumed to have caused the cancer. If VA can establish internal policy to grant service connection in non-Hiroshima/Nagasaki skin cancer claims falling under DTRA purview without regard to radiation dose (as discussed at the VBDR public meeting in January 2006), a lengthy CFR revision may not be necessary.
- At DTRA, the traditional interpretation of including "all material aspects of the radiation environment" in a dose reconstruction (32 CFR 218) has meant accounting for all exposure pathways without regard to their relative contributions to the overall dose. In contrast, efficiency measures currently in use under the Energy Employees Occupational Illness Compensation Program allow the National Institute for Occupational Safety and Health to apply a graded approach and expedite the dose reconstruction process. SC1 has agreed that expedited processing should not have a "material" impact on the outcome of non-Hiroshima/Nagasaki skin RDAs as long as benefit of the doubt is consistently applied with regard to skin dose uncertainty and screening dose.
- Expedited case processing and a significant cost savings can also be achieved by relieving DTRA of the requirement to calculate a central dose estimate for skin cases (which involve potentially significant uncertainty). This change has been endorsed by SC1 and seems particularly appropriate, since VA uses only the upper bound dose to adjudicate claims.

Conclusions

- The performance of non-Hiroshima/Nagasaki skin RDAs is an expensive process that prolongs the VA claims process, thereby delaying decisions for affected veterans and delaying dose reconstructions for all confirmed participants who apply for benefits with the hope of receiving compensation.
- Based on the available data, the costs associated with the performance of non-Hiroshima/Nagasaki skin RDAs are likely to significantly exceed the costs of any benefits provided to affected veterans.
- The potentially significant uncertainty of skin dose estimates and the low screening dose for BCC/MM suggests that a significant percentage of BCC/MM claims are likely to receive a favorable medical opinion and a successful adjudication result.
- SCC-related cases comprise only 30% of the pending skin RDA backlog (and the medical and compensation costs associated with the low percentage of service connection would likely be low, but the cost to perform non-Hiroshima/Nagasaki skin RDAs for SCC likely exceeds the cost of any benefits provided to the veteran.
- It is simply not in the best interest of the veterans or the Government to continue performing non-Hiroshima/Nagasaki skin RDAs.

RECOMMENDATIONS

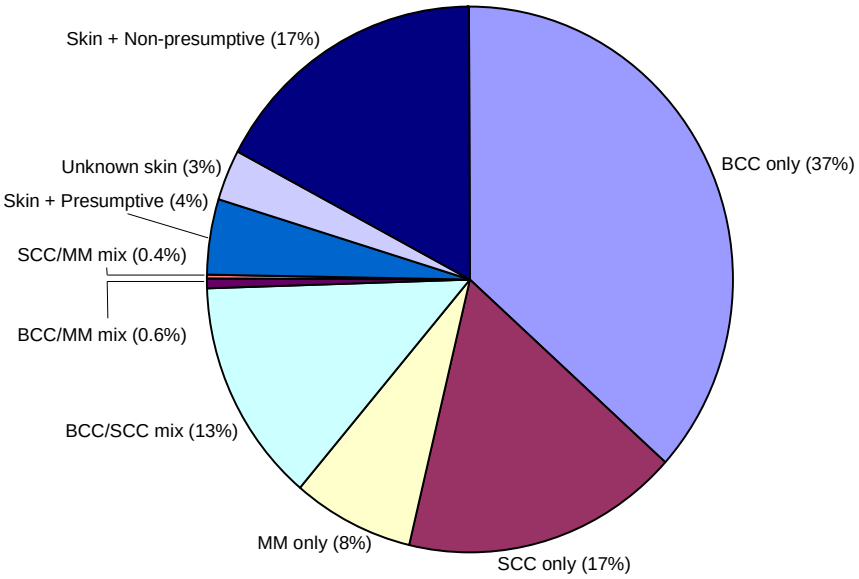
Recommendation 1
Eliminate the requirement to perform RDAs for all non-Hiroshima/Nagasaki BCC and MM cancer claims falling under DTRA purview by establishing internal VA policy to grant service connection without regard to skin dose for these claims. This would enable VA to immediately proceed with the adjudication of 366 to 396 pending veteran claims (46%-50% of all pending DTRA skin cancer cases and at least 26%-28% of the DTRA dose reconstruction backlog). In addition to expediting claims for veterans who are currently awaiting decisions, this action would result in an immediate cost savings of approximately $3.3 to 5.9 million (and up to approximately $1.4 million annually thereafter) when combined DTRA and VA costs are considered. Additional Government costs savings would be possible if approval of this initiative allows DTRA to forego pending analyses of skin dose uncertainty.

Recommendation 2
Eliminate the requirement to perform RDAs for all non-Hiroshima/Nagasaki SCC claims falling under DTRA purview by establishing internal VA policy to grant service connection without regard to skin dose for these claims. Although upper bound skin doses for SCC claims generally do not approach the applicable screening dose (and frequently contributes to unfavorable medical opinions), the cost of performing RDAs for these cases likely exceeds any medical and compensation costs associated with service connection. Elimination of the requirement to perform RDAs for SCC would enable VA to immediately proceed with the adjudication of an additional 257 veteran claims.

The acceptance of Recommendations 1 and 2 would allow VA to immediately proceed with the adjudication of 626 pending veteran skin cancer claims (79% of all pending DTRA skin cancer cases and 44% of the DTRA dose reconstruction backlog). In addition to expediting claims for waiting veterans, this action would result in an immediate cost savings of approximately $4.6 to 8.4 million when combined DTRA and VA costs are considered.

Recommendation 3
Implement various efficiency measures that enable DTRA to perform expedited processing, provide worst-case (maximum) skin doses to VA, and discontinue central dose estimates for skin RDAs. Although the schedule and cost impacts would be significantly less than projected in Recommendations 1 and 2, the recommendation would still enable accelerated adjudication of skin cancer claims.

NTPR Pending Skin Cancer Cases



Type of case pending	Number
All cases involving skin cancer	789
(Skin cancer only) & (Skin + Presumptive)	**653***
Skin cancer only	620
BCC or MM only	354
SCC-related only	241
Unknown Skin	25
BCC or MM + Presumptive (38 CFR 3.309)	12
SCC + Presumptive	16
Unknown Skin + Presumptive	5
Skin + Non-presumptive (38 CFR 3.311)	**136**

*: 626 of the 653 cases are non-Hiroshima/Nagasaki cases

All cases except Skin + Non-presumptive (which involve an additional condition requiring an RDA under 38 CFR 3.311) would immediately be removed from the DTRA dose reconstruction backlog and returned to VA for adjudication if Recommendations 1 and 2 are adopted.

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