

Howe, Donna-Beth

From: Pelke, Patricia
Sent: Monday, December 14, 2009 5:16 PM
To: White, Duane
Cc: Piskura, Deborah; Wiedeman, Darrel; Frazier, Cassandra; Lougheed, Patricia; Howe, Donna-Beth
Subject: NRC Assessment of Patient Doses; PVAMC patient data and SOL.doc
Attachments: PVAMC patient data and SOL.doc

Duane,

I am forwarding a compilation which identifies the medical events the NRC has identified (based on PVAMC's final dose assessments), indicated the cases that our consultant reviewed, and of those cases, indicated which cases the consultant noted and the adverse effects noted by the consultant. In addition, we highlighted the cases that are within the SOL.

Based on our review of the data provided by the PVAMC, we identified 74 medical events; 23 events could be retracted; and we identified 17 AO's (using the current criteria). Note that if we use the more restrictive AO criteria in place at the time some of the events occurred, the number of AO's will be higher.

If you have any questions, let me know. Thanks ... Patty

B-10

NRC EVALUATION OF VA DOSE ASSESSMENT

Patient cases highlighted are within the Statute of Limitations (effective date being November 6, 2004, five years from the NHPPs letter accepting the SOL). Patient cases marked with a "*" indicate the NRC's medical consultant reviewed the case; some cases marked "***" indicated that the medical consultant reviewed the case twice in 2008 and in 2009. Notes and comments by the NRC medical consultant are summarized for the reviewed cases. Case numbers which are underlined indicate significant patient symptoms/conditions as discussed in the medical consultant's reports. Five deceased patients noted; inspectors confirmed cause of death for these five patients was not related to their prostate brachytherapy procedure.

The following 67 cases were reported as medical events:

XRT 001* numerous seeds outside of correct region. Suspicious for failure (Phoenix criteria)
002* numerous seeds outside of correct region
003 DECEASED
005
006* numerous seeds outside of correct region
007* some seeds outside of correct region
008
009* patches of inflammation, possibly radiation proctitis
010* most of the seeds are outside of the prostate; patient doing well
011* DECEASED essentially all seeds outside of prostate, many near and in bladder, patient re-implanted at the VA Puget Sound; some seeds near the rectum;
013** most of the seeds are outside of the prostate
016
017* many seeds outside of the prostate and anterior; PSA has been rising
018** many seeds lateral to the bladder and near rectum; rectal bleeding; possible inflammatory bowel disease complicated by radiation effects; granular rectal mucosa suggesting edema with patches of erythematous mucosa.
019* seeds anterior to the bladder and near rectum
020 DECEASED
022* no comments on seed location; patient doing well
024
027* re-implantation at the VA Puget Sound
030
032* most seeds are clustered in the peripheral zone around the apex
035* several seeds in pelvic floor musculature. Patient re-implanted at VA Puget Sound. History of severe dysuria
036
037
040* clinical picture of radiation proctitis
042* seeds noted in the bladder
044
045
050
051
052* many seeds lateral to the bladder; stable PSA

053* incontinence, dysuria with bladder spasms. Considered for hyperbaric oxygen (HBO) therapy for radiation proctitis and cystitis. Initial seeds noted in the rectum. CT to evaluate extraprostate disease. In clinical relapse.

056

057

058* no comments on seed location

059

061

062* DECEASED no comments on seed location

064

065

066

068

069

070

071

072

077

078* no comments on seed location, increasing PSA

079

080

081

082

085** no comments on seed location, atypical glands suspicious for adenocarcinoma, increasing PSA velocity

087

088* radiation dose to the perineum, significant dysuria, seed in periprostatic tissue

089* no comments on seed location; no other comments

091

093

096* many seeds lateral to the bladder and near the rectum

097

098

102* many seeds inferior to the bladder and near the rectum

108* many seeds anterior to the bladder and near the rectum

109

110

112 DECEASED

114

7 Cases which were "indeterminate" meaning no post-plans were performed due to data corruption of the CTs. These cases were also reported as medical events:

25

31* endorectal advancement flap and s/p radiation therapy to the anal canal for rectal cancer. Possibly one seed in the rectum

33

76

84

104* hospitalized for rectal bleeding colonoscopy showed proctitis, 2 seeds close to rectum

111

23 Cases could be retracted based on the D-90 being greater than 80%:

- 004* no comments on seed location; no apparent clinical problems
- 012* many seeds anterior; unanticipated dose to the perineum
- 015* patches of telangiectasia, possibly radiation-related. Some rectal bleeding, relatively benign dilated blood vessels often seen as a result of high dose local radiation
- 021
- 023
- 026
- 028
- 038
- 041
- 048
- 049
- 054
- 063
- 067* no comments on seed location; some symptoms of dysuria
- 073
- 074
- 083
- 092* no comments on seed location;
- 094
- 095
- 100
- 103* no comments on seed location
- 105

17 cases would be Abnormal Occurrences based on current criteria:

- 001* numerous seeds outside of correct region; suspicious for failure (Phoenix criteria)
- 006* numerous seeds outside of correct region
- 010* most of the seeds are outside of the prostate; patient doing well
- 013* most of the seeds are outside of the prostate
- 018* many seeds lateral to the bladder and near rectum; rectal bleeding; possible inflammatory bowel disease complicated by radiation effects; granular rectal mucosa suggesting edema with patches of erythematous mucosa.
- 019* seeds anterior to the bladder and near rectum
- 027* Re-implanted at VA Puget Sound
- 037
- 044
- 057
- 066
- 078* no comments on seed location, increasing PSA
- 080
- 088* no comments on seed location, atypical glands suspicious for adenocarcinoma, increasing PSA velocity
- 096* many seeds lateral to the bladder and near the rectum
- 098
- 102* many seeds inferior to the bladder and near the rectum