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Mr. Tom Elkins
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Dear Mr. Elkins:

The current standards for "linac need" in the State Medical Facilities Plan are based in large part on recommendations from the 1991 edition of the ACR *Blue Book*, which itself was based on radiation oncology experience from the 1980's. There have been significant changes in radiation therapy over the last 20 years. For example, we are treating a much higher percentage of women with breast conserving therapy rather than mastectomy. The advent of stereotactic radiosurgery (SRS) has given us the ability to treat arteriovenous malformations (AVMs), acoustic neuromas, and a variety of low grade brain and base of skull tumors. SRS has also proven a reasonable substitute for open neurosurgery in treating brain metastases. In summary, we are using linacs to treat many conditions that were not treated 20 years ago.

Not only are we treating many new conditions, but also the intensity of our treatments has increased with more cases being treated with intensity-modulated radiation therapy (IMRT) and image-guided radiation therapy (IGRT). Modifications in the ESTV formula have been made to account for some of these changes in treatment intensity. For instance, the current formula allows increased ESTV weighting for SRS. The overall methodology, however, has not been reviewed comprehensively. The attached short article by Donald Goer, Ph.D. references the fact that treatments are taking longer and the demands on linac time are increasing. Unfortunately, there have been no updates to the 1991 ACR *Blue Book*, and none are planned.

Let me list the most significant technical changes in radiation oncology over the last 20 years that have increased linac utilization. I will then attempt to estimate their impact on linac utilization and thus "linac need."

1. Intensity modulated radiation therapy (IMRT) – With the advent of multi-leaf collimator (MLC)-equipped linacs, it has been possible for most centers to deliver IMRT radiation treatments. IMRT has specific advantages over standard radiation treatments in certain clinical settings. Currently, approximately 17% of radiation treatments in North Carolina are dèlivered using IMRT, and we estimate with time this percentage will rise to 25-30%. IMRT treatments take longer than the average standard radiation treatments, because each IMRT treatment involves 5-9 separate fields. Each one of those fields is treated with a more prolonged technique to achieve the desired "intensity modulation". It is our estimation that the average IMRT treatment takes approximately 50% longer than a standard radiation treatment.

2. Image-guided radiation therapy (IGRT) – IGRT techniques allow the more precise placement of the radiation field prior to treatment delivery. IGRT usually take 3-5 minutes to perform, and it is utilized EACH DAY before the radiation treatment is delivered. IGRT can be performed with several different technologies (ultrasound, cone beam CT, stereoscopic imaging). IGRT is used for all SRS and SRT treatments (see below), but it is also very useful in setting up a significant proportion of standard (non-IMRT, SRS or SRT) treatments.

3. Stereotactic radiosurgery (SRS) – Stereotactic radiosurgery is defined as high dose radiation treatment delivered in a single treatment and directed to a small intracranial target, utilizing stereoscopic IGRT localization prior to treatment delivered in a single treatment session. SRS performed on a linac requires 8-15 separate radiation fields. SRS is currently weighted by a factor of 3.0 ESTVs in the 2008 *State Medical Facilities Plan* (SMFP), but compared to the time for standard radiation treatment (12-15 minutes vs. 70-90 minutes), that is a 50-75% under estimate.

4. Stereotactic radiotherapy (SRT) – Stereotactic radiotherapy is defined as the delivery of high dose radiation to a small target with rapid dose fall off at the margins delivered with a total course of 2-5 fractions. SRT treatments can be directed to both cranial and body targets. Just as for SRS, SRT treatments are localized using IGRT and IGRT procedures. These treatments also involve multiple separate fields with a minimum of 5 and a maximum of approximately 12. Each SRT treatment typically requires 40 minutes.

Suggestions:
From our real world experience in our own department, it is clear that with the increasing use of SRS, SRT, IGRT and IMRT treatments, we are unable to treat as many patients

per day on each linac as we were in the days when all treatments were "standard". We suggest the following:

1. The current ESTV formula gives weekly port films a weighting of 0.5 ESTVs. Since weekly port films are no longer billable in the hospital setting, we recommend that the time for those weekly films be bundled into the standard ESTV count. This would increase the ESTV weighting for a standard treatment to 1.1 (1.0 + 0.5/5). We are also using IGRT localizations for an increasing percentage of standard (non-IMRT, SRS or SRT) radiation treatments. These IGRT procedures are performed prior to every daily treatment, and they take as much time as a standard weekly port film. If a standard radiation course were localized with daily IGRT, the appropriate ESTV weighting would be 1.5 (1.0 + 0.5). Since only about 10% of current standard radiation treatments will need IGRT set-ups, we suggest that an additional 0.05 ESTV (O.5 x 0.1) weight be given to all standard treatments. To account for both the port films that will no longer be counted and the IGRT time needed for some standard treatments, **we suggest an ESTV value of 1.15 for each standard radiation treatment.**

2. Since IMRT treatments take approximately 50% more time than non-IMRT treatments, **we suggest that each IMRT procedure be weighted at 1.5 ESTVs.**

3. Since SRS treatments typically require 70-90 minutes, **we suggest they be weighted at 5.5, assuming that a 0.5 weight represents the IGRT component needed prior to each SRS treatment.**

4. SRT procedures (either body or cranial) typically take 40 minutes each. **We suggest that they be attributed a weight of 3.5, again including the 0.5 weighting to account or the time involved with the daily IGRT setup.**

5. Due to the additional time required for the standard radiation treatments (IGRT), the increased frequency of more time-consuming IMRT treatments, and the additional tumors and benign lesions that we are treating with SRS and SRT vs. 15 years ago **we suggest that the population standard for generating linear accelerator need be reduced by 10% to 108,000 persons per linac**. As discussed below, we are also suggesting a new manner of assessing available linac capacity, the "equivalent linac." We suggest a population standard of 108,000 per equivalent linac.

6. Due to low utilization or non-applicability in our State, **we suggest that the following reporting be dropped: hemibody irradiation, intraoperative radiation therapy, neutron and proton therapy. We further suggest that limb salvage irradiation does not need a separate designation.**

7. We are in agreement that either a pediatric or adult patient under anesthesia should receive an ESTV weight of 2.0.

Evolving Linear Accelerator Technology:
Recent years have seen the arrival of a spectrum of new radiation machines, including GammaKnife, CyberKnife, Novalis, and TomoTherapy units. Some of these units are dedicated SRS-only (GammaKnife), and the *SMFP* has chosen to review GammaKnife in a need category separate from that for linacs. Of the remaining specialized stereotactic linacs, the CyberKnife unit is capable of only SRS and SRT treatments, while the Novalis and TomoTherapy units are capable of both standard therapy and SRS-SRT treatments. Furthermore, several vendors have developed 'add-on' technology that allows the conversion of a standard linac into a machine capable of delivering stereotactic radiation procedures. Finally, the newest linear accelerator models being sold have capabilities that will allow them to deliver SRS, SRT and/or standard radiation treatments with a single machine.

For all these reasons, we feel that there needs to be an adjustment in the way that we calculate the number of available linacs in a service area. We feel standard linacs that provide no SRS or SRT treatments (but that do provide IMRT treatments) should still be assigned a weighting of 1.0. While it is hard to quantitatively justify how much weight a dedicated SRS-SRT linac (like CyberKnife) should be weighted, our best estimate is that it should be equivalent to a 0.4 linac. (I would estimate 60% of the cases treated on a CyberKnife are "new" to the specialty of radiation oncology vs. 15 years ago (brain mets, AVMs, boosting liver metastasis, or focal treatment of liver or lung metastases), while the remaining 40% of treatments performed on that machine are in effect *replacing* treatments that would have otherwise been performed on a linear accelerator. For all the other SRS-SRT capable machines, which also can deliver standard treatments, we need to develop a methodology that counts them in the linac inventory in a manner appropriate to their use.

We propose the concept of an "equivalent linac", defined by the formula below. In essence, this formula decreases the capacity of a linac proportional to its increased use for delivering SRS and SRT treatments.

Equivalent Linac Capacity formula:

0.4 + 0.6 x (1.00 - [(#SRS x 5.5 + #SRT x 3.5)/(#SRS x 5.5 + #SRT x 3.5 + #XRT x 1.15)])

This formula would value any linac that was not performing any SRS or SRT procedures at 0.4 + 0.6 = 1.0 linac, no change from the present. For any linac used for both standard and hypo-fractionated stereotactic procedures (SRS and SRT), the formula decreases the linac capacity proportional to its increased use for SRS and SRT procedures. The formula utilizes the same ESTV values for SRS and SRT as previously proposed. We feel that the "equivalent linac" concept will produce a more realistic assessment of linac capacity in a service area where any of the linacs are used for these specialized stereotactic procedures.

Were the changes that we suggest in the ESTV formula, population standard, and linac capacity count to be adopted, our brief analysis suggests that there would be no immediate increase in linac need that would result. The changes proposed would let additional linac need be generated somewhat sooner, but we feel that is appropriate given the increasing linac utilization we have seen over the last 20 years.

Thank you for letting me comment on these issues.

Sincerely,

Robert W. Fraser

Robert W. Fraser, III, M.D.

cc: Dr. Christopher Ullrich