

SCIENCE COUNCIL SUMMARY
A SYMPOSIUM ON THE PROMISES AND PERILS OF PROTON RADIOTHERAPY

The Program Committee and AAPM leaders present at the *Symposium on the Promises and Perils of Proton Radiotherapy* have made the following observations based on the presentations and discussion sections in regards to Proton Radiation Therapy (PRT):

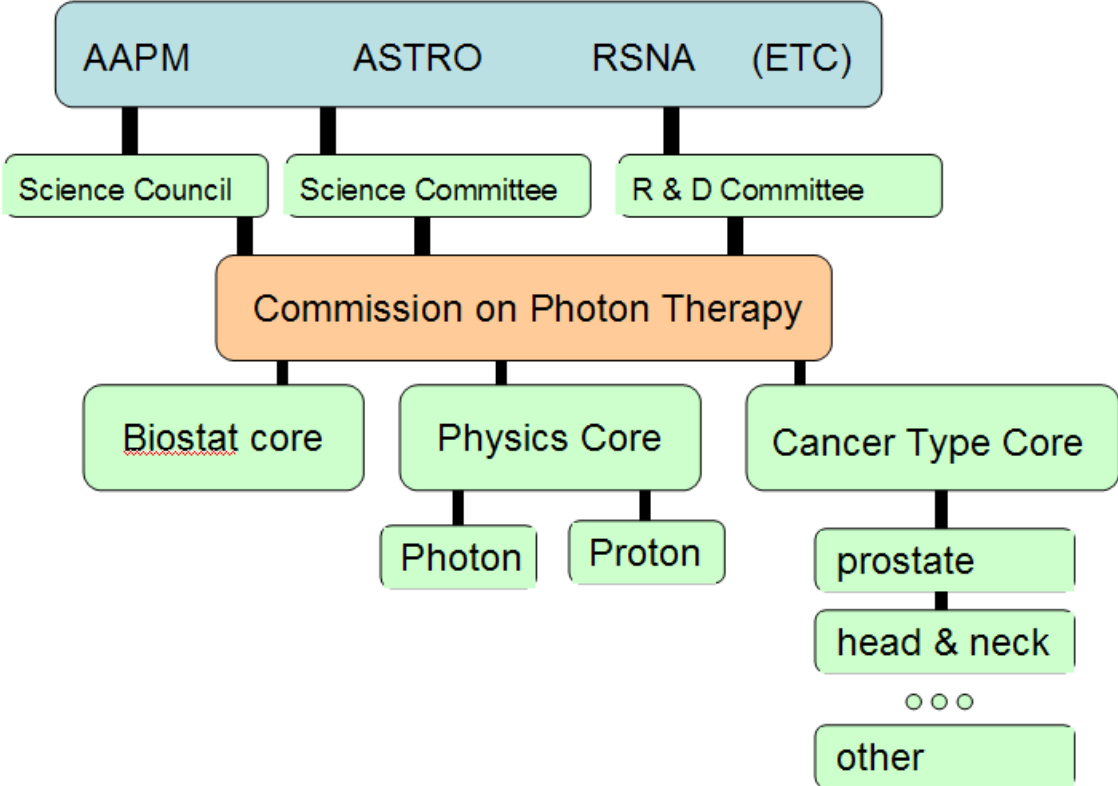
1. PRT has the strong potential to reduce integral dose compared to IMRT and this in turn can reduce the morbidity of RT for many patients and for younger patients can reduce the incidence of secondary neoplasms.
2. There was the feeling expressed by some symposium participants that PRT is in its technological infancy and will continue to improve over the next few years. This led some to believe that randomized clinical trials would be biased due to the maturity of photon RT.
3. Issues of equipoise were discussed and there was a difference of opinion among radiation oncologists as to how equipoise as practiced by individual physicians affects patient selection in proton RT facilities. This leads to a concern that a clinical trial comparing proton with photon RT would have natural biases including ethical issues complicating unbiased patient recruitment.
4. The financial costs and issues of ethical patient selection (equipoise) at proton RT centers make randomized clinical trials difficult and ethically challenging in some minds.
5. It was agreed upon at the symposium that a clinical study comparing proton with photon RT is necessary, which includes clinical outcomes.

Given the above observations, it is recognized that a true randomized clinical trial comparing proton RT with photon RT may not be feasible at this time. It is also recognized that registry based comparative research may not be comprehensive or thorough enough to make statistically valid conclusions at some point in the future. Therefore, **it is proposed that:**

ASTRO and AAPM form a jointly administered *Commission on Photon Therapy* (CPT) to organize, seek federal funding for, and run a case-controlled clinical trial comparing outcomes in both proton and photon RT. Photon RT patients should not be enrolled at proton facilities, to eliminate natural patient selection biases unique to each proton facility and to avoid ethical concerns in patient selection. Three to seven cancer types should be selected, including prostate, head and neck, appropriate pediatric sites and others to be selected by the Commission. The goal of this case-matched study will be to compare outcomes in patients with various cancers between photon and proton RT centers, while matching the comparison patient populations to the extent possible. Parameters to be measured during patient recruitment for each cancer type could include tumor volume, stage, grade, patient

gender, age, height, weight, race, ethnicity, glucose, lipid and other blood markers, economic status, family factors, and all other relevant patient specific factors that can be potentially matched to reduce bias in comparisons. Details of this would be dealt with the Commission and biostatistician consultants. Outcomes reported should include all complications of RT, other morbidity issues, and death by cause. Annual patient surveys could be used to assess quality of life, using previously established survey instruments. The treatment plan for each patient should be archived and collected by the Commission. The Commission should be composed of radiation oncologists, radiation physicists, biostatisticians, and other members as appropriate.

Other professional societies such as RSNA or ESTRO could also be included in the charter of this Commission. A sample organization chart for the Commission is shown below:



Program Committee:
 Jatinder Palta, Eric Klein, Christopher Rose, John Boone

AAPM Leaders Present:
 Jerry White, Chairman of the Board
 Michael Herman, President-elect
 John M Boone, Science Council Chair