RT Dose Prescription for Clinical Trials

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Dose Prescription

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Dose Prescription

- The clinical trial dose prescription is different than an institution's RT prescription
  - Institutions write prescriptions based on their own past experience or information gleaned from literature
    - Institution modify their prescription as more experience is gained
  - Cooperative groups write the prescription for a particular protocol based on what they think multiple institutions can achieve
  - The cooperative group prescription must include a technique for pushing each institution toward the best possible plan

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Dose Prescription

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  - Setup variations and movement due to respiration can result in PRV and PTV overlap

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  - Setup variations and movement due to respiration can result in PRV and PTV overlap

- Resolving overlap issues can lead to either of the following:

  - using different or a range of prescribed doses

  - varying the % coverage of PTV with single prescribed dose

Dose Prescription

- Resolving overlaps of PTV and PRV
  - Adjusting PTV coverage is a better way resolving overlap issues
    - since the target or critical structure does not reside at the edge of the PTV or PRV all of the time, adjusting the dose only where they overlap is better than reducing the dose to the entire PTV

Dose Prescription

- Using different prescribed doses to resolve overlap issues introduces the question of stratifying for dose when toxicity and/or survival are identified as an objectives

Dose Prescription

- Ingredients of a good prescription
  - single # statement of dose
  - % coverage of PTV (e.g., 95%)
  - max dose to any point within the PTV
  - min dose to any point within the PTV
  - size of volume representing the point dose (e.g., 0.03 cc or approximately 3x3x3 mm)
  - a description of all relevant critical structure doses represented as at least 2 points on DVH

Dose Prescription

- The dose prescription for a cooperative group clinical trial includes the Compliance Criteria

  – the Compliance Criteria serve to guide the clinician and dosimetrist to a high-quality treatment plan

Compliance Criteria

- Per Protocol
  - the prescription the institution should try to meet

- Variation Acceptable
  - a slight change in the per protocol prescribed dose that can be used to allow for more difficult target/critical structure geometries

- Deviation Unacceptable
  - the limits beyond which plans should not go

Compliance Criteria

- Deviation Unacceptable
  - The deviation unacceptable dose limits should clearly indicate the penalty associated with generating a plan falling in this category
    - Should they impact on institution's data score?
    - Should we use Rapid Review to avoid plans falling in this category?

Conclusion

- Dose prescriptions for cooperative group protocols are different
- Compliance Criteria are an essential part of the cooperative group protocol prescription
  - Institutions are encouraged to find Per Protocol treatment planning solutions
  - Creating plans with Variations Acceptable is discouraged
  - Penalties should be assigned for plans that are judged as Deviation Unacceptable