

Data-driven control in multi-institutional clinical trials



The Premise of my Talk

1. Clinical trials are scientific research where the more accurate the data, the clearer the true outcomes of the trial can be determined.
2. It is not acceptable to permit mediocre patient care. We should all strive to do better.
3. Radiation Oncology is based on the physical sciences and as such is quantifiable.



Single Institution vs. Multi-institution

The inclusion of trial data from many institutions increases variability in the delivery of a therapeutic radiation dose regardless of the protocol specifications.

1. contouring targets and healthy tissue
2. different dose calculation algorithms
3. different delivery machines
4. human interpretation and errors, etc.

Best example: RTOG 0617 std dose vs higher dose in the lung
single inst – higher dose better survival
multi institution – lower dose better survival

There's a need for consistency that QA can bring.

Quality in Radiation Oncology

- Radiation Oncology is versatile, complicated and important for many patients
- Intuitively, quality is very important
 - deliver the correct dose to the correct place
- Achieving optimal quality can be challenging as complexity increases
- Yet in Radiation Oncology we can quantify the delivery and its quality



What do we hope to achieve with Quality Assurance and Peer Review?

- Improve the accuracy of dose delivery to the intended location
- Compliance with protocol specifications
- Ensure the best possible treatment for our patients
- Improve outcomes from clinical trials
- Avoid errors and enhance patient safety
- Learn from our mistakes



KBP in Clinical Trials

- 1 NCTN Trial includes KBP
 - 176 cases have had KBP reports run
 - 15% of case were required to re-optimize their plan. Of which :
 - 3 were due to PTV or CT having unacceptable deviation
 - 23 were due to the OAR receiving an unacceptable deviation
- 5 NCTN Trial utilize KBP reports retrospectively

Knowledge-based Plan Quality Feedback Report

Dosimetric Analysis Summary:

Structure	dose criteria	KBP feedback statement
PTV 4500	All metrics meet protocol specifications	Some dose metrics could likely be improved
Bone Marrow Act	Some unacceptable deviations	Plan could be improved to meet protocol specifications
Bone Marrow	Some unacceptable deviations	Plan could be improved to meet protocol specifications
Bowel	Some acceptable deviations	Some dose metrics could likely be improved
Rectum	All metrics meet protocol specifications	Some dose metrics could likely be improved
Bladder	Some acceptable deviations	Plan could be improved to meet protocol specifications
Femurs	All metrics meet protocol specifications	Some dose metrics could likely be improved

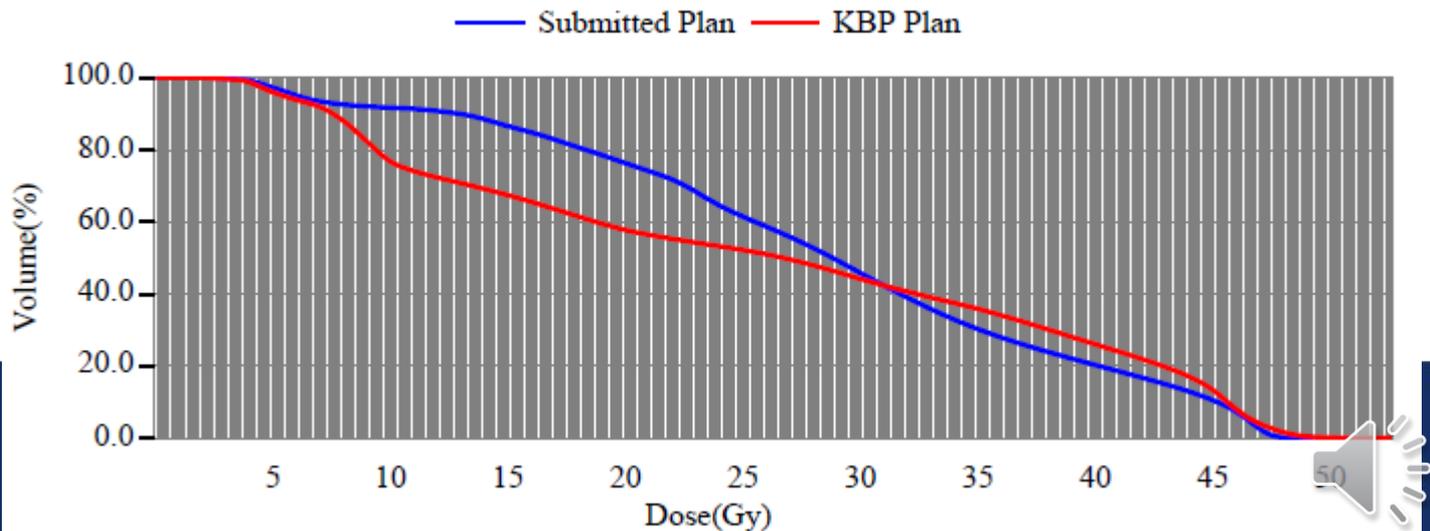
PTV

Structure: PTV 4500						
Dosimetric Parameter	Submitted Plan	NRG-GY006 protocol compliance criteria			Knowledge_based plan quality check	
		Per Protocol	Variation Acceptable	Deviation Unacceptable	KBP Plan	KBP Feedback
D95%(Gy)	44.97*	≥ 45.00	≥ 43.65	< 43.65	45.00	Plan meets per protocol specifications and is unlikely to be improved further
D97%(Gy)	44.52	≥ 43.65	≥ 40.5	< 40.5	44.78	Plan meets per protocol specifications, but this dose metric could likely be improved further
D99%(Gy)	43.77	≥ 40.5	≥ 39.6	< 39.6	44.17	Plan meets per protocol specifications, but this dose metric could likely be improved further
DMax(Gy)	50.23	≤ 51.75	≤ 54	> 54	50.71	Plan meets per protocol specifications and is unlikely to be improved further

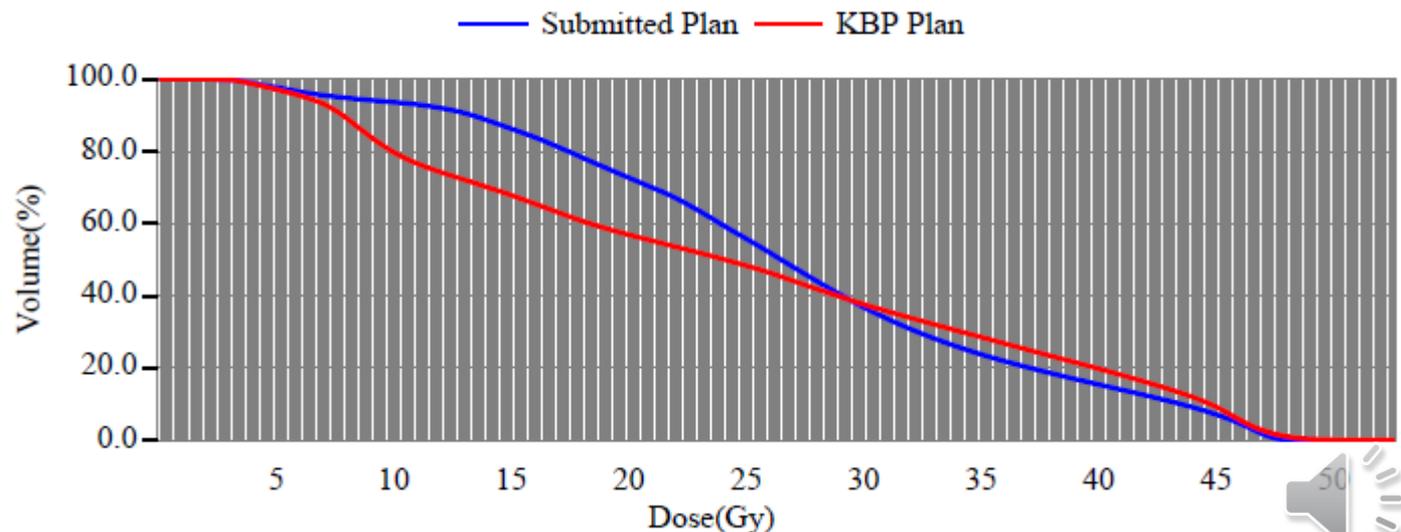
* Values within 0.1% of the threshold value are rounded up/down to the threshold for comparison

Structure: Bone Marrow Act

Dosimetric Parameter	Submitted Plan	NRG-GY006 protocol compliance criteria			Knowledge_based plan quality check	
		Per Protocol	Variation Acceptable	Deviation Unacceptable	KBP Plan	KBP Feedback
DMeanGy)	28.48	≤28.5	≤30	>30 (or KBP prediction)	26.05	Plan meets per protocol specifications, but this dose metric could likely be improved further
V10(%)	91.71	≤90%	≤90%	>90% (or KBP prediction)	76.75	Plan exceeds unacceptable variation but this dose metric could likely be improved to meet per protocol specifications
V20(%)	76.30	≤70%	≤75%	>75%(or KBP prediction)	57.76	Plan exceeds unacceptable variation but this dose metric could likely be improved to meet per protocol specifications



Structure: Bone Marrow						
Dosimetric Parameter	Submitted Plan	NRG-GY006 protocol compliance criteria			Knowledge_based plan quality check	
		Per Protocol	Variation Acceptable	Deviation Unacceptable	KBP Plan	KBP Feedback
DMeanGy)	26.96	≤27	≤29	>29 (or KBP prediction)	24.79	Plan meets per protocol specifications, but this dose metric could likely be improved further
V10(%)	93.63	≤85.5%	≤90%	>90% (or KBP prediction)	79.76	Plan exceeds unacceptable variation but this dose metric could likely be improved to meet per protocol specifications
V20(%)	72.73	≤66%	≤75%	>75% (or KBP prediction)	56.91	Plan exhibits acceptable variation but this dose metric could likely be improved to meet per protocol specifications



Dosimetric Analysis Summary:

Revised KBP

Structure	NRG GY006 dose criteria	KBP feedback statement
PTV 4500	Some acceptable deviations	Plan could be improved to meet protocol specifications
Bone Marrow Act	All metrics meet protocol specifications	Some dose metrics could likely be improved
Bone Marrow	All metrics meet protocol specifications	Some dose metrics could likely be improved
Bowel	Some acceptable deviations	Some dose metrics could likely be improved
Rectum	Some acceptable deviations	Plan could be improved to meet protocol specifications
Bladder	Some acceptable deviations	Some dose metrics could likely be improved
Femurs	All metrics meet protocol specifications	Some dose metrics could likely be improved

Dosimetric Analysis Summary:

Original KBP

Structure	dose criteria	KBP feedback statement
PTV 4500	All metrics meet protocol specifications	Some dose metrics could likely be improved
Bone Marrow Act	Some unacceptable deviations	Plan could be improved to meet protocol specifications
Bone Marrow	Some unacceptable deviations	Plan could be improved to meet protocol specifications
Bowel	Some acceptable deviations	Some dose metrics could likely be improved
Rectum	All metrics meet protocol specifications	Some dose metrics could likely be improved
Bladder	Some acceptable deviations	Plan could be improved to meet protocol specifications
Femurs	All metrics meet protocol specifications	Some dose metrics could likely be improved



Revised KBP - PTV

Structure: PTV_4500						
Dosimetric Parameter	Submitted Plan	NRG-GY006 protocol compliance criteria			Knowledge_based plan quality check	
		Per Protocol	Variation Acceptable	Deviation Unacceptable	KBP Plan	KBP Feedback
D95%(Gy)	44.98*	≥ 45.00	≥ 43.65	< 43.65	45.00	Plan meets per protocol specifications and is unlikely to be improved further
D97%(Gy)	44.55	≥ 43.65	≥ 40.5	< 40.5	44.78	Plan meets per protocol specifications, but this dose metric could likely be improved further
D99%(Gy)	43.51	≥ 40.5	≥ 39.6	< 39.6	44.17	Plan meets per protocol specifications, but this dose metric could likely be improved further
DMax(Gy)	51.82	≤ 51.75	≤ 54	> 54	50.71	Plan exhibits acceptable variation but this dose metric could likely be improved to meet per protocol specifications

* Values within 0.1% of the threshold value are rounded up/down to the threshold for comparison

Summary

- Multi-institutional trials increases variability in the delivery of a therapeutic radiation dose regardless of the protocol specifications.
- Continuous investigation into the use of KBP as a QA tool for NCTN clinical trials.



Thank You Questions?

