

Introduction

After passage of the Accountable Care Act (ACA) in 2010, much has been said about the need to optimize the way care is delivered, placing patient safety, quality of care, and cost reduction at the forefront. In keeping with these goals, treatment directives aimed at creating more uniform, standard measures of care are increasingly being utilized - with clinical guidelines such as those prepared by the National Comprehensive Cancer Network (NCCN) having been developed as decision trees that have come to play a major role in defining clinical oncologic care. In many instances, however, the descriptions concerning the delivery of radiation therapy in particular seem to fall short of clear instruction - lacking detail such as target dose, fractionation schemes, clinical set-up, nursing instructions, and dose constraints. The Radiation Therapy Oncology Group (RTOG) treatment protocols offer the clearest and most direct treatment pathways in radiation oncology; yet, they only reflect a small sampling of disease treatments and are not generally used outside of clinical trials.

Four factors in general come to mind when thinking about the factors that impact how radiation therapy is delivered: treatment directives, treatment assessments, billing management, and patient safety. For a rational approach towards developing a meaningful outcomes-oriented practice, there needs to be a better integration of these factors in terms of standardization, optimization, cross-linking and automation. Such efforts and studies are lacking in the literature and constitute the focus of this work.

Treatment directives are related to planning the actual course of treatment, but components of a treatment plan (image fusion, patient positioning, contouring, meeting target and normal dose constraints, etc.) are subject to great inter-physician variability. In terms of treatment assessments, the apparent loss of standardization of care during the course of treatments as well as with follow-ups hinders the ability to assess outcomes based on standards of treatment in the community outside of clinical trials, where the treatment of each patient enrolled in the study must be uniform. Related to billing management, Radiation Oncology Business Management (ROBM) companies have been increasingly dictating care as an effort to control the 'cost of care' as a value-add to the managed care industry and focus on minimal acceptable care standards for a given disease, which are not necessarily the best treatments available. And in an even broader context, due to the increasing complexity in both treatment planning and delivery, patient safety must be renewed and incorporated in practice in a more effective way.

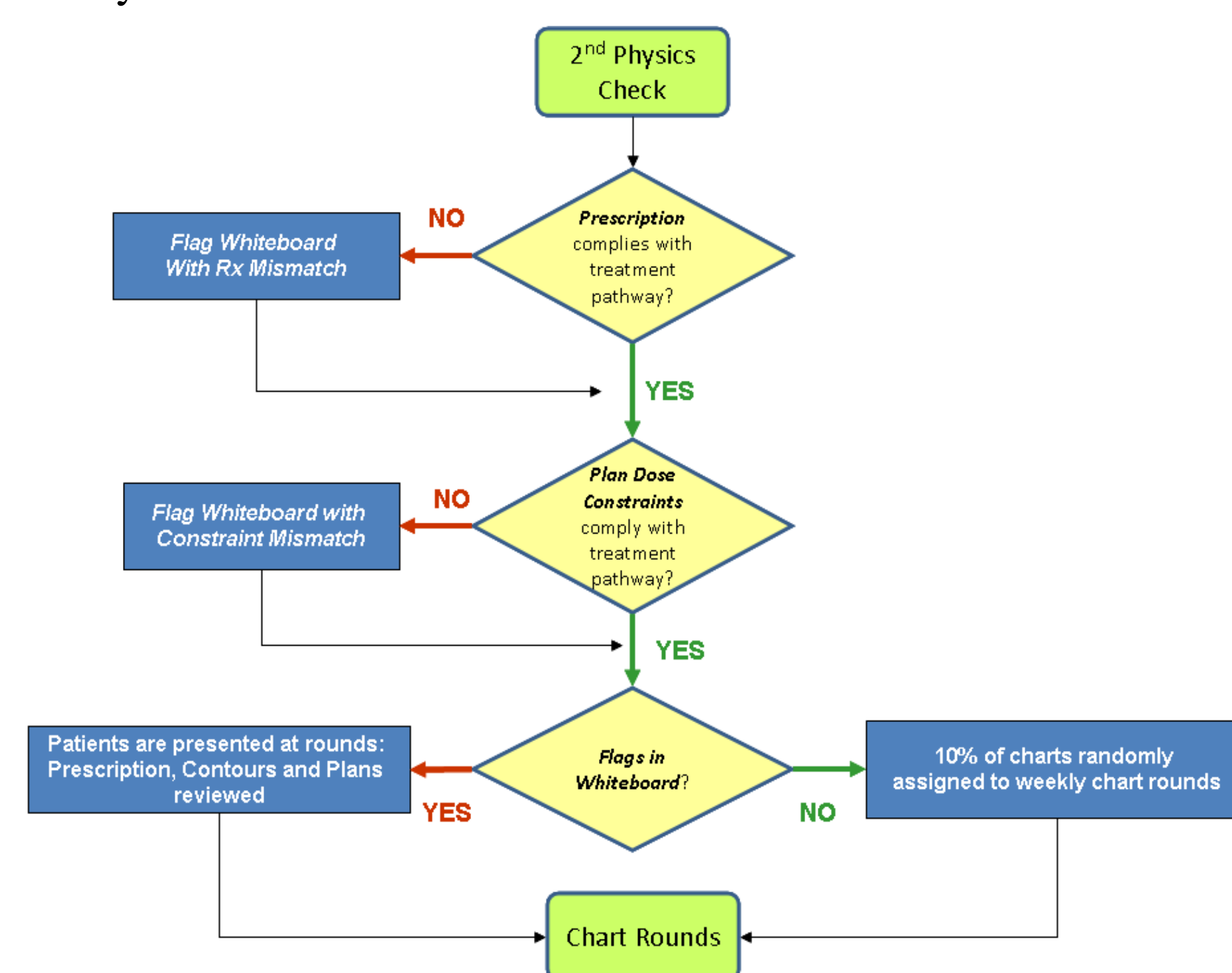
In this study, we report on the initial institution of our constructed pathways and our physician compliance with them, with the ultimate goal of standardizing care within our multi-institutional department thereby increasing efficiency, effectiveness, and patient safety. We outlined the process of developing evidence and consensus-based, outcomes-oriented treatment pathways that represent the amalgamation of treatment directives, assessments, and billing management. With respect to patient safety, we have previously developed several initiatives that apply more broadly to all treatments we administer.

Methods

Starting in 2007, the Department of Radiation Medicine at North Shore-LIJ Health System began the process of developing consensus-based treatment pathways based on the Institute of Medicine (IOM) outline for guideline development. A Guideline Committee was formed and charged with creating pathways based on a standard outline, taking into account evidence based treatment options, that would define all aspects of radiation therapy specific to that pathway. The pathways include: the treatment directive, which is composed of details on the prescription, including treatment site, technique, modality, prescribed dose, daily fraction dose, number of fractions, and treatment schedule; treatment planning parameters, inclusive of contouring definitions, and dose constraints to all targets and normal tissue; and treatment assessments, which include on-treatment nursing instructions, and survivorship details including a follow-up schedule and post treatment testing.

Each pathway was then distributed to all faculty and staff within the department for feedback, and a second final review by the committee was performed prior to inclusion in our electronic medical record. After a directive and assessment standard has been completed and approved, billing guidelines are established using CPT codes. All the implemented pathways are reviewed quarterly and modified based on real-life clinical issues that arise or as the evidence for a given pathway changes. The pathways were also reviewed in 2010 and updated based on the recommendations of the QUANTEC review that summarized dimensional dose/volume/outcome data for many organs that were refined in terms of normal tissue dose/volume tolerances.

Analytics of our paperless EMR environment for both breast and prostate cancer were performed to assess compliance with our constructed pathways. For quantitative analysis on the initial phase of implementation, we mined our EMR for patients with stage I/II cancer of the breast and prostate, and using the CPT code library for each pathway as well as the billing records, we established compliance of that pathway for each patient. Non-compliant patient charts were manually reviewed during routine weekly chart rounds.



Results

Between 2007 and 2010, a total of 67 treatment pathways were developed and implemented within the EMR of our department.

Given our retrospective analytic analysis of EMR data, overall compliance of breast and prostate cancer protocols was found to be 96% and 99%, respectively. The reason for non-compliance proved to be either a failure to complete the prescribed care based on grade II or III toxicity (n=6 breast, 3 prostate) or patient elected discontinuance of care (n=2 breast, 1 prostate).

Compliance of Prostate Cancer therapy based on treatment pathway dose and fractionation June 2010-June 2011

Prostate Pathways	Treatment Outline	n=348	%
Brachytherapy	Pd-103 to 145 Gy	84	28%
EBRT alone	81 Gy in 45 fractions	124	42%
	50.4 Gy in 28 fractions with 100Gy		
EBRT+Brachy	Pd-103	25	8%
RTOG 0815 EBRT*		8	3%
RTOG 0815 EBRT+Brachy*		12	4%
Post Prostatectomy	70.2 Gy in	30	10%
SBRT*	50 Gy in 5 fractions	5	2%
0415 28Fx*	70 Gy	2	1%
0415 41Fx*	73.8 Gy in 41 fractions	0	0%
Active Surveillance		54	18%
non-compliant		4	1%

*All patients consented to IRB study

Compliance of Breast Cancer therapy based on treatment pathway dose and fractionation June 2010-June 2011

Breast Directive	Fractions	n=222	%
Mammosite	5	14	6%
Canadian fractionation	16	69	31%
(+ Boost)	21	10	5%
200cGy/fx whole breast	25	19	9%
(+ Boost)	30	87	39%
180cGy/fx whole breast	26	0	0%
(+ Boost)	31	0	0%
180cGy/fx whole breast	28	5	2%
(+ Boost)	33	10	5%
non-compliant		8	4%

Bibliography

- Batumalai V, Koh ES, Delaney GP, Holloway LC, Jameson MG, Papadatos G, Loneragan DM. Interobserver variability in clinical target volume delineation in tangential breast irradiation: a comparison between radiation oncologists and radiation therapists. *Clin Oncol (R Coll Radiol)*. 2011 Mar;23(2):108-13.
- Emami B, Lyman J, Brown A, Coia L, Goitein M, Munzenrider JE, Shank B, Solin LJ, Wesson M. Tolerance of normal tissue to therapeutic irradiation. *Int J Radiat Oncol Biol Phys*. 1991 May;21(1):109-22.
- Fowler JF, Bewley DK, Morgan RL, Silvester JA, Alper T, Hornsey S. Dose-effect relationships for radiation damage to organized tissues. *Nature*. 1963 July;199:253-5.
- Kapur A, Potters L. Six Sigma tools for a patient safety-oriented, quality-checklist driven radiation medicine department. *Prac Radiat Oncol*. 2012 Apr;2(2):86-96.
- Pavy JJ, Denekamp J, Letschert J, et al. EORTC late effects working group. Late effects toxicity scoring: the SOMA scale. *Radiother Oncol* 1995;35:11-60.
- Potters L, Kapur A. Implementation of a "No Fly" safety culture in a multicenter radiation medicine department. *Prac Radiat Oncol*. 2012 Jan;2(1):18-26.

Conclusions

At its core, this study demonstrates that consensus and evidence-based treatment pathways can be developed and implemented in a multi-center department of radiation oncology with high degrees of compliance. The development and implementation of these pathways serves as a key component of our safety program, most notably in our effort to facilitate more consistent decision-making and reducing variation between physicians.

The pathways we developed provide the foundation for a physician to manage a treatment plan that is both evidence and consensus based, which can then be clinically managed both during and after treatment. Importantly, they provide the prescription and dosages necessary for that treatment as well as detailed instructions on how to manage the patient after the pathway has been selected. Furthermore, the rationale for these pathways is based upon the recommendations proposed by the Institute for Safe Medical Practices (ISMP), a federally certified non-profit organization devoted to patient safety in healthcare.

One of the obvious pitfalls of creating treatment directives such as these is the possibility of losing the personalized manner of delivering care that our institution strives for - creating boxes that each patient must fit into in order to receive proper care. But the pathways seem to serve more as a care library than a rigid case specific management plan - the use of these pathways was encouraged but not mandated and allowed the physician to edit the directives in order to cater to each patient's individual needs. The use of these pathways also does not obviate the role of peer review, such as chart rounds, and as new methods for automating patient auditing are implemented, peer review methods will be developed to include those patients that were treated outside of pathways or those that were non-compliant.

Having implemented these pathways directly into the EMR allows for the ease of selecting and optimizing treatment parameters for each patient and they surely serve as a means of creating standard approaches for a specialty that offers a wide variety of subjective treatment options that can often lead to misunderstanding and confusion. Direct input and transparency from all aspects of the department, including nursing, dosimetry and physics, when developing the pathways has allowed for a much better understanding of key issues that may be encountered when dealing with both routine and complex cases and has improved overall efficiency, compliance, and resource utilization. Essentially, these pathways serve as a bridge between the medical decision process and the technical process of treatment delivery, providing a working foundation for the entire patient experience.

We are currently working with several other departments on further validation of our created pathways and for any additional input, as well as the possibility of standardizing care within the partnered institutions. Our report may serve as a catalyst for other departments to consider pathways as a viable alternative to a more subjective approach to treatment. If a more generalized consensus can be reached across several departments, this could have a profound effect on the safe delivery of radiation, especially since traditional guidelines present appropriateness of treatment, but often do not offer detailed therapy directives.