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A consensus-based, process commissioning template for high-dose-rate gynecologic treatments

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ABSTRACT

PURPOSE: There is a lack of prescriptive, practical information for those doing the work of commissioning high-dose-rate (HDR) gynecologic (GYN) treatment equipment. The purpose of this work is to develop a vendor-neutral, consensus-based, commissioning template to improve standardization of the commissioning process.

METHODS AND MATERIALS: A series of commissioning procedures and tests specific to HDR GYN treatments were compiled within one institution. The list of procedures and tests was then sent to five external reviewers at clinics engaged in HDR GYN treatments. External reviewers were asked to (*1*) suggest deletions, additions, and improvements/modifications to descriptions, (*2*) link the procedures and tests to common, severe failure modes based on their effectiveness at mitigating those failure modes, and (*3*) rank the procedures and tests based on perceived level of importance.

RESULTS: External reviewers suggested the addition of 14 procedures and tests. The final template consists of 67 procedures and tests. ''Treatment process'' and ''staff training'' sections were identified as mitigating the highest number of commonly reported failure modes. The mean perceived importance for all procedures and tests was 4.4 of 5, and the mean for each section ranged from 3.6 to 4.8. Sections of the template that were identified as mitigating the highest number of commonly reported failure modes were not assigned the highest perceived importance.

CONCLUSION: The commissioning template developed here provides a standardized approach to process and equipment commissioning. The discord between perceived importance and mitigation of the highest number of failure modes suggests that increased focus should be placed on procedures and tests in ''treatment process'' and ''staff training'' sections.

Keywords: HDR; GYN; Commissioning; Standardization; Process

Introduction

Worldwide, cervical cancer is the fourth most common cancer in women and the second leading cause of cancer death in women, with 85% of the global burden occurring in less developed regions (1). Brachytherapy is a crucial part of the effective treatment of locally advanced cervical cancer and other gynecologic malignancies. A patterns of care study by Han *et al.* (2) concluded that ''Brachytherapy use is independently associated with significantly higher cause-specific survival and overall survival and should be implemented in all feasible cases.'' In addition, a recent editorial in the Red Journal was pointedly titled ''Curative radiation therapy for locally advanced cervical cancer: brachytherapy is NOT optional'' (3). These studies,

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combined with cervical cancer incidence statistics and the global effort to provide improved access to radiation therapy (4), mean that, at least globally, numerous high-dose-rate (HDR) gynecologic (GYN) brachytherapy programs are likely to be established in the coming years (even if brachytherapy use in the United States continues to decrease). It is also likely, and unfortunate, that each of these new programs will have to design and implement their own commissioning plan. This duplication of work is not only wasteful, it is potentially dangerous since important steps in the commissioning process may be missed or forgotten. The purpose of the current work is to fill the void in published, practical guidance on commissioning an HDR GYN brachytherapy program.

This is not to say that guidance for HDR brachytherapy does not exist in the literature. In fact, there is an abundance of very well-written, well-thought-out articles on HDR treatment process and quality assurance. While useful, none of these offer a practical, prescriptive approach to the process of commissioning an HDR unit for the treatment of GYN malignancies (5–17). This is despite a publication by Thomadsen *et al.* (12) that lists "Commissioning of the treatment unit, treatment planning system and each new source…" second in a list that describes "Key measures to avoid catastrophic failures" in HDR brachytherapy.

With the goal of reducing workload and standardizing the process of commissioning an HDR unit for GYN treatments, we have developed a simple, practical commissioning template. Although many of the procedures and tests presented in the template could be equally well applied to commissioning for other types of HDR brachytherapy, we have chose to focus our efforts on GYN treatments. Every effort has been made to ensure that the procedures and tests presented in the commissioning template are both vendor and isotope (^{192}Ir vs. ^{60}Co) neutral. Descriptions of procedures and tests are designed to be sufficiently detailed to allow the user of the tool to understand what is required, but generic enough that vendor-specific detail is not required. In an effort to facilitate the use of the tool and offer some guidance on the general utility of each procedure and test, a commissioning template and description of each of the procedures and tests is included in the appendices.

To demonstrate/validate the utility of each of the procedures and tests, expert reviewers were asked to rate the perceived importance of each procedure and test on a scale of 1–5 and to link procedures and tests to commonly reported or hypothesized severe failure modes. The list of failure modes used in for this purpose was derived from the reviews by Thomadsen *et al.* (18) and Richardson (19) of HDR incidents and the prospective hazard analysis by Wilkinson *et al.* (20). A summary of these failure modes, and the failure mode categorization used in the current work, is presented in Table 1.

Methods

A series of commissioning procedures and tests specific to HDR GYN brachytherapy treatments was compiled within the institution of authors DB, SS, and DS. This list is presented in Table 2 (Table 2 does present the final commissioning template—the final commissioning template is presented in Appendix A). The list of procedures and tests was vetted internally and then sent to a panel of external reviewers from academic ($n = 3$) and nonacademic ($n = 2$) clinics engaged in HDR GYN brachytherapy treatments. Internal reviewers (DB, SS, and DS) and external reviewers were asked (*1*) to review the recommended procedures and tests and to suggest deletions, additions to tests, and improvements/modifications to procedure and test descriptions, (*2*) to link procedures and tests to failure mode categories derived from commonly reported and hypothesized severe failure modes presented in the literature, and (*3*) to rank the procedures and tests based on perceived level of importance.

Deletions, additions, and improvements—Suggested procedure and test additions, deletions, and description improvements were incorporated into the final commissioning template. The final commissioning template is presented in Appendix A.

Linking procedures and tests to failure modes—To identify the effectiveness of the proposed procedures and tests reviewers were asked to assign, where appropriate, a failure mode category from Table 1 (listed as categories 1 through 8) to each procedure and test. Reviewers were not forced to assign failure mode categories if none were relevant and were free to assign multiple failure mode categories where appropriate.

Rating the perceived importance of procedures and tests—To determine the perceived level of importance of each procedure and test, reviewers were asked to rank these on an arbitrary scale of 1–5 (1 being not important, 5 being extremely important). In this context, perceived importance is a qualitative assessment made by the reviewers in regard to the perceived intrinsic value of the test.

Results

The original template contained 53 procedures and tests and the final, vetted version of the commissioning template is comprised of 67 procedures and tests, grouped into eight sections. Reviewers suggested the addition of 14 procedures and tests, whereas no procedures or tests were suggested for deletion. Table 2 presents the original list of procedures and tests with the associated number of failure mode categories and mean perceived importance rank. The mean perceived importance for all procedures and tests was 4.4 of 5, and the mean for each section ranged from 3.6 to 4.8. The six procedures and tests unanimously ranked with a perceived importance of 5 of 5 were (*1*) source