



Limitations in learning: How treatment verifications fail and what to do about it?

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ABSTRACT

PURPOSE: The purposes of this study were: to provide dialog on why classic incident learning systems have been insufficient for patient safety improvements, discuss failures in treatment verification, and to provide context to the reasons and lessons that can be learned from these failures.

METHODS AND MATERIALS: Historically, incident learning in brachytherapy is performed via database mining which might include reading of event reports and incidents followed by incorporating verification procedures to prevent similar incidents. A description of both classic event reporting databases and current incident learning and reporting systems is given. Real examples of treatment failures based on firsthand knowledge are presented to evaluate the effectiveness of verification. These failures will be described and analyzed by outlining potential pitfalls and problems based on firsthand knowledge.

RESULTS: Databases and incident learning systems can be limited in value and fail to provide enough detail for physicists seeking process improvement. Four examples of treatment verification failures experienced firsthand by experienced brachytherapy physicists are described. These include both underverification and oververification of various treatment processes.

CONCLUSIONS: Database mining is an insufficient method to affect substantial improvements in the practice of brachytherapy. New incident learning systems are still immature and being tested. Instead, a new method of shared learning and implementation of changes must be created. © 2017 American Brachytherapy Society. Published by Elsevier Inc. All rights reserved.

Keywords:

Brachytherapy; Treatment verification; Patient safety; Error reporting; Risk management

Introduction

Treatment verification is a quality control measure to assess the patient's overall treatment quality. The verification may involve the authentication of a variety of patient-specific parameters, such as those that are dosimetric, geometric, or patient safety oriented. Examples include confirming either the calculated dose to the patient or the localization of the patient relative to the planned treatment geometry. Patient geometry verification may be routine CT scanning of the cervix in patients to observe changes in bladder and rectal filling or *in vivo* dosimetry using fiber optics (1). Applicator-specific verification might

be as simple as a length verification check or as complex as electromagnetic tracking of needles during prostate high-dose-rate (HDR) brachytherapy (2). Much work has been done in terms of source-position and seed-position verification, including the use of diamond detectors and the use of portal imaging (3, 4). It may also involve treatment checklists, patient time-out procedures, and other related safety tasks. As reported by Williamson, most brachytherapy guidance focuses on testing of devices, although individual patient treatment quality assurance and the overall treatment process receive much less emphasis (5). With the American Association of Physicists in Medicine release of Task Group-100 and associated risk management processes, the spotlight of the role of a clinical medical physicist can evolve from one who manages equipment quality assurance to one who manages the patient's process quality management.

Through methods such as these, one attempts to ensure that the treatment of the patient will be performed both

Received 10 January 2017; received in revised form 22 September 2017; accepted 1 October 2017.

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safely and efficaciously. Contrarily, prolonged treatment verification may have diminishing returns. For example, historically, CT or MRI may not be performed for every fraction for vaginal cuff brachytherapy (6). The logic behind this may be sound in nature: in skipping routine scanning, the patient may be treated more quickly and may have the discomfort from the applicators for a shortened time as well as minimization of patient movement. The changes in the dosimetry due to small variations in the patient's anatomy may not be clinically significant. Alternatively, there are opinions that the need for individual fraction imaging is imperative (7, 8). Other than regulatorily required tests (that, by themselves, are not sufficient for quality or safety), the idea of which treatment verifications are important to perform and which are potentially unnecessary may be unclear to a brachytherapy physicist, particularly if they lack experience. Adding to the complexity is that brachytherapy treatments are typically rushed—for example, because of the discomfort of the patient from needles or applicators that are inserted or because of procedures occurring outside the department that requires collaborative scheduling (e.g., microspheres in interventional radiology, prostate implants in the operating room). Patient treatment plans may be performed without per-fraction imaging because the planning systems do not require the use of CT (or other) images to perform dwell-time calculations. The use of standardized plans has been a routine not only for speed but, in contrast, also for safety purposes (9, 10). Depending on the perspective, the gains from a standardized plan may outweigh those from a personalized treatment plan. For patient target delineations that might benefit from the use of MRI, the lack of in-house or department-specialized machines can be used as justification for omitting magnetic imaging. By eliminating patient-specific imaging, the patient may be treated more quickly at the risk that some problems may go undetected. Physicists know that quality control tests must be performed, but the decision process is inherently complicated because of the juxtaposition of efficiency and compromised safety. Knowing the correct balance can be problematic, which will be demonstrated in the examples given in the case studies section later.

Under some circumstances, all seemingly reasonable treatment verifications are performed and yet errors still occur. Perhaps, the person performing the verification does not realize the error or does not realize the severity of the problem. An example from the database of the U.S. Nuclear Regulatory Commission (NRC) shows a reported medical event involving partial-breast brachytherapy. The patient was being treated with a new (to the institution) applicator. Although a representative of the device manufacturer was there to help “guide” the treatment, the physicist measuring the length of the transfer guide tube and applicator performed the measurement incorrectly. With no known standard and a paucity of shared or printed information from the manufacturer, the physicist entered the wrong

treatment length for the patient. According to the report, the physicist even expressed concern about the length to the representative, who reassured them that it “sounded right.” Subsequently, the patient was irradiated laterally from the expected area resulting in dose that missed the target volume and irradiated unintended normal tissue (11). Other reports show incorrect positioning of the source relative to the applicator with unplanned doses in the 100–130 Gy range (12). Although this error was reported in a public event reporting database, it is well established that length measurement and length entry errors still occur on a regular basis. In the four fiscal years 2010–2014, there were four very similar events reported in the NRC's database.

The use of automatic forcing functions and interlocks needs to be increased in brachytherapy, but many quality control tests still require a physicist's judgment and execution. Even when appropriate tests are performed and verified, veracity may elude detection due to circumstances beyond control or imagination. Physicists are faced with the pressure to reduce the time to treatment and shorten, eliminate, and streamline quality assurance- and quality control-related tasks, while still providing an accurate and safe treatment. In addition, incident learning has been stressed recently because of an abundance of well-publicized medical events in the past decade. However, the path to “learn from others' mistakes” is shrouded as will be subsequently described. Consequently, the same errors are duplicated, such as the dosimetry output factor for a specific machine type that occurred with severe consequences both in France in 2006 and in Missouri in 2010 (13, 14). The fact that these errors were not known to every user supports that merely “reporting” an error is not enough. The potential for treatment verification improvement must be raised by demystifying error reporting and particularly improving the knowledge gains through incident learning systems. In this context, how can physicists incorporate, improve, and advocate for appropriate treatment verification to be performed for brachytherapy patients?

Methods and materials

Information from events, and sometimes from close calls to events, may be entered in several databases. The types of information that can be accessed from the different databases vary. One may submit events into databases in hopes of warning or alerting others for problems they have encountered, or one may hope to review incidents reported by others in an attempt to improve patient safety at their own institution. However, as described in the following, the conventional databases may not be as efficient or effective at transferring knowledge as one might think, particularly for brachytherapy incidents.

Nuclear Material Event Database (NMED) operated by the NRC gathers information on any event involving radioactive materials that surpass the threshold defined in Title

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