



## Does compliance to patient safety tasks improve and sustain when radiotherapy treatment processes are standardized?

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### A B S T R A C T

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**Purpose:** To realize safe radiotherapy treatment, processes must be stabilized. Standard operating procedures (SOP's) were expected to stabilize the treatment process and perceived task importance would increase sustainability in compliance. This paper presents the effects on compliance to safety related tasks of a process redesign based on lean principles.

**Method:** Compliance to patient safety tasks was measured by video recording of actual radiation treatment, before ( $T_0$ ), directly after ( $T_1$ ) and 1.5 years after ( $T_2$ ) a process redesign. Additionally, technologists were surveyed on perceived task importance and reported incidents were collected for three half-year periods between 2007 and 2009.

**Results:** Compliance to four out of eleven tasks increased at  $T_1$ , of which improvements on three sustained ( $T_2$ ). Perceived importance of tasks strongly correlated (0.82) to compliance rates at  $T_2$ . The two tasks, perceived as least important, presented low base-line compliance, improved ( $T_1$ ), but relapsed at  $T_2$ . The reported near misses (patient-level not reached) on accelerators increased ( $P < 0.001$ ) from 144 (2007) to 535 (2009), while the reported misses (patient-level reached) remained constant.

**Conclusions:** Compliance to specific tasks increased after introducing SOP's and improvements sustained after 1.5 years, indicating increased stability. Perceived importance of tasks correlated positively to compliance and sustainability. Raising the perception of task importance is thus crucial to increase compliance. The redesign resulted in increased willingness to report incidents, creating opportunities for patient safety improvement in radiotherapy treatment.

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### Introduction

The risk for patients being harmed from radiotherapy treatment is relatively low, when compared to other medical specialities (Munro, 2007). Although radiotherapy presents a long history with quality assurance, treatment errors still reach the patient-level (Clark et al., 2010; Shafiq et al., 2009). A considerable percentage of errors in

radiotherapy are due to errors in treatment set-up and delivery (Valentin, 2000). To assure quality and safety, protocols and procedures are mentioned as important elements and their absence or inadequacy are associated with errors (Pawlicki et al., 2011; Thwaites et al., 1995). Therefore, clearly stated protocols are one of the required aspects for a quality assurance system in radiotherapy (Leer et al., 1995). However, even when procedures are in place, these are not always followed. Employees could have forgotten about the procedures or were possibly not aware of the consequences of non-compliance (Dunscombe, 2012). Besides increasing quality standards, demand for radiotherapy has been growing and health care cost rising (Orszag and Ellis, 2007; Slotman and Vos, 2013; Williams et al., 2007). To realize sustainable quality improvements, quality and

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efficiency should be combined. Lean management is a strategy to improve both quality and efficiency. Lean was originally developed within the Toyota Motor Company, and later diffused within the global car manufacturing industry (Womack et al., 1990). This has inspired “lean health care” (Endsley et al., 2006; McCarthy, 2006; Rutledge et al., 2010). Processes are redesigned and improved towards a customer-focused ideal state by reducing waste. Waste includes tasks that do not directly benefit the patient and can be minimised through the regular redesign of processes (Liker, 2004). However, to create a solid base for continuous (quality) improvement, first unwanted variation should be reduced and processes should be stabilized, for instance by working with standard operating procedures (SOP's). SOP's are detailed written instructions outlining the tasks needed to complete a job. SOP's are clearly essential for quality improvement, but the required level of detail has not yet been established. To balance the simplicity and completeness of SOP's is challenging (Radiology et al., 2010). Furthermore, SOP's can only stabilize a process, when employees actually work according to them. Even when SOP's are available, questions remain about employees' compliance and how these SOP's affect the quality of care or patient safety. Effects of lean interventions on the quality or patient safety are rarely quantified (DelliFraine et al., 2010; Nicolay et al., 2011; Vest and Gamm, 2009), partly because patient safety measures are difficult to define and measure and are the result of technical as well as social practices (Dixon-Woods et al., 2012; Vincent et al., 2013). Widely used methods to retrospectively evaluate patient safety include incident reporting systems and root cause analyses (Clark et al., 2010; Reason, 2000; Rex et al., 2000; Shafiq et al., 2009; van Everdingen et al., 2007). Although these techniques give organizations many improvement opportunities, they are based on voluntary reporting and probably not all errors will be reported. Therefore, these retrospective data do not report safety objectively (Capuzzo et al., 2005). More objective methods include observations to determine the process reliability (Oakley et al., 2006; Simons et al., 2010). Therefore, we observed compliance to patient safety tasks on a linear accelerator, to detect an effect of a lean based process redesign of the radiotherapy treatment process on patient safety.

We hypothesized that the redesign of a treatment process, with the implementation of detailed SOP's, would stabilize the process, resulting in improved compliance. Furthermore, we hypothesized that tasks perceived as more important by employees would present higher compliance rates and increased sustainability of improvements.

## Methods

### Setting

This study was performed in the MAASTRO clinic, a radiotherapy department in the Netherlands, where on average 200 oncology patients receive radiation therapy every day. In 2007, three multidisciplinary units operated in the clinic. Each site specific unit (e.g. breast cancer, lung cancer) consisted of radiation-oncologists, technologists and physicists.

### Redesign of the radiation treatment process

For many years, the linear accelerators were operated by three technologists. One operated the accelerator from the treatment console, while the other two positioned the patient on the treatment table (“original treatment process” in Fig. 1). General medical protocols per treatment site and technical guidelines for daily practice were available. However, these allowed considerable variation in task completion. No procedure for structured communication existed, responsibilities were not explicitly

assigned to individual technologists, and process steps were not executed in a fixed order (i.e. only the outcome of the process was fixed, not the process itself).

In January 2007, a project team of 25 (out of the 60) technologists redesigned the process for the accelerator. Waste within the process was identified (indicated by the curved brackets in Fig. 1) by visualizing the process in a flow chart. Employees discussed the added value of all separate steps/tasks. Remarkably, little waste could be defined within the tasks. However, the sequence of the tasks and their assignment to individual technologists were rearranged (“redesign of treatment process” in Fig. 1). The project team decided to design and implement a SOP for two technologists. The SOP described the task sequence and responsibility in great detail. Two units implemented the SOP in October 2007 for breast cancer patients (Fig. 2) to start with. Implementation gradually expanded and since 2010, all patients are treated by two technologists following site specific SOP's.

### Compliance measurement

To detect increased process stability and sustainability of improvements, compliance to “procedures” was observed in daily practice. Observations were recorded before the process redesign ( $T_0$ ), directly following implementation ( $T_1$ ) and 1.5 years after ( $T_2$ ). A fixed camera system was installed on one of the accelerators in January 2007. The installation was approved by the medical staff and the works council. Employees' and patients' anonymity was guaranteed to protect their privacy. Patients were informed in their changing rooms about the possible observations. To increase reliability of observations, only about 1% of the patient treatments were actually recorded and technologists were unaware when observations took place. Furthermore, only treatments for breast cancer were observed to ensure the reliability of comparisons among  $T_0$ ,  $T_1$  and  $T_2$ .

To examine the variability of the radiotherapy treatment, a detailed process description was essential. The project team had already visualised the treatment procedure of breast cancer patients (Fig. 1). Since this is only a representation of the desired situation, daily practice was evaluated by comparing this flow chart to observations of actual treatments. Two observers with more than 10 years experience in radiotherapy treatment, including the first author of this paper, determined compliance using a previously developed score list. (Simons et al., 2010) Five random radiation technologists selected 11 tasks from the score list, which should be important for patient safety (Table 1). Seven technologists specialised in patient safety and a patient safety manager, separately selected the most crucial tasks for patient safety out of the 11 from Table 1. This resulted in five most crucial tasks for patient safety (see Table 1). Compliance was measured at three moments: at  $T_0$ , where every patient was treated by three technologists and only technical guidelines were present; at  $T_1$  directly after implementing the process redesign; and at  $T_2$  1.5 years after implementation. At  $T_1$  and  $T_2$ , patients were treated by two technologists following the SOP (Fig. 2). Task compliance was measured by dividing the number of times the task was performed by the total number of times the task should be performed.

### Survey on perceived task importance

A survey was developed on the perceived importance of tasks, to test our hypothesis that a task perceived as more important by employees would result in higher compliance rates and increased sustainability. Employees from both units were asked to rate how important they perceived nine tasks on a scale from 1 to 10 (1: not important and 10 extremely important). The survey was distributed between  $T_1$  and  $T_2$  and a Spearman correlation was calculated for perceived importance and compliance to tasks at  $T_1$  and  $T_2$ .

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