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

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Keywords: Compliance
Lean management
Standard operating procedures
Incident reporting
Task importance
Patient safety

A B S T R A C T

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 (T0), directly after (T1) and 1.5 years after (T2) 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 T1, of which improvements on three sustained (T2). Perceived importance of tasks strongly correlated (0.82) to compliance rates at T2. The two tasks, perceived as least important, presented low base-line compliance, improved (T1), but relapsed at T2. 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 specialties (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
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 regular redesign of processes (Likier, 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 (SOPs). SOPs are detailed written instructions outlining the tasks needed to complete a job. SOPs are clearly essential for quality improvement, but the required level of detail has not yet been established. To balance the simplicity and completeness of SOPs is challenging (Radiology et al., 2010). Furthermore, SOPs can only stabilize a process, when employees actually work according to them. Even when SOPs are available, questions remain about employees’ compliance and how these SOPs affect the quality of care or patient safety. Effects of lean interventions on the quality or patient safety are rarely quantified (Dellifraiene 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 SOPs, 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 SOPs.

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 $T_2$. 
Fig. 1. Flow chart of the irradiation treatment process presenting the process steps in a chronological order from left to right. The original process describes the process for three technologists (Techn. 1–3), where only medical protocols per treatment site and technical guidelines for daily practice were available. The flow chart presents many process steps in between technologist two and three, corresponding the lack of clear responsibilities. The chronological order of process steps varied between treatments. The curved brackets indicate waste for the individual technologists. A project group of 25 technologists redesigned the process to a future state for two technologists (redesign of the treatment process in the flow chart). In the process redesign, the chronological order of process steps was defined (left to right in flow chart) and tasks were explicitly assigned to individual technologists.
To detect possible effects of the process redesign on patient safety, data from incident reporting were gathered. The MAASTRO clinic has been using an incident reporting system (IRS) since 2003. Data were gathered from January to September for 2007, 2008 and 2009. The number of reported incidents (adjusted for the number of patients treated) was identified for the total organization and for accelerators in specific. The reported incidents were divided into misses (incidents reaching patient-level) and near misses (incidents not reaching patient-level), since the proportion of

**Incident reporting system**

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Results from 23 surveys on the importance of tasks perceived by the employees. No results for tasks 7 and 8 could be presented (NA), because these were not included in the survey.

<table>
<thead>
<tr>
<th>Key tasks to patient safety on the linear accelerator</th>
<th>% Performed</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Read communication form before calling patient by intercom</td>
<td>23</td>
<td>0.19</td>
</tr>
<tr>
<td>2. Check special actions</td>
<td>75</td>
<td>0.02</td>
</tr>
<tr>
<td>3. Check identification photo before getting patient out of change room</td>
<td>51</td>
<td>0.08</td>
</tr>
<tr>
<td>4. Call patient by name</td>
<td>29</td>
<td>0.03</td>
</tr>
<tr>
<td>5. Ask patient's date of birth</td>
<td>95</td>
<td>0.09</td>
</tr>
<tr>
<td>6. Check position of patient's hands using patient information</td>
<td>59</td>
<td>0.45</td>
</tr>
<tr>
<td>7. Communicate verbally about quality of ink lines on patient</td>
<td>52</td>
<td>0.39</td>
</tr>
<tr>
<td>8. Execute SHIFT movement (movement of table by hand following previously determined numbers)</td>
<td>100</td>
<td>0.31</td>
</tr>
<tr>
<td>9. Cross check of SHIFT movement</td>
<td>100</td>
<td>0.21</td>
</tr>
<tr>
<td>10. Check projection of treatment field on patient's skin</td>
<td>98</td>
<td>1.00</td>
</tr>
<tr>
<td>11. Communicate verbally about bolus (tool only needed in particular patients)</td>
<td>2</td>
<td>&lt;0.001</td>
</tr>
</tbody>
</table>

Overall compliance and the mean compliance to the crucial patient safety tasks were 62% (T0), 77% (T1), 77% (T2), 63% (T0–T1), 63% (T1–T2), and 63% (T0–T2), respectively. The P-values based on chi-square tests were <0.001, 0.002, 0.08, 0.02, 0.04, and 0.02, respectively.

NA: Not Applicable.

P-values based on chi-square tests.

The five most crucial tasks for patient safety.

Significant change due to a different number of not observable scores at T0 and T1.

Due to many missing values, reported numbers were not representative for reality.

P-values based on independent t-tests, means calculated per item.

Table 1: Compliance to the most important tasks for patient safety analysed by two observers on video recordings: T0 (2007, N = 56), T1 (2007, N = 56) and T2 (2009, N = 55).

Table 2: Results from 23 surveys on the importance of tasks perceived by the employees. No results for tasks 7 and 8 could be presented (NA), because these were not included in the survey.

<table>
<thead>
<tr>
<th>Key tasks to patient safety on the linear accelerator</th>
<th>Perceived importance (N = 23)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Overall</td>
</tr>
<tr>
<td>Read communication form before calling patient by intercom 1</td>
<td>7.4</td>
</tr>
<tr>
<td>Check special actions 2</td>
<td>8.7</td>
</tr>
<tr>
<td>Check identification photo before getting patient out of change room 3</td>
<td>7.7</td>
</tr>
<tr>
<td>Call patient by name 4</td>
<td>7.4</td>
</tr>
<tr>
<td>Ask patient's date of birth 5</td>
<td>8.6</td>
</tr>
<tr>
<td>Check position of patient's hands using patient information 6</td>
<td>8.0</td>
</tr>
<tr>
<td>Communicate verbally about quality of ink lines on patient 7</td>
<td>NA</td>
</tr>
<tr>
<td>Execute SHIFT movement (movement of table by hand following previously determined numbers) 8</td>
<td>NA</td>
</tr>
<tr>
<td>Cross check of SHIFT movement 9</td>
<td>9.8</td>
</tr>
<tr>
<td>Check projection of treatment field on patient's skin 10</td>
<td>8.7</td>
</tr>
<tr>
<td>Communicate verbally about bolus (tool only needed in particular patients) 11</td>
<td>8.4</td>
</tr>
</tbody>
</table>

NA: Not Applicable.

P-values based on a Mann–Whitney U test, a non-parametric test for independent samples.

The five most crucial tasks for patient safety.

Four tasks (5, 8, 9 and 10) showed high compliance rates at T0, leaving little or no room for improvement (Table 1). These high compliance rates sustained (95% or more) throughout all measurements.

Four tasks (1, 3, 4 and 11) improved from T0 to T1 (Table 1). Two tasks (6 and 7) with moderate compliance rates did not improve. Compliance to task 2 (check special actions) improved from 74% to 94% (T2). Compliance to task 4 (call patient by name) partly relapsed from 76% to 56%. Tasks 1 and 3 also indicated a (not significant) partial relapse.

At T2, 1.5 years after implementing the SOPs, compliance to four tasks had improved. Besides the four tasks with initial high compliance rates, compliance to task 7 (communicate about ink lines) did not change, remaining moderate with 51% to T2. Compliance to task 6 (check position of patients’ hands) decreased from 59% to 49%.

Overall compliance and the mean compliance to the crucial tasks for patient safety did not significantly differ between measures.

Compliance to tasks differed little between the units, only task 4 (calling patient by name) showed differences. Compliance improved from T0 (unit 1: 19%, unit 2: 43%, P = 0.17) to T1 for both units, showing significant higher compliance for unit 2 at T1 (unit 1: 69%, unit 2: 81%, P = 0.001). However, improvement sustained for unit 1, but partially relapsed for unit 2 at T2 (unit 1: 68%, unit 2: 43%, P = 0.21), resulting in no difference in the end.

Perceived importance of tasks

In January 2008 (between compliance measurement T1 and T2), 23 surveys (52% response) on the perceived importance of tasks

Analysis

Results were adjusted for missing values and not observable scores. The overall compliance was calculated using the mean of the proportion of compliance for all tasks. T-tests were used to determine differences in overall compliances. Chi-square tests were performed on the frequencies of compliance and non-compliance per task. Results on perceived task importance were presented in means and a non-parametric test for independent samples (Mann–Whitney U test) was performed to compare both units. Correlations with compliance were analysed by Spearman coefficients. Z-tests for two proportions were calculated for the IRS results. P-values ≤0.05 were considered statistically significant.

Results

Compliance measurements

In total, 167 recordings of treatments were videotaped and analysed. At T0 (February–March 2007) 56 treatments were recorded, at T1 (September–October 2007) 56 and at T2 (February–March 2009) 55.
were returned, equally distributed over both units. Employees scored the perceived importance of recorded tasks between 7.4 and 9.8 on a scale from 1 to 10 (Table 2). They perceived task 9 (cross-check of shift movement) as most important (9.8) followed by task 2 (check of special actions: 8.7), task 10 (projection of treatment check of shift movement) as most important (9.8) followed by task 1 and partial relapse at T2. The correlation between perceived importance and compliance to tasks was 0.50 (P = 0.17) at T1 and 0.82 (P = 0.006) at T2.

Data from the incident reporting system

The number of reported incidents increased from 886 in 2007 to 1250 in 2009 (Table 3). This increase was almost entirely based on incidents related to the linear accelerators (193 in 2007 to 586 in 2009, P < 0.001). The reported incidents were differentiated into misses (incidents reaching patient-level) and near misses (incidents not reaching patient-level). The number of reported misses remained stable over the years. However, the number of reported near misses increased 10% (P < 0.001) from 2007 to 2008 and another 17% from 2008 to 2009 (P < 0.001) for the treatment process (accelerators) in specific, while remaining constant for the rest of the organization. The large increase (>40%) in overall reported incidents was almost exclusively the result of increased reporting of near misses on the linear accelerator.

Discussion

The redesign of a treatment process and the implementation of SOPs resulted in improved compliance rates to specific patient safety tasks. Improvement sustained 1.5 years after the process redesign for most tasks, as hypothesized. Only compliance to task 4 (call patient by name) partly relapsed. Overall compliance to the 11 patient safety tasks did not differ between measurements, which could be partly explained by a large variation in observations and partly because compliance to four tasks showed little or no room for improvement due to high compliance rates at base line measurement. Overall compliance (T0: 62%, T1: 77%) was below our expectation, since only tasks important for patient safety were observed. However, results conformed to compliance percentages on health care performance elsewhere (Nolan et al., 2004; Swenne and Alexandrén, 2012).

Table 3

<p>| Data from the incident reporting system at MAASTRO clinic from three time periods. |
|---------------------------------|-----------------|-----------------|-----------------|-----------------|-----------------|</p>
<table>
<thead>
<tr>
<th>Data incident reporting system (IRS)</th>
<th>Jan–Sep ’07</th>
<th>Jan–Sep ’08</th>
<th>Jan–Sep ’09</th>
<th>P (’07–’08)</th>
<th>P (’08–’09)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total reported incidents</td>
<td>886</td>
<td>907</td>
<td>1250</td>
<td>NA</td>
<td>NA</td>
</tr>
<tr>
<td>Patients treated</td>
<td>1861</td>
<td>1919</td>
<td>1822</td>
<td>NA</td>
<td>NA</td>
</tr>
<tr>
<td>Total reported incidents/patients treated</td>
<td>48%</td>
<td>47%</td>
<td>69%</td>
<td>0.85</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Reported incidents on accelerators (total incidents)</td>
<td>193 (22%)</td>
<td>279 (31%)</td>
<td>586 (47%)</td>
<td>&lt;0.001</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Total reported incidents minus accelerators</td>
<td>628</td>
<td>664</td>
<td>NA</td>
<td>NA</td>
<td>NA</td>
</tr>
<tr>
<td>Miss (total incidents)</td>
<td>49 (6%)</td>
<td>47 (5%)</td>
<td>51 (4%)</td>
<td>0.82</td>
<td>0.23</td>
</tr>
<tr>
<td>Miss (incidents on accelerators)</td>
<td>49 (25%)</td>
<td>47 (17%)</td>
<td>51 (9%)</td>
<td>0.02</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Near miss (total organization (total incidents))</td>
<td>837 (94%)</td>
<td>858 (95%)</td>
<td>1199 (96%)</td>
<td>0.90</td>
<td>0.15</td>
</tr>
<tr>
<td>Near miss (on accelerators (incidents on accelerators))</td>
<td>144 (75%)</td>
<td>232 (83%)</td>
<td>535 (91%)</td>
<td>&lt;0.001</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Ratio of miss/near miss on accelerators</td>
<td>0.34</td>
<td>0.20</td>
<td>0.10</td>
<td>&lt;0.001</td>
<td>0.003</td>
</tr>
</tbody>
</table>

NA: Not Applicable (cq not relevant).

a P-value based on z-test for two proportions.
b Miss: incident that reached the patient.
c Near miss: incident that did not reach the patient.
d P-value based on z-test for a ratio.

Perceived importance of tasks associated with sustainability of change

Perceived importance of tasks was associated with higher levels of compliance and sustainable improvement of improvements. The tasks presenting high compliance rates at T1, were perceived as highly important for patient safety. At T1, perceived importance showed only moderate correlation to compliance. At T2, correlation increased, probably because employees had been confronted with the tasks presenting a discrepancy between perceived importance and low compliance rates. To further increase employees’ awareness, non-compliance to these tasks was related to error making by presenting harmful incidents from practice. Confirming our hypothesis, the correlation to the task perceived as least important (4: call patient by name), presented only partly sustainable improvements (T0: 29%; T1: 76%; T2: 56%). When analyzed in more detail, our hypothesis was not confirmed for unit 1. Although employees from unit 1 perceived this task as less important than unit 2, they presented sustainable improvements at T2. However, employees from unit 1 presented lower initial compliance rates (T0: 29% vs. T1: 76%; T2: 56%), while remaining constant for the rest of the organization. The large increase (>40%) in overall reported incidents was almost exclusively the result of increased reporting of near misses on the linear accelerator.

Increased willingness to report on the accelerators

The employees presented a large willingness to report, since only a small percentage of the reported incidents (5%, 49 of the 886 in the
first half of 2007) actually reached the patient-level. (Shaﬁq et al., 2009) During the implementation of the process redesign, the number of reported near misses (patient-level not reached) on the accelerator increased from 144 (2007) to 535 (2009). Since the number of incidents that actually reached the patient-level (misses) and potentially harm the patient remained constant, we ascribed the increased reporting to an increased willingness to report. This creates increased opportunities for safety improvement before patients are actually harmed. More open communication due to employees’ participation in the redesign, but also process deviations being more easy to detect when processes are stabilized, could explain the increase in the reporting of near misses (Liker, 2004). Although the initial willingness to report was high, it still significantly improved after the process redesign. This corresponds to the earlier presented problems regarding the objectivity of data from voluntary reporting systems. The results from the IRS must be interpreted with caution, since these were based on patients treated for any treatment site by all three units and the observations only included treatment for patients with breast cancer by units 1 and 2.

Positive side-effects of the process redesign

The lean process redesign focussed on standardizing the treatment processes, resulting in more process stability. Furthermore, since lean aims to create continuous improvement, the project team was stimulated to standardize, but also to continuously improve the process. During the group discussions, the team developed a sticker on the patient’s file as a reminder for a special task, which resulted in a decrease of reported incidents regarding this task. The development of SOPs did not stop with the treatment process. Since the start of the redesign, SOPs were developed throughout the entire organisation. The employees’ views regarding SOPs could be positively affected by their positive experience on designing SOPs and bringing them to practice. Efficiency increased as well, as all patients are being treated by two instead of three technologists. Although every employee expressed different experiences regarding the process redesign, nearly all experienced an increased sense of responsibility, clearer expectations and a better work atmosphere.

Conclusion

In conclusion, compliance to specific patient safety tasks and willingness to report were positively affected by the introduction of SOPs and effects sustained for 1.5 years. This could potentially indicate an increased level of patient safety climate and potentially increased process stability. A major outcome of this study was the positive correlation between perceived importance of tasks and the level of compliance. This could be an important factor for realizing sustainable improvements. To further improve or sustain increased compliance rates, we recommend regular feedback to the staff on all safety related tasks to raise employees’ awareness about the importance of these tasks. Further research could study the sustainability of the present findings and study how behaviour can be institutionalized, including its potential effects on work atmosphere.

Conflict of interest statement

None declared.

References


