ISSN 1980-5411 (On-line version)
Production, 33, e20220083, 2023
DOI: 10.1590/0103-6513.20220083

Research Article

# Process management and safety culture in radiotherapy services: impacts on quality patient care and safety

José Carlos de Toledo[a]*, Livia Silveira Almeida[a], Fabiane Letícia Lizarelli[a]
[a]Universidade Federal de São Carlos, São Carlos, SP, Brasil
*toledo@dep.ufscar.br

## Abstract

**Paper aims:** Analyzes the use of process management and safety culture practices in Radiotherapy Services and impacts on quality of patient care and safety.

**Originality:** Radiotherapy processes require controls and must be developed in an environment with safety. However, despite necessary practices, there are few studies that analyze their implementation and impacts.

**Research method:** Was conducted a survey and the data were analyzed using descriptive statistics and SEM-PLS.

**Main findings:** Process management practices and safety culture have been used in response to competitive environment and regulatory guidelines. The study confirmed the positive impact of using safety culture and process management practices.

**Implications for theory and practice:** Managerial support promoting management and improvement practices and safety culture, along use of process maps, feedback in response to incident reports, patient satisfaction surveys and teamwork contributes to the quality of care and safety. These practices can be prioritized to be deployed by managers and in theoretical models.

## Keywords:
Process management. Safety culture. Radiotherapy services. Care quality. Patient safety.

**How to cite this article:** Toledo, J. C., Almeida, L. S., & Lizarelli, F. L. (2023). Process management and safety culture in radiotherapy services: impacts on quality patient care and safety. *Production*, *33*, e20220083. https://doi.org/10.1590/0103-6513.20220083

Received: July 19, 2022; Accepted: Dec. 31, 2022.

## 1. Introduction

Radiotherapy treatment is a complex process that involves extensive knowledge on the principles of medical physics, radiobiology, radiological protective measures, simulation and treatment planning (World Health Organization, 2008). The Radiotherapy Services (RS) must guarantee the technical quality of the equipment and the quality of the processes (American Society for Radiation Oncology, 2019).

Each stage of the processes must have controls to avoid errors and to ensure that patients receive the correct treatment. These procedures are related to process management and involve control and standardization procedures such as monitoring the waiting time and application of procedures, to guarantee the replication of processes (World Health Organization, 2008; Emanuel et al., 2009; American Society for Radiation Oncology, 2019). The process management includes procedures for the identification of problems and proposition of improvements, such as the use of failure analysis and prevention methods and process mapping. The application of process management methods can impact patient care and safety (American Society for Radiation Oncology, 2019).

In the same perspective the RS can develop a safety culture. The high number of preventable incidents reinforces the need to strengthen the safety culture. Patient safety is a specific in the healthcare sector that applies methods to promote safety in order to maintain a reliable health care system (Emanuel et al., 2009). Safety culture evaluations are starting points for implementing action plans aimed at improving care and reducing incidents (Gouvêa & Travassos, 2010). The safety culture practices include that employees are free report incidents, they use learning method for incidents, teamwork to improve proactively and top management supports patient safety (Simons et al., 2014; Radicchi et al., 2020). Regulatory bodies like the National Nuclear Energy Commission (CNEN) in Brazil have set forth sector policies focused on promoting the use of incident learning systems aimed at patient safety.

There has been a worldwide trend towards conducting more discussions concerning patient safety (Institute of Medicine, 2000). This concern is no different for RS, as it is a complex service and with the recurrent introduction of new technologies, specific controls are needed aimed at patient safety. Process improvements and a properly disseminated safety culture can lead to reduced treatment start times, fall risk, and ensure that equipment is always available, while also increasing patient satisfaction and quality of care (Cionini et al., 2007; Chen et al., 2015; Huq et al., 2016; Mancosu et al., 2018; López Torrecilla et al., 2019; Chang et al., 2019; Lindberg et al., 2020). Formal methods of error mitigation and process analysis are needed for improvements and learning. Incidents have led to a need for improved internal processes; this improvement seeks to impact quality of patient care and safety.

Professionals in RS must have extensive knowledge of radiotherapy processes in order to adequately assimilate to the variability of these applications, since radiotherapy treatment is generally customized. The main responsibility of the medical physicist is to ensure the accuracy, efficacy, and safety of the physical aspects of radiotherapy treatment (Huq et al., 2016; Yan et al., 2021). Furthermore, they must guarantee patient safety and the quality of radiotherapy treatment (Chen et al., 2015; Yan et al., 2021). Proper process management and a disseminated safety culture within the organization are crucial for meeting patient safety requirements to eliminate incidents involving falls and injuries (Chang et al., 2019; Lindberg et al., 2020). It is important to understand how adopting process management practices and a safety culture can impact in the performance of patient safety and quality of care in this service.

Quality of care is the commitment to improving health care systems to the achievement of desired health care outcomes (Lohr & Schroeder, 1990; Institute of Medicine, 2001). The quality of care can be measured by the level of patient satisfaction, time until the start of treatment and equipment downtime rate (Lohr & Schroeder, 1990; Institute of Medicine, 2001; Gabriele et al., 2006; van Lent et al., 2013; Liu et al., 2019). Patient safety uses scientific methods to improve the health service system improving adverse outcomes. The patient safety can be measured by incident (severe and non-severe), patient fall and non-conformity indexes (Klein et al., 2005; Vissers & Beech, 2005; National Patient Safety Foundation, 2008; Royal College of Radiologists, 2008; Williamson & Thomadsen, 2008; International Atomic Energy Agency, 2016; Radicchi et al., 2020).

Studies focused on radiotherapy process management and safety culture practices are scarce, especially in Brazil. To our knowledge, there are no publications on the use and impacts of these practices in Brazil. This article seeks to understand the relationship between process management practices and safety culture and the performance of quality of care and patient safety in RS in Brazil. A survey was conducted using an on-line questionnaire.

Section 2 presents the theoretical framework for process management, safety culture, quality of care, and patient safety. Section 3 presents the research method and model. Section 4 presents a description and analysis of the results from the field survey. Section 5 presents the analysis and conclusions.

## 2. Theoretical review

Radiotherapy can be administered alone or combined with surgery and chemotherapy. A multidisciplinary team is part of the radiotherapy treatment planning process, which includes radiotherapists, medical physicists, technologists, and nurses (American Society for Radiation Oncology, 2019). The purpose of radiotherapy is to achieve maximum tumor control with minimal complications to normal tissue. This requires a high degree of precision relative to specific treatment aspects, e.g., the radiation dose, its distribution, and fractions (International Atomic Energy Agency, 2016).

Medical physicists perform and supervise the technical aspects of these treatments to guarantee safety and the efficacy of the radiation for therapeutic purposes. The practices adopted under their supervision can lead to opportunities for radiotherapy process management improvements, resulting in an increase in the safety and quality (Chen et al., 2015; Yan et al., 2021).

Radiotherapy treatment is carried out in complex technical environments which can result in safety risks. Sophisticated equipment and a team of highly trained professionals are required to mitigate errors. These professionals are trained in operational guidelines, which describe how to administer radiotherapy; however, they focus mainly on technical problems. Guidelines are also needed to manage the process and to foster a culture of patient safety (Klein et al., 2005; Williamson & Thomadsen, 2008; Simons et al., 2017; Liu et al., 2019).

## 2.1. Processes management

Health services are investing in managing and optimizing processes in order to increase operational efficiency and quality (Vissers & Beech, 2005). Process management promotes improvements in process flows, quality, costs, financial performance and customer satisfaction (Kohlbacher, 2010). The American Society for Radiation Oncology has developed standards and guidelines for safe and high quality radiotherapy programs, which have been endorsed by several organizations (American Society for Radiation Oncology, 2019). The radiotherapy processes must be evaluated, monitored and improved since they are subject to safety flaws and that it is not enough to focus merely on advanced treatment technique safety (Kapur & Potters, 2012; Mancosu et al., 2018; Liu et al., 2019; Mancosu et al., 2021).

The report developed by Task Group100-TG-100 proposed guides based on improving the quality of radiotherapy processes. A broad view was adopted since many errors in radiotherapy are related to failures in activity and process flows, and are not related to equipment and software failures. The report presents tools and practices for improving quality and safety, both for new and established technologies and processes. Tools like process mapping, failure mode analysis, and fault tree analysis, play a central role in designing workflows, as professionals seek optimizing clinical processes (Huq et al., 2016; Liu et al., 2019).

A literature review was carried out to identify practices and tools associated with process management that would be used in RS (Table 1).

## 2.2. Safety culture

The most common definition of safety culture in the health refers to the collective individual and group values, attitudes, skills, and behavior patterns that determine the commitment, style, and proficiency of an organization and safety management system. (International Atomic Energy Agency, 2007). Among the most cited safety culture practices are the freedom to report incidents, a non-punitive approach to reporting incidents, organizational learning, teamwork, the support of managers in promoting patient safety, and a shared belief in the importance of safety (Halligan & Zecevic, 2011).

Some specific practices for improving safety are related to the frequency and severity of incidents that have already occurred which reinforces the need to greatly improve safety culture. Evaluating incident reports can inform radiotherapy teams about improvements that could be made to the safety culture which gives better results for patients (International Atomic Energy Agency, 2016).

We identify practices and tools related to safety culture in the literature applied in hospital and radiotherapy services (Table 2).

**Table 1.** Process Management Practices.

| Code | Tools and Practices - Process Management | Authors |
|---|---|---|
| PM1 | Monitoring the patients' waiting time to start treatment | Kolybaba et al. (2009); Norsa'adah et al. (2021); Richard et al. (2010); Simons et al. (2017) |
| PM2 | Process Map | Kapur & Potters (2012); Mancosu et al. (2018); Marks et al. (2011); Radicchi et al. (2020); Schubert et al. (2016); Simons et al. (2017) |
| PM3 | Check list | Hendee & Herman (2011); International Atomic Energy Agency (2019); Kapur & Potters (2012); Liu et al. (2019); Marks et al. (2011); Fong de Los Santos et al. (2015); Schubert et al. (2016) |
| PM4 | Failure prevention and analysis method | Chera et al. (2015); International Atomic Energy Agency (2019); Kapur & Potters (2012); Kolybaba et al. (2009); Mancosu et al. (2018, 2021); Fong de Los Santos et al. (2015); Simons et al. (2017) |
| PM5 | Degree of autonomy and empowerment of employees | American Society for Radiation Oncology (2019) |
| PM6 | Employee training | American Society for Radiation Oncology (2019); International Atomic Energy Agency (2007); Kolybaba et al. (2009); World Health Organization (1988) |
| PM7 | Patient satisfaction survey | Kolybaba et al. (2009); Martin et al. (2007); Richard et al. (2010); Simons et al. (2017) |
| PM8 | Using Standard Operating Procedure | American Society for Radiation Oncology (2019); Baume (2002); International Atomic Energy Agency (2008); Kapur & Potters (2012); Marks et al. (2011) |

Table 2. Safety Culture practices and tools.

| Code | Tools and Practices -Safety Culture | Authors |
|---|---|---|
| SC1 | Employees are free to report and record incidents | Advisory Committee on the Safety of Nuclear Installations (1993); Halligan & Zecevic (2011); International Atomic Energy Agency (1991, 2016); Kusano et al. (2015); Leonard & O'Donovan (2018); Radicchi et al. (2020); Simons et al. (2014) |
| SC2 | Non-punitive response to employees due to incident reports | Advisory Committee on the Safety of Nuclear Installations (1993); Halligan & Zecevic (2011); Simons et al. (2014); Kusano et al. (2015); International Atomic Energy Agency (2016); Leonard & O'Donovan (2018); Radicchi et al. (2020) |
| SC3 | Using a learning method or practice for incidents | Halligan & Zecevic (2011); Simons et al. (2014); Kron et al. (2015); Kusano et al. (2015); Agency for Healthcare Research and Quality (2016); Campione & Famolaro (2017); Deufel et al. (2017); Liu et al. (2019) |
| SC4 | Post-incident report feedback to employees | Simons et al. (2014),; Kusano et al. (2015); Agency for Healthcare Research and Quality (2016); Campione & Famolaro (2017); Liu et al. (2019) |
| SC5 | Teamwork to promote a more proactive work environment | Simons et al. (2014); Marks et al. (2011); Halligan & Zecevic (2011); Agency for Healthcare Research and Quality (2016); Leonard & O'Donovan (2018); Radicchi et al. (2020) |
| SC6 | Manager support to promote patient safety | Halligan & Zecevic (2011); Simons et al. (2014); International Atomic Energy Agency (2016); Agency for Healthcare Research and Quality (2016); Leonard & O'Donovan (2018); Campione & Famolaro (2017) |
| SC7 | Using practices to adequately identify patients before planning and conducting treatment | Royal College of Radiologists (2008); International Atomic Energy Agency (2007, 2016); Liu et al. (2019) |

## 2.3. Quality of care

Quality of care is defined as the degree to which individuals and societies improve health care systems to obtain desired health care outcomes (Lohr & Schroeder, 1990; Institute of Medicine, 2001; Chiew et al., 2018). It represents a broad concept that has evolved over time, with an emphasis on compliance with standards for the care (Chiew et al., 2018).

A radiotherapy team developed a set of indicators that monitor the quality of care: treatment start times, which monitor the time elapsed from the patient's first consultation until the moment they receive their first treatment; the quality of the patient's clinical data record, which monitors the quality with which their data has been recorded, including the completeness, clarity and availability of clinical records; and the efficiency of the machines, which monitors the equipment downtime (Cionini et al., 2007).

Gabriele et al. (2006) highlight the importance of information about the level of patient satisfaction with RS. This way, teams can ensure that quality improvement initiatives are relevant and valued by patients (Martin et al., 2007; Kolybaba et al., 2009; Richard et al., 2010).

Quality of care indicators capture the construct performance, enabling the evaluation of the practices and improvements implemented. Table 3 shows radiotherapy quality of care indicators.

Table 3. Quality of Care Indicators.

| Code | Indicators - Quality of Care | Authors |
|---|---|---|
| QC1 | Treatment start time (time elapsed from the first consultation to the start of treatment) | Gabriele et al. (2006); Cionini et al. (2007); Norsa'adah et al. (2021) |
| QC2 | Patient satisfaction (how satisfied the patient is with the service) | Gabriele et al. (2006); van Lent et al. (2013); López Torrecilla et al. (2019) |
| QC3 | Patient clinical data record quality (perform a complete record of patient data) | Cionini et al. (2007); Liu et al. (2019) |
| QC4 | Equipment downtime rate (time unavailable due to failures) | Cionini et al. (2007); van Lent et al. (2013); López Torrecilla et al. (2019) |

## 2.4. Patient safety

Patient safety is a health care discipline that uses scientific safety methods to improve the health service system (International Atomic Energy Agency, 2016). The National Patient Safety Foundation defines patient safety as preventing and improving adverse outcomes, such as incidents or damage to the health care process (National Patient Safety Foundation, 2008). According to the International Atomic Energy Agency (IAEA), an incident is defined as any unintended event - including operational errors, equipment failures, accident precursors, near misses or other setbacks or unauthorized acts either malicious or non-malicious - which have significant consequences or potential consequences from a protection standpoint. A near miss is a potentially significant event that could have occurred, but did not occur, due to existing barriers (World Health Organization, 2008).

Research on safety in radiotherapy focuses on analyzing adverse events and near misses, in order to identify latent problems and weaknesses within a system. Thus, measuring incidents, adverse events, or failures in processes are important for creating a culture of learning from incidents, as well as for creating barriers to avoid errors which will reduce the frequency of incidents, since these practices lead to increased patient safety (International Atomic Energy Agency, 2019; Radicchi et al., 2020). Table 4 shows the radiotherapy patient safety indicators and authors.

**Table 4.** Patient Safety Indicators.

| Code | Indicators - Patient Safety | Authors |
|---|---|---|
| PS1 | Fall Rate (frequency of unplanned incidents that resulted in the patient falling, either causing injury or not) | Chang et al. (2019); Liu et al. (2019); Lindberg et al. (2020); Mancosu et al. (2021) |
| PS2 | Non-Severe incident index (frequency of events with mild severity) | World Health Organization (2008); Liu et al. (2019); Radicchi et al. (2020) |
| PS3 | Critical severity incident index (frequency of events with critical severity) | World Health Organization (2008); Liu et al. (2019); Radicchi et al. (2020) |
| PS4 | Non-conformity index (process failures that do not directly affect the patient) | World Health Organization (2008); Liu et al. (2019); Radicchi et al. (2020) |

## 2.5. Relationships between management practices and performance

There are studies that show that process management in health care services improves the performance of quality of care (Chandrasekaran et al., 2012).

The use of process management practices and tools can improve employees' understanding of the process, allowing greater control, identification of problems and solutions. These actions can positively impact the performance of the quality of care, since they can generate effects on activities, reducing waiting times, and on technical issues, decreasing, for example, the downtime rate.

The IAEA recommends the use of process management tools, such as checklists to improve safety and avoid unplanned incidents. Incident learning systems, like the SAFRON (SAFety on Radiation ONcology) provide reports that can contribute to RS processes and activity review. Statistical information can be used for RS training and learning sessions, giving priority to improving patient safety (International Atomic Energy Agency, 2019).

There is evidence that training employees to better understand and be able to perform processes increases patient safety and quality of care, because they are better able to identify problems, propose solutions and act proactively (Emanuel et al., 2009; American Society for Radiation Oncology, 2019). Establishing operational systems and processes, promoted by process management, can ensure patient safety and increases patient care reliability (Stock et al., 2010). Practices and process management tools like monitoring waiting times, using process maps, checklists, standard operating procedures and training, can positively impact quality of care and patient safety, as they make processes more consistent and replicable, supporting employees for their correct execution (Institute of Medicine, 2000; International Atomic Energy Agency, 2007, 2008; Simons et al., 2017). However, the practices of process management and its relationship with the quality of care and patient safety are still little explored in the context of RS.

Thus, the following hypotheses are proposed:

H1: Using process management practices positively impacts the performance of quality of care;

H2: Using process management practices positively impacts the performance of patient safety.

Culture change is important for incorporating the best practices, as cultural change impacts the quality of care and patient safety (World Health Organization, 2008). Changes in the safety culture must be implemented with care to allow good clinical practices to evolve and be incorporated by health services. The practices of report, feedback and record incidents, non-punishment due to incident reports and learning through incidents allow the safety culture to be strengthened, as well as manager support to promote patient safety. Improving safety culture is a key strategy for improving patient safety, since the implementation of safety culture practices should promote a reduction in the rate of incidents and even the number of severe and non-severe incidents. For the promotion of safety culture, ASTRO created a database for reporting incidents and promoting learning using report analysis. It also recommends using Failure Mode and Effect Analysis to prevent failures, identify process risks, and analyze the root causes in order to correct errors to improve patient safety (American Society for Radiation Oncology, 2019).

RS providers interested in increasing safety and quality of care should consider using an incident learning system to expand their knowledge about possible errors that could negatively impact practices, such as damage from inadequate treatment and poor quality results (International Atomic Energy Agency, 2016). The performance of the quality of care can be impacted by the safety culture because the practices promoted for the reduction of incidents promote records of patient information and should also increase satisfaction with the service.

Employees' perceptions on safety are refined more when managers demonstrate commitment and provide resources, incentives, and rewards to promote and improve safety (Halligan & Zecevic, 2011). Safety culture practices, like implementing an effective incident learning system, having non-punitive responses and promoting teamwork can all contribute to reducing real incidents. It can also encourage incident reporting and learning that can increase safety and quality (International Atomic Energy Agency, 2016; Leonard & O'Donovan, 2018; Simons et al., 2017). Improving patient safety should be a process priority since it affects the quality of healthcare. However, the proposed relationships are poorly studied in the context of RS, and this study proposes the hypotheses:

H3: Using safety culture practices positively impacts the performance of quality of care;

H4: Using safety culture practices positively impacts the performance of patient safety.

## 3. Methods

### 3.1. Data collection and sample

For conducting the empirical research we chose the survey method. The unit of analysis is the centers of RS and the target of the research are the centers located in the southeastern region of Brazil. Data of the RS were identified in the Brazilian Radiotherapy Society and the National Nuclear Energy Commission. This search resulted in 280 identified RSs in the country, of which 153 were in the southeastern region in February 2020.

We identified the medical physicist responsible for each of the 153 RS and your e-mail. Medical physicists were chosen as key respondent because they guarantee the technical quality of the treatment and equipment and must actively participate in improvement processes.

We carried out a pilot test with experts and target respondents to improve the questionnaire. The final version of the questionnaire was sent to the 153 medical physicists and we obtained a sample of 96, corresponding to a response rate of 63%. Of the 96 respondents, 49 are located in São Paulo state, 23 in Rio de Janeiro, 22 in Minas Gerais and 2 in Espírito Santo.

The questionnaire consisted of two sections, the first to capture information about the RS, and the second to identify the use of process management practices, safety culture and the performance of the quality of care and patient safety. The first section characterized the organizations by considering the category (exclusive radiotherapy services or hospitals with radiotherapy services), the regime (public, private, or private non-profit regimes), Accreditation, the use of some methodology for continuous improvements (Lean Healthcare, Lean Six Sigma, Total Quality Management, etc.), the service size (1; from 2 to 3; 4 or more machines), and the technology (2D, 3D, IMRT, VMAT, Radiosurgery, Extracranial Stereotactic Radiotherapy, TBI and HDR) (Table 5).

The second section contained 23 questions using a five-point Likert scale into four constructs, Process Management (8 questions), Safety Culture (7), Quality of Care (4), Patient Safety (4). For Process Management and Safety Culture, a Likert scale of frequency of use was used (Never, Rarely, Sometimes, Often and Always). For the Quality of Care and Patient Safety constructs, an agreement scale was used (Strongly Disagree, Disagree, Neither Agree or Disagree, Agree, Strongly Agree).

The adequacy of the sample was verified before validating the measurement model and analyzing the structural model. Four cases of multivariate outliers were identified using the Mahalanobis distance, and were discarded, resulting in a final sample size of 92 cases. The items of the questionnaire were randomized to avoid possible associations with a specific construct and to avoid possible bias.

### 3.2. Data analysis

The data were analyzed using Structural Equation Modeling using the Partial Least Squares Method (PLS-SEM). PLS-SEM was chosen as a technique for data analysis because it is indicated when distribution issues are a concern, such as lack of normality and the use of ordinal and non-continuous scales, when the sample is small and when the model involves many constructs, indicators and/or model relationships (Hair et al., 2017, 2019). The analysis was performed using the SmartPLS 3.2.8 software program.

Table 5. Sample Profile.

| Category | Frequency | Proportion(%) |
|---|---|---|
| Hospital with RS | 68 | 70.8 |
| Exclusive RS | 28 | 29.2 |
| **Total** | **96** | **100.0** |
| **Regime** | | |
| Public | 15 | 15.6 |
| Private | 46 | 47.9 |
| Private non-profit | 35 | 36.5 |
| **Total** | **96** | **100.0** |
| **Acreditation** | | |
| Yes | 28 | 29.2 |
| No | 68 | 70.8 |
| **Total** | **96** | **100.0** |
| **Quality improvement program** | | |
| Lean Healthcare | 5 | 5.2 |
| Lean Heathcare and Lean Sigma | 1 | 1.0 |
| Six Sigma | 0 | 0.0 |
| Total Quality Management | 4 | 4.2 |
| Kaizen | 1 | 1.0 |
| None | 85 | 88.5 |
| **Total** | **96** | **100.0** |
| **Service Scale** | | |
| 1 AL | 53 | 55.2 |
| 2 to 3 ALs | 39 | 40.6 |
| 4 or more ALs | 4 | 4.2 |
| **Total** | **96** | **100.0** |
| **Technologies** | | |
| 2D | 73 | 76.0 |
| 3D | 96 | 100.0 |
| IMRT | 68 | 70.8 |
| VMAT | 41 | 42.7 |
| Radiosurgery | 47 | 49.0 |
| Extracranial stereotactic | 29 | 30.2 |
| TBI | 20 | 20.8 |
| HDR | 36 | 37.5 |
| Other(s) | 19 | 19.8 |

A research model based on constructs composed of several indicators was used. This was carried out to guarantee the reliability of the constructs, since they are complex and abstract concepts such as patient safety and process management. This usage increases the reliability of the respondent's answer, given that there is more than one question on the same domain. For the analysis of whether the construct captures the domain, a measurement analysis (Measurement Model) is performed. The construction of the model was performed to verify statistically significant relationships between the constructs (Structural Model).

We assessed whether the size was suitable for the application of PLS-SEM. We used the minimum R-squared method, and the 92 respondents (final sample) exceeds the minimum required sample size (88 respondents) for an effective size ($f^2$) of 0.15, with a significance level of 0.05 and statistical power of 0.9, as calculated using the G*Power software program (Heinrich Heine Universität, 2022).

## 3.3. Common method variance

The adequacy of the sample was verified before validating the measurement model and analyzing the structural model. There was no missing data, and no cases of straight lining were identified. Four cases of multivariate outliers were identified using the Mahalanobis distance, and were discarded, resulting in a final sample size of 92 cases.

We followed the procedures recommended to prepare and write the questionnaire to avoid Common Method Bias (CMB). Respondent identification was not requested and the respondents were informed that there was no right or wrong answer. The items of the questionnaire were randomized to avoid possible associations with a specific construct and possible bias. We performed the Harman Single Factor Test (Podsakoff et al., 2003) to determine if the final sample contained CMB. The test resulted in 25.34% of the variance explained for this single factor, ensuring that there was no CMB.

## 4. Results

### 4.1. Descriptive analysis

The respondents mostly answered between "Always" and "Often" (widely used) for questions on Process Management (PM) (Table 6), and the highest used practice (83% of always and often) was for variable PM1 (How often is the treatment start time monitored, i.e., the time between the 1st consultation and the 1st treatment session?). The second variable with the highest degree of agreement was PM3, on the use of checklists for the RS parameters, showing that there is a concern with procedures. The lowest frequency of use (only 50% of the responses in always or often) was for variable PM2 (How often are process maps used to solve problems in the Radiotherapy processes?), followed by PM7, about satisfaction surveys. We can conclude that most RS believe that the time elapsed between consultation and the start of treatment is an important priority. By contrast, these RS do not use tools like process maps very frequently for solving problems. Process maps were shown to be even less relevant in this management phase, and few respondents had knowledge about their application. In general, it is not uncommon to view process mapping as a bureaucratic process and few see it as a means of visualizing and analyzing a process for improvements. The same happens with tools for the analysis of patient satisfaction.

The respondents mostly answered between "Often" and "Always" for the Safety Culture (SC), and the highest level of use (100% choose often or always) was for variable SC7 (How often are habitual practices used to adequately identify patients before planning or conducting radiotherapy treatment?). The second variable with the highest frequency of use was SC1, about the employees are free to report and record incidents. The lowest frequency of use was for variable SC6 (How often do managers praise and acknowledge the work of employees who follow safety procedures?), followed by SC5 about the commitment of employees to discuss the work and make it more proactive. Most RS are concerned about establishing patient safety practices, like adequately identifying patients prior to performing any procedures and report incidents. By contrast the results show that managers still do not frequently recognize employees for correctly performing procedures according to safety guidelines and there is no reinforcement for employees' commitment to improve work and make it more proactive. The theory suggests that recognition is important for employees to perceive and value safety practices.

The respondents mostly answered between "Agree" and "Strongly agree" for the Quality of Care (QC), and the highest level of agreement (89% of the sample) was for the variable QC3 (The patient's clinical data has been recorded properly in recent years), and the lowest level of agreement (65% of the sample) was for variable QC4 (The rate of equipment downtime due to failures has reduced in recent years). We can conclude that care is taken to adequately report the patient's clinical data, as this information is important for assisting the multidisciplinary team and of importance for ensuring the quality of patient care. We did not observe a significant reduction in the equipment's unavailability rate. The greater the equipment control for predicting failures, the better the quality of patient care. Some failures prevent the equipment from operating for hours or even days, which causes interruptions to the patient's treatment.

The respondents mostly answered between "Agree" and "Strongly agree" for the Patient Safety, and the highest level of agreement (75% of the sample) was for variable PS4 (The frequency of non-compliance has reduced in recent years), and the lowest level of agreement (58% of the sample) was for variable PS1 (The occurrence of patient falls has decreased in recent years). We can conclude that the RSs are investing in the reduction of non-compliance, however, there are still a number of undesirable incidents, such as falls.

### 4.2. Structural equation modeling

#### 4.2.1. Measurement model

The conceptual model comprised four reflective constructs. We followed the procedures recommended to validate the structural model with reflective constructs. Convergent validity is confirmed when the Average Variance Extracted (AVE) is > 0.5 for each construct. The AVE value is related to the outer loading (reflective

Table 6. Descriptive analysis of variables.

| Code | Description | Mean | Median | Standard deviation | 1* | 2 | 3 | 4 | 5 |
|---|---|---|---|---|---|---|---|---|---|
| | | of Indicator | of Indicator | of Indicator | % | % | % | % | % |
| PM1 | How often is the time monitored for the patient to start radiotherapy treatment (time between 1st consultation and 1st irradiation) monitored? | 4.30 | 5 | 0.92 | 2 | 2 | 13 | 30 | 53 |
| PM2 | How often are process maps used to solve problems in Radiotherapy processes? | 3.30 | 3.5 | 1.31 | 13 | 16 | 22 | 29 | 21 |
| PM3 | How often are checklists used to check pre-established parameters in the Radiotherapy processes? | 4.10 | 4 | 1.13 | 4 | 7 | 11 | 28 | 49 |
| PM4 | How often is a method used to prevent failures and analyze process risks? | 3.50 | 4 | 1.21 | 8 | 10 | 29 | 27 | 25 |
| PM5 | How often do employees, in general, have autonomy and decision-making powers given by their leaders, enabling them to act proactively and safely in the RS? | 3.78 | 4 | 0.88 | 1 | 7 | 24 | 48 | 20 |
| PM6 | How often is training carried out to improve the understanding and ability to carry out the processes? | 3.76 | 4 | 0.75 | 0 | 2 | 36 | 45 | 17 |
| PM7 | How often are patient satisfaction surveys carried out, compiling and analyzing results to improve processes? | 3.40 | 3.5 | 1.44 | 14 | 17 | 20 | 17 | 33 |
| PM8 | How often are Standard Operationing Procedures used to carry out the activities and processes of the radiotherapy? | 3.75 | 4 | 1.08 | 3 | 10 | 23 | 35 | 28 |
| SC1 | How often are employees free to report and record incidents (with potential for damage or that has affected the patient)? | 4.65 | 5 | 0.75 | 1 | 2 | 4 | 17 | 76 |
| SC2 | How often, when reporting an incident, are responses to employees non-punitive? | 3.93 | 4 | 1.15 | 5 | 6 | 20 | 28 | 41 |
| SC3 | How often is a structured incident learning method used? | 3.66 | 4 | 1.25 | 8 | 9 | 22 | 29 | 31 |
| SC4 | How often are feedbacks passed on to employees in response to incident reports? | 4.19 | 4 | 0.93 | 0 | 6 | 17 | 29 | 48 |
| SC5 | How often do employees, as a group, discuss work in order to make it more proactive? | 3.54 | 4 | 0.88 | 2 | 6 | 41 | 38 | 14 |
| SC6 | How often do managers praise and acknowledge the work of employees in accordance with safety procedures? | 3.20 | 3 | 1.03 | 6 | 15 | 44 | 24 | 11 |
| SC7 | How often are habitual practices used to adequately identify patients before planning or conducting radiotherapy treatment? | 4.79 | 5 | 0.41 | 0 | 0 | 0 | 21 | 79 |
| QC1 | The time from consultation to the start of treatment has reduced in recent years | 4.07 | 4 | 1.05 | 2 | 5 | 23 | 23 | 47 |
| QC2 | The degree of patient satisfaction with the service delivered by radiotherapy has increased in recent years | 4.16 | 4 | 0.73 | 0 | 1 | 23 | 35 | 41 |
| QC3 | The registration of the patient's clinical data has been completed adequately in recent years | 4.51 | 5 | 0.65 | 0 | 2 | 9 | 24 | 65 |
| QC4 | The rate of equipment unavailability due to failures has reduced in recent years | 3.94 | 4 | 0.95 | 0 | 6 | 28 | 31 | 34 |
| PS1 | The occurrence of patient falls has decreased in recent years | 3.88 | 4 | 0.92 | 1 | 2 | 39 | 25 | 33 |
| PS2 | The frequency of events (incidents) with a mild degree of severity (did not cause harm to the patient) has decreased in recent years | 4.15 | 4 | 0.93 | 1 | 2 | 26 | 23 | 48 |
| PS3 | The frequency of adverse events (incidents) with a critical degree of severity has reduced in recent years | 4.23 | 5 | 0.84 | 1 | 0 | 29 | 15 | 55 |
| PS4 | The frequency of non-compliance has reduced in recent years | 4.39 | 5 | 0.97 | 2 | 4 | 9 | 31 | 44 |

*1-5 – Likert scale.

construct) of each item of the construct, which must be above, or close to 0.7, for the latent variable to explain a substantial part of the variation of each indicator. Some items needed to be removed to improve reliability (PM1, PM3, PM4, PM5, SC1, SC2, SC7 and QC1) in the validation process. After removing the measurement items, the model was completed and is shown in Figure 1.

The Cronbach's Alfa (CA) values vary from 0.634 to 0.781 and the Composite Reliability (CR) vary from 0.799 to 0.831. All are above the minimum 0.60 value indicated for exploratory research (Hair et al., 2017). The AVE values for all modified constructs are above the recommended 0.5 value (Table 7).

The discriminant validity of the constructs was evaluated using Cross Loadings and the Fornell-Larcker criterion (Hair et al., 2017). Table 8 shows that there is discriminant validity.

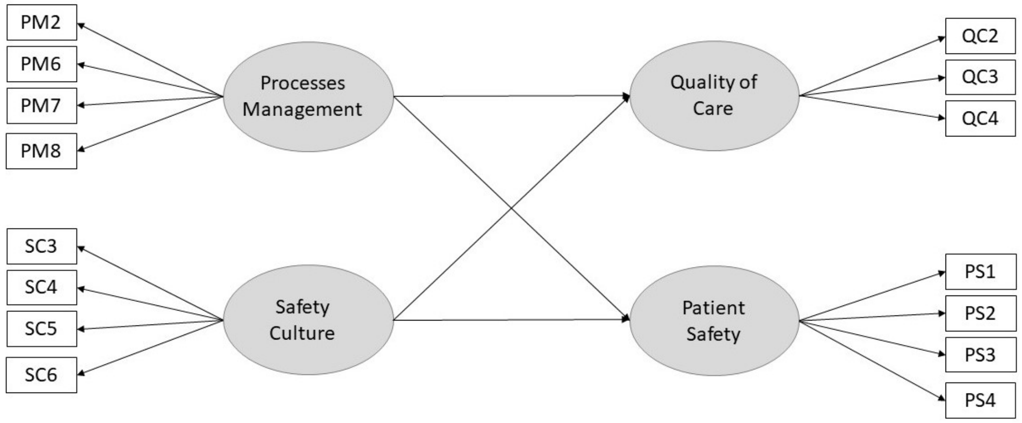


**Figure 1.** Model with alterations.

**Table 7.** Convergent Validity and Reliability Results.

| Construct | Item | Loadings | CA | CR | AVE |
|---|---|---|---|---|---|
| Process Management | PM2 | 0.606 | 0.747 | 0.823 | 0.541 |
| | PM6 | 0.779 | | | |
| | PM7 | 0.757 | | | |
| | PM8 | 0.7 84 | | | |
| Safety Culture | SC3 | 0.602 | 0.751 | 0.831 | 0.555 |
| | SC4 | 0.761 | | | |
| | SC5 | 0.758 | | | |
| | SC6 | 0.839 | | | |
| Quality of Care | QC2 | 0.803 | 0.634 | 0.799 | 0.570 |
| | QC3 | 0.711 | | | |
| | QC4 | 0.749 | | | |
| Patient Safety | PS1 | 0.863 | 0.781 | 0.801 | 0.513 |
| | PS2 | 0.813 | | | |
| | PS3 | 0.642 | | | |
| | PS4 | 0.484 | | | |

**Table 8.** Discriminant validity: Fornell-Larcker criterion.

| Construct | Safety Culture | Processes management | Quality of Care | Patient Safety |
|---|---|---|---|---|
| Safety Culture | **0.745** | | | |
| Process Management | 0.564 | **0.735** | | |
| Quality of Care | 0.389 | 0.368 | **0.755** | |
| Patient Safety | 0.405 | 0.319 | 0.658 | **0.716** |

Note: AVE values in bold diagonally.

### 4.2.2. Structural model

The first step is to verify collinearity, examining the variance inflation factor (VIF) values for all predictive constructs in the structural model. The VIF values in the model are all below the 5.0 limit and the highest is 1.466. The second step is to estimate the relationships of the structural model (path coefficients), which represent the hypothesis relationships between the constructs. It is necessary to examine the intensity of the path coefficients and levels of significance (p-value) using the Bootstrapping procedure (5000 subsamples) (Hair et al., 2017). PLS-SEM is a nonparametric method, i.e., makes no distributional assumptions and therefore, bootstrapping is used to determine statistical significance (Hair et al., 2017, 2019). In bootstrapping, a large number of samples are drawn from the original sample with replacement to estimate, for example, 5,000 PLS path models (Hair et al., 2017). The estimates of the path coefficients form a bootstrap distribution, and based on this distribution, it is possible to determine the standard error and the standard deviation of the estimated coefficients, being possible to calculate the significance of the relationships (Hair et al., 2017). Table 9 shows the results for the hypothesis tests.

**Table 9.** Hypothesis Testing.

| Hypothesis | Relationship | Path Coefficient (β) | P-value | Result |
|---|---|---|---|---|
| H1 | Process Management -> Quality of Care | 0.218 | 0.096** | Supported |
| H2 | Process Management -> Patient Safety | 0.133 | 0.314 | Not Supported |
| H3 | Safety Culture -> Quality of Care | 0.266 | 0.034* | Supported |
| H4 | Safety Culture -> Patient Safety | 0.330 | 0.004* | Supported |

*Supported at a 5% significance level; **Supported at a 10% significance level.

Three hypotheses are supported: the relationship between of Safety Culture and performance of Quality of Care (path coefficient = 0.266, p-value = 0.034), Safety Culture and performance of Patient Safety (path coefficient = 0.330, p-value = 0.004), Process Management and performance of Quality of Care (path coefficient = 0.218, p-value = 0.096). The unsupported hypothesis is related to Process Management and Patient Safety.

The three supported hypotheses help to reinforce the theoretical arguments present in literature that indicate the impact of these practices on the quality of care and patient safety. The statistical results were not sufficient to confirm the positive impact of Process Management practices on performance of Patient Safety, which contradicts many studies that emphasize and recommend using practices related to process management in order to impact patient safety (Institute of Medicine, 2000; International Atomic Energy Agency, 2007; Marks et al., 2011; Simons et al., 2014; International Atomic Energy Agency, 2016; American Society for Radiation Oncology, 2019). To better understand this difference in perceived results regarding the hypothesis not supported in this research in RS in Brazil and results in other countries and in the recommendations of guides adopted in the sector, it would be necessary to carry out a specific research on this hypothesis in the country and with greater depth in the definition of the variables that make up these constructs (Process Management and Patient Safety). Apparently because of this sample of RS in Brazil, managers would associate patient safety performance more exclusively with the adoption of Safety Culture practices, but not with process management practices. Process management practices would be seen more as complementary and secondary to patient safety.

The third step in evaluating the structural model is to observe the coefficients ($R^2$) for the endogenous variables (Hair et al., 2017), $R^2$ values = 0.02, 0.13, and 0.26 correspond to small, medium and large values, respectively. Thus, Safety Culture and Process Management explain a portion of the variance in the Quality of Care construct ($R^2$ = 0.165), while the Safety Culture construct also explains a portion of the variance in the endogenous Patient Safety construct ($R^2$ = 0.157).

The evaluation shows that the structural model identified statistically significant relationships between the constructs and explain the variance of the endogenous constructs.

### 4.2.3. Multigroup analysis

We analyzed the groups to identify differences in path coefficients considering variables like Accreditation, size (1 accelerator, or more) and whether the RS are being provided by hospital or exclusively for radiotherapy (Table 10). These variables were chosen because they are possible control variables.

**Table 10.** Difference in path coefficient (2000 permutations).

| Hypothesis | | Accreditation | | | Size | | | Type | | |
|---|---|---|---|---|---|---|---|---|---|---|
| | | Group 1 | Group 2 | p-value | Group 1 | Group 2 | p-value | Group 1 | Group 2 | p-value |
| H1 | Processes management -> Quality of Care | 0.161 | 0.456 | 0.295 | 0.222 | 0.165 | 0.821 | 0.197 | 0.122 | 0.801 |
| H2 | Processes management -> Patient Safety | 0.008 | 0.432 | 0.176 | 0.092 | 0.072 | 0.954 | 0.177 | 0.233 | 0.858 |
| H3 | Safety Culture -> Quality of Care | 0.296 | 0.107 | 0.478 | 0.370 | 0.301 | 0.758 | 0.301 | 0.435 | 0.613 |
| H4 | Safety Culture -> Patient Safety | 0.399 | 0.221 | 0.496 | 0.417 | 0.463 | 0.852 | 0.398 | 0.186 | 0.425 |

The first step in multigroup analysis is to verify whether the data possess configural invariance or compositional invariance, which can be obtained using the Measurement Invariance Assessment (MICOM) procedure. The MICOM test confirmed compositional invariance.

The non-parametric permutation test can be used to verify whether the path coefficients are similar or different for multigroup analysis. Table 10 shows the values of the path coefficients for each scenario and the p-value for testing the difference between the path coefficients using permutation. There are no differences in the path coefficients in any relationship (p-value> 0.05, the path coefficients are similar).

There is no difference in the path coefficients when considering the size, type of organization, or whether the organization is accredited, showing that the relationships identified are consistent, regardless of context.

## 5. Analysis and conclusions

The RSs in the sample use process management practices and also have a culture of patient safety, albeit at different intensities. Hypothesis H1 was confirmed, showing that process management practices, like employee training, using work instructions to carry out activities and using process maps, can improve the quality of patient care. This confirmation corroborates studies by several authors (Institute of Medicine, 2000; International Atomic Energy Agency, 2007, 2019; Simons et al., 2017).

Hypothesis H2, related to using process management practices to improve patient safety, was not statistically supported. These practices have been discussed in literature and are most likely employed by RS providers; however, the relationship cannot be confirmed. One explanation for this may be that the indicators used in this study may not have been sufficient enough to measure an impact on patient safety in function of process management practices. This presents an opportunity for future studies that considers a broader assessment in this construct.

Hypotheses H3 and H4 were statistically confirmed, showing that managerial support geared towards promoting a patient safety culture, along with feedback given to employees in response to incident reports, and teamwork contributes to the quality of care and patient safety. This study contributes to academic literature by corroborating the work of several authors (Simons et al., 2014; International Atomic Energy Agency, 2016; Leonard & O'Donovan, 2018), and by confirming the importance of using and disseminating these practices to increase patient quality of care and safety.

Establishing operational systems and processes ensures patient safety and increases patient care reliability. Studies and reports on the best practices in RS are, in most cases, from developed countries, and studies on management practices and quality improvements are still scarce in developing countries and in Brazil. This study has identified that process management and safety culture practices have been employed by RS in the southeastern region of Brazil. It is not frequent in Brazil to gather data on indicators related to quantifying radiotherapy risks and care processes. There are, therefore, still many challenges to making health care safer. Radiotherapy indicator results need to be integrated into learning practices with greater frequency. One indicator related to the quality of care is the degree of patient satisfaction. This indicator was identified as being one of the least practiced, and had the highest standard deviation of all the indicators. The perception of possible improvements from the perspective of patients does not always reach the knowledge of employees and managers. Thus, implementing and analyzing satisfaction measurement surveys could help identify and implement possible improvements to the quality of care.

This research uses an exploratory model based on the literature review, and despite a great effort to consult a wide range of sources in the literature review, there may have been a concentration of studies that follow a certain line of thought related to the health area and not radiotherapy services, limiting the domain of constructs, which made it difficult to confirm the relationship between patient safety in function of process management. The confirmation or refutation of hypotheses can also be the result of a sample that may have a certain internal cohesion, for example, being RS from a specific country and from a specific region.

For the continuity of this research, case studies in radiotherapy centers proposed to understand the confirmation or not of the hypotheses at the researched reasons will be prioritized, allowing us to understand how relationships occur, in addition to comparing the results of publications on the study of cases in other countries. Another direction that the present research will follow is to carry out an action research, with possible longitudinal data analysis, with the introduction of process management and safety culture practices to investigate the effects on the quality of care and patient safety.

## References


Advisory Committee on the Safety of Nuclear Installations – ACSNI, Study Group on Human Factor. (1993). *Organizing for Safety: third report of the Advisory Committee on the Safety of Nuclear Installations, HSE Books: Sudbury*. London.

Agency for Healthcare Research and Quality – AHRQ. (2016). *Hospital survey on patient safety culture*. Retrieved in 2022, July 19, from http://www.ahrq.gov/professionals/qualitypatientsafety/patientsafetyculture/hospital/index.html

American Society for Radiation Oncology – ASRO. (2019). *Safety is no accident: a framework for quality radiation oncology care*. Retrieved in 2022, July 19, from https://www.astro.org/uploadedfiles/main_site/clinical_practice/patient_safety/blue_book/safetyisnoaccident.pdf

Baume, P. (2002). *Report of the radiation oncology inquiry: a vision for radiotherapy*. Canberra: Commonwealth of Australia.

Campione, J., & Famolaro, T. (2017). Promising Practices for Improving Hospital Patient Safety Culture. *Joint Commission Journal on Quality and Patient Safety*, *44*(1), 23-32. http://dx.doi.org/10.1016/j.jcjq.2017.09.001. PMid:29290243.

Chandrasekaran, A., Senot, C., & Boyer, K. K. (2012). Process Management Impact on Clinical and Experiential Quality: managing tensions between safe and patient-centered healthcare. *Manufacturing & Service Operations Management*, *14*(4), 548-566. http://dx.doi.org/10.1287/msom.1110.0374.

Chang, S., Chen, W., Teng, T., Yeh, C. Y., & Yen, H. C. (2019). Fall risk program for oncology inpatients: addition of the "traffic light" fall risk assessment tool. *Journal of Nursing Care Quality*, *34*(2), 139-144. http://dx.doi.org/10.1097/NCQ.0000000000000353. PMid:30198946.

Chen, E., Arnone, A., Sillanpaa, J., Yu, Y., & Mills, M. D. (2015). A special report of current state of the medical physicist workforce - results of the 2012 ASTRO Comprehensive Workforce Study. *Journal of Applied Clinical Medical Physics*, *16*(3), 5232. http://dx.doi.org/10.1120/jacmp.v16i3.5232. PMid:26103483.

Chera, B. S., Mazur, L., Buchanan, I., Kim, H. J., Rockwell, J., Milowsky, M. I., & Marks, L. B. (2015). Improving patient safety in clinical oncology applying lessons from normal accident theory. *JAMA Oncology*, *1*(7), 958-964. http://dx.doi.org/10.1001/jamaoncol.2015.0891. PMid:26182183.

Chiew, K., Sundaresan, P., Jalaludin, B., & Vinod, S. K. (2018). A narrative synthesis of the quality of cancer care and development of an integrated conceptual framework. *European Journal of Cancer Care*, *27*(6), e12881. http://dx.doi.org/10.1111/ecc.12881. PMid:30028054.

Cionini, L., Gardani, G., Gabriele, P., Magri, S., Morosini, P. L., Rosi, A., & Viti, V. (2007). Quality indicators in radiotherapy. *Radiotherapy and Oncology: Journal of the European Society for Therapeutic Radiology and Oncology*, *82*(2), 191-200. http://dx.doi.org/10.1016/j.radonc.2006.12.009. PMid:17267059.

Deufel, C. L., McLemore, L. B., Fong de Los Santos , L. E., Classic, K. L., Park, S. S., & Furutani, K. M. (2017). Patient safety is improved with an incident learning system—Clinical evidence in brachytherapy. *Radiotherapy and Oncology: Journal of the European Society for Therapeutic Radiology and Oncology*, *125*(1), 94-100. http://dx.doi.org/10.1016/j.radonc.2017.07.032. PMid:28823406.

Emanuel, L., Berwick, D., Conway, J., Combes, J., Hatlie, M., Leape, L., Reason, J., Schyve, P., Vincent, C., & Walton, M. (2009). What exactly is patient safety*? Journal of Medical Licensure Discipline*, *95*(1), 13-24.

Fong de Los Santos, L. E., Evans, S., Ford, E. C., Gaiser, J. E., Hayden, S. E., Huffman, K. E., Johnson, J. L., Mechalakos, J. G., Stern, R. L., Terezakis, S., Thomadsen, B. R., Pronovost, P. J., & Fairobent, L. A. (2015). Medical physics practice guideline: development, implementation, use and maintenance of safety checklists. *Journal of Applied Clinical Medical Physics*, *16*(3), 5431. http://dx.doi.org/10.1120/jacmp.v16i3.5431. PMid:26103502.

Gabriele, P., Malinverni, G., Bona, C., Manfredi, M., Delmastro, E., Gatti, M., Penduzzu, G., Baiotto, B., & Stasi, M. (2006). Are quality indicators for radiotherapy useful in the evaluation of service efficacy in a new-based radiotherapy institution? *Tumori*, *92*(6), 496-502. http://dx.doi.org/10.1177/030089160609200606. PMid:17260490.

Gouvêa, C., & Travassos, C. (2010). Indicadores de segurança do paciente para hospitais de pacientes agudos: revisão sistemática. *Cadernos de Saúde Pública*, *26*(6), 1061-1078. http://dx.doi.org/10.1590/S0102-311X2010000600002. PMid:20657973.

Hair, J. F., Risher, J. J., Sarstedt, M., & Ringle, C. M. (2019). When to use and how to report the results of PLS-SEM. *European Business Review*, *31*(1), 2-24. http://dx.doi.org/10.1108/EBR-11-2018-0203.

Hair, J. F., Tomas, G., Hult, M., Ringle, C. M., & Sarstedt, M. (2017). *A primer on partial least squares structural equation modeling (PLS-SEM)*. Thousand Oaks: Sage.

Halligan, M., & Zecevic, A. (2011). Safety culture in healthcare: a review of concepts, dimensions, measures and progress. *BMJ Quality & Safety*, *20*(4), 338-343. http://dx.doi.org/10.1136/bmjqs.2010.040964. PMid:21303770.

Heinrich Heine Universität – HHU. (2022). *G*Power: statistical power analyses for Mac and Windows.* Düsseldorf. Retrieved in 2022, July 19, from http://www.gpower.hhu.de/

Hendee, W., & Herman, M. (2011). Improving patient safety in radiation oncology. *Medical Physics*, *38*(1), 78-82. http://dx.doi.org/10.1118/1.3522875. PMid:21361177.

Huq, M. S., Fraass, B. A., Dunscombe, P. B., Gibbons Junior, J. P., Ibbott, G. S., Mundt, A. J., Mutic, S., Palta, J. R., Rath, F., Thomadsen, B. R., Williamson, J. F., & Yorke, E. D. (2016). The report of Task Group 100 of the AAPM: application of risk analysis methods to radiation therapy quality management. *Medical Physics*, *43*(7), 4209-4262. http://dx.doi.org/10.1118/1.4947547. PMid:27370140.

Institute of Medicine – IM, Committee on Quality of Health Care in America. (2001). *Crossing the quality chasm: a new health system for the 21st century*. Washington, DC: National Academic Press.

Institute of Medicine – IM. (2000). *To err is human: building a safer health system*. Washington, DC: National Academies Press.

International Atomic Energy Agency – IAEA. (1991). *Safety culture* (Safety-Series, No. 75-INSAG-4). Vienna: International Safety Advisory Group.

International Atomic Energy Agency – IAEA. (2007). *Comprehensive audits of radiotherapy practices: a tool for quality improvement*. Vienna: Quality Assurance Team for Radiation Oncology (QUATRO).

International Atomic Energy Agency – IAEA. (2008). *Setting up a radiotherapy programme STI/PUP 1296.* Vienna.

International Atomic Energy Agency – IAEA. (2016). *A newsletter on patient safety in radiotherapy.* Retrieved in 2022, July 19, from https://rpop.iaea.org/SAFRON/Default.aspx

International Atomic Energy Agency – IAEA. (2019). *Updates on patient safety in radiotherapy.* Retrieved in 2022, July 19, from https://rpop.iaea.org/SAFRON/Default.aspx

Kapur, A., & Potters, L. (2012). Six sigma tools for a patient safety-oriented, quality-checklist driven radiation medicine department. *Practical Radiation Oncology*, *2*(2), 86-96. http://dx.doi.org/10.1016/j.prro.2011.06.010. PMid:24674084.

Klein, E., Drzymala, R., Purdy, J., & Michalski, J. (2005). Errors in radiation oncology: a study in pathways and dosimetric impact. *Journal of Applied Clinical Medical Physics*, *6*(3), 81-94. http://dx.doi.org/10.1120/jacmp.v6i3.2105. PMid:16143793.

Kohlbacher, M. (2010). The effects of process orientation: a literature review. *Business Process Management Journal*, *6*(1), 135-152. http://dx.doi.org/10.1108/14637151011017985.

Kolybaba, M., Kron, T., Harris, J., O'Brien, P., & Kenny, L. (2009). Survey of radiation oncology centers in Australia: report of the Radiation Oncology Treatment Quality Program. *Journal of Medical Imaging and Radiation Oncology*, *53*(4), 382-395. http://dx.doi.org/10.1111/j.1754-9485.2009.02080.x. PMid:19695046.

Kron, T., Dwyer, M., Smith, L., MacDonald, A., Pawsey, M., Raik, E., Arnold, A., Hill, B., & Duchesne, G. M. (2015). The development of practice standards for radiation oncology in Australia: a tripartite approach. *Clinical Oncology*, *27*(6), 325-329. http://dx.doi.org/10.1016/j.clon.2015.01.005. PMid:25669589.

Kusano, A., Nyflot, M., Zeng, J., Sponseller, P. A., Ermoian, R., Jordan, L., Carlson, J., Novak, A., Kane, G., & Ford, E. C. (2015). Measurable improvement in patient safety culture: a departmental experience with incident learning. *Practical Radiation Oncology*, *5*(3), e229-e237. http://dx.doi.org/10.1016/j.prro.2014.07.002. PMid:25413404.

Leonard, S., & O'Donovan, A. (2018). Measuring safety culture: application of the hospital survey on patient safety culture to radiotherapy departments worldwide. *Practical Radiation Oncology*, *8*(1), e17-e26. http://dx.doi.org/10.1016/j.prro.2017.08.005. PMid:28967578.

Lindberg, D., Prosperi, M., Bjarnadottir, R., Thomas, J., Crane, M., Chen, Z., Shear, K., Solberg, L. M., Snigurska, U. A., Wu, Y., Xia, Y., & Lucero, R. J. (2020). Identification of important factors in an inpatient fall risk prediction model to improve the quality of care using EHR and electronic administrative data. *International Journal of Medical Informatics*, *143*, 104272. http://dx.doi.org/10.1016/j.ijmedinf.2020.104272. PMid:32980667.

Liu, S., Bush, K. K., Bertini, J., Fu, Y., Lewis, J. M., Pham, D. J., Yang, Y., Niedermayr, T. R., Skinner, L., Xing, L., Beadle, B. M., Hsu, A., & Kovalchuk, N. (2019). Optimizing efficiency and safety in external beam radiotherapy using automated plan check (APC) tool and six sigma methodology. *Journal of Applied Clinical Medical Physics*, *20*(8), 56-64. http://dx.doi.org/10.1002/acm2.12678. PMid:31423729.

Lohr, K., & Schroeder, S. (1990). A strategy for quality assurance in Medicare. *The New England Journal of Medicine*, *322*(10), 707-712. http://dx.doi.org/10.1056/NEJM199003083221031. PMid:2406600.

López Torrecilla, J., Marín I Borràs, S., Ruiz-Alonso, A., Jaen Olasolo, J., Vázquez de la Torre, M. L., Bóveda Carro, E., Rodríguez, A., Ignacio García, E., Caballero Martínez, F., Campos Lucas, F. J., Lara Jiménez, P. C., Martínez, J. C., & Ferrer Albiach, C. (2019). Quality indicators in radiation oncology: proposal of the Spanish Society of Radiation Oncology for a continuous improvement of the quality of care in oncology. *Clinical & Translational Oncology*, *21*(4), 519-533. http://dx.doi.org/10.1007/s12094-018-1943-z. PMid:30311145.

Mancosu, P., Nicolini, G., Goretti, G., De Rose, F., Franceschini, D., Ferrari, C., Reggiori, G., Tomatis, S., & Scorsetti, M. (2018). Applying Lean-Six-Sigma Methodology in radiotherapy: Lessons learned by the breast daily repositioning case. *Radiotherapy and Oncology : Journal of the European Society for Therapeutic Radiology and Oncology*, *127*(2), 326-331. http://dx.doi.org/10.1016/j.radonc.2018.02.019. PMid:29523411.

Mancosu, P., Signori, C., Clerici, E., Comito, T., D'Agostino, G. R., Franceschini, D., Franzese, C., Lobefalo, F., Navarria, P., Paganini, L., Reggiori, G., Tomatis, S., & Scorsetti, M. (2021). Critical re-evaluation of a failure mode effect analysis in a radiation therapy department after ten years. *Practical Radiation Oncology*, *11*(3), e329-e338. http://dx.doi.org/10.1016/j.prro.2020.11.002. PMid:33197646.

Marks, L., Jackson, M., Xie, L., Chang, S. X., Burkhardt, K. D., Mazur, L., Jones, E. L., Saponaro, P., Lachapelle, D., Baynes, D. C., & Adams, R. D. (2011). The challenge of maximizing safety in radiation oncology. *Practical Radiation Oncology*, *1*(1), 2-14. http://dx.doi.org/10.1016/j.prro.2010.10.001. PMid:24673862.

Martin, L., Nelson, E., Lloyd, R., & Nolan, T. (2007). *Whole system measures* (IHI Innovation Series White Paper). Massachusetts: Institute for Healthcare Improvement. Retrieved in 2022, July 19, from http://www.ihi.org/IHI/Results/WhitePapers/WholeSystemMeasuresWhitePaper.htm

National Patient Safety Foundation – NPSF. (2008). Retrieved in 2022, July 19, from www.npsf.org/au/

Norsa'adah, B., Rampal, K., & Mohd Amin, R. (2021). Time taken for symptom recognition, first consultation, diagnosis and first definitive treatment and its associated factors among women with breast cancer. *Asian Pacific Journal of Cancer Prevention*, *22*(11), 3623-3631. http://dx.doi.org/10.31557/APJCP.2021.22.11.3623. PMid:34837921.

Podsakoff, P., Mackenzie, S., Lee, J. Y., & Podsakoff, N. P. (2003). Common methods biases in behavioral research: A critical review of the literature and recommended remedies. *The Journal of Applied Psychology*, *88*(5), 879-903. http://dx.doi.org/10.1037/0021-9010.88.5.879. PMid:14516251.

Radicchi, L. A., Toledo, J. C., & Alliprandini, D. H. (2020). Critical success factors for implementation of an incident learning system in radiation oncology department. *Reports of Practical Oncology and Radiotherapy : Journal of Greatpoland Cancer Center in Poznan and Polish Society of Radiation Oncology*, *25*(6), 994-1000. http://dx.doi.org/10.1016/j.rpor.2020.09.014. PMid:33132764.

Richard, M., Parmar, M., Calestagne, P., & McVey, L. (2010). Seeking patient feedback an important dimension of quality in cancer Care. *Journal of Nursing Care Quality*, *25*(4), 344-351. http://dx.doi.org/10.1097/NCQ.0b013e3181d5c055. PMid:20164806.

Royal College of Radiologists – RCR. (2008). *Towards safer radiotherapy.* Retrieved in 2022, July 19, from https://www.rcr.ac.uk/docs/oncology/pdf/Towards saferRT final.pdf

Schubert, L., Liu, A., Gan, G., Amini, A., Hutchison, R., Ernest, J., Thornton, D., Stoehr, S., Hinman, B., Stuhr, K., Westerly, D., Schefter, T., & Fisher, C. (2016). Practical implementation of quality improvement for high-dose-rate brachytherapy. *Practical Radiation Oncology*, *6*(1), 34-43. http://dx.doi.org/10.1016/j.prro.2015.09.003. PMid:26577008.

Simons, P., Backes, H., Bergs, J., Emans, D., Johannesma, M., Jacobs, M., Marneffe, W., & Vandijck, D. (2017). The effects of a lean transition on process times, patients and employees. *International Journal of Health Care Quality Assurance*, *30*(2), 103-118. http://dx.doi.org/10.1108/IJHCQA-08-2015-0106. PMid:28256930.

Simons, P., Houben, R., Vlayen, A., Hellings, J., Pijls-Johannesma, M., Marneffe, W., & Vandijck, D. (2014). Does Lean management improve patient safety culture? An extensive evaluation of safety culture in a radiotherapy institute. *European Journal of Oncology*, *19*(1), 29-37. PMid:25266845.

Stock, G., Mcfadden, K., & Gowen 3rd, C. (2010). Organizational culture, knowledge management, and patient safety in U.S. hospitals. *The Quality Management Journal*, *17*(2), 7-26. http://dx.doi.org/10.1080/10686967.2010.11918267.

van Lent, W., de Beer, R., van Triest, B., & van Harten, W. H. (2013). Selecting indicators for international benchmarking of radiotherapy centers. *Journal of Radiotherapy in Practice*, *12*(1), 26-38. http://dx.doi.org/10.1017/S1460396911000513.

Vissers, J., & Beech, R. (2005). Health operations management: patient flow logistics in health care. In J. Vissers & R. Beech (Eds.), *Health operations management: basic concepts and approaches* (pp. 39-51). New York: Routledge. http://dx.doi.org/10.4324/9780203356791.

Williamson, F., & Thomadsen, B. (2008). Foreword - Symposium quality assurance of radiation therapy: The challenges of advanced technologies. *International Journal of Radiation Oncology, Biology, Physics*, *71*(1, Suppl.), S1. http://dx.doi.org/10.1016/j.ijrobp.2007.11.033. PMid:18406904.

World Health Organization – WHO. (1988). *Quality assurance in radiotherapy.* Geneva: WHO.

World Health Organization – WHO. (2008). *Radiotherapy risk profile*. Geneva: WHO.

Yan, H., Hu, Z., Huang, P., Men, K., Zhang, Y., Wang, L.-H., Li, Y.-X., Dai, J.-R., & Hu, Y.-M. (2021). The status of medical physics in radiotherapy in China. *Physica Medica*, *85*, 147-157. http://dx.doi.org/10.1016/j.ejmp.2021.05.007. PMid:34010803.