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RESEARCH ARTICLE

DEVELOPMENT OF METHODOLOGY OF REGISTRATION AND TREATMENT OF NON-CONFORMITY FOR MEDICAL DIAGNOSTIC SERVICES BY IMAGE

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ABSTRACT

Health organizations are increasingly investing in the implementation of quality management systems. Although there are a number of difficulties in assessing quality in health care, there is unanimity among managers that appropriate evaluation systems and indicators need to be chosen to support the administration of services and to provide more effective and efficient decision-making. When a service or product fails to meet any demand, a nonconformity is configured. Some companies often do not know how to create or implement a nonconformity management methodology or take action against any existing ones. Therefore, the general objective of this article is to propose a methodology of registration and treatment of nonconformity for medical diagnostic services by image. It is a qualitative-quantitative research of applied nature in the mode of technological production that counted on 12 participants experts. For such, the research was conducted from two main stages. The methodology created requires the support of a professional in the area of Information Technology, definition of processes and responsibilities in the company and also a work of dissemination and training to avoid resistance of employees. The methodology made it possible to generate on-line nonconformities, follow e-mail records and reminders, apply cause analysis, action plan and even record the effectiveness check, as well as interact with the employee at any time, attach documents and manage - via the report, taking into account the standard of the Program of Accreditation in Diagnosis by Image of the Brazilian College of Radiology. It is concluded that the methodology created helps to systematize the process of registration and treatment of nonconformities which contributes to the reduction of costs, feeding of internal indicators and evidence the importance of processes that are often not built or implemented for lack of knowledge or time.

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INTRODUCTION

The new business focus, marked by the need for differentiation, qualification and survival in the market is strongly influenced by customers' demands, globalization, competition, social and environmental issues, among other factors (Foss; Pedersen, 2002). In health organizations is no different, to overcome these challenges from modernity, becomes a requirement, incorporating substantial modifications and measures, aiming at corporate longevity and subsidize health organizations (Karamitri *et al*., 2015). The quality aims at the rigid and continuous control of the safety of the processes that involve the main client of the health organizations, the patient.

Among the various tools that collaborate with the continuous improvement in quality management and the management of the business as a whole, the nonconformities register stands out. The recording and treatment of nonconformities, as well as the critical analysis of it, with the determination of its causes, evaluation of the need for actions to ensure that those nonconformities will not occur again, determination and implementation of the necessary actions, record of the results of the actions taken and critical analysis of corrective actions performed (NBR ISO / 9001: 2015; Padi, 2015) is a requirement for quality accreditation programs in Brazil. Therefore, the objective of this article is to propose a methodology for registration and nonconformity treatment for medical diagnostic imaging services.

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MATERIALS AND METHODS

This is a qualitative-quantitative approach applied in the technological production modality that developed a methodology called "Non-Conformity Manager (CNG)". A group of 12 Experts Group was included in the study. The criteria for inclusion in the group were: to have minimal training in secondary education, over 18 years of age, to work in health or technology organizations such as exam executor, nursing team, manager, administrative, developer or IT support for at least 3 years. In order for the professionals to be able to answer the questionnaire in a reliable way, the methodology was presented, which lasted approximately 20 minutes, and later the participants used the methodology. Each participant used the tool following an explanatory script. As a tool to evaluate the usability of the CNS and data collection, the questionnaire of the SUS scale - System Usability Scale was created by John Brooke (Brooke, 1996), composed of 10 questions with a scale of 1 to 5, representing the levels of disagreement and agreement, to be chosen by the respondent, for each presented question. The same was applied to the Individual Experts Group. For this research we chose the electronic collection, through the form of Google, composed of 17 questions.

The first 6 questions involved the identification of the respondent, the other questions were about the use of the tool. This research was approved by the Research Ethics Committee of the State Department of Health of Santa Catarina / SES, opinion no. 2,147,595, according to the Resolution of the National Health Council of the Ministry of Health 466/2012, an instrument of bioethical nature which regulates research with human beings (BRAZIL, 2012).

RESULTS

For the control and organization of the requirements, which made up the tool, a checklist with 77 items was initially created, based on what is recommended for registration and nonconformity treatment in the PADI standard. Of these items, 09 related to clinical events, 12 to Radioprotection, 11 to the acquisition and image process, and 45 to operational records, which monitor the operation and do not necessarily merit complete analysis for each entry. The nonconformities were separated into 4 categories: a) Clinical (CL): that involve the patient and should be analyzed, identified the causes, applied corrective action, root cause analysis and efficacy of correction; b) Radioprotection (RP): Related to the process of protection against ionizing radiation and should be analyzed, identified the causes, applied corrective action, root cause analysis and correction effectiveness; c) Technician (TEC): which involves the process of image acquisition and should be analyzed, identified the causes, applied corrective action, root cause analysis and correction effectiveness; d) Operational Register (RO): These are NCs that involve the operation in any area of the SDMI and that should be monitored, accounted for and presented in periodic critical analysis to define actions when necessary.

For Operational Register there is no need for immediate action and individual root cause analysis. The subcategory will be the precursor of the direction of the same to the manager who must treat it, that is, a type of nonconformity will only have one responsible, which will be automatically defined. The NC targeting criterion was defined according to the actors usually known within an SDMI: Administrative Manager (ADM), Customer Service Manager (GA), Production Manager (GP) and Technical Manager (RT). This targeting can be adapted according to the reality of the service, since the OTRS tool is parameterizable. OTRS is a tool that has no configuration, ie empty, but allows a variety of forms and order of configuration, being a very versatile tool and applied to different realities. For this reason the method of this research was created and the OTRS served as a tool for application of the methodology.

With the SNC, it is possible to generate on-line nonconformities, track records and reminders via e-mail, apply cause analysis, action plan and even record the effectiveness check, as well as interact with the employee at any time, attach documents and manage them via a report, according to the standard of the Program of Accreditation in Diagnosis by Image of the Brazilian College of Radiology. In this model almost 80 nonconformities were mapped. Also, a structure with 4 area managers was designed, but this configuration can be changed according to the structure and specificity of the company that use the tool. Great effort was made to make the timing of registration as easy as possible and thus reduce employee resistance and avoid underreporting.

A very important resource used in this research was the generic clerk, which allows the automatic classification of some criteria and in this way contributes to the minimization of errors from the beginning to the end of the process, assigning the non-compliance to the correct person and assigning the classification of high, normal and serious for the fulfillment of deadlines, for example. With this method the systematization and agility of the nonconformity management process was made possible, since there is no need to use paper. Also, through the suggestion of maximum treatment time of the NC, it is possible to devote efforts of the manager to the treatment of serious CN, without exceeding deadlines, after all, the tool will alert as to the arrival of NC or scheduling the maximum time for treatment of the event. As an example, we can cite a serious NC, Individual Protection Equipment or Defective Collectives. According to the method, it is necessary to initiate the immediate action until 24h (1 day) after the opening of the call. In this interaction corrective or preventive actions must be implemented. The analysis and solution should occur 48h (2 days) after the opening of the call and in this period we must carry out the analysis of the cause and apply the solution and finally, the evaluation of the efficacy should occur within a maximum of 72h (3 days) from the opening of the call and at this point the evaluation of effectiveness and closure of nonconformity must occur.

The method already automatically classifies NCs into clinical, radioprotection, technical and operational records. This classification was used to meet what is recommended for registration and treatment of non-compliance of the PADI standard. Also, it allows to classify the origin of the called and for this research the classifications meet the requested by the PADI: internal audits, external audits; process and customer complaints. Based on this information, managers are able to guide their decisions, because with all this information it is possible to have more quality in the indicators of the company. Table 1 lists all the features that can be perceived at the user level.

Table 1. Funcionalidades de SNC

Nº	Features available at the SNC
1	Internal and external access to the tool: from inside and outside the company
2	Registration of the event by the collaborator of any computer, just having a user and password
3	Receipt by the employee of confirmation of creation and closing of the NC by e-mail
4	Receipt, by the manager, of opening new NC via email
5	Receipt by the manager of reminders via e-mail with the respective deadline for treatment, according to the severity of the event
6	Possibility of total treatment of the NC according to the PADI standard of the CBR, that is: it allows to go through the situation of immediate action, analysis of the cause, plan of action and verification of the effectiveness
7	Possibility of attaching documents showing some stage of the process of non-conformity treatment
8	DefiningDifferentUserPrivileges
9	Creation and monitoring of reports
10	Traceability at any time of the information

Table 2. Example of nonconformities

Process	RegistrationInformation
Non-compliance with Radioprotection identified during internal audit	
Item audited:	Item 7.2.35 of the PADI Standard Version 3.0
Criterion:	The quality control of radiographic examinations must follow the guidelines of Federal Ordinance 453/98 and the Manual of Medical Radiodiagnosis: equipment and safety performance of Anvisa (2005) or any existing legislation or directives that may replace them. Records should be kept.
No observed compliance:	Evidence: At the time of the audit it was reported that radiology quality control was performed by the company responsible for medical physics, but the records were not found physically and the collaborators were unable to make available for conference in the audit.
Cause Analysis:	Technique used: 5 Whys Why were medical physics reports unavailable? Because there was no charge by the manager after the tests. Why was there no charge? Because the area manager does not feel responsible for this task and because there is no standard procedure for this critical activity (root cause).
Actionplan:	1) It should be described in the standard document defining roles and responsibilities that the monitoring and management of Medical Physics tasks is the responsibility of the Image Production Manager. 2) Create a manual describing this critical task, physical storage location of equipment test reports, periodicity of tests and also the maximum deadline for submission of reports by Medical Physics. 3) Review periodicity and evidence of all mandatory radiological protection tests.
Solution after efficacy assessment:	After completion of the action plan there was monitoring during and after the next cycle of tests by the company of Medical Physics and the procedure defined in Standard Manual was fulfilled, and there is no evidence of recurrence of this nonconformity.
Type:	Internal Audit

To illustrate the use of the tool, we developed an example of nonconformities and the possible treatment, according to table 2. In addition, it is possible to create and generate reports for monitoring and managing this process. Finally, it is important to mention that the proposed method ensures the traceability of information and at any time we can have quick access to all the non-compliance and due interactions that have occurred over time. At the end of this work, annon-compliance analysis form was made available which can contribute to the collaborators as a second option, simply by attaching to the tool for proper registration, traceability guarantee and physical filing of papers. Some of the positive aspects of the methodology are: gratuitousness, systematization of the process of management of nonconformities, definition of responsibilities and transparency, traceability of information, identification of recidivism, agility, reminders versus resoluteness, quick ordering, indicators and management, records history, planning and pre-registration mapping and usability. In relation to the difficulties faced in the implementation of this methodology: lack of support from a professional in the area of information technology, lack of mapped processes, situation of the call and resistance.

Conclusion

The content of this article provokes great theoretical discussions, besides having, in its applicability, a great challenge, since it is not observed, a culture of registration and treatment of nonconformity, in the segment of diagnostic by image.

Therefore, it presented a methodology of registration of nonconformity. It is strongly believed that process management enables the improvement of organizational processes, including, mainly, radiological protection. Although there are a number of difficulties and variables in assessing health quality, there is unanimity among managers that it is necessary to choose appropriate evaluation systems and indicators to support service management and enable more effective and efficient decision-making. The proposed methodology allows to systematize the process of registration and treatment of nonconformities, which indirectly will contribute to the reduction of costs, feeding of internal indicators, as well as to highlight the importance of the process in theme, which are often not built or implemented by lack of knowledge or time. Future work suggests the application of the usability questionnaire to all users of this tool, after some time of use in the organization, as a way to enable the continuous improvement of the tool. It is also suggested the construction and application of other forms of evaluation of the tool.

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