From reporting incidents in a radiation therapy department to enterprise risk management (ERM) based on the European Foundation for Quality Management philosophy (EFQM)

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Abstract

The radiation therapy department (RTD) initiated in 2009 a policy of open and transparent reporting of events not harming (near incidents) and potentially harming patients (incidents and accidents). This approach was immediately followed by the leader's decision to engage towards the European Foundation for Quality Management (EFQM) excellence model. The EFQM approach structured the journey of the RTD to enterprise risk management. We intend to demonstrate in the five main fields of the EFQM approach (leadership, policy and strategy, people/personnel, partnership and resources, processes), how the journey to continuous improvement in quality and safety did evolve and was accelerated in RTD. The assessment made by external evaluators evolved from a minimum of 90 points (basic requirement for level 1 in 2009) to a at least 180 points (basic requirement for level 2 in 2011), to reach 400 points in 2013 (270 required for level 3 and 450 required for level 4).

Keywords: Enterprise risk management, European Foundation for Quality Management, Event reporting, Radiotherapy

Introduction

There has always been particular interest in quality in the field of radiation therapy. Very soon the leaders of radiation therapy departments (RTDs), as well as medical and administrative authorities, have been aware about the necessity of benchmarking beam quality. This is only the technical top of the quality iceberg. In France, after the Epinal drama where thousands of patients did not receive the correct radiation dose, the government took the decision to implement an industrial approach of global quality management and asked airline industry to implement the ORION® methodology essentially based on the CREx approach (CREx='committee of experience return'). This relies on the 'no shame no blame policy' as practiced in a high reliability organization (HRO), pushing all employees to report events, whether these are harming or not the patients. This philosophy of reporting 'all by all', inclusive near incidents, allows analyzing deeply the system and identifying the root causes of error. As a result one can implement corrective actions and measure their effect. This approach is known as the virtuous Deming's cycle of plan-do-check-act leading to continuous improvement. Aware of this national policy in France, we took the decision in 2009 to start the same method in the RTD in Liège. The RTD was trained by instructors issued from the airline industry (AFM-42, spin-off from Air France Industry) after installing a 'no shame no blame policy' but in the context of a 'just culture' (wishful disregarding of rules and violations are unacceptable).

In the French speaking part of Belgium, as in other countries in Europe, the regional authorities organize a contest for enterprises in order to promote the long journey to the European Foundation for Quality Management (EFQM) accreditation.[1] The EFQM approach, which is a generic model, is used by more than 30 000 enterprises/organizations worldwide (The EFQM Excellence Model. Brussels: EFQM Representative Office, 1999). The model allows measuring

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quantitatively the maturity level of an organization and helps it to understand the strengths, weaknesses, opportunities, and threats and to exchange expertise in the field of enterprise risk management (ERM) with a common language. It consists of nine criteria grouped in 'enablers' and 'results'. The enablers are: leadership, policy and strategy, people, partnerships and resources, and processes. The results criteria are: customer results, people results, society results, and key performance results. Although it has been shown to be not only applicable in the healthcare sector, and effective in promoting quality, it has been considered challenging to be implemented in this sector for different reasons.[1–9]

The contest organized by MWQ (Mouvement Wallon pour la Qualité) is organized in four steps, preparing the organization to the European audit and helping it in a structured multi-level approach to ERM. Immediately after the implementation of a policy of reporting near incidents and incidents/accidents (incident reporting, IR), the leader of the RTD decided to participate in this contest. We intend to highlight the impact of IR in each domain of the enablers of the EFQM model and the resulting increase in EFQM score.

Methodology

In 2009, the leader of the RTD introduced the 'no shame no blame policy' but applying Dekker's concept of a 'just culture'.[10] A full time equivalent safety officer (SO) was hired in with a part time equivalent administrative support. The department as a whole has been trained by instructors issued from civil aviation and specialized in ERM. Some leaders of the department underwent a complimentary training provided by the Belgian Air Force and by the Southern California Safety Institute.

Events – reported by all team members – whether harming (incidents and accidents) or not harming (near incidents) were systematically registered, labeled according to the WHO taxonomy, analyzed and ranked according to the 'failure mode and effect analysis'. The most critical ones were selected by the safety committee (CREx), chaired by the SO, and joined in this effort by voluntary representatives of all professions in a balanced format (physicians, physicists, nurses, technologists, and administrative staff). Corrective actions were developed by 'pilots' designated within the safety committee, implemented, and their effect evaluated.

IR serve as the basis for development and implementation of actions in the fields of leadership, strategy, personnel, partners and resources, processes (=enablers). The efficiency of actions in these different fields is evaluated as much as possible by indicators, followed closely within the balance score card (BSC) (=results).

Results

Leadership

To develop the approach of IR within the department, the leadership defined first the vision, the mission, and the values within the department. This was done with the help of external auditors and resulted in the design of a campaign with posters to promote these at strategic points in the RTD at all levels. After 2 years, the leaders decided to run a second campaign, asking to brainstorm for keywords for vision, mission, and values at all levels of the organization. This resulted in a new set of word cloud posters (http://www.wordle.net).

The leaders from the various professional subgroups decided that during the weekly managerial meetings (COPIL = piloting committee), the majority of the time should be allocated to system analysis and its impact on the quality and safety. The SO is considered as a full and independent member of the (COPIL), and reports systematically on the activity of the CREx.

To promote and improve an open and transparent communication within the organization, the strategic decisions of the COPIL are published as posters and the most relevant information and decisions are projected on a screen in the 'coffee room'. Moreover, every 6 months there is a substantial time allocated to safety and quality issues during the department meeting where every single member of the RTD should attend. Once a year, there is a supplementary meeting of the RTD totally dedicated to quality and safety issues especially emphasizing on the results of the CREx. The communication model of the COPIL itself has been the subject of an external audit in order to be improved at all levels. International benchmarking is performed through the participation to the yearly French Inter-CREx meeting.

Strategy

The COPIL rapidly decided – after having defined mission, vision, and values – to build a tool to assess whether the strategic priorities were met. A BSC was developed and designed in such a way that it matches the five 'enablers' of the EFQM philosophy. For each of the main topics, there has been a selection of robust and easily (automatically) retrievable indicators as well as definition of target

values to be reached (the results of the EFQM model).

The indicators in the BSC are patient-oriented, resource-oriented, and process-oriented.

The first group encompasses, for example, patient load with a target of 1.5% yearly growth rate, the geographical distribution as an index of regional penetrance of the RTD, and the patient satisfaction score (85% of patients should score a high degree of satisfaction). Since spring 2013, more than 1000 questionnaires on patient's satisfaction have been gathered and in parallel interviews were conducted with a random selection of patients, but balanced among the various types of cancers. The results of this enquire will be submitted separately. We also register systematically the updates of treatment standards.

The second set of indicators contains the operational resources (technical and human) and all the financial targets (e.g. annual turnover, group turnover, operating cost). For the human resources, we measure training level, participation to continuous improvement programs, and scientific activity. For the technical resources, we register obviously down-time/up-time, reasons of technical interruptions, and reaction time of service providers.

The third set of indicators illustrates the efficiency of the organizational processes. This set contains the number of treatment sessions, numbers of highly complex treatments, mean delay between first contact (medical consultation) and start treatment, mean duration of treatment session, inter-session time interval. More recently, we decided to start the evaluation of 'cycle time' and calculate in a value stream model the percentage efficacy of the process. The next step is obviously to check the impact of corrective actions on this latter.

Our policy in the field of quality and safety became an integral and major part of the BSC. There has been a systematic registration of the number of events per month, the number of corrective actions designed, and the number of actions implemented within the a priori defined time limit.

The combination of all the indicators allowed us to fine-tune the investment plan and resulted in a financial equilibrium notwithstanding the fact that in the same period major investments were made aiming at increasing the quality and complexity of treatments. This had a direct impact on financial return with *in fine* a healthy and consolidated profit.

Personnel

The IR system highlighted a discrepancy between the professional profile as defined by the department of nursing care and the one defined by the COPIL in the RTD. Although this was expected, as in Belgium the law requires that radiation treatment application is done by nurses and not technologists trained to do so (the law has been changed in 2013), we were able to objectively define the lacunas in the nurse profile and decided for a formal training. This formal training has been validated by the academic authorities. In total, 52 persons were submitted to this education program (265 hours) and 112 are concerned by our continuous education program. The value of the education program itself and the teaching staff are systematically recorded in order to feed the virtuous cycle of Deming (continuous improvement process of the educational program). The leadership is totally convinced that a real safety culture relies on acquisition of basic knowledge to understand what we do, acquisition of technical and non-technical skills (integration, team work, and assertive communication). Moreover, the RTD plans to acquire in a near future a 'flight simulator' (a simulator of a linear accelerator) to provide training in practical skills and training in crew resource management.

Partners and resources

The more industrial approach in ERM in the RTD was made possible by a close collaboration with people from high schools in enterprise management (HEC-Liège). Students of HEC, coached by their mentors, were actively involved in a complete process mapping of the activities in the department. Process mapping has, for example, been performed for the treatment file flow throughout the RTD, nurse activity within the bunker, evaluation of patient's satisfaction, and the process of strategic decision making within the COPIL.

The combination IR and the process mapping allowed us to define professional subgroups accountable for some recurrent incidents and design targeted corrective actions. One of these corrective actions is, for example, the abovementioned training program for nurses.

Moreover, the translation of the activities of RTD in process maps highlights the complexity of the workflow. The leaders are trained nowadays in the basic concept of LEAN management in order to simplify the process and to render it less susceptible to unexpected incidents (make the easy thing the right thing to do) and to improve the efficiency of the system (value stream mapping). Now that the process maps are established, bottlenecks highlighted by IR, it is possible to design solutions directly targeting the problem and calculate the process efficiency. We are currently implementing

the value stream model to measure quantitatively the impact of the decisions on the process.

Patients are obviously partners. What we aim at is the satisfaction of the patients. As you can only manage what you measure, we implemented a systematic evaluation of the level of satisfaction. This has been incorporated as an indicator with a target value. These are obviously not the only partners and stakeholders and we do realize that a special effort should be dedicated for all.

Processes

In order to label an event as 'unexpected', the first thing to do is obviously to describe what is expected. All members at all levels of the department were asked to write down the standards. These standards were agreed upon between the various professionals and are collected in the manual of standard operating procedures (SOPs) after validation by the SO and the head of department. These standards are regularly reviewed and adapted. Team members are systematically involved to rethink the standards and do receive a flagged announcement of changes. At different levels of the process, there is a formal request to declare whether everything is running according to the standard or not. This allows screening the validity of the standard and the compliance to it within the organization. With this kind of IR, we observe that within the processes there are bottlenecks illustrated by the recurrence of reporting the same incidence over and over again, although a variety of corrective actions have been designed and implemented. As our approach of detailed task prescription allows – after analysis – to assign a professional accountability for these recurrent events, the COPIL is able to identify the target group of professionals and able to ask the identified frontline staff to search for new solutions to eliminate the bottleneck. Moreover, to ensure the total quality and safety, we implemented specific checklists at critical points and installed whenever possible a 'no-fly policy' to avoid less adequate treatment preparation and execution. The frontline staff has created and updated 276 standards and procedures, based on a database of more than 4000 events reported from 2009 on.

Effect on the EFQM score in the RTD (from 2009 to 2013)

At the first participation to the MWQ in 2009, the external evaluators and the regional jury not only attributed the first level (minimum requirement 90 points, i.e. 45% of the target being 200 points), but also granted the RTD the Walloon price for 'the most original approach to global quality management'. At the second participation in 2011, the requirements for the second level were fulfilled (minimal requirement 180 points upon 400 points) and again the RTD obtained two prices (the second level price and the price for 'the most original approach in human resource management and continuous education'). At the third participation in 2013, the RTD scored 400 points, reaching largely the third level (the required number of points being 270 at this level) and close to the fourth level (450 points upon the final total of 1000 points). Again the RTD was granted the price in the category. Each EFQM feedback report from the external evaluators significantly contributed to the progression in ERM.[2]

It is noteworthy that in Germany, most hospitals score 200–300 points.[2,5] In an initiative taken by the Basque Health Service only 32% of the health organizations exceed 400 points by self-assessment.[11] As a general rule the score is lower if the assessment is made by an external audit. In order to compare, the 'champions' in the industrial sector reached 650–750 points. In our RTD, the score has been attributed by the experienced external auditors issued from the EFQM initiative. It is noteworthy that to reach this level, the organizations need in general 6 years of continuous effort.

Conclusion

The management of safety and quality in the healthcare sector cannot be dissociated. Safety is an integral part of quality. By starting off measuring the safety, through the reporting of near incidents, incidents, and accidents, the department rapidly evolved to an ERM approach which is totally copy-pasted from the industrial HROs.

Through the multi-step approach, as promoted by this regional contest, we were able to structure the journey to ERM, to develop collaborations with HEC, and to modify the safety culture within the department. The presence of the SO, the safety committee (CREx), and the open IR in the context of 'a just culture' are considered nowadays as the way we work naturally. The registration and analysis of everything that happens in the department and which is not part of our SOPs allows us to refine our leadership view and strategy, to adapt our continuous education programs and training for personnel, to redesign workflow and processes.

The challenging use in our RTD of the EFQM global excellence model was essentially based on the systemic evaluation of safety and clinical effectiveness. Our IR system and analysis is patient-

and system-oriented and fits perfectly well with the proposed adaptation of the EFQM model to incorporate the essentials of the PATH (Performance Assessment Tool for quality improvement in Hospitals developed by the World Health Organization regional office for Europe).[12] In the PATH, the basic transversal dimensions are patient centeredness and safety, crossing the four dimensions (clinical effectiveness, production efficiency, staff effectiveness, and responsive governance which all are close to the enablers of the EFQM model).

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