

THE NEW ISO 9001:2015: A STEP CLOSER TO SUSTAINABLE INTEGRATED MANAGEMENT IN HEALTHCARE

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Abstract

Among norm-based management systems, healthcare organizations in Germany use ISO 9001 as it has become compulsory to have a quality management system. Until the innovative ISO 9001:2015 proposal it was no direct connection to other management systems like risk or knowledge management. Only some entities ensured inter-connections or solely linked to the strategic planning process. Still, healthcare encapsulates supplementary requirements that imply integrating different systems. In addition, the financial crisis encouraged the tendency to operate integrated reporting beyond merely financial aspects. This paper aims at presenting the development of an integrated management and reporting system dedicated to healthcare organizations as a tool for sustainability management. Accordingly, different norm-based management systems (quality management, environmental management) link strategic planning and controlling through a balanced scorecard and integrated reporting according to International Integrated Reporting Initiative model. The literature review clarified theoretical concepts, while the case study acquired comprehensive data on a medical German company, RNR AG, and specific knowledge. Contributing to closing the literature gap on fully integrated management and reporting system in healthcare, the findings will simultaneously assist practitioners and beyond. ISO 9001:2015 proposal designates integrated management system as the future for all certified entities, irrelevant to field of activity.

Keywords: ISO 9001:2015; quality management; sustainability; healthcare; integrated reporting; balanced scorecard.

JEL Classification: L2; M14; I10; G32.

1 Introduction

The integration of different management systems with the planning and reporting process is not yet a regular concept for sustainable management even if it delivers various advantages. Some business sectors, like healthcare, accept it more easily and logically because of legal requirements, rising expenditures (*Joint report on health systems, 2010*) whereas performance and quality stay behind. However, the interconnection of different modules is often weak. Therefore, to build an integrated management system without conceptual flaws, the basic management systems must be built upon a common norm like ISO 9001. After the first ISO 9001 version in 1987, 2008 brought clarifications and changes for improving consistency with other management systems. Compared to previous amendments, the forthcoming ISO 9001:2015 has an original 'high-Level-structure', warranting alike construction for all norm-based management systems. Beside, risk management, change management and knowledge management are new topics, supporting globally applicability for ISO certifications.

Unlike other industries, healthcare has had fewer ISO certificates, with a maximum of 3.58% for health and social work certificates of the worldwide figure in 2008, and only 3.01% in 2014 (authors' computations based on ISO survey 2013 data). This happened for different reasons. Quality management in healthcare is a young discipline and many QM-systems compete against each other (e.g.: *Kooperation für Transparenz und Qualität im Gesundheitswesen - KTQ*, *Qualität und Entwicklung in Praxen - QEP*, *European Foundation for Quality Management - EFQM*, *Total Quality Management -TQM*) according to Klanziga (2000). ISO 9001 was thought as inappropriate a long time, until in 2012, when ISO EN 15224, already dealing with risk management, adapted DIN ISO 9001 to healthcare systems.

The uniqueness of ISO 9001:2015 will shape the future, as all certified organizations must implement a risk and knowledge management system as part of their QM system.

Our research plans to fill in the theoretical gap on sustainability and IMRS in healthcare organizations. In addition, it encourages healthcare managers to implement an integrated system based on the existing norm-based management systems, by presenting the implementation of an IMRS in a large German healthcare company, RNR AG.

2 Methodological design and integrated management state of the art

The query of the German healthcare provider, RNR AG: *'How can we implement an integrated management system simultaneously with optimizing business processes, respecting complex healthcare regulations and QM (quality management) requirements, and reaching our strategically goals?'* became our research question on which the investigation methodology was designed.

The literature review delimited several theoretical themes. The operating concepts and their definitions in healthcare QM context, considering "demographic changes", "an ageing population" or "new and emerging health problems" (Shaw 2003) indicated a correlation with growing expenditures and need for a reliable reporting system on the impact of investments and quality of healthcare output (Groene et al. 2009). Initiatives for *international integrated reporting (IIRI)* or *'one report'* (Eccles and Krzus, 2010) offered a would-be solution of *'integrated thinking, decision-making and actions that focus on the creation of value over the short, medium and long term'* (IIRC, 2013). The empiric studies on integrated management systems (IMS) started about twenty years ago rose interest for business and academics.

Secondly, it was exhibited a unique definition for what integrated management system stands for in private healthcare, taking into account German medical industry. For contributing also to practice we selected a group of German medical companies which are in the *sustain stage* (Kaplan, 2010), meaning after considerable investments, the aim is increasing return on it. Still, profitability remains connected to expanding and national coverage.

The possibility to collect comprehensive data on a large healthcare company, specific knowledge on a real IMRS processes and procedures, and to generate advanced research hypothesis were the arguments for choosing a *descriptive case study* (Yin, 1984) as a research instrument. Taking interest in a unique aspect and analyzing its features through a description theory, contributed to new queries as it happened when defining IMRS. As the case study works with relevant data for a particular healthcare market, it will carry in the near future a complementary research for expanding the conclusions to the European healthcare.

3 Integrating approach in a German healthcare business

3.1 What is an integrated management system

Norm-based management systems contain indispensable elements, claiming to provide a holistic approach, but often are not part of the general management kit for organizational success and sustainability. The main complications are because:

- Weak/no connection between norm-based management system and strategic planning process or the strategic financial goals.
- The general controlling system does not include key features of norm-based management systems and sustainability.
- Healthcare legal constraints increase annually, leaving single norm-based management systems covering only several of them.

Additional reporting obligations towards different stakeholders (state, patients, health insurance companies, etc.) address quality aspects, relating new concepts and reporting initiatives like IIRI (International Integrated Reporting Initiative), “sustainability reporting” (Sustainability Reporting Guidelines - GRI, 2013) or “intellectual capital reports” (Abeysekera, 2013). It is challenging to deliver different interconnected reports for one entity, tracking completely different issues and stakeholders.

Consequently, we propose a definition of integrated management and reporting system followed by an implementation process in steps and at diverse organizational levels.

First level points at the *incorporation of all essential norm-based management systems within a healthcare business* into one single integrated management system - IMS (Fig. no. 1). The relevant management systems are:

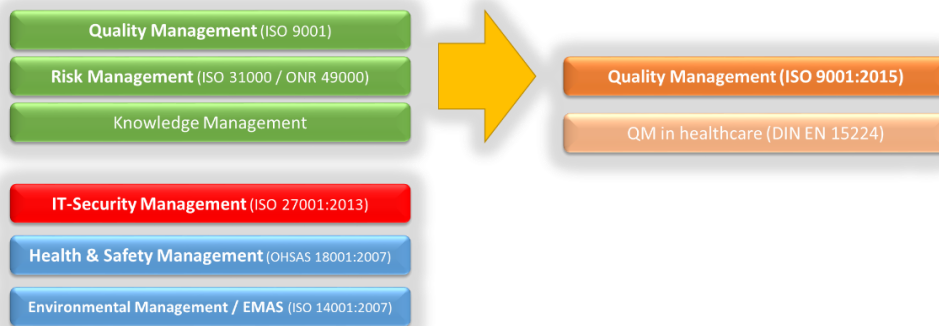
- Quality management system (ISO 9001:2008)
- Risk management system (ONR 49001 or ISO 31000)
- Knowledge Management (unregulated before by an international norm).
- IT-Security management (ISO 27001:2013)
- Health and safety management (OHSAS 18001:2007)
- Environmental management (ISO 14001:2007 or EMAS)

The first three norms are already included in the ISO 9001:2015 proposal or DIN EN 15224 “quality management in healthcare” regarding patient safety and clinical risks management.

The second level entails the integration of IMS into the strategic planning process by using a balanced scorecard - BSC. A complex strategically management and performance

evaluation instrument, the BSC joins strategic goals of organizations with diverse management perspectives (Kaplan. 2010).

Fig. no. 1 Norm-based elements of an IMS in the healthcare industry



Source: own compilation of the authors

Excepting the financial segment, the other perspectives are part of the norm-based management systems which implies to use the BSC as a connector (E. Grigoroudis et al. 2012).

This source is a reliable foundation for internal and external reporting, upgrading to the *third level of integration*. Finally, deriving our definition: an IMRS makes use of minimum norm-based management systems - *Quality management system, Risk Management system, Knowledge Management, IT-Security management, Health and safety management and Environmental management*, interrelated through the strategic planning via Balanced Scorecard and published through an integrated reporting system to ensure sustainability in healthcare.

3.2 RNR – the Company

RNR stands for a group of German companies, supplying medical services. The medical network consists of RNR AG, the parent company of RNR group and a shareholder company and three operational companies specialized in radiology and ray therapy. With 12 own locations providing services directly to patients, and other 13 sites located within different hospitals where it operates as part of the clinic services, the reliable experience and qualified employees RNR stands for one of the most important German medical organizations in its category.

The shareholders are the management team and the doctors. Started as a family business without external investors, the shareholders are interested in sustainable development and not in short-term profits. The administrative tasks (IT, human resources management or quality management) are concentrated in RNR AG and performed by around 200 employees, while the operational divisions sum up to 850 employees.

The group transformed considerably since January 2010, when it adopted the structure of a shareholder company for the leader enterprise, supported by three limited companies. Rising costs for radiology and ray therapy apparatus, high volume and complex activities put pressure, demanding management for profitability while valuing high quality standards.

4 Development of the IMRS project for the RNR Group

After obtaining the ISO 9001:2009 certification, RNR Group scheduled the expanding of the existing risk-management system to the operational part for 2014 by incorporating all management systems in one structure. Additional support came through the proposal for ISO 9001:2015 where the integration of risk- and knowledge management is compulsory. Following a first suggestion for the new ISO 9001 in December 2014, the QM-Team of RNR decided to start a project for implementing an IMRS, through the next steps.

4.1 Decision of the Board Members

To start an all-inclusive project it was necessary to get the commitment of the Board members. One key driver for of IMRS proposal in February 2015 was to offer a tool, which connects financial results with legal requirements covered by norm-based management systems. Classified as large enterprise, RNR group will be audited from different stakeholders' angles. The approval criteria was for processes and systems was to be 'lean', ensuring improvement without supplementary workforce, and 'agile' - adaptable to future growth.

4.2 Expanding Risk Management to the operational parts

After the restructuring in 2009, the RNR AG had to have a risk management system for strategic and financial risks. The requirements were fulfilled at the end of 2011, with the operating risk system according to ONR 49001. In the same year, ISO 15224 emerged as an interpretation of the general ISO 9001, chiefly for healthcare organizations. The ISO 15224:2012 (Norm DIN EN 15224) already contained concrete elements for risk management in healthcare. Furthermore, the 2013 external audit of the ISO 9001 at RNR indicated the rising interest of the auditors for risk management.

Hence, the overall development reinforced the choice of RNR for expanding its existing risk management towards operational risks. The big advantage was no need to start from the scratch. The risk management handbook, risk processes and tools for financial and strategic risks in RNR AG only had to be updated. The existing QM system also had previous elements concerning operational risks, adapted to conform requirements in risk management, hygienic management, radiation protection, safety management or privacy policy.

4.3 Integrating the different management systems in a unique system

Each of the management systems (Quality management, Risk Management, Knowledge Management, IT-Security management, Health and safety management, and Environmental management) have specific processes and applications.

In *quality management*, for example, were recognized:

- Online quality management handbook with standard operating procedures;
- Documentation of audit result in an online platform;
- Annual planning of internal and external audits;
- A regular management audit.

For the *risk management system*, the essentials already established:

- Online risk documentation and evaluation;
- Online documentation and administration of tasks dealing with risk;
- An annual risk report for the management;
- A web-based risk controlling application.

The objective was to use components of the two different management systems and combine them in one integrated system in order to fulfil the requirements for all systems, share resources and improve the acceptance level of users by operating with familiar features.

The risk management handbook for RNR AG was the start, adapted to cover as well operational risks in all the other companies of the group. It was also decided for the QM system to include an online handbook version, available to all employees. Next, the online platform included documentation and evaluation of risk to operational risks. While the old risk management system was solely accessible for RNR AG personnel, the new platform is open to all employees. This platform was introduced in two stages.

Originally, an online form to document “*unwanted events*” became available. The Risk Team of RNR AG evaluates unwanted events giving the criterion the event represents a potential risk or not. If the event was declared as a risk after a multilevel evaluation, then a group of experts have to decide how to reduce or avoid it. All steps are documented in an online workspace where every interested employee or external auditor can follow the current state of the risk.

Fig. no. 2 displays the risk reporting and controlling platform of RNR. On the left side one can choose between companies of the group, departments and reporting year. The risk matrix shows then the risks for the chosen setting according to the probability of appearance and possible damage. Risks with high probability levels are located in the upper right corner of the matrix. Below is tracked the development of the number of risks and an indicator for the development of potential amount of damage.

Fig. no. 2 Risks evaluation Matrix



Source: contribution of the authors using data from RNR group

In the second stage, the core processes of the business are analysed for potential risks against well-structured descriptions, experts describe potential process risks, evaluate them and decide about managing strategies.

Each step of a core process and possible deviations of a group of processes is necessary. All actions are again documented in online workspace for risk management. Later, internal audits expanded to operational risk management. The results of “unwanted events” documentation and process based risk analysis got included into the internal audit checklist. As novelty, auditors now verify if employees acknowledge and apply the standard operating procedures for dealing with risks.

4.4 Connecting and aligning the IMS-system with the strategic planning process

Before the beginning of each fiscal year, RNR group holds a strategic workshop for defining the business goals. Introduction of a BSC as instrument for connecting strategic planning process with IMS is on the 2015 agenda. Using BSC in a certified ISO 9001 healthcare organization is not complete new as many aspects of BSC are completed through ISO 9001. Still, the design of RNR group Balanced Scorecard is unlike (Fig. no. 3).

Fig. no. 3 The Balanced Scorecard of RNR group within the IMRS



Source: the own compilation of the authors

The “results perspective” is necessary especially in healthcare organisations because the number of patients or treatments often does not correlate with the financial aspects due to fixed budget in the public healthcare sector.

4.5 Implementing the integrated reporting system

The first aim was to build an internal integrated reporting system. The board members already received a monthly financial report, and an online Business-Intelligence tool presented daily the performance indicators. In addition, strategic and financial risks reports were issued every semester, and management audit evaluated the outcomes of QM systems once per year. The challenge was to consolidate the existing reporting systems.

The project team developed a reporting structure for covering needs of different internal stakeholders on frequency of reporting, how detailed the results should be and balance between quantitative and qualitative indicators. Technically, the team worked with the in-house developer of the Business Intelligence Solution, defining relevant data sources for the qualitative indicators and presentation technique in the online controlling platform.

The RNR group uses the external reporting system to communicate its results to banks, shareholders, and main partners. For the first part of IMRS project, external reporting was not a priority because of numerous related legal restrictions.

5. Practical implications of incorporating an IMS and conclusions

Implementing ISO 9001:2015 as part of IMRS is the logical next step for RNR. The company has organized the risk management for financial risks, as further expansion of risk management to operational parts was planned before because of ISO 15224 indications. This achievement and the ISO 9001 certifications will reflect into a short implementation period for the ISO 9001:2015 standard.

Another gain was cutting redundant work for management systems so future IMRS audits will include risk and knowledge aspects, without supplementary checks. It resulted also in an improvement in the quality of information used in the decision making process due to different management modules that function now as one. The contribution of each IMS activity to the strategic goals of is controllable with the BSC on every BSC-perspective, clearing connections between sub-components of IMS, strategy, mission, and business objectives. We underline again that ISO 9001:2015 with its 'high-level-structure' and innovative components are an important step towards a more integrated management system in all business areas. Nevertheless, our research effort goes beyond ISO 9001:2015. The success of an IMRS can only be guaranteed when it exist a deep integration with the strategic planning process over a BSC and a structured and integrated reporting System.

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