Operational Risk Management (ORM): the aviation safety model can be transposed into the medical sector

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Operational Risk Management is one of the most important attributes of High Reliability Organisations in the industrial sector. In this article it is questioned whether the Health Care Sector is a high reliability organisation. The application of safety models, widespread in the industrial sector is absolutely feasible in the medical sector. One should move from a shame-and-blame policy to a just culture. Pro-active search and reporting of unexpected events, incidents and accidents, coupled with root cause analysis and Deming's principle of continuous plan-do-check-act is the only way to improve system safety and reduce errors. These industrial methodologies have been implemented with success in our radiotherapy department since 2009. From reporting of incidents we were able to move to steering continuous education and process management. Facing the high human and economical societal burden linked to lack of a robust operational risk management in the health care sector, it is an ethical duty for leaders to define new values and behaviours, both defining a new culture!
(Belg J Med Oncol 2013;7(5):137-41)

Introduction

In some industrial sectors, "safety culture" is widespread. These particular industrial organisations are therefore rated high reliability organisations (HRO's). HRO's face high intrinsic hazards and yet perform successfully. These organisations treat safety systemically and systematically. One could raise the question whether the health care sector (HCS) is an HRO? At the first glance, it seems odd to consider that HCS is an "industrial" system. If one goes back to the definition of a "system" according to Bertalanffy, he has to admit that health care is one of these industrial systems. Indeed, a system is a set of interacting, interrelated, or interdependent elements that work together in a particular environment to perform the functions that are required to achieve the system's aim. The end-product in the health care sector is an effective treatment performed in conditions of optimal security and quality. Quality of care can be approached by Donabedian's 10-right framework.[1] The four structure-related rights are right information, setting, technology and personnel. The six process-related rights are right time, site, amount, care, fit and patient. Right care means incorporating evidence based care in local guidelines, protocols, care paths and standing orders. Right fit means patient centred care, i.e. considering patient's preferences in treatment approach.

There is however no doubt that the HCS is not performing as an HRO nowadays. Some authors claim that the HCS is the most poorly managed of all high-risk industries and very late in coming to recognize the importance of system factors that underlie adverse events (incidents and accidents).

If one reads the Institute of Medicine (IOM) report and the overwhelming amount of data on "medical error"

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published since then, he has to admit that the HCS has nothing to do with an HRO. To make it clear, the HCS is viewed as unwieldy, cumbersome, unfriendly and opaque to users. A world-wide known pilot, Captain Chesley B. Sullenberger commander of flight 1549 who landed his plane on the Hudson River, recently stated that if there were as many deaths as a result of accidents in the aviation industry as the rate reported in the HCS, there would be no plane which would take off any longer.

What is the epidemiology of error in HCS?

An earth-shaking report has been published in 1999 by the Institute of Medicine (IOM). The medical community in the US was not aware about the epidemiological importance of what has been called a "medical error". At the very start of this discussion, it seems important to replace the term "medical" error by "system" error. The reason for this will be explained.

Error is defined as "Unintended harm to the patient by an act of commission or omission or timing/sequencing or technique rather than by the underlying disease or condition of the patient". If one intends to implement an error-reducing strategy, he has to measure its importance. This obvious statement is a basic concept of management: you can only manage what you can measure!

The very first question, therefore, is "are we measuring error in HCS"? The general answer is unfortunately no! One of the reasons of not performing measurements is the universally spread *"shame and blame policy"*.[2,3] In order to obtain an objective measurement of the safety in the HCS the sector should move to a *"just culture"*. This is only possible if the dynamics of error are understood and when people are convinced to declare adverse events (AE). By the way, a just culture based on spontaneous declaration of events is also protecting at the end of the day the caregivers themselves.

The IOM report mentioned that 44,000 to 99,000 deaths per year in the hospital sector in the US are attributable to error.[4,5] This number of deaths corresponds to two crashes of a Boeing 747 a day. The risk of dying from an error is more than 1 upon a thousand hospital admissions. In Belgium, it can be estimated that 4,000 deaths a year are linked to system errors in the HCS. This number of deaths is larger than the one linked to road accidents![6] In 2011, for example, the surgeon operated the wrong side in 2,000 cases in France (source AFM42). These errors are at the origin of a longer hospital stay or significant mortality and morbidity. These drawbacks

represent an enormous cost burden to the society. It has been estimated that the total cost of preventable adverse events in the hospital sector in the US represents a yearly budget of 17 to 29 billion dollars.[7]

The high variability of medical errors reported in the literature might be linked to various reasons.[4,8] First of all the way an adverse event is defined may be different. Moreover there are methodological differences (type of events, method of documentation) and different perspectives (for example medico-legal versus quality improvement point of view).

However, there seems to be a consensus today that adverse events are in general largely underreported.[9] Therefore, in contrast to industrial HRO's, the implementation of a prevention strategy in the HCS has little chance to be successful nowadays as there is no real safety culture and no spontaneous report of adverse events. Very often, when an accident occurs, there is a retrospective analysis. This approach harbours enormous biases, as for example the hindsight bias (exaggerated extent to which individuals indicate they could have predicted the event before it occurred) and cognitive attribution (the observer tends to make dispositional attributions and view the mishap as evidence of some inherent character flaw or defect in the individual). In such conditions it is impossible to penetrate to the deep roots of the incidents and accidents.[10,11]

The systemic approach in error prevention: the theory of reason

The success of the safety management approach in commercial aviation can easily be explained by the fact that pilots are directly and personally interested by accident prevention! This is definitely not the case for the caregiver. However, one should not forget that in the HCS, the caregiver is indeed not the primary victim, but nevertheless he/she should be aware that very rapidly he/she will become the secondary victim.

In Reason's system approach, one should realize first of all that there are two types of failures: active and latent failures.[12,13] Active failures are the failures of the caregivers working at the sharp end of the system. These failures are actions of omission or commission. There are different failures we commit as humans in the system such as slips and lapses, mistakes and violations. A slip is observable and is unintended; it is not uncommon in busy environments and is a typical error of a human automation process more likely to occur with "experts". A lapse is a typical short-term memory failure. A mistake can be rule-based or knowledge-based. Violations cannot

be tolerated in whatever system. This wishful disregarding of rules is putting an enormous hazard in the system and creates a perfect soil for major incidents and accidents.

Latent failures are typically system failures. These failures are due to managerial decisions and organisational processes. These latent failures therefore reside as pathogens within the system in a latent phase but in a particular condition and constellation these pathogens can become extremely dangerous. The levels where latent failures can be incorporated in the system are external environment, management and physical environment (man-machine interface, social and organisational environment). Decisions taken mostly by direction and management at these levels located at the blunt end of the system highly define the working conditions of the operators including workload, supervision, communication, equipment, knowledge and ability. This is certainly not different in the HCS: managerial decisions at the blunt end of the "production line", highly define the way caregivers take decisions and perform at the sharp end. This model, therefore, illustrates that coping with operational risk means analysing the whole system. One should therefore avoid focusing merely on the "individual" error.

In such complex systems, safety barriers are introduced to avoid precursor events, not necessarily leading to any harm on the individual patient. The barriers in Reason's model are symbolized by the Swiss cheese model.[12] These slices of cheese are not perfect. These barriers contain wholes. If these wholes at the different levels of safety barriers are aligned, by alignment and summation of precursor events, an accident will inevitably occur. Moreover, the deep roots and causes at the origin of precursor events are exactly the same as the ones at the origin of incidents and accidents. In the industrial sector, based on Reason's theory, there is an active search for all unwanted precursor events as it is currently known that by acting on those events it will be possible to avoid major accidents. This principle has largely been implemented in HRO's. Every HRO's tends to a zero risk constellation, although they are aware that safety is performing in conditions of reduced risk and not absence of any risk.

As mentioned earlier, the HCS as any other industrial system is simply a set of interdependent components interacting to achieve a common specified goal. The IOM report states that the HCS is composed of a large set of interacting systems that are coupled in a loosely connected but intricate network of individuals, teams, procedures, regulations, communications, equipment and devices that function with diffused management in a variable and uncertain environment. This constellation is by definition a high-risk environment. There is often no pro-active reporting of precursor events leaving management in the most uncomfortable position to take decision in the field of operational risk management (ORM) without having the critical feedback return allowing eventual adaptation. This circle of plan, do, check and act well known as the circle of Deming, is lacking in the HCS, as there is no policy implemented to search for precursors, incidents and accidents, no evaluation of criticality and no organized way of implementation of corrective actions and feedback.

Implementing ORM in a radiotherapy department?

In 2008, the department of radiotherapy at CHU-Liège started with ORM. There is at least in every single radiotherapy department a minimum of quality management. In this sector, professionals are aware that they should at least check whether the machines are adequately functioning and do provide the requested dose. However, this is a very small part of what is required in ORM. As in the aviation sector, the majority of errors are nowadays not linked to technical factors but linked to the human component. Various studies show that 80% of errors in the HCS could be explained by a human factor, which is by the way a similar observation as the one made in the aviation industry.

Starting from this point, one should convince all collaborators to participate actively in ORM. To obtain global adherence, one should demystify the reporting of events. There is an essential move to perform, leaving behind a blame policy and evolving to a just culture. In this respect, a "no fault" policy was introduced, making obviously the distinction between failures (lapses, slips and mistakes) and unacceptable violations. All members of personnel were asked to report whatever event (precursor events, incidents and accidents). The first important issue is to define what an unexpected precursor event is. The whole team was asked to write down operational procedures and class solutions (based on evidence based medicine and/or consensus guidelines). There is no way out: if you want your people to report what is unexpected, you have to describe what you expect. A detailed description of all processes and procedures is the first essential step and this should be a regularly updated.

Registration of unexpected events is useless if it is not linked to analysis. To do so we created a "Quality &

Safety Unit" (QSU), consisting of a quality engineer and administrative support. This person does collect all reports, has to record and classify those reports according to the WHO taxonomy, adapted to the radiotherapy department. The unexpected events are rated according to their level of criticality and selected by a quality team consisting of representatives of all the professional sectors in the department. Criticality is defined as the product of gravity, frequency and ability to detect.

The professional experts issued from the field will select a couple of events on the level of criticality, perform a root cause analysis (RCA) and define the way to prevent such AE's. Their role is to adapt existing safety barriers or design new ones. These actions coordinated by a pilot chosen within and by the EFBC team (EFBC: Experience Feedback Committee, called CREx: Comité de Retour d'Expérience within our department), will be closely followed according to the PDCA philosophy (Plan-Do-Check-Act) and amended if required. The EFBC, consisting of the QSU and professionals from all sectors, are independent of the management team. The quality engineer, leading the QSU, is a member of the management team but all other members of the management team are by definition not taking part to the EFBC to keep spontaneity within the EFBC. In case of major events, it is obvious that the quality engineer will immediately report to the department's management team to obtain immediate corrective actions if necessary.

The EFBC methodology linked to FMEA (Failure Mode and Effect Analysis), Root Cause Analysis (RCA), and PDCA approach as described by Deming is now considered as an essential element in the department. Close to 4000 events have been reported since we started in 2009. More than 100 corrective actions have been decided and implemented. But make no mistake: ORM is a team sport and a never ending story.

What are the side products of such an approach?

Did the radiotherapy department evolve to an HRO? The 5 characteristics of an HRO are: preoccupation with failure, reluctance to simplify interpretations, sensitivity to operations, and commitment to resilience and deference to expertise. Did we reach those five essential characteristics?

We constantly focus on the ways the system can fail, even though we know that accidents are fortunately rare. A lot of energy is spend in investigating all possible factors that contribute to failure, recording not only incidents and accidents, but also unexpected events. Root Cause

Table 1. The nine dimensions of safety in the health care sector
• Overall commitment to quality
• Priority given to patient safety
• Perception of the causes of patient safety incidences and their identification
• Investigating patient safety incidents
• Organisational learning following a patient safety incident
• Communication about safety issues
• Personnel management and safety issues
• Staff education and training about safety issues
• Team working around safety issues

Analyses are performed, keeping on asking "why" until no more responses are obtained. Conventional explanations are not accepted. We are sensitive to operations and cultivate situational awareness. Moreover we try to stay ahead of the action in order to respond to minor deviations before these can end up in harming the patient(s). Resilience is cultivated as we know that errors will always occur. Therefore, adequate and equal resources are adressed to be mindful about errors and to correct the ones observed before they could lead to major accidents. We are deferent to expertise and it is the EFBC, constituted by professional experts directly coming from the interacting subfield, and not the management team, which takes the appropriate decisions concerning the modifications of existing safety barriers or creation of new ones. If one considers the nine dimensions of safety in the HCS (Table 1), the radiotherapy department seems to be on the right track and definitely well engage in total safety management.

The recording and analysis of precursor events, incidents and accidents yields important information on the possible gap between pre-defined professional profiles and the practical expertise. This allows steering the continuous education program within the department. On the other hand, the recording and analysis of precursor events, incidents and accidents and the analysis of their root causes allows redesigning our procedures and processes aiming at simplification and optimization, both at the organisational level as well at the level of reductions of the cost burden. Here, the quality and safety management touches basic principles of LEAN management.

Conclusion

As in any industrial sector, the promotion of safety pro-

Key messages for clinical practice

1. Operational risk management is one of the key characteristics of high reliability organisations in the industrial world.

2. The health care sector is an industrial system, and the methodology ubiquitously used in other industrial high reliability organisations can be transposed.

3. Leaders define values, values drive behaviour and behaviour defines culture. There is a need for a widespread implementation of a safety culture which should be a just culture!

ceeds through the identification and control of risk. Safety is a dynamic condition of acceptable risk. It is in no way freedom of any risk. Safe working in any industrial sector can only be achieved through managing of plant, processes and human resources. Managing plant means seeking for technical and hardware solution, i.e. "engineering" to make environment safe and users friendly. Managing processes includes training to ensure competence, inclusive CRM training (crew resource management), and specification of best practices (guidelines, standards and procedures). This dimension is called "enforcement". Managing people involves creating an organisational culture devoted to safety. The success in the industry in ORM, is mainly explained by leadership. Leaders drive values, values drive behaviours and behaviours define culture.

In the HCS, the road to an organisation which could be labelled as an HRO is still long! It will require a real cultural shock especially in medicine! Care processes will have to be redesigned, information technologies (IT) to automate clinical processes will have to be used effectively, the growing clinical knowledge should be managed properly, the clinical roles will need to be modified and process and outcome measures will need to be incorporated into daily work.

But first of all, it is impossible to design intelligent systems, protocols or processes to reduce errors in order to know where errors are occurring and why. Significant barriers will have to be overcome in the HCS to do so. These barriers are the burden of reporting, the fear of litigation and the professional shame. Safety policies are however mandatory to detect and intercept errors. These policies are also meant to mitigate the possible consequences if we are not able to intercept potential harming errors. Safety should, where possible, be designed in. Human factor analysis shows that hazards should be designed out by forcing functions and safety barriers. If such design solutions are not readily available, building defences, mitigating hazards and education and training should be intensified.

Let us not forget Descartes: "I am indeed amazed when I consider how weak my mind is and how prone to error".

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