AN ORGANISATIONAL MULTI-LEVEL MODEL FOR THE ANALYSIS OF FAILURES IN MEDICINE – THE CASE OF A FORTUITOUS CONNECTION

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1. Introduction

Research studies about errors in complex organizations show that critical conditions of the organization can produce frequently failures in the system. Blaming and removing the operators from their position it is not a solution. It does not help to eliminate the latent factors of risk. Bad events are going to happen again and again.

Reason (1990, 1997) was the first to introduce and study the relationship between active failures (committed by the operators at the front-office) and latent failures (embedded in the organizational system) in the analysis of dynamics of many accidents and disasters (Turner, 1976, 1978; Perrow, 1984; Vaughan, 1996; Roberts, 1990; Weick, 1990; Snook, 2000). Some recent studies developed the organizational approach to accidents by including the institutional, political and cultural factors (Reason, 1999; Bogner, 2003; Rasmussen, 1997; Leveson, 2004).

This paper introduces an organizational model based on different levels of analysis aimed at the understanding of failures from a systemic point of view. In order to do that, a very complex accident occurred in a big Italian Hospital will be analyzed.

2. The theoretical framework

The organizational theory about errors has been evolving day by day trying to clarify the relationship between the individual action and the condition of the organization they work in. As **Diane Vaughan** stated (1996), errors and mistakes are an organizational product, even if they are physically committed by people. Nevertheless, the existence of a blame culture and the stakeholders' interests drive our attention towards the individual actions. And when you look for the faults you always find a guilty person. But if the analysis is focused only on the individual level, the solution will be ineffective.

It is important to study failures in medicine through the use of more complex models which fit the complexity of the investigated object. Let's consider a real case. A nurse gives a vial of potassium chloride instead of sodium chloride to a child. The child dies. The nurse made a mistake in taking the wrong vial (individual failure); the vial had not to be in that armchair – it had never been there before actually – and, in any case, there were not adequate notices about the fact that it was dangerous (organizational failures). The two different vials look exactly the same, but with a different labels. This is not enough to break out the habit of the nurse and avoid her mistake. The designers of vials, do not adopt effective criteria of differentiation (inter-organizational failures). Even if the nurse is removed from her position the risk that the event is going to happen again is not eliminated. It is necessary to adopt strategies of prevention at the different level of the system: the individual, organizational (through differentiation and reporting) and inter-organizational ones (safer medicine packaging design).

The human error is a product of the organization. The individuals do not act as atoms – free will – but they act in high complex context. It is possible to identify three different levels of failures.

Individual level

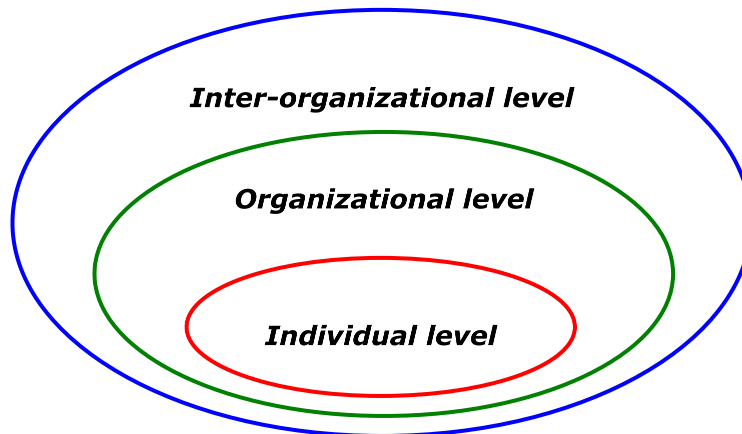
It is the world of human errors (slip, lapse, mistake) and violations. At this level, the focus is on the relationship between the intention (what people want to see), the expectation (what they expected to see) and the ambiguous stimulus (what they have seen).

The organizational level and the working context

People act in a specific working context. This is the level of the human-machine interaction, of the cooperative work, of communication and coordination process. At this level, the critical dimensions are the responsibility allocation, the division of labor, the coordination and control system, the training activities.

The inter-organizational level

The organizational level is embedded in an inter-organizational level. This level concerns the network among the units which are involved in the accident: the suppliers, the technology providers, the regulators and the supervisors. At this level, coordination and integration processes are the main dimensions: integration has to be developed as long as the differentiation process does. For coordinated action, highly differentiated units demand equally high levels of integration (Lawrence and Lorsch, 1967).



Levels of the accident analysis – Catino 2003

3. The case: a fortuitous connection

A young woman, suffering of a severe depression status, tried, as she already did many times previously, to commit suicide. She ingested a big amount of muriatic acid. Fortunately a neighbor found her and called emergency 118 on time, so she was recovered at the hospital in the Intensive care unit. In few hours, she underwent two surgical procedures. In the following days, her conditions were serious, but then she proceeded better and few weeks afterwards her conditions were stable. Feeding was assured by an adequate amount of an enteral fluid (which means that the food was administered by an enteral-feeding tube). Drug infusion was sub ministered by a central venous line with a triple lumen catheter.

Then, the patient is transferred to a General Surgery Unit of the same hospital, where she would get prepared for the next procedure aimed at the rehabilitation of the digestive function. Patient hospitalization went on regularly. She could manage autonomously the administration process of the enteral feeding, and she was able to manage both the central venous line and the infusion pump.

After 25 days spent in the Surgery Unit, she underwent a third procedure. It was a very complex operation in a patient whose general conditions remain critical. This case occurred very rarely in this hospital. Thus, they decide to send the patient back to the Intensive Care Unit, after the procedure. Here, the nurses saw that a new kind of nasal gastric tube was inserted. They had never used this kind of tube before. It had three different lumens: the first one at the level of the esophagus, the second one for the stomach and the third one, more distal in the jejunum. None of the surgeons informed them about the use of this tube and the nurses did not know how to start the enteral feeding again. Nevertheless, the jejunum access was set up so that it was possible to connect it to the flow-tube of the enteral fluid bag. But there was a problem: the beak of the bag flow-tube was incompatible with the connection of the tube, that was very similar to the ones of the venous catheters. It was necessary to use an adaptator, but they did not have any in the unit. Nurses of the Intensive Care Unit called their colleagues of the Surgery Unit asking what to do. But nurses of the Surgery unit told them that they used that type of tube for different purposes from that one of feeding the patients. In fact, they usually feed these patients through the parental way (through the venous line). Consequently, they could not help their colleagues. The coordinator of the nurses of the Intensive care unit called the pharmacy unit to get more information about the adaptator. The person responsible for the pharmacy consulted the list of devices provided by the firm who produced the enteral feeding tube and she found out that they produce the needed adaptator to use the jejunum for the feeding. It was possible to order it, but it would have been delivered only after few days. But the nurses needed to feed the patient right away. In order to overcome this obstacle, the operator decided to set up a fortuitous connection, by using some latex removed from the venous flow-tube.

They connected the beak of the flow-tube for the enteral fluid with one of the accesses of the nasal-gastric tube. In this way they did solve the problem and fed the patient. The post-operative course was very regular and after two weeks the patient left the Intensive Care Unit to go back to the General Surgery Unit. Here, the nurses kept on using the jejunum access of the tube with the modification. After three days spent in this unit, the patient was able to start to eat normally and at 10am of the fourth day the surgeon on shift decides to take the tube for nutrition off. After few minutes, the nurses take the tube off but they leave the bed-rod with nutrition-infusion pump, enteral fluid bag and flow-tube near the bed. After half an hour, a member of the technical staff saw that the patient beat her teeth and had thrills. She called immediately the surgeon who visited the patient before. He arrived immediately and called the physician of the Psychiatry unit who already knew the patient. It is 11 am when he made the diagnosis of steady aguish and prescribed a vial of Trittico. After one hour, another nurse of the unit noticed that the patient was cyanotic, even if she seemed quiet and sleepy. It is almost 1 pm when they call the physician of the Intensive Care Unit. She immediately realizes that the situation is very critical and goes back to her unit to get the pulsoxymeter.

Placed to the patient, it shows that there was a severe arterial desaturation. At this point, another doctor that had just arrived, notices, while the other ones were visiting the patient, that one of the three jugular catheter entries is connected to the enteral fluid bag and that the pump is switched on and it is working. The patient is immediately moved to the Intensive Care Unit. She is intubated and ventilated mechanically. But the effects on the blood saturation are very poor. She dies at 4pm. Autopsy will show the

presence, at the lungs, of small pieces of brownish material disseminated in the ramification of the pulmonary arteries and a severe pulmonary edema.

4. The analysis

In the illustrated case, it is possible to identify failures which are related to the three different organizational levels of the system described in the previous paragraphs.

4.1 The individual level

The most evident failure, related to the individual act, is the fact of having connected the enteral-feeding tube to the venous access, letting the food to go inside the blood suffocating and thus killing the patient. It is not still clear who was the person who did it. Was it a nurse? This hypothesis seems to be the less likeable to whom is leading the internal investigation. This error is considered too gross to be committed by one of the professional nurses that work in that unit. The most likeable hypothesis seems to be an accidental death caused by the patient. Thus, she was used to manage the equipment, so probably she re-activated the devices but she connected them in a wrong way.

Another active failure which happened after that one, in the chronology of events, is the error of diagnosis committed by the physicians when they visit the patient and believe that her bad conditions are related to her psychiatric status. This psychiatric status gives an interpretative scheme of the situation that induce the physicians to see what they believe to see (Catino, 2003) but that in this case is wrong. The sense that clinicians give to the situation, and shared by all the clinicians who take care of the patients (sense that does not make them suspect and verify immediately the wrong cannula placement), is the product of the combination of their previous experience and knowledge of the case (this patient has been hospitalized for attempted suicide and she showed, in the next days, to be unstable from the psychic point of view) and the clues collected in the emergency situation (Weick, 1995). The failure in the diagnosis and the related delay in the administration of the therapy is produced by the incongruence between the reality and the sense given by the people involved. The inadequate sense making is the most relevant cause of many famous accidents, as the one of Mann Gulch fire (Weick, 1993).

But the first active failure committed by the operators in the case is another.

In fact, the set up of the fortuitous connection is the first action acted by the individuals that set the premises for what is going to happen later. But, what is the reason why the operators decide to set up the adaptator? It is, actually, the only way to feed the patient, since the nasal-gastric tube is not compatible with the enteral fluid bag they usually use. In addition, the adaptator is not available in the hospital at the moment. Thus, they have a good reason (Boudon, 1992) to commit what we can call an exceptional and optimizing violation. It is an exceptional violation because this case situation did not occur frequently before in that hospital. Thus, none of the two units have the mentioned adaptator. The action acted by the operators is uncommon and violates a norm of the system. This norm stated that it is possible to use only the equipment whose functions are explicitly illustrated by the producer and approved through a ministerial act. The action is also an optimizing violation because it has been committed with the aim of guaranteeing the continuity of care. Even though, this act can increase the risk level of the system and attempt to the patient safety. Indeed, many studies, even in the recent literature, show that the purpose of guaranteeing the continuity of care and assuring the patient safety can be in conflict (Cook, 2000; Reason, 1997). The work conditions define the nurses' behavior and their options in acting. This confirms that each accident is built by the organizational system so that «every action acted by an actor is inscribed in an organizational "space" which is defined by the organizational and inter-organizational system» (Catino, 2003).

But, which are the conditions, latent in the system that induce people to commit this violation and the following active failures?

4.2 The organizational level (team and working context)

When the patient go back from the Operating Room to the Intensive Care Unit after the third procedure, she has applied a tube that the nurses don't know. This is not because of a lack of competencies of the operators but because that kind of nasal gastric tube is usually used only in the Surgery unit for different purposes from the one of feeding the patient. Especially, it is used by surgeons to verify that after that kind of operation there are not residuals at the different levels of the bowel. The tube access dedicated to the enteral nutrition is usually not used. Indeed, the Surgery unit protocol for the nutrition of these kind of patients stated that they have to be fed through the parental nutrition (venous line). Also, after the operation, these cases are usually transferred back to the Surgery unit, where the operators apply the protocol and know what to do. But in this story events go in a different way. We have a complex surgical procedure in a very critical patient (especially concerning her behavioral disturbances). Thus, she needs to be transferred in a different unit, the intensive care unit, after the operation.

This is an exceptional situation, different from the routine procedures. This is the main reason why the operators do not know how the nasal gastric tube works. In addition, the physicians of the Intensive care unit, follow a protocol for the nutrition of critical patients that is different from the one of the Surgery unit, they prefer the enteral feeding to the parental one. That's why they need to use the tube access that is usually left free by the surgeons. But, for its use it is necessary to have an adaptator that, due to the exceptionality of the case, is not available in the unit. The incongruence between the nutrition protocols of the two units, which is not a problem in the routine activities, becomes an obstacle in this case and push the operators to violate the ordinary procedures (related to the use of medical devices) and set up a fortuitous connection among the different devices. The invented solution seems to work out but creates what Reason (1997) in his model would call a hole in the safety system barriers. In fact, while the standard adaptator, which is not available at the moment of the event, is ad-hoc designed in order to be used only for specific activities, the fortuitous connection set up by the operator has not safety disposals and let the tube being connectable to any venous access. This hole in the safety system barriers remains opened, also because the operators decide to go on using that adaptator instead of asking to order the standard one. Leaving the bed-rod with nutrition-infusion pump, enteral fluid bag and flow-tube near the bed is another error inducing act that will leave to the fatal failure.

4.3 The inter-organizational level (other units and the environment)

There are some critical aspects of this case which do not concern only the unit where the accident happened, but also other units of the hospital (the Surgery unit and the Pharmacy) and some other external actors which operate in collaboration with the hospital (the firm that produces the nasal gastric tube placed to the patient at the last surgery).The story points out an incongruence of protocols between the Surgery and Intensive care units concerning the feeding treatment of critical patients whose care process needs, instead, a coordinated and consistent action of these two different units. What happened in this case makes explicit the lack of an effective communication between these two components of the system. This criticality does not emerge in the routine activities, when the two units operate independently, but it becomes clear when the process of care is more complex and needs a high coordination of the different tasks. Concerning the firm that produces the nasal gastric tube used in this case, in an interview to the Pharmacy unit manager, she declared that the adaptator used for patient nutrition is not included in the standard kit of that product. It is instead indicated with a different code on the list of products. This makes impossible for the pharmacy to consider the

possibility to order it. The only chance to have it is that the sales man claims its existence or that the units order it explicitly.

5. Conclusions: Normal behavior abnormal outcome

A first consideration arising from the analysis concerns the redefinition of the relationship between active and latent failures. The active failures, which are inevitable – to err is human – can produce an accident only when they are combined with critical organizational factors. The analysis of the case shows that also human errors, here defined as failures at the individual level are determined by organizational and inter-organizational failures. This means that the "space" for a human error is defined by the organization: what the operator can do badly is the consequence of a sequence of options that the system creates at the organizational and inter-organizational level.

It is necessary to overcome a conception of the human error where the actor is potentially free of acting and violate – or not – the rules of the system. It is important, instead, to consider the interaction between the actor and the system (Crozier e Friedberg, 1977; Friedberg, 1993) to understand the "good reasons" (Boudon, 1992) which induce the actor to act in that specific way. In the organizational analysis of accident in the complex systems it is important to identify the failures at the three different levels and the relationships among them.

Consequently, the solutions designed to reduce the frequency of errors and to improve the system defense and safety have to operate at all levels. Local remedies, as the sanctions for the individuals involved in the fact, do not eliminate the risk conditions. Patient safety and organizational reliability do not correspond to the reliability of a single component, rather they emerge from the reliable interaction of the different components.

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