ERGONOMIC CHALLENGES IN THE DESIGN AND MANAGEMENT OF ANESTHESIOLOGY DEVICES IN ARGENTINA

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TOPICS

Design for usability for surgical and medical devices

System reliability and patient safety

Accidents/incidents reporting systems and organizational learning

Medication errors

KEYWORDS

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1. INTRODUCTION

Devices and organizations are designed and regulated in a way that can generate errors that can be related to a certain underestimation of the anaesthesiologist environment's variability and of the patient's states evolution (De Keyser & Nyssen, 1997). Their evolution is also linked to the degree of normalization of deviance (Vaughan, 1996) and to the social control of these migrations. Our concern is to know how these organizational and systemic-related unsafe acts emerge in Argentina's hospitals, in order to determine what the main ergonomic challenges in the design of devices and work organization are for patient safety and anaesthesiologist's work improvement in that specific context.

From a theoretical perspective, we believe as Gauthereau (2003) that improving safety implies to think about it as a "social practice" (Figure 1), were many social actors are being involved in a negotiation process, which can or cannot deliver a safe result.

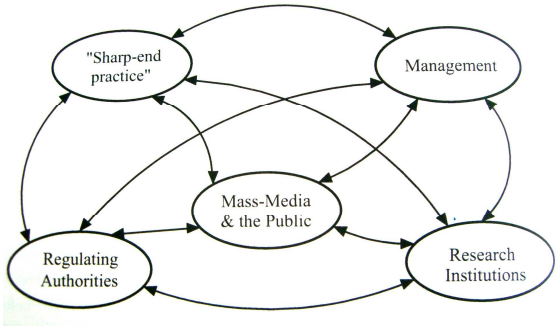

Figure 1: Some of the main actors participating in the negotiation of safety

This negotiating activity concerns the rule design process (Reynaud, 1993) but also the devices design process into which ergonomics is most often involved. We also believe, with Gauthereau, heedfulness' as a way of "*challenging the normal, current understanding of things*" is necessary to improve safety, in all contexts, and that it is one of the ergonomics roles. This heedfulness' is much more necessary in contexts like the anaesthesiology in Argentina, where the risks related to expert's judgment drift are very high, according to some late studies (Gallino, 2006). The drift in practices should be an object of heedfulness, according to what cognitive ergonomics and resilience engineering describe (Rasmussen, 1997; Amalberti, 2006). As a matter of fact, otherwise practices can get closer and closer to the accident-prone zone, as we can see in Figure 2:

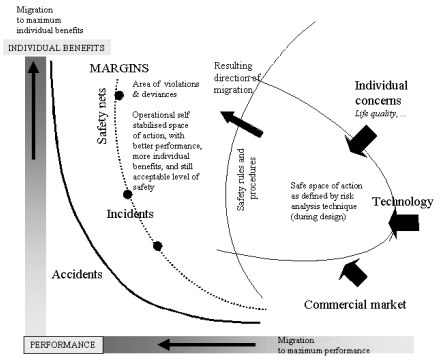

Figure 2. Migration of practices towards accident-prone margins

We believe one of the challenges of heedfulness is maintaining the system in the controlled and flexible central zone, without paralyzing the system, and avoiding it to enter the accident zone.

Argentina is a country where no specific research in the field of human factors applied to organizational reliability and industrial risks management is seriously developed. In fact, even if, after some very severe aviation, mine and other industrial accidents, some efforts[1] have been made, we believe the field is almost virgin. This has some good aspects, and some bad ones: we are free to work and develop new approaches of safety, without having to battle against old ideas of safety or to insist on destroying organizational structures that are obsolete; on the other hand, the process of organizational and devices design is not alive, and we have to generate its emergence. On the other hand, even if experts in the field of organizational and social management of safety are almost absent in argentine institutions, the context is evolving right now thanks to an important type of actor who generates the momentum for changes and negotiations in order to improve patient and workers safety and health: the "*whistle blowers*", well studied by Chateauraynaud & Torny (1999). In fact, some physicians are starting to act on their own to improve safety, without belonging to any negotiating entity listed in Gauthereau's model.

Therefore, we believe our strategy in the specific argentine context needs to start by understanding the negotiating activities – between sharp-end practice, Management, Regulation Authorities, mass media and public, and research institutions, including whistle blower's - that already take place between the existing actors in order to assess how they try to improve safety and help them to better succeed next time. This approach can help us better describe what the real situation regarding safety is nowadays in Argentina, were some things are starting to change thanks to individual efforts, even if institutions aren't really ready for the change. In fact, we had the great opportunity to study the activity of a whistle blower in the field of anaesthesiology. He is an argentine anaesthesiologist, and he has asked us to join him and some of his colleagues in their "lonely battles" to improve safety in his professional field (De Luca, 2005). That's how this joint work started one year ago, and the present work is a trace of our first collaborative experience.

[1] FUSAT (BID funding) has organized lately some seminars on industrial risk management; a research project has been launched with Universidad de San Andrés and the ICSI (France)

2. METHODOLOGY

We have tried to describe first the invariant problems of anaesthesiologists' activity in Argentina. On the other hand, we wanted to analyze the negotiation of safety developed by an anaesthesiologist with management and with the Regulating Authorities. The invariants were analyzed through different methods, but mainly through a reflective activity, based on the detection of incidents in an ecological situation and on the experience of an expert. The latter is the argentine anaesthesiologist whistle blower we mentioned in the introduction of this paper. He is very interested in ergonomics and in all kind of approaches to improve patient and workers safety. Besides, he is an actor in the social system that could be called a "whistle blower" since he is often voluntarily involved in law projects to improve anaesthesiologists working conditions. Our methods were the following:

1) Step 1: we started by interviewing the expert anaesthesiologist, having in mind two frameworks of reference to understand his work. The first one is based on the concepts of task and activity as developed by Leplat (1997), meaning by "task" what workers are prescribed to do. By activity we understand what workers really do to achieve the task, in the real situated context. Activity can be seen as the dynamic evolution of worker's task (Figure 3):

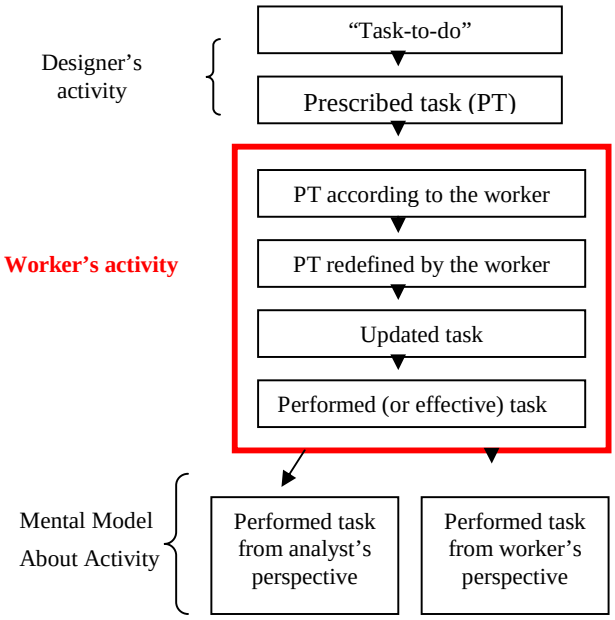

Figure 3. From "task to do" to Activity described in terms of tasks

The second concept we have introduced to understand anaesthesiologist's work is the idea of "developmental activities", inspired from activity theory framework (Clot, 2006). We believe it is necessary to introduce the idea of development to be able to put at its right place, linking it to the working situation, all the activity developed by the expert who's work we will analyze. Having said this, at this first stage the questions asked were open: a) what are you asked to do? b) By whom? c) What are your actual goals, compared to the prescribed? d) What means – mainly devices- do you have to perform these tasks? e) What are the problems you encounter when performing them?

2) Step 2: then we observed together a real case of surgical operation, in which he wasn't involved directly. Following an allo-confrontation method (Mollo, 2004), was asked him to identify the **problems related to devices usability on a** videotaped real operation. We focused on some of the main episodes where the videotaped anaesthesiologist encountered problems. We asked our expert a set of questions concerning the prescribed and the real work, as we did during the interview of step 1. Even if we based our work analysis on the main steps of the anaesthesiologist work as described in the literature (Nyssen, 1997), we tried to adapt this model by reflecting more precisely the expert's mental model of what the anaesthesiologist activity is about, following Leplat's general model of activity (Figure 3). We needed to understand the way he negotiated some of the safety issues, and it was important for us to know what the different tasks were. We tried to identify 3 levels of tasks: Task-to-do, PT according to him and some cases of redefined task.

3) Step 3: Based on his experience, we asked him to identify the invariants in the observed situations remembering the last 20 interventions he made: were the observed problems regularly encountered in those 20 situations?

4) Step 4: we analyzed the selected invariants and classified them into two categories: the ones that generated negotiations with the management and with the Regulating Authorities.

5) Step 5: we asked the expert, for each detected and selected invariant, which were the characteristics of the activities of negotiation he developed.

3. RESULTS

We will only share in this paper some of the results of our study, since the work is still underway:

- Anaesthesiologist tasks and activity
- Some of the classified invariants (Steps 2, 3 and 4)
- One example of negotiation from each category (Step 5)

3.1 Anesthesiologist's work & developments

We will describe two levels of the anaesthesiologist's activity: the first one is related to his work in the operating room, focusing on the tasks and on devices as activity shaping factors; the second one is related to his activity as a social actor "negotiating safety" to improve his and his colleagues working conditions as well as patient safety.

3.1.1 Anesthesiologist's working situation

3.1.1.1 Tasks-to-do and PT according to him

Anaesthesiologist's "task-to-do", in this case, is *to perform a **general anaesthesia***. According to its Greek etymology, the world anaesthesia means "without sensation". Technically, it is a "*pharmacologically induced coma*". Thus, performing a general anaesthesia involves on the one hand, *leading the patient into an altered functional state characterized by the reversible unconsciousness*. It also involves *analgesia of the whole body*: being unconscious doesn't mean our body doesn't feel and react to pain under surgery and anaesthesia, which are two kinds of aggressions to the body. Thus, a second task consists in preventing this pain through analgesia, while *maintaining patient's clinical variables into acceptable boundaries.* Indeed, surgical acts involve different kinds of changes and body aggressions that anaesthesiologist have to deal with: in case of hemorrhage he needs to replenish the necessary blood; if the surgeon moves too surgeon moves too strongly intestine, and this leads to patient's hypotension, anesthesiologist medicates the patient in order to stabilize his tension. Briefly, *it is not only a matter of avoiding sensation and pain, but also of maintaining into acceptable boundaries other clinical variables like cardiac frequency, body temperature, blood partial pressure of oxygen, carbon dioxide concentration, etc.* To achieve these goals, anaesthesiologist administers drugs to the patient: hypnotics, anesthetic and analgesic (opioids like morphine). Other tasks are achieving *patient's amnesia, his muscular relaxation and the stability of his autonomous nervous system's reflex.* Their associated goals are to prevent the patient to recall the surgery and to prevent him to breath on his own, enabling the breathing device to ventilate patient's lungs effectively (oxygen and anaesthetic inhalation and waste gases like carbon dioxide exhalation). Muscular relaxation is obtained through relaxing drugs that affect muscles but also the heart, the kidney and the liver. This implies mandatory clinical dosing. General anaesthesia is divided in the following "sub-tasks-to-do": 1) devices functioning checklist and preparation of the drugs 2) medication previous to anaesthesia 3) induction, 4) maintenance of the patient at a certain anaesthesia level, 5) awakening-recovery in the operating room, and 6) leading the patient to a recovery room.

The "prescribed tasks according to the anaesthesiologist" can be described as "*leading the patient into a coma state for him not to feel any pain, not to be conscious about what it is being done, and besides, in order to prevent all that pain to kill him: avoid infarcts, high pressure destroying brain veins, etc.".* He adds: "*I act clinically through intravenous or inhaled medication in order to maintain that coma at a certain level, and not above it, because otherwise I would kill the patient; I have to maintain the balance between preventing the patient to feel pain, enabling him to be unconscious, but most of all, preventing him to die*". At a different level of description of his PT according to his own view, he says: "*it is performing an anaesthesia which has to be adapted to the patient and its previous conditions, to the type of surgery, to the environment where it will take place, to the available devices and resources, and to the professionals that intervene in the surgical-anaesthesia act; I have to develop a situational awareness not only about my work, but also from the surgical team's work"*

3.1.1.2 Using the devices at his disposal

Since the anaesthesiologist doesn't have direct access to the patient (the surgical team surrounds him), the available devices enable him to measure the clinical variables and to administer drugs through these indirect and mediating artefacts. He uses different devices: patient monitoring, drug- administration (vaporizer and intravenous) and breathing devices (delivers the proper mixture of gases and oxygen). Some of these are integrated in the anaesthesia machine and some are peripheral monitoring devices (Figure 4). The anaesthesia machine is composed of a) a breathing system with its associated carbon dioxide absorption system, b) a flow meter (measures oxygen, nitrous oxide (N_2O) and compressed air) and a c) the anaesthesia liquid vaporizer which enables inhalation of anaesthetic liquid. There are some other complementary devices, more or less integrated into a unique device depending on the equipment available in the hospital or medical centre (Figure 4, right). These devices enable the monitoring of cardiac frequency, partial oxygen pressure in blood, arterial pressure, inhaled and exhaled gases (oxygen and carbon dioxide), body temperature and other important vital signs of the patient.

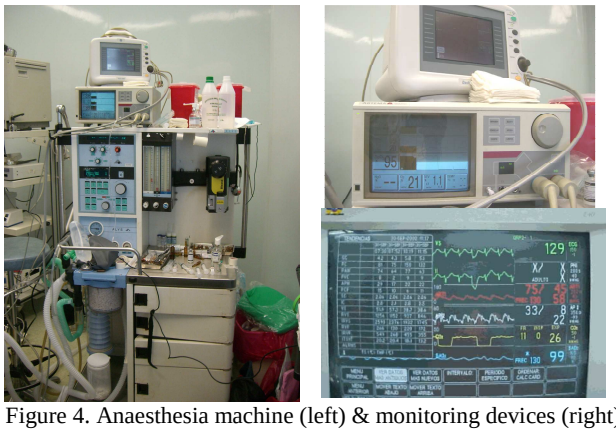

Figure 4. Anaesthesia machine (left) & monitoring devices (right)

3.1.1.3 PT as redefined by the Anesthesiologist

During anaesthesia, the anaesthesiologist has to deliver drugs to the patient and control his vital variables by using these devices. It seems, according to the experts opinion, that these devices introduce one kind of variability, preventing the "PT according to him" to take place: "*I am supposed to devote all my time to the patient; but when I enter an operating room there are many devices I will use, and I cannot only take care of the patient, I have to take care also of the problems raised by the devices*". Devises are mediating the prescribed tasks, and impose to redefine them from the beginning. In this sense, the new tasks are diverse, and are not always under control; they generate a suffering feeling the anaesthesiologist has to cope with: "*we are always trying to assess if the data displayed by the devises is real or not, since I don't trust the way they work… you can see in the videotape this was the same for my colleague*". Thus, according to Nyssen (1997) findings, we believe anaesthetist's activity is supervising the patient's vital signs, but also having to assess continually the functioning of the devices that enable that supervision. Besides, Argentina is a context where the prescribed lifetime of devices seems to be largely exceeded, and where conscious workers develop strategies to cope with the feeling of not trusting the devices. Other workers protect themselves through a defensive mechanism and accept these situations without even doubting.

3.1.2 Working as an whistle blower

In addition to his work as an anaesthesiologist, this expert also develops activities of research and dissemination of his findings. He works on many different projects to improve patient's safety and his own working conditions (. Nobody asks this physician to work as a whistle blower. He does it since he is historically concerned by the safety: first of all, his father was a hydraulic engineer in charge of the risk management of a very big group in Argentina. His father transmitted to him all his concerns for safety culture. Also he was a victim of a medical error that led him to severe disorders. He also lost some of the closest members of his family in a car driving accident. Finally, his brother and his best friends are all commercial pilots, also concerned by safety. This is the way he joined the aviation human factors community where we met. Being accountable for the life of his patients, he is very concerned by the risks of fatigue related to the bad design of the devices, rules and work organization he and his colleagues have to deal with. He is aware of the systemic and organizational causes of accidents. Thus, and believing there were no researchers in the field of human factors in Argentina to request any help to, he has developed on his own a very intense activity above his prescribed tasks, as a citizen. He designed norms (minimum equipment list in anaesthesiology), he is an advisor of the parliament health commission, etc. At the end of this chapter, we will give an example of this activity, in which he improves labelling usability.

3.2 Invariant problems related to the devices

Identified problems concerned the availability, the use and the reliability of the devices.

3.2.1 Devices are not available

The anaesthesiologist doesn't choose the equipment the organization will put at his disposal in order to work. When he arrives in an operating room, he asks for some equipment, but the final decision relies on the management of the hospital or medical centre.

3.2.1.1 No devises to supervise special patients

The devices are designed for certain kinds of patients: children, people within certain margins of weight, etc. The analyzed case was one of those where the available devices didn't fit the profile of the patient. We won't identify the case much more than with this description, due to confidential issues. But the main learning of this example is the kind of problem: devices don't always fit the patient's profile, and organizations leave with this problem. This means that the physician controls the situation most of the times by making a special effort to reinterpret the meaning of the displayed numbers indicating the level of oxygen, carbon dioxide, etc. Thus, he has to decide what to do with the patient by taking into account the automatic calculation made by the device is wrong. This means a higher mental workload for him and the introduction of error margins due to both the non-adapted use of a device for a certain case of patient, and to the fatigue this over workload leads to. This situation is not common yet, but obesity more and more frequent. Maybe the problem will increase. This is, according to our expert's point of view, related to a more systemic problem: the fact hospitals, insurances and medical centre's management don't want to pay the over cost that these different devices would involve. In the USA apparently this is taken into account by the insurance, people with obesity problems and other specific issues having to pay a higher insurance tariff. In Argentina, no one takes into account this aspect and only the physicians pay the price of the lack of consideration of this human variability.

3.2.1.2 No devises to protect health

Some parts of the anaesthesia machine participate into the scavenging process of venting out the exhaled anesthetic vapors and maintain a vapor-free operating theatre environment. They prevent the anaesthesia and surgical team as well as the patient from being intoxicated. This system is almost never operational in many medical centres in Argentina and also in Latina America. According to CLASA (Latin-American Confederation of Anaesthesiology Societies), this lack of equipments is responsible for many occupational and private problems of Latin-American anaesthesiologists.

3.2.2 Available devices are difficult to use

3.2.2.1 Drug Ampoules are not easy to identify

Some of the colors of the ampoules labeling are the same, for very different drugs. Some changes on the labeling have been introduced thanks to our expert's job (cf. 3.3.2), which improves

ampoule's usability by reducing, for instance, the time it takes to identify a certain type of drug. These changes are gradual, and nowadays you can find both the old and the new labeling (Figure 5) which is still complicating the sorting task of anesthetists.

Figure 5. Different ampoule labeling for the same drug

3.2.2.2 Devices interfere in surgical team workplace

Devices like the anesthesia machine are big and need to be placed close to the patient, who is also surrounded by the surgery team. Other devices like the tubes that carry the drugs shouldn't move or be disconnected are sensitive to the movements made by either the patient or the surgical team. This means devices bother the surgical team, and the surgical team bothers the anesthesiologist (Figure 6).

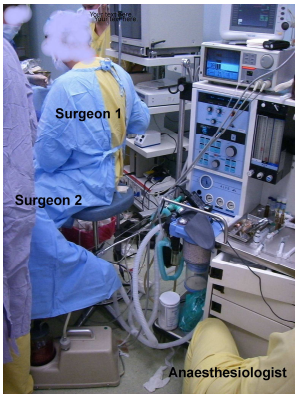

Figure 6. Devices bother the surgical team

As a matter of fact, the surgeon works in static and fatigue-prone postures almost all the time; in addition to this, he isn't allowed to easily move when he works close to the anesthesia equipment. Carbon dioxide venting out tubes, for example, are very fragile and any bad movement of the surgeon can crush it and modify the real measure of the gas. Anesthetist's work often involves supervising their state.

3.2.3 Available devises aren't reliable

3.2.3.1 Soda lime-based device doesn't turn purple

Soda lime is a mixture of chemicals, used in granular form in closed breathing environments, such as general anesthesia, to remove carbon dioxide from breathing gases to prevent CO2 retention and carbon dioxide poisoning. This device appears in grey in Figure 4, on the left side of the first drawer. When it works well, it turns purple if the maximum level of carbon dioxide absorption is reached, in order to alert the anesthesiologist about the risk of inhalation of that gas by the patient. During the operation, this device didn't turn purple as the prescription of the manufacturer indicates on the label of the product. This unreliable artifact conducted during some time the anesthesiologist into a wrong perception of what the real levels of CO2 in patient's blood were. Fortunately the physician didn't rely only on that indicators, and controlled the CO2 monitoring device that indicated a higher inhaled level than normal. This kind of problem has direct links, according to the expert, with the lack of control of the labeling of products of this type in Argentina. Soda Lime packaging should indicate some characteristics of the product as the diameter of the grains, its specific weight, porosity, the quality of the product, etc. in order to enable a good assessment of the reliability of the product. Regulating authorities haven't designed any norm concerning the use of this product, and our expert believes this absence of regulation can generate these kinds of incidents.

3.2.3.2 Two unreliable monitors are better than one

Quite often monitors don't seem to give reliable information to the anesthesiologist, and he doesn't believe what he reads. Thus, he adds a redundant system of monitoring (Figure 4, right, top). This kind of adjustment is part of the individual resilience of the system, which compensates the lack of system resilience, the one that should guarantee the maintenance and good design of the devices.

3.2.3.3 Lacking of maintenance of devices

During the observed surgical operation, the anesthetist detected at least two malfunctions of the devices: a contact was rusty, and some of the indicators of the breathing system didn't seem to be correct. He noticed that almost all the devices maintenance expiring dates were exceeded. The scavenging system in charge of venting out the anesthesia gases wasn't operational either, as well as the ventilating system of the operating room. The lack of maintenance is probably the cause of these incidents that have important consequences on anesthetist's health. This seems to be a systemic problem very difficult to change in the argentine context, according to our expert's opinion, due to economic issues. Besides the recurrent need of maintenance, none of these artifacts should be used after 10 years or 40000 hours of functioning. According to our expert's experience, this is always the case in Argentina.

3.3 Safety negotiation activities

3.3.1 Sharp-end practice and management

The last example related to the maintenance of devices gave place to a development of the anesthesiologist theoretical function: had to negotiate to be able to get the devices changed. He first asked to change the devices, and had to deal with two different levels of technical personnel in charge of distributing the machines in the different operating rooms. The first person, an operating room nurse, wasn't very convinced by the arguments of the physician and said: *"it's very strange, no one ever complains, everybody uses it all the time!"* Normalization of deviance was quite visible. She had to ask her manager to approve the request, since it is a quite disturbing change for the logistics of the organization, and that deviance from nominal operations needs to be decided by a higher level of manager. This manager came and tried to assess whether the request was justified or not, by a set of questions addressed to the anesthesiologist. Even though he didn't feel convinced either, he still proceeded to bring the requested equipment. The anesthesiologist waited almost half an hour before starting his work again. In this situation, there is a sort of "arm wrestling" between the organization –here represented by both persons in charge of delivering the devices – and the user of the requested equipment. It is not at all the anesthetist's prescribed

task, but still he needs to do develop this new task to be able to reduce the risks of accidents. His new developed activity is supposed to be done by the organization, which he momentarily works for. He is obliged to develop it in order to restore the safety goals in an environment, whose management has slowly drifted into the "accident-prone zone".

3.3.2 Sharp-end practice and regulating authorities

The consulted expert is also a whistle blower, and of a constructive kind. He developed, based on his experience, many "battlefronts" to improve his own safety prone working conditions, for his benefit, for his colleagues and for patient's safety.

3.3.2.1 The ampoules labeling

One of these fronts concerns the labeling of ampoules containing the drugs that all anesthetists' use in Argentina. He spent the last 10 years working on the best solutions to the problem of usability of these artifacts, and lately went to defend his project in front of the Health Commission of the Parliament. The Basic ideas about improving the labelling of drug ampoules are the following: they have to be easy to identify and don't have to be contaminated by too much information. Besides, grouping the same kind of drugs under the same label colour should help practitioners find them easily, when all the providers of ampoules will apply the designing guidelines (Gallino, Cheistwer & Andrete, 2008). Figure 6 shows, on the left side, a new design of an ampoule label following these principles.

3.3.2.2 Generic drugs reliability

Another front he develops is the need to have a strict correspondence between the content of the drugs, as described in the labels, and the effective content of the packaging. This incident didn't happen during the observed operation, but the expert anesthesiologist recalled that he often notes a difference between the effectiveness of the drug as produced by the original laboratory, and the one of the generic kind, supposed to be equivalent to the original one. He thus went to try to negotiate with the Ministry of Heath, and share with the authorities this important concern, but apparently no response has been given to the alert. Maybe, as suspected by the expert, there are some money interests in the middle that prevent the problem to be explicitly said at an official level, and thus resolved.

4. CONCLUSIONS

Our study confirms and details the central role of environment in the performance shaping factors of anaesthesiologist work in Argentina. We demonstrate that there are many existing activities to improve safety that follow the "safety as a social practice" path, even if the institutional accountability is very poor, or almost absent. A future step of the joint collaboration will consist to study the invariant detected factors in more situations, to verify if they are really representative of the problems for other expert anaesthesiologists working in other hospitals, with other devices, rules and work organization. We will try to make some new observations in other real situations in order to increase the number of sources of variability detected and generalize our findings. From a strategic perspective, we believe this kind of publication can help disseminate our findings, and little by little generate a positive safety culture dynamic in our country. It is important to show what the problems are, and also that some of them are resolvable. The example of the labelling redesign is the best one in this sense. But it is important to detect all the other needs to improve the system, which one man alone as a whistle blower cannot change on his own. We believe research projects on this field should be implemented to understand why theses organizational learning processes are blocked. Why is it so difficult to introduce devices in operating room that enable the evacuation of the remaining anaesthesia gases? Why is it so difficult to establish long-term maintenance programs? How can the anaesthesia devices design evolve to enable a better independence between the anaesthetist and the surgical team? These are some of the challenges that this first work on the subject in Argentina inaugurates for future research actions and ergonomic interventions.

5. ACKNOWLEDGMENTS

We are very thankful towards all the medical team that allowed us to share its work and learn from that experience.

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