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MEDICINE SAFETY IN ANESTHESIA MACHINE: A CONTINUOUS IMPROVEMENT IN OUTPATIENT SURGERY PROJECT

SEGURANÇA DO MEDICAMENTO NOS CARROS DE ANESTESIA: UM PROJETO DE MELHORIA CONTÍNUA EM CIRURGIA DE AMBULATÓRIO

SEGURIDAD DE MEDICAMENTOS EN COCHES DE ANESTESIA: UN PROYECTO DE MEJORA CONTINUA EN CIRUGÍA AMBULATORIA

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ABSTRACT

Introduction: Many medications used in anesthesia for outpatient surgery are considered high alert. A safe use of the same requirements is the development of a strategy that prevents the occurrence of errors and adverse events. This article tests an improvement project in the area of patient safety, developed in the context of outpatient surgery. It aims to standardize the organization and labeling of drugs in anesthesia machines in accordance with national standards and applicable institutional procedures, as well as to implement strategies for the safe use of these drugs.

Method: Risk assessment was carried out in the area of patient safety, with identification of risk factors, which led to the implementation of an improvement project using the PDSA methodology (Plan, Do, Study, Act) for problem solving. The experience report of a project to standardize anesthesia carts, developed in an Outpatient Surgery Unit, will be presented according to Standards for Quality Improvement Reporting Excellence (SQUIRE 2.0).

Results: Nine risk factors were identified, related to the content, disposition and labeling of drugs in anesthesia carts. The application of the PDSA methodology has entailed periodic verification and reorganization, in accordance with national and institutional recommendations. This process has promoted adaptation to the unit's needs and improved practice.

Conclusion: The need to respond to the unique situations of patients, conditions the performance of new procedures by different surgical specialties. Following the identification of risk factors related to medications in anesthesia machines, improvement measures were instituted, with the aim of increasing patient safety and care practice. This situation implies continuous monitoring by the multidisciplinary team.

Keywords: Ambulatory Surgical Procedures; Anesthesia; Drug Labeling; Patient Safety; Quality Improvement; Risk Assessment.

RESUMO

Introdução: Muitos medicamentos utilizados na anestesia, em cirurgia ambulatória, são considerados de alerta máximo. Uma utilização segura dos mesmos requer o desenvolvimento de estratégias que previnam a ocorrência de erros e eventos adversos. Este artigo descreve um projeto de melhoria na área da segurança do doente, desenvolvido em contexto de cirurgia ambulatória. Com este projeto pretende-se uniformizar a organização e rotulagem dos medicamentos dos carros de anestesia, de acordo com normas nacionais e procedimentos institucionais aplicáveis, bem como implementar estratégias promotoras de uma utilização segura destes medicamentos.

Método: Realizada avaliação do risco na área da segurança do doente, com identificação de fatores de risco, que conduziram à implementação de um projeto de melhoria com recurso à metodologia PDSA (*Plan, Do, Study, Act*) para resolução de problemas. Será apresentado o relato de experiência de um projeto de normalização dos carros de anestesia, desenvolvido numa Unidade de Cirurgia Ambulatória, de acordo com *Standards for Quality Improvement Reporting Excellence* (SQUIRE 2.0).

Resultados: Foram identificados 9 fatores de risco, relativos ao conteúdo, organização e rotulagem dos medicamentos nos carros de anestesia. A aplicação da metodologia PDSA tem implicado uma verificação e reorganização periódica, de acordo com recomendações nacionais e institucionais. Este processo tem promovido a adequação às necessidades da Unidade e melhoria da prática.

Conclusão: A necessidade de resposta às situações singulares dos doentes, condiciona a realização de novos procedimentos por diferentes especialidades cirúrgicas. Na sequência da identificação de fatores de risco relacionados com os medicamentos dos carros de anestesia, foram instituídas medidas de melhoria, com o intuito de aumentar a segurança do doente e da prática assistencial. Este processo implica uma monitorização contínua pela equipa multidisciplinar.

Palavras-chave: Anestesia; Avaliação de Risco; Melhoria da Qualidade; Procedimentos Cirúrgicos Ambulatórios; Rotulagem de Medicamentos; Segurança do Doente.

RESUMEN

Introducción: Muchos fármacos que se utilizan en la anestesia para la cirugía ambulatoria se consideran de alerta máxima. Un uso seguro de los mismos requisitos es el desarrollo de una estrategia que evite la ocurrencia de errores y eventos adversos. Este artículo prueba un proyecto de mejora en el área de la seguridad del paciente, desarrollado en el contexto de la cirugía ambulatoria. Esto tiene como objetivo estandarizar la organización y etiquetado de los medicamentos en los carros de anestesia, de acuerdo con los estándares nacionales y los procedimientos institucionales aplicables, así como implementar estrategias para el uso seguro de estos medicamentos.

Método: Se realizó una evaluación de riesgos en el área de seguridad del paciente, con identificación de factores de riesgo, lo que llevó a la implementación de un proyecto de mejora utilizando la metodología PDSA (Planificar, Hacer, Estudiar, Actuar) para la resolución de problemas. Se presentará el relato de experiencia de un proyecto de estandarización de carros de anestesia, desarrollado en una Unidad de Cirugía Ambulatoria de acuerdo con los *Standards for Quality Improvement Reporting Excellence* (SQUIRE 2.0)

Resultados: Se identificaron nueve factores de riesgo, relacionados con el contenido, disposición y etiquetado de los medicamentos en los carros de anestesia. La aplicación de la metodología PDSA ha implicado una verificación y reorganización periódica, de acuerdo con las recomendaciones nacionales e institucionales. Este proceso ha promovido la adaptación a las necesidades de la unidad y la mejora de la práctica.

Conclusión: La necesidad de dar respuesta a las situaciones singulares de los pacientes, condiciona la realización de nuevos procedimientos por diferentes especialidades quirúrgicas. Tras la identificación de los factores de riesgo relacionados con los fármacos en los coches de anestesia, se instituyeron medidas de mejora, con el objetivo de incrementar la seguridad del paciente y la práctica asistencial. Esta situación implica un seguimiento continuo por parte del equipo multidisciplinario.

Descriptores: Anestesia; Etiquetado de Medicamentos; Evaluación de Riesgo; Mejoramiento de la Calidad; Procedimientos Quirúrgicos Ambulatorios; Seguridad del Paciente.

INTRODUCTION

Outpatient surgery presupposes the performance of scheduled surgical interventions, in which the person's admission and discharge takes place within a period of less than 24 hours. This surgical modality represents an important instrument to increase the effectiveness of the quality of care and efficiency in the hospital organization, due to the associated advantages, namely: recovery of the operated person in the family environment; organization of the hospital structure in order to dedicate hospitalization to more complex situations, rationalizing health expenditure with a correct reorientation of hospital costs[1]. However, the operating room is a highly complex context, which implies the use of sophisticated technological means and multidisciplinary interaction, strongly influenced by the conditions of the work environment. Individual, team and organizational factors, conditioned by the enormous pressure and stress in responding to situations of high risk for the patient, thus combining in an interaction that involves the performance of highly variable tasks[2,3].

The World Health Organization (WHO) estimates that at least half of incidents resulting from the provision of health care occur during surgery, considering that 50% of complications associated with surgical practice are preventable[3].

As part of their quality improvement processes, healthcare organizations were encouraged to develop risk management methodologies. A structured approach promotes safer work systems and practices, based on awareness of the existence of risks and on the responsibility of all those involved in their identification and control[4]. Thus, risk assessment in critical environments, such as the intraoperative context in outpatient surgery, assumes particular relevance, namely in the medication circuit. Errors with medications can occur at various stages of the perioperative period. However, most medications used in anesthetic and surgical contexts are considered to be of maximum alert, as they have an increased risk of causing significant harm to the patient as a result of failures in their use process[3-5]. This risk is increased by use simultaneous use of different drugs, which rapidly produce effects on the respiratory and circulatory systems, combined with different routes of administration. The similarity of names, packaging and labels (LASA drugs – "look-alike" and "sound-alike") has also had a growing expression. These factors, when combined, increase the probability of errors occurring, namely: the wrong administration of medications (e.g., by changing syringes or ampoules; incomplete, confusing or non-existent labeling); omission or duplication of administration (e.g. due to miscommunication, distraction or other interruption); dosage error (e.g. due to miscommunication, dilution error or failure to parameterize electronic perfusion devices, miscalcula-

tion); incorrect route of administration; administration of drugs with a history of adverse reactions or documented allergy[6]. These considerations reinforce the importance of implementing complementary security strategies that prevent the occurrence of errors or that identify them early when they happen, in order to mitigate their consequences[7].

With simple changes, the probability of occurrence of high severity errors can be minimized. One of the strategies to be adopted in this context is the standardization of anesthesia machines, a measure that is part of a culture of safety[8]. This standardization, in addition to the goals of safety and efficiency, is also assumed to facilitate the organization of work, contributing to the increase in the satisfaction of health professionals[9].

In order to increase the safety in the use of drugs in an Outpatient Surgery Unit, an intervention project was developed, related to the standardization of labeling and packaging of drugs in anesthesia machines. This article intends to describe the process developed for the implementation of this project.

METHODS

It is an experience report of a project to reorganize and to standardize drugs in anesthesia machines, developed by the Ambulatory Surgery Unit in close collaboration with the Patient Safety Department of Centro Hospitalar Universitário Lisboa Central (CHULC). It will be presented in accordance with the Standards for Quality Improvement Reporting Excellence (SQUIRE 2.0)[10].

Interventions

CHULC is a health institution with more than two decades of work in the area of quality and patient safety, being nationally and internationally certified and accredited.

This hospital has a risk identification and assessment methodology, applied annually to the different units that comprise it. In the process of risk identification and reassessment carried out at the Ambulatory Surgery Unit, discrepancies were found in the organization and content of the anesthetic support medication carts in the different operating rooms.

The recognition that this lack of standardization constituted an increased risk of error in the use of the medicines stored there, led to the development of a project to improve and patient safety, which began in 2015[11].

Interventions study

Inserting this project within the scope of continuous quality improvement processes, we chose to use the PDSA cycle, a methodology developed by Deming[12]. This option was based on the assumption underlying this tool, often applied to health contexts, which includes the constant evaluation of the system, in order to identify points for improvement in processes and tasks, in order to solve problems and improve results. It implies systematically testing possible solutions, evaluating the results and implementing those that are most effective.

Project aims

To achieve this improvement project, the following objectives were defined:

- To standardize the organization and labeling of existing drugs in anesthesia machines;
- To comply with national rules and institutional procedures related to drug labeling, especially LASA and high alert;
- To implement strategies for promoting the safe use of existing drugs in anesthesia carts.

Ethical Considerations

This project was submitted for approval by the Research Center and Ethics Committee of the respective organization, being assigned the internal reference INV 301, with a favorable preliminary opinion, but awaiting a final opinion. It should be noted that the development of this project does not imply the use of data relating to patients and/or companions, or professionals. The monitoring processes do not imply the direct observation of professional practices, therefore it is not possible to affect them individually to professionals.

RESULTS AND DISCUSSION

The process developed involved carrying out different activities that will be presented, according to the stage of the PDSA cycle (Plan, Do, Study, Act) in which they belong.

Plan

Problem identification

As a result of the risk assessment carried out at the Ambulatory Surgery Unit, several risk factors related to the storage of medicines in the anesthesia machines of the different operating rooms were identified, namely:

- Machines from the different operating rooms that is not uniformed;
- Organization of medicines without defined criteria;
- Drugs for exclusive administration in the neuroaxis, for regional anesthesia, stored together with drugs for intravenous administration;
- Existence of medicines that is not used regularly;
- Existence of medications for regular use without a defined space;
- Partitions with incomplete labeling;
- Existence of partitions with different labeling styles (in some the identification was printed, in others handwritten);
- Lack of differentiation of LASA drugs (e.g. levobupivacaine, ropivacaine; bupivacaine);
- Existence of partitions with more than one drug or with different dosages of the same drug.

Definition of intervention plan

After identifying the risk factors, several activities were carried out to define work strategies that are shown in Table 1↗.

Do

As a result of the changes proposed by the various professionals, the following **improvement measures** were implemented:

- Unused or less frequently used medications withdrawn;
- Defined the frequency of checking and replacing drug levels – daily replacement;
- Defined specific locations for storing each drug;
- Storage of medicines for exclusive administration in the neuroaxis, in a place separate from other medicines;
- Individualization of storage – one drug per partition;
- Placing medications with different dosages in different partitions;
- Standardization of the type of label. In a first phase, the labeling adopted was printed, based on differentiating the routes of administration by color, using signaling on high alert drugs and LASA drugs, and in these cases, tall man lettering was also used. Subsequently, the institutionally defined labeling was adopted by a working group constituted for this purpose. Currently, labeling includes: drug name; dose; internal code; route of administration; pharmaceutical form; level; signaling high-alert medications with insertion of the STOP pictogram; differentiation of LASA drugs using tall man lettering and contrasting background.
- Storage of medications not in alphabetical order (e.g. aTROPine is located opposite and far from adrenaline). The organization of drugs is based on priority and type of use (emergent, general use and antagonists).

Study

The replacement of the medication of the anesthesia machines is performed daily. However, a verification of its content started to be carried out weekly, namely: levels, compliance of the storage of medicines in pre-defined places, general appearance and integrity of the labels; identified non-conformities and measures taken to correct them. This verification is recorded in a specific instrument.

The review of the content, organization of the machines and verification of the expiration dates of the medicines, started to be carried out quarterly or whenever there is a significant change (e.g. new surgical procedure; start of activity of other surgical specialties). The composition and organization of anesthesia machines are expressed in a specific document, available to all professionals who use them.

Act

Periodic checks have made it possible to detect non-conformities that are immediately corrected. The most frequent problem is the existence of more medicines than established, which leads to the use of dividers intended for other medicines, thus increasing the risk of misuse.

These findings reinforce the importance of regular checking for timely detection and correction of errors that may compromise patient safety during the anesthetic procedure.

Aspects related to checking and overhauling the cars are discussed at regular team meetings, with the aim of identifying problems and suggestions for improvement. This way, it is intended to promote a better adaptation of the same to the professional practices, as well as to promote the adhesion of the team to the implemented measures.

As a result of this process, other interventions were carried out, such as the organization of a car for exclusive use in regional anesthesia. It was also decided that adrenaline would be placed in a specific container with a lid, in order to avoid easy access and possible misuse.

Also the dissemination of new guidelines issued by national reference entities, such as the Association of Portuguese Operating Room Nurses (Associação dos Enfermeiros de Sala de Operações Portugueses – AESOP) and the Portuguese Society of Anesthesiology (Sociedade Portuguesa de Anestesiologia – SPA), motivated updates, namely, the redefinition of drug levels for the amount needed for just one working day[9].

The PDSA methodology used for the development of this project is represented in Fig. 1↗:

The annual reassessment process and changes implemented were influenced by several events shown in Fig. 2↗:

The relevance of this project also justified its presentation in training sessions and scientific meetings related to patient safety, as an example of good practices, given the possibility of replication in other work contexts.

Continuous improvement process

Over the years, other complementary strategies have also been developed, defined in institutional procedures and based on recommendations from the DGS and WHO, aimed at preventing errors in the use of existing drugs in anesthesia carts, of which the following stand out:

- Limitation and control of access exclusively by authorized professionals;
- Use of independent double verification in its use;
- Correct identification of syringes, using pre-printed labels, with distinctive colors and pictograms (ColorADD) of the respective drug group;
- Training and involvement of professionals throughout the development process of this project.

With a view to the continuous improvement of this process, more recently new interventions were defined, namely:

- Elaboration of an internal audit plan and respective verification grid, regarding the organization of medication in anesthesia carts, to be applied every six months, having as a reference the standards of the General Directorate of Health and internal procedures related to the topic;
- Holding of training sessions on this topic, with sharing of audit results.

The inevitability of operative risk makes it essential to develop systems that promote the safety of the care provided[13].

A systematic review carried out by Wahr *et al*[14] analyzed 74 articles that presented recommendations regarding medication safety in the operating room. The composition of the anesthetic machine is one of the 6 categories created, with recommendations relating to it in 34 articles. Thus, recommendations were found related to: organization and standardization of storage locations (12); management of high-alert medications (13); general organization (6) and regionally administered medicines (3).

Applying safety rules and mechanisms presupposes a commitment that calls for the understanding of individual and collective responsibility in promoting patient safety[15]. However, strategies to minimize the occurrence of adverse events do not eliminate the human factor. It is essential that health institutions, through the involvement of multidisciplinary teams, continuously assess and monitor the effectiveness of the improvement measures developed and implement new measures that constitute barriers to error[16]. These examples could be:

- Adoption of a drug traceability system, through bar codes[14].

- Use of devices designated NRFit, according to ISO 80369-6:2016, intended for regional and neuraxial anesthetic procedures, which do not allow their connection to systems for other routes of administration.

Limitations

Limitations of this experience report were the difficulty in identifying errors in the use of medications that may have occurred in this work context, as well as demonstrating the effectiveness of the improvement measures implemented through the development of this project, in preventing errors.

CONCLUSION

The current evolutionary context of outpatient surgery requires continuous adaptation and flexibility of teams, in order to obtain better health outcomes. Quality improvement processes presuppose a continuous (re)assessment of clinical systems and practices.

The CHULC Outpatient Surgery Unit, in the development of its activity, integrates all the phases that constitute the perioperative period, assuming itself as a critical environment, with a high level of demand. In this reality, risk management becomes fundamental in all areas, but above all with regard to safety in the use of medicines, which are mostly considered to be high-alert.

Following the risk assessment process carried out annually, risk factors related to the organization and storage of existing drugs in anesthesia carts were identified, which determined the need to develop a project, which was based on a methodology of continuous improvement – PDSA

The involvement of the unit's managers, the multidisciplinary team and the Patient Safety Office, has contributed to the implementation of this project in a broader perspective, both in the identification of problems and in the definition of improvement measures. Of these, the following stand out: the redefinition of the drugs that should compose the anesthesia carts, adjusted to the current surgical activity; readjustment of medication levels according to daily consumption; standardization of labeling, with signaling of high-alert drugs and differentiation of LASA drugs; definition of the medication storage places, namely those for exclusive administration in the neuro-axis, for regional anesthesia, in a separate place.

The sharing of projects by health institutions is essential to promote their replicability in different contexts. In this way, research in this area can be promoted, which will support fundamental changes in the processes of improving the quality and safety of care.

Authors' contributions

AMD: Design and coordination, data collection, review and discussion of results.
MND: Study design, data collection, storage and analysis, review and discussion of results.
SMR: Collection, storage and analysis of data, review and discussion of results.
CH: Design, review and discussion of results.
All authors read and agreed with the version published in the manuscript.

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Responsabilidades Éticas

Conflitos de Interesse: Os autores declaram a inexistência de conflitos de interesse na realização do presente trabalho.
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Proveniência e Revisão por Pares: Não comissionado; revisão externa por pares.

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Table 1 – Activities defined in the project planning phase.

Activities	Finality
Bibliographic research	– To identify good practices in the use and storage of medicines
Meetings with the Patient Safety Office	– To discuss the identified risk factors – To analyze good practices in the use and storage of medication, according to institutional procedures, international and national recommendations, namely: Norm no. 014/2015 "High alert medications"; Standard 020/2014 "Drugs with orthographic, phonetic or similar appearance" by the DGS. – To identify proposals for improvement on drug labeling and organization of machines
Meetings with the multidisciplinary team	– To discuss the identified risk factors – To identify proposals for improvement on drug labeling and organization of machines
Observation and analysis of machines in collaboration with the Anesthesiology team	– To evaluate the existing conditions for redefining the organization and composition of anesthesia machines
Meetings with heads of the Unit (Nursing and Anesthesiology) and Pharmacy	– Review the consumption of the unit, according to the type of surgical and anesthetic procedures performed, measuring levels and medications: • That remains in use; • With increased consumption; • With less frequent use; • Not used; • Introduced again. – To define the drugs that must compose the anesthesia machines and their levels.

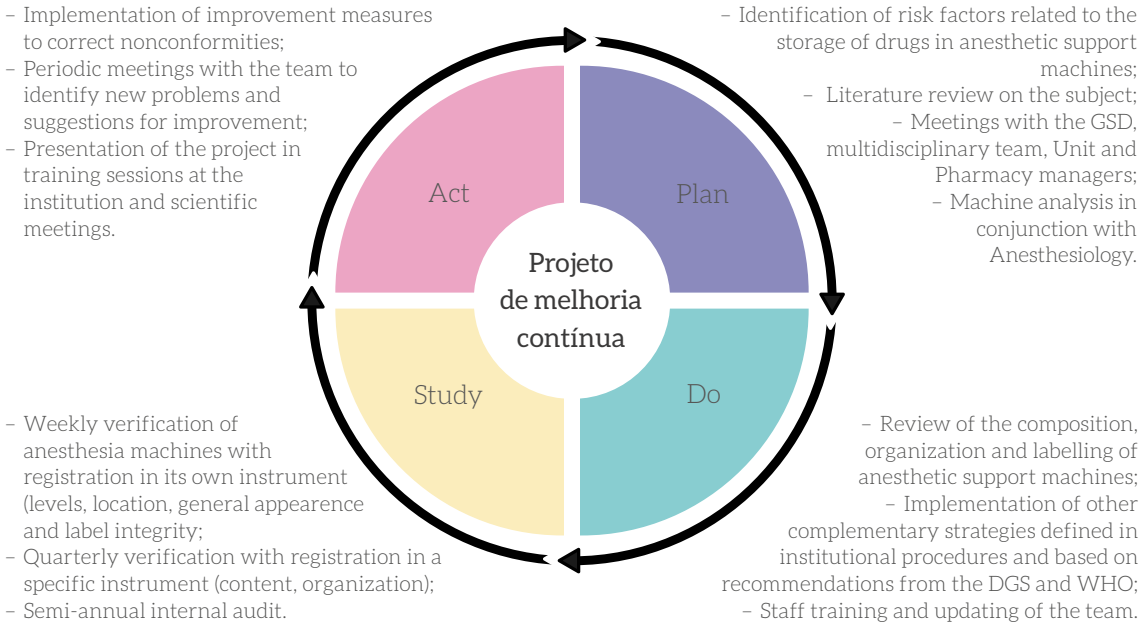

Figure 1 – PDSA cycle adapted to the project to improve drug safety in anesthesia carts at the CHULC Outpatient Surgery Unit.↖

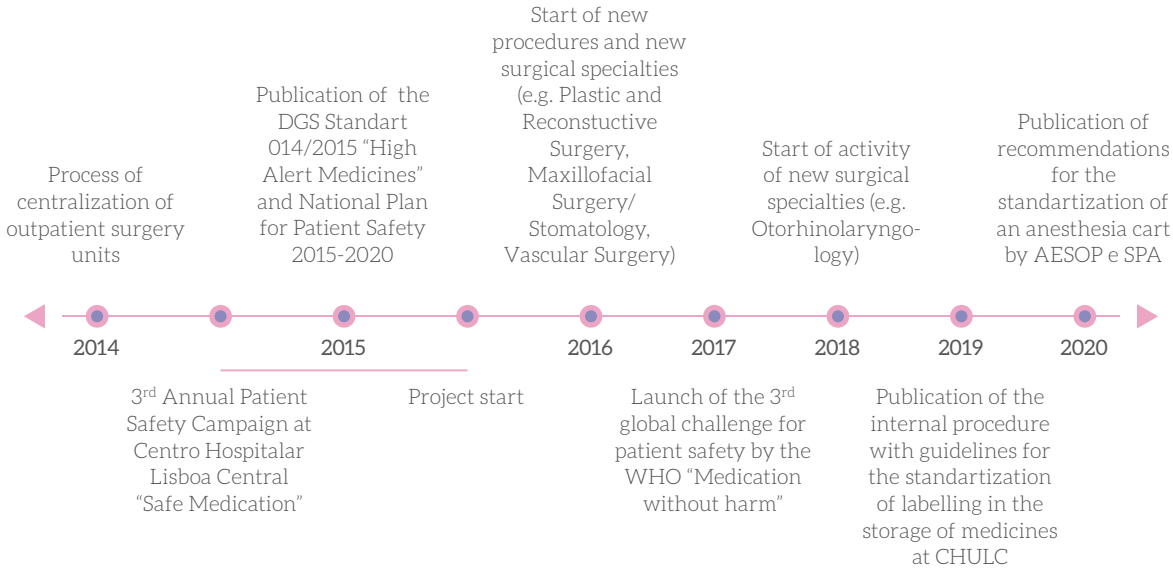

Figure 2 – Chronology of relevant events that required revision of anesthesia machines.↖