


Contribution of proactive management of healthcare risks to the reduction of adverse events in a maternity hospital

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ABSTRACT

Background The risks of the childbirth assistance process are still very high, both for mothers and babies. According to the WHO, birth-related asphyxia accounts for 23% of all 3.3 million annual neonatal deaths and an even larger number of survivors with disabilities. On the other hand, maternal mortality is still a global challenge, affecting 17 mothers per 100 000 births in the USA. This is associated with the use of outdated technologies and a lack of well-defined processes in monitoring labour and early recognition of maternal clinical deterioration.

Method This study used Lean methodology to map the care flow for pregnant women in a Brazilian maternity hospital (Hospital Israelita Albert Einstein) in order to identify the risks within this process and a set of actions to minimise them. The work team consisted of 29 individuals, including local medical and nursing leaders, as well as healthcare professionals. The What-if tool was used to categorise the levels of risks, and the proportion of severe and catastrophic adverse events was evaluated before and after the implementation of changes.

Results After the implementation of the actions, 100% of the extreme risks (28 risks) and 8% of the high risks (4 risks) were eliminated. This led to a reduction in the interval between severe/catastrophic events from 126 to 284 days, even with an increase in the average monthly number of visits from 367 to 449. Consequently, the weighted value of events decreased from 7.91 to 3.29 per 1000 patients treated, resulting in an annual cost savings of R\$693 646.80 (US\$139 000.00).

Discussion The construction of a process based on Lean methodology was essential for mapping the involved risks and implementing a set of actions to minimise them. The participation of the healthcare team and leadership seemed to be important in choosing the measures to be adopted and their applicability. The results found can be attributed to both the established changes and the safety culture brought about by this constructive process.

INTRODUCTION

Since the publication of the book ‘To Err Is Human’ by the Institute of Medicine in the year 2000, more than 20 years later, despite progressive advancements, ensuring patient safety during healthcare delivery remains a global challenge.¹

WHAT IS ALREADY KNOWN ON THIS TOPIC

⇒ It is widely acknowledged that safety in maternity care is a significant concern for the majority of healthcare providers and patients, as it is closely associated with financial, emotional and reputational implications. Consequently, various initiatives aimed at reducing maternal mortality and fetal risks have been under scrutiny, including the standardisation of processes through the application of methodologies from other domains, such as the Lean process, despite the lack of data exposure and diverse methodologies.

WHAT THIS STUDY ADDS

⇒ This current study showcases the application of the Lean process method in maternal-fetal care at a maternity hospital and the favourable outcomes achieved after its implementation.

HOW THIS STUDY MIGHT AFFECT RESEARCH, PRACTICE OR POLICY

⇒ It presents a model that can be replicated in other maternity hospitals, with local adaptations, or expanded to assess the effectiveness of each action independently.

Currently, the term, high-reliability organisations, typically applied in the aviation industry, nuclear power plants and other industries, has been replicated in healthcare systems, considering their similarities in complexity and challenges to conduct operational processes free of incidents. Definitions of high reliability are comprehensive, but there are common strategies described by different experts, such as constant concern for failures, reluctance to simplify, situational awareness, commitment to resilience and respect for those who know.^{2,3}

The challenge of high reliability is greater in obstetrics, especially because it involves care for both the mother and the fetus, and the difficulty of assessing the well-being of the fetus. At the same time, high maternal

mortality rates are still observed in various parts of the world.

Regarding perinatal asphyxia, it is difficult to determine its true incidence, so the data are based on observations of newborns with perinatal hypoxic-ischaemic encephalopathy (HIE). However, this condition represents one of the main causes of neonatal morbidity and mortality.^{4 5} According to the WHO, birth-related asphyxia accounts for 23% of all 3.3 million annual neonatal deaths, in addition to a larger number of survivors with disabilities.⁶ It is estimated that the incidence of neonatal encephalopathy ranges from 2 to 9 cases per 1000 births, many of which occur without identifiable risk factors.^{7 8} Additionally, this condition is associated with high financial, psychological, legal and reputational costs. In Denmark, the average lifetime cost of a child affected by HIE, considering both direct and indirect expenses (including intellectual disability, visual and hearing impairments), is estimated to be around US\$900 000.⁹ Analysing 822 cases of therapeutic hypothermia, a treatment applied to severe neonatal anoxia, Massaro *et al* found that the average cost in the neonatal intensive care unit was US\$58 552 among survivors and US\$29 760 among those who died.¹⁰

Among the various causes of HIE, intrapartum hypoxia is one of the main factors. However, the same complementary method for evaluating fetal well-being during labour has been used since the late 1950s: cardiotocography.^{8 11} The different classifications and variable guidelines regarding the group of patients eligible for this examination, as well as the frequency at which it should be performed, demonstrate the difficulty in achieving high specificity for the test.^{12–16} The use of near-infrared spectroscopy to assess fetal circulation oxygenation during labour, whether in the fetal head or placental area, has been tested but still has limited and inconclusive results.^{17 18}

Maternal mortality remains a global challenge. In the USA, for example, maternal deaths increased from 7 to over 17 per 100 000 live births between 1987 and 2018.¹⁹ The situation in Brazil is even more dramatic, with the maternal mortality ratio rising from 50.1 to 72 per 100 000 live births between 2000 and 2020.²⁰ Obviously, the numbers related to near misses are likely to be even higher. In the reality, it is not all that different when you look at it regionally. In the state of São Paulo, the biggest in the land, during this same time, the ratio of maternal death, it increased from 45.1 to 45.6 per 100 000 born alive.²⁰

The causes of maternal death are diverse, but haemorrhage, infection and pre-eclampsia are the leading causes, accounting for 25%, 15% and 12%, respectively.³¹ Moreover, most cases could be prevented with early diagnosis and effective intervention.

It is clear that something needs to be done to reverse this situation, involving not only diagnostic methods but also consistent improvement in processes.

One way to identify weaknesses within processes in detail and intervene to reduce the variability of care is

using Lean methodology. Originating in the Japanese industry in the 1950s, the method is guided by the DMAIC approach (Define, Measure, Analyse, Improve and Control), which involves defining the objectives of applying the method, measuring the initial performance of the process through data measurement, critically analysing the collected indicators, implementing actions focused on mitigating identified weaknesses (such as reducing risks), and monitoring the results to sustain or continuously improve the achieved improvements.²² Popularly known for increasing productivity, the Lean method has been applied in the healthcare system to enhance the effectiveness of care processes. In this system, effective processes avoid waste of any kind and promote value in healthcare by providing accurate care and treatments, which have greatly contributed to achieving high reliability.^{23–26}

Given the aforementioned factors in obstetrics, it seems that the use of process analysis methodologies is gaining increasing importance in the pursuit of more favourable outcomes in a lot of ways.^{27 28} This study here, it is about showing how Lean methodology was used in a maternity ward to cut down on bad stuff happening, especially when it is about newborns not getting enough oxygen.

MATERIALS AND METHODS

This study aimed to map the care flow for pregnant women and the labour process at the Albert Einstein Israelite Hospital (São Paulo—Brazil) in order to identify weaknesses that could contribute to perinatal anoxia and take action on them. The Lean methodology was used for this purpose. No specific patient information was accessed by the authors who only analysed the data regarding the process.

The scope of the study was the obstetrics unit of the hospital, which consists of the following sectors: Obstetric Emergency Department and Birth Centre. These sectors are in the same physical area and are intended for the exclusive care of gynaecological and obstetric emergencies in two examination rooms and four observation beds, as well as the conduct of vaginal deliveries in five labour delivery rooms.

The initial step in applying the method was the selection of participants. This was done through invitations after a scheduled meeting with the entire team to present the project proposal. The work team was composed of 29 people, including local medical and nursing leaders, as well as healthcare professionals, including 10 doctors, 11 nurses, 3 nursing technicians, 2 clinical pharmacists and 3 administrative professionals. A schedule was established that covered the entire project, allocating each stage of the DMAIC tool and reserving the work team's agenda for each stage.

The DMAIC methodology starts with defining the problem (D). In this case, there was institutional discomfort related to the number of adverse events in the maternity ward, which was going against the hospital's

intention to become a high-reliability institution. Next comes the measurement (M), which begins with the process mapping (predelivery, delivery, postdelivery) from the expectant mother's arrival at the maternity ward to her discharge, assessing the performance of each stage through both quantitative and qualitative data and identifying any possible existing flaws.

The next step is the analysis (A), where the team needs to uncover the root causes of the major flaws found and propose solutions to mitigate them. For this, the 'What-if' tool mentioned below is used, along with the causes of events and their location and timing between adverse events. It is important to note that all events go through a root cause analysis process and are influenced by the institutional risk surveillance team with the support of technical leadership.

After that, it is time to implement (I) the proposed changes at each stage of the process, assessing and addressing the challenges within the process. Finally, there is the need to control (C) and monitor the findings, establishing control indicators and individuals responsible for the measures.²²

Definition

The mapping of work processes began with five meetings in December 2019 of approximately 90 min each, during which brain-writing sessions were conducted using yellow post-it notes by the team. Together and simultaneously,

they defined the entire path taken by the pregnant patient. The care was evaluated from the perspective of a single linear, continuous and uninterrupted flow that involved different processes and activities from arrival to discharge of the patient (online supplemental annex 1). To facilitate targeted interventions and address the most critical and common situations in obstetric hospital care, this flow was later digitised into four flowcharts: (1) clinical analysis of the complaint, (2) therapeutic management for cases of amniotic fluid loss or bleeding, (3) fetal vitality assessment and (4) management of labour and immediate postpartum care.

Measurement

The next step of the analysis took place in January 2020 with a presentation to the work team of some basic concepts about risk analysis methodology, causes and consequences (What-if tool).²⁹ Then, each member of the team quantitatively classified (from 1 to 5) the probability of failure occurring at each step of the designed process. Subsequently, a new quantitative analysis (from 1 to 5) was conducted regarding the potential damage caused once the failure occurs (table 1). In the event of discrepancies in scoring among team members, clinical discussions were held until consensus was reached. The team was also responsible for presenting the reasons for possible failures.

Table 1 Classification and definition of frequencies and consequences of adverse events for use in the What-if tool²⁹

Frequency	Descriptor	Definition	Consequence	Descriptor	Patient harm
5	Frequent	It is practically certain and unequivocal that the event will occur within the next 3 months, as the circumstances clearly indicate this possibility.	5	Catastrophic	Permanent harm or preventable death. Example: Incorrect limb amputation and/or an event leading to fatality.
4	Probable	It is expected that the event will occur within the next 6 months, as the circumstances strongly indicate this possibility.	4	Serious	Temporary harm requiring increased intervention and/or escalation of resources to support/maintain the patient's life. Example: Retained foreign object; ICU admission.
3	Possible	The event may occur in the next year, to some extent, as the circumstances moderately indicate this possibility.	3	Moderate	Temporary harm without the need for escalated support/maintenance of the patient's life. Example: immobilisation.
2	Unlikely	In exceptional situations, the event may occur within the next 2 years, but nothing in the circumstances indicates this possibility.	2	Mild	Temporary harm without the need for intervention. Example: pain relief (analgesia).
1	Rare	Unexpectedly or casually, the event may occur within the next 5 years, as the circumstances indicate this possibility to a small extent.	1	Low/absent	Minimal or no harm. No intervention is necessary.

ICU, intensive care unit.

Risks with LR \geq 15 per phases of care in Obstetric Emergency and Birthing Center (n=28)

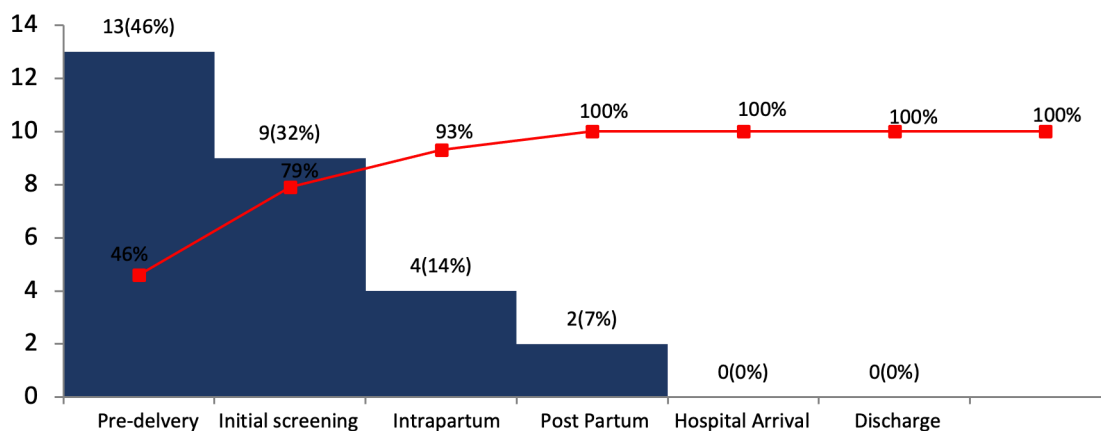


Figure 1 Distribution of care-related risks according to the stage of hospital care for pregnant women. LR = level risk according what-if tool (product of the probability of an adverse event occurring and the potential damage associated with it).

The final level of risk for each particular step was determined by multiplying the value assigned to the probability of its occurrence by the value assigned to the potential damage caused. Therefore, this risk varied quantitatively between 1 and 25. Risk levels between 1 and 3 were considered low, 4–6 were moderate, 8–12 were high and 15–25 were critical. At the same time, during the meetings, various suggestions and ideas brought by the team were absorbed, with a focus on improving patient safety.

Analysis

Only patient care risks with the potential to cause physical impact or harm to patients were considered in the analysis. Thus, a total of 112 different patient care risks were identified during the following months, distributed according to priority levels as follows: 7 (6%) low, 29 (26%) moderate, 48 (43%) high and 28 (25%) critical.

Focusing on the 28 critical risks, they were distributed among each stage of patient care, from arrival to hospital discharge (figure 1). It was identified that 13 (46%) of them were related to the predelivery phase, which involves decision-making prior to the initiation of labour induction. Nine (32%) risks were identified during the initial patient screening, that is, the initial care provided at the obstetric emergency department. Four (14%) risks were associated with the intrapartum phase, and two (7%) risks were related to the postpartum phase, as follows:

- **Predelivery:** The criticality was particularly represented by variability in care management, whether due to technical difficulties related to interpreting cardiocotography, psychological insecurity in discussing clinical conditions and decision-making with the team or lack of standardisation in the care process. The variability in interpreting uncertain cardiocotographs and a lack of knowledge regarding the parameters to be analysed were subjectively observed in interviews. This highlighted the need for ongoing training for the

team since these issues could potentially lead to delays in intervention or even unnecessary interventions.

- **Initial screening:** The absence of criteria for risk classification and prioritisation of care posed significant risks, potentially leading to delays in appropriate management and treatment according to the clinical manifestations of pregnant women.
- **Intrapartum:** Difficulties in accessing less frequently used materials, such as compresses or larger calibre vascular catheters, as well as critical medications with restricted access that may be required for obstetric emergencies, such as misoprostol, tranexamic acid, atosiban, methylergometrine and vitamin K1. This means that crucial medications to mitigate the primary postdelivery risk, which is haemorrhage, were not easily accessible. These medications were stored in a satellite pharmacy, distant from the delivery centre, necessitating the need for improved accessibility.
- **Postpartum:** Risks were identified related to errors in the administration of oxytocin (dose and rate), placental delivery (placenta examination) and delay in newborn identification (figure 1).

Intervention and control

After presenting the 28 critical risks to the work team, along with their main causes and potential consequences, actions were proposed to address and reduce the risk levels in four areas of work: (1) review of care practices, (2) training and capacity building, (3) technology and automation of care and (4) local infrastructure (including professionals). A total of 24 actions were identified in these four areas (online supplemental annex 2), and their implementation took place between September and December 2020.

Two actions were considered fundamental for the others: the development of a protocol for fetal vitality assessment during labour and the creation of another

protocol for labour induction that included periodic evaluation of fetal vitality during the process. The creation of these two different protocols established guidelines for standardising care practices, such as performing cardiotocography every 3 hours, a maximum resolution time of 20 min for category 3 cardiotocography cases and 60 min for category 2, with continuous monitoring under these conditions. Particularly in category 3 cases, the aim of the approach was to provide an additional 10 min of safety to the proposed 30 min for preintervention examination analysis.³⁰ On detecting changes in fetal vitality, a child-birth code is activated, which summons, through mobile extensions, the on-call obstetrician, neonatologist and anaesthesiologist to the caesarean section room. The healthcare provider attending to the patient, typically an obstetric nurse, guides her to this location. The time between activation and the arrival of the medical professionals should be 5 min, and this can be tracked through the internal system.

In the analysis, it was observed that, as important as the fetal vitality protocols, reinforcing actions to mitigate the risk of vaginal bleeding was crucial. The hospital had an existing practice of collecting blood in vaginal deliveries and weighing compresses to estimate vaginal bleeding. Additionally, there was a code H (a red code) in place, which, through mobile extensions, alerted the blood bank, laboratory and ICU to prioritise the case and also called in a surgeon for on-site assistance. Both the surgeon and the person responsible for collecting laboratory samples were required to arrive within 5 min, a time frame monitored by the interval between the activation of the code and the professional's registered arrival via the mobile extension. To enhance these measures, a haemorrhage box was introduced, containing medications that promote uterine contractions (such as misoprostol, methylergometrine and oxytocin), as well as a Bakri balloon. The code is activated whenever vaginal bleeding exceeds 500 mL in vaginal deliveries or 1000 mL in caesarean sections, coupled with maternal haemodynamic instability.

The intention behind these actions was to reduce variations in case management, promoting greater safety for

patients and the healthcare team by implementing established practices endorsed by the institution and experts.

After the implementation of these actions, a blind re-evaluation (without consulting the previous scores) of the frequency of occurrence and potential consequences for each of the 112 identified risks was conducted. This evaluation was performed with the support of the same multidisciplinary team that participated in the mapping and classification of risk levels.

RESULTS

Based on the conceptual principle that a risk cannot be completely eliminated but rather shifted to other levels of criticality, in [figure 2](#), it can be observed that after the implementation of the actions, all 28 (100%) of the extreme risks were eliminated, accompanied by an increase in the quantity of risks at lower levels. In other words, the 28 critical risks were shifted to moderate and low levels, which increased by 28% (8 risks) and 34% (24 risks), respectively, rather than to high levels as would be more intuitive.³¹ Conversely, the risks considered high also decreased by 8% (4 risks) ([figure 2](#)).

In numerical terms, considering the unit's historical series from July 2017 to the implementation of the reported actions, the longest interval observed between severe and catastrophic events was 219 days, with an average of 126 days. During the same period, the average number of patient care interactions in the birthing centre was 367 per month, of which 100 were vaginal deliveries and 266 were urgent obstetric consultations. After the implementation of the actions, even with an increase in the number of consultations to 449 per month (339 obstetric consultations and 110 vaginal deliveries), the maximum interval between severe or catastrophic events increased to 669 days, with an average of 284 days ([figure 3](#)). This represents a change from a weighted value of 7.91 adverse events to 3.29 per 1000 patients treated, resulting in a reduction of 2.07 severe or catastrophic adverse events per year. In financial terms, this reduction represents an annual savings of R\$693 646.80 (US\$139 000.00) in expenses related to the management

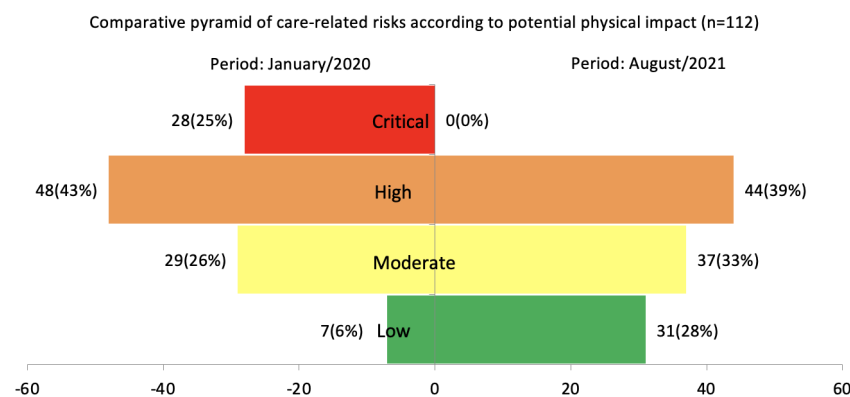


Figure 2 Comparative analysis of care-related risks, calculated by the What-if tool, before and after the implementation of changes.

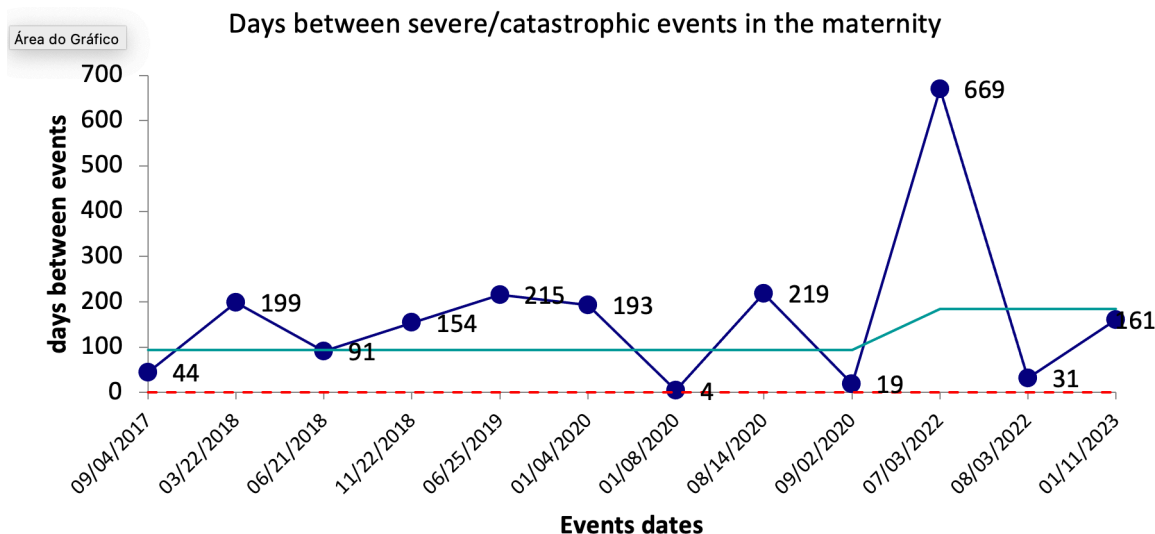


Figure 3 Days between severe and catastrophic events in maternity.

of preventable event complications. It is worth noting that 47% of the events were related to neonatal anoxia, particularly concerning the lack of standardisation in the timing between exams and a failure to identify changes in fetal vitality. 14% were related to haemorrhage, while the remainder involved medication errors, delays in detecting clinical deterioration and elopement (figure 3).

DISCUSSION

Given that childbirth is a physiological process and, for the most part, anticipated and valued by families, adverse outcomes in childbirth often have significant consequences. This is precisely why obstetrics is the medical specialty most prone to lawsuits in Brazil and ranks fourth in the Medscape system in the USA.^{32 33}

All of this highlights the need for the creation of safer monitoring processes for labouring women in order to ensure maternal and fetal health.

The simple creation of care protocols, especially those consisting of lengthy pages, does not guarantee their applicability or even widespread knowledge among those responsible for providing care. Furthermore, without creating processes and structures for implementing such protocols, they remain mere guidelines for ideal care. Therefore, a set of actions to enforce the designed processes and the application of protocols appears to be the foundation for creating a safer maternity environment.³⁴

For this reason, it was understood that the best strategy for transforming this reality would be the Lean method, with the participation of professionals directly involved in patient care. Through this method, it was possible to map the entire flow of the maternal–fetal dyad within the hospital, identifying the most critical points, sometimes unnoticed before the brainstorming, and taking effective and feasible actions to address them.

The entire process was not only monitored but also carried out by the team responsible for patient care in

collaboration with leadership, who prioritised this initiative. The importance of team participation and leadership in the constructive process of change is supported by the literature and is essential for the team's definitive adherence to the new processes.^{35 36}

Aware of their weaknesses and the actions that are possible or not to implement, the multidisciplinary team understood that the main bottleneck in caring for pregnant women would lie in fetal well-being, especially in standardising the performance and analysis of cardiocotography, which is supported by the literature.^{37 38} Therefore, it was understood that initially unifying the report and finally creating a structure to ensure adherence to a periodicity of performing and analysing tests was necessary. This led to the adoption of the WHO classification for cardiocotography exams, the mandatory and biennial development of e-learning on the exam, and the creation of an alert system for exceeding the time interval between exams, connected to the hospital's monitoring centre.³⁹ Obviously, this is just one example of the various actions taken, which also included reducing maternal risks and caring for newborns.

It is noticeable that process standardisation permeates the various actions, a measure known to make them safer.⁴⁰

The adopted actions allowed the risks to be shifted downward since they cannot be eliminated but minimised.³¹ Thus, the base of the risk pyramid was widened.

The literature categorises risk treatment actions as weak, intermediate and strong recommendations according to the probability of eliminating the risk and the team's adherence.⁴¹ The dynamics of risk shifting occurred especially at the level of treatment assigned to critical risks, where mainly intermediate interventions were applied (such as the implementation of care protocols, standardisation of practice, review of the number of available medical professionals and nurses, and definition of roles and responsibilities of each team member) and strong

interventions (such as the implementation of specialised artificial intelligence capable of assisting in the interpretation of cardiocography and issuing panic alerts in cases of suspected or identified fetal distress). The reduction in risks observed was accompanied by an improvement in care with a longer interval between events.

Contrary to popular belief that the adoption of safety measures only leads to increased costs, it can be observed that they also result in financial returns. An analysis of the monetary costs applied to the management of complications showed a reduction of nearly R\$700 000 (or US\$140 000) per year for the care of pregnant women and newborns. This does not even consider the other minimised impacts that were not measured in the study, such as the sustainability of the healthcare system and the emotional consequences for pregnant women, family members, healthcare professionals and the organisation.

An improvement in the quality and safety of professionals who attend to these events is expected since we are aware of the concept of the second victim, which refers to the emotional distress experienced by healthcare professionals who have been involved in adverse events and suffer in a similar way to the 'first victim'.⁴² A recent review on the subject showed that over 80% of second victims experience memory problems, and over 70% experience anxiety, remorse and self-anger.⁴³

In summary, based on this experience, it can be said that the creation of secure processes begins with the measurement of data that highlights the necessary corrections. This is followed by a search in the scientific literature for proven ways to address these shortcomings. Subsequently, these issues are brought to the healthcare team for their input, adapting the suggested changes to the local reality while simultaneously establishing a purpose in the change, in this case, providing safer care. Monitoring the process to understand and minimise difficulties is also crucial. Lastly, it is essential to evaluate whether the results are favourable and maintain continuous control of actions through a responsible team and indicators. In this case, the team responsible for the change remains engaged daily and collects indicators monthly to ensure the sustainability of the process, even with team member turnover.

Unfortunately, it is not possible to measure the impact of each individual action, but rather the collective impact of all actions. It is also important to note that it cannot be definitively concluded that the Lean process alone generated the best results, even though it was the only intervention carried out before the observed improvements. It is worth highlighting that process changes can bring about negative results as well as personnel turnover when individuals do not adapt to these changes. It is also important to note that discussing the topic has brought situational awareness to the entire team, raising their level of attention, regardless of the new measures adopted. Finally, since these are rare events, it is necessary to allow more time to verify if the actions are sustainable in the long term.

CONCLUSION

The construction of a process based on Lean methodology for mapping and mitigating high and critical risks within a maternity ward, with the participation of leadership and a multidisciplinary care team, appears to have an impact on reducing severe and catastrophic adverse events over time. This can be attributed both to the established changes and to the culture of safety brought about by this constructive process.

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