ARTICLE
https://doi.org/10.22239/2317-269x.01909

Actions developed by hospital risk management teams in post-market surveillance

Ações desenvolvidas por gerências de risco hospitalar na vigilância pós-comercialização

Márcia Danieli Schmitt*

Selma Regina de Andrade

Universidade Federal de Santa Catarina, Florianópolis, SC, Brasil

* **E-mail:** marciaschmitt@hotmail.com

Received: 23 Mar 2021
Approved: 04 Nov 2021

ABSTRACT

Introduction: The unsatisfactory and questionable quality of some products marketed for health care is one of the problems faced by hospital institutions. Some hospitals have risk management and are part of the Sentinela Network, implemented by the National Health Surveillance Agency (Anvisa) to face this problem. **Objective:** Analyze the actions taken by hospital risk management teams in post-marketing surveillance. **Method:** Multiple case study, with a qualitative approach composed of four public hospital institutions that are part of the Sentinela Network in Florianópolis, Santa Catarina. Data were collected through triangulation, with semi-structured interview techniques, non-participant direct observation and documentary research, from February to June 2017. Data analysis occurred through the cross-synthesis of cases, from which two categories emerged: organizational structure of risk management and actions developed by risk management. **Results:** The similarities between the actions taken by the hospital risk management are: an encouragement of notifications, the investigation of notifications, feedback on notification, and the training of professionals on the subject. Among the main contrasts, we can mention the organizational structure of risk management in each institution and the internal communication of risks. **Conclusions:** Among the actions developed, the forwarding of notifications to Anvisa is highlighted via the Notivisa system. This action is essential for the agency to carry out health surveillance of products used in health care, in the post-marketing phase.

KEYWORDS: Public Health Surveillance; Brazilian Health Surveillance Agency; Risk Management; Quality Assurance, Health Care; Product Surveillance, Postmarketing Surveillance

RESUMO

Introdução: A qualidade insatisfatória e questionável de alguns produtos comercializados para a assistência à saúde constitui um dos problemas enfrentados pelas instituições hospitalares. Alguns hospitais contam com a gerência de risco e fazem parte da Rede Sentinela, implantada pela Agência Nacional de Vigilância Sanitária (Anvisa) para enfrentar esse problema. **Objetivo:** Analisar as ações desenvolvidas por gerências de risco hospitalares na vigilância pós-comercialização. **Método:** Estudo de casos múltiplos, com abordagem qualitativa, composto por quatro instituições hospitalares públicas integrantes da Rede Sentinela, em Florianópolis, Santa Catarina. Os dados foram coletados por meio de triangulação, com as técnicas de entrevista semiestruturada, observação direta não participante e pesquisa documental, no período de fevereiro a junho de 2017. A análise dos dados ocorreu por meio da síntese cruzada dos casos, da qual emergiram duas categorias: a estrutura organizacional da gerência de risco e as ações desenvolvidas pela gerência de risco. **Resultados:** Entre as similaridades nas ações realizadas pela gerência de risco hospitalar estavam o estímulo à notificação, a investigação das notificações, o *feedback* sobre a notificação e a capacitação dos profissionais sobre a temática. Entre os principais contrastes encontrou-se a estrutura organizacional da gerência de risco em cada instituição e o processo de comunicação interna dos riscos. **Conclusões:** Entre as

ações desenvolvidas, destaca-se o encaminhamento das notificações para a Anvisa, via o sistema Notivisa. Essa ação é fundamental para que a agência realize a vigilância sanitária dos produtos utilizados na assistência à saúde na fase pós-comercialização.

PALAVRAS-CHAVE: Vigilância em Saúde Pública; Agência Nacional de Vigilância Sanitária; Gestão de Riscos; Garantia da Qualidade dos Cuidados de Saúde; Vigilância de Produtos Comercializados

INTRODUCTION

The complexity of the hospital environment increases with the advancement of health technologies, which brings risks and benefits in the care provided. There is no way to guarantee the absence of risks, regardless of the product used. Health services and Health Surveillance are responsible for preventing harm to patients using equipment and articles for medical and hospital use[1]. Conceptually, health technologies are recognized as a set of equipment, medicines, supplies, and procedures/processes used in the provision of health services. These resources involve the infrastructure, as well as the organization of institutions that provide health care[2].

In order to obtain qualified information on the products after their sale and to develop in-hospital health surveillance actions, the Brazilian National Health Surveillance Agency (Anvisa) implemented the Sentinel Network in 2002[3]. Since then, a network of qualified hospital institutions has been structured in Brazil to monitor and notify technical complaints (TC) and adverse events (AE) of products used in health care subject to Health Surveillance[4].

The network is an observatory on the use of health technologies and a notifier for the Health Surveillance Notification and Investigation System (VIGIPÓS). VIGIPÓS is a surveillance dimension that maintains a systematic observation of AE and quality deviations or TC of products under health surveillance in the country[3], involving blood and blood products, medicines, health products, sanitizers, cosmetics, and health care[4].

Hospitals accredited to the Sentinel Network are committed to implementing a risk management system in the institution, responsible for training the team and fostering a culture of notification. In addition, these services must appoint a professional as a risk manager, who will be responsible for coordinating the actions of identifying, investigating, and notifying in the institution and making the interface between the actions of intra-hospital health surveillance and Anvisa[5,6].

In view of this scenario, this study is justified by the focus on risk management in institutions accredited to the Sentinel Network, with the expectation of producing empirical evidence on the monitoring actions of products used in health care in the post-marketing phase. With this perspective, the following propositions are accepted: 1) hospital risk management is characterized as the link between the hospital and Anvisa, which identifies, analyses, evaluates, monitors, and communicates risks, under the coordination of the risk manager; 2) the Sentinel Network is an observatory for the post-market of health products, which implemented VIGIPÓS' actions in the hospital environment.

Based on these propositions, the question is: how are the actions developed by hospital risk management in post-market surveillance evidenced? This study aimed to analyze the actions developed by hospital risk management in post-market surveillance.

METHOD

Multiple case study with a qualitative approach. The multiple case study is composed of a group of individual cases that allows to understand and investigate in depth the phenomenon studied. They are considered more robust and allow greater certainty about the results[7].

The cases studied corresponded to four public hospitals that are part of the Sentinel Network in Florianópolis, Santa Catarina (one federal university hospital and three state hospitals). Within the multiple case study, each hospital institution corresponded to one case. The selection criteria for key informants were: 1) being a risk manager or a professional designated for this function; 2) be a professional working together with the risk manager in post-market health surveillance, regardless of training and length of experience in the sector.

Data were collected from March to July 2017, through semi-structured interviews, direct non-participant observation, and documentary research. The semi-structured interviews were previously scheduled via telephone and carried out individually, in a place determined by the study participant, being recorded after their authorization with the aid of a voice recorder. Subsequently, these interviews were transcribed in full and returned to the participants via e-mail for validation.

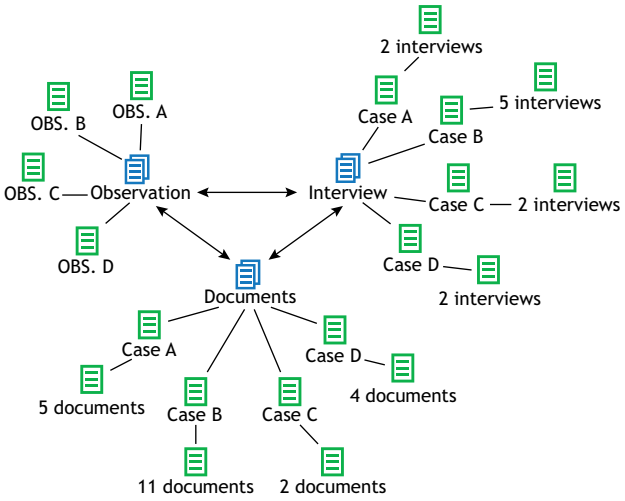
Direct, non-participant observations were carried out at each risk management for an approximate period of four hours and were scheduled in person on the day of the interview, or carried out at different times, while the researcher awaited the interview. Documentary research was carried out by verbally requesting documents, mostly made available by e-mail. Information available on the institutions' websites was also consulted. The analysis of the documents was carried out based on the reading and systematization of the document contents, for later comparison with the other data collection techniques.

In order to preserve the anonymity of the participants, the cases are named A, B, C, and D. Risk managers and other professionals who work in post-marketing health surveillance are identified by the letter that determines the case, followed by a number from 1 to 5 that represents the professional. The documents are identified

by the abbreviation DOC., followed by a number that represents the document and the letter that identifies the case. Observations are identified by the abbreviation OBS., followed by the letter that identifies the case. The Figure illustrates the set of data collected.

For data analysis, the MaxQDA®plus software was used, which made it possible to codify, categorize, and perform triangulation of the data collected in the semi-structured interviews, in the non-participant direct observations, and in the documents. Data analysis was performed through cross-case synthesis, a technique used for the analysis of multiple cases. This analysis technique is relevant in studies that have at least two cases[7]. After processing the data with the support of the software, tables were structured, in which the data were grouped into two categories: the organizational structure of risk management and the actions developed by risk management.

The study was submitted for consideration by the Ethics Committee in Research Involving Human Beings and was approved under CAAE nº 63084416.6.0000.0121.



Source: Elaborated by the authors, 2021.

Figure. Source of research evidence.

RESULTS

All the cases studied are state reference hospitals and are accredited in the participating profile of the Sentinel Network. The institutions have a risk manager, however, without exclusive dedication to the activities of the sector. All cases made notifications in the areas of techno-surveillance, hemovigilance, pharmacovigilance, and care errors but only case B made notifications in the area of bio-surveillance. The characteristics of each case are described in Chart 1.

Next, the two categories that emerged from the data triangulation are described: the organizational structure of risk management and the actions developed by risk management. The first addresses how each risk management is structured within the institution. The second presents the actions that are carried out by risk management.

Risk management organizational structure

The risk management organizational structure presents similarities and contrasts between the cases. In cases B and C, the risk manager is responsible for coordinating a multi-professional team, which worked together in the post-market Health Surveillance actions. During the observation period, it was possible to notice that the risk manager in case B coordinated four professionals, each responsible for specific areas in pharmacovigilance, techno-surveillance, hemovigilance, and in the Patient Safety Centers (NUSEP). The risk management of case C included, in addition to the aforementioned areas, the Waste Management, the Permanent Commission for Technical Opinion on Materials (CPPTM) and the Epidemiological Surveillance Nucleus.

> [...] my contribution to risk management is to be the manager. [...] And how is the set, of hemovigilance, pharmacovigilance, techno-surveillance, bio-surveillance, and the part of patient safety. So, for each related area, there are people responsible [...] (B2).

Chart 1. Characteristics of risk management in the cases studied. Florianópolis, SC, 2017.

Analysis elements	Case A	Case B	Case C	Case D
Number of beds	120	209	126	159
Year of risk management implementation	2009	2002	2011	2002
Risk manager training	Pharmacy	Medicine	Pharmacy	Nursing
Time of risk manager performance in the institution	5 years	13 years	9 months	4 years
Time of risk manager performance in risk management	5 years	3 years	7 months	1 month and 15 days
Number of professionals working at VIGIPÓS	2	5	2	1
Risk management has its own office	Shared environment	Yes	Yes	Shared environment
Event communication system	Manual notification	Manual and computerized notification	Manual notification	Manual and computerized notification
Patient Safety Center	Incorporated into risk management	Incorporated into risk management	Incorporated into risk management	Risk manager is a member

Source: Elaborated by the authors, 2021.

> I am appointed by the Board as a risk manager [...] the risk management here at the hospital is designed as a big umbrella, contemplating Waste Management, CPPTM and NUSEP, and the Epidemiological Surveillance Nucleus [...] (C1).

In cases A and D, the sector was structured differently. During the observation period, it was noticed that, in case A, two professionals worked together in the actions of risk management and NUSEP. In case D, the risk manager acted alone and had their actions focused on pharmacovigilance, techno-surveillance, and hemovigilance.

> [...] we carry out the activities together. [...] after the structuring of NUSEP, it was also assigned to us (A2).

> In addition to risk management [...] pharmacovigilance, techno-surveillance, and hemovigilance (D2).

The contrast between the cases is related to the structure and organization of the sector within each institution.

Actions developed by risk management

Among the actions developed, encouraging notification was cited as the main attribution of risk management. The actions developed by the risk management are articulated with each other, being triggered from the notification.

> I always saw it as the main action, and the rest was the consequence, to encourage professionals to carry out the notifications [...] (D2).

Among the actions developed by the professionals who worked in the risk management of cases A, B, and D, were receiving the notifications, investigating the notified event, notifying the Health Surveillance Notification System (Notivisa), seeking to solve the incident that caused the notification and following up the notified event within the institution and in the Notivisa system.

> [...] the main tasks are basically these: receive notifications, notify, try to solve, and follow up. [...] when there is a solution in the case, I close the notification (A1).

> Going after all the risks, all the adverse events reported in the institution, is helping in the investigation of some and monitoring the events that are notifiable in Notivisa (B2).

Another action developed by risk management was the active search. In case B, the professionals who worked in techno-surveillance, hemovigilance, and patient safety carried out an active search in the evolution of the patients' medical records and in the care units, involving other sectors such as the warehouse. The active search aims to identify events not reported by the health team and verify the quantity of medical-hospital articles reported in the institution, in order to decide the necessary actions.

Case C indicated that most notifications focusing on patient safety protocols are identified through the active search, which is performed daily in all patient records. Case D developed as a strategy the active search through personal contact with professionals in the units, questioning them about possible AE and TC that occurred in the sectors.

> And also, the active search in the evolutions of the nurses that we did, to see if there is any adverse event that they did not report, that we need to investigate. In evolutions, in the system (B5).

> [...] most of the notifications are identified through the active search performed in 100% of the patients' electronic medical records [...] (C1).

> And I also did that melee search, and asked: I'm getting the notifications, does anyone else have any notifications? (D2).

In the document analysis, it was possible to perceive that, in case B, the consultation with health professionals and patients was also carried out. The participation of health professionals is highlighted as essential to expand and qualify this process (DOC. 11 B).

Case A did not perform an active search. This is justified due to the risk management actions being developed in the pharmacy and reconciled with the activities of this sector. In case B, pharmacovigilance did not carry out an active search due to the restricted workload of the professional who worked in the area.

> We were not able to do an active search [...] this is the great difficulty for being in the pharmacy area, because, sometimes, many things happen during patient care, there on a daily basis, that the pharmacist has no contact with. This impairs both the understanding of what is happening and the collection of these notifications [...] (A1).

> [...] I still have a very restricted workload, I can't do an active search (B1).

All the cases studied showed similarity in the actions that involve the investigation of notifications received by the sector and in the changes in internal processes caused by the notification/investigation. The investigation takes place through a search in medical records and interaction with the authors involved in the notified event, with the most serious events being prioritized. This results in action plans, changes in internal processes, and the creation of barriers, with the aim of preventing a new event from occurring. The cases highlighted that risk management works to offer solutions to identified failures and that most problems are solved by changing internal processes and training professionals.

> [...] the investigation is one of the functions... which is important because it is often where you will be able to make a flow and have a plan that will improve what is happening, be it an event, or an anomalous situation that is happening at that moment. [...] Many things, sometimes, are process errors. People do not have the correct information or have not been trained (D2).

In the document analysis, it was observed that the risk management actions were aimed at improvements, corrections, and/or prevention of the recurrence of events related to hospital health

risks. The information generated by risk management must be used to improve processes and preventive and corrective measures, since it is not enough to follow the notifications without using them for internal improvement (DOC. 11 B). The notification forms have guidelines to detail the incident, with the aim of establishing preventive measures (DOC. 1 A).

Another action developed by risk management was the return to the notifier, the sectors, and/or the professional involved in the reported incident. In case B, the return was made to the notifier (when they identify themselves) by e-mail or in person. It all depends on the severity of the event. Feedback was also made to the sectors and teams that performed the service, especially when it involved issues related to patient safety or events generated by failures in internal processes. In these cases, risk management's concern was to avoid characterizing the event as an individual event, centered on the professional involved in the event.

Case C established an internal flow, in which the risk management prepared an action plan based on the demands that emerged from the notified, which was forwarded to the sectors, which executed the plan, correcting the flaws in the work processes. In case D, the return was made to the professional who erroneously prescribed some medication. In the document analysis, it was noticed that the letter explained the consequences that this can cause to the patient, suggesting improvements in the process (DOC. 3 D).

> Usually, these notifications are returned to the notifier. [...] which takes place by means of a letter... or by e-mail. [...] when it is a more serious case, there is a return to the sector. It is not directly related to the person (the letter), when it involves a process problem... so as not to characterize any problem, especially in relation to patient safety, as an individual (D2).

> We designed a flowchart, which forwards the notified demands to the responsible sectors to design action plans [...] in order to correct the flaws in the work processes and with a determined deadline for compliance (C1).

In addition, cases A, B, and D, when they identified TC or AE in medical-hospital items and/or medications, reported what had happened to the supplier. This, in turn, evaluated the need to train professionals on the use of the product, as well as the need to change batch/brand/replace the material. In case B, the bidding and purchasing sector was also communicated, so that it was aware of what was happening. In case C, after the information was passed on to Notivisa, the techno-surveillance notification was forwarded to the Health Department, which carried out the procedures with the suppliers. Cases A and D were also referred to the Health Department, however, it was highlighted that, in case D, due to the delay in returning from the Department, the risk management contacted the supplier.

> [...] with material quality deviation [...] I call the company's Customer Service, which directs [...] collects the material, or comes here and checks if it is necessary to train employees on its use, or replace, or change the batch of material. [...] I scan it (notification form) and send it to a hospital material commission at the secretariat (Health Department) (A1).

> [...] when it is due to material problems, the return is given to the company, so that they know which batch of material is troubled and, usually, they come to find out about the institution or, at least, by e-mail or some means of communication to know what happened to their products (B2).

Case D developed an action that differentiates it from the other cases. The risk manager was responsible for verifying whether the medical-hospital articles have reported TC or AE, before forwarding them to the sectors to carry out the technical opinion.

> [...] So these are things that I have to look at Notivisa if there are any technical complaints, if not and forward them. It is the risk management that sees if there is any material complaint (D1).

Respondents in cases A, B, and D reported that samples of medical-hospital items or notified drugs were archived by risk management. This is Anvisa's guidance that is also used as an argument when contacting the supplier. In the document analysis, it was found that the notification forms had the guidance to forward the notified product to risk management (DOC. 4 A, DOC. 4 B, DOC. 2 D).

> We received guidance from Anvisa that we had to leave the material, as it says here: keep the sample in your possession (B3).

> It is our orientation to send them together, because, when contacting the company, we already show the material with problems [...] (D1).

In view of the professionals' reports, it was noticed that case B presented some contrasts in relation to the other cases. Risk management developed actions aimed at internal risk communication. This occurred through pharmacovigilance newsletters (carried out in specific situations) and screening and passing on of Anvisa's technical alerts to the hospital sectors. It was observed that the first action taken by the professional at the beginning of their work process was to consult the Anvisa website (in the space "consultation of the irregular product") to identify the alerts issued and communicate to the sectors that, if necessary, they must remove the medical-hospital article and/or medication circulating in the institution (OBS. B).

> Sometimes I issue some pharmacovigilance bulletins when there is some event or a recurring medication error or specific information about drug dilution, stability, then I do a newsletter. [...] It's printed. But it doesn't have a circulation, a specific frequency. It is when a one-off situation occurs (B1).

In the document analysis, it was also possible to perceive that the direction and the main managers of the institution were informed about the AEs that caused harm to the patient. This action aims to keep them aware of what is happening in the institution (DOC. 11 B).

Chart 2. Synthesis of actions developed by hospital risk management in post-market surveillance: similarities and contrasts between the cases studied. Florianópolis, SC, 2017.

Similarities	Contrasts
Notification stimulus	Different risk management organizational structure
Notification investigation	Consultation strategies for health professionals and patients to expand and qualify risk management
Changes to internal processes caused by notification/investigation	Different ways of verifying the existence of adverse events and technical complaints of medical-hospital articles before referring them for a technical opinion
Return to the notifier, sectors, and/or the professional involved in the reported incident	Internal risk communication mode through newsletters
Training of the team on the areas of activity of risk management	Way of passing on Anvisa's technical alerts to the hospital sectors

Source: Elaborated by the authors, 2021.

The four cases studied showed similarities in the team's training actions in the areas of risk management.

> Capacitate your teams. We have taken a lot of courses here at the hospital at all levels (C1).

Case B highlighted the responsibility of risk management to provide biannual reports to Sentinel Network. In the speech of the professional in case D, it was also possible to perceive the completion of the report.

> And also provide the Sentinel Network with the semiannual reports they require (B2).

> A newsletter comes out every six months from the Sentinel Network, and our hospital was in group A (D2).

In the document analysis, it was noticed that case A also issued the report, since it was made available for analysis.

Chart 2 presents the main similarities and contrasts between the cases studied.

DISCUSSION

The results of the study made it possible to compare, in the four cases studied, the actions carried out by risk management in post-market health surveillance. The cases showed similarities in most actions and some contrasts.

All the cases studied were accredited in the participant profile, thus, they are committed to having implemented an active risk management in the institution that feeds the VIGIPÓS data. Hospital institutions are voluntarily accredited by the Sentinel Network and can opt for different accreditation profiles, which do not have hierarchies or are excluding[3].

The adhesion of hospitals to the Sentinel Network makes it possible to know the TC and AE in the areas of pharmacovigilance, techno-surveillance, hemovigilance, bio-surveillance, and care mistakes. However, there is a need for greater strengthening of the Sentinel Network in the country, which is capable of making it a reference in the surveillance of products used in health care at national and international levels, especially in relation to the importance that the notification process has for obtaining qualified information for health regulations[8].

Furthermore, the notifications allow the investigation of identified nonconformities, which reflects on decision-making in actions aimed at patient safety[9]. In this context, the importance of the commitment of the institutions accredited in the Sentinel Network, with Anvisa's proposal, is highlighted.

In this study, it was possible to perceive the articulation between risk management and NUSEP, which develop joint actions in the institutions studied. Anvisa's initial focus on the post-market of health products expanded with the introduction of AE notifications resulting from the provision of health services, notifications that are incorporated into the National Health Surveillance System[3]

The organizational structure of the risk managements studied was organized according to the structure (human resources, physical structure) institutionally made available. It is worth mentioning that the formal designation of a professional to act as a risk manager is a basic criterion for accreditation in the Sentinel Network[3]. It was noticed that the greater the structure provided (mainly human resources), the greater the number of actions developed by risk management.

A study emphasizes the role of the risk manager as a profession and highlights the need for this manager to monitor their productivity in order to demonstrate their value in achieving the institution's goals[10].

Inadequate sizing and turnover of professionals interfere with the operationalization of risk management actions. This results in underreporting, which impairs the implementation of improvements, the analysis of risks and events that occur[11], in addition to weakening the safety culture in the institution[12]

The difficulty encountered by health institutions in allocating resources for risk management is highlighted. This is because the sector is typically considered a department that does not generate profits for the institution[10]. However, it should be considered that, when institutional risks are managed effectively, risk management contributes to reducing the exposure of professionals, in addition to promoting the quality and safety of the care provided[13].

The actions developed by the risk management of the cases studied are, in part, similar to studies carried out in other countries. In the United States, professionals responsible for risk management in hospitals, in addition to developing and implementing risk management programs, are committed to creating and/or reviewing policies and procedures related to their own management[13]. In the same country, another study presented as activities carried out the identification and analysis of risks, loss prevention, activities focused on patient safety, providing feedback to employees, training the team, and reviewing contracts and policies[10].

The active search, carried out by most of the cases studied, is highlighted as a way of getting to know the institution itself. This fact corroborates the study that characterizes the active search as a management strategy that allows to know the risk situations[14]. Furthermore, carrying out an active search for incidents has proved to be a management strategy, as it helps to identify risk situations in hospitals[14].

The return to the notifier, to the sector, and/or to the professional involved in the notified event is carried out in different ways in the cases studied. The feedback establishes a communication channel, which allows the institution to provide feedback on the actions taken to solve the problem, in addition to passing on guidelines and information to professionals[15].

In this study, risk management contacts the supplier and follows Anvisa's guidelines, filing product/drug samples and notifications, which corroborates another study, carried out at an institution accredited to the Sentinel Network[16]. In this way, the importance of risk management in monitoring and controlling the quality of products used in health facilities is emphasized, as well as the importance of a pre-qualification system for medical and hospital articles that enables the adequate selection of products and that demands quality even before acquisition[17]. A study carried out in Thailand showed that hospitals also performed risk management of products used in health care by investigating complaints, monitoring inappropriate advertising, and maintaining risk management and surveillance databases[18].

The involvement of health professionals is essential for the success of risk management actions. These professionals contribute to the identification, analysis, and treatment of risks, which results in a decrease in incidents in the institution. The awareness and training of professionals on this topic encourage a change in organizational culture and contribute to the increase in the number of notifications[19]. However, the analysis of accidents can be refined with the use of techniques and theories that help to identify the causes of the incident, preventing the simple attribution of blame to the professionals involved[20].

The transmission of Adverse Event Notification newsletters to professionals proved to be relevant in this study, since it establishes a means of communication about their occurrence and allows the creation of an internal database with problem situations and identified risks. Furthermore, the data can be used in continuing education, with the aim of mitigating incidents and, consequently, improving the quality of care provided[21].

It is noteworthy that managing risks in health institutions is a proactive function that aims to minimize financial losses through measures that seek to reduce the frequency and severity of incidents, and possible legal claims, included in a business risk management scope[22].

It is considered as a limitation of this research that the study covers only public institutions accredited to the Sentinel Network, which may limit the understanding of the phenomenon studied in the context of private hospitals. However, the methodology used made it possible to systematize relevant evidence that demonstrates the actions developed by risk management, which positively contributes to Anvisa achieving its purpose in post-market surveillance.

CONCLUSIONS

The actions developed by the hospital risk management are triggered from the notifications. Among these actions, we highlight the forwarding of notifications to Anvisa, via the Notivisa system, an action that is essential for the agency to carry out health surveillance of products used in health care in the post-market phase.

Furthermore, risk management seeks solutions for identified failures, given that most problems are solved by changing internal processes; risk management also identifies unsuitable products for use and trains professionals. Such actions promote positive impacts on the safety and quality of care provided by hospital institutions.

REFERENCES

1. Costa EAM. Reflexões sobre segurança sanitária em reprocessamento de produtos para saúde. Vigil Sanit Debate. 2014;2(1):7-13. https://doi.org/10.3395/vd.v2n1.119
2. Lima RA, Brazorotto SJ. Qual o status da incorporação de tecnologias em saúde no contexto hospitalar? Rev Bras Inov Tecnol Saúde. 2019;9(3):35-55. https://doi.org/10.18816/r-bits.vi0.18736
3. Agência Nacional de Vigilância Sanitária – Anvisa. Experiências da rede sentinela para a vigilância sanitária: uma referência para o programa nacional de segurança do paciente. Brasília: Ministério da Saúde; 2014[acesso 12 nov 2021]. Disponível em: http://bvsms.saude.gov.br/bvs/publicacoes/documento_referencia_programa_nacional_seguranca.pdf
4. Teixeira APCP, Leitão LO, Barbosa PFT, Cammarota DMOT, Rocha VLC. Perfil de estabelecimentos de saúde brasileiros participantes da rede sentinela. Vigil Sanit Debate. 2017;5(4):88-93. https://doi.org/10.22239/2317-269x.01006
5. Agência Nacional de Vigilância Sanitária – Anvisa. Rede sentinela. Brasília: Agência Nacional de Vigilância Sanitária; 2020[acesso 20 mar 2021]. Disponível em: http://portal.anvisa.gov.br/rede-sentinela

6. Luz MKS, Sousa JPS, Oliveira ECS. Queixas técnicas de produtos para a saúde: monitoramento para qualidade da assistência. Rev Enferm Digit Cuid Promoção Saúde. 2020;5(1):13-8. https://doi.org/10.5935/2446-5682.20200004
7. Yin RK. Estudo de caso: planejamento e métodos. 5a ed. Porto Alegre: Bookman; 2015.
8. Martins MAF, Teixeira APCP. Desafios e perspectivas na vigilância sanitária pós-comercialização/uso. Vigil Sanit Debate. 2019;7(4):3-9. https://doi.org/10.22239/2317-269x.01425
9. Mascarello A, Massaroli A, Pitilin EB, Araújo JS, Rodrigues ME, Souza JB. Incidents and adverse events notified at hospital level. Rev Rene. 2021;22:1-8. https://doi.org/10.15253/2175-6783.20212260001
10. Howard CM, Felton KW. Determining hospital risk management staffing through analytics. J Healthc Risk Manag. 2013;33(2):36-42. https://doi.org/10.1002/jhrm.21125
11. Siqueira CL, Silva CC, Teles JKN, Feldman LB. Management: perception of nurses of two hospitals in the south of the state of Minas Gerais, Brazil. Rev Min Enferm. 2015;19(4):919-26. https://doi.org/10.5935/1415-2762.20150071
12. Mourão KQ, Oliveira AMM. Notificação de eventos: avanços e desafios no contexto da segurança do paciente. Rev Eletr Acervo Saúde. 2019;(Supl. 24):1-6. https://doi.org/10.25248/reas.e492.2019
13. Miller VB, Miginsky CS, Connelly NC. The risk manager's contribution to patient safety and risk management in the ambulatory or physician practice setting. J Heal Risk Manag. 2012;31(4):31-9. https://doi.org/10.1002/jhrm.20102
14. Santos RP, Luz MAP, Borges F, Carvalho ARS. Active search contributes to the identification of adverse events and incidents in intensive care unit. Enferm Global. 2017;16(4):476-87. https://doi.org/10.6018/eglobal.16.4.269601
15. Paiva MCMS, Popim RC, Melleiro MM, Tronchim DMR, Lima SAM, Juliani CMCM. The reasons of the nursing staff to notify adverse events. Rev Latino-Am Enfermagem. 2014;22(5):747-54. https://doi.org/10.1590/0104-1169.3556.2476
16. Schmitt MD, Haddad MCFL, Rossaneis MA, Pissinati PSC, Vannuchi MTO. Análise das notificações de queixas técnicas em tecnovigilância em hospital universitário público. Vigil Sanit Debate. 2016;4(3):35-41. https://doi.org/10.22239/2317-269x.00750
17. Sousa RS, Pontes LPP, Maia JLB, Araújo HAWP, Rocha TPO, Diniz RP. Risk management in technovigilance: analysis of reports from a sentinel hospital. Rev Enferm UERJ. 2017;25;1-7. https://doi.org/10.12957/reuerj.2017.22730
18. Kanjanarach T, Jaisa-Ard R, Poonaovarat N. Performance of health product risk management and surveillance conducted by health personnel at sub-district health promotion hospitals in the northeast region of Thailand. Risk Manag Health Policy. 2014;7(1):189-97. https://doi.org/10.2147/RMHP.S70653
19. Ventura PFEV, Silva DM, Alves M. Cultura organizacional no trabalho da enfermagem: influências na adesão às práticas de qualidade e segurança. Rev Min Enferm. 2020;24:1-9. https://doi.org/10.5935/1415-2762.20200067
20. Leveson N, Samost A, Dekker S, Finkelstein SMD, Raman JMD. Uma abordagem de sistemas para analisar e prevenir eventos adversos em hospitais. J Patient Saf. 2020;16(2):162-7. https://doi.org/10.1097/PTS.0000000000000263
21. Silva HR, Costa RHF, Pinheiro Neto JC, Macedo Júnior CAA, Nascimento PB, Moraes RA et al. Analysis of incidents notified to the National Health Surveillance Notification System (Notivisa) in Brazil from 2014 to 2019. Res Soc Develop. 2020;9(7):1-17. https://doi.org/10.33448/rsd-v9i7.4524
22. Etges APBS, Souza JS, Kliemann Neto FJ, Felix EA. Um modelo de gestão de risco empresarial proposto para organizações de saúde. J Risk Res. 2018;22(4):513-31. https://doi.org/10.1080/13669877.2017.1422780

Acknowledgment

To the National Council for Scientific and Technological Development (CNPq), for the financial support.

Author's Contributions

Schmitt MD, Andrade SR - Conception, planning (study design), acquisition, analysis, data interpretation, and writing of the work. All authors approved the final version of the work.

Conflict of Interests

The authors inform that there is no potential conflict of interest with peers and institutions, politicians, or financial in this study.

Conflict of Interest

Authors have no potential conflict of interest to declare, related to this study's political or financial peers and institutions.