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IMPLEMENTATION AND PERFORMANCE OF TRACKERS FOR THE DETECTION OF SURGICAL ADVERSE EVENTS

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ABSTRACT

Objective: to identify the frequency and performance of the Canadian Adverse Events Study tracking criteria for the confirmation of surgical adverse events in adult patients.
Method: a descriptive and retrospective study conducted in a public hospital in the state of Paraná from May to November 2017. A retrospective review of 192 medical records was conducted using 16 tracking criteria; and the confirmation of adverse events was in charge of a committee of experts composed of a physician and nurses. Data was analyzed by means of descriptive statistics.
Results: the mean performance of the trackers was 73.3%. A total of 70 trackers were confirmed in 21.8% of the medical records with adverse events. The mean number of trackers was 0.4 per medical record (varying from zero to three). Adverse reaction to the medication; unplanned return to the operating room; unplanned removal, injury or correction of an organ or structure during surgery or invasive procedure; cardiopulmonary arrest reversed and hospital infection/sepsis were classified as high performance trackers (100.0%). Eight trackers did not contribute to the identification of adverse events.
Conclusion: high-performance trackers can assist in detecting adverse events; there is potential to improve the tracking tool, contributing to its performance as a research method in Brazilian hospitals.

DESCRIPTORS: Adverse events. Tracking programs. Quality indicators in health care. Patient safety. Surgical centers.

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APLICAÇÃO E DESEMPENHO DE RASTREADORES PARA DETECÇÃO DE EVENTOS ADVERSOS CIRÚRGICOS

RESUMO

Objetivo: identificar a frequência e desempenho dos critérios de rastreamento do *Canadian Adverse Events Study* para confirmação de eventos adversos cirúrgicos em pacientes adultos.
Método: estudo descritivo e retrospectivo realizado em hospital público do estado do Paraná de maio a novembro de 2017. Realizou-se revisão retrospectiva de 192 prontuários utilizando 16 critérios de rastreamento; a confirmação do evento adverso ocorreu por comitê de especialistas composto por médico e enfermeiros. Os dados foram analisados por estatística descritiva.
Resultados: o rendimento médio dos rastreadores foi de 73,3%. Foram confirmados 70 rastreadores em 21,8% de prontuários com eventos adversos. A média de rastreador foi de 0,4 por prontuário (variação de zero a três). Reação adversa ao medicamento; retorno não planejado à sala de cirurgia; remoção, lesão ou correção não planejada de um órgão ou estrutura durante cirurgia ou procedimento invasivo; parada cardiorrespiratória revertida e infecção/sepse hospitalar foram classificados como rastreadores de alto desempenho (100,0%). Oito rastreadores não contribuíram para identificação de eventos adversos.
Conclusão: os rastreadores de alto desempenho podem auxiliar na detecção dos eventos adversos; há potencial para aprimorar a ferramenta de rastreamento contribuindo para seu desempenho como método de investigação em hospitais brasileiros.

DESCRITORES: Eventos adversos. Programas de rastreamento. Indicadores de qualidade em assistência à saúde. Segurança do paciente. Centros cirúrgicos.

APLICACIÓN Y RENDIMIENTO DE RASTREADORES PARA LA DETECCIÓN DE EVENTOS ADVERSOS QUIRÚRGICOS

RESUMEN

Objetivo: identificar la frecuencia y el rendimiento de los criterios de rastreo del *Canadian Adverse Events Study* para la confirmación de eventos adversos quirúrgicos en pacientes adultos.
Método: estudio descriptivo y retrospectivo realizado en un hospital público del estado de Paraná entre mayo y noviembre de 2017. Se realizó una revisión retrospectiva de 192 historias clínicas utilizando 16 criterios de rastreo; la confirmación del evento adverso estuvo a cargo de un comité de especialistas compuesto por un médico y por profesionales de Enfermería. Los datos se analizaron por medio de estadística descriptiva.
Resultados: el rendimiento medio de los rastreadores fue del 73,3%. Se confirmaron 70 rastreadores en el 21,8% de las historias clínicas con eventos adversos. La cantidad media de rastreadores fue de 0,4 por historia clínica (con una variación de cero a tres). Reacción adversa al medicamento; retorno no planificado a la sala de operaciones; remoción, lesión o corrección no planificada de un órgano o de una estructura durante la cirugía o durante el procedimiento invasivo; parada cardiopulmonar revertida e infección/sepsis hospitalaria se clasificaron como rastreadores de alto rendimiento (100,0%). Ocho rastreadores no contribuyeron en la identificación de eventos adversos.
Conclusión: los rastreadores de alto rendimiento pueden ser útiles en la detección de los eventos adversos; hay potencial para mejorar la herramienta de rastreo, contribuyendo así para su rendimiento como como método de investigación en hospitales de Brasil.

DESCRIPTORES: Eventos adversos. Programas de rastreo. Indicadores de calidad en la atención a la salud. Seguridad del paciente. Centros quirúrgicos.

INTRODUCTION

It is estimated that 230 million surgeries are performed worldwide each year with seven million adverse events (AEs), and one million surgical patients progressing to death.[1] Despite the undeniable advances that have occurred in the safety of surgical patients after the publication of the WHO second global patient safety challenge called "Safe Surgeries Save Lives", the high incidence of AEs[2–3] persists, as well as the cost related to their occurrence,[4] still underestimated due to the gaps in the notification and investigation of these problems.

AE notification is a fundamental tool to promote patient safety. It provides important data in quality improvement processes, assuming analyses and evaluations, implementation of barriers, and reviews of assistance and management processes.[5] Traditionally, the detection of these events is supported by voluntary error notification and tracking.[6] However, the practice of reporting AEs by the health professionals remains limited,[7–8] and often associated with the professional's difficulty in identifying whether the event is reportable, as well as with the fear/stigma related to the communication and notification of an AE.[8]

In view of this scenario, it is necessary to list reliable methods to measure AEs, their preventability and the main contributing factors, as well as to enable consistent actions to improve quality and ensure safety in surgical interventions.[1,9] Invalid or unreliable instruments to quantify patient safety can lead to inadequate diagnosis and, subsequently, to the implementation of inappropriate interventions[10] that entail additional costs and discredit of the health team.

Thus, the measurement of AEs can also occur by means of safety indicators[11] and by reviewing medical records, either separately or with the use of a tracking tool.[12] Among the most used retrospective record review methods are the *Global Trigger Tool*, developed by the Institute of Healthcare Improvement,[6] and the tracking criteria based on the Harvard method and recommended by the Canadian Adverse Events Study.[13] Both tools basically consist of a retrospective review of a random sample of the medical records of hospitalized patients, using "trackers" (signs, clues) previously defined to identify potential adverse events (pAEs),[6] confirmed later, or not, by a medical professional.

It is observed that the review of medical records, associated with the use of tracking tools, is considered the gold standard for the identification of AEs.[6,12,14] In addition, this method has as its main advantage the potential to characterize the most frequent AEs, enabling to prioritize actions so as to improve quality and enhance the ability of the health professionals in relation to patient safety for harm resolution.[15]

Considering the growing need for surgical treatment worldwide[16] and the promising use of tools for tracking AEs resulting from health care, this research aimed to identify the frequency and performance of the tracking criteria of the Canadian Adverse Events Study for the confirmation of surgical adverse events in adult patients.

METHOD

This is a descriptive and retrospective study conducted in five surgical inpatient units (Orthopedics, General and Digestive Surgery, Neurosurgery, Plastic Surgery and Liver Transplantation) and in a surgical center of a public hospital in the State of Paraná, with more than 600 beds funded by the Unified Health System, which performs a mean of 890 surgeries/month. Data collection took place between May and November 2017.

The population consisted of patients who underwent surgery from June 2014 to May 2015. The time frame results from the hospital under study having started an administrative transition in the second half of 2014; a fact that may or may not have an impact on safety and quality of care. The inclusion criteria were patients aged ≥18 years old and with a minimum hospital stay of 24 hours.

Those diagnosed with psychiatric illnesses were excluded, as previously established in the protocol of the Canadian Adverse Events Study[13] and a cross-culturally adapted version for Brazil[17]. A total of 2,593 patients were chosen for the study, and a simple random sample of 192 was extracted, estimated from the 16% incidence of surgical complications,[1] a sampling error of 5%, and a significance level of 5%. There were no irreplaceable losses.

The technique selected to review the patients medical records used the tracking criteria translated and cross-culturally adapted for Brazil.[17] These trackers are proposed by the protocol of the Canadian Adverse Events Study, which advocates the identification and analysis of AEs in two phases.[13] Phase I refers to the tracking of pAEs guided by explicit criteria, which was performed by double review of medical records by two nurses with experience in the surgical field. When detecting the presence of at least one tracking criterion, regardless the tracker, the pAE investigation form was filled out and the medical record was included for review in the next phase.

Phase II refers to the confirmation, or not, of the AE, by implicit structured review, which was carried out by a committee of experts composed of a physician and two nurses with more than 20 years of experience in the field of quality management and patient safety. The consensus was guided by the definition of the AE and the degree of physical harm proposed by the WHO, that is, any incident that resulted in mild, moderate and severe harm to the patient,[1] and by the application of two scales. The first was to determine whether the AE was caused by the care provided to the patient, and the second to assess the degree of preventability. The scales have six points, and an event was considered as an AE and with potential for preventability when the score reached ≥4 points.[13,18]

A total of 16 pAE tracking criteria related to surgical and anesthetic procedures, use of drugs, diagnosis, care and non-medication treatment, from the original list, were used.[13,17] For identification of the pAEs related to surgical site infection (SSI) occurring after hospital discharge, the records contained in the outpatient appointment records were used and the criteria recommended by the Centers for Disease Control and Prevention were taken into account, which define SSI as that which occurs within 30 days after the surgical procedure and/or 90 days after implant insertion.[19]

For the analysis of the performance of the tracking criteria and their ability to identify surgical AEs, the performance model proposed by previous studies[20–21] was used and analyzed in three components. The first was calculated by dividing the number of records of each tracker by the total number of records evaluated, multiplied by 100 (1). The second component resulted from the division of the number of surgical AEs identified by means of the trackers by the total number of medical records evaluated, multiplied by 100 (2); and the third tracker was calculated by dividing the result of the second component (2) by the first (1), multiplied by 100. The latter corresponds to the proportion that defines the tracker performance and expresses, in relative values, the potential of each of them to identify surgical AEs.

It should be noted that, for the calculation of component 2, it is necessary to consider that the same event can be identified by more than one tracker. Thus, after consensus of the experts committee, the tracker that best represented the event judged was considered. The trackers were grouped into performance categories based on the mean performance value: high-performance (100%); medium-performance (between the mean value and 99.9%); and low-performance (below the mean) trackers.[20,22]

The data collected were transferred to a Microsoft Office Excel 2016® spreadsheet by double typing for validation and checking for inconsistencies and were analyzed using descriptive statistics. This research followed the precepts of Resolution No. 466/12 of the National Health Council and was approved by the Institutional Research Ethics Committee.

RESULTS

A total of 82 trackers were identified, of which 70 (85.4%) were considered positive for the detection of 60 surgical AEs. The mean number of trackers was 0.4 per patient, ranging from zero to three. The use of trackers shows that 21.8% of the medical records presented surgical AEs and made it possible to identify from one to five AEs per patient (Figure 1).

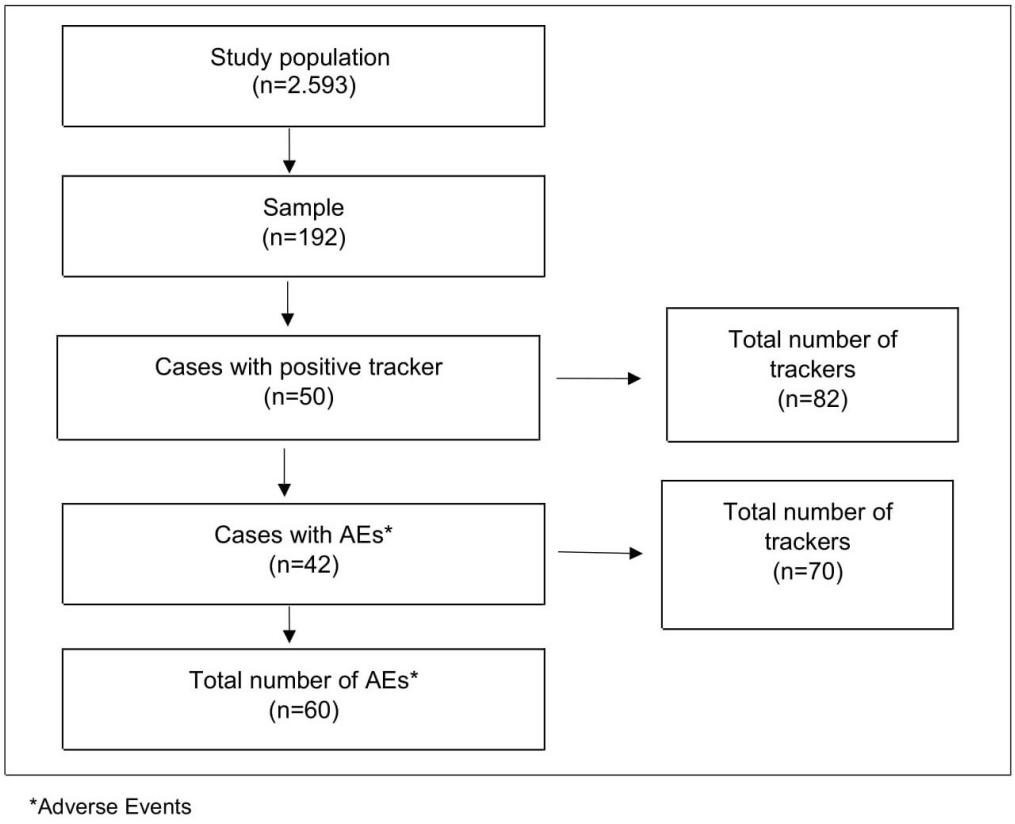

Figure 1 – Flowchart of the review of the medical records and distribution of the trackers and surgical adverse events. Curitiba, PR, Brazil, 2017.

The mean performance of the trackers was 73.3%; five trackers were considered high-performance trackers, as shown in Table 1.

Eight trackers did not identify pAEs, namely: unplanned transfer to another acute care hospital; development of neurological alteration absent at admission, but present at the time of leaving index hospitalization; death; inappropriate hospital discharge/inadequate discharge planning for index hospitalization (excludes discharge by default); dissatisfaction with the care received documented in the medical record or evidence of complaint filed; documentation or correspondence indicating litigation, whether it is only intention or effective action; starting from normal creatinine during hospitalization, was there a doubling of its value during the hospital stay?; and any other unwanted events not mentioned in the list of trackers.

Table 2 shows the performance of the trackers in relation to the degree of harm of the surgical AE. It is verified that, although the high-performance trackers detect a greater number of AEs, it was among the low-performance trackers that the highest frequency of moderate to severe harm was identified (n=17; 28.4%).

Table 1 – Frequency and performance of trackers of surgical adverse events. Curitiba, PR, Brazil, 2017. (n=50)

Tracking and performance criteria	n* (%)	Tracker per 100 medical records (Component 1) n	Surgical AE† per 100 medical records (Component 2) n	Relative performance of the tracker (Component 3) %
High performance				
Adverse reaction to the medication	05 (6.1)	2.6	2.6	100.0
Unplanned return to the operating room	05 (6.1)	2.6	2.6	100.0
Unplanned removal, injury or correction of an organ or structure during surgery or invasive procedure	01 (1.2)	0.5	0.5	100.0
Cardiopulmonary arrest reversed	01 (1.2)	0.5	0.5	100.0
Hospital infection/sepsis	23 (28.0)	12.0	12.0	100.0
Low performance				
Other unexpected complications which occurred during hospitalization that are not the normal evolution of the patient or an expected result of the treatment	41 (50.0)	21.4	12.0	56.1
Occurrence of injury to the patient during hospitalization	02 (2.5)	1.0	0.5	50.0
Unplanned transfer to the intensive and semi-intensive care unit	04 (4.9)	2.1	0.5	23.8
Total	82	42.7	31.3	73.3

*A single medical record can have more than one tracker †Adverse Event

Table 2 – Distribution of tracker performance and degree of harm from surgical adverse events. Curitiba, PR, Brazil, 2017. (n=42)

Tracking/Performance criteria	Degree of harm		
	Slight n (%)	Moderate n (%)	Severe n (%)
High performance			
Adverse reaction to the medication	5 (8.3)	–	–
Unplanned return to the operating room	–	3 (5)	2 (3.3)
Unplanned removal, injury or correction of an organ or structure during surgery or invasive procedure	–	–	1 (1.7)
Cardiopulmonary arrest reversed	–	–	1 (1.7)
Hospital infection/sepsis	15 (25)	8 (13.3)	–
Low performance			
Other unexpected complications which occurred during hospitalization that are not the normal evolution of the patient or an expected result of the treatment	8 (13.3)	14 (23.3)	1 (1.7)
Occurrence of injury to the patient during hospitalization	–	1 (1.7)	–
Unplanned transfer to the intensive and semi-intensive care unit	–	–	1 (1.7)
Total*	28 (46.7)	26 (43.3)	6 (10)

*A single medical record/patient can have more than one tracker

DISCUSSION

In the primary review, the use of trackers allowed identifying 26% of medical records with positive trackers for surgical pAEs. It should also be considered that 82 trackers were detected, of which 70 contributed to the confirmation of at least one AE in 21.8% of the records reviewed in Phase II. In contrast, a study on AEs in Irish hospitals, with an analysis of 1,580 medical records, showed an index of 45% of positive trackers in the primary phase.[23] In China, after reviewing 480 medical records of older adult patients,1,904 trackers were identified and 610 AEs were detected.[24]

The divergences found between the results of this research and others presented can be related to the profile of patients undergoing the surgical procedure, to the sample size, and to aspects related to hospital management. The frequency of each tracker found in the primary phase can also be conditioned by the completeness of the notes/records, aggravated by the institutional use of physical records, which contributes to underestimate the detection of the pAEs.[25]

These factors partially explain the eight trackers that were not found in this study, such as neurological alteration absent at admission but present at the time of hospital discharge, as well as the doubling of the patient's creatinine level during hospitalization. These trackers require continuous registration and access to complementary examinations in which, many times, this information was not obtained and/or it was not possible to identify them attached in the medical records analyzed.

The study hospital, as it is considered of high-complexity and for using state-of-the-art technologies, rarely needs to transfer patients for continuity of treatment in other health institutions, which justifies not having found the tracker "Unplanned transfer to another acute care hospital" in the sample, which means, therefore, the need for institutions to adapt the list of trackers to their reality of care, as recommended by a previous study,[26] so that, in this way, they obtain reliable data of AEs.

Additionally, the literature indicates that not performing laboratory and microbiological tests related to trackers routinely ends up not allowing for the assessment of the ability of all the trackers to identify AEs, especially those related to medication administration.[26] This circumstance interferes in the mean number of trackers, which, on a side note, was relatively low in this study when compared to other health scenarios. In an Oncology center in the United States of America, for example, when applying a screening tool with similar trackers, the researchers found a mean of 1.98% tracker per medical record.[27]

It should be noted that this finding needs to be interpreted with caution, given that the total number of trackers, as well as the methodological path used, makes it difficult and even impossible to compare results.[15] In contrast, the development and adaptation of the retrospective review method is important to provide health professionals with adequate information on gaps and risks in the health systems, in addition to allowing for further research studies on the epidemiology of the AE.[28] A systematic review including 48 studies distributed in 16 countries reinforces that the differences in the AE rates are associated with methodological differences and with divergent interpretations by the reviewers.[15] Another factor that contributes to these divergences in results is the number of reviewers. The reliability of the record review is statistically higher in groups of five members at the most; that is, a small group of reviewers encourages working together, resulting in less variation in the review methodology and in more consensus on the definition of the incident that caused harm to the patient.[10]

Despite these limitations, the use of tools with AE trackers is promising to improve safety and quality of care, as well as to reduce the costs of the health services.[24] However, their use requires time for execution[29] and appropriation of the methodology by the researchers, both to reduce the risk of bias and to improve the already existing tools. As an example, we can mention optimizing the efficiency of the instrument with the creation of automated electronic triggers for use in real-time AE detection and mitigation algorithms.[27] Thus, given the importance of this method for the clinical practice and to

identify problems related to patient safety, it is believed that the inclusion of this theme and the use of this tracking tool in the practice during the training of health professionals will effectively contribute to the primary and secondary review process. This provides for improving the identification of trackers and filling this gap in the professional health and nursing practice.

The overall performance of the trackers was 73.3% (varying from 0.0% to 100.0%) among the 16 trackers used. Although not directly comparable, there seems to be divergences between the overall performance found in several investigations, in particular, the trackers used to detect drug-related AEs, which showed a 22.5% performance rate;[22] and the use of a tool containing 88 pediatric triggers, which revealed an overall positive predictive value of 22.9% (range: 0.0%-100.0%).[28] In Spain, the positive predictive value was 89% after application of an AE tracking tool in patients undergoing general surgery.[30] The existing inconsistencies regarding the tracker's ability to capture pAEs possibly depends on the context under study, on the number of trackers applied, on the reliability between reviewers, and on the quality of the records analyzed. Thus, it becomes feasible to evaluate the sensitivity and specificity of the trackers to test the validity of these instruments, which remain insufficiently studied.[10]

Regarding the individual performance of the trackers, it was noted that five were classified as high-performance trackers (100.0%). Among these, it is noteworthy that the most identified surgical AEs were related to the hospital infection/sepsis tracker (12.0/100 medical records) with less severity when compared to the "unplanned return to the operating room" tracker, which was efficient in identifying more severe AEs. Similar results were found in a study conducted in Europe, which revealed that the triggering factors for nosocomial infection, unplanned return to the operating room, and unplanned removal/injury during surgery had the greatest relative risks for determining subsequent AEs with 5.3, 4.8 and 4.7, respectively.[23]

In Oncology, examples of high-performance trackers included return to the operating room or interventional radiology, with a positive predictive value of 0.38% for preventable AEs occurring in the first 30 days after the surgical procedure.[27] Thus, these trackers become valid and relevant for capturing AEs in patients admitted to surgical inpatient units. There are several factors that explain the prominence of these trackers in the identification and confirmation of AEs. One of them focuses on the fact that the most identified trackers reflect the greater ease of being found in the medical records, and imply a high workload in their analysis process.[22] It is known that surgical site infection, for example, remains as one of the most common causes of severe AEs[1] and most likely to be found in health team records.

On the other hand, a previous study pointed out that trackers categorized as high-performance are not necessarily the most frequently recorded in the medical charts. However, when found, they demonstrate the occurrence of AEs,[22] corroborating the findings in this study. When analyzing the most prevalent tracker, the "Other unexpected complications that occurred during hospitalization" tracker (21.4/100 records) stood out, with a relative performance of 51.6%. Despite being considered a low-performance tracker, it requires the reviewer's expertise to proceed in the analysis of the cases, mainly due to the identification of severe AEs, as pointed out in this research. Complications such as acute myocardial infarction, stroke and pulmonary embolism, among others, presented a sensitivity of 21.3%, a specificity of 95.4%, positive and negative predictive values (41.7% and 88.7%, respectively) and a relative risk of 3.7 for determining AEs in hospitalizations of adult patients from eight Irish hospitals.[23] This incites the need to improve the tool in this regard, as well as to list other methods for excellence in the investigation of these AEs by the primary reviewers.

The tool used in this study showed a high number of trackers considered of low performance for identifying AEs in the surgical context, with emphasis on the death tracker, which was not identified in the medical record, possibly due to methodological issues (probabilistic sampling techniques).

In this case, it was considered an unsatisfactory tracker to measure surgical AEs; however, it is an important trigger for the surgical practice, as its occurrence portrays the relative risk of AEs.[23]

Among the limitations of this research is the lack of studies with similar tracking methods, which makes it difficult to compare results. Despite the recommendation that individual hospitals should not carry out exhaustive studies to assess reliability between evaluators,[15] it is emphasized that failure to perform statistical tests for this purpose, as well as to analyze the sensitivity and specificity of each tracker in isolation, can contribute to the limits of this research. Such limitations imply caution in generalizing the results and indicate the need to include these variables in analyses of subsequent studies.

CONCLUSION

High-performance trackers have contributed to the detection of surgical AEs and can be used to monitor improvements in the safety and quality of perioperative care. New studies may contribute to the improvement of the tracking tool to improve its performance and ensure high reliability in the investigation method for Brazilian hospitals.

It is suggested to prepare a guide to control and standardize parameters to be used during the retrospective chart review phase, and the creation of software to sign potential AEs during the electronic records made by the health professionals in the surgical context.

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NOTES

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CONTRIBUTION OF AUTHORITY

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Discussion of the results: Batista J, Silva DP, Cruz EDA.
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CONFLICT OF INTEREST

There is no conflict of interest.

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