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Infusion pump risk management

Gerenciamento de risco em bombas de infusão

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ABSTRACT

Introduction: The increasing incidence of problems related to medical care equipment - infusion pumps. **Objective:** To make a situational diagnosis regarding the preventive maintenance of peristaltic volumetric infusion pumps. **Method:** Descriptive, quantitative research, conducted in a federal hospital in the city of Rio de Janeiro from April to June 2017. **Results:** 371 peristaltic volumetric infusion pumps of two different brands. Regarding the record of the last preventive maintenance identified, less than 10.0% of the equipment studied had maintenance on the day, 54.5% (n = 202) had a record of expired preventive maintenance, 5.9% (n = 22) had an unreadable record of preventive maintenance and 29.9% (n = 111) had no record of preventive maintenance. **Conclusions:** This situational diagnosis revealed an outdated technology park, with a significant lag in relation to the validity of preventive maintenance of peristaltic volumetric infusion pumps. The improvement actions began with the updating of the patrimony data referring to the quantity of peristaltic volumetric infusion pumps of the hospital. Subsequently, equipment with expired, ineligible and absent preventive maintenance was gradually collected for replacement. Finally, a monitoring of the conditions of the peristaltic volumetric infusion pumps was initiated so that there is a continuous control of the conditions of this equipment.

KEYWORDS: Infusion Pump; Biomedical Technology Assessment; Patient Safety

RESUMO

Introdução: As bombas de infusão vêm sendo relacionadas ao aumento da incidência de problemas relacionados aos equipamentos médico-assistenciais. **Objetivo:** Realizar um diagnóstico situacional referente à manutenção preventiva das bombas de infusão volumétricas peristálticas. **Método:** Pesquisa descritiva, quantitativa, realizada em um hospital federal da cidade do Rio de Janeiro nos meses de abril a junho de 2017. **Resultados:** Foram analisadas 371 bombas de infusão volumétricas peristálticas, de duas marcas distintas. Em relação ao registro da última manutenção preventiva, identificou-se que menos de 10,0% dos equipamentos estudados estavam com a manutenção em dia, 54,5% (n = 202) apresentavam registro de manutenção preventiva vencido, 5,9% (n = 22) possuíam registro de manutenção preventiva ilegível e 29,9% (n = 111), ausência de registro de manutenção preventiva. **Conclusões:** O diagnóstico situacional encontrado através da pesquisa foi um parque tecnológico desatualizado, com uma defasagem importante em relação à validade da manutenção preventiva das bombas de infusão volumétricas peristálticas. As ações de melhoria iniciaram-se com a atualização dos dados do patrimônio referente ao quantitativo de bombas de infusão volumétricas peristálticas da instituição hospitalar. Posteriormente, os equipamentos com manutenção preventiva vencida, inelegível e ausente foram recolhidos, gradualmente, para substituição. Por fim, foi iniciado um monitoramento das condições das bombas de infusão volumétricas peristálticas para que haja um controle contínuo das condições destes equipamentos.

PALAVRAS-CHAVE: Bomba de Infusão; Avaliação da Tecnologia Biomédica; Segurança do Paciente

INTRODUCTION

In recent years there has been an increase in worldwide concerns about patient safety. Since the publication of the *To err is Human: Building a safer health care system* report by the United States Institute of Medicine, initiatives and proposed patient care safety measures have been gaining momentum[1].

In Brazil, Resolution of the Collegiate Board n. 36 was enacted in July 25, 2013. It established actions for patient safety in public or private healthcare services. This Resolution encourages the creation of Patient Safety Centers (NSP) to promote a safety culture and support risk management actions in healthcare facilities. One of the principles adopted by NSPs is related to the detection and assessment of nonconformities in processes and procedures, as well as in the use of equipment, medicines and supplies, in order to promote preventive and corrective actions[2].

The Emergency Care Research Institute (ECRI) annually publishes a report on safety issues involving the use of medical devices and systems. Based on an international database and scientific analysis done by professionals from various areas (engineers, scientists, clinicians, safety analysts, and others), the institute prepares a list with the top ten incidents related to health technologies[3].

In the latest ECRI reports, infusion pumps (IPs) are related to events that pose health risks associated with the use of technologies. This discussion aims to alert healthcare institutions to detect potential technology-related risk situations and to adopt measures to minimize the likelihood and impact of adverse events[3].

IPs are common hospital devices designed to regulate the infusion of fluids like medications into the bloodstream. The devices produce a flow of liquid at a pressure higher than the patient's blood pressure. They are used for continuous drug administration, in the amount and time period set by the operator. They can be classified according to their flow control (volumetric or non-volumetric), or according to the infusion mechanism (peristaltic, piston or syringe)[4].

According to the Brazilian Health Surveillance Agency (Anvisa), IPs are classified as high-risk medical care devices (EMA) – class III, in other words, devices with high likelihood of occurrence of adverse events[5]. Incidents with these devices compromise patient safety and result in longer stay in the healthcare unit, permanent harm, life-sustaining intervention, or possible contribution to death[6].

Within this context and based on the experience gained in the Risk Management of the hospital where this study was conducted, an increase in the incidence of IP-related problems was identified. Thus, the objective of this research was to make a situation diagnosis of the recording of preventive maintenance of volumetric peristaltic IPs.

METHOD

This is a descriptive study with a quantitative approach. It was conducted in a federal hospital in Rio de Janeiro, Brazil, with four operating rooms and 165 hospitalization beds, of which 60 were in the intensive care unit (ICU). The hospital is also a member of the Brazilian Sentinel Network. The study was approved by the Research Ethics Committee (CEP) of the hospital in which the present study was conducted under protocol n. 3.154.197.

The literature review was made in the following databases: Virtual Health Library (VHL), Latin American and Caribbean Health Sciences Literature (LILACS) and Scientific Electronic Library Online (SciELO), using the following descriptors: "infusion pumps", "biomedical technology assessment" and "patient safety" and the AND Boolean operator among them.

Initially, data were collected from hospital assets to determine types, brands, models and number of IPs in several hospital sectors (wards, ICU, surgical center and hemodynamics).

Active search was performed in all hospital sectors that used volumetric peristaltic IPs to manage infusion therapy. We designed a data collection instrument that contained the following items: sector in which the IP was located, device registration number and last and next preventive maintenance labels. Based on that instrument, we performed the analysis of the preventive maintenance records of the volumetric peristaltic IPs.

As inclusion criteria, the available volumetric peristaltic IPs of all sectors of the hospital were analyzed, excluding syringe volumetric IPs, enteral diet volumetric IPs and peristaltic IPs that were damaged or under maintenance.

The sampling was done by convenience and "composed of individuals who met the entry criteria and were easily accessible to the researcher"[7]. The sample size was also determined by the convenience of observing the IPs available in every sector. Data collection occurred during the day (from 7 a.m. to 7 p.m.), on alternate weekdays, between April and June 2017.

After data collection, we compared the survey of the assets with the research data.

Data were organized in MS Excel, where descriptive analyses were performed with simple statistics and percentage for the variables under study.

RESULTS AND DISCUSSION

We analyzed 371 volumetric peristaltic IPs by two different brands, which will be called brand 1 and brand 2. According to the latest survey conducted by the hospital's administration, there were 343 volumetric peristaltic IPs by two different brands.

We noticed that we analyzed a larger number of pumps than that recorded in the hospital files (n = 343). At the end of the research, this problem was taken to the responsible manager for the appropriate updates in the asset records.

The results show that 22.1% (n = 82) of the IPs were by brand 1 and 77.9% (n = 289) were by brand 2. About 66.8% (n = 248) of the IPs were located in the ICU, 26.7% (n = 99) in the wards, 4.9% (n = 18) in the surgical center and 1.6% (n = 6) in hemodynamics (Table 1).

In the present study we found the use of two IP brands. That is a matter of concern and it is not recommended by Anvisa's prescription, use and administration safety protocol[8], which recommends the standardization of IPs to reduce the variety of options and thus reduce the risk of errors. This concern is based on scientific evidence relating the occurrence of medication errors to the operator and the handling of equipment, causing incidents and/or harm to patients[6].

Today, increasing innovation and dependence on technology in hospitals are causing continuous growth of healthcare expenses and requiring more operational skills from the professionals who operate these technologies. However, the EMA supply curve, especially for IPs, is not proportional to the learning curve of the professionals to enable them to operate these technologies effectively and safely[9].

The concept of operational skill has been discussed in the scientific literature and can be understood as "an analysis of external and internal variables that will influence the performance of technology and the service that uses technology"[9]. Within this scope, the term usability stands out. It is "a characteristic of the human factor related to ease of use, effectiveness, efficiency and user satisfaction"[9].

It is understood that a wide variety of devices with the same purpose contributes to the absence or ineffectiveness of operational skills, making the environment unsafe and hindering patient safety. Scientific studies[6,10] have shown that professionals' lack of technical skills in handling IPs resulted in a significant increase in the number of incidents with that technology.

Although IPs are established technologies, widely used and associated with a reduction in medication error rates, the safety promised by these devices is only fulfilled when the devices are operated by skilled humans. Technology and the human factor increasingly need to be aligned and up-to-date for the end result to be satisfactory to patients[11,12,13].

Therefore, the safe use of the technology requires the effective training of the users so that they can understand the features of the equipment and how these features can be useful for patient care. A Brazilian study has shown that the lack of effective training is the main reason for knowledge gaps and inadequate use and performance of technologies. As a result, operators – healthcare professionals – fail to take full advantage of the benefits of these technologies[13].

Regarding the sectors of the hospital where the IPs were located, there was a predominance of these devices in the ICU, which was expected, since these settings are intended to assist critically ill and hemodynamically unstable patients who demand specialized, high-complexity care. They commonly use intravenous therapy via IPs because of their accuracy and safety, and as a result, intensive care professionals need to observe and understand the codes issued by IPs in order to provide proper care to patients and promptly intervene whenever necessary[6,14].

In this setting, the concept of alarm fatigue is often observed and is characterized by "time delay or lack of response from healthcare professionals to alarms"[15]. This phenomenon occurs due to excessive noise and alarms within an ICU setting, resulting in sensory stress and desensitization, which eventually compromises patient safety[15].

This discussion is important given the latest reports published by the ECRI, which warn about the risks of alarms when they are not properly prioritized or when they are improperly parameterized[16,17], especially in ICUs, where there is much need for constant vigilance of the equipment that assists in the maintenance and treatment of patients. However, not only in ICUs, but also in sectors where the technological apparatus is smaller, like wards, vigilance in the use of IPs must be thorough and patient safety must always be prioritized.

We also noted that brand 1 IPs were placed in the wards and hemodynamics and brand 2 IPs were placed in the ICU and surgical center. This result demonstrates the importance of

Table 1. Infusion pump distribution by sector, by percentage and absolute number. Rio de Janeiro, 2019.

	Brand 1		Brand 2		Total	
	%	(N)	%	(N)	%	(N)
Intensive Care Unit	2.7	10	64.1	238	66.8	248
Ward	17.8	66	8.9	33	26.7	99
Surgical Center	0.0	0	4.9	18	4.9	18
Hemodynamics	1.6	6	0.0	0	1.6	6
Total	22.1	82	77.9	289	100.0	371

Source: Research database.

operational skills, since the selection and placement of IPs in the hospital's sectors must be based on the staff's technical expertise with the equipment, which will directly influence the drug therapy to be performed.

Healthcare professionals must have technical expertise in operating the IPs so that graphs like start-up curve and trumpet curve can be properly understood. The first is important for operators to learn whether there are long periods of zero flow and how long it takes for the IP to achieve the programmed flow rate. The second helps the operators identify the continuity of the flow. For fast-acting drugs, flow continuity is of the utmost importance. Based on this information it is possible to place the IPs in specific sectors, for example: using the IPs with lower trumpet and start-up curves is necessary due to the profile of hemodynamically unstable patients and the use of vasoactive amines that require rapid infusion at the lowest possible flow fluctuation rate[4,18,19].

Regarding the record of the last preventive maintenance of volumetric peristaltic IPs, we found that less than 10.0% of the studied devices were up-to-date with their maintenance, 54.5% (n = 202) had a record of expired preventive maintenance, 5.9% (n = 22) had illegible preventive maintenance records and 29.9% (n = 111) had no preventive maintenance records at all (Table 2).

In order to reduce the likelihood of errors, IPs must undergo a technical checkup every year (or according to the period determined by the manufacturer) for the performance of mechanical wear tests, sensor calibration and infusion accuracy and for the effective functioning of safety mechanisms that reduce the risk of intravenous therapy-related incidents.

Furthermore, to ensure normal device performance, it is recommended that preventive maintenance be done every three years, including battery and pumping membrane replacement[4,18,19].

The results of this research indicate that 90.3% (n = 235) of the IPs used had expired, illegible or absent preventive maintenance records. It is noteworthy that these IPs were predominantly in the ICU, where high vigilance regarding infusion therapy is required due to the use of potentially hazardous drugs. In this setting, intravenous IP therapy becomes unsafe and can lead to ineffective (low flow) or toxic (high flow) therapy, depending on the failure of the equipment[4].

IPs work by generating a continuous, accurate and often highly secure flow. When properly calibrated and used, incident risks are low compared to other technologies. Conventional (or manual) modes of continuous infusion therapy result in fluctuations in drug concentration and do not guarantee flow accuracy, which may lead to variations in patient treatment values. This being the case, drug infusion through an IP tends to lead to continuous flow, reducing fluctuations and ensuring greater therapeutic efficacy[4,20] (Figure).

However, for the infusion therapy to be performed with the minimum acceptable risk, the healthcare professional (operator) must be trained to operate the IP properly. Additionally, the parameterization of the data must be made without errors (infusion speed data, total volume, time etc.) and the IP must be calibrated within the acceptable thresholds described in the instruction manual, by the manufacturers and by relevant standards[20].

IPs that are calibrated and inspected annually may also be defective. When this occurs, the alarms are activated and halt their operation. This mechanism considerably improves infusion safety but does not completely eliminate potential errors. Other incidents like equipment failure, staff failure, and usage errors can influence equipment performance and negatively impact patient safety in drug administration[4,21].

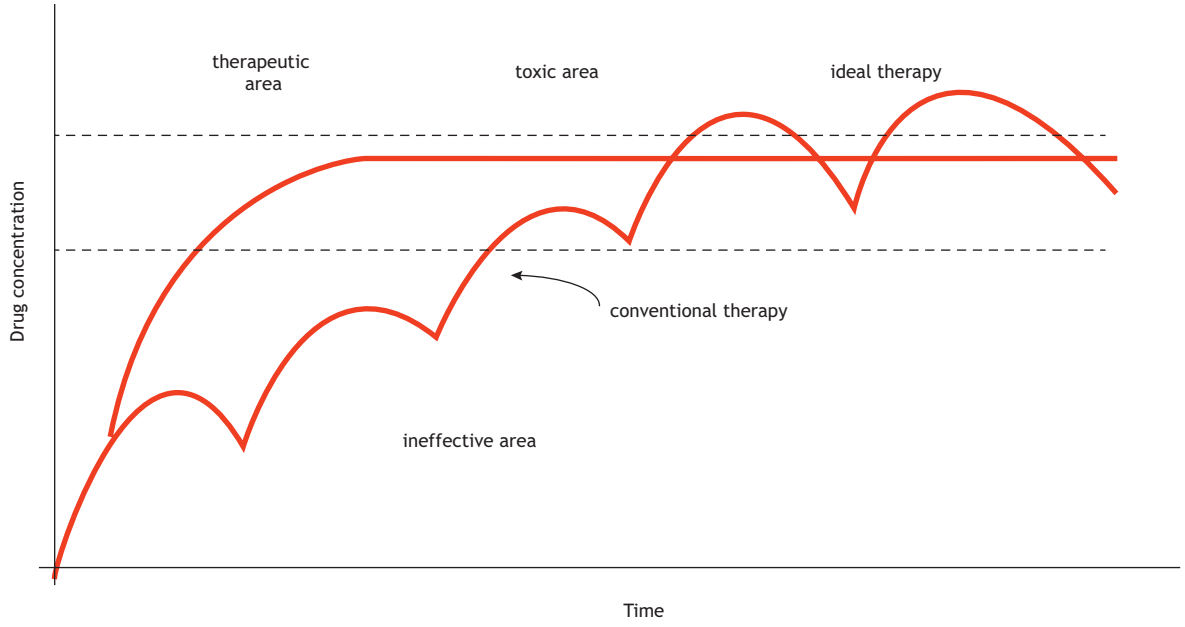
After this situation diagnosis about volumetric peristaltic IPs, it was possible to identify where priority intervention is needed. The improvement actions started with the updating of the asset-related data on the amount of volumetric peristaltic IPs in the hospital under study. Next, devices with expired, illegible and absent preventive maintenance records were gradually collected for replacement. Finally, the conditions of the volumetric peristaltic IPs began to be constantly monitored so that there is a continuous control of the conditions of these devices.

After these improvements, reports like free flow and volume not compatible with infusion time were no longer detected. However, in the analysis of previous reports, we could not state that there was a causal relationship with operational skills, since there was no training in the studied period.

Table 2. Distribution of preventive maintenance records of infusion pumps, by percentage and absolute number. Rio de Janeiro, 2019.

	Brand 1		Brand 2		Total	
	%	(N)	%	(N)	%	(N)
Preventive maintenance record within validity period	8.1	30	1.6	6	9.7	36
Expired preventive maintenance record	12.4	46	42.0	156	54.5	202
Illegible preventive maintenance record	1.1	4	4.9	18	5.9	22
No record of preventive maintenance	0.5	2	29.4	109	29.9	111
Total	22.1	82	77.9	289	100.0	371

Source: Research database.



Source: National Health Surveillance Agency[4].

Figure. Comparison of therapeutic performance between conventional and continuous administration.

CONCLUSIONS

This research diagnosed the situation of an outdated technology park, with significant shortcomings in relation to the validity of preventive maintenance of volumetric peristaltic IPs.

Based on the results, improvement actions were adopted to ensure that patient safety pervades the entire care process, from procurement of related products to infusion therapy, based on health technology assessment, training of users, risk management and outcome assessment.

IP-related operational errors are not solely responsible for incidents and patient harm. Hospitals must be aware of and manage the risks of the technologies available to their professionals. Creating device use conditions as close as possible to the ideal is of paramount importance to minimize the risk of operational errors.

This study contributed to the review of care processes, the design of an action plan for incident mitigation and risk management for the safe use of medical care equipment at the institution where the research was conducted.

REFERENCES

1. Agência Nacional de Vigilância Sanitária - Anvisa. Documento de referência para o programa nacional de segurança do paciente. Brasília: Agência Nacional de Vigilância Sanitária; 2014[acesso 25 abr 2019]. Disponível em: http://bvsms.saude.gov.br/bvs/publicacoes/documento_referencia_programa_nacional_seguranca.pdf
2. Agência Nacional de Vigilância Sanitária - Anvisa. Resolução RDC Nº 36, de 25 de julho de 2013. Institui ações para a segurança do paciente em serviços de saúde e dá outras providências. Diário Oficial União. 25 jul 2013.
3. Emergency Care Research Institute - ECRI. 2019 top 10 health technology hazards: executive brief. Plymouth Meeting: ECRI Institute; 2018[acesso 5 jun 2019]. Disponível: https://www.ecri.org/Resources/Whitepapers_and_reports/Haz_19.pdf
4. Agência Nacional de Vigilância Sanitária - Anvisa. Manual de tecnovigilância: abordagens de vigilância sanitária de produtos para a saúde comercializados no Brasil. Brasília: Agência Nacional de Vigilância Sanitária; 2010[acesso 10 maio 2019]. Disponível em: http://portal.anvisa.gov.br/documents/33868/327133/Manual+de+Tecnovig il%C3%A2ncia ++abordagens+de+vigil%C3%A2ncia+sanit%C3%A1ria+de+produtos+para+a+sa%C3%BAde+comercializados+no+Brasil/0967528 c-4af7-4df4-939b-95c6b327b09f
5. Agência Nacional de Vigilância Sanitária - Anvisa. Manual para regularização de equipamentos médicos na Anvisa. Brasília: Agência Nacional de Vigilância Sanitária; 2017[acesso 10 maio 2019]. Disponível em: http://portal.anvisa.gov.br /documents/33912/264673/Manual+para+regulariza%C3%A7%C3%A3o+de+equipamentos+m%C3%A9dicos +na+Anvisa/ad655639-303e-471d-ac47-a3cf36ef23f9
6. Ribeiro GSR, Silva RC, Ferreira MA, Silva GR. Slips, lapses and mistakes in the use of equipment by nurses in an intensive care unit. Rev Esc Enferm USP. 2016;50(3):419-26. https://doi.org/10.1590/S0080-623420160000400007

7. Hulley SB, Cummings SR, Browner WS, Grady DG, Newman TB. Delineando a pesquisa clínica: uma abordagem epidemiológica. 3a ed. Porto Alegre: Artmed; 2008.
8. Agência Nacional de Vigilância Sanitária - Anvisa. Protocolo de segurança na prescrição, uso e administração de medicamentos. Brasília: Agência Nacional de Vigilância Sanitária; 2013[acesso 10 maio 2019]. Disponível em: https://www20.anvisa.gov.br/segurancadopaciente/index.php/publicacoes/item/seguranca-na-prescricao-uso-e-administracao-demedicamentos
9. Ministério da Saúde (BR). Diretrizes metodológicas: elaboração de estudos para avaliação de equipamentos médicos assistenciais. Brasília: Ministério da Saúde; 2013[acesso 5 jun 2019]. Disponível em: http://rebrats.saude.gov.br/phocadownload/diretrizes/Manual_EMAPT_WEB.pdf
10. Jardim DP, Machado LVL. Pacientes intensivos na recuperação pós-anestésica: dificuldades na assistência de enfermagem. Rev SOBECC. 2019;24(1):43-9. https://doi.org/10.5327/10.5327/Z1414-4425201900010009
11. Cestari VRF, Ferreira MA, Garce TS, Moreira TMM, Pessoa VLMP, Barbosa IV. Aplicabilidade de inovações e tecnologias assistenciais para a segurança do paciente: revisão integrativa. Cogitare Enferm. 2017;3(22):454-80. https://doi.org/10.5380/ce.v22i3.45480
12. Guiuliano KK. Intravenous smart pumps: usability issues, intravenous medication administration error, and patient safety. Crit Care Nurs Clin North Am. 2018;30(2):215-24. https://doi.org/10.1016/j.cnc.2018.02.004
13. Moreira APA, Escudeiro CL, Christovam BP, Silvino ZR, Carvalho MF, Silva RCL. Use of technologies in intravenous therapy: contributions to a safer practice. Rev Bras Enferm. 2017;70(3):595-601. https://doi.org/10.1590/0034-7167-2016-0216
14. Backes MTS, Erdmann AL, Buscher A. The living, dynamic and complex environment care in intensive care unit. Rev Latinoam Enferm. 2015;23(3):411-8. https://doi.org/10.1590/0104-1169.0568.2570
15. Franco AS, Luna AA, Camerini FG, Henrique DM, Almeida LF, Silva RCL. Segurança na utilização de bombas infusoras: análise dos alarmes. Rev Enferm UFPE. 2018;12(5):1331-7. https://doi.org/10.5205/1981-8963-v12i5a231286p1331-1337-2018
16. Emergency Care Research Institute - ECRI. Health device: top 10 health technology hazards for 2015. Plymouth Meeting: ECRI Institute; 2015[acesso 25 abr 2019]. Disponível: https://www.ecri.org/Resources/Whitepapers_and_reports/Top_Ten_Technology_Hazards_2015.pdf
17. Franco AS, Bridi AC, Karam MA, Moreira APA, Andrade KBS, Silva RCL. Stimulus-response time to alarms of the intra-aortic balloon pump: safe care practices. Rev Bras Enferm. 2017;70(6):1206-11. https://doi.org/10.1590/0034-7167-2016-0432
18. Autor desconhecido. Bomba de infusão: manual do usuário. Pelotas: [s.n]; 2017.
19. Autor desconhecido. Bomba de infusão volumétrica: instrução de uso. São Paulo: [s.n]; 2013.
20. Reis RBS, Milagre ST, Pereira AA, Souza DB, Sá ACB. Análise metrológica e incertezas de medição como auxílio na avaliação de qualidade de bombas de infusão. Uberlândia: Universidade Federal de Uberlândia; 2012[acesso 2 jun 2019]. Disponível em: https://www.peteletricaufu.com/static/ceel/doc/artigos/artigos2012/ceel2012_artigo085_r01.pdf
21. Ribeiro GSR, Silva RC, Ferreira MA. Technologies in intensive care: causes of adverse events and implications to nursing. Rev Bras Enferm. 2016;69(5):915-23. https://doi.org/10.1590/0034-7167.2016690505

Conflict of Interest

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