BRIEF COMMUNICATION
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Improvement of health surveillance actions: harmonization and decentralization

Qualificação das ações de vigilância sanitária: harmonização e descentralização

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ABSTRACT

Introduction: The performance of the National Health Surveillance System (SNVS) involves the actions of the three spheres of government considering the inherent characteristics of the Brazilian federative model and the Brazilian Health System management. **Objective:** To develop a proposal for health surveillance (Visa) activities, which would enable the harmonization of activities and practices, as a way to improve the effectiveness of actions and the identification of criteria for implementing these actions, as a guide for Visa agreements and schedules. **Method:** Descriptive qualitative study with narrative review on the process of harmonization and decentralization of Visa actions, based on the individualized and collective practices observed in the three SNVS management spheres. The proposal was developed in workshops represented states and municipalities, and the National Council of State Health Secretaries and the National Council of Municipal Health Secretaries. **Results:** Twelve critical actions were indicated, nine of which were related to the inspection action. The categorization of critical actions considered: focus and scope of the action; execution time; end materializable products; practices and activities that comprise the action; and the expected results. The practices to be harmonized were prioritized and detailed regarding the requirements to be met for implementation by the Sanitary Surveillance: legal, cognitive; ethical; logistics; and structuring to support the process of decentralization of actions. **Conclusions:** The effective qualification of sanitary surveillance actions strengthens the collective construction processes, since it is associated with the definition of responsibilities, supported by technical criteria of competence and by uniformity in the execution of their actions, with impact on the health protection of the population.

KEYWORDS: Parameters; Regulations; Health Systems; Health Surveillance

RESUMO

Introdução: O desempenho do Sistema Nacional de Vigilância Sanitária (SNVS) envolve a atuação das três esferas de governo considerando as características inerentes ao modelo federativo brasileiro e a gestão do Sistema Único de Saúde. **Objetivo:** Desenvolver proposta de atuação de vigilância sanitária (Visa) que possibilite a harmonização de atividades e práticas, como forma de aprimorar a efetividade das ações e a identificação de critérios de execução das ações, como orientador das pactuações e programações de Visa. **Método:** Estudo qualitativo descritivo, com revisão narrativa sobre o processo de harmonização e descentralização das ações de Visa, a partir das práticas individualizadas e coletivas observadas nas três esferas de gestão do SNVS. A proposta foi desenvolvida em oficinas de trabalho com representação de estados e municípios, do Conselho Nacional de Secretários Estaduais de Saúde e do Conselho Nacional de Secretários Municipais de Saúde. **Resultados:** Foram indicadas 12 ações críticas, sendo que nove delas estavam relacionadas à ação de inspeção. A categorização das ações críticas considerou: foco e abrangência da ação; momento de execução; produtos finais materializáveis; práticas e atividades que compõem a ação; e os resultados esperados. As práticas a serem harmonizadas foram

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priorizadas e detalhadas quanto aos requisitos a serem atendidos para a execução pela Vigilância Sanitária: legais; cognitivos; éticos; logísticos; e estruturantes para subsidiar o processo de descentralização de ações. **Conclusões:** A efetiva qualificação das ações de Visa vem fortalecer os processos de construção coletiva, uma vez que está associada à definição das responsabilidades, suportada em critérios técnicos de competência e na uniformidade na execução de suas ações, com impacto na proteção da saúde a da população.

PALAVRAS-CHAVE: Parâmetros; Regulamentos; Sistemas de Saúde; Vigilância Sanitária

INTRODUCTION

Health surveillance is defined as a set of activities capable of eliminating, reducing or preventing health risks and of intervening in health problems arising from the environment, the production and circulation of goods and the provision of services relevant to health. It includes the control of consumer goods and comprises all stages and processes, from production to consumption and the control of the provision of services that are directly or indirectly related to health[1,2,3]. In Brazil, after the creation of the Unified Health System (SUS), health surveillance was recognized as a health policy and its activities were placed under the competence of the SUS[4].

To guarantee the scope of Visa's activities, Brazil opted for the creation of the National Health Surveillance System (SNVS), which comprises the set of activities carried out by institutions of the Union's direct and indirect public administration, the states, the Federal District and the municipalities, which perform activities of regulation, standardization, control and inspection in the field of health surveillance. As provided for in the Law that created the National Health Surveillance Agency (Anvisa) – Law n. 9.782, of January 26, 1999[3] – the Agency is responsible for coordinating the SNVS. The SNVS coordination was guided by the deliberations of the National Conference on Health Surveillance that took place in 2001, followed by the Master Plan on Health Surveillance (PDVISA) that took place in 2006[5,6]. PDVISA was the result of the efforts of representatives of the three levels of SUS management (Union, states, Federal District and municipalities), with the objective of strengthening and consolidating the SNVS, taking into account local particularities.

More recently, the 2015 Health Surveillance Debate Cycle[7] provided a rich and timely space for exchanging experiences, reflections and debates on health surveillance operations and challenges, among which technological progress and the globalized circulation and use of goods, products and services stand out. Among the most important topics presented for debate, the federal coordination of health surveillance actions stood out as an important challenge due to the lack of articulation between SNVS entities. The resulting fragmentation is one of the main problems posed to structuring the System and its federative coordination of health surveillance actions. Another aspect that stood out was the lack of planning and establishment of predetermined instruments in the process of decentralizing health surveillance actions (Track 3 – Challenge 7 of the Health Surveillance Debate Cycle)[7].

According to Lucchese[8], the poor debate about the SNVS, formalized in the same legislation that created the Agency, proposes an arrangement with the Union, states and municipalities, which is precariously articulated in an extremely diversified arrangement[8]. The analysis of these challenges shows the difficulties that have arisen in the process of structuring the SNVS, especially regarding the definition of roles, the decentralization process and the federative coordination of the system[9].

The mechanisms of agreement between the levels of government have been one of the most important aspects for the improvement and consolidation of the SUS[4]. However, in many situations, these mechanisms need adjustment. In the case of health surveillance, since oftentimes more than one public entity is involved in the same activity, the situation entails greater complexity, but also the possibility of timely delivery of what is required from the stakeholders for the fulfillment of their responsibilities.

Despite the debate and the instruments synthesized in these movements, the SNVS coordination capacity remains a major challenge, mainly due to the fast-paced digital transformation process – with new technological tools – and the communication mechanisms between the federated entities. The results are the poor quality of some actions, the lack of knowledge about how the actions done within the system are funded, and especially the absence of systematic processes for monitoring and assessing the actions and the results achieved by the SNVS[10].

It is in this context that the IntegraVisa project is inserted. This project was conducted by Anvisa in partnership with Hospital Alemão Hospital Oswaldo Cruz (HAOC), through the Institutional Development Support Program of the Unified Health System (Proadi-SUS), 2015-2017 triennium. The objective of this project was to design a proposition for the improvement of some health surveillance initiatives that are considered critical for the SNVS, presenting strategies and methodologies that contribute to harmonizing the most relevant actions carried out within the system, identifying criteria for more effective decentralization in the conduction of health surveillance actions, and drafting a proposition for monitoring and assessing the results achieved by the system in an integrated and permanent fashion.

METHOD

Qualitative descriptive study, with narrative review, with information collected from workshops, with representation of health surveillance technicians and managers from the three

management levels that make up the SNVS. The selection of municipal and state health surveillance teams considered regional representation with the existence of high-risk services/establishments and processes/products in their territories. The workshops were attended by approximately 100 professionals: Health Surveillance bodies of ten states in the five major Brazilian regions – one state in the North Region, one in the Center-West Region, three states in the Northeast Region, three states in the Southeast Region and two states in the South Region; and 50 municipalities, five from each of the participating states – with the capital of the states always represented; technicians from Anvisa areas and representatives from the Health Surveillance Work Subgroup (GTVisa), composed of representatives of the National Council of State Health Secretaries (CONASS) and representatives of the National Council of Municipal Health Secretaries (CONASEMS).

The work process of the IntegraVisa management group included preliminary meetings with state managers, decentralized workshops in the Health Surveillance bodies of ten Brazilian states, with the participation of the municipalities involved. The activities were focused on building collectively shared concepts and creating subsidies for the process of harmonizing and decentralizing health surveillance actions.

Health surveillance practices were established based on the perception of risk – virtual hazard or threat of injury[11] – preceded by the detailed definition of the health surveillance actions to be addressed by the participants. In this sense, among the high-risk actions, the actions considered critical and/or priority for the SNVS were identified through internal consultations with Anvisa's technical areas, and with the representatives of CONASS and CONASEMS that comprised the GTVisa. Critical actions for the IntegraVisa project were considered to be those processes, procedures and/or products with a high risk to the health of the population, which could have significant economic impact, and which required high technological complexity or specific expertise for their execution.

The workshops were built with spaces for collective construction, in a structured and consensual manner. This enabled focused reflection based on previously established triggers, which, in turn, enabled the deepening and integration of knowledge and practices in the construction of propositions to address the health surveillance issues in the territory. After the workshops, we mapped the practices and the different realities faced by the Health Surveillance bodies that supported the theoretical and methodological basis involved in the process of harmonizing and decentralizing health surveillance actions.

The content produced in the workshops on harmonization and construction of the criteria for the decentralization of critical actions in the SNVS fulfilled the following methodological requirements:

- Detailed description of critical actions, with emphasis on aspects of their context, concepts, results, products and components (harmonized practices and activities);
- Survey of the harmonization status in the territories;
- Identification of activities to be harmonized in practice;
- Construction of the action activities prioritization matrix;
- Construction of action descriptors;
- Preparation of general guidelines for the Harmonization Process;
- Recognition of nature and types of requirements for the execution of critical actions;
- Definition of parameters for the requirements of critical actions;
- Preparation of general guidelines to support the decentralization process; and
- Model validation of criteria and parameterized requirements.

For the purposes of this study, the term "harmonize" means the identification of common actions, activities and ways of acting and, thus, of producing common agreements that enable conformity of practices, activities and results. On the other hand, the term "decentralize" considered the identification of criteria and requirements for assigning competences and responsibilities that contribute to the better, more adequate and more effective execution of prioritized critical actions.

RESULTS

The process of building the identification of critical actions, with moments of refinement and validation, both internal and external to Anvisa, came up with a list of 12 actions, of which nine are related to the inspection action:

- Inspect the drug and active pharmaceutical ingredient (API) industry;
- Inspect the industry of class III and IV health products;
- Inspect blood, tissue, cell and organ services (STCO);
- Inspect compounding pharmacies;
- Inspect special-purpose food and food supplement industries;
- Inspect industrial kitchens;
- In hospital environments, inspect the services of: intensive care unit (ICU), material sterilization center, radiodiagnosis, radiation therapy, hospital infection control service, patient safety unit; solid health waste management;
- Inspect chemotherapy and parenteral nutrition, radiation therapy, radiodiagnosis, dialysis and endoscopy services;
- Inspect companies that prepare and sterilize medical and hospital materials for use in hospital environments;

- Manage adverse events and technical complaints of products and services subject to health surveillance;
- Outline health surveillance actions in mass events;
- Investigate emergency products and services subject to health surveillance.

The critical actions were detailed in relation to their expected results, the products resulting from them, the practices associated with their conduction and the activities that make up every health surveillance practice. These descriptors were composed of the following elements: (a) focus of the action; (b) scope of the action; (c) time of execution [macroprocess]; (d) materializable final products; (e) practices and activities that make up the action; (f) result of the action (Chart 1).

Regarding the harmonization of activities and practices, the workshops pointed out different realities faced by health surveillance, which enabled the design and agreement of a proposition for harmonization. During the description of each critical action, it was possible to notice the repetition of practices and activities in several actions, with the identification of many common structures between them. Likewise, many activities were recognized as common units of different practices and actions and, therefore, capable of being *componentizable*, for example: inspection report preparation procedure[12].

The analysis indicates that these common components must be harmonized prior to specific technical discussions more related to thematic actions by more structured fields of knowledge, in order to standardize the common core of activities (Charts 2 and 3).

Based on the analysis of the conditions needed for the performance of the activities associated with the 12 actions identified as critical and their components, we built clusters of requirements and detailed the general and specific requirements for carrying out each action, regardless of the executing entity. Five categories of requirements were considered:

- Legal - legal frameworks needed for the execution of an action (technical standards, health code, legal designation of the supervisor);
- Cognitive - skills, competences and professional and technical training required to perform an action;
- Ethics - conduct required to carry out a health surveillance action (code of ethics, conflict of interest, among others);
- Logistics - supplies, materials and all the necessary means to carry out an action; and
- Structuring - elements like access to information, access to the laboratory, training of staff and other infrastructure conditions necessary to carry out a health surveillance action.

During the discussions, we identified that some execution conditions are common to all health surveillance actions, either critical or not, and, therefore, these were considered as a limiting condition for a Health Surveillance body to take on responsibility for the execution of any action. With this in

Chart 1. Detail matrix of critical inspection actions. IntegraVisa Project, 2017.

(a) Focus of the action	Inspect: inspection is defined as the set of technical and administrative procedures aimed at the onsite verification of compliance with the health legislation of the activities and the work environment. The inspection enables the adoption of measures to guide and/or correct situations that may jeopardize the health of the population.
(b) Scope of the action	Identification of the health surveillance object to be considered in the action: includes aspects of post-marketing surveillance (pharmacovigilance – identification, evaluation, understanding and prevention of adverse events or any problems related to its use).
(c) Moment of execution (macroprocess)	Carried out both in the pre-market (certification and regularization) and in the post-market (inspection and monitoring) phases.
(d) Materializable final products	1. Issuance of qualification, certification (CBPF, Export, among others) and regularization (licensing and authorization) instruments; 2. Inspection Report – formal document prepared by the inspection team that describes the conditions of the company – according to the type of inspection; 3. Legal terms drawn up when necessary.
(e) Practices and activities that make up the action	1. Inspection planning: (i) Preparing the inspection plan according to the complexity, laboratory need, particularities and risk of the establishment, definition of the scope (whether routine or investigative); (ii) Doing a prior survey of information (legal framework, reporting systems, reports of previous inspections, registered products, among others); (iii) Communication with the company or establishment; and (iv) Preparing the inspection (staff, scripts, materials, legal designation of the inspectors); 2. Conducting the inspection: (i) Holding an initial meeting; (ii) Verifying compliance with the rules; (iii) Searching for evidence (sample collection, photos, interviews, historical and documentary analysis) using standardized scripts; and (iv) Holding a final meeting to draft terms and inform the next steps; 3. Drafting the report: (i) Writing a report in compliance with the report template (structure, items and defined topics); (ii) Doing the establishment's risk assessment; (iii) Indicating categorization of non-conformities; and (iv) Writing a final conclusion with the measures adopted and the legal terms drawn up; 4. Communication: (i) Establishing an information flow with the stakeholders (SNVS, SUS, regulated sector and society in general); and (ii) Submitting an inspection report to the regulated party; 5. Post-inspection activities: (i) Monitoring required measures and (ii) Performing prevention and control activities.
(f) Result of the action	Increasing the security of products and services offered to the population.

CBPF: Certificate of Good Manufacturing Practices; SNVS: National Health Surveillance System; SUS Unified Health System.
Source: IntegraVisa Project. Anvisa, 2017.

Chart 2. Activities to be harmonized according to the critical inspection action. IntegraVisa Project, 2017.

Related critical actions	Harmonizable activities
Inspection	Preparing inspection report according to the type of inspection and including the adopted measures.
	Verifying compliance with the standards by looking for evidence, according to the type of inspection.
	Categorizing the non-conformities, considering the risk assessment.
	Planning the inspection of the establishment or service according to complexity, laboratory need, particularities and risk of the establishment or service.
	Submitting the report to the regulated party.
	Preparing the inspection (staff, scripts, materials, company or establishment communication, designation of inspectors, calendar, among others).
	Monitoring compliance with the measures required in the inspection
	Performing a prior survey of the information (legal framework, Notivisa, previous inspections, registered products, post-surveillance data, among others).
	Finishing the documentation related to the inspection (report, final conclusion, measures adopted and legal terms drawn up).
	Holding onsite meetings during the inspection (initial, intermediate and final).
	Systematizing the information surveillance process (Notivisa, sentinel events, complaints and others).
All critical actions	Establishing a risk communication process for the stakeholders (reports, alerts, risk communication).
	Standardizing rules for sample collection, packaging and transportation.
	Drawing up legal terms.

Notivisa: Health Surveillance Reporting System.
Source: IntegraVisa Project. Anvisa, 2017.

Chart 3. Prioritization of inspection activities to be harmonized according to consensus among the participants. IntegraVisa Project, 2017.

Priority	Description of the activity
1	Preparing inspection report according to the type of inspection and including the adopted measures.
2	Verifying compliance with the standards and seek evidence, according to the type of inspection.
3	Categorizing the non-conformities, considering the risk assessment.
4	Planning the inspection of the establishment or service according to complexity, laboratory need, particularities and risk of the establishment or service.
5	Establishing a risk communication process for the stakeholders (reports, alerts, risk communication).
6	Submitting the report to the regulated party.

Source: IntegraVisa Project. Anvisa, 2017.

mind, these factors were considered as general requirements in the legal, ethical, logistical and structuring fields (Chart 4). The specific requirements focused on the structuring and cognitive categories (Chart 5).

Based on these requirements, parameters were determined for each general and specific requirement of the 12 critical actions, which are contained in the Harmonization and Decentralization Plans documents that resulted from the project. These parameters are directly related to the specific action and established according to the needs and characteristics of the action.

DISCUSSION

The federative model of the SUS, of which health surveillance is part, is characterized by the autonomy of its entities[1]. The challenge of harmonizing procedures and agreeing on criteria and requirements for implementation implies the need for a process in which qualified representatives of the stakeholders can carry out this identification in an agreed manner. This participation is necessary for mapping and recognizing the different situations faced by states and municipalities, both central and more remote. By ensuring the representation of this diversity, the process also ensures richer results, as well as the commitment to the consistency of a process that is essentially collective, of building consensus and negotiations based on cooperation between autonomous but interdependent stakeholders, as it should be in a system of this kind.

With the representativeness of the participants in the scope of this study, we sought to legitimize the construction process, making it possible for the agreements at the bipartite level to be a natural result, both as regards the execution of critical actions, as well as regarding the adoption of harmonized

Chart 4. Details of the general requirements for the execution of critical actions.

Category	Requirement	Description
Structuring	Laboratory	Have access to the laboratory network for necessary analysis.
Structuring	Access to information	Have access to basic information needed to evaluate the establishment and/or product.
Logistics	Locomotion feature	Have availability of mobility that meets the needs of the action.
Logistics	Material resources	Have equipment, technical and administrative supplies and documents needed for the action.
Ethical	Absence of conflict of interest	Have an annual declaration of absence of conflict of interest: document signed by a professional who performs the inspection.
Legal	Existence of legal protection for the actions	Adopt a health code that contains updated legal protection for inspection actions (federal, state or municipal).
Legal	Existence of legal protection for the actions	Follow specific legislation in force (laws, resolutions, technical standards, ordinances and other similar laws) sufficient for the inspection action.
Legal	Existence of legal protection for the actions	Have a Health Surveillance professional designated and appointed with law enforcement power.

Source: IntegraVisa Project. Anvisa, 2017.

Chart 5. Details of the general requirements for the execution of critical actions.

Category	Requirement	Description	Unit of measure
Structuring	Health Surveillance team	Have sufficient Health Surveillance personnel to carry out the action.	Unit (professional)
Structuring	Harmonized procedures	Have the following SOPs harmonized in the SNVS.	Unit (harmonized procedure)
Cognitive	Qualification (training)	Have a certified professional with basic health surveillance training.	Hours (classroom hours of specific content)
Cognitive	Qualification (training)	Have a certified Health Surveillance professional with a specific refresher course, or in-service training.	Hours (classroom hours)
Cognitive	Qualification (exhibition)	Have a health surveillance professional with practical experience (exposure) in carrying out this action.	Unit (exhibition)
Cognitive	Education (training)	Have a Health Surveillance professional trained to perform the action.	Unit (professional)

Visa: health surveillance; SOP: Standard operational procedure; SNVS: National Health Surveillance System.
Source: IntegraVisa Project. Anvisa, 2017.

procedures. The ten states participating in the project, in addition to covering all the regions of the Federation and having establishments and services that demanded the most critical actions of health surveillance, concentrated about 72% of the Brazilian population in 2018. Regarding the 50 municipalities that participated in the IntegraVisa project, all had a population greater than 50,000 inhabitants.

The need to harmonize the practices and activities of health surveillance was recognized as fundamental to strengthen the System. This can promote the alignment of actions between health surveillance bodies, regulatory convergence and predictability of actions, in addition to enabling the stakeholders to act in a harmonious and predictable manner and deal with situations in ways that are not questionable or subjective. There is also the need to strengthen the mechanisms of federative coordination in the context of the political-administrative structure. This need is perceived daily in the search for greater complementarity, since the federated units have different competencies and execution capacities.[3] Law n. 9.782/1999[3] did not contribute to ordering this coordination, since the components and the very functioning of the System were not explicitly defined. Clearly establishing criteria, funds and limits for this execution is fundamental for the best use of the available resources, to avoid parallel work and achieve better results.

It is worth mentioning that, as a result of the prioritization of inspection activities carried out by health surveillance agents, the participants came to a consensus as to the importance of preparing the inspection report, verifying compliance with the standards and carrying out the categorization of non-conformities considering the assessment of risk as activities that directly impact the work of the inspectors as law enforcement agents. Therefore, this work cannot have much variation is its form of execution nor be based on subjective judgment.

The establishment of the necessary conditions for the conduction of health surveillance actions between states and municipalities

has occurred in an incipient and occasional manner. We must consider the technical and operational capacity of each entity and incorporate the associated legal, cognitive, logistical, ethical and structural requirements. Furthermore, this process must respect the different realities of each entity and, at the same time, enable significant progress and improvement of health surveillance initiatives. It should be noted that the discussion regarding the harmonization of practices and activities was incorporated as a specific structuring requirement for all the critical actions we evaluated.

The definition of what to do, how to do it and who will take the responsibility for doing it, within the scope of the SNVS, must consider the potential of the risk and the management capacity of each place and time of agreement. Some municipalities will occasionally not be able – technically, organizationally or politically – to perform certain health-related tasks. This dynamic reality requires attentive coordination and permanent and regionalized cooperation. This also reveals the relevance of the states in the provision of services in a complementary manner, a situation that will probably last for some time.

In this sense, the creation of health surveillance-specific live negotiation spaces, within the scope of the state management and/or the Bipartite Intergovernmental Commissions (CIB), will enable the design of strategies to improve the structure and achieve results in new responsibilities.

CONCLUSIONS

This study presented subsidies derived from health surveillance actions that can be considered critical and in the knowledge of a set of activities that could be harmonized. These contents were addressed and delivered as products of the IntegraVisa Project to Anvisa. The decentralization of responsibilities between federated entities is an almost mandatory condition within a federation, since its existence incorporates the recognition of autonomous subnational governments, but also with interdependent relations and with republican responsibilities. In addition, within a federation there is the concept of subsidiarity, which refers to the creation of mechanisms to compensate for the inequality between federative entities.

The criteria and requirements that were established as references to guide and improve the decentralization of health surveillance actions among the three federated entities are understood as requirements for the subsequent negotiation and agreement of said actions between them. The effort summarized here expanded the scope of this process and incorporated specific technical questions for all actions considered critical. This was achieved using a participatory methodology that, in addition to Anvisa technicians, had the participation of technicians and managers from 10 Brazilian states, from 50 municipalities (five from each state) and representatives of the GTVisa. Therefore, the result achieved can be considered to be faithful to the reality of the SNVS group.

This proposition does not intend to establish a single model for the agreement between the federated entities, but to clarify the needs experienced and prioritized by the health surveillance agents when aligned with the purpose of a more uniform, transparent and predictable performance, as well as the requirements and guidelines that may contribute to the consolidation of the SNVS in each government level. The SNVS must be an integral part of a process of continuous improvement, together with the institutions involved in it, which includes the expansion of strategic quality management skills, and instruments that facilitate the fulfillment of the institutional missions of all stakeholders.

Resolution of the Collegiate Board (RDC) n. 207, of January 3, 2018[13], which provides for the organization of health surveillance actions done by the Union, states, Federal District and municipalities, incorporated the adoption of the requirements as a principle of delegating responsibility for the execution of actions. Additionally, the harmonization process was understood as a structuring requirement among the criteria to be agreed upon.

It is essential that these and other propositions, as well as new strategies of agreement and relationship between the entities, provided that they bring relevant content to the specific negotiations for the definition of health responsibilities among the entities that make up the SNVS, be included in the interpartite negotiation agendas within the scope of the SUS[14].

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Conflict of Interest

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