

Implementation of health technologies in Brazil: analysis of federal guidelines for the public health system

1

THEMATIC ARTICLE

Sarah Nascimento Silva (<https://orcid.org/0000-0002-1087-9819>)¹
Nicole Freitas de Mello (<https://orcid.org/0000-0002-5228-6691>)²
Laís Raquel Ribeiro (<https://orcid.org/0000-0002-3590-1840>)¹
Rosiana Estéfane da Silva (<https://orcid.org/0000-0002-6111-0954>)¹
Gláucia Cota (<https://orcid.org/0000-0003-0538-7403>)¹

Abstract *This study aimed to identify the regulatory framework and federal guidelines that support the process of implementing health technologies in the Unified Health System (SUS) through analysis of documents and legislation related to the National Health Technology Management Policy, published between 2009 and 2021. The search and selection of documents and subsequent data extraction were carried out. The documents were grouped into three categories: structural regulatory documents, recommendations on evaluation of technologies, and recommendations on clinical guidelines. In 38.8% of the regulatory documents, citations to implementation related mainly to SUS clinical guidelines were identified; however, no document dedicated to guiding implementation actions was identified. Recommendations related to implementations were identified in 27.1% of the reports and 66.1% of the guidelines, although without standardization and, in general, in little detail, focusing on resources and actions needed for making technology available rather than on methods and interventions for its implementation. The results evidence a gap in formal guidelines to guide the implementation process in Brazil, representing an opportunity for the development of models aligned with the reality of the SUS.*

Key words *Implementation Science, Unified Health System, Technology Assessment, Biomedical, Health policy, Government Regulation*

¹ Instituto Renné Rachou, Fiocruz Minas. Av. Augusto de Lima 1715, Barro Preto. 30190-002 Belo Horizonte MG Brasil. sarah.nascimento@fiocruz.br

² Ministério da Saúde. Brasília DF Brasil.

Introduction

The use of health technology in clinical practice is closely related to implementation strategies used and guidelines disseminated in health systems¹. In addition to representing a complex process comprising multiple stages and strategies², implementation is still considered a neglected stage in the technology management cycle, either due to the lack of understanding of its importance or the lack of investment in implementation research, representing a major issue for middle- and low-income countries³.

Several years are required before an innovation identified in the research is turned to benefit its potential users^{4,5}. The use of health technologies depends on the interaction between various actors, such as patients, healthcare professionals, managers, and health services, which requires planning strategies that can interfere with the process of adherence, acceptability, and availability of technologies⁶. In health systems, the organization of this process must be planned and guided by strategies linked to various dimensions, guiding the translation of evidence into the consolidation of service practices⁷.

Brazil's public health system offers comprehensive and universal coverage for the population, with seven out of 10 Brazilians depending exclusively on the Unified Health System (SUS)⁸. Management of this large system has a national Health Technology Management Policy (*Política Nacional de Gestão de Tecnologias em Saúde* - PNGTS), published in 2009, which is structured around the concept of Health Technology Assessment (HTA) for decision making^{9,10}. The process of inclusion, alteration, and exclusion of health technologies, focused mainly on hard technologies such as medicines, procedures, and medical materials, adopts well-defined criteria and an organized flow to analyze internal and external demands on the SUS⁹, linked to a transparent administrative process with well-defined deadlines, consolidated from 2011^{9,11}. In contrast to a well-defined evaluation stage⁹ that includes significant investments in innovative technologies¹², implementing incorporated technologies, that is, their effective use in clinical practice, is still a challenge in Brazil^{13,14}. Although the PNGTS publication and Law No. 12.401/2011 are important legal milestones, there are few guidelines for managers when it comes to implementation, monitoring of results, and reassessment of technologies in the three levels of government^{15,16}, which are fundamental actions to promote access, proper use,

and measurement of desired health benefits with the inclusion of new technologies¹⁷.

Although implementation of health technologies usually occurs at the local level, carried out by state and municipal managers, federal guidelines would represent an important strategy to standardize processes throughout the nation, allowing effective support to managers in implementing technologies and stimulating evaluation, monitoring, and continuous improvement of the health system¹⁸. The combination of approaches and the convergence of efforts, bringing together the local and national levels, have the potential to improve the implementation process¹⁹. Therefore, knowing the legal aspects, recommendations that involve each stage of technology management, and the tools capable of guiding the implementation already available represents an initial step for proposing improvements in managing this process in SUS²⁰.

This study aims to identify and analyze the federal guidelines for implementing health technologies in the SUS, adopted from the PNGTS publication. The opportunities and challenges to improve technology management in Brazil are also discussed.

Methodology

This is a descriptive study that uses the documentary analysis method to identify formal guidelines, within the scope of federal management, regarding the implementation of health technologies. The methodology comprised sequential stages of search, selection, extraction, and analysis of information according to established criteria.

Eligibility criteria

Regulatory or technical documents related to the management of health technologies, which address the process of evaluation, incorporation, dissemination, and management of the use or withdrawal of technologies from the health system, were included²¹. In addition, documents prepared by an agency belonging to federal administration of the SUS were selected between 2009 and 2021 as inclusion criteria. Methodology guidelines and strategy documents guiding the technology used in SUS were also included for full reading.

Documents with different themes of technology management, duplicate files or information, and legislation repealed during the analysis pe-

riod (May 2022) were excluded from the analysis. In addition, ordinances that did not promoted the incorporation of technologies into the SUS were excluded since they refer only to assessment of technology evaluation and have no impact or guidelines for its implementation in the health system.

Information sources and search strategy

Official digital platforms that bring together legislation, regulatory, or recommendation documents within the scope of federal public health in Brazil were used as sources of information, as follows: *Portal da Saúde* (www.saude.gov.br), *Portal da Legislação* (planalto.gov.br), website of the National Commission for the Incorporation of Technologies (*Comissão Nacional de Incorporação de Tecnologias* - CONITEC; www.conitec.saude.gov.br) in SUS and website of the National Council of Health Secretaries (*Conselho Nacional dos Secretários de Saúde* - CONASS; conass.org.br). As a search strategy, the keywords “technology assessment,” “technology management,” and “technology incorporation” were used to identify documents related to health technology management published between 2009 and 2021. The search was conducted on 05/31/2022 by a researcher experienced in SUS legislation and structural documents.

A conference stage was conducted to assess whether the identified document was in force, based on the direct conference at the issuing body of the publication (Presidency portal, Ministry of Health, and CONASS portal) on 06/02/2022. A manual search of documents referenced in the publications was also performed, even if they were available in another domain requiring additional searches. SUS structural regulatory documents, responsible for incorporating actions related to technology management, which were in force during the period analyzed, were also evaluated.

Data selection and extraction process

Titles, abstracts, and summaries of the documents were independently evaluated by two reviewers. After the initial selection, a full reading of each document was performed by a reviewer. Disagreements were resolved by consensus, and the included documents were grouped and categorized into: 1. structural regulatory documents; 2. recommendation documents on technology assessment; and 3. recommendation documents on clinical guidelines.

Recommendation documents related to the implementation actions described at any stage of the technology management cycle were extracted from the documents, including from the evaluation and incorporation process, expressed in the reports, recommendation ordinances, and respective requirements, to guidelines for the effective implementation in clinical practice or for the withdrawal of the technology²². The information was collected and summarized in Excel, with 70% of the data extracted in duplicate and checked by a second independent reviewer.

Method of data synthesis and analysis

The synthesis of the extracted data was performed according to the category of the document. In the structural regulatory documents (category 1), the citations on implementation were presented according to their relationship with the technology management in SUS (direct or indirect). In the recommendation documents (categories 2 and 3), information on the recommendation ordinances and the respective annexes, which include technical reports or clinical guidelines, were analyzed.

Analysis of the recommendation ordinances included the thematic synthesis of requirements described for the recommendation of technologies. The requirements comprise concrete actions capable of influencing stages of the implementation process, such as maximum incorporation price, technical assistance criteria for allocation, the structure and logistics necessary for technology implementation, and the monitoring of the incorporated technology, when relevant, designated as managed access from 2022 onward²³.

In the technical reports and clinical guidelines, the citations on implementation were related to analysis groups based on the methodology steps of evidence implementation described in the model developed by the Joanna Briggs Institute (JBI)²⁴. This model was chosen because it focuses on the health area and is centered around evidence-based practices. The implementation stages listed by this model are: context analysis, considering organizational aspects and actors involved; change facilitation, which reports interventions and proposed actions for change within the organization; and evaluation of the process and results related to implementation. From these stages, nine analysis groups were established: I - planning and methods; II - managers' responsibility; III - resources; IV - scenario; V - targeted interventions; VI - implementation monitoring;

VII - implementation results; VIII - programs or policies; and IX - others.

Based on the summarized information, two experienced researchers listed challenges, opportunities, and proposals for improvements to enhance the technology management process in SUS. This analysis was carried out based on the phases of the technology management cycle: evaluation, implementation planning (acquisition and organization of flows), and development of clinical guidelines (recommendations for use in services), considering the opportunity to develop actions already practiced in some universal health systems²⁵⁻²⁷. All documents gathered in the present study are publicly accessible, and no stage required the request of data to the institutions or submission to an ethics and research committee.

Results

Six hundred sixty-six documents were identified as addressing the topic of health technology management (evaluation, incorporation, dissemination, management of the use and withdrawal of technologies from the health system); of them, 434 (65.1%) were eligible for analysis, and 166 (38.2%) addressed information or citation related to the implementation process (Figure 1).

Eighteen structural regulatory documents published during the analysis period were identified, comprising ordinances, decrees, and methodology guidelines that structure and guide health technology management in the country. Seven regulatory documents (38.8%) cited, directly or indirectly, technology implementation actions, such as general guidelines, principles, actions, and steps (Chart 1). Most of the citations found in the regulatory documents address the stage of insertion of technology in care practice, in particular, guidelines for elaborating clinical guidelines.

The analysis of the ordinances of incorporation, alteration, or exclusion of technologies was performed with the recommendation reports issued by CONITEC, which constitute the publication's main annex. Two hundred ninety-eight ordinances were analyzed, of which 109 (36.5%) presented at least one requirement for the conclusion of the incorporation. The main requirement is related to the development or updating of a clinical protocol or guideline (69.0%), followed by negotiation or adjustment of the price of the technology (19%) (Figure 2).

Of the 298 recommendation reports analyzed, 81 presented at least one citation on implementa-

tion, totaling 100 citations in the texts. Citations were classified into nine groups, the most frequent being those related to the physical structure and resources necessary for implementation (43%) or responsibilities inherent to the process of making technologies available (25%) (Chart 2).

In 17 reports, the citations describe the need for no specific actions to implement the technologies under analysis (infrastructure adjustments, special logistical measures, and organizational restructuring of the pharmaceutical care network). Of these, seven reports indicate that the implementation issues of the technology under analysis were already established in the SUS and had no important barriers to implementation. In the economic evaluation, only one report considered the costs related to technology implementation in the care network.

One hundred eighteen ordinances for the publication of protocols/guidelines and their respective annexes were identified on the CONITEC website. The publication ordinances of the Clinical Protocols and Therapeutic Guidelines (*Protocolos Clínicos e Diretrizes Terapêuticas* - PCDT) and clinical guidelines present a general text informing - the responsibility of state, district, and municipal managers of the SUS, according to the agreement, in structuring the care network and defining reference services and care flows. The annexes of these ordinances present the full texts of the protocols and guidelines, of which 78 had a citation on implementation. The most described information is related to the structure of the care network and clinical conduct (81.8%), considering aspects of the service infrastructure and the technical team of patient care professionals. In six clinical guidelines developed according to the GRADE methodology, aspects of guideline acceptability and feasibility were included through the Evidence-to-Decision table. The "regulatory/control/evaluation" session of the protocols and guidelines presented the most information related to the implementation of recommendations.

Although 27.1% of the reports and 66.1% of the guidelines present citations related to implementation, concrete guidelines for implementing the technologies in SUS are limited. In addition, implementation approaches are not yet standardized in recommendation reports and guidelines, are poorly detailed, and focus on orientation regarding required resources or essential actions already defined in the legislation for technology availability. Chart 3 shows a critical analysis of the revised documents and the challenges and opportunities in the implementation process.

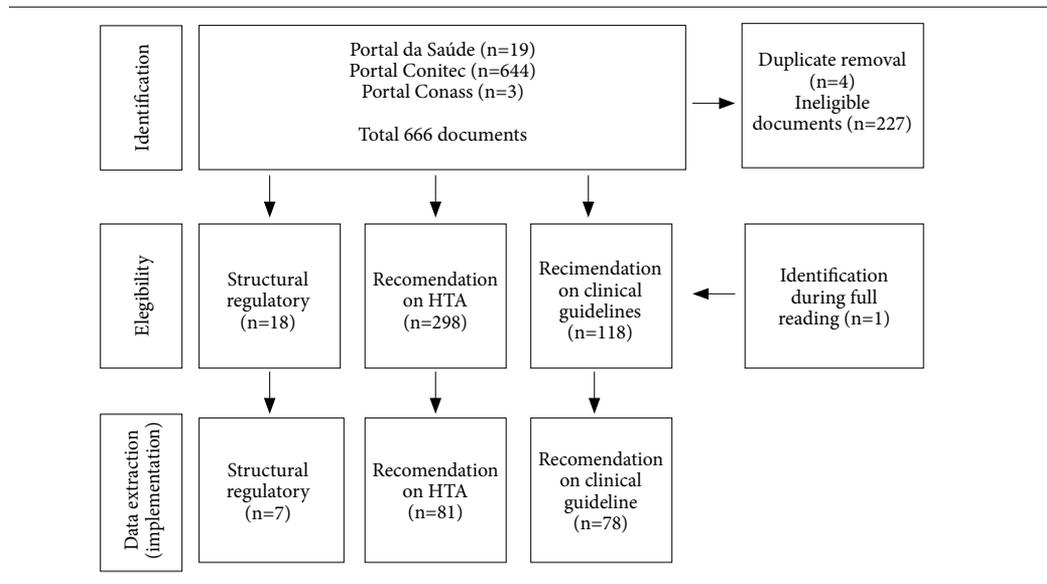


Figure 1. Results of the exploratory search for regulatory documents and documents related to technology management in SUS published between 2009 and 2021.

Source: Authors.

Chart 1. Structural regulatory documents of the Unified Health System (SUS) and health technology implementation approach at the federal level (2009-2021).

Structural regulatory documents	Year of publication	Title/description	Citation type (implementation approach)
Ordinance No. 2,690	2009	Establishes PNGTS.	Indirect (policy principles that guide technology management and encompass implementation aspects).
Ordinance No. 27 SCTIE/MS	2015	Approves the workflow for preparing and updating the PCDT within the scope of CONITEC.	Direct (attribution of the management committee: IV - define the dissemination forms of the PCDT and strategies for its implementation).
Ordinance No. 18	2016	Approves the methodology guideline for the preparation of Clinical Guidelines.	Direct (chapter 3 of the guideline: guidelines, concepts, and implementation strategies. It also emphasizes the monitoring of implementation).
Ordinance No. 41	2016	Approves the methodology guideline for health technology performance assessment.	Indirect (indicators related to technology performance measures involve an approach to the implementation process).
Methodology guidelines - Ministry of Health	2014	Methodology guidelines: tools for adapting clinical guidelines – 1st edition.	Direct (consists of step 5 of the configuration phase of the adaptation process, including strategies for implementing and disseminating the guidelines).
Methodology guidelines - Ministry of Health	2019	Preparation guide: scope for clinical protocols and clinical guidelines.	Direct (definition of implementation indicators in the process of drafting the scope of the guidelines).
Methodology guidelines - Ministry of Health	2021	Methodology guidelines: preparation of clinical guidelines (2020); updated version.	Direct (chapter 9: diffusion, dissemination, and implementation of guidelines).

Notes: Conitec - National Commission for the Incorporation of Technologies; PCDT - Clinical Protocols and Therapeutic Guidelines; PNGTS - Health Technology Management Policy; SCTIE/MS - Department of Science, Technology, Innovation, and Strategic Inputs of the Ministry of Health.

Source: Authors.

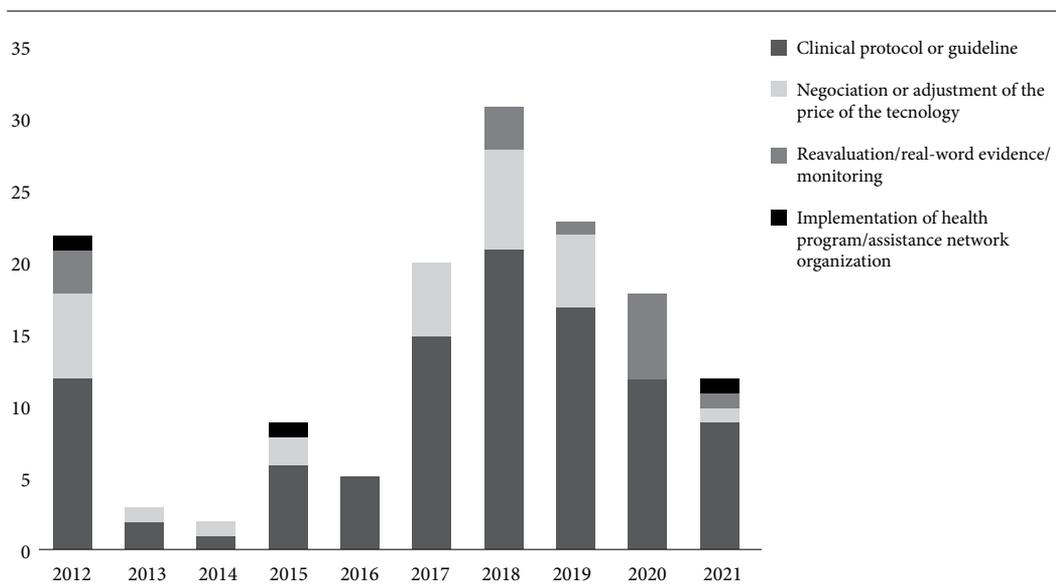


Figure 2. Ordinance requirements for the incorporation, alteration, and exclusion of technologies in SUS published between 2012 and 2021*.

*Ordinances with no effect were excluded (repealed legislation and ordinances that did not include incorporation of technologies in SUS).

Source: Authors.

This assessment identified the opportunity to include more variables in the technology evaluation process to compose the decision analysis, including data on acceptability and feasibility, discussion of successful strategies, and implementation cost analysis. These data may guide the analysis of barriers and facilitators, permitting a complete discussion of the actions involved in implementing the technologies. Within the scope of planning actions, opportunities were identified to interconnect information previously identified during the evaluation to guide actions in the contexts experienced by policymakers. The dissemination of implementation methods and the development of orientation documents for implementing clinical guidelines were identified as opportunities to direct local implementation strategies.

Discussion

The federal guidelines for implementation of technologies in SUS proved to be little detailed; they are not yet standardized in the evaluation reports of technologies and clinical guidelines,

focusing instead on guidelines for the availability of technologies. Critical analysis of this scenario allowed the preparation of proposals based on three critical points identified in technology management: actual availability of technology, the low dissemination of explicit strategies and methods to support technology implementation, and the need to integrate management steps with coordinated planning actions. These three critical points are closely related to the requirements included in the incorporation ordinances, which often translate necessary actions and requirements previously identified in the evaluation process, capable of impacting the time, form of availability, and implementation of technologies²⁸.

Initially, the concepts of implementation and availability, which are sometimes used interchangeably but relate to different stages in the management of health technologies, need to be aligned. The availability of technology in the SUS comprises its health service offer after the incorporation process, which must occur within 180 days of the incorporation decision⁹. Implementation, on the other hand, comprises a specific set of actions to put into practice a policy or intervention^{3,29}. Thus, implementation encompasses strategies so that

Chart 2. Analysis of CONITEC's (National Commission for the Incorporation of Technologies) recommendation reports between 2012 and 2021.

Analysis groups	Number of citations	Topics covered (citations)
I - planning and implementation methods (audit, feedback, reminders, academic details, and others)	10	Team training (educational actions).
II - managers' responsibility (guidelines for implementing the technology in the service)	8	Development of operational plan or initial implementation plan; description of services; centralized offer; definition of service flow; definition of certified centers; regulations on package inserts (off-label use).
III - physical structure, team, resources, and requirements to promote the technology implementation	43	Highly specialized team; appropriate infrastructure; specific instruments; strengthening of the laboratory network and adequate biosafety level; qualified centers/specialized services; logistics and operational structure; new structure for acquiring and distributing technology; pharmaceutical assistance network.
IV - information on the implementation scenario (scenarios, facilitators, barriers, and others)	7	Recommendations on gradual technology implementation (preferred locations for implementation where skilled teams are present); description of the scenario and recommendations for analysis before prescribing the technology; scenario for implementing the technology (important barriers to implementation).
V - Targeted interventions	1	Directly observed treatment (DOT)
VI - Analysis of implementation/ withdrawal of technologies (results, indicators)	1	Patient monitoring and contact system.
VII - Evaluation after implementation (results related to the use of technology)	3	Continuous monitoring of disease trends to assess the impact of technology incorporation; monitoring program; technology use to measure adherence.
VIII - Implementation program or policies	1	Program structure (need for a comprehensive and detailed plan to enable implementation); development of guidelines and implementation plan.
IX - Other (standard actions related to funding, acquisition, and agreement)	26	Responsibilities for acquiring and funding technologies must be agreed upon within the scope of the Tripartite Intermanagerial Commission.

Source: Authors.

the available technology can be used in the normal routine of services. Many citations on implementation identified in the analyzed reports and guidelines actually correspond to actions to promote technology availability, presenting aspects like the agreement of funding responsibilities and acquisition of technology, the preparation/ updating of the clinical guidelines, and the structural requirements for the services.

Technology availability is an essential requirement for its implementation. Although the deadline is standardized⁹, an analysis between 2017 and 2019 found that it took an average of five times longer than the legal deadline to achieve

availability²⁸, in addition to a longer average time for availability of oncological drugs verified in another study¹³. This scenario may reflect various aspects of the technology's trajectory, which ideally should be managed in a coordinated manner as soon as it is introduced, including agreements on funding, acquisition, and structuring of services among the three levels of government. Another challenge is the combination of the roles of making and executing recommendations, unlike the model adopted by other public systems, in which agencies dedicated to technology assessment draw up recommendations for health systems to execute^{30,31}.

Chart 3. Current context, challenges, and opportunities for implementing health technologies in different technology management stages in Brazil.

Análise	Decision-maker (analysis for incorporation)	Implementation planning (acquisition and organization of flows)	Preparation of clinical guidelines (recommendations for use in services)
Current context	Little information to contextualize other important dimensions of HTA related to technology implementation (organizational dimension and patient perspective).	Information included in some reports but without sufficient details or standardization to be explored in subsequent steps.	Limited information to direct local guideline implementation strategies.
Challenges	Diversity of scenarios and flows in services, multiple management levels, and policy organization.	Detail requirements and recommendations in the ordinances and reports to direct proper organization and planning of the implementation.	Orientation on implementation strategies should be part of the guidelines for their adaptation in different contexts.
Opportunities	Add information on barriers, enablers, successful implementation strategies, costs, necessary structures, acceptability data, and feasibility of technologies under evaluation.	Add scientific evidence and a systematic method of planning the process of reorganization and implementation of health policies.	Describe guidelines and methods to guide the local implementation process. Develop plans to guide managers and healthcare professionals.
Suggestions	Standardize sections in technology assessment reports covering implementation aspects.	Align necessary and responsible actions, minimize obstacles, and integrate management of levels of government.	Develop national guidelines to disseminate methods for implementing recommendations in clinical practice and explicit orientation.

Note: HTA - Health Technology Assessment.

Source: Authors.

Among the obstacles to technology availability, we highlight the use of the “price negotiation” requirement in technology incorporation ordinances, found in many incorporations between 2012 and 2019 and now in disuse²⁸. For many years, this requirement represented an attempt to pay fairer prices for technologies incorporated into the SUS, through negotiation with manufacturers, after the incorporation process. Contrary to expectations, this strategy was recognized as a late and ineffective action, which negatively impacted the time it took to supply the technology, according to an analysis by the Government Accountability Office (*Controladoria-Geral da União - CGU*)²⁸. Rethinking technology pricing for the SUS, the correlation with the HTA stages, and the authorities responsible for each of them is a necessary action. Several countries have de-

veloped strategies to deal with this aspect, which involves interaction with technology manufacturers. The UK technology assessment agency (National Institute for Health and Care Excellence - NICE) discusses technology pricing in the implementation phase of HTA. In turn, Germany³¹ adopted an interrelated model that provides for subsequent reassessment of costs. The importance of this topic lies in the fact that it directly impacts the time required to make the technology available, reinforcing the need to evaluate the flows and authorities responsible for establishing responsibilities in the stages after the incorporation in order to ensure compliance with the legal deadlines set out in the legislation.

A second critical point identified was the lack of documents dedicated to supporting practical implementation actions. Within the scope of

SUS, clinical guidelines are the documents responsible for synthesizing the recommendations for use, supported by the conclusions derived from the evaluation conducted. However, they do not explore the methodology aspect of effective implementation. Notably, the need to prepare or update clinical guidelines was the most frequently identified requirement in incorporation ordinances in recent years. This confirms the central role of these technical documents guiding the practice, in addition to revealing an opportunity to plan and coordinate the actions to implement clinical guidelines following targeted methods³² and strategies³³ in the different scenarios of technology use. In the public health systems of England, Australia, and Canada, actions to implement clinical guidelines are integrated and coordinated with various phases of technology management^{25-27,34}.

NICE presents a guide for implementing clinical guidelines³⁴ using quality control practices and practical experiences¹⁹. In addition, it provides services aimed at managers focusing on the implementation strategy through audits²⁵. The Canadian agency offers a similar service, with a dedicated support team in different provinces, offering technical implementation support²⁷. In Australia, the presentation of an implementation plan based on project management principles is valued when approving clinical guidelines²⁶. These examples highlight the importance of developing guiding documents and committees that drive the process of implementing guidelines in Brazil as a sequential action in assessing technologies and drafting recommendations for clinical practice. Initial actions have been carried out to support the implementation and dissemination of guidelines in Brazil, such as a pilot project that developed new formats for clinical guidelines³⁵. This represents an opportunity to expand the knowledge base on strategies aimed at the SUS.

Implementation planning is another point of concern in the health technology management process that should consider integrating the incorporation process with technology implementation in health services. In the history of technology assessment in Brazil, it is possible to identify specific documents from 2012, 2015, and 2021 in which plans for implementing a health program or organization of the care network were used as incorporation requirements. As of 2018, with the increased demand for incorporation of technologies that apply to rare diseases, requirements related to the reassessment and monitoring of real-world data emerge in the discussion of new

incorporation models and risk-sharing agreements³⁶ to compare the actual performance of technologies. Analysis of these reports and guidelines pointed out some indicators to be measured, which certainly guide the planning of actions to put forward technologies but still require specific implementation strategies and methods to help the teams that will be involved in the assistance.

The organizational principles of decentralization and single command of the SUS ensure the autonomy of local managers to define structures, flows, and different proposals for technology implementation. However, this can also represent a barrier to organization of the Brazilian health system and optimization of available resources so that the entire population has adequate and equitable access to their health needs. For several reasons, local managers might not have technical resources capable of structural implementation strategies, which can cause a lack of standards and a weakening of the management chain, in addition to a loss of resources invested in the process. Some implementation experiences in SUS report managers' challenges in operationalizing services locally, emphasizing the need for the policy provider to establish implementation guidelines and technical support, considering different contexts³⁷. Adopting and standardizing methods aimed at the reality of the health system are also important actions to improve implementation in the SUS. This was a need perceived in a study that developed a method for implementing a health policy, which presented a more detailed orientation of this process and a cycle of activities, including developing local plans, mentoring, and permanent education in health³⁸.

Specific publications for implementing guidelines based on evidence-informed policy tools are important examples to support the guideline implementation process, such as the work developed for the Brazilian guidelines on normal childbirth, which presented important insights to guide the development of an implementation plan^{39,40}. In addition, issues inherent to interstate management must be considered, which require integrated and multidisciplinary coordination actions that, when successfully addressed, have added resoluteness to the actions implemented by national programs⁴¹.

This study is limited by the analysis focused only on the regulatory and structural documents in implementing health technologies at the federal level, published by the PNGTS institution. Assessing other records and the effectiveness of interventions is a future perspective to be developed to

understand implementation. Similarly, the analysis of some SUS structural regulatory documents in force before the analysis period focused on recovering objective citations on the implementation process. Therefore, complementary studies should be conducted to capture across-the-board actions that certainly influence the implementation process but were not obtained in the present study. The lack of consensus in the use of some terms and the use of interpretation to understand the reports can influence the identification and extraction of data, although standardized and categorized by researchers, given the diversity of meanings used by the different actors working in the technology management and reflected in the documents analyzed. Another limitation related to the fact that this study gathered documents essentially focused on implementing hard technologies, such as diagnostic methods and therapies incorporated into the health system. That is, in the documents retrieved, the implementation of health programs or across-the-board policies regarding incorporated technologies was not addressed but deserves a specific methodology to be evaluated in subsequent research.

In addition, the identification of documents may have been limited by unavailability of data, some with a limited repository, others with daily changes, and even changes in formats during the preparation of the research. We tried to minimize this by using extensive manual searches. Even so, the documents gathered were sufficient to map implementation actions currently recommended within the SUS regulatory framework, emphasizing those related to PCDT and indicating gaps between the phases of technology management.

This study presents three potentially useful observations for directing future actions

within the scope of health technology management policy. 1 - Orientation at the federal level has the potential to assist and facilitate technology implementation in SUS. 2 - The structural and regulatory character of PCDT and clinical guidelines in the SUS organization is, *per se*, an opportunity to guide technology implementation strategies, so the development of guidelines and implementation plans linked to clinical practice guides are promising strategies. 3 - The standardization, planning, and insertion of technology implementation strategies in the initial phase of evaluation for incorporation can promote not only greater efficiency in user access to technology but also introduce the use of the dimensions of acceptability, feasibility, organizational specificities, sustainability, and finally, the preferences of patients in the construction of a more resolute health service and adequate to the needs of the population.

Consolidating the implementation process as a sequential and continuous stage of technology management is a necessary action to overcome barriers. Among the various challenges, using regulatory and recommended instruments as tools to harmonize actions and, ultimately, promote effective access of the Brazilian population to health innovations seems to be the first step in optimizing health technology implementation. The existing regulatory definitions are still insufficient to organize the practice of implementation in the health field in Brazil. In this context, this study diagnoses situationally existing regulations and recommendations and can guide the development of systematic and generalizable strategies for implementing health technologies, essential aspects to consolidate a virtuous cycle of technology management in SUS.

Collaborations

SN Silva, NF Mello and G Cota: conception and planning of the manuscript. SN Silva, NF Mello, LR Ribeiro and RE Silva: data collection, analysis and interpretation. SN Silva, NF Mello, LR Ribeiro, RE Silva and G Cota: elaboration, critical review and approval of the manuscript by all authors, taking the responsibility for all aspects of the work.

Funding

Conselho Nacional de Desenvolvimento Científico e Tecnológico - 400194/2022-9.

References

1. Van Gemert-Pijnen JL. Implementation of health technology: Directions for research and practice. *Front Digit Heal* 2022; 4:1030194.
2. Pantoja T, Opiyo N, Lewin S, Paulsen E, Ciapponi A, Wiysonge CS, Herrera CA, Rada G, Peñaloza B, Dudley L, Gagnon MP, Garcia Marti S, Oxman AD. Implementation strategies for health systems in low-income countries: an overview of systematic reviews. *Cochrane Database Syst Rev* 2017; 9:CD011086.
3. Peters DH, Tran NT, Adam T. *Implementation Research in Health: A Practical Guide*. Geneva: Alliance Health Policy Systems Research, WHO; 2013.
4. Morris ZS, Wooding S, Grant J. The answer is 17 years, what is the question: Understanding time lags in translational research. *J R Soc Med* 2011; 104(12):510-520.
5. Hanney SR, Castle-Clarke S, Grant J, Guthrie S, Henshall C, Mestre-Ferrandiz J, Pistollato M, Pollitt A, Sussex J, Wooding S. How long does biomedical research take? Studying the time taken between biomedical and health research and its translation into products, policy, and practice. *Health Res Policy Syst* 2015; 13:1.
6. Klaic M, Kapp S, Hudson P, Chapman W, Denehy L, Story D, Francis JJ. Implementability of healthcare interventions: an overview of reviews and development of a conceptual framework. *Implement Sci* 2022; 17(1):10.
7. Glasgow RE, Vogt TM, Boles SM. Evaluating the public health impact of health promotion interventions: the RE-AIM framework. *Am J Public Health* 1999; 89(9):1322-1327.
8. Instituto Brasileiro de Geografia e estatística (IBGE). *Pesquisa nacional de saúde: 2019: informações sobre domicílios, acesso e utilização dos serviços de saúde: Brasil, grandes regiões e unidades da federação*. Rio de Janeiro: IBGE; 2020.
9. Brasil. Lei nº 12.401, de 28 de abril de 2011. Altera a Lei nº 8.080, de 19 de setembro de 1990, para dispor sobre a assistência terapêutica e a incorporação de tecnologia em saúde no âmbito do Sistema Único de Saúde - SUS. *Diário Oficial da União*; 2011.
10. Brasil. Lei nº 8.080, de 19 de setembro de 1990. Dispõe sobre as condições para a promoção, proteção e recuperação da saúde, a organização e o funcionamento dos serviços correspondentes e dá outras providências. *Diário Oficial da União* 1990; 20 set.
11. Rabelo RB, Petramale CA, Silveira LC, Santos VCC, Gonçalves HC. A comissão nacional de incorporação de tecnologias no SUS: um balanço dos primeiros anos de atuação. *Rev Eletr Gestao Saude* 2015; 4:3225-3240.
12. Brasil. Ministério da Saúde (MS). Comissão Nacional de Incorporação de Tecnologias em Saúde. Conitec em números [Internet]. [acessado 2023 nov 13]. Disponível em: <https://lookerstudio.google.com/embed/u/0/reporting/afb9eff6-9786-4172-a4f0-a403580ff5f6/page/PzCbB>.
13. Capucho HC, Brito A, Maiolino A, Kaliks RA, Pinto RP. Incorporação de medicamentos no SUS: comparação entre oncologia e componente especializado da assistência farmacêutica. *Cien Saude Colet* 2022; 27(6):2471-2479.
14. Lupatini EO, Zimmermann IR, Barreto JOM, Silva EN. How long does it take to translate research findings into routine healthcare practice? - the case of biological drugs for rheumatoid arthritis in Brazil. *Ann Transl Med* 2022; 10(13):738.
15. Novaes HMD, Soárez PC. A Avaliação das Tecnologias em Saúde: origem, desenvolvimento e desafios atuais. Panorama internacional e Brasil. *Cad Saude Publica* 2020; 36(9):e00006820.

16. Brasil. Ministério da Saúde (MS). *Diretrizes Metodológicas: avaliação de desempenho de tecnologias em saúde*. Brasília: MS; 2017.
17. Toma TS, Pereira TV, Vanni T, Barreto JOM. *Avaliação de tecnologias de saúde e políticas informadas por evidências*. São Paulo: Instituto de Saúde; 2017.
18. Brasil. Ministério da Saúde (MS). *Diretrizes Metodológicas: Elaboração de Diretrizes Clínicas*. Brasília: MS; 2016.
19. Leng G, Partridge G. Achieving high-quality care: a view from NICE. *Heart* 2018; 104(1):10-15.
20. Brasil. Decreto nº 7.508, de 29 de junho de 2011. Regulamenta a Lei nº 8.080, de 19 de setembro de 1990, para dispor sobre a organização do Sistema Único de Saúde - SUS, o planejamento da saúde, a assistência à saúde e a articulação interfederativa, e dá outras providências. *Diário Oficial da União*; 2011.
21. Brasil. Ministério da Saúde (MS). Portaria nº 2.690, de 5 de novembro de 2009. Institui, no âmbito do Sistema Único de Saúde (SUS), a Política Nacional de Gestão de Tecnologias em Saúde. *Diário Oficial da União*; 2009.
22. Brasil. Ministério da Saúde (MS). Portaria de Consolidação GM/MS nº 1, de 28 de setembro de 2017. Consolidação das normas sobre os direitos e deveres dos usuários da saúde, a organização e o funcionamento do Sistema Único de Saúde. *Diário Oficial da União*; 2017.
23. Brasil. Ministério da Saúde (MS). Portaria GM/MS nº 4.228, de 6 de dezembro de 2022. Altera a Portaria de Consolidação GM/MS nº 1, de 28 de setembro de 2017, para dispor sobre o processo administrativo de incorporação de tecnologias em saúde no Sistema Único de Saúde - SUS. *Diário Oficial da União*; 2022.
24. Porritt K, McArthur A, Lockwood C, Munn Z, editors. *JBI Handbook for Evidence Implementation* [Internet]. [acessado 2023 nov 13]. Disponível em: <https://jbi-global-wiki.refined.site/space/JHEI/4851782/Downloadable+PDF>.
25. National Institute for Health and Care Excellence (NICE). *Implementing NICE guidance* [Internet]. 2022 [acessado 2023 nov 13]. Disponível em: <https://www.nice.org.uk/about/what-we-do/into-practice/implementing-nice-guidance>.
26. National Health and Medical Research Council (NHMRC). *Guidelines for Guidelines* [Internet]. 2022 [acessado 2023 nov 13]. Disponível em: <https://nhmrc.gov.au/guidelinesforguidelines/implement/implementation31>.
27. Canada's Drug and Health Technology Agency (CADTH). *Implementation support* [Internet]. 2022 [acessado 2023 nov 13]. Disponível em: <https://www.cadth.ca/implementation-support-and-liaison-officers>.
28. Brasil. Controladoria-Geral da União Relatório (CGU). *Relatório de Avaliação. Órgão: Ministério da Saúde; Processo de Incorporação de Tecnologias em Saúde (833608)* [Internet]. 2021 [acessado 2023 nov 13]. Disponível em: https://www.gov.br/conitec/pt-br/midias/auditorias/relatorio_avaliacao_cgu-processo-de-incorporacao-de-tecnologias-em-saude.pdf.
29. D'Esposito F, Thomas EE, Oldenburg B. *A guide to implementation research in the prevention and control of noncommunicable diseases*. Geneva: WHO; 2016.
30. Lima SGG, Brito C, Andrade CJC. O processo de incorporação de tecnologias em saúde no Brasil em uma perspectiva internacional. *Cien Saude Colet* 2019; 24(5):1709-1722.
31. Polanczyk CA. *Experiências internacionais em avaliação de tecnologias em saúde: Implicações para o Brasil*. São Paulo: Instituto de Estudos de Saúde Suplementar; 2021.
32. World Health Organization (WHO). *Handbook for Guideline development*. 2ª ed. Geneva: WHO; 2014.
33. Pereira VC, Silva SN, Carvalho VKS, Zanghelini F, Barreto JOM. Strategies for the implementation of clinical practice guidelines in public health: an overview of systematic reviews. *Health Res Policy Syst* 2022; 20(1):13.
34. Jones E. *Practical steps to improving the quality of care and services using NICE guidance* [Internet]. 2018 [cited 2023 nov 13]. Available from: <https://into-practice.nice.org.uk/practical-steps-improving-quality-of-care-services-using-nice-guidance/index.html>.
35. Pereira VC, Silva SN, Vidal ÁT, Lins GV, Barreto JOM. How to improve the dissemination of clinical practice guidelines in the Brazilian Unified Health System? Report of a pilot project. *Heal Res Policy Syst* 2023; 21:22.
36. Hauegen, RC. *Risk Sharing Agreements: Acordos de Partilha de Risco e o Sistema Público de Saúde no Brasil - Oportunidades e Desafios* [tese]. Rio de Janeiro: Universidade Federal do Rio de Janeiro; 2014.
37. Chaves MBG, Cardoso AM, Almeida C. Implementação da política de saúde indígena no Pólo-base Angra dos Reis, Rio de Janeiro, Brasil: entraves e perspectivas. *Cad Saude Publica* 2006; 22(2):295-385.
38. Santos MC, Tesser CD. A method for the implementation and promotion of access to comprehensive and complementary primary healthcare practices. *Cien Saude Colet* 2012; 17(11):3011-3024.
39. Vidal ÁT, Barreto JOM, Rattner D. Barriers to implementing childbirth recommendations in Brazil: The women's perspective. *Rev Panam Salud Publica* 2021; 45:e17.
40. Barreto JOM, Bortoli MC, Luquine Jr CD, Oliveira CF, Toma TS, Ribeiro AAV, Tesser TR, Rattner D, Vidal A, Mendes Y, Carvalho V, Neri MA, Chapman E. Implementation of national childbirth guidelines in Brazil: barriers and strategies. *Rev Panam Salud Publica* 2020; 44:e170.
41. Magalhães R, Senna MDCM. Local implementation of the Family Health Program in Brazil. *Cad Saude Publica* 2006; 22(12):2549-2559.

Article submitted 10/01/2023

Approved 09/05/2023

Final version submitted 11/05/2023

Chief editors: Romeu Gomes, Antônio Augusto Moura da Silva