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Brief Report

Supporting Decisions of the Brazilian Regulatory Agency for Supplementary Healthcare: A Case Study

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ABSTRACT

Objectives: This study aimed to report implementation and partial results of the project "Supporting the Brazilian regulatory agency for supplementary healthcare through health technology assessment actions" conducted at Hospital Sírio-Libanês, Brazil, from 2020 to 2023, through Programa de Apoio ao Desenvolvimento Institucional do Sistema Único de Saúde, a Brazilian Ministry of Health initiative.

Methods: This was a case study conducted at Health Technology Center, Hospital Sírio-Libanês.

Results: From its inception, in 2020, to July 2022, the following activities and products were completed: 59 technical-methodological reports assessing the efficacy, safety, cost-effectiveness, and budget impact of technologies received by Agência Nacional de Saúde Suplementar (ANS) to compose its catalog of drugs products and services; 50 analyses of society contributions from public consultation; 34 methodological or clinical tutorial sessions to support ANS team; 2 templates to systematize the update process of ANS catalog; and one training course on systematic reviews and meta-analysis for ANS team.

Conclusion: The project has contributed to increasing ANS autonomy in the health technology assessment, collaborating to efficiency in technologies offer to the users. By adopting and fostering evidence-based knowledge construction, the project reinforces its bridging role for supporting the consonance between public and supplementary healthcare sectors in Brazil.

Keywords: Brazilian Ministry of Health, health technology assessment, supplementary healthcare.

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Context

The Brazilian health system is comprised by a public system (Sistema Único de Saúde [SUS]), with universal coverage, and a supplementary health sector contracted by almost 50 million individuals.[1] The *Agência Nacional de Saúde Suplementar* (*ANS*, the National Supplementary Health Agency) is an autonomous government agency that regulates the supplementary sector including the relationship between users and health insurance operators, and is responsible for the maintenance of a catalog that states drugs, devices, and procedures that must be at least provided by health plans. This minimum coverage catalog is valid for health insurances contracted from January 1999 and is periodically updated to add, replace, or exclude technologies. This continuous update has been based on a transparent, timely, and inclusive process by relying on social participation. More recently, the process was substantially qualified when implementing standardizations and adopting health technology assessment (HTA) guides and evidence-based health concepts, bringing the HTA approach by ANS closer to the approach adopted by other HTA agencies.

Patient representatives, health professional associations, pharmaceutical industries, researchers, or any member of civil society may submit a proposal to include a healthy technology in the catalog. The submission is electronic and must contain scientific evidence related to the efficacy, safety, or accuracy of the technology (ie, by means of a systematic review), cost-effectiveness or cost-utility, and budget impact analysis related to the incorporation of technologies and information on installed capacity.[2]

In brief, the received proposals follow these stages: (1) analysis for eligibility; (2) critical appraisal of the proposals focused on methodological rigor and adequacy and production of a technical-methodological report; (3) initial internal and external discussions about the report content; (4) emission of a preliminary recommendation from ANS, on whether or not to incorporate the technology; (5) public consultation or public hearing about the preliminary recommendation; (6) quantitative and qualitative analyses of social contribution received; (7) final internal/external discussions; and (8) ANS final recommendation.

Table 1. List of technical and critical reports assessing the efficacy, safety, cost-effectiveness, and budget impact of the technologies received by ANS for incorporation on its catalog.

Technical and critical reports		
Number	Intervention	Population
1	Abemaciclib	Early breast cancer HR+ HER2− with positive lymph nodes and high risk of recurrence
2	Acalabrutinib	Chronic lymphocytic leukemia (first line)
3	Acalabrutinib	Relapsed or refractory chronic lymphocytic leukemia
4	Acalabrutinib	Relapsed or refractory mantle cell lymphoma
5	Apalutamide	Nonmetastatic, castration-resistant prostate cancer with high risk of metastases
6	Apalutamide	Metastatic, castration-sensitive prostate cancer
7	Cabozantinib plus nivolumab	Advanced renal cell carcinoma (first line)
8	Direct biopsy by cholangioscopy (ERCP)	Biliary tract lesions or stenosis suspicious for malignancy
9	Dupilumab	Severe eosinophilic asthma
10	Dupilumab	Severe allergic asthma
11	Drug provocation test (oral and injectable)	Diagnosis of drug hypersensitivity reactions
12	Etonogestrel subdermal implant	Contraception
13	Fecal calprotectin	Diagnosis and monitoring of inflammatory bowel diseases
14	FilmArray® Respiratory Panel	Respiratory tract infections in immunocompromised patients
15	FilmArray Meningitis Encephalitis Panel	Central nervous system infections
16	Gilteritinib	Relapsed or refractory acute myeloid leukemia with FLT3 mutation
17	Ibrutinib	Chronic lymphocytic leukemia/small cell lymphocytic lymphoma (first line)
18	Ibrutinib	Chronic lymphocytic leukemia small cell lymphocytic lymphoma (resistant or relapsed)
19	Integrated photopheresis system	Acute and chronic graft-versus-host disease after allogeneic blood stem cell transplantation, resistant to corticosteroids
20	Intraoperative electron radiotherapy	Early breast cancer
21	Ixazomib	Resistant or relapsed multiple myeloma.
22	Lenalidomide	Multiple myeloma—as first-line therapy or for those cases not eligible for autologous hematopoietic stem cell transplantation
23	Lenalidomide	Multiple myeloma after autologous hematopoietic stem cell transplantation
24	Lenalidomide	Resistant or relapsed multiple myeloma
25	Lenalidomide	Transfusion-dependent anemia due to low or intermediate-1 risk myelodysplastic syndrome associated with cytogenetic abnormality of 5q deletion, with or without additional cytogenetic abnormalities
26	Lenvatinib	Advanced or unresectable hepatocellular carcinoma (first line)
27	Lenvatinib	Locally advanced or metastatic differentiated thyroid carcinoma, refractory to conventional surgical therapy combined with radioiodine ablation, hormone suppression, or external radiation therapy
28	Lenvatinib	Advanced or unresectable hepatocellular carcinoma (first line)
29	Levonorgestrel-releasing intrauterine system	Idiopathic menorrhagia
30	Liver radioembolization	Hepatocellular carcinoma
31	Long-acting reversible hormonal subdermal implant	Contraception
32	Midostaurin plus standard chemotherapy	Early diagnosed acute myeloid leukemia with FLT3 mutation (first line)
33	Neuronavigation	Spine surgery
34	Neuronavigation during surgical therapy	Intracranial tumors
35	Nilotinib	Early diagnosed chronic myeloid leukemia Ph+ with a high-risk Sokal score
36	Olaparib	Relapsed platinum-sensitive high-grade serous ovarian carcinoma with BRCA mutation 1 and, or 2

continued on next page

Table 1. Continued

Technical and critical reports		
37	Olaparib	High-grade ovarian cancer with BRCA mutation and responsive to first-line chemotherapy
38	Onabotulinum toxin	Chronic migraine
39	Online hemodiafiltration	End-stage chronic kidney disease
40	Oral provocation test	Suspected food allergy
41	Pembrolizumab plus axitinib	Advanced or metastatic renal cell carcinoma with intermediate and unfavorable IMDC risk (first line)
42	Radioembolization	Intermediate or advanced hepatocellular carcinoma
43	Radioembolization	Liver-dominant metastatic and unresectable colorectal cancer
44	Regorafenib	Hepatocellular carcinoma (second line)
45	Ruxolitinib	Polycythemia vera (second line)
46	Single-level cervical disc arthroplasty	Myelopathy or radiculopathy refractory to conservative treatment, with indication for surgical therapy
47	Skin test (puncture or intradermal) with drug	Suspected drug allergy
48	Thermoablation	Bone tumors
49	Thermoablation	Lung tumors
50	Thermoablation	Liver metastases
51	Thermoablation	Benign thyroid tumors
52	Thermoablation	Kidney tumors.
53	Trifluridine/tipiracil hydrochloride	Gastric cancer
54	Trifluridine/tipiracil hydrochloride	Metastatic colorectal cancer
55	Ustekinumab	Moderate and severe active ulcerative colitis
56	Vandetanib	Unresectable or metastatic locally advanced medullar thyroid carcinoma
57	Venetoclax	Chronic lymphocytic leukemia after at least one prior therapy
58	Venetoclax	Acute myeloid leukemia ineligible for intensive chemotherapy
59	Vismodegib	Metastatic or locally advanced basal cell carcinoma ineligible for surgery or radiation therapy

Note. IMDC is a risk model for predict survival in in patients with metastatic renal cell carcinoma treated with systemic therapy.
ANS indicates *Agência Nacional de Saúde Suplementar*; BRCA, breast cancer gene; ERCP, endoscopic retrograde cholangiopancreatography; FLT, FMS-like tyrosine kinase 3; HER, human epidermal growth factor; HR, hormone receptor; IMDC, International Metastatic Renal Cell Carcinoma Database Consortium.

All this standardized process has guaranteed robustness and trustworthiness to the decision making, in addition to keep it in line with the methods adopted by SUS. Nevertheless, to proceed within an adequate timeframe and also by adopting rigorous methods during the stages that involve methodological evaluation, the ANS has counted on the impartial support of institutions of excellence in research and HTA and with recognized good reputation.

To enable these collaborations, one of the options available to ANS, as an autonomous government agency, is to establish partnerships in the ambit of the *Programa de Apoio ao Desenvolvimento Institucional do Sistema Único de Saúde* (PROADI-SUS). This initiative was created in 2009 to support and strengthen the SUS through projects demanded by the Brazilian Ministry of Health and focused on human capacity building, research, HTA, governance of health system, and specialized health assistance.[3] The initiative brings together nonprofit hospitals that are a benchmark for healthcare quality and health management in Brazil and that transfer to the population their expertise in actions and products that supply the demands of the SUS.[3]

Objectives

This study aimed to report the implementation and the partial results of the project "Supporting the Brazilian regulatory agency for supplementary healthcare through health technology assessment actions" within the scope of the PROADI-SUS initiative.

Methods

This was a case study conducted at the Health Technology Center from Hospital Sírio-Libanês (HSL), São Paulo, Brazil, within the scope of the PROADI-SUS initiative, and through a partnership with ANS and the Brazilian Ministry of Health.

Results

Project Details

Since 2020, the Health Technology Center – HSL has supported the activities of the ANS through a structural project entitled

Table 2. Methodological and clinical tutorial sessions.

Tutorial sessions		
Methodological (n = 14)	1. Content: methodological issues related to evidence synthesis, cost-effectiveness studies, budget impact analyses and others. 2. Duration: up to 2 hours 3. Setting: remote (Microsoft Teams® platform). 4. Tutors: researchers from Health Technology Center – Hospital Sírio-Libanês.	1. Critical analysis of the ANS template for technical-methodological report 2. Critical appraisal of systematic reviews 3. Critical appraisal of technical-scientific reports 4. Development of a checklist for critical appraisal of budget impact 5. Development of a budget impact worksheet in Microsoft Excel® 6. Development of a checklist for critical appraisal of economic evaluation studies 7. Development of a checklist for critical appraisal of systematic reviews 8. Development of a checklist for critical appraisal of technical-scientific reports 9. Development of a template for condition and technology description 10. Methods for network meta-analysis 11. Methods for budget impact analyses 1 12. Methods for budget impact analyses 2 13. Matching-adjusted indirect comparison 14. Risk of bias of comparative studies and evidence certainty assessment (GRADE approach)
Clinical (n = 20)	5. Content: clinical issues related to practical aspects for using a technology (doses, scheme and duration of the treatment, cointerventions, infrastructure, others) and/or diagnostic criteria for health conditions 6. Duration: up to 2 hours. 7. Setting: remote (Microsoft Teams platform). 8. Tutors: expert physicians from the Hospital Sírio-Libanês staff.	15. Ankylosing spondylitis 16. Antiglaucomatous surgery 17. Autism spectrum disorders 18. Axial spondyloarthritis and psoriatic arthritis 19. Cardiopulmonary bypass and extracorporeal membrane oxygenation 20. Crohn's disease 21. Customized orthoses, prostheses, and special materials 22. Electrical impedance tomography 23. Factor V Leiden mutation 24. Hemotherapy 25. Juvenile idiopathic arthritis 26. Keratoscopy, customized refractive surgery, and cyclotherapy 27. Molecular DNA analysis 28. Multiple sclerosis 29. Nystagmus, iris suture, and blepharochalasis 30. Psoriasis 31. Radiotherapy for head and neck tumors 32. Severe asthma 33. Severe psoriatic arthritis 34. Ulcerative colitis

ANS indicates Agência Nacional de Saúde Suplementar; GRADE, Group Reading Assessment and Diagnostic Evaluation.

"Supporting the Brazilian regulatory agency for supplementary healthcare through health technology assessment actions." The project is conducted under the PROADI-SUS, which brings together HSL team to partner with the ANS team under a formal collaboration. An initial phase was conducted along the year 2020. Given the positive impact of the project in accomplishing its purpose successfully within the established timeframe, it has been renewed for the 3-year period 2021 to 2023.

Therefore, aiming to enhance the process of update the catalog of drugs, devices, and procedures of the ANS, the project comprises 5 mainstream activities and products: (1) development of technical-methodological reports assessing the efficacy, safety, cost-effectiveness, and budget impact of the technologies received by ANS for incorporation on its catalog; (2) analysis of society contributions received during the public consultation about the ANS preliminary recommendation (favor or against incorporation); (3) support to the ANS team, involved in the evaluation of incorporation proposals through tutorials on methodological or clinical issues; (4) elaboration/update of templates to qualify and systematize the catalog update process; and (5) short-duration courses on HTA topics for ANS team.

On-demand prespecified activities and products are requested by ANS team in accordance with their internal demand and are discussed with the HSL team to align activities with the scope of the project.

Project Budget

For the initial phase conducted during 2020, a budget of US dollar (USD) 111 250.45 was approved, with a total of USD 178 110.34 being executed (conversion rate: 1 USD = 4.801 Brazilian Real [BRL]; December 16, 2019, date of project official

approval). For the triennium 2021 to 2023, a total of USD 614 542.65 was approved (conversion rate: 1 USD = 5.497 BRL; April 22, 20219, date of project official approval).

Project Team

The activities and products were elaborated by the research team of the Health Technology Center – HSL composed of 5 health professionals, who graduated in different areas (medicine, physiotherapy, and psychology), with experience in HTA, clinical epidemiology, and evidence-based medicine. In addition, expert physicians from the clinical staff of the hospital participate of specific tutorial sessions to support the ANS team in drawing up practical guidance for using recently incorporated technologies.

Completed Activities and Products

From its inception, in 2020, to July 2022, the following activities and products were completed:

- A total of 59 technical-methodological reports assessing the efficacy, safety, cost-effectiveness, and budget impact of the technologies received by ANS for incorporation on its catalog (Table 1). In its process, there is an evaluation of the efficacy after a complete synthesis of efficacy (usually a systematic review), a full cost-effectiveness analysis, and a budget impact analysis from the perspective of the Brazilian supplementary health system. The economic analysis considers costs relevant to the expenditure of health insurance operators, and incremental budget impacts are considered by ANS in the decision process to maintain an efficient supplementary system. The methodological reports follow the recommendations of the guidelines proposed by the Brazilian Ministry of Health.[4-8] Each technical and critical report is followed by a 2-hour workshop, conducted by the Health Technology Center – HSL team aiming to clarify any issue raised by ANS team after an in-depth reading of the report.
- A total of 50 analyses of society contributions received during the public consultation about the ANS preliminary recommendation (favor or against incorporation) regarding each title are listed in Table 1. The analyses include both a qualitative and a quantitative component synthesizing the number of contributions, direction of the contribution (in agreement, disagreement, or partial agreement with the preliminary recommendation), and type of contributor (patient, family member/friend/caregiver, health professional, professional council, medical society, patient advocacy organization, pharmaceutical industry, individual or representative of health insurance, academic institution, others). All contributions and questions of methodological nature are fully answered. Each analysis is followed by a 2-hour workshop, conducted by the Health Technology Center – HSL team aiming to clarify any issue raised by ANS team after reading the analysis and their respective responses to the society queries.
- A total of 34 tutorials sessions to address methodological (n = 14) or clinical (n = 20) issues of interest for ANS team. The topics addressed during each 2-hour session are listed in Table 2.
- A total of 2 templates to qualify and to standardize the planning, conduction and presentation of the technical-methodological reports that assess the efficacy, safety, cost-effectiveness, and budget impact of proposed technologies. These templates were adopted by all research institutions collaborating with the ANS in the process of updating the catalog and also included a budget impact worksheet model.
- One short-duration course for 25 technical members from ANS and Brazilian Ministry of Health about systematic reviews and meta-analyses. This theoretical-practical 97-hour course was conducted in the remote modality.[9] At the end of the course, 7 protocols or complete systematic reviews were produced by groups of participants, supported by one tutor from the Health Technology Center – HSL. These scientific products addressed the following questions of interest: (1) curcumin for Alzheimer's disease, (2) electroconvulsive therapy versus transcranial magnetic therapy for drug-refractory major depression, (3) electroconvulsive therapy versus antidepressants for major depression, (4) erdafitinib for locally advanced urothelial carcinoma, (5) lurasidone for bipolar affective disorder, (6) pronated position for acute respiratory distress syndrome, and (7) thrombopoietin agonists for refractory idiopathic thrombocytopenic purpura.

Upcoming Activities and Products

Up to December 2023, the following activities are expected to be concluded: 36 technical-methodological reports, 45 analyses of society contributions, 19 clinical or methodological tutorial sessions, and 1 short-duration (40 hours), hybrid-format, theoretical-practical course entitled "Clinical interpretation and critical methodological of studies about oncology drugs and procedures," scheduled to start in October 2022.

Discussion

The performance of health indicators in Brazil depends on both the public health system (SUS) and the supplementary health sector. Several public practices have been progressively incorporated into the supplementary sector, and in parallel, some recommendations about incorporation of procedures, tests, and drugs originated in the supplementary sector and are later evaluated under the broader perspective of the public health system. Therefore, the construction of knowledge based on the best scientific evidence available is an intangible inheritance of the health system as a whole, regardless of whether it is from public or supplementary healthcare.

The overlapping and also parallelism between the 2 systems have led to governmental support toward qualifying the supplementary health in Brazil. In this respect, strategies are necessary to continuously promote the adoption of systematized scientific methods during the evaluation process of the incorporation of new technologies in the ANS catalog, which also includes the need for a technical team qualified in HTA methods.

Through PROADI-SUS initiative, our project completed so far 59 technical-methodological reports assessing the efficacy, safety, cost-effectiveness, and budget impact of the technologies received by ANS; 50 analyses of society contributions from public consultation; 34 tutorial sessions for support ANS team; 2 templates to qualify and systematize the update process; and one training course on systematic reviews and meta-analysis methods.

As a complex project, with external partnerships, over its course, some barriers have been identified and actions to deal with them have been proposed. Such mitigation proposals are more easily and timely implemented when the activity or product depends uniquely upon the operator. Given that the demands from the ANS to the Health Technology Center – HSL depend primarily on the periodicity of the applicants' submissions, there is an evident oscillation in the submissions flow, which has repercussions on the work process and workload of the HSL team. In this volatile scenario, additional caution must be taken to avoid any error and delays in the completion of products and activities.

Given that the process of updating the catalog is continuous and there is a period between the submission of the proposal by the applicant and analysis of the evidence by the HSL team, we have eventually handled with some inconsistencies between the comparators considered in the proposals or in the technical-methodological report and the comparator currently available in the catalog. This has been solved in an effective and transparent manner through extra meetings for agreements between the ANS and HSL at the time of the transfer of the demand, during the conduction of the report, and also during the respective workshop.

The process related to the planning, development, and completion of the activities and products foreseen in the project depends on organizational aspects, such as work methods, internal flows, and compliance, and on the mobilization and articulation of human and infrastructure resources offered by the organizations involved. Thus, facilitators identified during the project, that have been essential to assure the agility and quality of the products and activities, are the use of standardized support tools made available by the ANS and improved during the project, the highly qualified human resources to conduct the tutorial sessions, the operational support of HSL for the feasibility of activities, the effective communication, and the respectful relationship between ANS and HSL teams.

Under the concern of maintaining a service of quality and excellence and respecting the commitment to ANS, the Health Technology Center – HSL has been diligent in applying structured and anonymous questionnaires to evaluate the satisfaction and opinion of the members of ANS after each activity. The analysis of the answers allows for continuous improvement, identification of subliminal issues, and construction of mitigation proposals.

Finally, as expected impact, the actions developed in the project, through technical deliveries, are structuring and have the potential to contribute to the rational choice of technologies made available to users of the supplementary health sector, improving the efficiency of this system

Conclusion

By means of this case study, it was noted that the project "Supporting the Brazilian regulatory agency for supplementary healthcare through health technology assessment actions" has contributed to increasing the autonomy of ANS in the HTA, collaborating with its efficiency in the offer of technologies to the users. By adopting and fostering evidence-based knowledge construction, the project reinforces its bridging role for supporting the consonance between public and supplementary healthcare in Brazil.

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