Development of hard technology for the treatment of diabetic foot: a case study from the perspective of public health

Desenvolvimento de tecnologia dura para tratamento do pé diabético: um estudo de caso na perspectiva da saúde coletiva

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ABSTRACT This is a case study that is aimed at analyzing, from the perspective of public health, the process of development of medical equipment for the treatment of diabetic foot performed by the partnership between the Ministry of Health (MS) and the University of Brasilia (UnB) from December 2016 to January 2019. The analysis observed the behavior of the research group responsible for the production of hard technology in the face of the difficulties in transforming the research into a product with market potential that can be assimilated into the coverage of the Brazilian Unified Health System (SUS), concomitantly with the participation of public health in overcoming some barriers. The partnership between MS and UnB was used as a case study, supported in the qualitative research model with emphasis on methodological processes of mixed typology, but prioritizing participatory observation methods whose unit of analysis is linked to public health. The results showed that the contribution of public health on the production of hard technology minimized gaps for the probable transformation of the idea into a product assimilated by SUS. The participation of public health narrowed the gaps between the areas of knowledge involved, bringing the university closer to a private initiative and regulating institutions.

KEYWORDS Public health. Diabetic foot. Health technology. Public health policies.

RESUMO *Este é um estudo de caso que objetivou analisar, na perspectiva da saúde coletiva, o processo de desenvolvimento do equipamento médico para o tratamento do pé diabético realizado pela parceria entre o Ministério da Saúde (MS) e a Universidade de Brasília (UnB) no período de dezembro de 2016 a janeiro de 2019. A análise observou o comportamento do grupo de pesquisa responsável pela produção da tecnologia dura mediante as dificuldades em transformar a pesquisa em um produto com viés mercadológico capaz de ser assimilado na cobertura do Sistema Único de Saúde (SUS), concomitantemente à participação da saúde coletiva na superação de alguns entraves. Utilizou-se como estudo de caso a parceria entre o MS e a UnB apoiado no modelo de investigação qualitativa com ênfase em processos metodológicos de tipologia mista, mas com prioridade aos métodos de observação participante cuja unidade de análise está vinculada à saúde coletiva. Os resultados observados evidenciaram que a contribuição da saúde coletiva na produção da tecnologia dura minimizou lacunas para a provável transformação da ideia em produto assimilável pelo SUS. A participação da saúde coletiva diminuiu os espaços entre as áreas do conhecimento envolvidas, aproximando a universidade da iniciativa privada e dos órgãos reguladores.*

PALAVRAS-CHAVE *Saúde coletiva. Pé diabético. Tecnologia em saúde. Políticas públicas de saúde.*

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Introduction

Currently, experiences of several governments translated into public policies suggest that the idea of maturity of processes of development and production of new health technologies, more specifically hard technologies[1], can meet expectations in reducing health inequities. Government efforts supported by the triple helix – according to Etzkowitz, "interactions between university-industry-government are the key to innovation in increasingly knowledge-based societies"[2(1)] – have become more present. In Brazil, an important bottleneck for the Science, Technology and Innovation (ST&I) sector is the low rate of technological transfer from universities. If, on the one hand, Brazilian academies have relevance in scientific and technological development, on the other hand, they are immature in the transformation of hard technologies into products with market biases, that is, those capable of being used by health systems, a problem that this article sought to discuss.

According to epidemiological data widely disseminated, in Brazil, chronic non-communicable diseases such as Diabetes Mellitus (DM) are a huge health problem. According to Agência Brasil[3], international studies estimate that around 20% of the cases of wounds and ulcers in the feet of those affected by diabetes – the Diabetic Foot Ulcers (DFU) – can evolve to amputation, reaching an average of 42 thousand lower limb amputations every year. In Brazil, the Unified Health System (SUS) invested around US$ 30 million[4] in 2014 aiming, at treating and monitoring DM patients affected by the DFU, which is considered a condition that imposes

> significant burden on health and economy for the Brazilian Health System, emphasizing the need for health policies aimed at its prevention and improved care[4(10)].

Nevertheless, rationalities such as the medical-sanitary[5,6] and scientific-technological[7] ones are placed side by side. Those related to health, linked to health-disease processes, seek to meet the health needs of subjects based on the protocols, products and processes available in the coverage of the health system; and the scientific-technological ones, which are linked to the development and production of hard technologies, seek to survive the unfavorable environment of innovation and are aimed at meeting the health system's needs through the incorporation of its results. Amid this articulation, the collective health may promote a dialogue with the production of hard technologies that have potential to be incorporated by SUS. Its theoretical-methodological framework may contribute to the reduction of gaps that affect the process of transferring knowledge to benefit of society from the perspective of the development of hard technologies.

Based on this expectation – i.e., from processes that go from the bench to the bedside and that have impact on the population[8] involving universities, government and the private industry – the need to build and consolidate actions that can facilitate the release of academic and technological flows developed within universities is justified so that the outcome of their application actually reaches health systems. To better understand this scenario, this work observed the routine of a research group – called developers – linked to the University of Brasilia (UnB) in the development of hard technology and its interactions with the Brazilian Federal Government and the private industry.

In this context, there is the hypothesis that the actions and practices of collective health can help to transform research into technologies compatible with SUS.

The Unified Health System, Science, Technology and Innovation and the Rapha equipment

Historically, health systems have become complex structures, providing health services that use thousands of products, processes,

procedures and technical standards[9]. Law No. 8.080, of September 19, 1990, known as one of the laws of SUS, shows the conditions for the promotion, protection and recovery of health, organization and operation of the corresponding services. Paragraph 1 of art. 4 includes in the practices and actions of SUS the possibility of research and production of inputs and equipment for health; while art. 6, item VI, presents as one of the actions of SUS the formulation of the policy of equipment and the participation in production[10], which are features that encouraged practices aiming at improving productive and scientific sectors so that there was an increase in the levels of technological incorporation in the network. However, incentives of this nature depend on political regulations, i.e., on the interpretation and government willingness to generate and support healthy conditions so that the phenomenon of the closure of the full cycle occurs more and more – from idea to market.

Meanwhile, concepts such as the economic-industrial complex of health[11] found support and incentive in the Secretariat of Science, Technology and Strategic Inputs (SCTIE), created in 2003, and in its boards – the Department of Science and Technology (Decit) and the Department of Industrial Complex and Innovation in Health (Deciis) – created in 2009 –, demonstrating that the public economic and scientific agenda for the development and production of drugs, inputs and equipment converged. Public policies in health, such as public-private partnerships (PDP) and between the Ministry of Health (MS) and universities, demonstrate that the Brazilian Federal Government seeks to induce favorable and self-sustainable scenarios of ST&I in health. The research project represented by the partnership between the MS and the UnB for the development and production of the Rapha equipment is the case study of this work. It is a portable medical equipment for tissue neoformation to treat and heal lower limb wounds, such as diabetic foot, and can potentially have SUS coverage. The equipment comprises: 1) latex dressings that promote tissue neoformation; and 2) LED light emitter capable of accelerating skin healing, which shows the partnership between the MS and the university for the development of hard health technology. In May 2019, the structure of SCTIE was modified: Deciis was removed, and the 'innovation' component was assigned to the Department that houses the National Commission for Incorporation of Technologies in SUS (Conitec), which is now called the Department of Management and Incorporation of Technologies and Innovation in Health.

Collective Health in Action: contributions to solve problems

Universities are not only responsible for training highly qualified workforce and producing original research, but there is also the expectation of generating innovative technologies that reach society. Open access platforms such as the Brazilian Digital Library of Theses and Dissertations (BDTD) and the Scientific Electronic Library Online (SciELO) – an electronic library that includes a selected collection of Brazilian and Latin American scientific journals – demonstrate that Brazilian universities have reached satisfactory levels to advance the issue of teaching and research, given the number of high impact scientific publications. However, there are few indexed studies that disseminate processes of transferring knowledge from Brazilian universities directly into health systems. It is worth noting that the data that represent the production of innovative technologies that surpass the laboratory environments

and actually reach the market have low dissemination, especially in relation to the development of hard technologies. However, many studies are focused on the measurement of the ST&I indicators that seek to update the panorama on the key elements that sustain growth, competitiveness and development of companies, industries, regions and countries[12].

In this context, collective health is capable of reducing the distances between sanitary and technological rationalities with respect to hard technologies, because it has knowledge about dimensions that travel between scenarios such as health territorialization, health-disease processes, epidemiology, health systems, health policies, health education, social determinants in health, among others[13]. These components are relevant and essential so that the process of technological development carried out within the university incorporates into the hard technology in production aspects that support the performance of activities, such as economic and social impact studies capable of subsidizing technological incorporation with characteristics that help the provision of health services and SUS self-financing.

For the concrete case observed in this study, which is represented by the development of medical equipment developed by UnB for the treatment of diabetic foot with marketable characteristics in compliance with the requirements of Conitec, the role of collective health in seeking to fill the gaps related to overcoming bottlenecks between university research and the appropriation of knowledge by the health system was evident.

In a recent study, Fleury Rosa[14] provided an overview of the influence of interdisciplinary research and the contexts of the field of collective health as methodological perspectives capable of accelerating the development processes of medical equipment. The author suggests that the dialogue between the most varied fields of knowledge and the influence of collective health actions and practices positively influences the innovative environment of universities in the context of hard technology production. In addition, the area of collective health, supported by the triad on epidemiology, management and policies and by social sciences in health, including knowledge on public policies in health, bureaucracies and routines of health systems[15], can reduce gaps that lead to failures in the chain of development, production, marketing and assimilation of hard technology by the Brazilian health system.

Methodology

Methodological Introduction

When we think about health care models, two of them can be characterized as prevalent in Brazil: the health care assistance and the sanitary one. According to Teixeira and Vilasbôas[16(29)],

> SUS 'inherited' the model of hospital-centered and privatized medical care, thus becoming a space for conflicts and negotiations and around proposals for changes or conservation of the care model.

In addition to dealing with these models, supported by MS, SUS is responsible for promoting the development of hard technologies aiming at the return to the system and its self-financing; and the variable health financing[17] is fundamental in the maintenance of these services, since "scarcity is, by definition, an inherent characteristic of resources in any field of human activity"[17(29)]. In this context, as universities are privileged spaces to perform ST&I, they are increasingly becoming co-responsible for the rates of incorporation of technologies in the health system, acting as operating agencies in this process.

However, from the perspective of technological production for equipment, only the process of academic and scientific development is not enough to close the complete cycle, i.e., to leave the research bench and, in fact, meet the health needs of the population. These efforts in the academic field need to go further and break the vicious cycle, in which much of the equipment produced in laboratories and research centers linked to universities is often stored on the 'shelves' of these laboratories, and take a step forward, that is, overcome the valley of death[18]. For ST&I, the valley of death represents the non-transformation of scientific research into innovation, i.e., not transforming scientific research into marketable equipment identified by the registrations and records at the National Health Surveillance Agency (Anvisa) and the Institute of Metrology, Quality and Technology (Inmetro), among other aspects.

In this work, the development of the Rapha equipment was used as a case study[19]. In this scenario, the traditional articulations between government and university were observed and, based on this observation, we sought to verify possible gaps/improvements that exist in this interaction and that are aimed at supplying SUS with hard technology. The method triangulation approach – content analysis, participant observation and bibliographic perspective –, as recommended by Minayo[20], has methodologically guided the data collection and analysis procedure.

Methodological design

The methodological design was based on the qualitative research model with emphasis on methodological processes of mixed typology, prioritizing participant observation methods, whose unit of analysis (qualitative/quantitative) is linked to the interactions of collective health in the development of hard technology. The methodological approach of the qualitative research of Poupart et al.[21], which favors direct observation by selecting place of observation and access to data, was adopted according to the model discussed by Jaccoud and Mayer[22]. This model suggests the description and/or responses to five guiding elements:

> 1) Where are we? It is a description of the place – the place, the objects, the environment; 2) Who are the participants? It is a description of the participants – their names, job positions, characteristics, etc.; 3) Why are the participants there? It is a description of the aims and objectives – the formal or official reasons for their presence there, the other reasons, etc.; 4) What is going on? It is the description of the action – the gestures, the speeches, the interactions, etc.; 5) What is repeated and since when? It is the description of the duration and frequency –background of the group, frequency of the action, etc.[22(267)].

Despite the difficulties of separation between object and researcher, the research routine leads gradually to the design of significant unit formation. In this work, these units are represented by the social actors included in the case study, namely: researchers-developers, liberal professionals, managers of public policies in health, research laboratories and private companies. Understanding, measuring and cataloguing the physical spaces, the participants, the institutions involved, and the integrating public policies are part of the methodological process on a qualitative basis and help to establish a certain distance from the object of analysis. In this work, the applied methodology sought to balance "the rigor of the supposed objectivity of numbers and the fecundity of subjectivity"[23(304)].

Between December 2016 and January 2019, the development process of the Rapha equipment institutionalized people – scholarships, research scholarships and services – and companies. *Chart 1* shows the number of people and companies that participated in this phase.

Chart 1. Quantitative Data: service hiring – people and companies

Development and production of hard technology in health (Dec. 2016 to Jan. 2019)		
Type of institutionalization	**Quantities**	**Area/Services**
scholarships	32	interdisciplinary research
Research scholarships	72	interdisciplinary research
Services provided by people	17	Liberal professionals / various services
Services provided by companies	18	permanent material and consumption

Source: The authors' elaboration. Participant observation/bibliographic source – archive (Support Center for Technological Development – CDT/UnB)[21].

The quantities shown in *chart 1* consist of approximate numbers, which relate type of items inserted in the context of the Rapha project (financial aid to researchers and students; other services provided by people and companies). It is worth mentioning that many contracts linked to scholarships and research had very short periods of validity and/or were cancelled even before they were honored. In this survey, based on data extracted from bibliographic and observational sources, there was an expressive variety of disciplinary matrices involved in the development of the equipment, characterizing the possibility of applying the interdisciplinary process in science, technology and innovation[25].

When the university establishes partnerships for the development of hard technologies, in addition to specialized workforce and investment, the physical space is fundamental. For the Rapha project, the establishment of partnerships between laboratories in various areas was observed, and gradually this approach enabled a scientific circuit focused on problem solutions. We present some laboratories that have been part of this circuit:

• Faculdade do Gamma (FGA/UnB), Faculdade de Ceilândia (FCE/UnB), Faculdade de Tecnologia (FT/UnB), Institute of Biology (IB/UnB), Institute of Chemistry (IQ/UnB);

• Technology Development Support Centre (CDT/UnB);

• Engineering and Biomaterials Laboratory (BioEngLab/FGA/UnB), Biomedical Engineering Laboratory (LAB/FT/UnB), Physics Laboratory (IF/UnB), Chemistry Laboratory (IQ/UnB), Chemical Technology (Lateq/IQ and TecBor);

• Graduate Program in Biomedical Engineering (PPGEB/FGA/UnB); Graduate Program in Health Sciences and Technologies (PPGCTS/FCE/UnB);

• Federal University of Campina Grande (UFCG); Academic Unit of Materials Engineering/CCT/UFCG; Laboratory for Evaluation and Development of Northeast Biomaterials (CERTBIO/UFCG);

• Reference Outpatient Clinic for Diabetes of the Ceilândia Regional Hospital (HRC).

This network represents the separation of goals and research activities, since each laboratory, within its specificity, contributed to the Rapha project by promoting greater chances in overcoming the challenges inherent to this nature of development. Regarding the axis of public managers identified as financing partners, the list of social actors involved in the process of hard technology development increases. Here are some examples of partners:

• Ministry of Health (MS);

• National Health Fund (FNS);

• Secretariat of Science, Technology and Strategic Inputs (SCTIE);

• Department of Industrial Complex and Innovation in Health (Deciis).

It could be observed that the MS follows the evolution of this partnership under two aspects, FNS from the budgetary/financial perspective, and SCTIE and its board of directors in the perspective of scientific and technological development.

On the other hand, methodologies such as the theory and practice in human and social sciences – such as in Paim and Almeida Filho[26] – whose authors discuss interdisciplinary research processes and collective health, complement the methodological design of this work. Furthermore, the case study as a research strategy, according to Yin[19(20)],

> [was privileged in the methodological context] in many situations, to contribute to the knowledge we have of individual, organizational, social, political and group phenomena, in addition to other related phenomena.

Every methodological framework guided this work to monitor the participation of some professionals linked to collective health in the process of development of hard technology.

This work is in accordance with Resolution No. 510, of April 7, 2016[27], as per standards applicable to the humanities. The clinical design was performed at the Ceilândia Regional Hospital (HRC), authorized by the Research Ethics Committee of the UnB, with favorable opinion: CAAE 52305715.6.0000.5553.

Results and discussion

Collective health professionals linked to the Rapha project demonstrated knowledge about interdisciplinary research processes, public health policies and health systems management, which proved to be fundamental to produce hard technology with the possibility of a SUS coverage. Their actions began to be noticed as non-technological/technological problems linked to hard technology began to stand out.

Two aspects were privileged in this work: the scientific and technological development led by the biomedical engineering area, supported by the interdisciplinary research process with emphasis on the role of collective health for the integration of the partnership between the university and the Federal Government; and the events adhering to the process of knowledge translation with possibilities of assimilation in SUS coverage. The participation of collective health in this context is evident through the materialization of some categories resulting from analyses obtained by the application of the qualitative research method, such as 'research activities', 'face-to-face meetings' and 'technical visits'. On these occasions, aspects of Health Promotion in the context of medical equipment were also discussed.

The proposal of the Rapha equipment is guided by the biomedical engineering knowledge area. However, other areas such as Health – Medicine, Pharmacy, Nursing, Public Health, Biological Sciences and General Biology – and Human Sciences – History, Administration, Economy and Political Science – are important in this process.

The themes necessary for the knowledge transfer to SUS – institutions such as Conitec, the Secretariat of Health Care (SAS), the Brazilian Network of Health Technology Assessment (Rebrats) – and their respective attributions were unknown by researchers. Activities related to the productive sector, such as the production of pilot batches with Good Manufacturing Practices (GMP), brochures to request registrations and records from Anvisa and Inmetro, and clinical research with the GMP equipment – scenarios inherent to a favorable environment for innovation – were

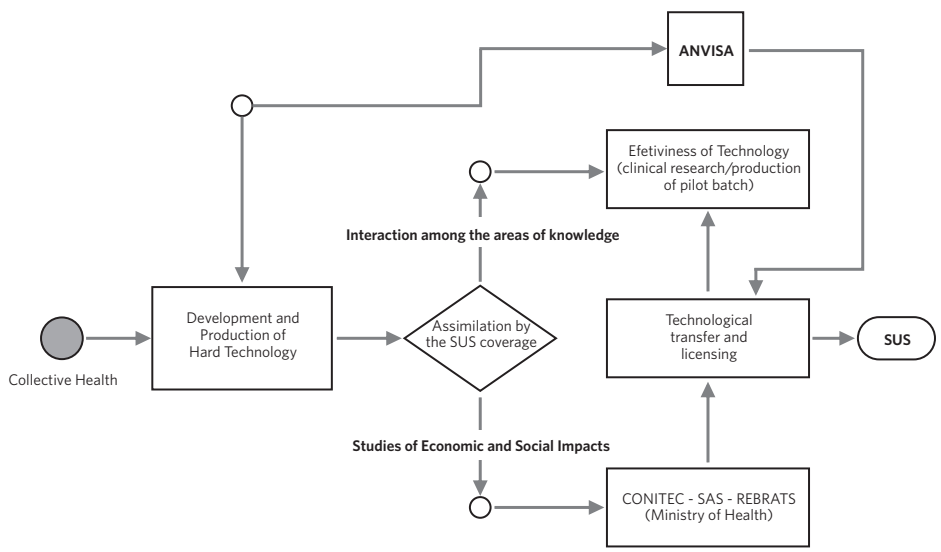
not systematized. The integration of these topics in the development and production process of the Rapha equipment was achieved as they were problematized with collective health support.

The lack of discussions related to the themes mentioned above demonstrated academic immaturity and real risks for the closure of the complete cycle for the Rapha equipment, reinforcing the vicious cycle of only producing intelligent prototypes without any commercial appeal and, still, without any connection with real health needs. In this sense, aiming at reducing these knowledge gaps, two major challenges were faced: to insert in its schedule of activities tasks that included the process of interdisciplinarity in science, technology and innovation; to include in the agenda of this development issues from political, economic and social spheres, bringing to the research the influence of public managers in health, regulatory agencies, market and health promotion. The coordination of the Rapha project was articulated to overcome these difficulties, encouraging collective health professionals to fill in these knowledge gaps.

Collective health was positioned as a facilitator for the development of technology when it took on the responsibility of encouraging changes in the behavior of the group responsible for the development, since it provided practical actions for integrating the areas of knowledge with public managers, the private industry and social aspects in health. Collective health articulated this change by reducing distances: i. promoted activities of an interdisciplinary nature; ii. problematized goals with health managers and the private industry; and iii. introduced economic and social aspects of technology. Actions that enable as outcomes the increase of chances of assimilation of hard technology by SUS have gradually inserted in the development contexts of the Rapha equipment the importance of studying health-disease processes for the epidemiological perspective concomitantly with the maps of technology assimilation by SUS, which is necessarily mediated by private companies.

Figure 1 shows the contribution of collective health in the context of the development of hard technology with the perspective of assimilation by SUS.

Figure 1. Organization chart of action linked to collective health in the production of hard technologies



Source: Own elaboration. Participant observation/bibliographic aspect - contributions of public health in the development of hard technologies.

The capacity of public health to articulate with the reality of low, medium and high complexity care in SUS and its transit within and outside the scenario traditionally recognized as a health sector has accredited it to include in the activities of the Rapha project actions that favor the interaction between areas of knowledge (interdisciplinarity) and prospects and studies of economic and social impacts (assimilation by SUS). Meeting Conitec's conditions, in dialogue with Rebrats and SAS, were aspects that collective health identified and prioritized as necessary in the context of the development of the Rapha equipment.

In this work, from the involvement of collective health, identifying, cataloguing and performing actions that meet the conditions of the guidelines of the agencies linked to the process of incorporation of technologies into SUS are practices that should advance together with the procedures of electronic and biomedical bases that are aimed at taking the research of hard technologies conducted on the bench to the beds of health systems.

All professionals at the same level

Electronic circuits, LED light, blades and/or latex bandages, tissue healing and/or regeneration, debridement of wounds, glycemic levels, health-disease processes, systematic review, epidemiology, public health policies, health systems, financial budget, Anvisa, Conitec, Rebrats and SAS represent actions that occurred in the daily activities related to the development of the Rapha equipment. In the eagerness of events, searching for the transformation of the idea into a product that was compatible with the regulatory and market ordering that, according to the case study, occurred within the laboratories of the UnB, the difficulty in dividing all tasks into separate and overlapping 'boxes' was noticed.

The tendency observed was to apply methodological processes that could, with a certain regularity, delineate a common thread that would tune the largest number of collaborators into the same standard during the longest time possible. This methodology was supported by the interdisciplinary research process in science, technology and innovation and, according to Paul[28(236)],

> this approach is rich, in particular, because it opens to multireferentiality. This supposes a plurality of corpus, models, representations that offer different, contrary or contradictory clarifications to each other.

Collective health was found to have implemented practical actions aimed at integrating and exchanging experiences among professionals from different areas who were institutionalized in the Rapha project. The first action was summarized in 12 events divided into seminars, workshops, mini-workshops and presentations organized by project collaborators and related to some part of the research at that time. This initiative was aimed at bringing together undergraduates, masters, doctors, teachers, public administrators, patients, liberal professionals and representatives of the private industry to discuss specific issues involving topics such as the electrical part of the equipment, latex dressings, patents, production of prototypes, pre-clinical and clinical research and the assimilation process by the health system. The results were satisfactory as the interdisciplinarity was worshipped in practice by the members of the groups focused on the development of hard technology.

Meanwhile, this so-called 'research activity' effort has been designed and applied by collective health in the context of the development of hard technology with the purpose of putting the areas of knowledge to work together. This activity made the interdisciplinary discussion a routine in the development of the Rapha equipment because it was 'compulsory' for all people who received a scholarship.

Round tables: debates and discussions

Another initiative implemented by collective health professionals aiming at the interaction among the areas involved, as observed, was the attempt, through 'face-to-face meetings', to provide a favorable environment to establish a dialogue between the scientific body responsible for technological development and the private sector. In the case of the Rapha equipment, this liaison between the university and the private industry took place for two main reasons: 1) to establish contact with companies that could produce the pilot batch of the Rapha equipment with GMP, a sine qua non condition to reach the Anvisa/Inmetro registrations and records, a stage considered prior to the submission of the hard technology to Conitec; and 2) to initiate technological licensing processes with companies interested in producing the equipment on an industrial scale. Managers trained in contemplating various viewpoints in different organizations and institutions linked to the health sector have made this activity operational.

In practice, the research group oversees scientific and technological development, clinical trials with equipment produced with GMP, registration and record procedures at Anvisa/Inmetro and the assimilation process of hard technology in SUS. Therefore, the participation of the university is not limited to academic and scientific issues. The research group responsible for the partnership with the government needs to add maturity and, within the scope of the project, insert tasks that correspond to the interactions with companies and regulatory agencies.

From the perspective of the Rapha project, approximately 70 face-to-face meetings were held and discussed to find companies to provide services to the project and produce hard technology on an industrial scale, as well as issues related to scientific and technological development and those related to health promotion and prevention. This high number of meetings sponsored by collective health generated more and more healthy conditions for the implementation of the triple helix[29] and for understanding the need to generate data such as economic and social impacts of the use of hard technology. When we carried out documentary analysis linked to face-to-face meetings, such as the calls for such meetings, attendance lists, images of these and minutes on the topics discussed and decisions made, we observed the conceptual evolution of the Rapha project in the perspective of transforming an idea into an equipment that could be assimilated by SUS.

Technical visits: alignment of conducts

Another issue of analysis used in this work was the so-called 'technical visit'. The expectation of demonstrating the results achieved by the research group linked to the Rapha project to the financing and technical public managers, represented by the FNS and Deciis, which did not participate in the constant meetings, is consolidated as meetings between the parties take place, which was not a trivial task in itself. The technical visits were formal and exceptional and were carried out as a method of bringing the university and the MS closer together and vice versa. As the participant observations and textual analysis show, the area of collective health, supported by its experience in public policies in health and planning and management of health systems, converted the technical visits into environments to discuss strategies for the good development of the Rapha project. From this perspective, public health thoroughly explored issues involving the assimilation process of hard technology to treat diabetic foot in SUS coverage. On these occasions, public health managers linked to the MS gradually brought new information on the equipment insertion map to SUS network.

The technical visits depended almost exclusively on logistics and political articulation. Logistics had to do with having to present empirical results that proved the material

development of the research (goals achieved) – which implied the preparation of the research group and demonstration of efficiency and effectiveness of the equipment – and political articulation for the fact that it is not usual, for example, to have the participation of the FNS in this type of meeting, since it has no role in the technical aspect, but only in the financial one.

At the time of the technical visits, specific themes embedded in the process of assimilation of hard technology by SUS were gradually becoming naturalized as mandatory activities within the Rapha equipment research. By analyzing the documental body generated by the technical visits, we noticed that the collective health, with its expertise in processes and management of health systems, was able to extract precise information to help in the constant readjustments made in the activities of the Rapha project in order to meet the demands of Conitec, such as preparing material that demonstrates the economic and social impacts of this technology in health.

Conclusions

This study showed complexity from a methodological point of view, in particular regarding data collection. However, the methodological option applied was the most appropriate when it came to establish the problem and the research questions. Still, in the data analysis, it was possible to see that the UnB has the know-how for the development of hard technology to treat and heal diabetic foot, but it shows little experience in transforming this asset into a product assimilated by the health system. It was also possible to see that public health has made valuable contributions to reduce the difficulties of the research group responsible for the development in understanding and interpreting the conditions for the incorporation of the Rapha equipment in SUS coverage by the private industry. The low rate of incorporation of hard technologies coming from the university by the health system was found to occur less because of the maturity of scientific and technological development and more because of the scarce relationship between the actions and practices of the research group with the determinations of the private initiative and the recommendations requested by the regulatory agencies and those co-responsible for the incorporation processes.

In the analyzed documents and in the experiences, we could observe the prominent role of biomedical engineering and the involvement of the health, biological and human sciences areas in the process of scientific and technological development. They also demonstrated that, for medical equipment, this model is effective. However, the interaction between these areas was pendular, which represented, on the one hand, the functionality of the prototype and, on the other hand, the absence of basic requirements to meet the requests of regulatory agencies and SUS itself. This feature may justify the large amount of functional prototypes being produced by universities that are not able to reach the hospital beds simply because in the beginning of the research it was not thought how to meet the basic requirements related to the market and health systems.

Integration exercises among the social actors involved, such as 'research activities', 'face-to-face meetings' and 'technical visits' were found to have strengthened the links between the areas of knowledge, generating greater approximation between technology and biomedical-based research with the rules of the market and incorporation into the health system. Seminars, workshops, miniworkshops and presentations organized to discuss relevant and multivariate themes of the Rapha equipment research generated a favorable environment for interdisciplinarity. The numerous face-to-face meetings, in the form of round tables, put opposite sides face-to-face with criticism and outbursts that resulted in solutions to specific problems. In

addition, the technical visits raised the discussion to a turning point: the hard technology that is aimed at being part of SUS coverage needs to be approved by the private initiative (Anvisa/Inmetro registrations and records) and Conitec (economic and social impacts, systematic review and other scientific evidence). On all these occasions, insights gradually filled the existing gaps in the innovation environment for the development of hard technology with a market bias. It can be concluded that collective health had a prominent role in enabling the integrations made from the activities listed above.

In the general context, it is necessary that the university include in the inception of its research project to produce hard technology activities aimed at producing the pilot batch with good manufacturing practices; brochures to meet the determinations of Anvisa, conducting clinical research in humans with a market perspective, and strategies to be well evaluated in the controls of technology incorporation in SUS. It is worth mentioning that the research of the Rapha equipment it not concluded and soon we will be able to disclose the outcome of this academic, scientific and technological effort in a scientific narrative format.

In conclusion, as collective health is part of the great area of health sciences and has scientific knowledge on health policies, planning and management of health systems and services for this case study, it has brought important dynamics in the interrelationship between the bench and the bed of SUS, by aligning in the same context medical-sanitary and scientific-technological rationalities.

Collaborators

The authors made different contributions. Rosa MFF (0000-0002-4821-9007)* contributed to the theoretical-methodological conception and the preparation of the work, as well as data acquisition, analysis and interpretation. He was responsible for the entire work and approval of the final version. Guimarães SMF (0000-0002-2097-2355)* contributed to the theoretical-methodological conception and preparation of the work, as well as data acquisition, analysis and interpretation. She was responsible for the entire work and approval of the final version. Dominguez AGD (0000-0002-6481-6055)* contributed to the theoretical-methodological conception and preparation of the work, as well as data acquisition, analysis and interpretation. She was responsible for the entire work and approval of the final version. Assis RS (0000-0001-9446-1286)* contributed to the theoretical-methodological conception and preparation of the work, as well as data acquisition, analysis and interpretation. She was responsible for the entire work and approval of the final version. Reis CB (0000-0003-3982-3939)* contributed to the theoretical-methodological conception and preparation of the work; acquisition, analysis and data interpretation. She was responsible for the entire work and approval of the final version. Rosa SSRF (0000-0002-1247-9050)* contributed to the acquisition, analysis and interpretation of the data. She was responsible for the entire work and approval of the final version. ■

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