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Experience of importation of equipment for research in the ELSA-Brasil

ABSTRACT

OBJECTIVE: Policies that promote research in health were established in the last decade, developing the Brazilian scientific production. This development has not been accompanied by an improvement in the legal-institutional framework, thus hindering the development of research projects, including equipment importation activities. The present study aimed to analyze the equipment importation process for the Brazilian Longitudinal Study for Adult Health (ELSA-Brasil).

METHODS: A case study was performed with data collected from internal ELSA-Brasil documents in five Investigation Centers and their respective supporting foundations. The following importation documents were analyzed: pulse wave velocity, bioimaging and retinography. Additionally, non-structured interviews with researchers and key informers were conducted in the foundations. Data were treated and organized into three stages: administrative-operational, exchange rate, and fiscal. Lengths of duration of these stages were calculated comparatively among centers.

RESULTS: The need to standardize equipment in a multicenter study required a joint action of implementing institutions and foundations. Of all pieces of equipment analyzed, the first stage was administrative-operational, with a varying duration (minimum of eight, maximum of 101, and mean of 55 days) which was longer when legal opinions were included. The second stage was the exchange rate, which was longer than the former and did not pose any obstacles to the process (minimum of 11, maximum of 381, and mean of 196 days). The third stage was fiscal, which was the longest one (minimum of 43, maximum of 388, and mean of 215.5 days), due to the release of equipment without registration into the country. There were other factors that posed obstacles: inexperience of investigation centers and institutions in networking; inadequacy of the national legislation on scientific research particularities; and the lack of specialized professionals in scientific project management.

CONCLUSIONS: The results show the slowness of the equipment importation process in Brazil, especially due to legal, bureaucratic and managerial obstacles.

DESCRIPTORS: Biomedical Technology, legislation & jurisprudence. Durable Medical Equipment. Diagnostic Equipment. Importation of Products. Multicenter Studies as Topic, methods. Cohort Studies. Scientific Research and Technological Development.

INTRODUCTION

Health research in Brazil has always been emphasized. In 2004, it corresponded to 30% of this country's scientific production, primarily developed by Health Sciences groups.^{8,9}

Since the 1950s, there have been initiatives to promote Brazilian research,⁷ but the actual establishment of policies on health research promotion only occurred in the last decade. The following events stand out: in 2000, the creation of the Department of Science and Technology and, in 2003, the Office of Science, Technology and Strategic Inputs – organs belonging to the Ministry of Health, aimed at promoting research on a sector level.^{6,13,a,b}

In 2004, at the 2nd National Conference on Science and Technology and Health Innovation, the National Policy on Science, Technology and Health Innovation was established,^c in agreement with the Brazilian Agenda of Health Research Priorities, with 24 sub-agendas, geared towards the need to develop the *Sistema Único de Saúde* (SUS – Brazilian Unified Health System).^{10,a,b} Additionally, in 2004, the Ministry of Science and Technology and the Ministry of Health signed the first agreement on technical cooperation, establishing the common objectives and goals for health research.^a This institutional interaction gave a great impulse to such research, especially with the release of public notices promoting larger, more complex and extensive investigations, including the formation of research networks.

The interaction between ministries and state institutions that promote research and public resource provision from different sources, according to common policies and agendas, contributed to the significant increase in the public resources invested and the growth in the number of publications in this area, in a relatively short period of time. Since 2003, it is estimated that approximately R\$ 700 million were allocated for 3,600 studies aimed at the challenges of the Brazilian public health.^b However, the institutional-legal foundation, i.e. the legislation on public administration procedures for the acquisition of goods and hiring of individuals or services for research, has not been improved to follow the changes. Consequently, serious operational obstacles remain, hindering research development and probably reducing its productive potential.

The importance of purchasing activities for research projects has increased proportionally with the volume of resources available and complexity of investigations. Their management is considered to be strategic,^{3,12} although the national literature on this theme is still scarce.

The Brazilian Longitudinal Study for Adult Health (ELSA-Brasil) is a multicenter study aimed at following the health of 15,000 adult women and men to investigate the incidence of chronic diseases, especially cardiovascular diseases and diabetes.¹ This study includes six centers from three Brazilian regions and, as any multicenter study,^{2,4,5} its development poses the challenge of standardizing procedures such as specialized tests and respective equipment. In this way, the purchasing activity is particularly challenging and essential to achieve the proposed objectives.

The present study aimed to analyze the acquisition process of medical equipment importation for the ELSA-Brasil.

METHODS

A case study was conducted on the importation of medical equipment for the following three procedures performed in the ELSA-Brasil: pulse wave velocity (PWV), ultrasonography and retinography (Table 1).

Aiming to meet the need for uniformity of clinical tests and technical standardization of equipment, importation was performed jointly by six Investigation Centers (IC) of the ELSA-Brasil. This joint process required the definition of activities to be shared among the ICs and those that could be performed independently (Table 2).

Documentary research was conducted between 2007 and 2009 – the period of equipment importation. Internal reports on management, budgets, tax receipts and equipment importation documents filed in the five ICs (Federal Universities of Bahia, Minas Gerais and Rio Grande do Sul, Oswaldo Cruz Foundation in Rio de Janeiro and University of São Paulo – USP) were consulted. The IC located in the Federal University of Espírito Santo (UFES) was excluded from the analysis as it did not have sufficient data to identify the importation stages and processes. A more in-depth analysis of administrative processes was performed in the state of Bahia, where non-structured interviews were conducted with researchers and key informers (customs officer, importation sector technicians and other institution professionals).

Data were treated and organized into three stages representative of the importation process: administrative-operational, exchange rate-oriented and fiscal. The first stage included specification, approval and negotiation activities, in addition to the documents required for importation. The exchange rate-oriented stage included exchange closing and payment. The fiscal stage included shipping, unloading and customs release and delivery of goods (Table 2). The

^a Ministério da Saúde, Departamento de Ciência e Tecnologia, Secretaria de Ciência, Tecnologia e Insumos Estratégicos. Programa de fomento à pesquisa para os sistemas e serviços locais de saúde: gestão compartilhada em saúde. *Rev Saude Publica*. 2006;40(6):1131-6. DOI:10.1590/S0034-89102006000700025

^b Ministério da Saúde, Departamento de Ciência e Tecnologia, Secretaria de Ciência, Tecnologia e Insumos Estratégicos. Comunicação e informação do Decit: desafios para difusão e monitoramento das ações de fomento. *Rev Saude Publica*. 2007;41(2):313-6. DOI:10.1590/S0034-89102007000200022

^c Ministério da Saúde, Secretaria de Ciência, Tecnologia e Insumos Estratégicos, Departamento de Ciência e Tecnologia. Política nacional de ciência, tecnologia e inovação em saúde. 2.ed. Brasília (DF); 2008. (Série B. Textos Básicos em Saúde).

Table 1. Characteristics of the equipment imported by the ELSA-Brasil.

Test (Equipment)	Function	Characteristics	Responsible for the technical specification	Registered with the Anvisa
Pulse Wave Velocity (Complior SP, Artech Medical, Paris, France).	To measure arterial stiffness, an objective indicator of the level of arterial aging in individuals.	World reference in large studies, the only one on a commercial scale. It enables fast and easy training and does not require a physician to perform it.	Cardiovascular Physiology Reading Center (CP RC).	No
Echocardiography / Ultrasonography (Aplio XG, Toshiba Inc., Toshihi, Japan).	To obtain echocardiography and ultrasound images of the carotid arteries, liver and abdominal wall.	Consolidated the performance of ultrasonography and echocardiography test protocols, associated with the transmission of images to the Data Center and Reading Centers. It is operated by specialized physicians.	Ultrasonography Reading Center (SP IC) and Echocardiography Reading Center (RS IC).	No
Retinography (Canon CR-1 non-midriatic system with EOS40D, digital camera, Cannon, New York, USA).	To photograph the retina and ocular microcirculation.	Ultra-sensitive digital photographic camera connected to a specific software program. It combines wide commercial use, tradition and international recognition of the manufacturer. It enables fast and easy training and does not require a physician to operate it.	Retinography Reading Center (RS IC).	Yes for the 1 st model No for the 2 nd model

ANVISA: Agência Nacional de Vigilância Sanitária (National Health Surveillance Agency)

durations of these stages were calculated comparatively between investigation centers and pieces of equipment. The following categories of analysis were considered for the identification of facilitating factors and obstacles: administrative processes of importation, legal-normative basis, institution's role in the processes and conditions for the acquisition/importation of equipment.

RESULTS

Administrative-operational stage

After the selection of tests by the Assistant Committee of Clinical Tests and remaining technical-scientific levels and their approval by the Directive Committee, the responsible Reading Center (RC) had the task of defining the technical specification of the respective equipment (Table 1).

The Directive Committee defined an IC to consolidate and unify contacts and information, facilitating the joint negotiation of price and warranty conditions and thus enabling significant discounts and an expanded warranty, according to the information available on the "Proforma Invoices", as international invoices are known (data not shown).

A manager responsible for requesting the Proforma Invoice, handling impasses and difficulties, sharing experiences, socializing solutions and, on certain occasions, conciliating the parties involved was designated for each IC. The manager was in charge of informing everyone about the importation in each IC to unify processes and meet the study's general agenda.

Aiming to comply with the criterion of unenforceability (article 25, sections 1, 2 and 3, Law 8,666/93),^d the respective suppliers were asked to submit a "letter of exclusivity", i.e. a document stating that only a certain manufacturer/supplier had the equipment with exclusivity. The legal departments of the foundations understand the need for an official opinion that confirms compliance with the legislation in different ways. Among the five cities studied, three of them (Research and Extension Support Foundation, Foundation for Scientific and Technological Development in Health, and State of Rio Grande do Sul Medical Foundation) included this activity in the process. The administrative-operational stage of certain ICs had the highest number of consecutive days, due to the legal analysis to grant exemption from public tender. Despite the initial difficulty in having a global negotiation and subsequently dividing it among the ICs, the administrative-operational stage was the fastest of the three and lasted a minimum of eight days for the PWV equipment (RJ IC) and a maximum of 101 days for PWV equipment as well (BA IC), with a mean of 55 days. Its length of time of execution was acceptable, although this time could be reduced.

Exchange rate stage

After the administrative-operational stage was concluded, exchange rate closing began, i.e. the procedures performed to pay for the equipment. Law 8,010/90,^e which regulates the importation of goods that are not produced in Brazil and aimed at scientific and technological research in

^d Brasil. Lei nº 8.666, de 21 de junho de 1993. Regulamenta o art. 37, inciso XXI, da Constituição Federal, institui normas para licitações e contratos da Administração Pública e dá outras providências. *Diário Oficial Uniao*. 21 de junho de 1993. Seção 1, p.8269.

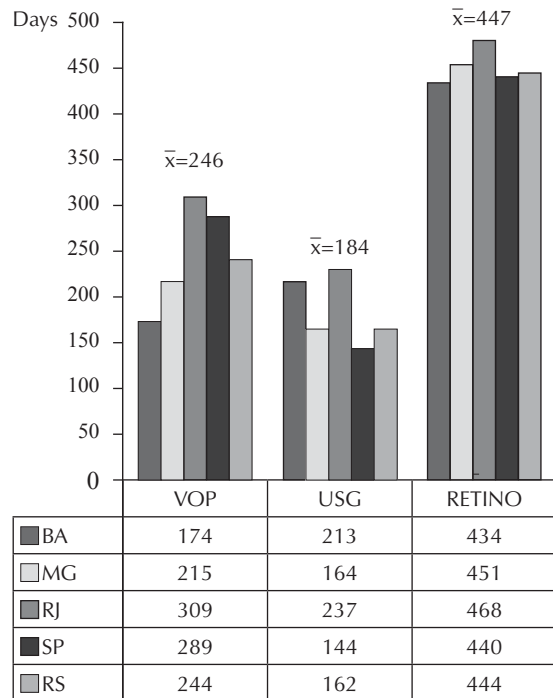
^e Brasil. Lei nº 8.010 de 29 de março de 1990. Dispõe sobre importações de bens destinados à pesquisa científica e tecnológica, e dá outras providências. *Diário Oficial Uniao*. 2 abril de 1990. Seção 1, p.6405.

this country, provides for tax exemption as long as the executing higher education institution and its respective foundation have paid the federal taxes and complied with the requirements. It is the responsibility of the *Conselho Nacional de Desenvolvimento Científico e Tecnológico* (CNPq – National Council for Scientific and Technological Development) to send the list of importing organizations, authorized merchandise, values and amounts to the Federal Revenue Service and the *Banco do Brasil* (BB), particularly to the Foreign Trade Department. The CNPq is the organization that distributes and controls the global quota of importations for research, defined by the Ministry of Economy in agreement with the Ministry of Science and Technology. This information is made available in the beginning of the year and it is known as “importation window” in the jargon of the foundations. Once the authorization is confirmed, the operational activities begin in each foundation (Table 2).

The foundations made a financial commitment, allocating the required amount from the project’s account to guarantee the payment of the equipment, after adjusting the exchange rate according to the foreign currency shown in the proforma invoice. The Importation Permit is the electronic document of authorization processed in the Federal Revenue Service’s Integrated Foreign Trade System, prior to dispatching merchandise abroad and valid for 60 days. After being issued, the BB sent a letter of credit to the exporter – a document proving the financial commitment and international purchase order. The shipping instructions were sent to the exporter, the document with information about shipping with insurance, including the recommended customs officer who was authorized to perform the customs dispatch. The exchange rate stage is centered on foundation activities and it was divided into five activities (Table 2). The exchange rate stage lasted a minimum of 11 days for the PWV equipment (Bahia [BA] IC) and a maximum of 381 days for the retinography equipment (São Paulo [SP] IC), with a mean of 196 days to be concluded.

Fiscal stage

This stage begins with the shipping of the equipment by the supplier and ends when it is delivered to its destination. This is when the equipment is dispatched by the Federal Revenue Service, with the payment of taxes to the Infraero (Brazilian Airport Infrastructure Company) and release by the *Agência Nacional de Vigilância Sanitária* (ANVISA – National Health Surveillance Agency). The customs officer is a dispatcher specialized in importation, regulated and specified by the Foundation, who performs in the majority of the seven activities of this stage (Table 2). After being released by customs, the equipment is transported to the project, where the delivery conditions are confirmed to be adequate by the IC coordinator to make the payment as stated in the letter of credit, thus ending the importation process. In the ELSA-Brasil, this stage was the longest one, lasting a minimum of 43 days for retinography equipment (SP IC) and a maximum of 388 days for retinography equipment as well (Rio Grande do Sul



PWV: Pulse wave velocity

USG: ultrasonography

RETINO: retinography

Figure 1. Duration of the importation process by Investigation Center and mean number of days by type of equipment. ELSA-Brasil.

[RS] IC), with a mean of 215.5 days. This long duration had a direct impact on the study timetable.

RESULTS

The PWV equipment was the first to be standardized and the first to be negotiated jointly as a pilot to adjust procedures and contacts between the ICs and their foundations. The Cardiovascular Physiology RC, responsible for reading 15,000 PWV tests, defined the equipment and its technical specifications. The BA IC was selected to lead the first purchase.

The total time spent between the first attempt to start the importation and the delivery of the equipment in the last IC was approximately ten months, varying from 174 days in the BA IC to 309 days in the Rio de Janeiro [RJ] IC, with an average of 246 days (Figure 1).

Due to the lack of a national registration, the ANVISA required 96 days to release the importation of the PWV equipment, which represented the majority of the 101 days of the administrative-operational stage (Figure 2a).

The importation of the bioimaging device, led by the SP IC, was the one with the highest technical complexity, as it had to comply with the ultrasonography and echocardiography specifications, in addition to enabling the transmission of images produced in the IC to all RCs and

Table 2. Stages and activities for the importation of equipment for the ELSA-Brasil.

Stage	Activities	Documents	Responsible unit
Administrative-operational	1 – Technical specification of equipment	Report and technical justification	Reading Center
	2 – Equipment approval	Directive Committee meeting minutes	Directive Committee
	3 - Contacts with the supplier to negotiate values, warranties and technical support and to request the Proforma Invoice (acquisition proposal and conditions)	Email	Acquisition manager
	4 – Receiving of Proforma Invoices	Proforma Invoice, letter of exclusivity	Acquisition manager
	5 - Sending of equipment documents to the foundation for the start of the importation	Letter of request of acquisition	IC coordination
	6 - Issuing of legal opinions to guarantee that the importation complies with the legislation	Exemption of public tender with legal opinion	Foundation of each IC
	7 - Beginning of acquisition: issuing of internal purchase request	Internal purchase request	Foundation of each IC
Exchange rate	Checking of importation quotas with the CNPq and Federal Revenue Service	Email from the CNPq to inform about importation quotas and deadlines.	Foundation of each IC
	2 - Issuing of the Importation Permit	Importation Permit	Foundation of each IC
	3 - Exchange rate closing by the Banco do Brasil (conversion of the Proforma value into Reais)	Banco do Brasil exchange rate contract	Foundation of each IC
	4 - Issuing of the letters of credit by the bank and of the purchase order by the Foundation to the supplier	Letter of Credit	Foundation of each IC
	5 - Issuing of the international purchase order and payment and shipping instructions	Purchase order and shipping instructions	Foundation of each IC
Fiscal	Shipping of equipment	Proforma Invoice and shipping instructions	Equipment supplier
	Arrival of equipment	E-mail from the supplier	Dispatcher
	Dispatch by the Federal Revenue Service	Federal Revenue Service release	Dispatcher
	Release and payment to the Infraero	Payment of equipment release tax	Dispatcher
	Release by the Anvisa	Authorization for importation	Dispatcher
	Local transport of equipment	Authorization and payment of transport	Transporter, dispatcher and foundation.
	Receiving, checking and confirmation of delivery	Tax receipt confirming delivery	IC coordination

IC: Investigation Center; CNPq: *Conselho Nacional de Desenvolvimento Científico e Tecnológico* (National Council for Scientific and Technological Development); ANVISA: *Agência Nacional de Vigilância Sanitária* (National Health Surveillance Agency).

Data Center (DC). The equipment selected had not been previously registered with ANVISA and it was necessary to wait for its registration to start the importation. Despite the complexity, the total time spent from the beginning of the importation process to the delivery of the equipment to the last center was approximately eight months, varying between 144 days in the SP IC and 237 days in the RJ IC, with a mean of 184 days (Figures 1 and 2b).

The retinography equipment was quickly defined by the Retina RC and the RS IC was the importation manager. The model selected was registered with the ANVISA, as it

had been previously used in the country on a commercial scale. This aspect, which facilitated the process, had not occurred in previous acquisitions, although the importation of this equipment became one of the greatest political-bureaucratic impasses faced by the ELSA-Brasil. As required by the representative of the American company in Brazil, foundations made the payment in advance and the exchange rate stage was quickly concluded, with the exception of the University of São Paulo Medical School, which did not pay in advance and consequently causing this stage to be extended. When the delivery deadline of

60 days expired, the equipment had not been delivered. As it turned out, the American manufacturer had disagreements with the representative in Brazil and claimed that the payment of the six pieces of equipment had not been made. A possible international legal action was discussed. Several contacts were made until the questions regarding this issue were finally clarified, when researchers found out that the model selected for this study was not being manufactured any longer. Consequently, the manufacturer decided to deliver the new model corresponding to the one previously selected, which required new importation documentation and request to the ANVISA, as the new model had not been registered in the country yet. There was a long request process with this health institution until Resolution RDC 1 of January 22nd 2008 from the ANVISA'S Collegiate Board of Directors was published in the Federal Official Gazette on January 23rd 2008. In this resolution, the ANVISA provides for the importation and exportation for scientific research performed by non-profit institutions and/or researchers, enabling the release of equipment for this study. According to the RDC 1, in its article 6, "The inspection and release of imported materials for scientific and technological research purposes will be prioritized. After the protocol and legal requirements are met, a permit will be issued **within 24 hours.**" [bolded emphasis added].

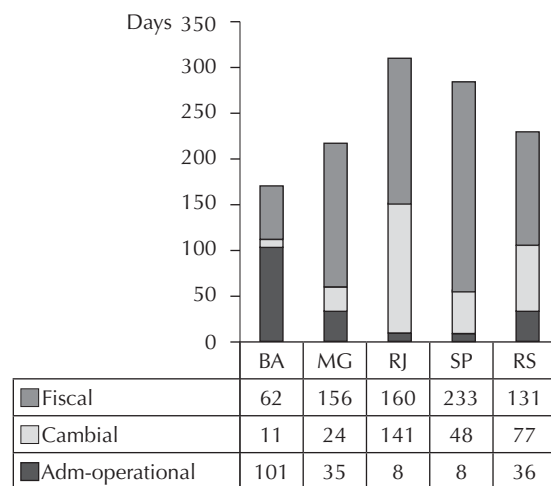
The time spent between the beginning of the importation process by the RS IC and the delivery of the last piece of equipment was the longest of the three, totaling 15 months, without great variations among the ICs and with a mean of 447 days (Figure 1). This caused the retinography equipment fiscal stage to be the longest of all ELSA-Brasil importations (Figure 2c).

When analyzing the contribution of each stage to the duration of the importation process of different pieces of equipment in each IC (Figures 2a, 2b and 2c), the administrative-operational stage – which primarily depends on the flows of activities in the foundation and on the relationship between this foundation and the coordination of each IC – is found to be highly varied, tending to be longer when this stage included the issue of legal opinions (overall mean of 55 days). At times, the situation was worse if these opinions differed from each other significantly, when the Research Funding Agency (FINEP) had to be included to resolve conflicts of interpretation of the legislation and, in this way, continue the importation activities.

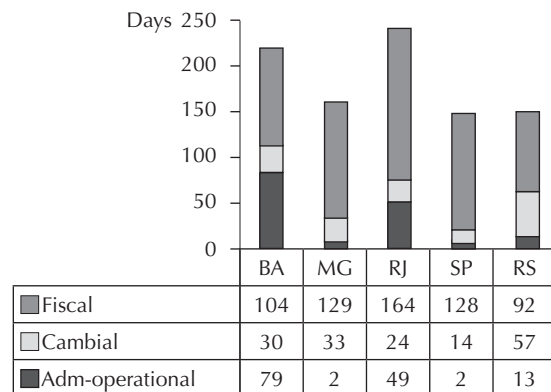
Delays in the exchange rate stage resulted from problems related to the CNPq's institutional quotas and to the "importation window", as it was necessary to wait for the release of annual institutional quotas for importation. This stage lasted 196 days on average from beginning to end (Figures 2a, 2b and 2c).

The fiscal stage was the longest, due to the lack of previous registration in the country, especially for the re-issuing of the retinography equipment importation documents resulting from expired validation deadlines and changes in the model (Figures 2a, 2b and 2c).

a) Pulse wave velocity



b) Ultrasonography equipment



c) Retinography equipment

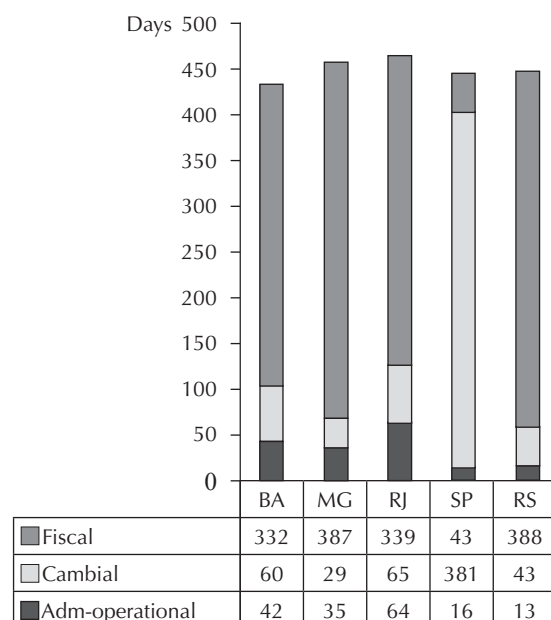


Figure 2. Duration of the importation process by stage and Investigation Center by type of equipment. ELSA- Brasil

DISCUSSION

There were no systematic records on the information required to assess the management of equipment acquisition processes, thus posing a great challenge to the performance of the present study. This resulted, among other things, in the exclusion of one IC that did not have sufficient data on the stages under analysis.

Foundations that support institutions have wide experience in research support with well-defined lifecycles. However, their managerial structure must be adjusted to support longitudinal studies such as the ELSA-Brasil, which require permanent management.

The specificities of a multicenter study, including six implementing institutions and their respective foundations, posed new challenges as they required the standardization of procedures and equipment. This frequently challenged the interpretation of the legal implications by the parties involved, thus increasing the duration of the administrative-operational stage.

The foundations' inexperience in networking was a hindering factor, often resulting in the omission of information and decisions. However, the integration required by this multicenter study led to a broad exchange of experiences, equally productive for centers and foundations. This exchange generated new knowledge and enabled the adoption of corrective measures in the internal routines of foundations and ICs.

The unified negotiation allowed better purchasing conditions with lower prices and an extended warranty of up to 36 months. However, communication between the manager of each IC and the respective foundation was not usually sufficient, requiring processes to be performed again. The technical body of these institutions was not always aware of the decisions of the Directive Committee, which at times prevented the flow of documents required for importation.

What stands out is the importance of previously checking whether the equipment is registered with the ANVISA and whether a special authorization of importation for research is required, including the reason and documentation and calculating the corresponding deadlines in the study planning.

The Brazilian legislation needs to be improved to meet the new requirements of health research activities.¹¹ Law 8,666/93⁴ does not provide for the specificities of scientific research. It should be emphasized that Law 8,010/90^c certainly enabled the conditions of national health research production to be similar to those of international research. This law provides for importation tax exemption in the case of products aimed at scientific and technological research performed by the CNPq, allowing Brazilian researchers to have access to new technologies and input that are unavailable in the national market.

Researchers, regulatory institutions and research support agencies need to improve control mechanisms for importation aimed at Brazilian research to become more dynamic and faster. A more integrated context should be developed, resulting in technological advance and real innovations for society through research funded by public resources. The traditional and strict decision-making structure, apart from the non-specific legislation on science, goes against a process which is dynamic, requires flexibility and has to adapt quickly to the changes imposed by a globalized context.³

Based on the description of the stages required for the acquisition of imported medical equipment and the description of the difficulties, researchers of this study hope to have contributed to the improvement in the management of subsequent ELSA-Brasil stages and other Brazilian research projects funded by public resources and with similar needs.

A manual describing the stages required, legislation involved and information about the types of payment implemented can be useful for research project management, researchers, managers and foundations. It can answer questions, enable administrative processes to be more efficient, and support the qualification and capacity-building of new managers in science and technology, recording the organizational knowledge acquired in the exercise of activities.

The acquisition of materials and goods aimed at scientific research is a concern for all participants involved in this process. It includes the cost and quality of the products acquired, but especially the capacity of public organizations to supply their stocks as fast as it is required, within the deadline of the projects.³

The adequate planning of activities associated with the importation of equipment enables, among other aspects, the reduction in the durations of the three stages previously described. In research, this is reflected in the greater productivity in the execution and compliance with the goals and in the rational use of public resources.

The scarce literature on the theme studied emphasizes the need to invest in project management to guarantee the reduction in its costs and lifecycle.^f With the increase in the financial investment in health research in Brazil,⁹ adequate planning and professionalization of management are key factors to guarantee fast and effective control of processes, especially because this does not turn researchers away from research activities. As a result, high-quality scientific knowledge is produced, which can be the basis for public policies on health.

However, more managers need to be qualified, who, in addition to managing projects, enable the interaction between the academia and public policy institutions, strengthening the purpose of the Ministry of Health and Ministry of Science and Technology.⁸

^f Telles M, Costa S. Gestão de projetos de pesquisa financiados por órgãos de fomento: o caso da Diretoria de Metrologia Científica e Industrial do Inmetro. In: 3. Simpósio de Excelência em Gestão e Tecnologia; 2006 out 16-18; Resende, RJ. Rio de Janeiro: ANGRAD; 2006. p.12.

Research projects are complex processes, including interdependent activities and a high level of uncertainty of results, thus challenging the prediction of risks and hindering management.¹² The ELSA-Brasil, due to its multicenter, multi-disciplinary and longitudinal design, brings new challenges and solutions which foundations, researchers and funding agencies had not experienced before. This study showed results that enable one to rethink the concepts and modus operandi, aiming to help overcome inflexible models of research project management in Brazil. Thus, researchers hope to contribute to the construction of a new context of science, technology and innovation in health and to support promotion policies so

they can achieve their expected results, increasing this country's rank in scientific knowledge production.

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