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DEVELOPMENT OF A NEW REAGENT INVENTORY MANAGEMENT SOFTWARE IN RESEARCH AND CLINICAL LABORATORIES

DESENVOLVIMENTO DE UM NOVO SOFTWARE DE GESTÃO DE INVENTÁRIO DE REAGENTES EM LABORATÓRIOS DE PESQUISA E CLÍNICOS

Thiago Lourenço Cavalcante[1], Alexandre Gomes Vizzoni[2], Danielly Corrêa-Moreira[3], Manoel Marques Evangelista Oliveira[4]

ABSTRACT

Research laboratories and clinical laboratories move, every year, a high number of resources to acquire reagents. However, up to this moment several institutions have no unified system for the management of laboratory reagents in stock, which are essential for the working of these units. Unfortunately, there is currently no free software available to improve stock and reagent replacement plan management in a satisfactory manner. Thus, our objective was to develop and implement a specific platform for the Laboratory Information System (LIS) to control inventory of laboratory reagent kits for the Oswaldo Cruz Foundation (Fiocruz). Being this software developed with open-source technologies, ABC curve, customizable alerts, and application for mobile devices and licensed for open source and free use. We observed a gain in productivity and savings inputs and specialized labor with the development and implementation of the automated platform.

Keywords: clinical laboratory information systems; laboratory reagents; strategic stock.

RESUMO

Laboratórios de pesquisa e laboratórios clínicos movimentam, a cada ano, um elevado número de recursos para aquisição de reagentes. Contudo, até ao momento diversas instituições não dispõem de um sistema unificado para a gestão dos reagentes laboratoriais em estoque, essenciais ao funcionamento destas unidades. Infelizmente, atualmente não há software gratuito disponível para melhorar a gestão do plano de reposição de estoques e reagentes de forma satisfatória. Assim, nosso objetivo foi desenvolver e implementar uma plataforma específica para o Sistema de Informação Laboratorial (LIS) para controle de estoque de kits de reagentes laboratoriais da Fundação Oswaldo Cruz (Fiocruz), sendo esse um software desenvolvido com tecnologias de código aberto, curva ABC, alertas personalizáveis e aplicativo para dispositivos móveis e licenciado para uso livre e de código aberto. Observamos ganho de produtividade e economia de insumos e mão de obra especializada com o desenvolvimento e implantação da plataforma automatizada.

Palavras-chave: *sistemas de informação de laboratórios clínicos; reagentes de laboratório; estoque estratégico.*

1 Information and Communication Technology Service, Evandro Chagas National Institute of Infectious Diseases, Oswaldo Cruz Foundation; Rio de Janeiro, RJ, Brazil. E-mail: thiago.cavalcante@ini.fiocruz.br. ORCID: https://orcid.org/0000-0002-4849-2353

2 Transfusion Agency, Evandro Chagas National Institute of Infectious Diseases, Oswaldo Cruz Foundation; Rio de Janeiro, RJ, Brazil. E-mail: alexandre.vizzoni@ini.fiocruz.br. ORCID: https://orcid.org/0000-0003-0004-5084

3 Laboratory of Taxonomy, Biochemistry and Bioprospecting of Fungi, Oswaldo Cruz Institute, Oswaldo Cruz Foundation; Rio de Janeiro, RJ, Brazil. E-mail: dcorrea@ioc.fiocruz.br. ORCID: https://orcid.org/0000-0002-0931-4204

4 Laboratory of Taxonomy, Biochemistry and Bioprospecting of Fungi, Oswaldo Cruz Institute, Oswaldo Cruz Foundation; Rio de Janeiro, RJ, Brazil. E-mail: manoel.marques@ioc.fiocruz.br. ORCID: https://orcid.org/0000-0001-7670-9225

INTRODUCTION

Research and clinical laboratories move, every year, a high number of resources to acquire reagents. These financial resources are the drive of the health system when it comes to service providing, and one of the main concerns of managers both of the public and private sector, as in most countries health systems face a financial crisis with a funding cut (ABOLHALLAJE, M. *et al.*, 2014; AUTOMATTIC, 2005; BRITTO, 1995; CARPI , 2020).

Over its 121 years of history, the Oswaldo Cruz Foundation (Fiocruz), a reference research center in Brazil and abroad as a center for clinical research, has built different laboratory facilities, with the objective to obtain excellence in clinical research. These facilities, however, often end up operating in a decentralized fashion. Furthermore, until this moment they have no unified system for the management of laboratory of the stock inputs, which are essential for the working of these units. Unfortunately, there is currently no free software available to improve stock management in a satisfactory manner (COLLEGE OF AMERICAN PATHOLOGISTS, 2020; CONTROLLAB CONTROLE DE QUALIDADE PARA LABORATÓRIOS, 2020).

The Evandro Chagas National Infectious Diseases Institute (INI) and the Oswaldo Cruz Institute (IOC), both units of Fiocruz, have high-quality infrastructure, especially in terms of specialized labor, and run many clinical analysis laboratories, as well as laboratories that are national references and others that work with basic and applied research. Some of these laboratories have their analyses regularly audited by national (Controllab) and international (College of American Pathologists) institutions, as they are considered diagnostic and reference laboratories for the Ministry of Health (DANGOTT , 2016; ETEMAD *et al.*, 2015).

Two laboratories of these units are worthy of mention, the Transfusion Agency (AT) at INI, and the Taxonomy, Biochemistry and Bioprospection of Fungi Laboratory (LTBBF), at the IOC. The first is a clinical testing laboratory, while the latter is a research lab. They both provide services to the Research Center. The AT is a hemotherapy service whose mission is to provide the blood components necessary to treat patients hospitalized in the hospital center of Fiocruz, expanded in 2020 for the fight against COVID-19 pandemic. The hospital has 196 beds. The LTBBF does research involving the morphologic, biochemical and molecular characterization of fungi and the authentication of isolates in services made available by the Collection of Filamentous Fungi (CCFF-IOC), as well as the bioprospection of potential therapeutical and diagnostic targets.

The research lines/services developed by these Fiocruz technical-scientific units are mostly funded by national and international sponsoring agencies, and they currently monitor the stock of reagents using manual and/or electronic spreadsheets. The number of reagents and consumables exceeds 500 items.

In the scenario, it becomes complicated and challenging to carry out a systemic management of the institution's laboratory reagents, as each laboratory can work individually, with its own resources, acquiring and using the substances needed for their research projects. Thus, laboratories possess their own stocks of reagents, some of which are in excess and some in insufficient quantities, due to the absence of an electronic management for these substances. This ends up causing or worsening reagent waste, especially due to their expiry date.

In additional to several operational issues, these types of control can also hamper the certification of the units by the different audits they must be submitted to on a regular basis. Among the requisites demanded by some of these audits are full compliance with standard NIT-DICLA-083 (Inmetro Technical Standard - Laboratory Accreditation Division), which describes the need for a minimum, formal and efficient infrastructure necessary for the management of laboratory reagent kits (FACCHINI , *et al*., 2019).

There are countless options of software for this purpose in the market, but very few with demo mode, i.e. available for download for installation or available free online. Some of the free trial alternatives available are: Bika LIMS, Open LIMS, Senaite, eLabFTW, MetaLIMS, Clover, ERPNext: Laboratory Module, GNU Health, C4G BLIS, and OpenELIS. They all have in common the fact that they do not respond in a simple and efficient fashion to the demands of the units under study, requiring steep learning curves in order to be implemented and supported by local teams, altering laboratory routine far too much, presenting little evolution, and sometimes being discontinued (FAESARELLA, 2006; FRAPPE TECHNOLOGIES LIMITED, 2020; FUNDAÇÃO OSWALDO CRUZ, 2021; GEORGIA INSTITUTE OF TECHNOLOGY, 2020; GNU SOLIDARIO, 2020; HENRICKS *et al*., 2016; KONERTZ, 2020; MARKIN and WHALEN, 2000; MEHROLHASSANI *et al*., 2014; MOODLE PTY LTD, 2001).

These systems can be separated as general or specialized. A LIS (Laboratory Information System) is specialized and designed to carry out a limited number of tasks, with the goal of attending to a specific need of the laboratories; they are optimized only for the activities they were designed for. General LIS systems attempt to attend to a higher number of activities or even to all the demands of laboratory units, from technical processes to administrative ones (OPENELIS, 2022; OTWELL, 2019; PONTES, 2014). The concept of LIS first appeared in 1960 and was described as a system consisting of one or more hardware and software modules linked either directly or indirectly to each other, with the goal of managing laboratory information. This information can be technical, administrative, operational, managerial, or a mixture of data (OPENELIS, 2022).

Based on the needs and specificities of the institutions included in the study, as the diversity of services offered, costs involved, freedom to structure the software in a simple way to comply fully with the needs of the institution, with minimum alterations of laboratory routines, we chose to develop new software in a LIS system. The software is available and licensed (register number BR512021002735-3), to be freely used by any governmental institution, including universities, research centers, as well as in Brazil, also in SUS health units.

METHODOLOGY

The project initially identified software options destined to manage stocks of laboratory consumables that offered free trial through download for installation or free online use. After identification, the following software options were tested: Open LIMS, Senaite, eLabFTW, MetaLIMS, Clover, ERPNext: Laboratory Module, GNU Health, and C4G BLIS.

The characteristics evaluated were: a) easiness of use by laboratory teams; b) impact on routine; c), documentation; d), easiness of installation; e), support; f), maintenance by IT teams and g) cycle of active development for the software.

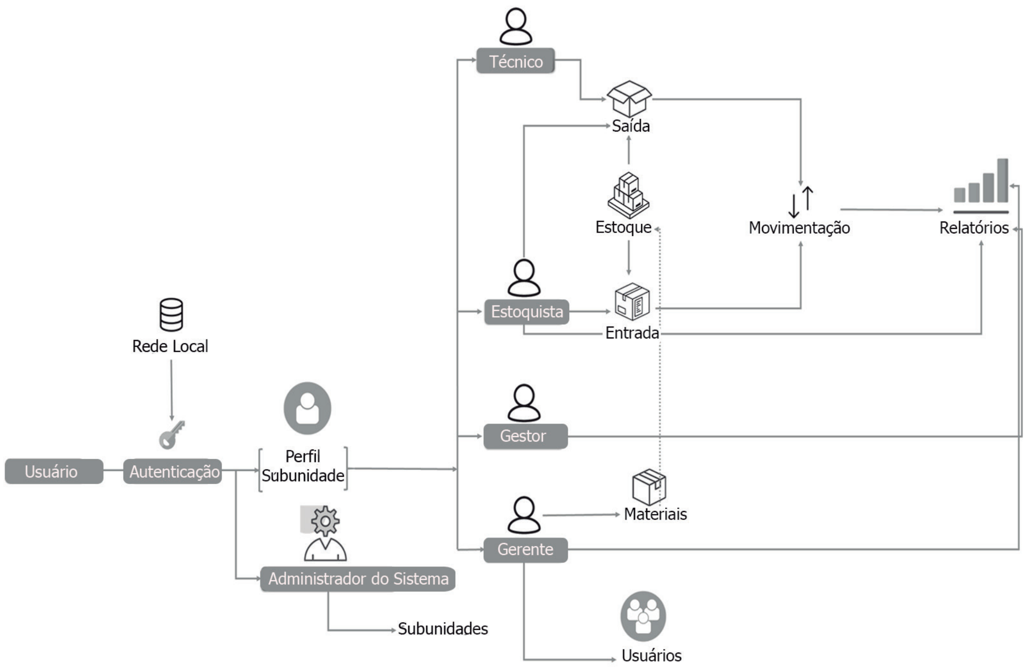
The development of the tool was based on technologies of free use and widely used by the interactional technology community. Control of laboratory reagent kits had to be based on the application of the ABC curve for the management of laboratory reagent kit. In the case of the Brazilian public system, it was necessary to offer the possibility to be integrated with the catalog of materials of the federal government (CATMAT).

The study began at the AT, with the goal of building a system designed to operate with the smoothest possible learning curve and with the lowest costs of implementation for technology teams. For this reason, the system was divided in 5 levels of activity: 1) system administrator; 2) laboratory unit administrator; 3) stock manager; 4) technician; 5) manager. During the second phase, it was implemented at the LTBBF for the adaptation of multi-unit functions, allowing the system to adapt to any of the institution's laboratory units. Access to data is therefore centralized, online, and in real time.

The development structure consists completely of free and public domain software, creating an ensemble with the Linux operative system, PHP programming language, MySQL database managing system, and the Apache web server. This platform is also known as LAMP (**L** - Linux/Operational system; **A** - Apache/Web Server; **M** - MySQL/Database; **PHP** - Programming language) and by the Laravel development base framework. These are all tools that have been available for more than 20 years and that are constantly evolving; they are currently responsible for the infrastructure of a significant part of the Internet and of acknowledged platforms such as Wordpress, REDCap, Moodle, GLPI, and many others REDCAP CONSORTIUM, 2006; RIDING BYTES GMBH, 2020; SENAITE, 2022; SINGAPORE CENTER FOR ENVIRONMENTAL LIFE SCIENCES AND ENGINEERING, 2020; TECLIB, 2015). The hardware infrastructure used is a simple server, containing one X86 processor (64 bits), 1 gigabyte of memory, and 80 gigabytes for data storage.

The Figure 1 is the graphic representation of the formulation of the main resources of the system, making it possible to quickly understand the flows between its resources. It is designed to be read from left to right, beginning with the user, who must log into the system. After authentication, the profiles are read with the goal of defining access to system functions, according to the activities attributed to each user. Once logged into the system, be it through an external account - single institutional login - or an internal one, the user is directed to his/her unit(s) and has his/her access permissions validated and his/her workflow enabled.

Figure 1 - Graphic representation of the formulation of the main resources of the system.



Each user profile has authorizations and attributions suitable for their levels: the System Administration profile has access to all functions above all sub-units and can manage the catalog of users and insert new sub-units, stocks, and access to all system functions. It is destined for the IT department and its access should be restricted to the smallest possible number of professionals. The sub-unit manager(s) is authorized to grant access to technician and stock manager profiles, in addition to material catalogs and alarms generated by the system. The Stock Manager profile is authorized to manage the stock of the sub-unit(s) and can therefore enter input, output, corrections in moving, elimination due to expiry, and access to reports. The Technician oversees entering the removal of sub-unit(s) from stock but has limited actions when it comes to controlling movement and its information. The Manager can extract reports from enabled sub-units, be they financial, of materials stock, or consumption, allowing for managerial decisions.

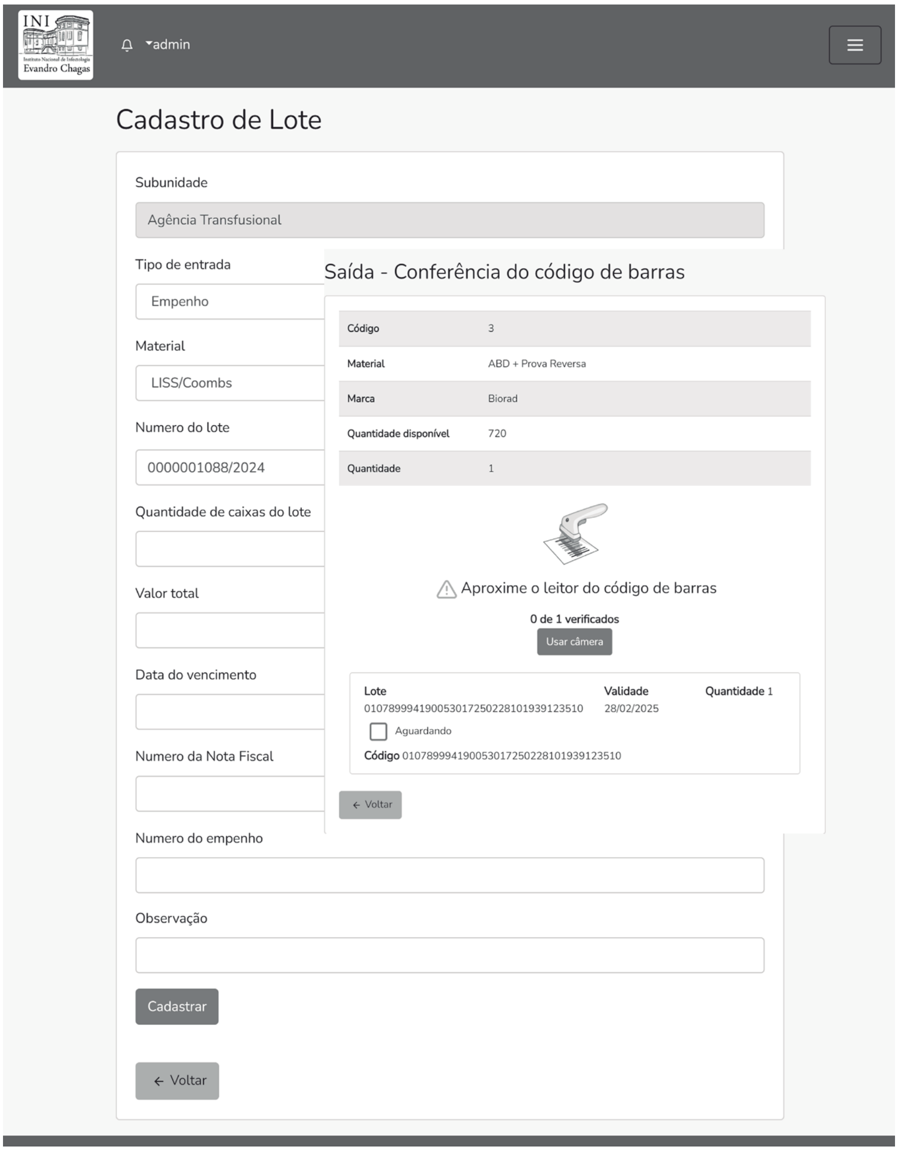
To achieve the final design of the software, some rounds of conversation were made with members of the AT and LTBBF teams, to identify the requisites for the unit to function. An initial version was then developed, and it was evolved several times until a final version was obtained. This final version was tested and then produced, first at the AT and later at the LTBBF. Our ALKINI software is an attractive and free solution for laboratories, providing remote access and focused on the challenge of keeping accurate records of reagent and consumable stocks.

RESULTS

A simple and intuitive system was developed, through which it is possible to adapt functionalities to the unit being used and which can be accessed remotely from anywhere. Additionally, the system provides, in real time, all the information necessary to maintain the activities of the laboratory units included in the study.

ALKINI was personalized during the initial phase: Adaptation to the Laboratory Context in the ALKINI personalized "laboratory" Guidelines contains a customizable document that will provide laboratory members with instructions on software use, with a step-by-step description and rules. A "Manual" menu is always visible in the menu bar of the software, giving access to this document (Figure 2). This document offers instructions on how to enter reagents and consumables into the system and how to register their removal for use.

Figure 2 - Instructions on how to register "Stock in/ Stock out" of reagents and consumables.



The user module can also be customized: It is possible alter parameters according to the specificities of each laboratory, and they are displayed in drop-down menus in user mode. These menu options are customizable, but can only be edited by the laboratory administrator, in administrator mode. In this manner, software options can correspond to the needs of each laboratory.

USER MODE

As the software is started, the user interface can be accessed with username and password. The user must then click on the upper menus (Figure 2) on the home page, where system profiles are displayed, together with some information on the updated status of the consumables available.

ADDING REAGENTS AND CONSUMABLES TO THE DATABASE

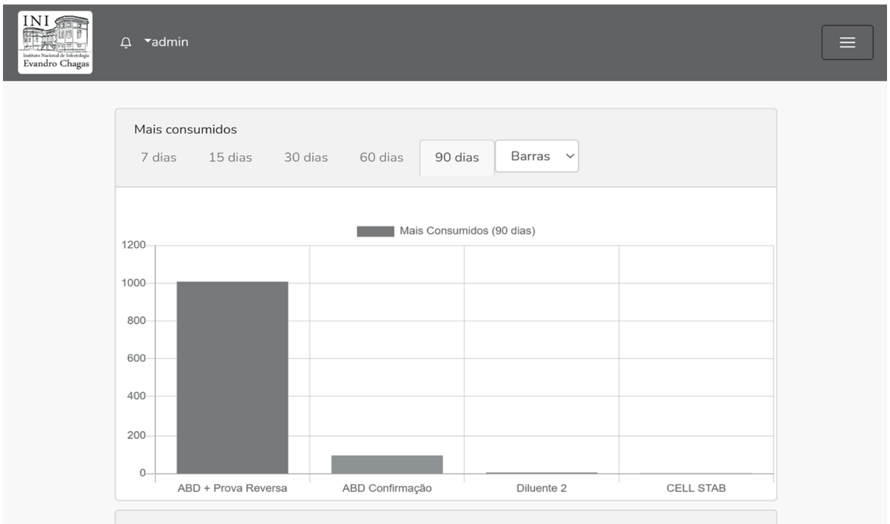
Users can include an item to the "In" menu, entering any information available in the empty fields of the New Entry of the database (Figure 2). Most fields are optional and can be filled in later. To avoid incorrect assumptions when registering data, compulsory fields are marked as such and it is necessary to enter the product's codes provided by the manufacturer. All data can easily be saved, concluded, or modified at any given time by clicking on the edit buttons. Inputs coming in and going out are logged using the barcode or QR code reader (Figure 2). It is also possible to use a smartphone for the same purpose.

The CATMAT screen, a system used exclusively by the public administration of the Brazilian government, containing laboratory consumables is an example of the material registration screen used by the units and all the information that can be entered for reagents and continually updated regarding stock status. To add a new product, the user must only fill in the compulsory fields: Input type, Material, Batch number, Number of boxes, Total value, and Receipt number.

GRAPHIC REPRESENTATION OF STOCK AND UPDATES

After logging into the system, the home screen displays a graphic representation (bars or pie) of the history for a period of 7, 15, 30, 60 or 90 days, for the main items of the laboratory. The goal is to be able to visualize consumption quickly and in real time (Figure 3). These items can be in a table containing the ABC curve data and can be selected by value or units in stock.

Figure 3 - Graphic representation of the items in stock.



An important point is that this system prevents the user from opening a new box or product while there are still reagents available in a box or in a previously used container. It also automatically selects the items closest to the date of expiry, so they are used first. Reagents with a longer date of expiry cannot be used. The manager of the lab unit can follow the expiry of reagents through the "Stock, Expired Batches| menu.

The tool used is 5W2H, applied to different phases of the production cycle or of the providing of services. These tools can be classified as organizational, such as **5W2H** (**W**hat/**W**hy/**W**here/**W**hen is going to be done? /**W**ho is doing to do it? /**H**ow is it going to be done? /**H**ow much is it going to cost?) and Failure Mode and Effect Analysis (FMEA), a model for the analysis of failure modes and their effects. Statistic tools, such as the Pareto diagram (ABC curve) and control graphs were also used (YUSEFZADEH *et al.*, 2015).

For effective stock management, a table display mode was selected, to make it easier for the unit's manager to analyze the ABC curve. The curve is the result of dividing data in three different categories, classes A, B and C, to classify products as for price, yield and criticality. In addition to the ABC curve, a criticality curve known as XYZ curve is also used (Table 1). After treating the data and dividing them into classes, they are arranged in a table or in a graph.

Table 1 - XYZ criticality classification of the items in stock.

Items	Characteristics
Class X	Low criticality. Its shortage does not interrupt the activities of the organization. High possibility of replacement.
Class Y	Medium criticality. Vital for carrying out work. Can be replaced relatively easily.
Class Z	Maximum criticality. Its shortage results in the paralysis of one or more operational phases or the organization. Cannot be replaced.

Source: Adapted from PONTES, 2014.

In the ABC curve (Table 2), products from group A tend to possess 80% of the overall monetary value concentrated into a maximum of 20% of items. Group B products tend to account for 15% of the overall monetary value into 30% of the items. Group C products concentrate 5% of the overall monetary value in 50% of the items. The system is initially working with these values, but they can be altered for full adaptation (PONTES, 2014).

Table 2 - ABC curve.

Items	Characteristics
Group A	80% of the overall monetary value in 20% of the items.
Group B	15% of overall monetary value in 30% of the items.
Group C	5% of overall monetary value in 50% of the items.

Source: Adapted from PONTES, 2014; FACCHINI *et al.*, 2019.

The software was also developed to be used as an app for Android smartphones, with all system functions. It has not been developed for iOS use, but full access is possible through a browser. The software can be scaled for national and international level. In version of launch this software the language is stayed only in Portuguese until registration liberation. This software in Brazil, it can be very useful for the SUS, centralizing laboratory management for basic health units all the way to large hospitals. The only instrument needed is a cell phone with Internet access.

DISCUSSION

With the advancement of technology in recent decades, some activities have increasingly demanded the development of software to help manage public or private laboratories. There is several software for this purpose, but very few with demo mode, available for download for installation or free online.

They all have in common the fact that they do not respond in a simple and efficient fashion to the demands of the units under study, requiring steep learning curves in order to be implemented and supported by local teams, altering lab routine far too much, presenting little evolution, and sometimes being discontinued. Once identifying the requisites, we noticed the need to use management tools in order to guarantee the effectiveness and reliability of the product.

Some laboratory units of the INI and the IOC currently fulfill, in part, item 6.5.3 of the NIT-DICLA-083[9] standard on the mandatory management systems for lab reagent kits. However, the standard does not provide details on the characteristics of these systems, which can lead to non-conformities detected by the audits required for their functioning. This situation has been promoting not only the above-mentioned non-conformity, but also several limitations regarding the control of these reagents, in addition to financial and scientific losses and a drop in the quality of the services provided to users of the institutions and other units of the Unified Health System (SUS) covered by these laboratories (FACCHINI *et al*., 2019).

Stock management is certainly relevant for the activities of government and private companies. The absence of low- or high-turnover materials in stock can generate difficulties to the organization of these companies and sometimes even result in financial losses. The IT tool allows for a correct and efficient management of the stock, minimizing losses for various reasons, from inadequate storage to handling mistakes, and cutting costs of acquisition using predictability, avoiding the use of emergency purchases, which are remarkably more costly (PONTES, 2014). In this context, the ABC curve and the 5W2H methodology are well-established and widely used tools available in the market. However, they are not enough to suppress the risks of shortage. The curve is the result of dividing data in three different categories, classes A, B and C, to classify products as for price, yield and criticality (YUSEFZADEH *et al*., 2013; PONTES, 2014).

The digital tools designed for this purpose are still relatively recent but have evolved quickly in the past few years and companies that have not yet adopted them find themselves at a considerable disadvantage in the current scenario. In early 2020, as the Covid-19 pandemic began, an exponential increase in the consumption of reagent kits occurred as a hospital center was created at Fiocruz. In one of the units of the study became home to 196 Covid-19 beds, which made it impossible to work with the old manual methods, without a standardized stock control.

The system also allows for the use of reagent kits through agreements for exchanges and donations between internal laboratories (within the institution) or external ones, as an additional tool to minimize acquisition costs with reagents. An item not often used at a certain laboratory may be necessary for another one. Moving the products between laboratories generates economy by reducing waste and creating the best possible use for the items purchased.

In short, as time goes by, the ABC curve will provide important information for the annual planning of acquisitions for all units of the institution. In the long run, financial losses due to expired products can be reduced as the yearly provisioning plan of the laboratory units is improved by the digital control of these stocks (PONTES, 2014).

CONCLUSION

The ALKINI software made it possible to centralize the consumption information of the laboratories studied in the institution, minimizing losses and generating economy, helping avoid shortages and, as a consequence, resulting in better service provided to users seeking Fiocruz, a center of assistance and research, a reference in Brazil and in many partner nations.

HIGHLIGHTS

- A simple web system through which it is possible to adapt functionality for the unit and can be accessed remotely.
- The software was developed to be used as an app for Android smartphones.
- The system allows for the use of kits through for exchanges and donations between laboratories.
- The ALKIN made it possible to minimizing losses and generating economy for laboratories.

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