

**The impact of online management systems: a qualitative assessment of staff perception  
at a clinical research laboratory**

**O impacto dos sistemas de gestão online: uma avaliação qualitativa da percepção do  
pessoal em um laboratório de pesquisa clínica**

**El impacto de los sistemas de gestión en línea: una evaluación cualitativa de la  
percepción del personal en un laboratorio de investigación clínica**

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## Abstract

Good Clinical Laboratory Practices (GCLP) increase the quality and traceability of results in clinical research. However, high turnover of staff, insufficient resources, and lack of training in lab management may limit its implementation at Academic Health Centers (AHCs). This work aimed to qualitatively assess the staff perception of the implementation of a freeware Online Management System (OMS) on the workflow of an academic clinical research laboratory. A free online OMS (Quartzy, Quartzy Inc., USA) was selected and implemented from 2012-2016. After training interventions, a qualitative analysis was performed for the staff attitude towards the implementation, including a structured questionnaire (30 participants) and focus group assessments (16 participants). Indicators of management performance were also compared before and after the implementation. The results indicate that lab members perceive improvement in organization, communication, and commitment of staff, who reported the system as user-friendly and a facilitator for the autonomy of group members. On the other hand, there is a recognition of the need for constant training and engagement at the management level. These findings suggest that full-scope OMS may represent useful tools to assist in staff engagement in compliance with GCLP at AHC laboratories.

**Keywords:** Software; Academic health centers; Laboratory personnel; Management information systems; Clinical laboratory information systems.

## Resumo

As Boas Práticas de Laboratório Clínico (GCLP) aumentam a qualidade e a rastreabilidade dos resultados na pesquisa clínica. No entanto, a alta rotatividade de pessoal, recursos insuficientes e falta de treinamento em gestão de laboratório podem limitar sua implantação nos Centros Acadêmicos de Saúde (CAS). Este trabalho teve como objetivo avaliar qualitativamente a percepção dos usuários sobre a implementação de um Sistema de Gerenciamento Online (SGO) gratuito no fluxo de trabalho de um laboratório de pesquisa clínica acadêmica. Um software online gratuito (Quartzy, Quartzy Inc., EUA) foi selecionado e implementado de 2012-2016. Após as intervenções de treinamento, foi realizada uma análise qualitativa da atitude da equipe em relação à implementação, incluindo um questionário estruturado (30 participantes) e avaliações de grupos focais (16 participantes). Indicadores de desempenho de gestão também foram comparados antes e depois da implementação. Os resultados indicam que os membros do laboratório percebem melhora na organização, comunicação e comprometimento da equipe, a qual relatou o sistema como

amigável e facilitador da autonomia dos membros do grupo. Por outro lado, há o reconhecimento da necessidade de treinamento e engajamento constantes do nível gerencial. Essas descobertas sugerem que SGOs podem representar ferramentas úteis para auxiliar no envolvimento da equipe em conformidade com o GCLP em laboratórios de centros acadêmicos.

**Palavras-chave:** Software; Centros acadêmicos de saúde; Pessoal de laboratório; Sistemas de gerenciamento de; Sistemas de informação de laboratório clínico.

## Resumen

Las Buenas Prácticas de Laboratorio Clínico (GCLP) aumentan la calidad y la trazabilidad de los resultados en la investigación clínica. Sin embargo, la alta rotación de personal, los recursos insuficientes y la falta de capacitación en la gestión del laboratorio pueden limitar su implementación en los Centros de Salud Académicos (CSA). Este trabajo tuvo como objetivo evaluar cualitativamente la percepción del personal sobre la implementación de un Sistema de Gestión Online (OMS) gratis en el flujo de trabajo de un laboratorio académico de investigación clínica. Se seleccionó e implementó un software en línea gratuito (Quartz, Quartz Inc., EE. UU.) entre 2012 y 2016. Luego de las intervenciones de capacitación, se realizó un análisis cualitativo de la actitud del personal hacia la implementación, incluyendo un cuestionario estructurado (30 participantes) y evaluaciones de grupos focales (16 participantes). También se compararon los indicadores del desempeño de la gestión antes y después de la implementación. Los resultados indican que los integrantes del laboratorio perciben una mejora en la organización, comunicación y compromiso del personal, quienes informaron que el sistema es amigable para el usuario y un facilitador para la autonomía de los integrantes del grupo. Por otro lado, se reconoce la necesidad de una formación y un compromiso constantes a nivel de gestión. Estos hallazgos sugieren que softwares de alcance completo pueden representar herramientas útiles para ayudar en la participación del personal en cumplimiento de GCLP en los laboratorios de AHC.

**Palabras clave:** Software; Centros de salud académicos; Personal de laboratorio; Sistemas de información gerencial; Sistemas de información de laboratorio clínico.

## 1. Introduction

Academic Health Centers (AHCs) are complex organizations often defined by their "tripartite" mission: to achieve high standards of clinical care, conduct laboratory research,

and educate health professionals (Adamo et al., 2012; Edelman et al., 2017). In the last decades, these university-linked hospitals have increasingly focused on the integration of education, patient care, and research, aiming at the production of knowledge and evidence to serve as the basis for the improvement of the health of patients and populations (Kohn, 2004). In the context of medical sciences and evidence-based medicine, the clinical research is one of the most essential tools for the investigation of pathological basis of diseases, as well as the efficacy of different treatments and procedures, demanding the assurance of quality and integrity of data, with consistent, traceable, reproducible, auditable and reliable results (Ezzelle et al., 2008; Todd et al., 2014). Quality systems such as Good Clinical Laboratory Practice (GCLP) propose guidelines for the organizational process under which studies are planned, performed, monitored, recorded, archived, and reported. (World Health Organization [WHO], 2009). The core elements of GCLP include organization and personnel, laboratory equipment and testing facility operations, quality control program, the verification of performance, sample management, staff safety, and laboratory information systems (Ezzelle et al., 2008).

However, peculiarities of Academic Health Centers increase the challenges for the implementation of quality assurance and good practices, including the lack of trained management staff, limited funding, low focus on customers, and a high turnover of staff, often composed of medical students (Adamo et al., 2012; Grochau & Caten, 2012; Souza et al., 2011; Wartman, 2015). AHC laboratory managers should overcome these challenges by using the available resources in a manner consistent with their institutional reality (Alemnji et al., 2014; Yao et al., 2010). In this context, low-cost, user-friendly tools such as medical informatics may be considered as a key to workflow improvement (Sluss, 2014), and decisive for utilization management (Baron & Dighe, 2014). Indeed, there is a broad range of available laboratory management software, such as laboratory information management systems (LIMS) (Avery et al., 2000). However, these systems are designed mainly with a focus on the management of scientific data and custody of samples and do not contemplate the complete scope of GCLP-related issues.

In the last decade, other types of Online Management Software (OMS) were developed, with a full-scope profile, offering a broader range of management tools. However, there are no reports assessing their suitability to medical research/teaching laboratories, or how laboratory personnel perceives online management and its utility in compliance with good practices.

Therefore, the present study aimed to investigate the implementation of a selected freeware online management system at the clinical research unit of a public, non-profit Academic Health Center, by qualitatively assessing the staff attitude and perception of its adequacy in the search for good practices.

## **2. Materials and Methods**

This work is a quali-quantitative exploratory research, as described in Pereira et al., 2018, based on a Case Study of the implementation of an OMS at a Clinical Research academic laboratory. Briefly, a laboratory management software was chosen and implemented and, after four years of follow-up, the attitude of staff members towards online management was assessed both through a questionnaire of open and closed questions, and interviews on focus groups. Furthermore, a few numerical indicators of changes on workflow and lab usage were compared through data from before and after the implementation of the online laboratory management.

This research was approved by the local Research Ethics Committee (CAAE:53301816.1.0000.5243), and all the participants signed a Free and Informed Consent Term. The consolidated criteria for reporting qualitative research (COREQ) guided the reporting of findings (Tong et al., 2007). Adherence to COREQ Checklist is documented in the Supplementary Table available at the database Mendeley Data, through the link <http://dx.doi.org/10.17632/d5n68ykxjx.1>.

### **2.1 Study setting**

The assessment was performed at the Clinical Research Unit (UPC) at the Antonio Pedro Hospital of the Fluminense Federal University, in the city of Niteroi, Brazil. It consists of a multi-user space, hosting several different clinical research studies. There is a permanent laboratory staff (5 members, including managers and lab technicians), and a variable flow of researchers, scholars, and academics from different healthcare backgrounds. The coexistence of several different studies and respective staff demands careful management and good communication among research groups in order to share equipment, reagents, and facilities.

## **2.2 Selection of the online management system**

Two authors with previous experience in management software conducted an online survey by 2012 (Google, PubMed, Scopus, Web of Science), screening laboratory management systems that offered the broadest range of services provided. Since limited resources are among the main limitations of academic laboratories, the chosen software would have to present as prerequisites: (i) to be available without costs (free) (ii) does not limit itself to a single function and (iii) allow unlimited remote access to the system functionalities. The search identified 158 OMS, from which the majority offered only a limited scope of services (data traceability, test results, or patient/client management). The list of OMS identified through the internet search is available and briefly described as a supplementary Mendeley Dataset (<http://dx.doi.org/10.17632/6sgzw2zk9b.1>). Among the few systems that offered a broader scope of services, the single one offered free of charge was chosen for the present assessment.

Quartzy (Quartzy Company, Palo Alto, USA, [www.quartzy.com](http://www.quartzy.com)), the selected software, is an entirely online-based software for laboratory management created in 2010, available through registration, without restrictions. By the time of its implementation, this system was divided into six management modules: Dashboard (communications module), Inventory, Order Requests, Documents, Equipment Sign-Up (equipment schedule and maintenance), and a "Groups" module for the management of members and staff.

## **2.3 Implementation of the online management system**

The management system was implemented and evaluated from 2012 to 2016. An inventory management plan was started with the reorganization of rooms and exact locations for storage of reagents and materials, the definition of the minimum stock levels (through the consumable output jacks), expiration alerts, reagent safety data, and vendor registration forms. This plan allowed setting the parameters for the uploading of data into the module.

The training was conducted by the laboratory manager, and each step of the implementation was discussed during weekly team meetings. In order to extract the maximum benefits from the OMS, the staff was trained as follows: (i) a four hours workshop on Good Laboratory Practices and GCLP, focusing on how it should and could be applied their actual routine; (ii) a two hours seminar showing software interface and the main functionalities and modules; (iii) an individual practical training where each user became the responsible for the

uploading and registering of data on Quartzzy for at least a week, under supervision. This training was the chance of every user to propose improvements and standardize procedures such as material reception and storage. All thirty research participants were present during training and participated in the next weekly staff meetings, which still reinforced topics on GCLP and the OMS use.

## 2.4 Qualitative and quantitative evaluation of staff perception

*Participants and sampling:* A qualitative evaluation was performed to determine if the software contributed to the improvement of the laboratory in various demands, as perceived by the staff. For this evaluation, purposive sampling was performed with all members of the laboratory who participated in training during the implementation period (n=49). Nineteen of those refused to participate without any declared reason, by not answering the proposed questionnaire and not signing the free and informed consent term, leaving a total sample of 30 participants. This sample was composed of members from all the management and technical levels, including two lab managers, three researchers, one pharmacist, fifteen postgraduate students, seven undergraduate students, and two lab technicians.

There was no drop out during the evaluation. Since a total population sampling was conducted, this study did not consider data saturation.

*Online questionnaire:* Each participant anonymously answered an online questionnaire, with 15 questions, eight of those using a 1 to 5 Likert scale, specifying their level of agreement with a statement or question regarding their attitude towards the online management system, where number 1 would correspond to complete disagreement with the statement, and number 5 corresponds to complete agreement. Four questions were also open and offered space for the answerer to digit his opinion without space limit. The English-translated version of the online questionnaire is available in the link <https://goo.gl/forms/wrQZfj1fkJ0Uv1Bp1>.

Piloting of the questionnaire was performed with three graduate students, in order to assess if the categories were understandable and if answers to the open questions were adequate for the research.

Even though qualitative in nature, the data from answers of the questionnaire on the Likert scale had their frequencies reported as median  $\pm$  interquartile range, that is, there was a statistical treatment. Considering that qualitative and quantitative methods are not excluded



and complement each other, the numerical data lead to a better understanding of the study and greater robustness in the results. (Pereira et al., 2018).

*Focus group:* After the evaluation of the data from the questionnaires, two focus group interviews were conducted on different days, one composed of 16 members, and the other with four members, all from the same sample that answered to the previous questionnaire. The interviews were conducted by two facilitators, a biologist (Ph.D.) and a pharmacist (MSc), both from the management staff of the Laboratory, and experienced in qualitative research. The participants already had a professional relationship with the interviewers, established before study commencement, and were aware of the interviewer's interest in assessing the lab workflow and the OMS. Each meeting included representatives of all management levels. The meetings had a duration from 2-4 hours, where each result of the online questionnaire was presented and openly discussed, with facilitators summarizing the main points and asking for further feedback. The discussions were audio-recorded, transcribed verbatim, compared with field notes and tabulated for subsequent qualitative discourse analysis. Participants were identified in the transcriptions only by their role in the laboratory, followed by a distinctive number. Participants' quotes presented in this work are close translations that preserve original meaning, with authors' inferences inside brackets).

*Coding and data analysis:* The open answer to the questionnaire and recordings of the focus groups were evaluated on a thematic analysis, with a coding tree similar to that of previous reports (Orri et al., 2014). After brief piloting, consisting of a joint evaluation of three questionnaires, the coding of open questions was made with pre-established initial categories and ascertained during reading by two independent coders (MT and DCS, both evaluators with expertise on good laboratory practices). Novel frequent categories and subcategories of answers were included. After definition of the final coding categories, all answers were reevaluated. Discrepant cases were solved by a third author (GGA, a researcher with expertise in qualitative analysis). The frequency of answers containing each coded category was treated numerically and tabulated on Microsoft Excel. The final coding categories and results were submitted to independent checking by an expert researcher (JMG) that had no acquaintance or previous professional relationship with the research participants.

## **2.5 Retrospective analysis**

By 2016, two years after completion of deployment (since it was considered as entirely performed by 2014), a retrospective analysis was performed comparing GCLP and



management-related laboratory workflow indicators, before and after the deployment of the OMS implementation, including the documentation and registry of use of the facilities, and the ratio of users. The retrospective data were collected from the available files at the laboratory secretary and explored by two authors (MT and GA), who tabulated the data on an Excel Spreadsheet for the determination of frequency of use. The data of usage after implementation of the OMS was obtained by printing reports directly from the software.

### **3. Results and Discussion**

#### **3.1 Acceptance and attitude of staff towards the Online Management System**

Two years after the complete deployment of OMS and training, an online questionnaire was applied to all members of the leading research team at UPC (30 members), to evaluate their perception of the impact of the OMS in the lab workflow. Those users were mostly students and trainees, with 37% of respondents (n=11) with less than a year in the laboratory, and another 13% (n=4) with 1 to 2 years of experience in laboratory work at the UPC. From the more experienced participants, four were considered as management-level personnel.

Table 1 shows the results of the Analysis of questions regarding the frequency and ease of use of the Online Management System and its different modules. Most members (80%, n=24) considered themselves adequately trained in the use of the software and its various modules. On a Likert scale of 1 to 5, a median of 4.0 was found for their mastery of the software. Similarly, when asked if they were able to train other users on the platform, the median score was also 4.0, suggesting that training developed confidence in the users, as they judge themselves capable of transmitting this knowledge. During the Focus Group discussion, several members declared that participative and engaged management is fundamental for this confidence, and consequently to the success of implementation.

Concerning the frequency and complexity of the use of the Management System, the modules presented different frequencies of use, reflecting the laboratory workflow. The most used module was the “Equipment Sign-Up,” with a median of 4.5, indicating high adherence to its functions. It is the only module of mandatory use and serves as a facilitator of one of the most common functions of the laboratory activities for most staff members.

**Table 1.** Analysis of questions regarding the frequency and ease of use of the Online Management System and its different modules.

Question	Median (IQR)
Do you master the use of Quartzzy?	4.0(1.1)
Are you able to train others in the use of Quartzzy?	4.0(1.2)
<b>How often do you use the following modules: (1 = never, 5 = always)</b>	
Equipment Sign-Up	4.5(1.5)
Inventory	3.0(1.4)
Order Requests	1.0(0.0)
Documents	2.0(0.7)
Dashboard	3.0(1.4)
What is the easiness of finding items in inventory? (1 = very hard; 5 = very easy)	4.0(0.7)
What is the relevance of the messages posted on the Dashboard? (1 = unimportant; 5 = very important)	5.0(0.0)
Do you know the content of the files available in the Documents module? (1 = none; 5 = all)	3.5(0.8)
Have you used them?	Number of Answers
Yes	16
No	14
<b>If yes, the most used documents were (total number of answers):</b>	
SOP's: 8	MSDS: 4
Minutes of Meetings: 4	

Medians calculated from answers by 30 respondents. IQR = Interquartile Range. Source: Authors.

In the focus group, staff members recognized the differences in equipment sign-up before the OMS:

[Graduate student 1]: Now we can do it online, but I remember we had to schedule equipment use on a notepad, attached to them, weekly, always at Fridays (...) if I had a problem and could not come to cancel, we had to call someone at the lab. We had cases of entire mornings of scheduling lost, with the equipment idle.

[Lab technician 1]: I regret that we did not have the possibility of advanced scheduling (of facilities) before. It saves us a lot of worries during planning.

On the other hand, the “Order Requests” module presented low compliance, mostly due to the already described restriction of its local use, as well as the nature of its offered

functionalities, more related to management-level job descriptions. While the frequency of use of the Inventory module is somewhat neutral (median of 3.0), a higher score (4.0) was attained when users were asked if the items were easy to find (median of 4.0). These results might suggest that users often know the availability and locations of the most common materials in the laboratory. The focal group revealed that they mostly seek the OMS after items that do not belong to their daily routine. As a limitation, it was noted that this module demanded intense training and management for proper registration of materials and equipment in general, and to keep stock updated with materials' entry/exit tables.

Nevertheless, users recognized the utility of the tool by increasing the responsibility of staff members on inventory management and stock control:

[Lab technician 1]: During the training of Quartzzy, everyone had to sit in front of the computer and contribute to the stock survey, to add or delete purchased and used materials... everyone started to have a notion of the amount of material available, or if some item is lacking or almost finished.

[Graduate student 2]: I believe it brings us more awareness and shared responsibility.

[Lab technician 1]: Yes! And if, during the planning of an experiment I need, say, 3 culture bottles, and check on Quartzzy that there are only five available, I now that I should notify the responsible for the purchases.

[Graduate student 1]: I believe that we all contribute to the management, and, even if we have low resources, with the control of stock, we can predict and adequate the use to the budget.

The Dashboard module also presented a neutral 3.0 median for the declaration of use, even though the content of the messages was considered highly relevant (5.0). During the Focal Group discussion, users confirmed that they consider this module an adequate way by which management can reach all the other users:

[Lab technician 2]: It is something very interesting that Quartzzy brought... As an example, sometimes I had to phone call diverse research group leaders to, let us say,

spread the information that a given facility would be idle for “housekeeping” or maintenance. With Quartzzy, we post on the dashboard and reach all the participants!

[Researcher 1]: I think the list of collaborators' e-mails was never updated, with all the comings and goings of the research teams...

The Focus Group discussion brought the observation of the demand of the use of valid, regularly read e-mails (in contrast to faster communications media such as Whatsapp), and the risk of pollution with low-priority messages:

[Graduate student 1]: I am old fashioned... I think that serious management briefings should be sent by email and registered... the new lab access rules, for example, is not something I would spread only through Whatsapp... and this is where I think the Dashboard (module) enters.

[Graduate student 2]: Whatsapp provides more the possibility of conversation, of discussing in real-time the lab problems.

[Lab Technician 1]: I believe it is like that: in the Dashboard, people consider the messages as high priority... something we read and paid attention to, but mostly posted by the management staff.

The Documents module is a meaningful way to manage the distribution of controlled documents critical to the implementation of GCLP. The standardization of procedures from unified SOPs, as well as other documents such as protocols, articles, reports, and others, may strongly benefit from adequate archival methodologies. In the OMS, however, its declared use was attained a 2.0 score, although users declared to know relatively well the files available in this module (median score of 3.5). About half (53%, n=16) of users declared consulting documents in Quartzzy regularly, mainly SOPs (50%, n=15), Material Safety Data Sheets (MSDS) (27%, n=8) and minutes of meetings (27%, n=8), while the other half declared to prioritize the use printed copies available at the workplaces, equipment, and facilities, and online consultation was sometimes limited to planning activities outside the laboratory. The focus group provided some insights on the relevance of the module, regardless of the declared low use:

[Lab Technician 1]: I use it (Documents Module) eventually... I think everyone was used to the printed SOPs, the most important documents there (more than MSDS, maintenance tables...). Moreover, a lot of users have copies annexed to their own notebooks.

[Lab technician 2]: I am always checking the MSDS (at the OMS) to stamp the reagents with (NFPA 704) fire diamonds... for SOPs, the printed copies are more practical on daily use.

[Lab manager 1]: Yes, but to print it, the file must be available somewhere....

[Graduate student 1]: For me, it depends on the procedure or equipment... I usually check it from home when performing something new.

[Graduate student 2]: I think it (Documents Module) is especially interesting for novel users, with doubts on how to use, clean or maintain facilities... It is easier now, and good to know that the documents are all there. I think that the very habit of performing experiments by the SOPs was reinforced during the training and implementation of Quartz (...) the idea that one can only start to use facilities after reading the documentation. People did not necessarily have this habit before.

Table 2 presents the analysis of the questions regarding the impact, advantages, and disadvantages of the implementation of the Online Management System, showing that the potential uses of online management systems could impact the attitude of staff toward the routine of the lab. In this sense, 80% (n=24) of the staff members declared the OMS contributes to some extent to the laboratory workflow.

**Table 2.** Analysis of the questions regarding the impact, advantages, and disadvantages of the implementation of the Online Management System.

<b>How much the implementation of the OMS improved lab workflow?</b>			
Much Improved	22		
Shortly Improved	2		
Not Improved	4		
<b>Benefits</b>		<b>Disadvantages</b>	
Facilitated organization / management	24	There is no Disadvantage	10
Rapid and improved communication	13	Dependence on Internet Access	4
Facilitates scheduling of equipment	16	Need for Constant training	2
Availability of useful documents	6	Constant feeding of data	1
Increases Staff's involvement	4	Monopolization of equipment	1
Generates autonomy in team	5	Idiom (English)	3
		Entry errors	2

Data represent the number of responders out of a total of 30. Source: Authors.

It is important to notice that the remaining 20% (n=4) of the respondents were exclusively composed by recently added staff (graduate students with less than one year experience), who also declared themselves on the questionnaire as not well-acquainted with the software and, therefore, unable to envision an impact on their activities. For the majority that perceived a positive impact on workflow, however, the main pointed reasons are related to an increase in the organization (71% of answers, n=17), and the problem solving related to equipment use and scheduling. Four respondents felt that improved management increases the commitment of the whole group to quality and good practices, and five indicated an increased sensation of autonomy (Table 2). The focus group brought insights into these perceptions:

[Lab technician 2]: Yes, I think that (during OMS implementation) everyone should contribute a little to enable the software to work, so it ended increasing the general commitment.

[Graduate student 4]: You are more independent if you can perform a complete experiment knowing where all the materials are located, where you can obtain the

SOPs or equipment documentation. (You can) schedule the facilities in advance, from home. You do not have to ask anyone, because it is all there (at the OMS).

[Graduate student 1]: the commitment, autonomy, independence increases, at individual rates, obviously... but the responsibility also increases, accordingly.

[Former graduate student 1]: the surprising difference I observed at the selective process I passed (for a job in the biotechnology industry), was that I had a notion of management, stock control and survey, scheduling and maintenance of resources... You do not learn only how to perform a research project, but also to ensure its continuity (...). I think the experience (with OMS) contributes to this differential to graduate students.

Among the limitations of the system, users have recognized the strong dependence of stable access to the internet (13%, n=4) and the need for constant training and maintenance of the online platform (7%, n=2). The focus group discussion has shown, however, that this limitation is surpassed with advancements in communications technology:

[Lab technician 2]: when we had an unstable internet (at the laboratory), it was really a problem. We tried to use a dedicated tablet at the cell culture facility, but you could not count on it every time for consulting an SOP.

[Researcher 1]: but it changed quickly... now almost everyone has rapid internet access on their smartphone, don't it?

[Graduate student 3]: Exactly! And this is good! I do not even depend on our computers to access the OMS if I really need it.

The remote and advanced scheduling of equipment was pointed out as a possible source of monopolization of specific equipment by some users. However, some users pointed out that this problem may be avoided with tools such as the "Favorites" button, which prompts all users (and the equipment manager) when a single user is heavily scheduling a device. The risk of unreported last-minute cancellation of use or scheduling of equipment by



untrained users were also pointed as limitations to be issued case-by-case by each designated equipment manager.

### 3.2 Indicators of laboratory management

A retrospective evaluation was also performed comparing the use of each of the modules with the previous management procedures. Table 3 shows the changes in management-related indicators after four years (2012 to 2016) of the use of the OMS. There was an evident increase, when comparing the initial and final indicators.

**Table 3.** Comparison of laboratory workflow indicators before and after the implementation of the Online Management System.

Indicator	Before OMS implementation	After OMS Implementation
<b>Multi-user Platform</b>		
Registered research groups	5	10
Registered facility users	15	68
Available Multiuser Equipment/facilities	5	20
Average Registered Schedules/month*	20.2	134.7
<b>Availability of Documents</b>		
MSDS	0	47
Guides (ex: ISO-17025)	1	7
Minutes of staff meetings/year**	4	19
SOP`s	20	58
Registered Inventory Items	103	663

\* represented as an average of three consecutive months \*\* represented as an average of four years.  
Source: Authors.

The group's module offered a link for personal messages to the registered email of any other member, which is very useful in a multi-user environment where mixed research teams coexist. The total of registered research groups by the end of implementation, with a four-fold increase in the number of members with access to UPC facilities and scheduling of services

(Table 3). While this increase may be related to several factors not necessarily related to the online management, it was pointed out by a management-level staff member during the focus group that the attractiveness and wide online spreading of the platform may facilitate the recruitment of new research lines.

Regarding the Inventory module, Table 3 shows the marked increase in the number of different items registered and controlled after OMS implementation. According to the focus group, this increase is more related to the addition of previously existing unregistered items than to the acquisition of novel products:

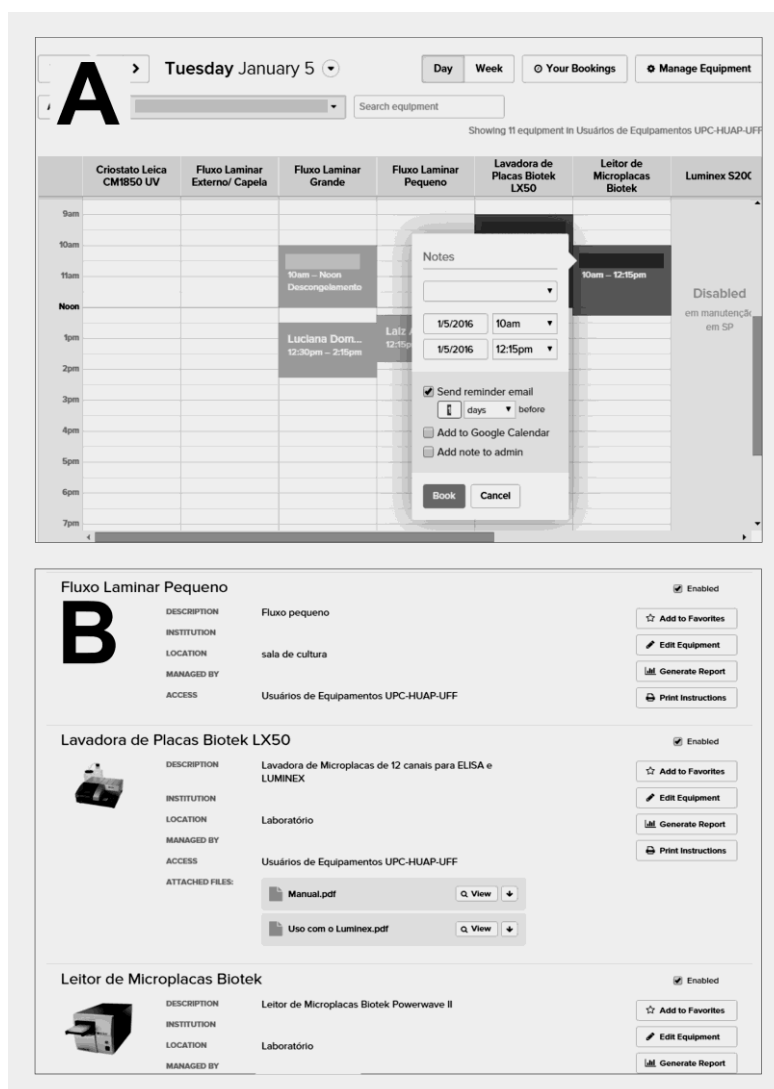
[Lab Manager 1]: The quantitative data available online now allows me to promptly find materials we did not even remember we had... also, the evaluation of the real need to purchase new items, avoiding the repurchase of existing materials. (...) we can also track of expiry dates, using the pre-set warnings of the end of valid use.

The availability of registered documents in the laboratory after implementation of the Documents module also presented, as shown in Table 3, a five-fold increase when compared to the pre-implementation period. This increase permeated all types of GCLP-related documents (MSDS, guides, minutes of staff meetings and SOPs).

After the implementation of the multi-user scheduling through the Equipment Sign-Up Module, users could identify online the existing schedules for each equipment and book their needs by checking the time on the calendar which was automatically updated. Though the "Favorites" field, regular users of any given equipment could mark their preference for improved information on selected items, and include a warning sent by e-mail every time other users scheduled it. Each equipment's technical manager may insert files on maintenance, manuals, SOPs, and even enable or disable assets on the "Manage equipment" field. Table 3 shows an increase in monthly use of equipment by almost seven times, as well as the mean scheduling per user (from 1.35 before the OMS to 1.98 after implementation). This comparison is possibly more related to sub-notification of use before the implementing of electronic registration, as participants reported, during the focus groups, that they often did not use the printed scheduling tables while using the equipment.

Figure 1 shows two screenshots of the OMS, on its equipment management section, where scheduling could be performed online by users (Fig. 1A), and data pertaining to maintenance, management and functioning status could be accessed by any member of the platform (Fig. 1B).

**Figure 1.** Screen captures of the "Equipment" module.



A. Appointments within the Online Management System. The menu for the equipment schedule includes the option for reminder emails and annotations. B. Equipment Management function, including the name of the manager, location, links to manuals and documents, and other data. The button "Add to Favorites" at the top right, allows the inclusion of the equipment on a preferred list, including warnings by e-mail. The names of users were suppressed for anonymity. Reproduced with authorization from Quartzy Inc. Source: Authors.

The data collected from the questionnaires and the discussions during the focus group regarding the different modules of the OMS enabled a comparison with the different scopes of GCLP compliance (3), which is shown in Table 4. It is possible to observe that all modules present applicabilities in the compliance of at least one GCLP item, even though presenting declared limitations and critical points in their implementation.

**Table 4.** Main strengths and limitations of the OMS modules for the compliance with GCLP items.

Module/Interface	Applicability	Item of GCLP*	Critical points/Limitations
<b>Groups</b>	Easy inclusion/removal of users and sub-groups to integrate laboratory teams; Establish levels of access to equipment, facilities, and documents.	Contributes to <b>Organization &amp; Personnel</b> , by keeping track of staff numbers, identification, and organizational charts.	Demands rigorous control and updating of the membership and access to the different interfaces of the OMS.
<b>Dashboard</b>	Exchange messages for specific users or groups Posting of documents of general use for download	Enables the establishment of a Communications Plan, with traceability of exchanged messages for <b>Quality Management</b> .	Demands the use of valid, regularly read e-mails Risk of pollution with low-priority messages
<b>Documents</b>	Filing and distribution of documents Keeps track of staff meeting records (minutes).	Traceability for <b>Records &amp; Reports</b>  Distribution of documentation (MSDS) for <b>Personnel Safety</b>  Ample distribution of SOPs for <b>Testing Facility Operations</b>	Demands continuously active internet connection for consults  Control of experimental data and reports usually less complex and efficient than conventional LIMS
<b>Inventory</b>	Keeps registration of all materials, reagents, kits, consumables and office supplies; Easy location of required materials; Easy inventory update.	Allows inventory control and organization of storage, as demanded by <b>Test and Control</b> .	Needs training for proper registration of materials and equipment in general. Demands tight management to keep stock updated with material entry/exit tables
<b>Equipment Signup</b>	Easy remote scheduling for multi-user equipment; Control of equipment used by different groups  Allows attachment of documents, guides and maintenance data	Digital traceability of maintenance and calibration of <b>Equipment</b>	Risk of unequal distribution of use caused by high loads of advance scheduling  Risk of unreported last-minute cancellation of use.  Risk of the scheduling of equipment by untrained users.

<b>Order Requests</b>	Keep a register of suppliers of materials and reagents. Allows direct purchases from registered funding sources.	Tracking of lot data for materials in the <b>Test Facility Operation</b> . Improves assay repeatability by registering suppliers.	It only accepts purchases from specific international suppliers.
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\* Items identified in bold excerpted from the WHO Good Clinical Laboratory Practice Guide (3).  
Source: Authors.

Clinical research activities conducted following good practices can contribute to the development of new drugs, procedures, and strategies (Adamo et al., 2014), that could be positively impacted by improved laboratory management at AHCs. However, the lack of evidence in the scientific literature on how the use of informatics, through online management systems, may contribute to administration of communications, stock, and shared used of resources, limits the rational use of these tools in the search for quality and good practices at academic environments. In this regard, different methodological approaches may contribute to assess the impact of online management, including the evaluation of quantitative indicators of performance on outcomes related to service provision, of particular relevance in commercial laboratories, or those providing regular services such as clinical test results. However, the complex nature of the provided services of a multiuser, academic clinical research laboratory, supporting multiple projects with different aims (academic publications, research, and development of products, advice to public health policies, among others), specificities and schedules, may impair the obtention of feedback through comparable quantitative indicators. Nevertheless, other parameters may effectively contribute to understanding the influence of OMS on the search for quality at academic clinical research laboratories, such as the perception and attitudes of staff towards laboratory management and workflow. Indeed, several authors (Lulie et al., 2014; Presot et al., 2014; Rusanganwa et al., 2019) have shown that insights on the experience and perception of the laboratory staff and collaborators may provide data for the development or improvement of actions and strategies, as well as training the workforce in the dissemination of laboratory quality, and strengthening management toward accreditation.

This study employed mainly a qualitative approach to investigate if the implementation of an online system would positively impact their perception of involvement in laboratory management at an Academic Health Center. A possible source of bias in the present study must be noted, since part of the data were collected by two interviewers with previous professional relations with the participants, and all respondents knew the objective

and intentions of the research. In order to reduce the interviewer/interviewee relationship interference on data interpretation, the analysis was submitted to outside check by an independent evaluator. Nevertheless, the concordance of results from the focus groups and the anonymously answered questionnaires points to consistence on the data, that altogether, indicate a positive perception towards the implementation of the OMS on the multi-user lab environment. Furthermore, such perception also reflected on the staff attitude, as they considered the online management a mediator of engagement and commitment to steps related to the compliance with core GCLP issues (Todd et al., 2014).

Since academic laboratories usually have a high turnover of staff (students, researchers), the existence of a Group's module becomes a facilitator for the administrator/manager to add, remove, or determine the level of access of members, keeping the history of changes within the system and ensuring traceability, and also actively contributing to planned approaches for the prolongation of useful life for healthcare equipment (Halbwachs, 2000). After the OMS implementation, an increased number of healthcare professionals could benefit from the facilitated access to the multi-user environment, without loss of track of the laboratory organizational chart, one of the most critical items of the Organization & Personnel section of GCLP (WHO, 2009), which the OMS may help to comply. However, the rigorous control and updating of the membership remain a responsibility of the lab (and online platform) administrators, as pointed out during the focus group.

Quality management is another aspect of GCLP that could strongly rely on informatized tools, mostly regarding the establishment of a Communications Plan (WHO, 2009), with traceability of exchanged messages. In the tested OMS, the Dashboard module was the place where fast communication occurred between users, including scheduling of meetings, urgent warnings, and dissemination of general information, and has been systematically used to communicate all the activities between the different Clinical Research teams. It also provided a calendar that could be filled with the main events of the laboratory automatically sending alerts to all members. Nevertheless, users declared to rely on other channels of communication (including phone and internet-based communities) for specific work-related comments, pointing to the previously reported necessity of considering (and maintaining) different channels of communication in effective lab management (Garcia, 2014).

The availability and control of documents for the standardization of procedures and tasks is another core requirement of GCLP (Adamo et al., 2012; Ezzelle et al., 2008), which

contributes to increased repeatability and, consequently, reliability in results. As a result, it is of utmost importance for compliance with the WHO Good Clinical Laboratory Practice Guide (WHO, 2009), in sections such as “Records & Reports,” “Personnel Safety” (mostly by the distribution of safety documentation) as well as SOPs for “Testing Facility Operations.” During the reported implementation, all documents related to GCLP, quality assurance, and laboratory workflow were gathered and made available to the OMS users. Such online organization and distribution ensured continuity, uniformity, historical control of changes and revisions. Furthermore, it facilitates the exchange of those documents between the research groups of a multi-user laboratory. A possible drawback pointed by users in the questionnaires was the increased dependency on fast internet access for consulting even the most routinely documents. Nonetheless, a solution was also offered and widely employed by users during the implementation: the keeping of printed copies of the most used SOPs near their respective equipment and facilities – in fact, a recommendation of GCLP guidance (Ezzelle et al., 2008).

The GCLP’s specific topic “Test and Control” demands inventory management and organization of storage, with a direct impact on both traceability of results and the optimization of costs and resources (WHO, 2009). In the present study, before the OMS implementation, the registration of all incoming and spent material was performed on periodically reviewed paper spreadsheets and tables. This process was highly time-consuming and more prone to errors, without efficacy in the control of quantities, costs, and shelflife. In this regard, as pointed out in the focus groups, the tested OMS enables users to create any category they need in the “Inventory” module (e.g., saliva samples, cell line culture, kits, reagents), to suit the reality and address the unique needs of each laboratory. While the users perceived that this tool required tight control and management, the Inventory module was declared as a facilitator for the average user, while for management-level users it represents a valuable tool for stock control, of particular utility in the reality of low-budget academic laboratories that often lack dedicated staff for such function (Susanto et al., 2017).

Similarly, planning and managing the use, maintenance, and documentation is a major concern to ensure the sustainable use of laboratory equipment (Fonjungo et al., 2012). An essential common issue on the scenario of academic laboratories is the shared use of equipment and multi-user platforms, which increases the risk of mismanagement and loss of traceability. In the studied AHC, there was no adequate schedule policy for equipment use before the implementation of the online system, and it was limited to paper-based weekly schedules physically attached to them. The use was negotiated between the groups, without planning or previous notice, and the records were often made after use. In fact, “Equipment



Sign-Up” was the more frequently used OMS module after implementation and was identified as a facilitator of one of the most common functions of the laboratory activities for most staff members. Nevertheless, it is important to notice that the OMS is only a facilitator and does not ensure compliance by itself. Therefore, potential problems and risks such as unequal distribution of use, unreported last-minute cancellations and scheduling by untrained users still demand careful actions from the management personnel, as pointed out by users in the questionnaires and focus groups.

In the studied OMS, the Order Requests module enables performing requests through registered international suppliers, who are also the supporters of the software company. In this study, this asset could not be adequately assessed, since this module was only partially used as a means to register new suppliers, catalogs, contacts and pricing data. Some data about each vendor might also be filled, such as speed of delivery, the type of payment or if it can be made by direct purchase. These management features are of relevance to keep tight control of the supply chain, which is a valuable tool to help AHC researchers and managers that lack training in financial administration, and to the strengthening of health systems from a resource-poor setting (Birx et al., 2009).

It is worth noting that one of the critical points for a positive outcome of quality assurance is the engagement at the management level (Grochau & Caten, 2012). The management system must be monitored on an ongoing basis, and managers have a fundamental role in generating trust and involving the team. Antes et al. (2019) have recently investigated the common practices of “exemplary,” successful research investigators, which included encouraging shared ownership, ensuring adequate training, fostering positive attitudes about compliance, and following standard procedures. Gumba et al. (2019) reported that a structure that provides leadership and direction contributes to the staff interest in the implementation process of GCLP. Also, to foment the new routine and present repeatability and traceability associated with system-related procedures, constant training is required, a perception commonly shared by all levels of personnel, as indicated by a previous survey (Rodrigues et al., 2012). It also reinforces the role of senior staff as the main propagators of good practices for students and trainees in training programs in academic environments (Adamo et al., 2012; Hancock, 2002). In this context, during the focus group discussions, participants declared that participative and engaged management was fundamental for the confidence, and consequently, to the success of implementation. At the same time, the OMS was also considered a factor that contributes to greater autonomy of the team members through the remote availability of documents and equipment scheduling, allowing remote

work planning, without compromising collaborative and shared work. Indeed, the very process of implementation has this goal achieved by ensuring that all members have participated in several steps considered necessary for the operation of a management system at an AHC (Yao et al., 2010).

A significant drawback observed in the literature is the general lack of available low-cost, module-based tools for different steps of GCLP (Ravinetto et al., 2013), worsened by the discontinuity of several important modules of Quartzy since 2016 (after the completion of this study). Indeed, the high costs of development and maintenance of this kind of software probably result in the low frequency of freeware OMS. Nevertheless, it also points to the relevance of innovative initiatives for the development of free or low-cost integrated management software, as alternatives which could account for different needs of laboratories facing limited budgets. On the other hand, the present results on a modular system suggest that lab managers may also use different software to complete comprehensive online management. While there is some evidence in the literature for the efficacy of integration of different software in the management of laboratory data (Machina & Wild, 2013), the lack of published studies on the performance of laboratory management software makes it challenging to compare the present results with the scientific literature. Nevertheless, the present results indicate that full-scope Online Management Systems contribute to staff awareness and engagement on the management of clinical research laboratories at Academic Health Centers, mostly on topics related to compliance with good practices, such as organization, communication, traceability, and sharing resources.

#### **4. Final Remarks**

Further studies are needed to assess the impact of the use of multiple, non-integrated software-based management models. Furthermore, the present data reinforces the need for research on the development of novel low-cost software to cope with the lack of adequate focused management software, that significantly contribute with compliance and the diffusion of good practices in public laboratories and Institutions such as AHCs, with direct impact on the quality of both research and specialized services in public health.

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