Chelonian Conservation And Biology

Vol. 17No.2 (2022) | https://www.acgpublishing.com/ | ISSN - 1071-8443

DOI:doi.org/10.18011/2022.04(1) 1783.1792

IMPACT OF IMPLEMENTING LABORATORY INFORMATION MANAGEMENT SYSTEMS (LIMS) ON IMPROVING DATA MANAGEMENT AND REPORTING

Mazen Abdulrahman Mohammed Alamer, Talag Mohammed H. Gafary, Rashad Ali Mohammad Refae, Khalid Mohammed Derbeshi, Ali Hassan Ali Arishi, Mohammed Yahya Jarradi Ammari, Abdulmajeed Ali Abdulqader Alaqi, Ahlam Ibrahim Hadi Sowadi, Nadia Ali Qassim Juhynah, Amenah Mohammed Ahmed Bokar, Radha Mohammed Ali Makaramei, Amani Yahya E Hazmi, Waleed Abdulrahman Salem Alattas, Khalid Salem Alanazi, Sami Abdullah Alotaibi

Abstract

Implementing Good Laboratory Practices (GLP) enhances the precision and accountability of findings in the field of health sciences research. Nevertheless, the adoption of these practices in research and academic labs may be hindered by reasons such as frequent staff turnover, inadequate resources, and insufficient training for management. The objective of this Scoping Review was to identify digital technologies used for the management of academic health sciences and experimental medicine labs, as well as their association with best practices. Using the PRISMA-ScR 2018 criteria, a search strategy was implemented up to April 2021 in the PUBMED, Web of Sciences, and Health Virtual Library databases. An evaluation of the chosen references was carried out, followed by the organization of data into a chart. The search found twenty-one acceptable papers, mostly from high-income nations, that discussed the creation and/or use of thirty-two electronic management systems. The majority of the studies focused on describing the features of the program. However, nine studies specifically assessed and addressed the effects on management, noting both enhancements in the workflow and limitations of the system during installation. Overall, the research indicates that there is a connection to various management challenges associated with GLP principles. To summarize, this analysis has shown that digital laboratory management systems have the potential to be valuable aids in adhering to the standards of good practices in experimental medicine and health sciences research, as new evidence continues to emerge.

Keywords: scoping review; academic health centers; software; laboratory management.

1. Introduction

Laboratory research is crucial for generating data to support translational medicine and develop sustainable healthcare solutions [1]. Nevertheless, the dependence on experimental medicine necessitates enhanced traceability and data integrity, guaranteeing the excellence of transferable outcomes in the clinical environment. Recently, the scientific community has been more conscious of a reproducibility problem. This crisis is caused by variables such as the pressure to publish, limited statistical power, and inadequate supervision [2]. Conversely, effective management, training, and adherence to best practices may enhance data quality by optimizing workflow, preventing mistakes, and ensuring traceability [2].

Good laboratory practices (GLP) may be characterized as a quality system that includes the organizational procedures and circumstances in which investigations are planned, conducted, monitored, recorded, and reported [3]. The Principles of Good Laboratory Practice were first formulated by a team of experts in Good Laboratory Practice (GLP) headed by the United States. This team was founded in 1978 as part of the Special Program on the Control of Chemicals. The principles were based on the standards set by the Food and Drug Administration (FDA) for non-clinical laboratory investigations. In January 1998, the Principles of Good Laboratory Practice and Compliance Monitoring were released by the Organization for Economic Cooperation and Development (OECD) [3]. Since its inception, it has been the foremost collection of globally recognized standards for ensuring quality, dependability, and integrity. These standards provide a robust framework for managing research labs [4].

Nevertheless, academic labs face several significant obstacles when it comes to establishing and using a GLP-compliant infrastructure [5]. The restrictions include inadequate management training, insufficient money for compliance expenses, and frequent staff turnover resulting from reliance on students as temporary workforce [6]. Thus, it is advisable for laboratory managers at academic institutes to investigate methods that streamline oversight and pinpoint crucial stages in the laboratory process. Within this particular framework, digital systems are regarded as crucial instruments for effective administration, including specialized computer software as well as mobile phone apps. Laboratory information management systems (LIMS) provide databases and automation [7] for the purpose of recording and storing experimental data [8]. Additional software and digital services that do not fit into the original LIMS classification offer a wider range of solutions for managing laboratories. These solutions address various aspects of quality assurance, such as communication, staff management, scheduling and maintenance of equipment used by multiple users, standard procedures, and inventory control. These aspects are essential for managing all aspects of a laboratory's workflow.

Although these digital technologies have the potential to be useful in some parts of laboratory administration, it is yet unclear how these systems may directly or indirectly support adherence to the principles of Good Laboratory Practice (GLP). The purpose of this review was to gather evidence on the topic by examining the scientific literature for digital tools that are specifically designed to manage health sciences and experimental medicine laboratories. The review also

aimed to discuss the evaluations of these tools in terms of their effectiveness, acceptance, and potential for compliance with various aspects of good laboratory practices.

Management topics in each laboratory were addressed using digital systems. These systems were used for many purposes, including purchasing, administrative activities, cell collection control, general inventory management, and storage of data. They were also used to manage animal colonies. All thirty-two software programs described in the documents of good laboratory practices [3] address various aspects of management, such as experimental workflow, data storage, integration with laboratory equipment, statistical analysis, comparison of experimental data, animal colonies, biorepositories, inventory, and risks. The figure displayed in Figure 1 identifies the integration of work needs in university health sciences labs and compliance with the GLP requirements.

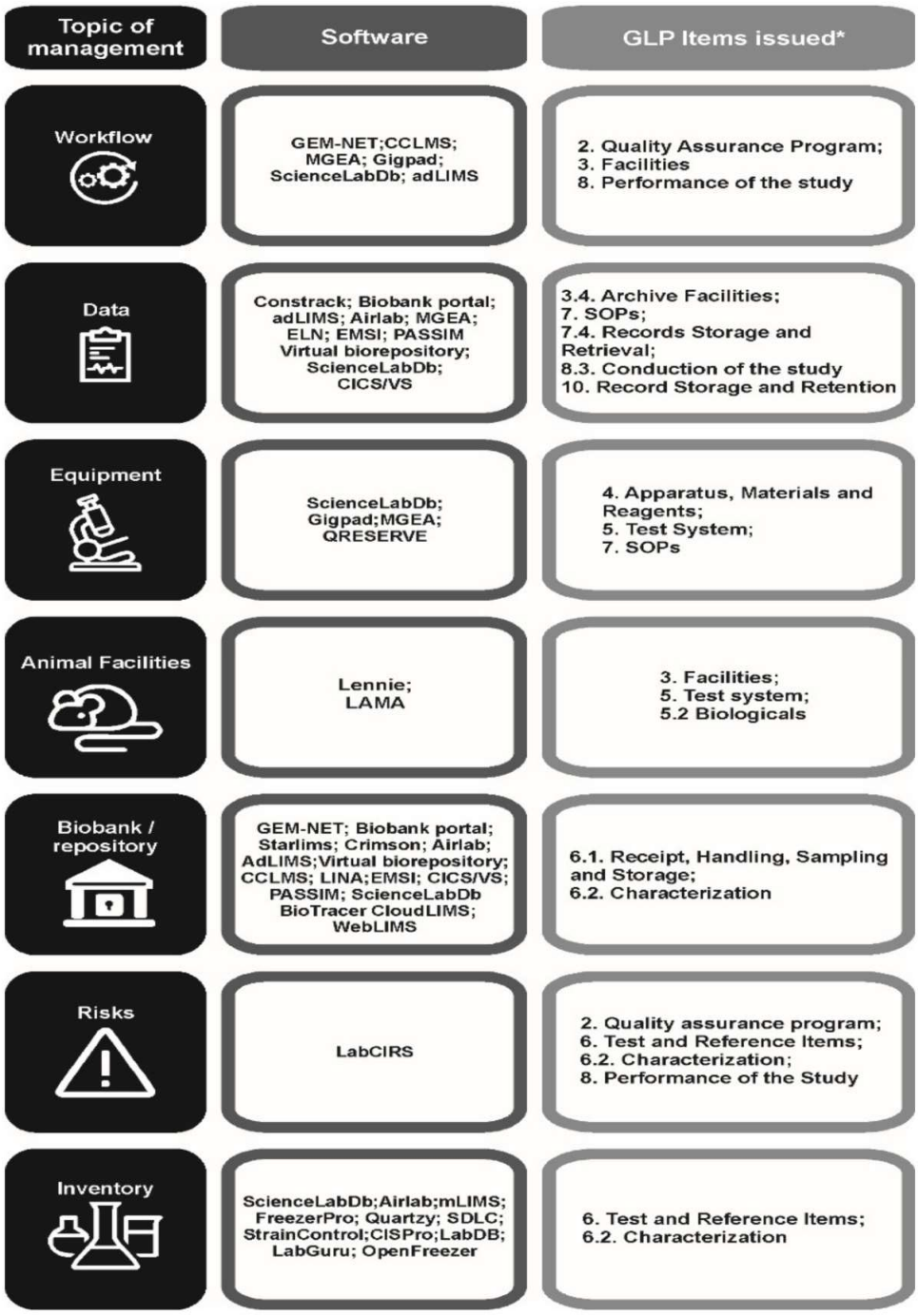

Figure 1. The primary uses of the indicated software across several parts and chapters of the OECD GLP Principles [3].

2. Contributions to GLP Principle Adherence

Although the search technique utilized in this study found several laboratory management systems, only a small number of the eligible publications included a detailed discussion on this specific issue. The absence of empirical scientific data restricts the current study from

quantitatively evaluating the degree to which digital technologies may collectively contribute to achieving certification. However, all of the software that was found addressed management challenges associated with at least one of the GLP principles. In several studies, multiple software programs were used to fulfill the various requirements of quality systems.

The method suggested by Timoteo et al. [6] might be used to analyze the current data sources and identify the key management themes influenced by these programs and systems associated with best practice recommendations. The figure shown in Figure 2 illustrates the correlation between the forms of management facilitated by the software in academic labs and various elements from Section II of the OECD GLP Principles [3]. This relationship is demonstrated through a focus on the duties of staff and facilities management, the organization of work, the presence of standard operational procedures (SOPs) that encompass all study activities, analysis of procedures, utilization and upkeep of equipment, as well as the implementation of standards for receiving test samples, maintaining their chain of custody and logistics, inventory control, and the traceability of reagents and validation of methods. To enhance comprehension of the functioning of these systems, a concise overview will be provided, with a focus on aligning the computerized systems with the GLP principles outlined in Figure 1.

3. Data management

Within the GLP principles, there is a need for the safe storage, organization, and retrieval of research data (item 7.4), which includes study plans, raw data, final reports, test system samples, and specimens (item 8.3), as well as the necessary archival facilities (item 3.4). Moreover, item 7 (standard operating procedures) mandates the creation and adherence to papers that ensure the quality and reliability of the data produced by the research. Sub-item 7.4 specifies that while dealing with computerized systems, it is necessary to adhere to validation, operation, maintenance, security, change control, and backup system protocols.

Among the chosen papers, we discovered a report on computerized systems that were used to handle data from different laboratory settings and how they were accessible to the research teams. During the early 1980s, Delorme and Cournoyer [15] conducted a test on the CCIS/VS (Customer Information Control System/Virtual Storage) in a microbiology laboratory at a University Hospital. The CCIS/VS was a customer data repository that utilized a central computer shared with medical records databases, admission offices, patient accounting, and other medical-administrative services. The system functioned as a virtual storage system, including data from microbiological samples. The operations carried out included report printing, data quality control, epidemiological aid, germ identification, education, and research in several subspecialties of microbiology. The authors conducted a comprehensive evaluation, using both qualitative and quantitative methods, to discover an enhancement in workflow efficiency without the need for additional staff. This improvement was also accompanied by a decrease in report production time, system downtime, and other relevant metrics.

Viksna et al. [20] concentrated on the electronic management of collecting, saving, and retrieving data on study participants and biological materials. The researchers suggested using the PASSIM (Patient and Sample System for Information Management), a customisable web-based system. This system would allow for the sending, management, and retrieval of samples and data from study subjects while maintaining the confidentiality of the information. This technology played a crucial role in managing information in clinical research studies involving human subjects and replaced the costlier Laboratory Information Management System (LIMS), which necessitates expenditures of time, effort, and resources that were not always accessible.

Electronic laboratory notebooks (ELN) are software applications specifically developed to replace conventional research notebooks. These electronic instruments have the capability to record procedures, field/lab observations, notes, and other data using a computer or mobile device. They provide several benefits compared to traditional paper notebooks [19]. Machina and Wild (22) examined the significance of Electronic Laboratory Notebooks (ELNs) when combined with other computer tools, including laboratory information management systems, analytical apparatus, data management systems, and scientific data. The researchers noted that the specific kind of laboratory (analytical, synthesis, clinical, research) was a significant factor in the challenges faced when attempting to integrate ELN with the existing equipment. Hence, considering the absence of a well-defined method for the successful incorporation of these tools, the authors choose to assess and appraise many of the implemented strategies.

In 2015, Calabria et al. created adLIMS, a program designed to manage biological samples, particularly DNA, together with associated information for patient samples and experimental methods. The authors detailed the process of creating this system by modifying an existing open-source program, ADempiere ERP. Initially, the needs of the end-users were gathered, ensuring that the intended features of the system and Graphical User Interface (GUI) were verified. Subsequently, the available tools that satisfied the necessary criteria were assessed, including a range of options from pure LIMS to content management and corporate information systems. The authors state that the system facilitated important aspects of sample monitoring, data standardization, and automation pertaining to NGS (next-generation sequencing).

In 2021, Cooper et al. [30] documented the use of integrated systems that facilitate the exchange of crucial data for ongoing research. The authors conducted a study on the 15-year progress and use of the LabDB system. Originally designed to handle structural biology experiments, the system has evolved into a complex platform that combines several types of experimental biochemical, biophysical, and crystallographic data. The LabDB central software module manages data related to the administration of laboratory workers, chemical inventory, and storage areas. Currently, the American/Canadian collaboration CSGID (Center for Structural Genomics of Infectious Diseases) and several renowned research facilities use it. The key restriction mentioned by the authors is the reluctance and challenges faced by some researchers in adopting these systems. This is mostly due to the work required to transfer data from

electronic notebooks or laboratory spreadsheets, which most researchers are already used to. However, the authors believe that this endeavor is worthwhile since previous methods fail to eliminate or monitor discrepancies and do not effectively adjust to the demands of contemporary research.

It is crucial to acknowledge that, in order to get accreditation, hosted services (such as cloud archiving, backup, or procedures) require formal agreements that clearly outline the duties of the informatics services. Test facility management should be cognizant of possible hazards to data integrity that may arise from storing data with third-party providers.

4. Summary

The current literature review surveyed numerous studies conducted over the past forty years, which proposed and assessed the influence of digital tools on the management of health sciences research laboratories. These tools have been applied to various areas, including the management of administrative workflows, data traceability, and virtual biobanking. These functions have the capacity to enhance adherence to certain GLP principles. Nevertheless, the available information supporting their usefulness remains insufficient and necessitates more investigation endeavors.

References

1. Dennert, K.; Friedrich, L.; Kumar, R. Creating an Affordable, User-Friendly Electronic Inventory System for Lab Samples. *SLAS Technol.* **2020**.

2. Baker, M. Is there a reproducibility crisis? *Nature* **2016**, *533*, 452–454.

3. Organization for Economic Co-Operation and Development (OECD). OECD Principles of Good Laboratory Practice. In *Series on Principles of Good Laboratory Practice (GLP) and Compliance Monitoring*; OECD Environmental Health and Safety Publications: Paris, France, 1998; pp. 1–41.

4. World Health Organization (WHO). *Handbook—Good Clinical Laboratory Practice (GCLP)*; World Health Organization on behalf of the Special Programme for Research and Training in Tropical Diseases: Geneva, Switzerland, 2009; pp. 1–28.

5. Adamo, J.E.; Bauer, G.; Berro, M.; Burnett, B.K.; Hartman, K.A.; Masiello, L.M.; Moorman-White, D.; Rubinstein, E.P.; Schuff, K.G. A Roadmap for Academic Health Centers to Establish Good Laboratory Practice–Compliant Infrastructure. *Acad. Med.* **2012**, *87*, 279–284.

6. Timoteo, M.O.; Brochado, A.C.B.; Costa-Silva, D.; Granjeiro, J.M.; Olej, B.; Alves, G.G. The impact of online management systems: A qualitative assessment of staff perception at a clinical research laboratory. *Res. Soc. Dev.* **2020**, *9*, e9239109188.

7. Bianchi, V.; Ceol, A.; Ogier, A.G.; De Pretis, S.; Galeota, E.; Kishore, K.; Bora, P.; Croci, O.; Campaner, S.; Amati, B.; et al. Integrated Systems for NGS Data Management and Analysis: Open Issues and Available Solutions. *Front. Genet.* **2016**, *7*, 75.

8. Milisavljevic, M.; Hearty, T.; Wong, T.Y.; Portales-Casamar, E.; Simpson, E.M.; Wasserman, W.W. Laboratory Animal Management Assistant (LAMA): A LIMS for active research colonies. *Mamm. Genome* **2010**, *5–6*, 224–230.

9. Perkel, J.M. Lab-inventory management: Time to take stock. *Nat. News* **2015**, *524*, 125–126.

10. Gumba, H.; Musyoki, J.; Mosobo, M.; Lowe, B. Implementation of Good Clinical Laboratory Practice in an Immunology Basic Research Laboratory: The KEMRI-Wellcome Trust Research Laboratories Experience. *Am. J. Clin. Pathol.* **2018**, *151*, 270–274.

11. Gaffney, S.G.; Ad, O.; Smaga, S.; Schepartz, A.; Townsend, J.P. GEM-NET: Lessons in Multi-Institution Teamwork Using Collaboration Software. *ACS Cent. Sci.* **2019**, *5*, 1159–1169.

12. Tricco, A.C.; Lillie, E.; Zarin, W.; O'Brien, K.K.; Colquhoun, H.; Levac, D.; Moher, D.; Peters, M.D.; Horsley, T.; Weeks, L.; et al. PRISMA extension for scoping reviews (PRISMA-ScR): Checklist and explanation. *Ann. Intern. Med.* **2018**, *169*, 467–473.

13. Kelly, A.M.; Cronin, P. How to Perform a Critically Appraised Topic: Part 1, Ask, Search, and Apply. *Am. J. Roent.* **2011**, *197*, 1039–1047.

14. Whittemore, R.; Knafl, K. The integrative review: Updated methodology. *J. Adv. Nurs.* **2005**, *52*, 546–553.

15. Delorme, J.; Cournoyer, G. Computer system for a hospital microbiology laboratory. *Am. J. Clin. Pathol.* **1980**, *74*, 51–60.

16. Goodman, N.; Rozen, S.; Stein, L.D. The LabFlow system for workflow management in large scale biology research laboratories. *Proc. Int. Conf. Intell. Syst. Mol. Biol.* **1998**, *6*, 69–77.

17. Nayler, O.; Stamm, S. ScienceLabDatabase: A computer program to organize a molecular biology laboratory. *Biotechniques* **1999**, *6*, 1186–1191.

18. Selznick, S.H.; Thatcher, M.L.; Brown, K.S.; Haussler, C.A. Development and application of computer software for cell culture laboratory management. *In Vitro Cell Dev. Biol. Anim.* **2001**, *37*, 55–61.

19. Anderson, N.R.; Ash, J.S.; Tarczy-Hornoch, P. A qualitative study of the implementation of a bioinformatics tool in a biological research laboratory. *Int. J. Med. Inform.* **2007**, *76*, 821–828.

20. Viksna, J.; Celms, E.; Opmanis, M.; Podnieks, K.; Rucevskis, P.; Zarins, A.; Barrett, A.; Neogi, S.G.; Krestyaninova, M.; McCarthy, M.I.; et al. PASSIM—An open-source software system for managing information in biomedical studies. *BMC Bioinform.* **2007**, *8*, 52.

21. Yousef, A.F.; Baggili, I.M.; Bartlett, G.; Kane, M.D.; Mymryk, J.S. LINA: A laboratory inventory system for oligonucleotides, microbial strains, and cell lines. *J. Lab. Autom.* **2011**, *16*, 82–89.

22. Machina, H.K.; Wild, D.J. Electronic Laboratory Notebooks Progress and Challenges in Implementation. *J. Lab. Autom.* **2013**, *18*, 264–268.

23. Allwood, M.A.; Griffith, D.; Allen, C.; Reed, J.; Mahmoud, Q.H.; Brunt, K.R.; Simpson, J.A. Lennie: A smartphone application with novel implications for the management of animal colonies. *Lab. Anim.* **2015**, *49*, 258–262.

24. Calabria, A.; Spinozzi, G.; Benedicenti, F.; Tenderini, E.; Montini, E. adLIMS: A customized open-source software that allows bridging clinical and basic molecular research studies. *BMC Bioinform.* **2015**, *16*, S5.

25. Boutin, N.; Holzbach, A.; Mahanta, L.; Aldama, J.; Cerretani, X.; Embree, K.; Leon, I.; Rathi, N.; Vickers, M. The Information Technology Infrastructure for the Translational Genomics Core and the Partners Biobank at Partners Personalized Medicine. *J. Pers. Med.* **2016**, *6*, 6.

26. Catena, R.; Özcan, A.; Jacobs, A.; Chevrier, S.; Bodenmiller, B. AirLab: A cloud-based platform to manage and share antibody-based single-cell research. *Genome Biol.* **2016**, *17*, 142.

27. Dirnagl, U.; Przesdzing, I.; Kurreck, C.; Major, S. A Laboratory Critical Incident and Error Reporting System for Experimental Biomedicine. *PLoS Biol.* **2016**, *14*, e2000705.

28. Manca, C.; Hill, C.; Hujer, A.M.; Patel, R.; Evans, S.R.; Bonomo, R.A.; Kreiswirth, B.N. Laboratory Center of the Antibacterial Resistance Leadership Group (ARLG). Leading Antibacterial Laboratory Research by Integrating Conventional and Innovative

Approaches: The Laboratory Center of the Antibacterial Resistance Leadership Group. *Clin. Infect. Dis.* **2017**, *64*, S13–S17.

29. Paul, S.; Gade, A.; Mallipeddi, S. The State of Cloud-Based Biospecimen and Biobank Data Management Tools. *Biopreserv. Biobank.* **2017**, *15*, 169–172.

30. Cooper, D.R.; Grabowski, M.; Zimmerman, M.D.; Porebski, P.J.; Shabalin, I.G.; Woinska, M.; Domagalski, M.J.; Zheng, H.; Sroka, P.; Cymborowski, M.; et al. State-of-the-Art Data Management: Improving the Reproducibility, Consistency, and Traceability of Structural Biology and in Vitro Biochemical Experiments. *Methods Mol. Biol.* **2021**, *2199*, 209–236.