sciendo

Med Biochem 2019; 38 (4) DOI: 10.2478/jomb-2019-0021

UDK 577.1 : 61 **ISSN 1452-8258**

J Med Biochem 38: 401–406, 2019

Review paper
Revijski rad

PROJECT MANAGEMENT IN LABORATORY MEDICINE

PRIMENA MENADŽMENTA U LABORATORIJSKOJ MEDICINI

Giuseppe Lippi[1], *Camilla Mattiuzzi*[2]

[1]*Section of Clinical Biochemistry, University of Verona, Verona, Italy*
[2]*Service of Clinical Governance, Provincial Agency for Social and Sanitary Services, Trento, Italy*

Summary

The role and responsibilities of laboratory managers have considerably evolved during the past decades. This revolution has been mostly driven by biological, technical, economic and social factors, such as deepened understanding of the pathophysiology of human diseases, technical innovations, renewed focus on patient safety, cost-containment strategies and patient empowerment. One of the leading consequences is an ongoing process of reorganization, consolidation and automation of laboratory services, whose propitious realization strongly relies on establishing an efficient project management plan. In a practical perspective, the leading drivers of project management in laboratory medicine encompass various activities supporting a clear definition of the local environment, an accurate planning of technical resources, the acknowledgement of staff availability and qualification, along with the establishment of a positive and constructive interplay with hospital administrators. Therefore, the aim of this article is to provide a personal overview on the main drivers and outcomes of project management in laboratory medicine, which will expectedly contribute to construct a new consciousness and an innovative and multifaceted job description of laboratory professionals worldwide.

Keywords: laboratory medicine, diagnostic testing, project management, automation

Kratak sadržaj

Uvod: Uloga i odgovornost laboratorijskog menadžera posebno je dobila na značaju poslednjih decenija. Ovo je uslovljeno uglavnom zbog bioloških, tehničkih, ekonomskih i socijalnih faktora, kao i zbog boljeg razumevanja patofiziologije humanih oboljenja, tehničkih inovacija, usmeravanja pažnje na sigurnost pacijenta, strategije troškova i potreba pacijenata. Jedna od glavnih posledica jeste uvođenje procesa reorganizacije, konsolidacije i automatizacije laboratorijske službe, a što je uslovljeno efikasnom primenom projekta plana menadžmenta. Praktično gledano, vodeći pravci projekta menadžmenta za laboratorijsku medicinu su uslovljeni nizom različitih aktivnosti jasno definisanih zavisno od lokalne okoline, pravilnog planiranja tehničkih mogućnosti, znanja osoblja i postizanja njihove odgovarajuće kvalifikacije kao i uspostavljanja pozitivne i konstruktivne veze sa bolničkom administracijom. Prema tome, cilj ovog rada je pružanje ličnog pogleda na mogućnosti pojedinca u sprovođenju projekta menadžmenta u laboratorijskoj medicini, na koji način će ova disciplina biti unapređenja kod laboratorijskih profesionalaca širom sveta.

Ključne reči: laboratorijska medicina, dijagnostičko ispitivanje, primena menadžmenta, automatizacija

Address for correspondence:

Prof. Giuseppe Lippi
Section of Clinical Biochemistry
University Hospital of Verona
Piazzale LA Scuro, 37134 – Verona, Italy
e-mail: giuseppe.lippi@univr.it

Introduction

Laboratory medicine is conventionally defined as a science committed to generate clinical information through analysis of concentration, composition and/or structure of different analytes in different biological fluids (1). To be thoughtfully capable of providing a valued contribution to the clinical decision making, services of laboratory medicine shall hence be developed and organized for maximizing productive efficiency and optimizing clinical efficacy. Unlike many years ago, when healthcare services were not so strongly plagued by shortage of funding and could benefit from ample economic resources, the current scenario is now overwhelmed by an unprecedented worldwide economic crisis (2), which has also obligated laboratory managers to increase volume and complexity of testing, contextually preserving quality and cutting down costs. This altered scenario has inevitably forced laboratory managers and laboratory professionals to become familiar with many different instruments borrowed from other professions, such as leadership skills (3), budgeting activities (4) and, last but not least, project management.

According to a common inception, project management can be defined as the practice of initiating, planning, executing, monitoring and closing a specific work, aimed at achieving specific goals at a specified time. Project management is hence conventionally dictated by six main paradigms, i.e., efficiency, efficacy, quality, safety, sustainability and satisfaction. The practical translation of these essential factors in the field of laboratory medicine is summarized in *Table I*. Briefly, efficiency implies achieving maximum laboratory productivity with minimum wasted effort or expense, efficacy is mainly directed towards improving diagnoses and clinical outcomes, quality encompasses reaching the highest possible degree of reliability and safety of laboratory data, safety develops through limiting the risk of injury or damage to patients and staff, sustainability requires avoiding depletion of human and economic resources, whilst satisfaction is achieved by fulfilling wishes, expectations or needs of both laboratory staff and its stakeholders (i.e., patients and doctors). In a practical perspective, the main drivers of project management in laboratory medicine encompass some fundamental but not essentially sequential steps, which entail a clear definition of the environment, an accurate planning of technical resources, the acknowledgement of staff availability and qualification, along with the establishment of a positive and constructive interplay with hospital administrators.

Step 1 – Defining the environment

As laboratory medicine continues to evolve from performance of many manual activities towards automatization of several steps throughout the total testing process (5), the so-called open-plan layouts are becoming commonplace to efficiently respond to the emerging issue of connecting many laboratory analyzers within the same system and developing an efficient workflow, from arrival of samples in the laboratory to their final discharge or storage once testing has been completed (6). Space availability and organization shall hence be regarded as major limiting steps when projecting the final layout, since the preexisting environment may not be suited to accommodate multiple laboratory analyzers and their connecting systems within the available space. Although the possibility to start from zero (i.e., constructing a new purpose-built structure) is indeed the most desirable and advisable scenario, this rarely happens since the reorganization of most laboratory services goes through »cosmetic« rearrangements or modernization of preexisting buildings (7). This would actually force laboratory managers to find a reasonable way »to fit the elephant (i.e., automated laboratory instrumentation) into the room (i.e., preexisting environment)«. Indeed, many different solutions have been made available after the development of »flexible« laboratory automation, spanning from narrow automation of diagnostic areas (i.e., automation of clinical chemistry and/or immunochemistry testing), up to complete automation of the largest part of laboratory diagnostics (i.e., total laboratory automation; TLA). The choice between the many available solutions of laboratory automation is dependent on the available space for connecting multiple instrumentation and the residual (i.e., vital) space necessary for allowing the laboratory staff to work on the instrumentation and contextually perform maintenance or repairing, when these activities will be needed.

Table I The six paradigms of project management in laboratory medicine.

- Efficiency: achieve maximum laboratory productivity with minimum wasted effort or expense
- Efficacy: achieve better diagnoses and improved clinical outcome
- Quality: develop the highest possible degree of reliability and safety in test results
- Safety: limit the risk of injury or damage to patients and laboratory staff
- Sustainability: avoid depleting human and economic resources
- Satisfaction: fulfil both laboratory staff and stakeholders' (i.e., patients', doctors') wishes, expectations and needs

Whatever solution can be finally implemented, laboratory managers shall be aware of the risk of the so-called »point of no return«, which is defined by the impossibility of easily and inexpensively reorganizing an inefficient laboratory layout once this has been definitely developed. In the unfortunate option that the final project is partially or totally inefficient and nonfunctional, changing the layout could lead to catastrophic economic consequence, or can even be unfeasible.

Step 2 – Planning technical resources

In the complex effort of planning the technical resources needed for achieving a given target (i.e., constructing a new laboratory layout), developing and documenting the project vision, mission, goals and deliverables are essential prerequisites. More often than not, these activities are overlooked or completely ignored, whilst the vision and mission of the clinical laboratory should be aligned with those of the complex organization where the laboratory operates. Notably, laboratory services are now frequently organized in networks, with the reference center in the middle (i.e., the so-called »hub« facility) and many decentralized laboratories in periphery (i.e., the so-called »spokes«), interconnected with an efficient system of sample deliverance and a versatile laboratory information system (LIS) (8, 9). This actual organization requires developing the clear-cut concepts of »clinical-laboratory liaison« and »diagnostic stewardship«, according to which the laboratory shall be engaged in reorganizing its structure (instrumentation, tests, staff) for providing an effective technical and advisory support to the local clinical needs within the network, whilst clinicians shall fairly cooperate with the laboratory staff for identifying the most efficient and effective solutions according to location and resources availability (10). An optimal balance should hence be always identified between case-mix (i.e., clinical complexity) of the healthcare facility where the laboratory is set and the locally available panel of diagnostic tests.

As an example, a regional reference center for management of severe bleeding disorders shall be equipped with a clinical laboratory capable to perform second-line and even third-line hemostasis tests, whilst a peripheral hospital within the same network would only need a basic hemostasis laboratory, since patients with severe bleeding disorder, either congenital or acquired, would be generally admitted and managed elsewhere (11). In the case that a patient with a bleeding syndrome is brought to a peripheral facility, the local »spoke« laboratory can then support clinicians with a panel of first-line (screening) hemostasis tests (e.g., prothrombin time, activated partial thromboplastin time, fibrinogen, platelet count, screening of platelet function). In most cases these tests, along with the clinical history, signs and symptoms, will be sufficient to guide the clinical decision making and deciding as to whether the patient may need to be referred to the reference center (where the »hub« laboratory is available) for being further investigated and eventually managed, or can else be locally treated or safely discharged. This paradigmatic example can then be translated to the vast majority of laboratory medicine areas (e.g., hematology, immunochemistry, microbiology), by defining a clear hierarchy of tests that should be available in the different laboratories operating within a network. Regardless of personal inclinations and interests, »spoke« laboratories will generally need to be equipped with basic (first-line) laboratory tests, whereas »hub« laboratories will require more complex, time-consuming and expensive (second- and third-line) analyses. As previously discussed, decisions on the final organization of laboratory diagnostics within a network of laboratory services shall be taken in accordance with clinicians and hospital administrators, thus fulfilling clinical needs (12), principles of cost-effectiveness (13) and preanalytical requirements (14). Dissipating both human and economic resources for performing obsolete, redundant, clinically questionable or potentially unreliable analyses would not be beneficial for the healthcare system as a whole.

An accurate plan of technical resources will hence encompass a thorough analysis of the local situation, which will then influence the design of laboratory layout, preferably driven by validated tools such as Lean management systems, which contextually enable to maximize efficiency and create a culture of continuous improvement (15). The leading factors that will be part of this process are volume and complexity (i.e., capacity), equipment and utility lists, staffing model, work schedule along with regulatory, safety ergonomic requirements and, occasionally, with availability of space for research and education (i.e., in Academic centers).

Step 3 – Staff availability and qualification

Whether this third step shall follow or anticipate the planning of technical resources remains debated. This is mostly due to a recent metamorphosis occurred in staff availability. Personnel requirements have basically evolved from a demand conditioned by workflow, complexity and environment, to a new scenario where shortage of public healthcare funding has contributed to make environment and staff availability (and qualification) the leading drivers of workflow and complexity. In 2014, a statistics of the World Health Organization (WHO) has alarmingly highlighted that the global shortage of doctors, nurses, midwives and other healthcare professionals had already reached a 4.3 million deficit around the world (16). The situation has even worsened in recent years, so that the predicted worldwide shortage of health care workers will probably exceed 15 million in

the year 2030 (17). Laboratory medicine makes no exception to this rule, since an inefficient turnover has involved almost each category of laboratory professionals, especially during the past decade (18). It is hence rather understandable that laboratory managers shall place staff availability among the top list of drivers of project management. Rome wasn't built in a day, though it would have never been built without a huge and skilled Roman workforce. *Mutatis mutandis*, volume and complexity of laboratory testing shall be accurately commensurate to the local availability of staff and to specific personnel education and qualification. Importantly, when the available human resources do not meet predefined requirements of workforce and skills, additional strategies shall be planned. These basically entail further elimination of manual activities, automation of additional parts of the total testing process, expanded consolidation of many different diagnostic areas, up to the worst possible scenario, characterized by reduction of volume and complexity of diagnostic testing, up to outsourcing tests to private facilities (13, 19). Among the possible solutions, this last opportunity has recently gained large momentum, and has become especially appealing for some healthcare administrators, who are seeking to save money by cutting down laboratory funding and externalizing large volumes of tests. Whether or not this strategy is cost-effective remains largely disputed, although recent published evidence attests that outsourcing laboratory services decreases sample quality, increases turnaround time and enhances the overall risk of diagnostic errors (20). Sizeable privatization of diagnostic testing is neither a clear-cut solution to the problem, since no reliable evidence has been provided that this will generate improved services and overall cost savings. Moreover, many doubts have been raised on the fact that private contractors do not need to openly disclose how public health money are spent, allocated or collected. Theranos, a comet star quickly appeared in the firmament of laboratory medicine and just as rapidly disappeared, taught us to be very cautious to move towards certain types of deregulated diagnostic testing (21).

Notably, critical issues in staff regulations (e.g., time on turn, recovery) shall be clearly identified, and staff necessity should then be defined accordingly. A final consideration about the personnel is that laboratory directors cannot usually select the staff, but are rather constrained to develop leadership skills which will enable them to manage the existing personnel, thus placing the right person, in the right place, for doing the right activity, at the right time. This obviously entails accurately knowing the persons (i.e., weakness and strengths), trying to fulfilling personal inclinations (whenever possible) and, especially, not blaming people when something goes wrong, since errors are very frequently caused by a system failure rather than by individual mistakes.

Step 4 – Interplay with hospital administration

As already anticipated in some previous parts of this article, laboratory professionals are increasingly involved in administrative duties, mostly encompassing test menu optimization, delivering training or education, and administering budgets (22). It is increasingly essential that laboratory directors and managers have a profound understanding of the budget of their laboratory, use that information for developing appropriate strategies for responding to a clinical demand, learn to manage budgets on the basis of a cost model, and have enough details to meet the needs of financial managers. These many aspects have become virtually unavoidable because laboratory diagnostics is now assimilated to many other economic industries by policymakers and administrators, and is hence subjected to scale economy and evaluated accordingly. To put it simply, laboratory managers should aim to establishing a favorable and constructive interplay with hospital administrators. They will also need to learn the language of hospital administrators and policymakers, since it is very unlikely that these two categories will be ever strongly committed to speak a »clinical« language (23). Regardless of the local organization, however, it is now undeniable that the future of laboratory medicine will be mostly driven by national healthcare policies, which are typically defined by a number of paradigms such as the amount of public funding for in vitro diagnostic testing, health insurance strategies and test reimbursement policies. On a local basis, it will become more and more essential to define medium- and long-term trajectories with hospital administrators, especially in terms of reorganization of healthcare network (which will then influence number and size of laboratory services), number of hospital beds and outpatient flow (which will then influence test volume) and case-mix evolution (which will then influence test menu). Knowing this information in advance is unavoidable for developing an efficient and effective project management plan in laboratory medicine.

Conclusions

Several lines of evidence now attest that role and responsibilities of laboratory managers have considerably evolved during the past decades (24). These paradigm shifts have been mostly driven by some clinical, technical, economic and social factors, mainly encompassing deepened understanding of the pathophysiology of human diseases, technological innovations, renewed focus on patient safety, cost-containment strategies and patient empowerment. The most obvious consequence has been the development of an ongoing process of reorganization, consolidation and automation of laboratory services, whose effective realization requires to define an efficient project management plan, together with

Table II Leading drivers of project management in laboratory medicine.

1. Step 1 – Defining the environment
   a. Define space availability and organization
   b. Identify the most suitable local model of laboratory automation
2. Step 2 – Planning technical resources
   a. Define the geographical context ("hub« or »spoke« laboratory)
   b. Recognize local clinical educational and research needs
   c. Identify predicted volume and complexity of tests
   d. Develop clinical-laboratory liaison and diagnostic stewardship
   e. Take advantage from using a Lean management system
3. Step 3 – Staff availability and qualification
   a. Define the number of available persons
   b. Acknowledge technical and clinical qualification of the staff
   c. Adapt volume and complexity of testing to available staff
   d. Identify critical issues in staff regulations (e.g., time on turn, recovery)
   e. Place the right person, in the right place, for doing the right activity, at the right time
   f. Safeguard personnel and patient safety
4. Step 4 – Interplay with hospital administration
   a. Search a constructive dialogue with hospital administrators
   b. Acknowledge the local political context
   c. Be aware of local healthcare plans (e.g., reorganization of healthcare network, number of beds, evolution of case-mix)
   d. Be familiar with administrative duties and budgeting process
5. Step 5 – Additional drivers
   a. Identify political or ideological resistances to the changes
   b. Share the strategic plan with laboratory staff, local authorities, syndicates and stakeholders (i.e., clinicians and patients)
   c. Define reliable performance indicators (qualitative and quantitative)
   d. Monitor continuously staff and stakeholders satisfaction
   e. Identify an alternative solution (i.e., »plan B«)
   f. Publicize results (when successful)

construction of a new consciousness and an innovative and multifaceted job description of laboratory professionals worldwide. Notably, some other important drivers and outcome measures shall be considered when restructuring or redesigning the layout of a laboratory service, as briefly summarized in *Table II*. These essentially include the identification and management of potential political or ideological resistances to the changes, the need to share the strategic plan with laboratory staff, local authorities, syndicates and stakeholders (i.e., clinicians and patients), the definition of reliable performance indicators (both qualitative and quantitative) which will help assessing as to whether the new project is efficient and effective, along with continuous monitoring of staff and stakeholders satisfaction. Common experience also teaches that the delineation of a so-call »B-plan« (i.e., an alternative solution) may be certainly helpful to overcome possible technical failures of a new project. Whenever possible, the switch from the old to the new laboratory layout, especially when entailing the use of novel instrumentation, should not be irreversible, whilst the two solutions should be allowed to run in parallel for a certain period of time, until most of the possible problems have been identified and solved. Last but not least, provided that the final project will be successful, results shall be publicized, so that others may take profit from local translation of favourable outcomes.

Acknowledgements. This article is a detailed summary of an oral presentation delivered during the 15th Belgrade Symposium for Balkan Region. Belgrade (Serbia), 11–12 April, 2019.

Conflict of interest statement

The authors state that they have no conflicts of interest regarding the publication of this article.

References

1. Lippi G. The Irreplaceable Value of Laboratory Diagnostics: Four Recent Tests that have Revolutionized Clinical Practice. EJIFCC 2019; 30: 7–13.
2. Lippi G. Weighting healthcare efficiency against available resources: value is the goal. Diagnosis (Berl) 2018; 5: 39–40.
3. Majkić-Singh N. Laboratory Medicine Management: Leadership Skills for Effective Laboratory. J Med Biochem 2017; 36: 207–10.
4. Price CP, Wolstenholme J, McGinley P, St John A. Translational health economics: The key to accountable adoption of in vitro diagnostic technologies. Health Serv Manage Res 2018; 31: 43–50.
5. Hawker CD. Nonanalytic Laboratory Automation: A Quarter Century of Progress. Clin Chem 2017; 63: 1074–82.
6. Genzen JR, Burnham CD, Felder RA, Hawker CD, Lippi G, Peck Palmer OM. Challenges and Opportunities in Implementing Total Laboratory Automation. Clin Chem 2018; 64: 259–64.
7. Lippi G, Da Rin G. Advantages and limitations of total laboratory automation: a personal overview. Clin Chem Lab Med. 2019 Feb 2. doi: 10.1515/cclm-2018-1323. [Epub ahead of print].
8. Lippi G, Simundic AM. Laboratory networking and sample quality: a still relevant issue for patient safety. Clin Chem Lab Med 2012; 50: 1703–5.
9. Lukić V. Laboratory Information System – Where are we Today? J Med Biochem 2017; 36: 220–4.
10. Plebani M, Laposata M, Lippi G. Driving the route of laboratory medicine: a manifesto for the future. Intern Emerg Med 2019; 14: 337–40.
11. Lippi G, Favaloro EJ. Laboratory hemostasis: from biology to the bench. Clin Chem Lab Med 2018; 56: 1035–45.
12. Jørgensen PE. Leadership and Management in Clinical Biochemistry. J Med Biochem 2017; 36: 216–9.
13. Lippi G, Plebani M. Cost, profitability and value of laboratory diagnostics: in God we trust, all others bring data. J Lab Med 2019; 43: 1–3.
14. Lippi G, Cadamuro J. Novel Opportunities for Improving the Quality of Preanalytical Phase. A Glimpse to the Future? J Med Biochem 2017; 36: 293–300.
15. Knowles S, Barnes I. Lean laboratories: laboratory medicine needs to learn from other industries how to deliver more for less. J Clin Pathol 2013; 66: 635–7.
16. Aluttis C, Bishaw T, Frank MW. The workforce for health in a globalized context--global shortages and international migration. Glob Health Action 2014; 7: 23611.
17. Liu JX, Goryakin Y, Maeda A, Bruckner T, Scheffler R. Global Health Workforce Labor Market Projections for 2030. Hum Resour Health 2017; 15: 11.
18. Cortelyou-Ward K, Ramirez B, Rotarius T. The laboratory workforce shortage: a managerial perspective. Health Care Manag (Frederick) 2011; 30: 148–55.
19. Lippi G, Plebani M. The add value of laboratory diagnostics: the many reasons why decision-makers should actually care. J Lab Precis Med 2017; 2: 100.
20. Chasin BS, Elliott SP, Klotz SA. Medical errors arising from outsourcing laboratory and radiology services. Am J Med 2007; 120: 819.e9–11.
21. Lackner KJ, Gillery P, Lippi G, Melichar B, Schlattmann P, Tate JR, et al. The Theranos phenomenon, scientific transparency and freedom of speech. Clin Chem Lab Med 2016; 54: 1403–5.
22. Plebani M, Laposata M, Lippi G. A manifesto for the future of laboratory medicine professionals. Clin Chim Acta 2019; 489: 49–52.
23. Horvath AR. From evidence to best practice in laboratory medicine. Clin Biochem Rev 2013; 34: 47–60.
24. Jassam N, Lake J, Dabrowska M, Queralto J, Rizos D, Lichtinghagen R, et al. The European Federation of Clinical Chemistry and Laboratory Medicine syllabus for postgraduate education and training for Specialists in Laboratory Medicine: version 5 – 2018. Clin Chem Lab Med 2018; 56: 1846–63.

Received: April 4, 2019

Accepted: April 6, 2019