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Performance evaluation of the introduction of full sample traceability system within the specimen collection process

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Abstract

Objectives: To evaluate the efficacy, safety and efficiency performances related to the introduction of innovative traceability platforms and integrated blood collection systems, for the improvement of a total testing process, thus also assessing the economic and organizational sustainability of these innovative technologies.

Methods: A mixed-method approach was utilized. A key-performance indicators dashboard was created based on a narrative literature review and expert consensus and was assessed through a real-life data collection from the University Hospital of Padova, Italy, comparing three scenarios over time (2013, 2016, 2019) with varying levels of technological integration. The economic and organizational sustainability was determined considering all the activities performed from the tube check-in to the validation of the results, with the integration of the management of the prevalent errors occurred during the process.

Results: The introduction of integrated venous blood collection and full sample traceability systems resulted in significant improvements in laboratory performance. Errors in samples collected in inappropriate tubes decreased by 42 %, mislabelled samples by 47 %, and samples with irregularities by 100 %. Economic analysis revealed a cost saving of 12.7 % per tube, equating to a total saving of 447,263.80 € over a 12-month period. Organizational efficiency improved with a reduction of 13,061.95 h in time spent on sample management, allowing for increased laboratory capacity and throughput.

Conclusions: Results revealed the strategic relevance of introducing integrated venous blood collection and full sample traceability systems, within the Laboratory setting, with a real-life demonstration of TLA economic and organizational sustainability, generating an overall improvement of the process efficiency.

Keywords: value-based laboratory medicine; traceability systems; integrated venous blood collection systems; performance assessment; economic sustainability; organizational impact

Introduction

In recent years, most clinical laboratories have encountered several difficulties resulting from the gradual and continuous increase in the number of samples being received with limited budgets and personnel shortages, thus being forced to optimize their workflow to gain productivity, while maintaining analytical quality [1–3].

Laboratory testing represents a complex process commonly called the total testing process (TTP) that was originally described by Lundberg [4] and modified by Plebani and colleagues [5] and it is usually subdivided into three traditional (pre-, intra-, and post-) analytical phases [6].

Within the laboratory setting, diagnostic blood samples collected by phlebotomy are the most common type of biological specimens drawn and sent to medical laboratory, for being analyzed, thus supporting clinicians in patient diagnosis, follow-up and/or therapeutic monitoring [7]. As such, medical laboratory testing plays a crucial role in the early detection, diagnosis, and treatment of diseases in patients, to support clinical decision-making [8, 9]: up to 70 % of clinical decisions are based on laboratory results [10–14], underscoring the importance of accuracy throughout the total testing process (TTP).

The quality of results and patients' outcomes is strongly related not only on analytical accuracy but also on the pre-analytical step, representing "the process of accepting samples by the laboratory, centrifuging, aliquoting, diluting, and sorting the biological samples" [15].

Errors in this phase, such as incorrect sample collection, mislabeling, or inappropriate handling, can significantly

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impact the quality of laboratory results and ultimately affect patient outcomes with a consequent healthcare costs' increase [16–25], thus also leading to significant inefficiencies within a healthcare setting that is already under unprecedent pressure.

Of all errors in TTP, approximately one fourth have consequences for the patient, which include a delayed test result or new sample collection but may also have a life-threatening impact [11, 12, 17, 18]. In this regard, scientific societies worldwide (such as the International Federation of Clinical Chemistry) have raised awareness concerning the need to identify quality assurance tools (in terms of quality indicators) that are effective in reducing the error rate and enhancing patient safety, with the aim to assess and monitor all the critical events occurring in the different phase of TTP [21, 22, 26–29].

As such, it is crucial to have high quality samples, properly collected, identified, and matched with the right patient, correctly labelled, and transported in the right conditions [25].

Considering all these factors, any strategies and tools able to prevent and/or limit the occurrence rate of such errors plays a key role in laboratory medicine, with an improvement in patients' healthcare outcomes [30], thus optimizing the overall laboratory internal processes, from an organizational and efficiency perspective.

Within this setting, innovative technologies, grounding on an effective traceability systems (based on electronic patient and sample identification, through a barcode reading technology and a user interface to guide, track and digitalize the sample collection process) and integrated venous blood collection systems (in terms of system where components are from a single manufacturer or from different manufacturers declaring mutual compatibility [31]), were developed to support phlebotomists in the draw phase by detecting manual errors at the blood collection point, trying to minimize the errors in the process and enabling a total process testing management [32], thus enhancing the overall efficiency and improving safety for patients and healthcare workers [20, 33]. These pre-analytical technologies consist in platforms and integrated blood collection systems that brings sample traceability, guiding phlebotomists through the entire process, by assuring that patient ID, tests and tube types are correctly matched and tracked, thus reducing errors, and improving the quality of testing, as well as labelling activities [34, 35]. The integrated adoption of such technologies would allow to achieve a standardization of all the activities occurring in the preanalytical phase, being compliant with international guidelines [26, 30].

However, while the theoretical benefits of these technologies are well-documented, empirical evidence supporting their economic and organizational sustainability in real-world settings remains limited.

Moving from these premises, the present paper, in the attempt to overcome this knowledge gap, aims at defining the real-life efficacy, safety and efficiency outcomes performance, in the implementation of traceability platforms and integrated blood collection systems, enabling a TTP management, from blood sample collection tubes processing to results reporting activities, thus also defining the related economic and organizational sustainability. This topic is important since continuous monitoring of laboratory performances is a key activity for identifying errors and fostering further improvements in Laboratory Medicine [21, 22].

Hence, the achievement of such a broad objective would answer the following specific research questions (RQ).

- RQ1: "Which is the real-life impact on efficacy and safety performance related to the introduction of innovative traceability platforms and integrated blood collection systems, for the improvement of a total testing process, thus supporting a full traceability of blood samples?"
- RQ2: "Would the introduction innovative traceability platforms and integrated blood collection systems in the pre-analytical laboratory phase represent a feasible and sustainable option, from an efficiency, economic and organizational perspective, thus enhancing the overall efficiency of laboratory services?".

By addressing these research questions, this study aims to provide robust evidence on the impact of advanced traceability systems and integrated blood collection technologies, thereby offering insights that could inform future investments in laboratory medicine and contribute to the broader goal of enhancing patient safety and healthcare efficiency.

Materials and methods

For the achievement of the above challenging objectives a mixed-method approach [36] was implemented, thus integrating evidence-based information with expert opinions and real-life quantitative data.

In general terms, the research methodology consisted of two distinct stages.

At first, a performance measurement tool tailored to the study's needs was defined, based on a narrative literature review [37–39], useful to understand the state of art of efficacy and safety indicators used within the laboratory setting, focusing on the pre-analytical activities.

After having selected the main indicators to be used, a real-life data collection based on retrospective information was conducted within the laboratory of the University Hospital of Padova in Veneto Region (Italy) presenting a ISO15189 certification, thus demonstrating a significant application

example, testing the real-life performance within a concrete setting. This stage was designed to address RQ1.

Based on the above collected information, the efficiency, economic and organizational sustainability concerning the introduction of innovative traceability platforms and integrated blood collection systems in the pre-analytical phases was assessed. This second stage was designed to address RQ2.

In particular, the study design (Figure 1), related to both stages, focused on the comparison among the following real-life scenarios occurring within the hospital involved, in three different time frames, differing from an alternative level of innovative technologies being introduced over the time.

- Real-life Scenario #1: adoption of combined venous blood collection system (tubes, needles, sets), referring to the hospital practice occurring in the year 2013.
- Real-life Scenario #2: adoption of integrated venous blood collection system, and an effective traceability system based on electronic patient and sample identification, through a barcode reading technology and a user interface to guide, track and digitalize the entire sample collection process, referring to the hospital practice occurring in the year 2016 and considering the first year after the innovative technologies' implementation.
- Real-life Scenario #3: adoption of integrated venous blood collection system, and an effective traceability system based on electronic patient and sample identification, through a barcode reading technology and a user interface to guide, track and digitalize the entire sample collection process, referring to the hospital practice occurring in the year 2019, after 3 years from innovative technologies' implementation, when healthcare professionals achieved a complete knowledge in the practical use of such innovative technologies.

The design of a key-performance indicator dashboard

For the definition of a key-performance indicators (KPIs) dashboard, a narrative literature review was initially conducted, thus identifying the most important measurement aspects related to the introduction of integrated venous blood collection system, and an effective traceability system based on electronic patient and sample identification, through a barcode reading technology and a user interface to guide, track and digitalize the sample collection process, within the pre-analytical phase of laboratory procedures. This was important to synthesize and help providers visualize large quantities of continuously updated data and to facilitate clinical, operational, and strategic decision-making [40].

As such, the design of a KPIs dashboard to be used to monitor the pre-analytical phases within laboratory procedure, in the attempt to improve patient safety and to reduce avoidable errors, is a key priority for healthcare systems, being consistent with ISO15189 standards.

The KPIs dashboard, by continuously monitoring and updating relevant metrics such as sample mislabeling, inappropriate tube usage, and sample integrity issues,

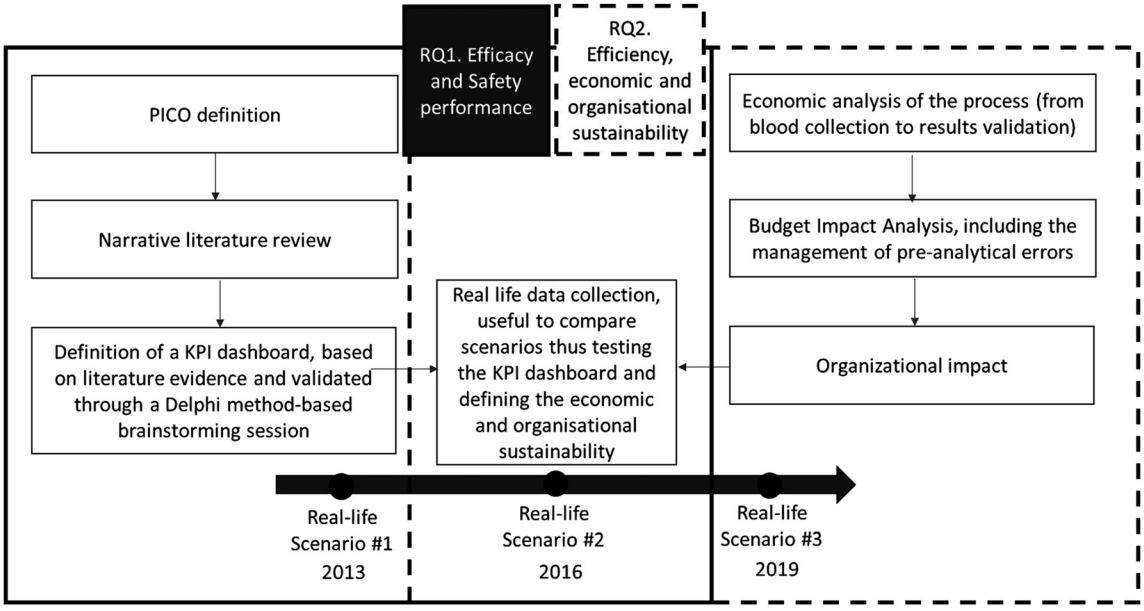

Figure 1: Study design.

allows healthcare providers to identify potential issues early in the diagnostic process. This early identification enables timely corrective actions, reducing the risk of diagnostic errors, delayed results, and subsequent inappropriate clinical decisions. Moreover, by providing a clear visualization of trends and outliers, the dashboard may support clinicians in understanding the reliability of laboratory data upon which they base their diagnostic and therapeutic decisions.

Before undertaking the literature review, a "PICO" (Patient, Intervention, Comparator, Outcome) was defined [41], as follows.

P = "Patient/population" = total testing management process – from blood sample collection to results reporting activities in laboratory (for in-patient and out-patient)

I = "Intervention" = presence of integrated venous blood collection system, and full sample collection traceability system to digitalize the entire sample collection process.

C = "Comparator" = absence of integrated venous blood collection system, and full sample collection traceability system to digitalize the entire sample collection process.

O = "Outcome" = efficacy and Safety indicators, in terms of errors and risks that may occur in the use of the investigated technologies.

Literature evidence came from the search of literature databases (Pubmed, Embase, Scopus electronic and Cochrane Library databases), with no restriction in terms of time horizon and language. Titles and abstracts were screened by two independent researchers. The review included primary studies (any design) and secondary studies (systematic reviews, overviews, and other evidence syntheses): grey literature was excluded.

The main search terms used for the development of narrative literature review were the followings, thus also included synonyms or periphrasis: "blood sample", "pre-analytical workstation", "laboratory medicine", "traceability systems", "collection tubes", "preanalytical error", "Quality indicators".

The search strategies included all the combination of the above-mentioned keywords.

Based on the above, out of 119 papers, 9 records [20–22, 30, 32, 42–45] were eligible for the creation of the performance tool, thus proposing a set of KPIs, concerning efficiency, and organizational factors, all related to the introduction of innovative traceability platforms and integrated blood collection systems within the pre-analytical phase.

To further refine the selection of KPIs and ensure their relevance and applicability in a real-world laboratory setting, structured interviews with experts and a Delphi method-based brainstorming session were conducted [46]. This process involved six experts representing three distinct groups in Italy: laboratory professionals, technology manufacturing company managers, and academics specializing in healthcare and performance measurement. Initially, the experts participated in a brainstorming session to identify the primary features and performance indicators recognized in the literature review.

Following this, an initial draft of the performance measurement tool was developed and circulated among the experts. A two-round Delphi method process was then employed to achieve a robust consensus on the most critical KPIs to be included in the dashboard. This iterative process allowed for the refinement of indicators and ensured that the final set was both comprehensive and practical for real-life application.

The resulting KPIs were consistent with the quality indicators proposed by the International Federation of Clinical Chemistry and Laboratory Medicine (IFCC) [21, 22], providing a solid foundation for ongoing monitoring and improvement of laboratory performance. The specific KPIs dashboard is available in Supplementary Table 1.

Real-life data collection

The real-life data collection was used to observe the differences among scenarios, regarding the previously defined KPIs dashboard, determining the value of integrated venous blood collection system, and full sample collection traceability platforms, enabling a total testing management process (answering to RQ1), within the pre-analytical phase. In addition, real-life information was useful to define the economic and organizational sustainability related to the introduction of the above innovative technologies in the laboratory pre-analytical phase (addressing the RQ2).

Data was collected from real-world evidence in an anonymous and aggregated manner, to understand the performance of such innovative technologies in the real and routinary clinical practice, with an observational retrospective study based on specific information already available in the Laboratory Information System (LIS), covering all the items defined with the performance indicators, according to different time-frames related to the technological switches occurred in the hospital involved during the years 2013–2019. Each scenario comprised the blood collection activities performed within a 12-month time horizon, thus being comparable, referring to the above-mentioned years 2013 (Real-life Scenario #1), 2016 (Real-life Scenario #2) and 2019 (Real-life Scenario #3). This time horizon was chosen to obviate any problems related to the pandemic.

The data collection was approved by LIUC University Ethical Committee (protocol number R12-23 dated 23rd June 2023), as retrospective analysis of anonymous data.

Economic and organizational impact assessment

While the primary objective of this study is on the impact of a traceability system for samples, particularly in the pre-analytical phase, the evaluation of total laboratory costs over six years encompasses broader changes within the laboratory, including potential updates in instrumentation and organizational structure.

To correctly assess the economic and organizational sustainability of the introduction of innovative technology to support a complete blood traceability (from blood collection to results' validation) within the clinical practice, a process mapping technique, grounding on a time-driven activity-based costing approach – TDABC – was implemented to define the costs related to the management of blood sample with (Real-life Scenario #2 and Scenario #3) or without (Real-life Scenario #1) the introduction of innovative technologies [47–49]. By focusing on the time and resources directly impacted by the traceability system (such as reduced errors in sample handling, decreased time spent on reprocessing samples, and improved workflow efficiency), the cost savings attributable to the system itself have been isolated.

This was thus useful to highlight all the costs related to each technology and verify the level of resources consumption, assuming the hospital perspective, within a 12-month time horizon. In fact, the potential confounding effects of changes in instrumentation and organizational practices were controlled by comparing scenarios over specific time frames (2013, 2016, and 2019). Each scenario was analyzed independently, with a focus on the year immediately following the introduction of the traceability system (2016) and a subsequent year after the system had been fully integrated and optimized (2019). This approach allowed the assessment of the impact of the traceability system at different stages of its implementation, while accounting for other changes in the laboratory environment.

Based on the clinical practice performed in the hospital involved, the process was divided in the following phases: (1) collection; (2) check-in; (3) preparation; (4) analysis and (5) validation. For each of the above phases, the following healthcare direct costs were determined.

i. **Human resources**, in terms of time by each healthcare professional along the entire process, valorized in accordance with the Italian National Labor Contracts per professional class, considered as labor costs. This approach was useful to allocate a cost for each activity in terms of the work factor, thus calculating the cost per minute for each healthcare professional involved.
ii. **Equipment**, considering typology of equipment implemented for the management of blood samples during the entire process. For the economic evaluation of the equipment, the analysis considers the depreciations of each equipment and their costs related to the number of samples analyzed and processed, assuming a 12-month time horizon, based on hospital tender procedures.
iii. **Consumables and medical devices**, collecting the number of the different consumables and medical devices spent for the proper management of blood samples within a Hospital Laboratory, based on hospital tenders' procedures.

Besides the above items of costs, the analysis also considered the hospital general and fixed costs, consisting of all those costs different from labor factors, consumables, and equipment usage, being necessary to perform laboratory activities thus accounting for the 20 % of healthcare directs costs [50].

Furthermore, the economic analysis also considered the management of any errors that may occur within the laboratory procedures. The occurrence rate of such deviations derived from the real-life data collections, based on the KPIs identified within the first stage. As such, it was relevant to define the costs related to their management, based on the need to repeat the entire process of blood collection, analysis, and validation or to require a technical intervention. The management strategies of such deviations derived from the clinical practice declared by the healthcare professionals involved, according to a Delphi method approach [49], as depicted in Table 1.

After the definition of the economic resources per single process, a budget impact analysis (BIA) was developed [51], thus evaluating the financial sustainability regarding the introduction of innovative solutions in the laboratory setting within the specific pre-analytical phase. The BIA assumed the hospital perspective, over a 12-month time horizon and measured a complete technological modification (replacement rate equal to 100 %), considering the overall tubes analyzed and processed on annual basis (assuming the year 2019), investigating the historical volume of clinical laboratory procedures retrospectively collected.

The same analysis was conducted for the organizational assessment [52, 53], to define a release in the time spent by human resources to perform the process and manage blood samples. As for the BIA, the identification of the potential organisational system capacity was performed, based on the overall historical volume of laboratory procedures, considering a 12-month time horizon.

Table 1: Management of the prevalent deviations occurred in the pre-analytical phase.

Errors occurring within the pre-analytical phase	Management of such errors
Samples collected in inappropriate tube	100 % repetition of the entire process of blood collection, analysis, and validation
Sample with underfilled tube	
Samples with irregularities (i.e. clotted samples or specimen contamination)	20 % repetition of the entire process of blood collection, analysis, and validation 80 % technical intervention
Misidentified sample	100 % repetition of the entire process of blood collection, analysis, and validation, considering two persons
Mislabelled samples	
Samples carried at temperature out of limit	30 % repetition of the entire process of blood collection, analysis, and validation 70 % technical intervention

Results

Performance measurement in the laboratory setting

Table 2 depicts a synthesis of the comparative real-life information among Scenarios, presenting data extracted from the LIS useful to assess the occurrence of preanalytical errors in each phase of the study.

Table 2: Synthesis of the comparative real-life information among Scenarios.

	Real-life Scenario #1 year 2013 n (%)	Real-life Scenario #2 year 2016 n (%)	Real-life Scenario #3 year 2019 n (%)	p-Value
Number of the overall samples collected and analyzed	307,992	276,150	381,474	Not applicable
% of samples collected in inappropriate tube	1,160 (0.38 %)	701 (0.25 %)	672 (0.18 %)	0.003
% of samples with underfilled tube	347 (0.11 %)	710 (0.26 %)	0 (0.00 %)	0.032
% of samples with irregularities (i.e. clotted samples or specimen contamination)	125 (0.04 %)	240 (0.09 %)	0 (0.00 %)	<0.001
% of misidentified samples	0 (0.00 %)	0 (0.00 %)	6 (0.002 %)	0.039
% of mislabelled samples	628 (0.20 %)	682 (0.25 %)	334 (0.09 %)	<0.001
% of samples carried at temperature out of limit	36 (0.01 %)	45 (0.02 %)	411 (0.11 %)	0.002

The trend registered concerning the number of the overall samples collected and analysed demonstrated an incremental activities volume during years, in line with the statistics highlighted by the clinical laboratories in the Italian National context, where the growing impact of the analyses requested is evident.

The introduction of integrated venous blood collection system, and full sample collection traceability system, considering a complete learning curve (Real-life Scenario #3), is related to a decrease in samples collected in an inappropriate tube (from 1,160 samples to 672, –42 %), with a statistically significant difference among scenarios. The same trend emerged concerning the number of samples with underfilled tube, reporting a decrease over the time (p-value=0.032). All these results demonstrated how and how much samples full traceability system may support the healthcare professionals avoiding such complication that implies the repetition of the blood sample and consequently inefficiency. In addition, Real-life Scenario #3 is related to the complete absence of occurrence rate of sample with irregularities (in terms of incorrect samples, due to specimen contamination or clotted samples), thus confirming the capability of innovative technologies to avoid any error, incorrection or irregularity and increase the capacity to detect irregularities (p-value <0.001), through the enhancement of the precision and the consistency of the blood collection process. In addition, the use of such innovative technologies may standardize the blood collection process by guiding the phlebotomist through each step, ensuring that proper techniques are followed consistently, also ensuring that the correct tube with the appropriate anticoagulant is used for each type of test. Besides the opportunity to use specific blood collection system, it should be noted that the traceability system improves the efficiency of the workflow, ensuring that samples are processed more quickly, limiting the exposure to varying temperatures or delays in mixing with anticoagulants. Results also demonstrate a decrease in mislabeled samples (–47 %), contributing to an improvement in the workflow (p-value <0.001). A slight increase can be noted between Real-life Scenario #1 and #2 concerning the occurrence of both mislabeled samples and sample with irregularities even if no statistically significant differences emerged (p-value >0.05), due to the learning curve of the laboratory staff devoted to know, implement and use all the innovative technologies functions.

On the other hand, the increased percentage of errors for the misidentifies sample depends on the informatic traceability system introduction (p-value=0.039), leading to a more accurate analysis and investigation of this specific step, in the broader technology cycle. The same consideration could be drawn about the samples carried at temperature

out of limit. Results show a considerable increase (+1,042 %) between Real-life Scenario #1 and #3 (p-value=0.002). Most likely, in Scenario #1 data concerning the rate of samples carried at temperature out of limit were not observed or registered accurately, while in Scenario #3 (given the presence of such innovative technologies) the detection of the samples is easier and consequently the laboratory can organize and manage better this problem, to give the priority to improve the quality of laboratory analyses and the care of patients. This further confirms the need for automatic detection of errors and risk of errors in some steps of the laboratory cycle.

Economic and organizational impact assessment

Table 3 depicts the cost per tube related to each Scenario. It should be noted here that, from an economic perspective, Real-life Scenario #2 and #3 are superimposable in their costs measurement since they comprise the same panel of technologies.

The introduction of innovative solutions, despite being more expensive in terms of equipment (+9.6 %), would lead to an economic saving per tube equal to 12.7 %, in comparison to Real-life Scenario #1, reporting a statistically significant difference (p-value=0.003). This benefit is mostly due to human resources involved, whose effort is significantly lower in case of innovative technologies implementation (p-value=0.018), given a reduction of mislabeled samples, underfilled tubes, and other errors that require costly reprocessing.

A decrease of 20 % (1.25 min for Real-life Scenario #1 vs. 1.00 for Real-life Scenario #2 and #3) emerged, considering the time spent by a nurse in conducted the blood draw. The same advantages emerged considering the time spent by the clinician, with lower minutes spent for each process, about the validation of results. In conclusion, a time reduction of 50 % emerged (3.00 min for Real-life Scenario #1 vs. 1.50 for Real-life Scenario #2 and #3), with reference to the time specifically spent by the administrative staff to check in the test tube.

In considering 381,474 tubes being analyzed on annual basis, the BIA (Table 4) reports that the introduction of integrated venous blood collection system, and full sample collection traceability (Real-life Scenario #1 vs. Scenario #3) would lead to an economic saving equal to −447,263.80 € (−13.15 %), thus also comprising the cost related to the management of any preanalytical errors. Positive results, in terms of achievement of ceasing costs, emerged also considering the first year after the introduction of innovative technologies: in the comparison

Table 3: Economic assessment of the process, stratified among Scenarios.

	Real-life Scenario #1	Real-life Scenario #2 and Scenario #3	Difference, €	Difference, %
Human resources	4.74 €	3.80 €	−0.94 €	−19.8 %
Equipment	0.95 €	1.04 €	0.09 €	9.6 %
Consumables	1.67 €	1.59 €	−0.08 €	−5.1 %
Fixed costs	1.47 €	1.28 €	−0.19 €	−12.7 %
Total costs of the process (from blood collection to results validation)	**8.83 €**	**7.71 €**	**−1.12 €**	**−12.7 %**

Table 4: Budget impact analysis, considering a 12-month time horizon.

Costs	Real-life Scenario #1	Real-life Scenario #2	Real-life Scenario #3
Cost of the process	3,368,479.44 €	2,941,128.41 €	2,941,128.41 €
Cost related to the management of samples collected in inappropriate tube	12,686.81 €	7,465.98 €	5,181.06 €
Cost related to the management of samples with underfilled tube	3,806.38 €	7,558.70 €	0.00 €
Cost related to the management of sample with irregularities	1,110.79 €	2,282.68 €	0.00 €
Cost related to the management of misidentified samples	0.00 €	0.00 €	117.65 €
Cost related to the management of mislabelled samples	13,743.40 €	14,529.17 €	5,176.39 €
Cost related to the management of samples carried at temperature out of limit	157.80 €	165.53 €	1,117.31 €
Total costs	**3,399,984.61 €**	**2,973,130.48 €**	**2,952,720.81 €**
BIA between Real-life Scenario #1 and Real-life Scenario #2		**−426.854,13 €** **−12.55 %**	
BIA between Real-life Scenario #2 and Real-life Scenario #3		**−20.409,67 €** **−0.69 %**	
BIA between Real-life Scenario #1 and Real-life Scenario #3		**−447.263,80 €** **−13.15 %**	

Table 5: Total time related to each Scenario, considering a 12-month time horizon.

Time	Real-life Scenario #1	Real-life Scenario #2	Real-life Scenario #3
Time related to the process, hours	54,042.15	41,326.35	41,326.35
Time related to the management of samples collected in inappropriate tube, hours	203.54	104.91	72.80
Time related to the management of samples with underfilled tube, hours	61.07	106.21	0.00
Time related to the management of sample with irregularities, hours	25.29	51.44	0.00
Time related to the management of misidentified samples, hours	0.00	0.00	1.65
Time related to the management of mislabelled samples, hours	220.49	204.15	72.73
Time related to the management of samples carried at temperature out of limit, hours	3.55	3.05	20.60
Total time, hours	**54,556.08**	**41,796.11**	**41,494.14**
System capacity between Real-life Scenario #1 and Real-life Scenario #2		**−12,759.97 h −23.39 %**	
System capacity between Real-life Scenario #2 and Real-life Scenario #3		**−301.97 h −0.72 %**	
System capacity between Real-life Scenario #1 and Real-life Scenario #3		**−13,061,95 h −23.94 %**	

between Real-life Scenario #1 and Scenario #2, an economic advantage equal to −12.55 % is reported (representative of-426,854.13 €). In general terms, the impact related to the management of any errors on the total costs has decrease over time, ranging from 0.93 % related to Real-life Scenario #1 to 0.39 % related to Real-life Scenario #3.

From an organizational perspective, the process mapping revealed a decrease in the time spent by healthcare professionals in the management of blood samples if traceability and integrated systems are adopted, thus being equal to 8 min 50 s for Real-life Scenario #1 and 6 min 50 s for both Scenario #2 and #Scenario 3 (p-value=0.013).

In processing 381,474 over a 12-month time horizon, in the comparison between Real-life Scenario #1 and Real-life Scenario #3, the presence of innovative technologies generates organisational savings equal to 13.06195 h, that could be devoted, based on a cost-opportunity approach, to process additional samples or to perform other core activities for a laboratory (Table 5).

Discussion

The results of the present study provided new evidence about the performance of laboratory technologies used within the pre-analytical phase, thus achieving a multidimensional and holistic vision of the performance related to laboratory activities in the pre-analytical phase (RQ#1), covering efficacy and safety domains, but also gathering data to complete an economic and organizational analysis useful to enhance the overall efficiency process (RQ#2).

The interest in assessing the quality in laboratory medicine has become increasingly relevant as scientific evidence highlights the crucial role it plays in the clinical decision-making process and patient management. Over the years, the assessment of quality indicators' performance has become a priority to control the most critical TTP procedures and activities, and to improve the processes. This monitoring activity should therefore be part of a coherent and integrated quality improvement strategy implemented according to International Standard for Medical Laboratories Accreditation (ISO15189: 2022) [54].

The present study reports the real-life results regarding the measurement of specific quality indicators within the laboratory pre-analytical phase, comparing different phases of technological advancements, in particular regarding the adoption of specific healthcare technologies (such as traceability and integrated blood collection systems) within the TTP. This is consistent with the main principles of KPIs measurement, suggesting that the development of dashboards asks the question of the definition of KPI, the description of their interconnections and their temporality of driving, because static performance reporting systems are not able to completely satisfy healthcare manager's decision support needs [54–57].

Results, derived from real-life data collection in Italy, demonstrated several advantages due to the introduction of traceability and integrated blood collection systems in laboratory medicine. The development of a tool for the measurement of the performance of the laboratory processes, and the consequent real-life observation of such performances, through a comparative scenario approach, allowed an answer to RQ1. An important reduction of samples collected in inappropriate tubes (−42 %) and of mislabeled samples (−47 %) emerged, thus being consistent with literature on the topic [30, 42, 45], and strengthening the need to utilize a proper blood collection system. This feature

acquires a strategic relevance: labelling is an unavoidable procedure in clinical and laboratory practice, and consists, in the pre-analytical phase, to attach to the blood tube an adhesive paper label, with specific information (patient data, the tests that will be performed, etc. …). However labeling process could be eliminated through the pre-barcoded tubes. In this case the digitalized management of the collection system should include an adequate software able to match inseparably and in univocal way patient tests ordered to pre-barcoded tubes with the aim to assure reduction of sample preparation timing, wrong tube selection, wrong labelling, and avoiding repetitive tasks for the operators.

Based on the improvement of performance indicators, results have also demonstrated the economic and organisational sustainability related to the introduction of integrated venous blood collection system, and full sample collection traceability platform within the pre-analytical phase. Over a 12-month period, hospitals acquiring such innovative technologies may benefit from an economic saving equal to 13.15 % and from an organizational advantage, in terms of release of human resources involved in the process, equal to 13,061.95 h saved. This could be translated, considering a cost-opportunity approach, in a potential capability of the hospital to process 120,572 additional tubes, referring to on average 40,191 additional patients requiring laboratory activities. The above results would consequently allow us to answer RQ2.

Despite the relevance of the results, it is important to discuss on their limitations The generalization of results and conclusions from this study to other laboratory settings should be taken into consideration because the data utilized may be representative of the unique characteristics of a specific setting. However, data reflect an Italian real clinical practice, represented by a big hub hospital with high volume. Secondly, despite innovative technologies positive impact on the process efficiency improvement, their adoption may be related to a professional resilience to change, because of new technologies being perceived as disruptive innovations. In this view, it is important to collect and integrate the perceptions of all the healthcare professionals involved in the blood collection and validation phase, to understand the main drivers impacting on traceability platforms and integrated blood collection systems introduction in Italy. Based on the above, an interesting topic for further research would be the definition of level of acceptability of such technologies. In fact, the acceptability of innovative technologies, with their consequent intention to use in the routinely clinical practice, implies a specific validation, concerning the degree of intention to use of this technology, that will be required by the clinicians and the overall healthcare professionals directly involved in its use.

However, this study offers practitioners a valuable tool for analyzing and managing pre-analytical performance, engaging discussions on the topic of full sample traceability platform and integrated venous blood collection system in laboratory settings. Consequently, this paper delivers practical insights and substantive content for policymaking considerations. Furthermore, it contributes to raising awareness among professionals, particularly those involved in laboratory services. On one hand, results would be useful to inform decision-making in terms of healthcare planning. On the other hand, the findings could help scholars to identify the need of data, related to safety and efficacy, but also in terms of organizational impact both in the short and in the long run, useful to assess the laboratory KPIs. In addition, practitioners could understand the reasons why they are called to use different technologies and why hospitals could invest in innovative technologies, even if the traditional approach seemed to be consolidated. Thus, both the economic and the organizational advantages here presented may be greater if other innovative technologies, able to monitor the preanalytical phase, such as radio-frequency identification systems to monitor temperature at predetermined intervals, from sample dispatch to sample reception, may be implemented and adopted at hospital level.

The authors emphasize the significance of disseminating these results and practical implications internationally to stimulate additional projects aimed at assessing the performance of laboratory technologies currently deployed in a local experience, involving diverse national contexts, to make the available results and evidence more robust. Having a broader panel of hospitals able to measure the proposed indicators in different steps during the change in the pre-analytical process could positively impact on the production of additional data of interest for comparisons and benchmarking activities, necessary and useful for improving the healthcare system performance.

In conclusions, in an era of spending reviews and paucity of resources, all strategies able to prevent a higher economic burden for healthcare systems, and to re-engineer internal processes should be evaluated, and then, if affordable and feasible, implemented.

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