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A real-world evidence-based approach to laboratory reorganization using e-Valuate benchmarking data

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Abstract

Background: Pressure to cut health-care costs has involved clinical laboratories underpinning the need to reduce cost per test through programs designed to consolidate activities and increase volumes. Currently, however, there is little evidence of the effectiveness of these measures. The aim of the present study was to verify whether a rational, evidence-based decision-making process might be achieved based on an activity-based cost analysis performed by collecting the data of all variables affecting cost per test.

Methods: An activity-based costing analysis was performed using a program that provides collected data on performance indicators, benchmark between different laboratories based on performance indicators, and information on reorganization initiatives.

Results: The data provided were used in two different settings to (1) verify the results of the internal re-organization of specific protein assay and (2) simulate some scenarios for the reorganization of autoimmune testing in the network of clinical laboratories in a large territory.

Conclusions: The data produced by the e-Valuate project enabled the quantification of variation in costs, the utilization of human and technological resources and efficiency, both as final result of a reorganization project (proteins) and as a simulation of a possible future organization (autoimmune tests).

Keywords: activity-based costing analysis; clinical laboratory; costs; efficiency; performance indicators; reorganization.

Introduction

In the last few decades, the growth in national spending for health care escalated rapidly in most developed countries and the sustainability of the system represents a controversial issue worldwide. Health-care costs, have increased three-fold faster than wages over the past decade, putting a strain on government resources, employers, and families [1]. All health-care systems are under huge pressure from the demographic bulge and rising per-enrollee spending. While the problem is well known, the strategies designed to solve it are still widely debated. As highlighted in a seminal paper by Daniel Callahan, “cost controls that are likely to be politically acceptable will not be very effective, and what might be effective will not be acceptable” [2]. The debate on cost containment has finally shifted from rationing to waste-avoidance. Berwick and Hackbarth have reported that in the US, spending on interventions that do not benefit patients amounts around 30% of the total budget, this waste being a major driver of cost increases [3]. While all branches of medicine have been involved in cost-reduction measures, increasing economic pressure has impacted on the organization of clinical laboratory activities through the consolidation, merger, and other actions aiming to reduce the cost per test, mainly increasing volumes. Clinical laboratories, with their transparent service costs, have been under particular pressure. Cost containment, the simplest possible economic approach to use in enhancing efficiency, has usually been undertaken without taking into consideration all the variables affecting the final and true cost per test. It has, for example, been taken for granted that an increase in volumes automatically leads to a reduction in costs [4]. Volumes is a reasonable proxy measure, but Barletta et al. [5] and Lippi and Mattiuzzi [6] have demonstrated that several variables other than

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volumes influence the end cost per test. In addition, cost minimization efforts do not comply with the goal of waste avoidance that, in the case of laboratory medicine, translates into inappropriate and duplicated test requesting, poor analytical quality, and inappropriately interpreted and utilized laboratory reports. While the evaluation of outcomes (both economical and clinical) is the ultimate and true indicator of laboratory service quality [7], activity-based cost analysis is of value since it (a) it obliges the laboratory staff to collect the data of all procedures and processes needed to perform a laboratory test or a group of tests; (b) allows the true cost per test to be obtained and compared with the reimbursement; (c) allows a benchmark between different laboratories on the basis of objective data; (d) enables the clinical laboratory staff to identify some priorities and related corrective actions for enhancing efficiency; and (f) allows laboratory efficiency to be evaluated over time [8–10].

The aim of this study was to ascertain whether an activity-based cost analysis performed by collecting the data of all variables affecting cost per test allows (1) a rational and evidence-based decision-making process for continuously measuring and improving laboratory processes and (2) a reliable evaluation of the results of any corrective/preventive actions undertaken.

The program's efficiency and effectiveness was evaluated in one of the clinical laboratories (Pontedera Hospital Laboratory) participating in the program as from 2011. This laboratory was chosen, as it used the data collected not only for internal reorganization projects, but also

for suggesting possible strategies for re-organizing the network of laboratory services in a large territory (north-west Tuscany area).

Materials and methods

Activity-based costing tool

The activity-based costing analysis was performed according to the principles described by Cooper and Kaplan [8, 9] and Cao et al. [4] using the “e-Valuate” program (formerly “ProcessQC”) provided by Gene.sys of G. Barletta (based in Poggio a Caiano, PO, Italy). “e-Valuate”, a commercial program, has enrolled 37 Italian Laboratory sites of 17 health-care organizations (all public except one) when the study was initiated. A map of the internal processes of each laboratory site was defined and the resources (materials, instruments, staff, utilities) allocated to the appropriate part of the process in order to produce the indicators listed in Table 1. Detailed information on the program has been reported elsewhere [5].

The program gives participating clinical laboratories three main outputs: (a) data collected over time on performance indicators: numeric data on a quarterly base are provided for each indicator listed in Table 1; (b) benchmarking between different laboratories based on performance indicators: the position of the laboratory is defined as its percentile value versus that of the other laboratories within the same cluster (the program calculates three clusters for each indicator, based on workload volumes); the higher the percentile value, the better the performance, and (c) a simulation tool: the program provides dispersion graphs for each indicator; a “trend line” calculated on the basis of the 50th percentile can be used as a suggestion for the possible result when a scenario analysis based on workload is performed.

Table 1: Indicators used in e-Valuate project.

Indicator	Meaning	Use
Cost per test	Total cost/number of tests per year	Sales price definition, trend, benchmarking
Supplies costs	Total cost for materials, instruments and services pertaining to the process	Trend, budget variation, benchmarking
Staff costs	Staff cost for the time dedicated to the process	Trend, budget variance, benchmarking
General ledger	General ledger (facilities, utilities, shared services) involved in the process	Trend, budget variance. Not used in benchmarking report of excessively high differences in the ways of assigning general ledger to the structures within health-care organizations
Total cost	Sum of supplies costs and staff costs	Trend, budget variance, benchmarking
Staff hours	Total number hours worked within the process	Trend, budget variance, benchmarking
Managers hours	Number hours worked by lab managers within the process	Trend, budget variance, benchmarking
Technical staff hours	Number of hours by technical staff within the process	Trend, budget variance, benchmarking
Technical staff/managers ratio	Technical staff hours/managers' hours	Benchmarking
Productivity	Number of tests per year/staff hours	Benchmarking
Profitability (ROI index)	Revenues/total cost	Trend, budget variance, benchmarking

Setting

Two cases are discussed:

1. Internal reorganization results: the case of specific protein assay.

The goal was to improve upon staff allocation. Benchmarking report for year 2011 showed a poor performance for the technical staff hours indicator (33rd percentile). A corrective action was taken, the diagnostics of specific proteins being moved from the traditional standalone nephelometry workstation to the core-lab, using an Advia Vista platform (which allows the simultaneous measurement of clinical chemistry, specific proteins, and some immunoassays tests) starting from June 2012. Nephelometry cost per test and staff cost both in the protein section and in the Dimension Vista workstation was monitored throughout 2011, 2012 and 2013 with the internal e-Valuate reports. A simple Student's t-test was made to verify the significance of costs changes during the years considered.

2. Strategies for addressing the reorganization of the network of clinical laboratories in a vast territorial area: a possible scenario for autoimmunity testing.

A pilot project on autoimmunity diagnostics guided by the "e-Valuate" data was performed, in accordance with a resolution of the Tuscany Region (DGRT no. 1235, December 2012), calling for a reorganization of laboratory services according to a networking design. Pontedera Hospital Laboratory performed 10,257 autoimmunity tests during 2013. The benchmarking analysis highlighted its poor degree of efficiency, with a cost per test of €9.82 (29th percentile), while laboratories performing more than 20,000 test per year had an average cost per test of around €6.00 (range, €5.08–€7.96).

According to the overall goal of the reorganization program, a project of consolidation of autoimmunity tests (72,620 total tests) in one of the three laboratories of the same area was designed considering three different scenarios:

- Scenario 1 (S1): using the sum of the resources actually spread on the three laboratories;
- Scenario 2 (S2): using only the staff resources of one laboratory (i.e. Pontedera Hospital Laboratory);
- Scenario 3 (S3): balancing the resources according to evidence and quality needs. To define the best possible balance between the two extreme scenarios previously described, an analysis was made of the activities actually undertaken in the Autoimmunity Section of Pontedera Hospital Laboratory. An evaluation was also made of the activities needed in the scenario starting from the upgrade of the technologies for the autoimmunity section. Moreover, an automation project involving pre-analytical and analytical phases both for EIA and IFA tests was developed. An EIA instrument was to be attached to the main automation within the core-lab that includes an automatic storage module. For IFA tests, a robotic microscope was to be used as well as expert software for patterns interpretation. The use of middleware was planned to manage the post-analytical phase, with the potential to compare results for IFA, EIA and immunoblot results, additional reflex tests and the reporting of pre-defined comments. To estimate the costs of instrumenttion, the laboratory manager requested a quote for autoimmunity testing technologies for the entire system from the main supplier.

Table 2 shows the changes in activities. For the current situation, the activities performed and the average time per test are reported; for the expected scenario, the changes in activities and the average time per test are reported. The time per test in the scenario was calculated assuming that 1.0 FTE of technical staff would be required to operate the instruments and 0.2 FTE for the remaining activities (retrieving/loading /unloading samples). For the consultant, the current unit time for microscope reading IFA tests was reported. For S3 it was assumed that a wide area pole with almost 500,000 inhabitants called for the use of 0.7 FTE to cover consultancy for autoimmunity tests. As the software was able to automatically read all negative samples (currently 80%), it was assumed that positive and doubtful

Table 2: Activities and average time per test according to current and predicted scenarios.

	Staff type	Current situation		Scenario S3			
		Current activities	Min/test	Scenario S3 activities	Min/test	Total hours	
EIA tests	Technician	Sample check-in	4.37	Automated	1.26	1946	
	Technician	Aliquoting		Automated			
	Technician	Storage		Automated			
	Technician	Sample retrieval		Automated			
	Technician	Loading/unloading tubes		Automated			
	Technician	Instrument run conduction		Instrument run conduction			
IFA tests	Technician	Sample check-in	10.57	Automated	3.05		
	Technician	Aliquoting		Automated			
	Technician	Storage		Automated			
	Technician	Sample retrieval		Partly automated			
	Technician	Loading/unloading tubes		Partially automated			
	Technician	Instrument run conduction		Instrument run conduction			
	Consultant	Microscope reading (100% samples)	1.72	Microscope reading (20% samples)			81
		Consultancy		Consultancy			1186
	Section management		Section management		423		

negative samples were read by the consultant (81 h per year, 0.05 FTE). It was estimated that another 0.25 FTE was necessary for the management of the section.

Since a network of carriers already in place was sufficient for moving the autoimmunity tubes without requiring any upgrades, it was assumed that no change in transport costs occurred.

In all three scenarios (S1, S2, and S3), the number of tests per year is the sum of the numbers for the three laboratories; managers and technical staff hours are defined according to the three hypotheses; in S1 and S2, supplies costs are the sum of the costs for the three laboratories; in S3, supplies costs are derived from the supplier's offer.

The simulation tool contained in the benchmarking report enables a comparison to be made between the simulation data and the real data of all the participating laboratories. The dispersion graph for each indicator is shown in Table 1; the software can automatically draw a line defining the theoretical position of the 50th percentile for any volume of production. The respective values for each indicator were used as benchmarks.

Results

First case – specific proteins diagnostics

Table 3 shows the data before and after the reorganization of the workflow in the diagnostic area of specific proteins.

The decrease in the cost per test in 2013 was statistically significant ($p < 0.05$). The same statistical significance was demonstrated for the cost of staff in the protein section.

Second case – wide area laboratory network reorganization (autoimmunity diagnostics)

The data obtained for the three scenarios with the protocol described in the Materials and methods section were filled into the simulation tool provided with the benchmarking report of “e-Valuate”, to check the percentage deviation from the benchmark (defined as the 50th percentile calculated by the software for the workload volume). The three key indicators shown in Table 4 are: Supplies costs, Consultant yearly hours, Technicians yearly hours.

A comparison of S3 scenario with the current situation was made assuming that a virtual Lab with the sum of workload and resources of the existing situation for the three Laboratories (that is exactly the S1 scenario) could simulate correctly the “as is” situation. In Table 5, we have reported the percentile and the absolute value of the S1 and S3 scenarios. The last two columns of Table 5 report the differences in absolute value and in percentage between S1 and S3.

Discussion

First case: specific protein diagnostics

As shown in Table 2, the cost per test decreased from €4.73 to €2.90 (–38%). A decrease in costs for human resources from 197.305 to 139.763 (–29%) euros was achieved.

Table 3: Costs of specific proteins diagnostics before and after reorganization guided by the e-Valuate data.

	2011 (Year)	2012 (First half)	2012 (Second half)	2013 (Year)
Test allocation	Nephelometer (protein section)	Nephelometer (protein section)	Advia Vista (core-lab)	Advia Vista (core-lab)
Cost per test (nephelometry tests)	€4.73	€4.42	€3.04	€2.90
Staff cost (protein section)	€197,305	€169,809		€139,763
Staff cost (Dimension/Advia Vista)	€119,709	€125,527		€125,287

Table 4: Shows the differences (in percentage) between the data and the benchmark.

Scenarios	# Tests	Supplies costs	% Deviation from the 50th percentage	Consultants hours	% Deviation from the 50th percentage	Technical staff hours	% Deviation from the 50th percentage
S1: sum of resources	72,620	€240,590.00	–3%	2262	41%	3607	49%
S2: only Pontedera resources	72,620	€240,590.00	–3%	108	–93%	1245	–48%
S3: balanced resources based on a technologic upgrade	72,620	€300,423.00	21%	1694	6%	1946	–19%

Table 5: Comparison between S3 scenario and the simulation of the current situation (S1).

Indicator	S1 percentile	S3 percentile	S1 value	S2 value	Absolute Δ	% Δ
Cost per test	35	47	€7.54	€6.69	-€0.85	-11%
Supplies costs	59	47	€240,419.00	€300,423.00	€60,004.00	25%
Staff cost	12	53	€307,431.14	€185,715.34	-€121,715.00	-40%
Total cost	35	47	€547,850.23	€486,138.34	-€61,711.00	-11%
Managers hours	18	53	H 2673	H 1694	H -979	-37%
Technical staff hours	41	82	H 3616	H 1946	H -1670	-46%
Technical staff/managers ratio	18	18	O/M 1.35	O/M 1.15	O/M -0.20	-15%

Second case: wide-area laboratory network reorganization (autoimmunity diagnostics)

In Table 4, the three scenarios are compared with the performances of the autoimmunity sections of the other laboratories participating in the e-Valuate project. The 50th percentile, calculated by the software, was taken as the benchmark for each indicator. In the first scenario (Table 4 – S1), supply costs are closely related with the benchmark, while managers and technical staff hours were found to be markedly higher than the benchmark. In the second scenario (Table 4 – S2), staff resources are markedly lower than the benchmark, thus highlighting the risk of having an insufficient number of people working in the section. Finally, the third scenario (Table 4 – S3), shows the best fit with the benchmark, showing in detail that supplies costs will be 21% higher, consultancy hours somewhat higher (+6%) and technical staff hours 19% lower than the benchmark.

Table 5 shows an increment of the percentile value for all indicators, except for supplies costs (which decrease) and the technical staff/managers ratio (unchanged). These data are not surprising: it is known that there is a need for investment in technology in order to automate the process.

An increment of €60,004 (+25%) in supplies costs is well balanced by expected savings in staff (-€121,715, -40%). The total cost might be -€61,711 and staff productivity could increase from an average of 11.95–19.95 tests an hour.

Because wide area managers are willing to allocate the most of the time of consultants to the activity of consultancy support, the technical staff/consultants ratio will decrease (-15%).

Conclusions

There is an increasing emphasis on using cost-effectiveness analysis to achieve a higher value for money

invested in laboratory medicine, avoiding waste and unnecessary costs, but few studies based on reliable methodologies, such as the activity-based costing analysis, have been published [5, 11, 12]. The e-Valuate tool provides clinical laboratory management valuable information that enables it to guide improvement projects designed to decrease costs and waste, and to enhance efficiency based on objective data. This paper describes two paradigmatic situations in which the data obtained using the e-Valuate program have addressed the decision to reorganize an individual sector of a laboratory (specific proteins) and another diagnostics (autoimmunity) in an extensive geographical area following objective criteria (evidence-based laboratory medicine). In both situations, the improvement projects guided by the e-Valuate data led to a significant reduction in costs, maximized the utilization of human and technological resources and increased efficiency. The added value of e-Valuate is to provide data on the efficiency and costs of laboratory services obtained with a widely accepted activity-based costing analysis that allows a valuable benchmark between different sections of the same laboratory as well as between different clinical laboratories.

However, this analysis calls for additional studies based on the clinical effectiveness of the reorganization processes with a view to demonstrating not only increased efficiency but also an improvement in analytical quality, a decrease in the error rates and a valuable contribution to better clinical outcomes. As recently highlighted by Porter, efforts should be made to “shifting focus from the volume of services delivered to the value created for patients”, with “value” defined as the outcomes achieved relative to the costs [13]. In laboratory medicine, the search for better clinical outcomes should start by improving appropriateness in test requesting, making further efforts to reduce waste and inefficiency in all processes, assuring analytical accuracy and, finally, facilitating the reading and interpretation of laboratory results. The contribution of laboratory information to improving the diagnostic and therapeutic pathways is of crucial importance in

contributing to a better quality of care. e-Valuate is a valuable tool for starting this process, as it assures a valuable source of data that should guide improvement processes on the basis of objective data regarding the contribution of different items to total costs and efficiency in delivering laboratory services.

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