



EFLM
EUROPEAN FEDERATION OF CLINICAL CHEMISTRY
AND LABORATORY MEDICINE



**15th
BELGRADE SYMPOSIUM
FOR BALKAN
REGION**

Neighbouring Countries:
The Same Professional Aim

Under IFCC and EFLM Auspices

PROGRAMME

April 11 and 12, 2019, Belgrade, Serbia
Hyatt Regency Beograd
www.dmbj.org.rs
www.bclf.info

Pobednik (Serbian Cyrillic: Победник, English: The Victor) is a monument in the Upper Town of the Belgrade Fortress, built to commemorate Serbia's victory over Ottoman and Austro-Hungarian Empire during the Balkan Wars and the First World War. Erected in 1928, and standing at 14 metres (46 ft) high, it is one of the most famous works of Ivan Meštrović. It is also one of the most visited tourist attractions in Belgrade and the city's most recognizable landmark. It is a standing bronze male figure with a falcon in the left hand and a sword in the right, modelled by the sculptor Ivan Meštrović, set on a pedestal in the form of a Doric column on a tall cubic base, designed by the architect Petar Bajalović. The statue looks forward across the confluence of the Sava and the Danube, and over the vast Pannonian plain, towards the very distant Fruška Gora mountain (until 1918 a domain of Austro-Hungarian empire), it is probably the most powerful, most popular visual symbol of Belgrade.



**12:00–13:30
Session II – Leadership skills**

Chairs: Ana-Maria Šimundić, Vesna Kalimanovska Spasojević

Leadership skills

Ana-Maria Šimundić (Croatia)

Project management

Giuseppe Lippi (Italy)

Communication between the clinical laboratory and its users

Graham H. Beastall (UK)

Discussion



Let's get started with... a definition:

Project management is the practice of **initiating, planning, executing, monitoring and closing** a specific teamwork, for achieving:

- specific **goals** (meeting specific criteria)
- at a **specified time**.





QMS18

Process Management

Leading purposes of project management in lab medicine:

- ▶ Ability to reduce or eliminate errors
- ▶ Likelihood of meeting customer expectations
- ▶ Effectiveness and efficiency of laboratory operations
- ▶ Potential for successful governmental and accreditation assessments and customer satisfaction
- ▶ Sustainable attainment of quality objectives



J Med Biochem, 2019

PROJECT MANAGEMENT IN LABORATORY MEDICINE

Giuseppe Lippi¹, Camilla Mattiuzzi²

Paradigms of project management

1. Efficiency
2. Efficacy
3. Quality
4. Safety
5. Sustainability
6. Satisfaction





HOW THESE PARADIGM TRANSLATES INTO OUR DAILY PRACTICE?

Efficiency

- Achieve maximum (**lab**) productivity with minimum wasted effort or expense

Efficacy

- Achieve the desired or intended result (**improve diagnoses AND clinical outcomes**)

Quality

- Achieve the high possible degree of excellence (**in test results**)

Safety

- Achieve prevention of injury or damage (**to patients and staff**)

Sustainability

- Avoid depleting human and economic resources

Satisfaction

- Fulfil both personal and stakeholders' wishes, expectations or needs



Keynotes of lab project management:

- Define your environment
- Plan technical resources
- Identify staff availability and qualification
- Interplay with hospital administration
- *Education*
- *Research*





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Clin Chem Lab Med 2019; aop

Giuseppe Lippi* and Giorgio Da Rin

Advantages and limitations of total laboratory automation: a personal overview

- Space requirements and infrastructure constraints are major issues in project management of laboratory services.
- Accommodating multiple modern analyzers and new hardware into a preexisting environment may be challenging, especially when the building is not purpose-built or fit for this scope.



Clin Chem Lab Med 2019; aop

Giuseppe Lippi* and Giorgio Da Rin

Advantages and limitations of total laboratory automation: a personal overview





Clin Chem Lab Med 2019; aop

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Advantages and limitations of total laboratory automation: a personal overview

Therefore...

... as laboratory work continues to move away from manual bench testing to increasingly more automated processes, **open-plan designs** are providing the necessary flexibility for labs to easily connect analyzers and provide more efficient workflows.



The ideal scenario...



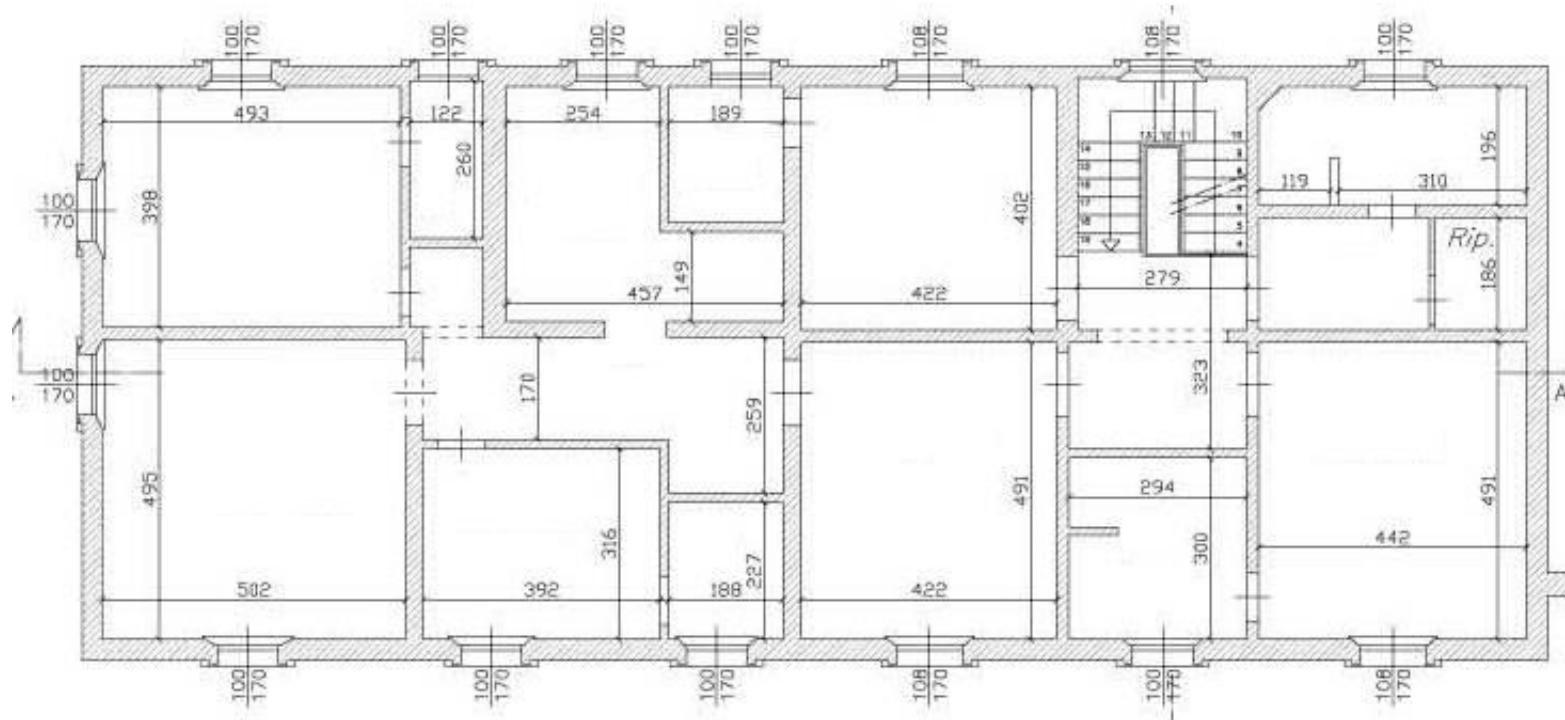
Kicking a penalty on a empty goal

The real scenario...



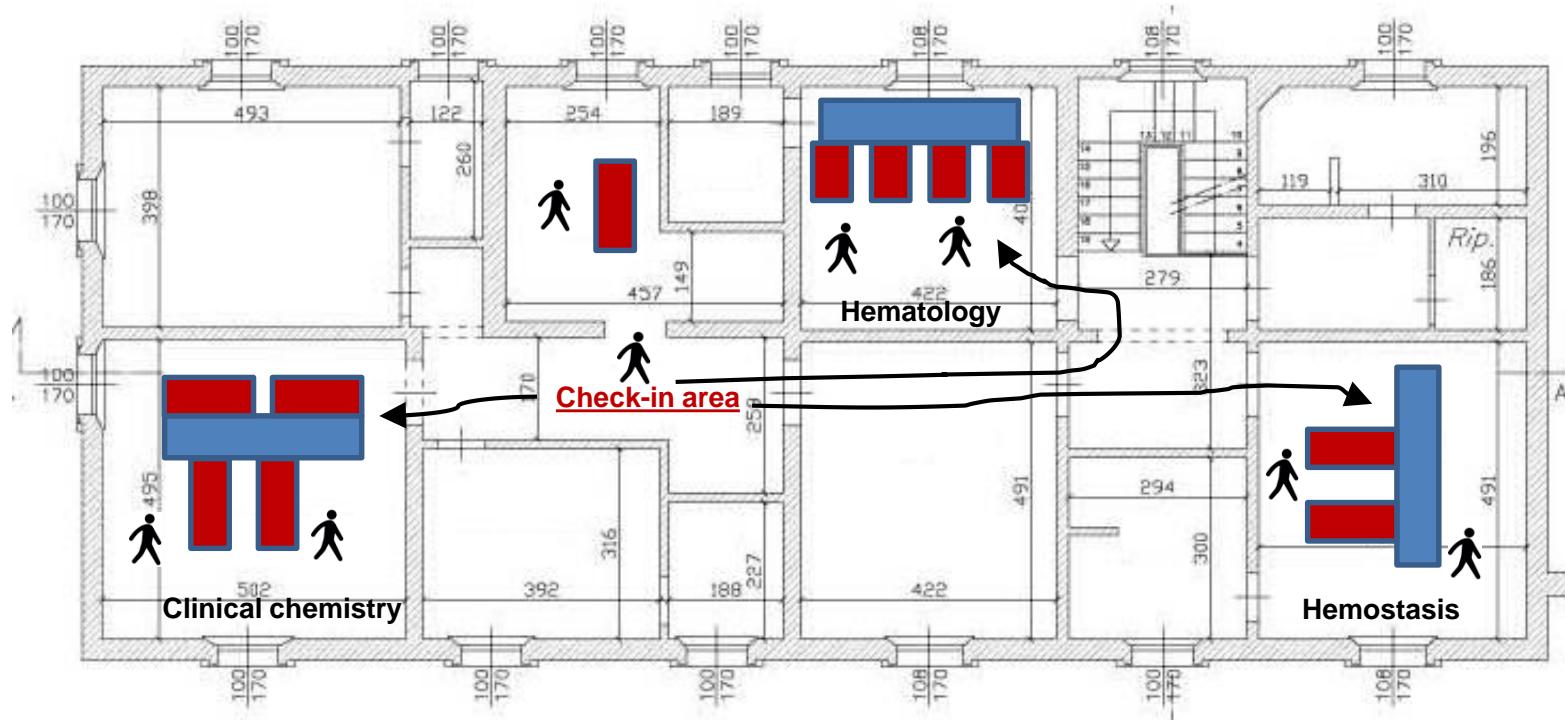


Laboratory Service – University Hospital of Verona



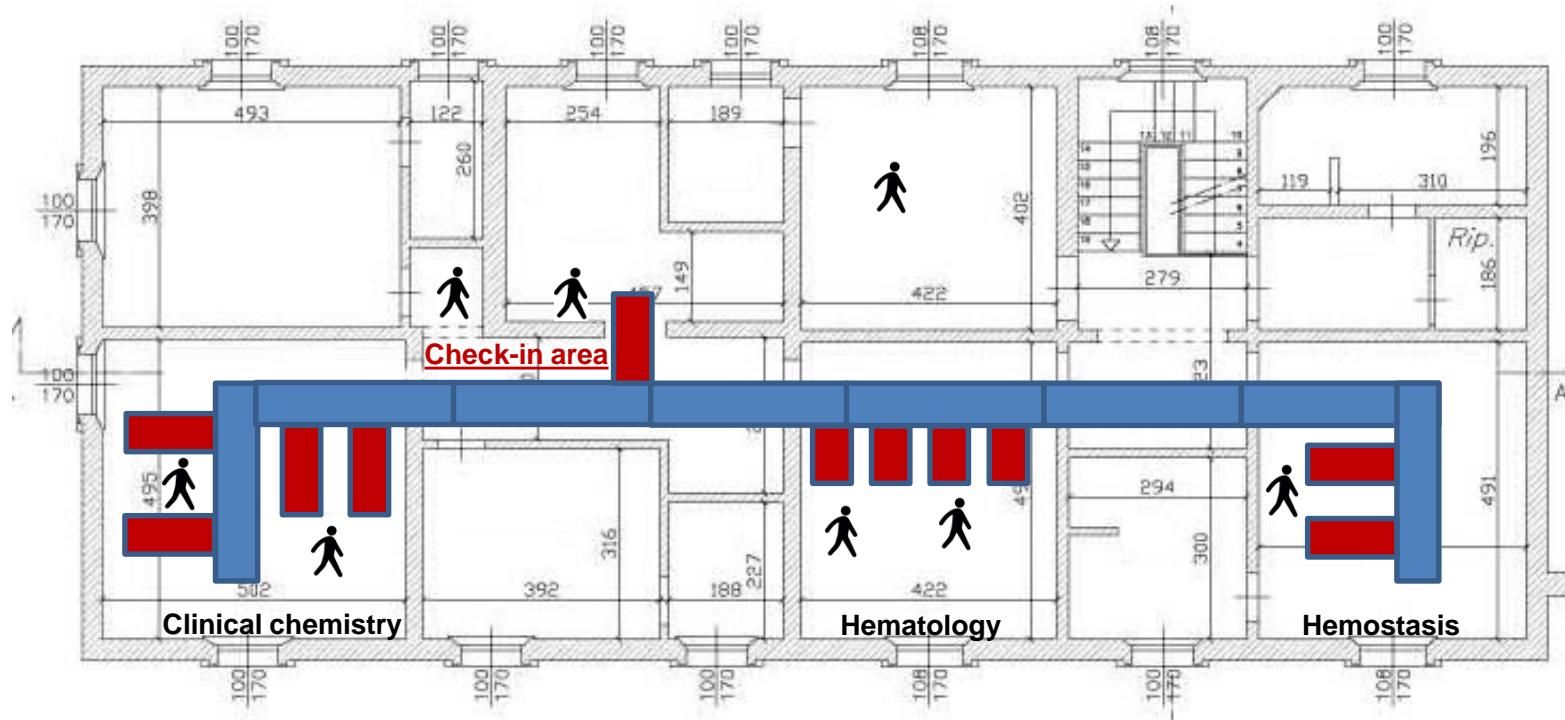


This is how we started (October 2015)





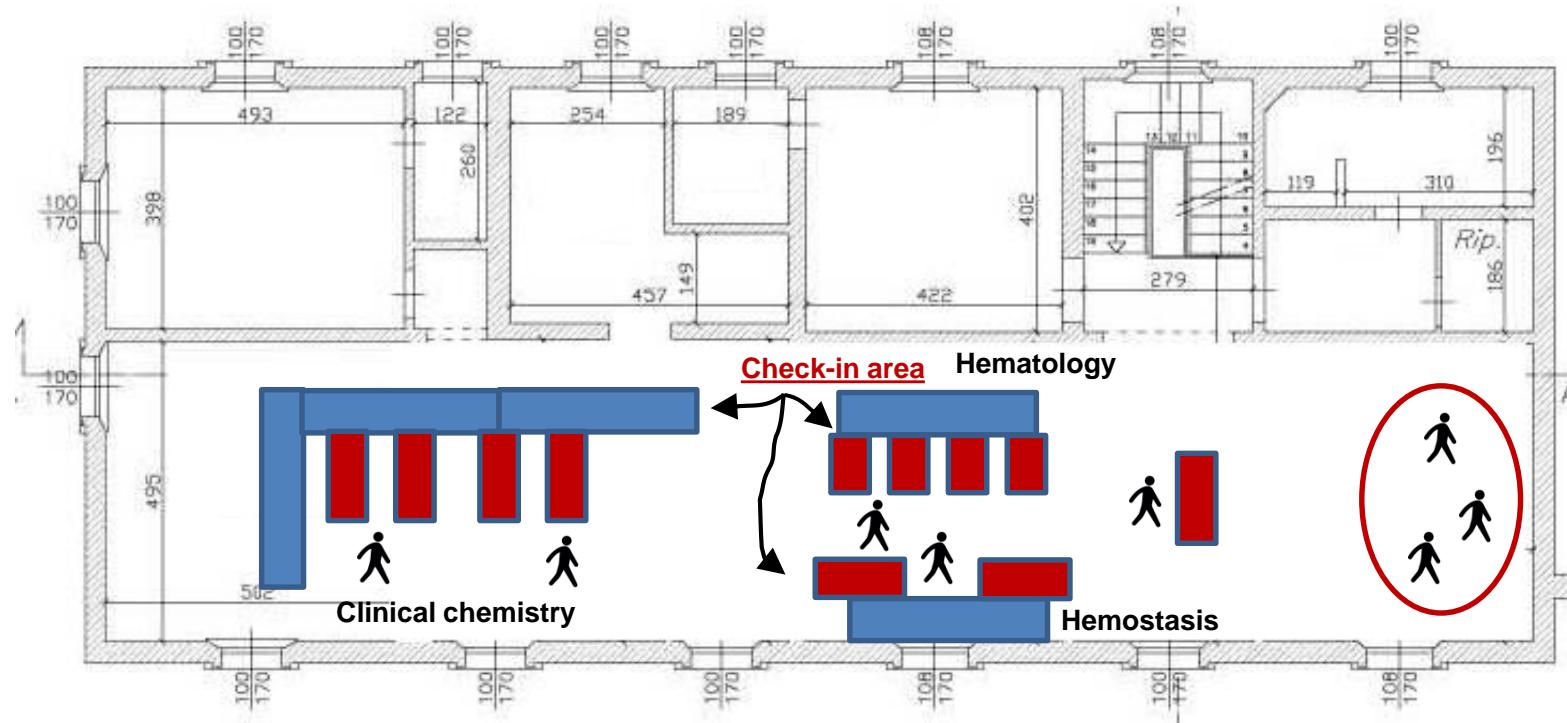
Initial proposal (cTLA*) from Hospital engineers



*** crazy Total Laboratory Automation**



This is how we ended up (37% of staff saved) – April 3, 2019



Total cost of works: 285,000 €

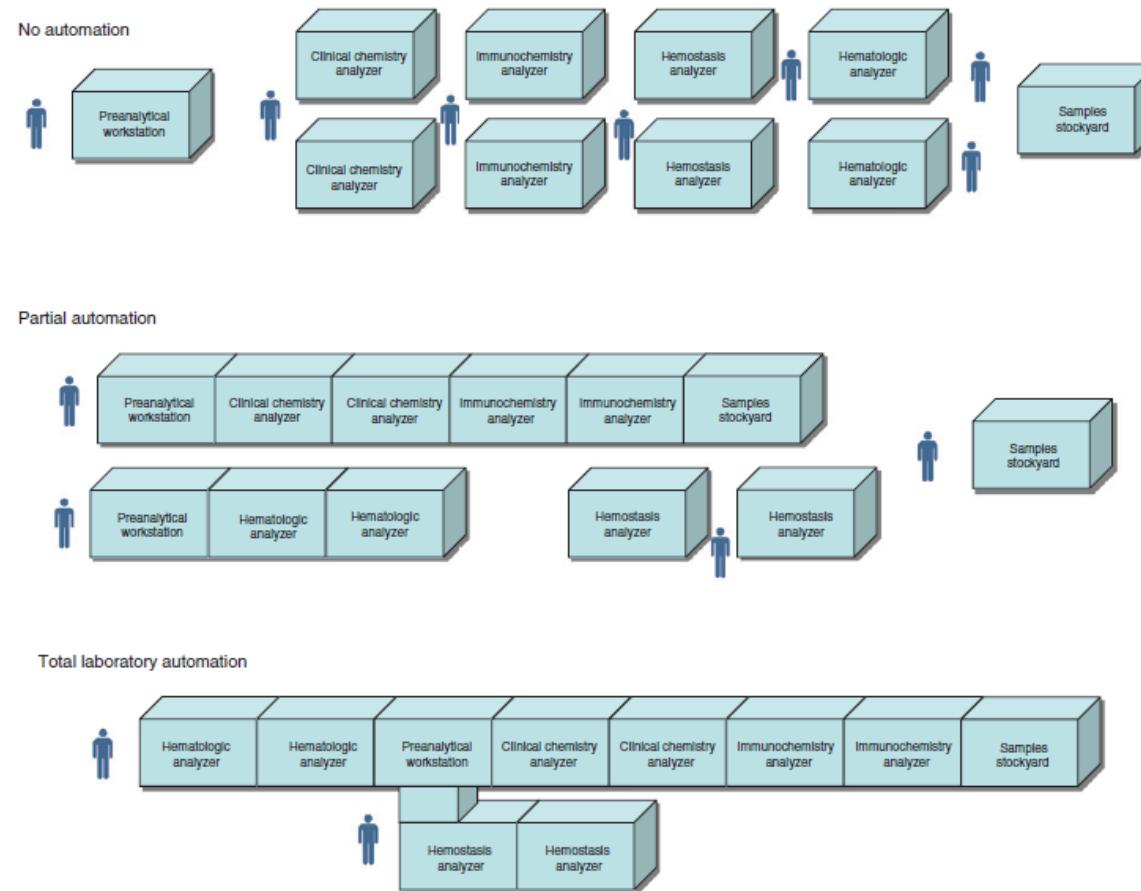
Total saving of lab staff: 33,000 € x 3 x 10 years: 990,000 €



Clin Chem Lab Med 2019; aop

Giuseppe Lippi* and Giorgio Da Rin

Advantages and limitations of total laboratory automation: a personal overview





Advantages and limitations of total laboratory automation: a personal overview

Advantages	Limitations
<ul style="list-style-type: none">– Lower costs in the long term– Reduction of manual workforce– Lower number of blood tubes– Decreased congestion– Improved efficiency<ul style="list-style-type: none">– Shorter TAT– Higher throughput– Enhanced complexity– Possibility to manage different tubes types and sizes– Lower need of urgent testing– Improved sample management<ul style="list-style-type: none">– More efficient management of rerun– More efficient management of reflex testing– Easier add-on– Enhanced traceability– Improved process standardization for certification/accreditation– Improved quality of testing<ul style="list-style-type: none">– Enhanced standardization– Lower risk of errors– Lower sample volume– More efficient integration of tests results– Lower biological risk for operators– Staff requalification and job satisfaction	<ul style="list-style-type: none">– Higher costs in the short term<ul style="list-style-type: none">– Project accommodation– Installation– Larger equipment– Increased costs for supplies<ul style="list-style-type: none">– Maintenance– Energy– Water– Tips for aliquotters and caps for sealers– Space requirement and infrastructure constraints– Overcrowding of personnel– Increased generation of noise, heat and vibration– Higher risk of downtime<ul style="list-style-type: none">– Higher risk of system failures– Shortage of personnel for response to emergency situations– Psychological dependence on automation– Differential requirements for sample management– Generation of potential bottlenecks– Disruption of staff trained in specific technologies– Risk of transition toward a manufacturer's-driven laboratory



Whatever solution you will implement...
be aware of the so-called “**point of no return**”





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PROJECT MANAGEMENT IN LABORATORY MEDICINE

Giuseppe Lippi¹, Camilla Mattiuzzi²



Step 1. Project development.

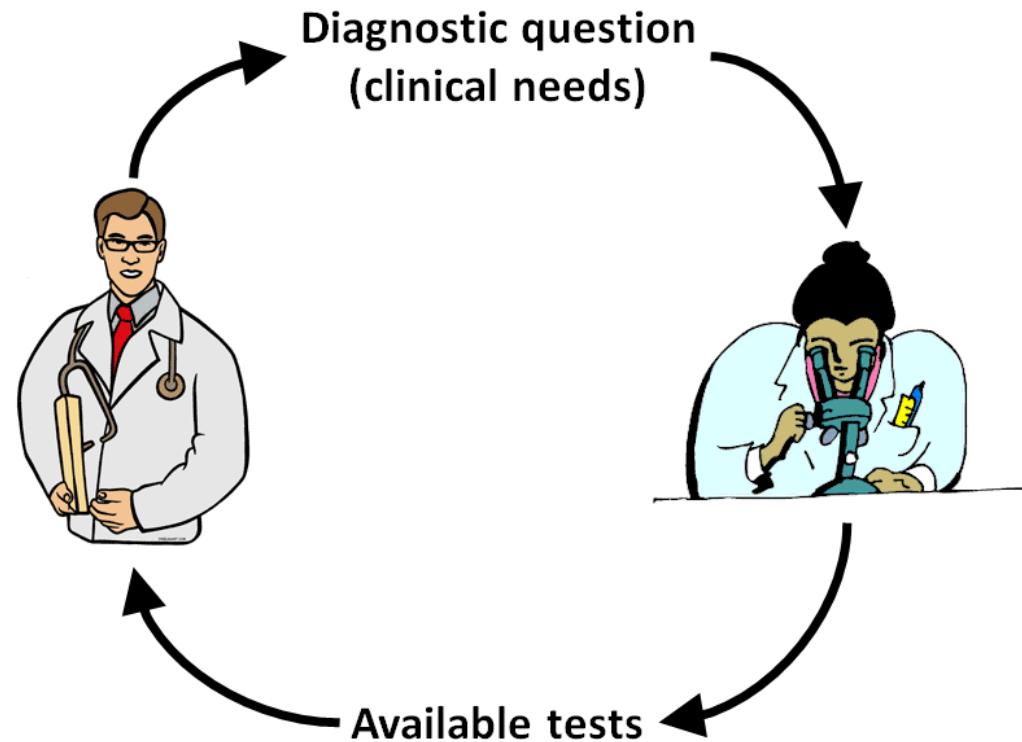
The first step is to develop and document the **project vision, mission, goals** and **deliverables**. More often than not, this is overlooked or completely ignored. However, the **vision** and **mission** of the clinical laboratory should be aligned with those of the organization.



Emergency Care Journal 2019

“La liaison fructueuse”: Laboratory and Emergency Medicine

Giuseppe Lippi, Gianfranco Cervellin





Emergency Care Journal 2019

“La liaison fructueuse”: Laboratory and Emergency Medicine

Giuseppe Lippi, Gianfranco Cervellin

A clinical-laboratory liaison translates into the clear-cut concepts that:

- (i) physicians shall pose diagnostic questions to the laboratory, and the laboratory – in turn – should be embarked into a constructive effort to rearrange its organization to fulfill these needs whilst,
- (ii) laboratory professionals shall loyally discuss with emergency physicians the locally availability of tests and, altogether, they should define a reliable list of analyses that can be ordered.

Notably, clinical needs shall always be evaluated for cost-effectiveness, since distracting resources for obsolete, redundant or clinically questionable tests would generate adverse consequences on the whole healthcare system.



A clinical laboratory is not a juke-box!





J Med Biochem, 2019

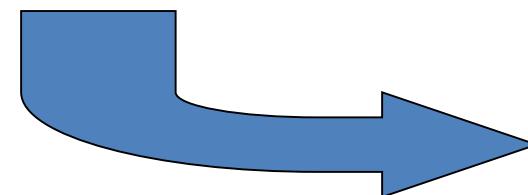
PROJECT MANAGEMENT IN LABORATORY MEDICINE

Giuseppe Lippi¹, Camilla Mattiuzzi²

Step 2. Analysis and program development.

Analyze the laboratory data collected in the previous step into information that can drive future design. This may be in the form of current and future process maps, encompassing:

- Projected test volume
 - Predicted test complexity
 - Equipment and utility lists
 - Staffing models
 - Work schedules
 - Regulatory, safety and ergonomic requirements
- (Capacity analysis)





Clinical Chemistry

Immunochemistry

Hematology

Hemostasis

Molecular biology

Waved testing

**Volume
Type of tests**



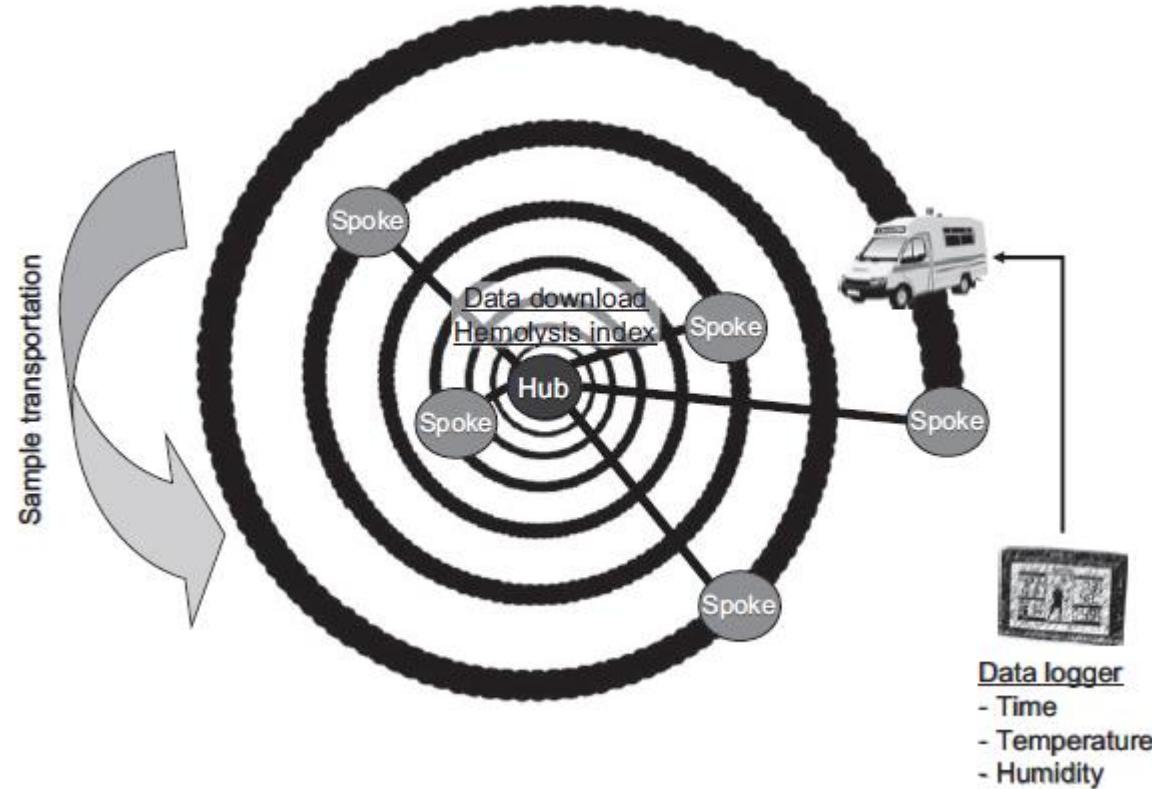
Needs



Clin Chem Lab Med 2012;50(10):1703–1705

Laboratory networking and sample quality: a still relevant issue for patient safety

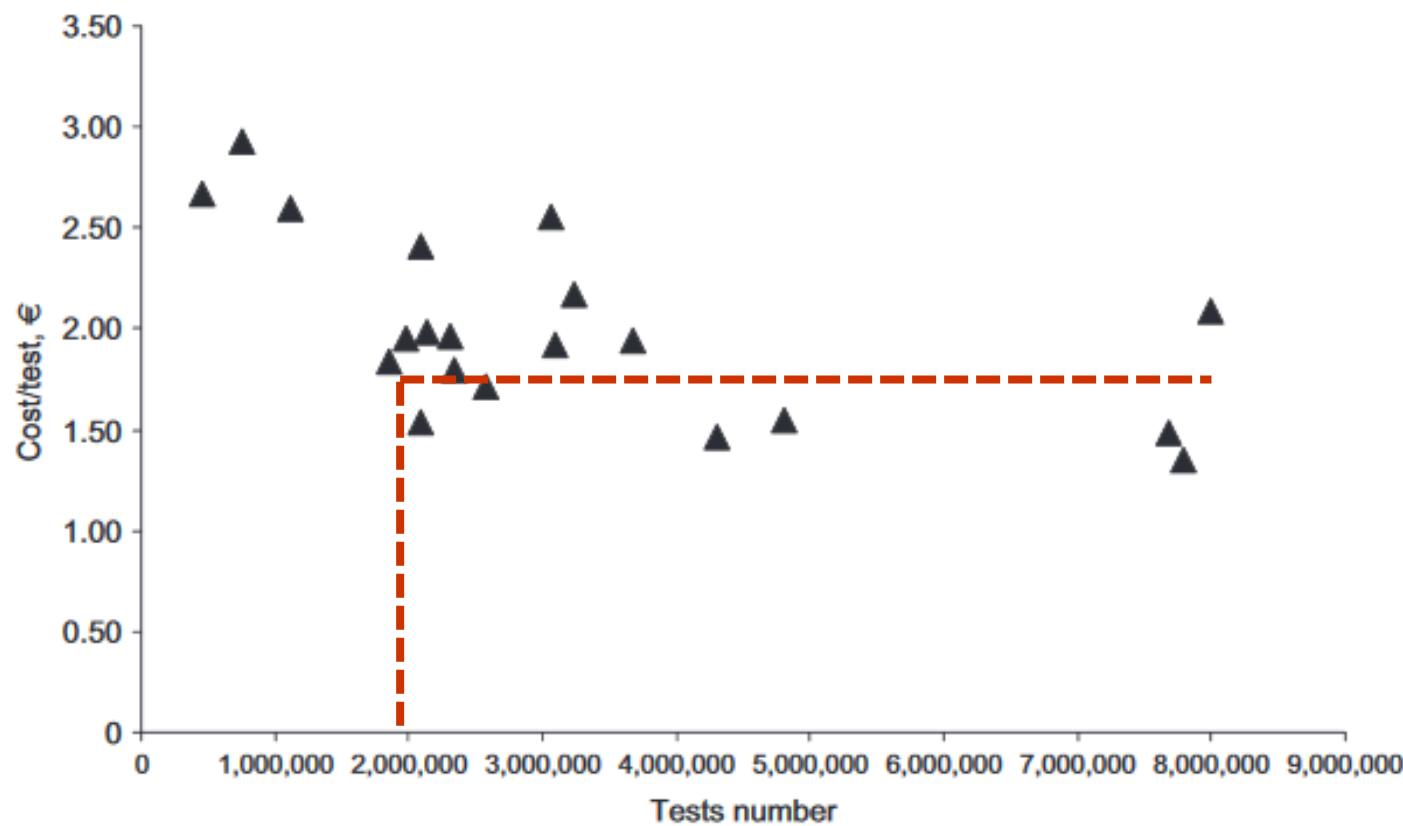
Giuseppe Lippi and Ana-Maria Simundic

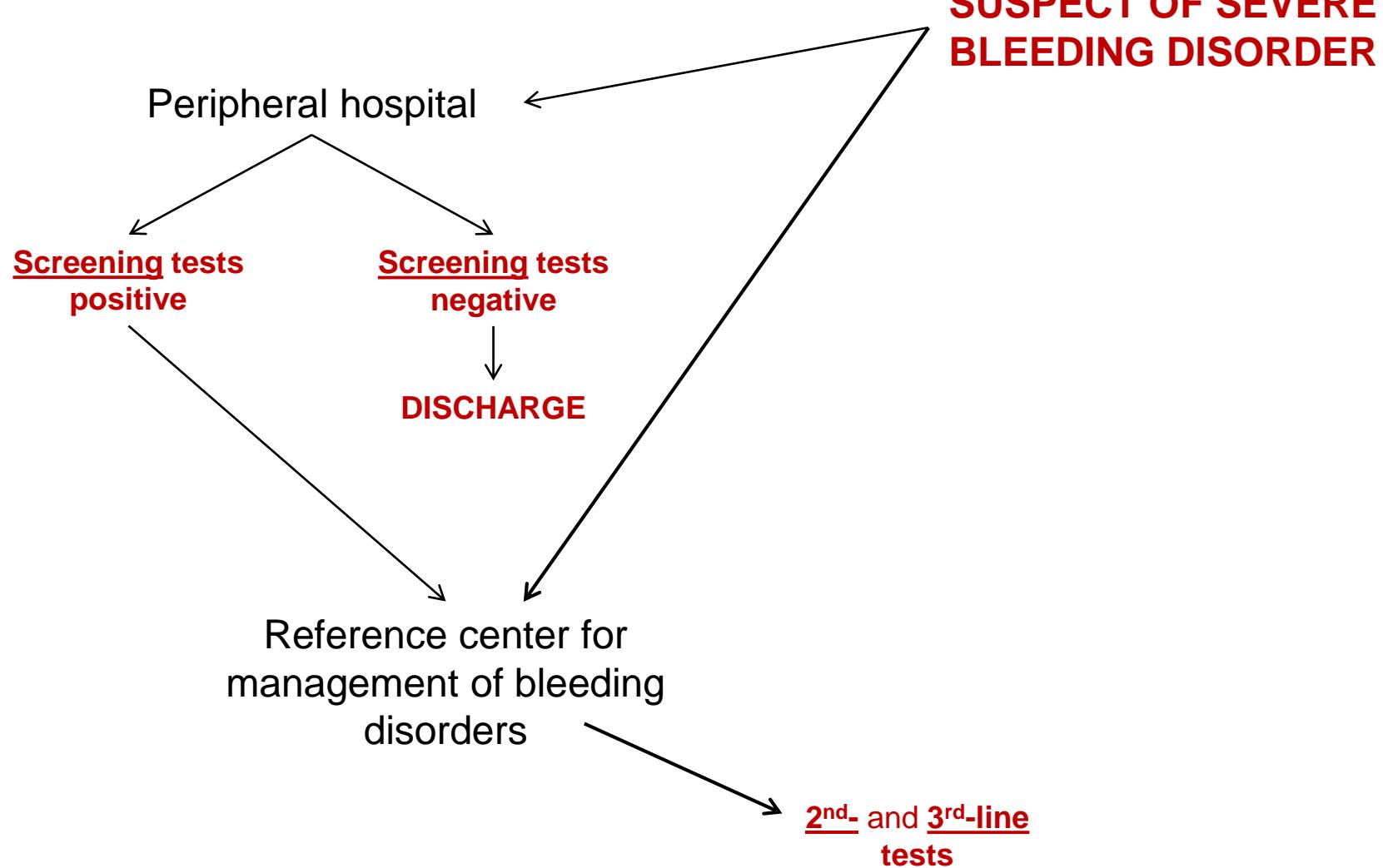


Clin Chem Lab Med 2013; 51(2): 295–301

Giovanni Barletta, Martina Zaninotto, Diego Faggian and Mario Plebani*

Shop for quality or quantity? Volumes and costs in clinical laboratories







Keynotes of lab project management:

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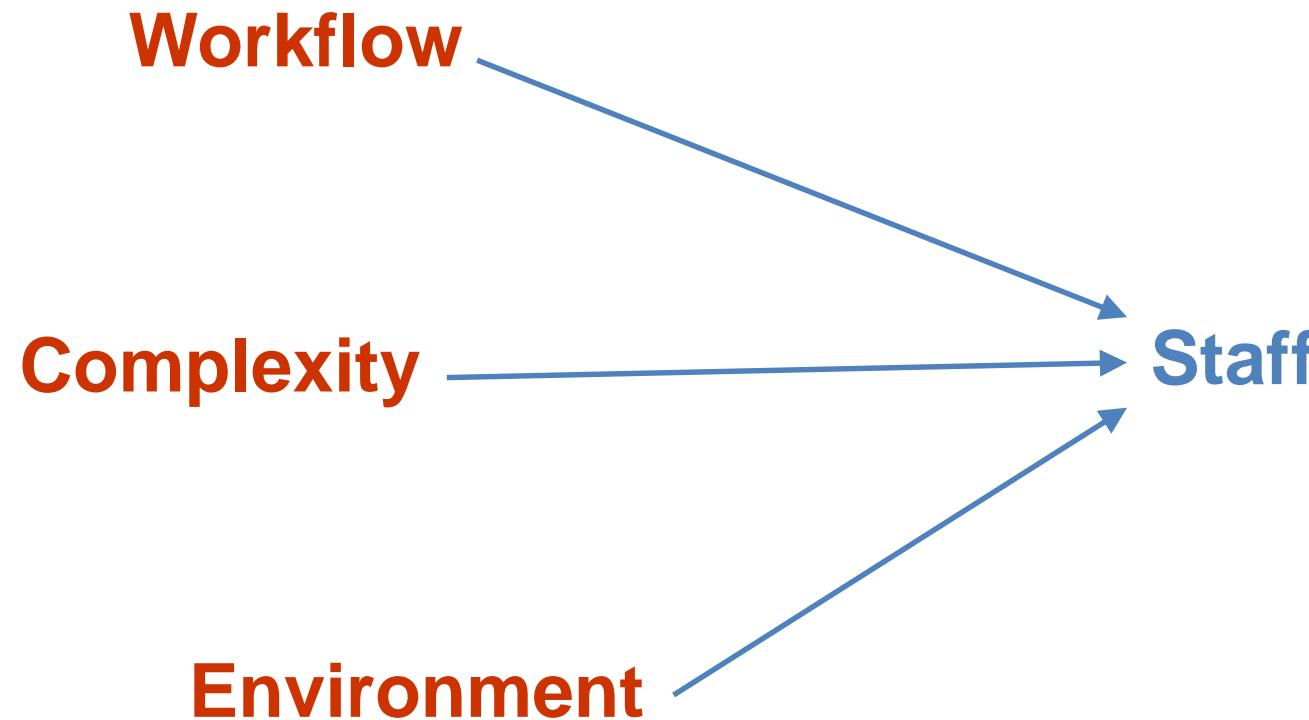
Rome wasn't built in a day...



*... though it would have never been built
without a huge and skilled Roman workforce...*

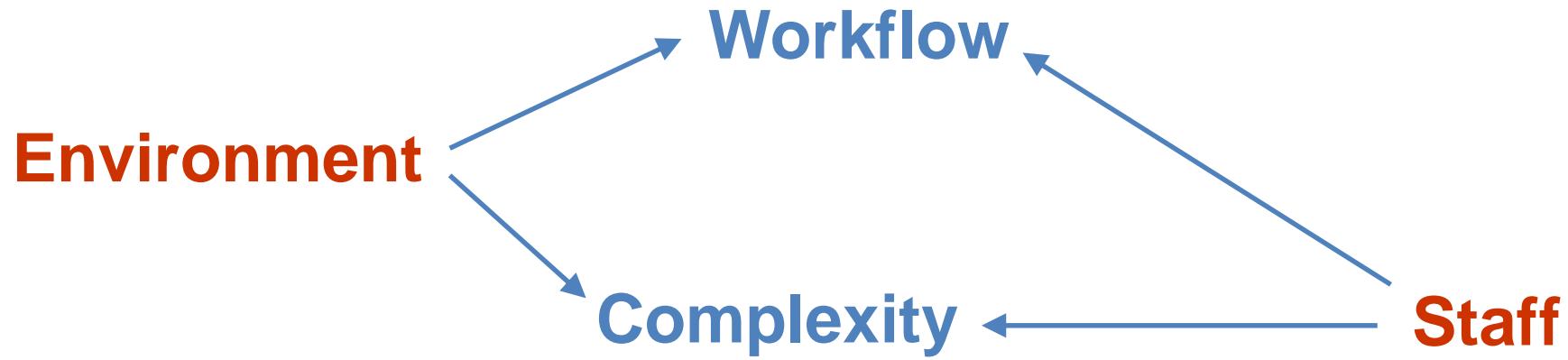


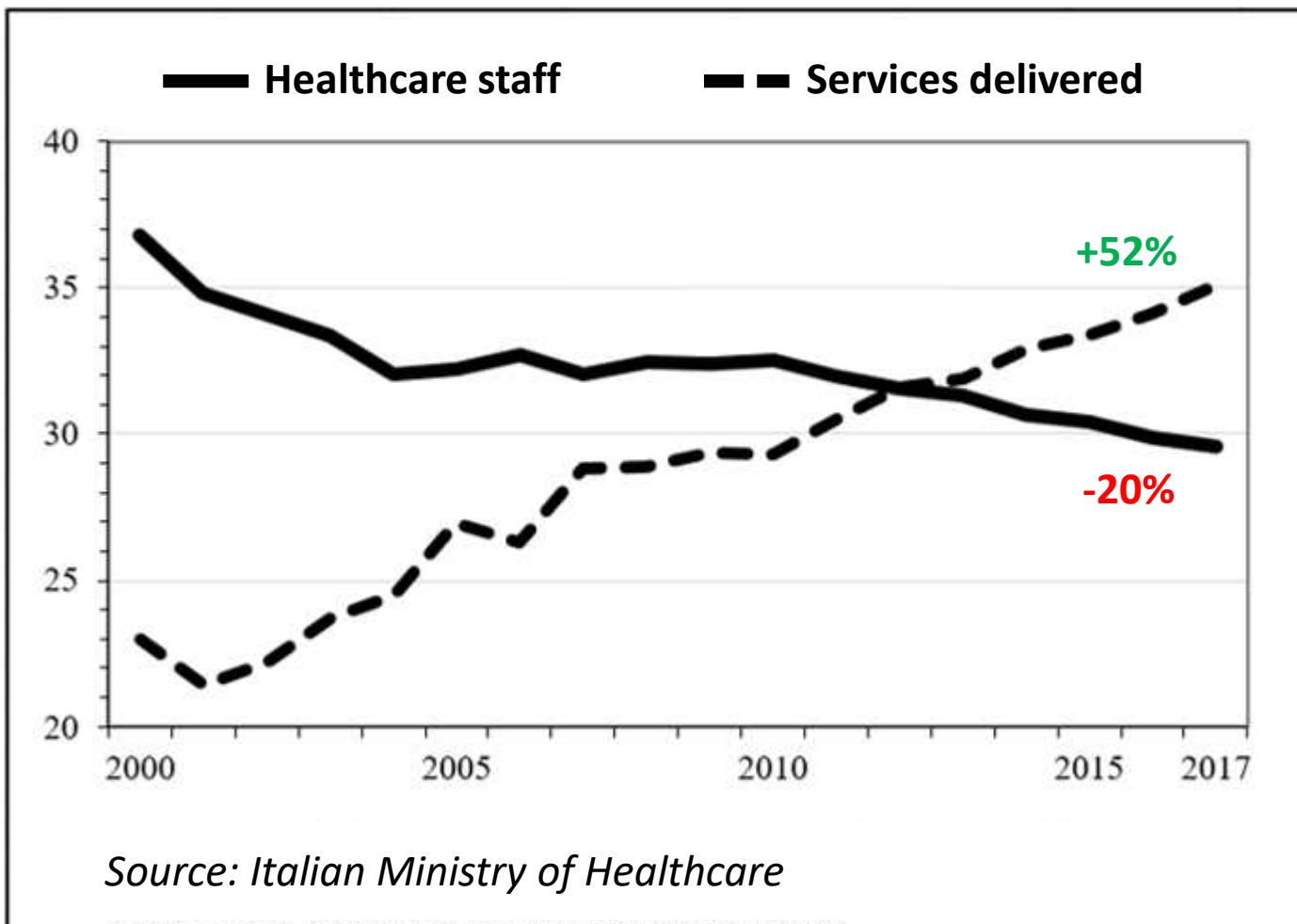
Time ago...





Now...







Lab Medicine Services (n=2) – University Hospital of Verona

	2015	2019	Dif (%)
Lab Managers	32	25	-22%
Lab Techs	89	82	-8%
Auxiliary staff	33	28	-15%
Secretary	15	13	-13%
Nurses	26	23	-12%
TOT	195	171	-12%

Shortage of staff - possible solutions

- Elimination of manual activities?
- Automation?
- Consolidation?
- Reduce volumes?
- Reduce complexity?
- Outsourcing?
- ... don't care????





The American Journal of Medicine (2007) 120, 819.e9-819.e11

Medical Errors Arising from Outsourcing Laboratory and Radiology Services

Brian S. Chasin, MD,^a Sean P. Elliott, MD,^b Stephen A. Klotz, MD^a

Table 1 Examples of Errors Committed at Outsource Laboratories and Their Consequences

Test Ordered	Outsource Laboratory Report	Consequences of the Error and/or Comments
Any blood or urine test	Specimen improperly collected, inadvertently discarded, request overlooked, and results not communicated in timely fashion	Commonplace mistakes; these errors lead to repeating the test, cancellation of a scheduled outpatient visit, and/or delaying or interfering with therapy
Specific examples		
Viral culture for Herpes simplex	Collection date not noted at outsource laboratory site, therefore, culture discarded	Lesion disappeared and consequently there was no definitive diagnosis
Brucella serology	Test not performed; inappropriate specimen	Patient never had the test performed; refused to drive 90 miles to repeat it
HIV-1 RNA	Wrong test performed; sometimes HIV-1 DNA or HCV RNA are erroneously performed	Physician must recognize the problem and reorder the test
Nitroblue tetrazolium assay	Test not performed; technician unfamiliar with test and unable to identify test code	Diagnosis of chronic granulomatous disease delayed by 2 months due to inability to perform tests at outsource laboratory (test finally performed elsewhere)

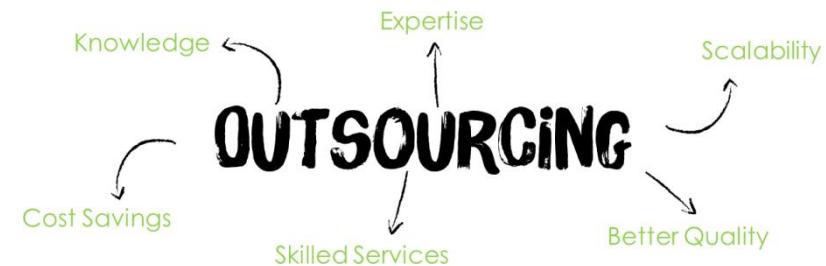


The American Journal of Medicine (2007) 120, 819.e9-819.e11

Medical Errors Arising from Outsourcing Laboratory and Radiology Services

Brian S. Chasin, MD,^a Sean P. Elliott, MD,^b Stephen A. Klotz, MD^a

- ↑ Turnaround times for test reports
- ↓ Specimens quality
- ↑ Errors





**Friends of
Medicare**

Government Must Stop and Reverse Privatization of Laboratory Services

- Privatization of health care **is not a solution to a public problem.**
- There is no evidence that **privatization will lead to improved services and overall cost savings.**
- These private contractors **does not have to disclose how public health dollars are spent, allocated or collected.**



And, remember that NOT ALWAYS you can select your team!





So place:

- **the right person**
- **in the right place**
- **for doing the right activity**
- **at the right time**

J Med Biochem, 2019

PROJECT MANAGEMENT IN LABORATORY MEDICINE

Giuseppe Lippi¹, Camilla Mattiuzzi²

This entails:

- Knowing your staff (weakness and strengths)
- Fulfilling personal inclinations (when possible)
- Not blaming people; blame the process



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Clinica Chimica Acta 489 (2019) 49–52

A manifesto for the future of laboratory medicine professionals

Mario Plebani^{a,*}, Michael Laposata^b, Giuseppe Lippi^c

Along with clinical activities, laboratory professionals are now involved in many administrative activities heading for:

- Optimizing test menus
- Providing adequate training and education
- Administering budget

The large majority of these activities require clinical expertise and scientific/technical training, whilst other tasks need **administrative skills**.



Laboratorymedicine> July 2003> number 7> volume 34

Elements of a Typical Laboratory Budget

Donna H. MacMillan, BS, MT(ASCP), MBA

Description	Current Actual	Current Budget	\$ Var	% Var	YTD Actual	YTD Budget	\$ Var	% Var
Inpatient Charges	\$ 246,958	\$ 219,370	\$ 27,588	12.6%	\$ 3,207,440	\$ 2,621,718	\$ 585,722	22.3%
Outpatient Charges	\$ 1,574,862	\$ 1,476,560	\$ 98,302	6.7%	\$ 20,663,446	\$ 17,223,536	\$ 3,439,910	20.0%
Total Charges	\$ 1,821,820	\$ 1,695,930	\$ 125,890	7.4%	\$ 23,870,886	\$ 19,845,254	\$ 4,025,632	20.3%
Salary-Professional	\$ 36,484	\$ 35,213	\$ (1,271)	-3.6%	\$ 126,000	\$ 128,000	\$ 2,000	1.6%
Salary-Technical, Regular	\$ 50,548	\$ 53,030	\$ 2,482	4.7%	\$ 691,650	\$ 664,790	\$ (26,860)	-4.0%
Salary-Technical, Overtime	\$ 9,438	\$ 2,610	\$ (6,828)	-261.6%	\$ 101,354	\$ 33,862	\$ (67,492)	-199.3%
Total Salary	\$ 96,470	\$ 90,853	\$ (5,617)	-6.2%	\$ 919,004	\$ 826,652	\$ (92,352)	-11.2%
General Lab Supplies	\$ 24,546	\$ 19,476	\$ (5,070)	-26.0%	\$ 218,482	\$ 233,712	\$ 15,230	6.5%
Reagents	\$ 130,356	\$ 75,464	\$ (54,892)	-72.7%	\$ 869,418	\$ 906,380	\$ 36,962	4.1%
Lease, Rental	\$ 2,070	\$ 2,070	\$ —	0.0%	\$ 24,840	\$ 24,840	\$ —	0.0%
Total Supply Expense	\$ 156,972	\$ 97,010	\$ (59,962)	-61.8%	\$ 1,112,740	\$ 1,164,932	\$ 52,192	4.5%
Total Expense	\$ 253,442	\$ 187,863	\$ (65,579)	-34.9%	\$ 2,031,744	\$ 1,991,584	\$ (40,160)	-2.0%



UOC Laboratorio Analisi

Descrizione conto	2017	Budget 2018	1° Semestre 2017	1° Semestre 2018	Scostamento 1° Semestre 2018 - 1° Semestre 2017
B.1.A.1.1) Medicinali con A/C, ad eccezione di vaccini ed emoderivati di produzione regionale	6.718,58€	6.720,00€	2.269,90€	1.201,92€	-47,05%
B.1.A.1.2) Medicinali senza A/C	26,29€	30,00€	6,88€	17,24€	150,58%
B.1.A.11.2) Altri beni e prodotti sanitari: altro	89.213,54€	89.215,00€	43.775,19€	92.584,88€	111,50%
B.1.A.3.1.B) Dispositivi medici altro	8.723,72€	8.725,00€	5.329,63€	7.215,13€	35,38%
B.1.A.3.3) Dispositivi medico diagnostici in vitro (IVD)	5.114.940,44€	5.114.820,00€	2.654.788,53€	2.484.990,58€	-6,40%
B.1.A.6) Prodotti chimici	12.364,39€	12.365,00€	5.966,02€	6.561,67€	9,98%
Totale materiale sanitario	5.231.986,96€	5.231.875,00€	2.712.136,25€	2.592.571,42€	-4,41%
B.1.B.1) Prodotti alimentari	0,00€	0,00€	0,00€	0,00€	0,00%
B.1.B.2) Mat.guardaroba,pulizia e di conv.in genere	960,83€	965,00€	489,08€	403,67€	-17,46%
B.1.B.4) Supporti informatici e cancelleria	13.032,02€	13.035,00€	6.318,36€	4.849,68€	-23,24%
B.1.B.5.1) Materiale per manutenz.e riparaz.	2.816,25€	2.820,00€	2.281,34€	52,52€	-97,70%
B.1.B.5.2) Mater.per manut.attrezz.sanit.	0,00€	0,00€	0,00€	0,00€	0,00%
B.1.B.5.3) Materiale vario per l'informatica	0,00€	0,00€	0,00€	0,00€	0,00%
B.1.B.6.1) Altri beni non sanitari	0,00€	0,00€	0,00€	0,00€	0,00%
Totale materiale economici	16.809,10€	16.820,00€	9.088,78€	5.305,87€	-41,62%
B.2.B.1.1) Lavanderia	0,00€	0,00€	0,00€	0,00€	0,00%
B.2.B.1.2) Pulizia	1.332,83€	0,00€	614,33€	715,02€	16,39%
B.2.B.1.3.A) Mensa degenti	0,00€	0,00€	0,00€	0,00€	0,00%
B.2.B.1.6) Servizi trasporti (non sanitari)	219,60€	0,00€	146,40€	24,40€	-83,33%
B.2.B.1.12.E) Abbonamenti, libri e giornali	0,00€	0,00€	0,00€	186,56€	0,00%
B.3.B.1) Manutenzioni elaboratori e software	915,00€	0,00€	915,00€	0,00€	-100,00%
B.3.B.2) Manutenzione macchine d'uff.	482,63€	0,00€	48,80€	0,00€	-100,00%
B.3.B.3) Manutenzione mobili e arredi	0,00€	0,00€	0,00€	0,00€	0,00%
B.3.C) Manut.e rip.alte attr.tec.-scient.san.	3.747,89€	0,00€	1.972,79€	0,00€	-100,00%
B.3.E) Altre manutenzioni e riparazioni	0,00€	0,00€	0,00€	0,00€	0,00%
B.4.B.1) Canoni di noleggio - area sanitaria	1.703.413,80€	0,00€	828.259,49€	775.463,74€	-6,37%
B.2.A.15.4.3) Altri servizi sanitari da privato	0,00€	0,00€	0,00€	0,00€	0,00%
B.9.C.2.1) Spese generali	3.823,76€	0,00€	2.056,16€	601,99€	-70,72%
Totale Altri Costi	1.713.935,51€	0,00€	834.012,97€	776.391,71€	-6,84%
Totale UOC Laboratorio Analisi	6.962.731,57€		3.555.238,00€	3.374.869,00€	



Elements of a Typical Laboratory Budget

Donna H. MacMillan, BS, MT(ASCP), MBA

It is important that the laboratory Directors and Managers have:

- A complete understanding of the budget of their laboratory
- Use that information to develop strategies that will respond to these demands
- Learn to manage budgets (on a cost model)
- Have sufficient detail to meet the needs of the financial manager



J Lab Med 2018; aop

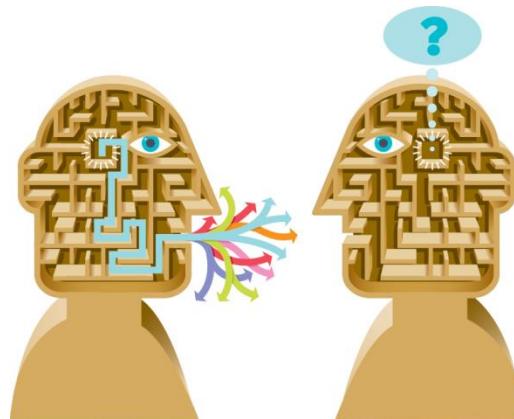
Giuseppe Lippi* and Mario Plebani

Cost, profitability and value of laboratory diagnostics: in God we trust, all others bring data

Albeit it may appear paradoxical, or even illogical and unreasonable, laboratory diagnostics **is currently seen as many other economic industries** by some policymakers and administrators, and is hence subjected to **scale economy** and assessed accordingly.

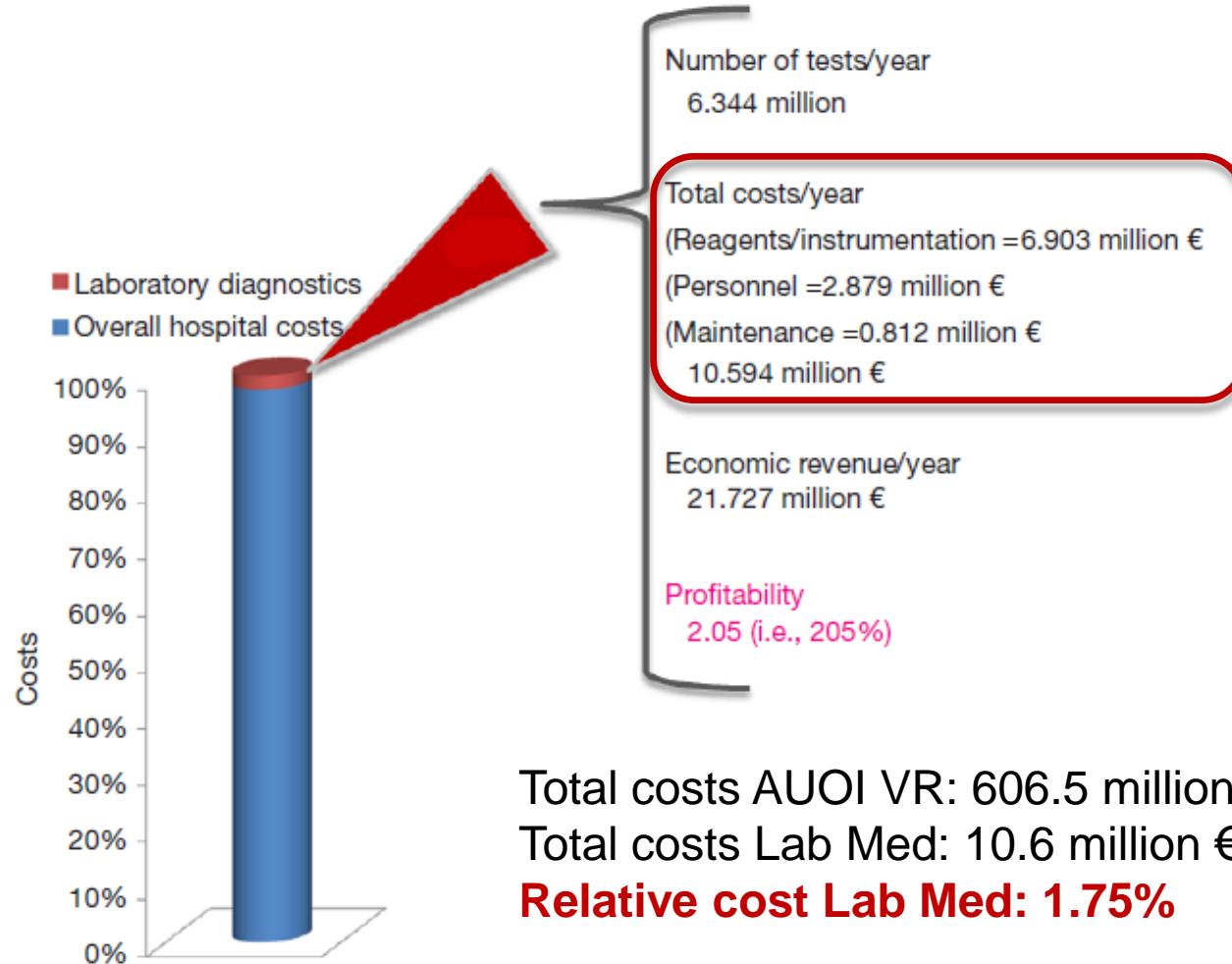


Laboratory managers shall learn to speak the language of administrators and policymakers, since it is very unlikely that these two categories will ever be committed to speak our language.



The add value of laboratory diagnostics: the many reasons why decision-makers should actually care

Giuseppe Lippi¹, Mario Plebani^{1,2}

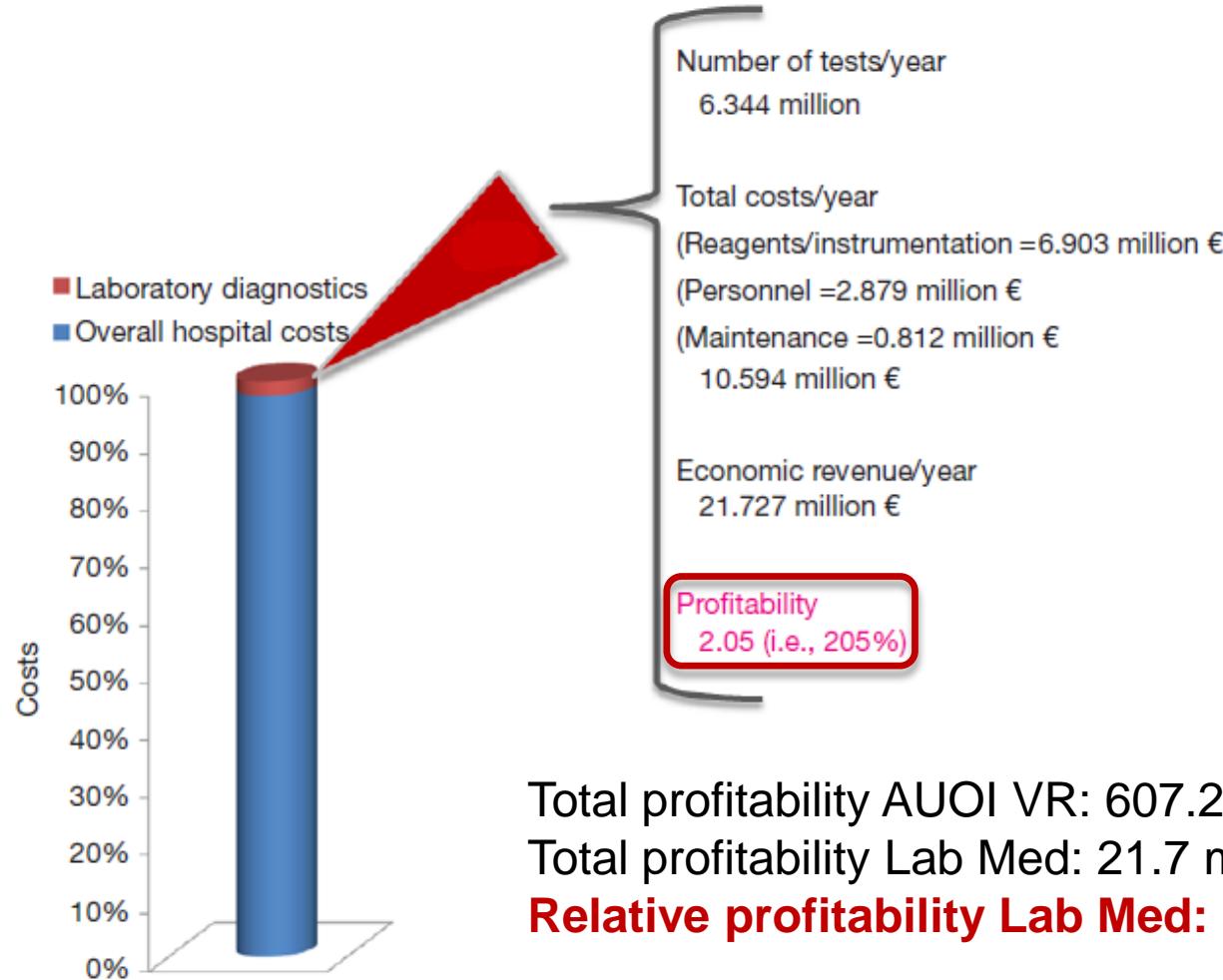




J Lab Precis Med 2017

The add value of laboratory diagnostics: the many reasons why decision-makers should actually care

Giuseppe Lippi¹, Mario Plebani²





J Lab Precis Med 2017

The add value of laboratory diagnostics: the many reasons why decision-makers should actually care

Giuseppe Lippi¹, Mario Plebani²

According to the prestigious journal *Forbes*, the top five most profitable worldwide industries are:

- Generic pharmaceutic industry (30% net profit margin),
- Investment (29.1% net profit margin)
- Tobacco (27.2% net profit margin)
- Internet software/services (25% net profit margin)
- Biotechnology (24.6% net profit margin).

Realistically, public clinical laboratories can hence ensure a **net profit margin that is nearly 7-fold higher than whatever other industry**, and would actually be approximately **10-fold larger than banks and information technology** (both 23% net profit margin).



J Med Biochem, 2019

PROJECT MANAGEMENT IN LABORATORY MEDICINE

Giuseppe Lippi¹, Camilla Mattiuzzi²

WHY INTERPLAYING WITH HOSPITAL ADMINISTRATION IS NOW AS ESSENTIAL AS EVER?

- Reorganization of healthcare network**

Will influence **number** and **size** of laboratory services

- Number of hospital beds and organization of outpatient districts**

Will influence **test volume**

- Evolution of case-mix**

Will influence **test menu**



Clinica Chimica Acta 489 (2019) 49–52

A manifesto for the future of laboratory medicine professionals

Mario Plebani^{a,*}, Michael Laposata^b, Giuseppe Lippi^c

Laboratory professionals: what should do now and in the future.

- 1) Convert results in clinical information
 - 2) Cooperate in reducing the risk of diagnostic errors
 - 3) Implement a reliable laboratory medicine stewardship
 - 4) Combine data of all laboratory subspecialties and diagnostic imaging in the same report
 - 5) Establish reliable reference ranges and decision limits
 - 6) Facilitate more effective teamwork and be actively involved in interdisciplinary teams
 - 7) Promote the shift from volume-based reimbursement models to clinical value
 - 8) Improve and update the way laboratory medicine is taught
 - 9) Do not neglect administrative competences and duties
 - 10) Promote the value of the profession
-



Process management (summary):

Step 1 - Defining the environment

- Define space availability and its organization
- Identify the most suitable strategy for automation

Step 2 - Planning technical resources

- Define the environmental context ("hub" or "spoke" laboratory)
- Recognize clinical needs
- Identify predicted volume and complexity of tests
- Develop clinical-laboratory liaison and diagnostic stewardship
- Take advantage from using a Lean management system

Step 3 - Staff availability and qualification

- Define the number of available persons
- Acknowledge the technical and clinical qualification of the staff
- Adapt volume and complexity of testing to face personnel shortage
- Identify critical issues in staff regulations (e.g., time on turn, recovery)
- Place the right person, in the right place, for doing the right activity, at the right time
- Safeguard personal and patient safety

Step 4 - Interplay with hospital administration

- Search the dialogue with hospital administrators
- Acknowledge the local political context
- Be aware of future local healthcare plans (e.g., reorganization of healthcare network, number of beds, evolution of case-mix)
- Be familiar with administrative duties and budgeting process

Step 5 - Additional drivers

- Identify political or ideological resistances
- Share the strategic plan with your laboratory staff and with local authorities, syndicates and stakeholders (i.e., clinicians and patients)
- Define reliable performance indicators (qualitative and quantitative)
- Monitor continuously staff and stakeholders satisfaction
- Identify an alternative solution (i.e., "plan B")
- Publicize results (when successful)

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