Organisms
Journal of Biological Sciences

LETTERS

Vol. 3, 1 (July 2019)
ISSN: 2532-5876
DOI: 10.13133/2532-5876_5.1

The role of the laboratory in health savings. Beyond the current paradigm

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Citation: Verna, R. and Laposata, M., 2019, "The role of the laboratory in health savings. Beyond the current paradigm", *Organisms. Journal of Biological Sciences*, vol. 3, no. 1, pp. 5-8. DOI: 10.13133/2532-5876_5.1

1. Overestimated impact on health policies

All Nations are aware that the role of vaccines and of the access to cure are a paradigm of how financial resources should be re-modulated. A very important awareness in itself, but unfortunately there is scarce evidence about the fundamental role of laboratory and in particular of early diagnosis, in the decrease of expense for the National Health System.

Since several years the Italian government is driving a spending review, according to which it is necessary to retrain social health spending, making cuts to costs and also to staff, starting from the laboratory.

Nevertheless, what the medical world and patients demand is that the quality of the protection of patient's health should not be changed.

The role of the laboratory to protect patient health and allow health savings, means to combine the protection of patients' health with the savings needs of the NHS through the improvement of quality in laboratories. Quality means to do what needs when it needs; in brief terms, appropriateness.

Clinical diagnostics are largely based on laboratory: over 70% of diagnoses are built on laboratory data. We reach almost 100% in Microbiology and Virology. Today, advanced molecular diagnostics are crucial for the early identification of a large number of diseases. It is obvious that in most cases, early diagnosis not only greatly decreases the patient's risk by contributing to faster recovery, but is also a source of safe savings because it avoids a large number of complications, which arise as a result of a late diagnosis. Through the research in the field of pharmacogenetics, we have come to the personalized medicine for a more and more defined therapy on the needs of the patient, so much so that nowadays we talk of precision medicine.

The laboratory is therefore a jewel for clinical diagnosis but, like all jewels, has its costs. But not even so much; anyway the current necessity is that nothing can cost without making results.

2. Is the cost truly affordable?

Unfortunately, no one takes into consideration the fact that the cost of laboratory tests is infinitesimal if compared to the enormous savings that they can determine in defining the correct therapeutic treatment of a subject. In Italy, the cost of laboratory tests is only the 2-3% of the health expenditure, while the cost of inappropriate recoveries reaches up to 15% (Fortino et al, 2001; Nicolussi Moro, 2013). The only limit of the clinical laboratory lies in the lack of awareness that the citizen - and with him a large part of those who manage the economic flows - has about the usefulness of the

laboratory, because this is considered a service like any other, without evaluating its effectiveness. Having to undergo a therapy or a surgery, you are informed about the quality of this or that doctor, of this or that hospital; nobody, however, thinks of choosing one or the other structure on the basis of the laboratory of which it makes use. The laboratory: this stranger, we could say.

Yet it should be pointed out that a reliable test, of the cost of a few cents or at most a few euros, can save thousands of euros and, sometimes, millions. Some time ago, the Center for Microcythemia in Rome, active since 1960, has been closed. The prevention carried out by the Center, practically eradicating thalassemia in the Region, has led to savings of around 10 million euros per year. Now, its closure will lead in a few years, thanks also to the considerable migratory flows, to a strong re-emergence of that pathology, with huge health costs.

Managers and politics are trying to reduce the cost of laboratory tests both by means of linear cuts, without an assessment of diagnostic appropriateness, and by reducing the laboratories and staff involved, with the creation of vast areas, trusting in the savings determined by the scale economy. This solution does not seem to be the best, because it depersonalizes the patient and does not guarantee the desired savings. In fact, it has been seen that the scale economy is accompanied by an increase in costs determined by transport needs and a reduction in quality determined by the increase in the time for time and often the need to repeat the test for the sample deterioration. The majority of laboratory errors (over 60%) occur in the "pre-analytic phase", which is precisely what is put at greater risk in large areas, where the collection centers are also one hundred kilometres from the place where the analysis. Problems of storage and transport of samples and consequent need of having to repeat the exams or, worse, to give inadequate answers, would increase and not reduce costs. Furthermore, the choice might make sense if such mega laboratories were located within large hospitals, while they are typically cathedrals in the desert, easy prey to multinational corporations without the primary health objective.

Why laboratory is under considered? In addition, what are the main problems concerning the waste of resources?

What happens if a surgeon mistakenly removes the wrong kidney in case of a renal carcinoma? Or if a patient with breast cancer dies from the overdose of the chemotherapeutic agent if as a result of a transcription error is given 4 times a standard dose of chemotherapy? Or, finally, if a patient has a pulmonary embolism, but the emergency room physician thinks he has asthma and fails to order a diagnostic test for pulmonary embolism, the D-dimer test, and the patient dies?

Do these doctors realize that these events could be avoided?

How often are errors in test selection and result interpretation major cause of morbidity and mortality? Probably tens of thousands of times every year – and this commentary describes how to address this problem.

Diagnostic error is a major public safety problem.

The main questions are the following: has the right test been ordered? Moreover, is there an error between result receipt and action? Possible misunderstandings lead to errors.

There is an important difference between school and practice. Medical School dedicates a lot of time to Anatomic Pathology, a little less to Radiology, but very few time to Laboratory Medicine. In the everyday practice, a doctor will face an enormous amount of Clinical Laboratory Tests, an amount of Radiology tests and a very small number of Anatomic Pathology tests. In addition, no Radiologist could release an image of the patient compared to the normal image; also, Anatomic pathologists are required of an interpretation. But no one asks an interpretation to the laboratory practitioner. They only ask for numbers. And the only thing that the laboratory adds to numbers is the reference interval that means additional numbers (Laposata, 2016; Sarkar, 2017; Laposata 2014a; Laposata, 2014b). Why is it acceptable for clinical laboratorians to give complex clinical laboratory test results back to physicians without interpretation – when they know just as little about the test results - beyond the routine ones - as they do about images in radiology and histopathology?

An additional cause of misunderstanding is given by the many different names used for some tests. Are we sure that the ordering doctor really wanted the correct test? The example of the many names for the test to measure the function of an important coagulation-related protein-von Willebrand factor and the many names of vitamin D are paradigmatic.

3. Rationalization of the diagnosis

Clinical doctors are not requested to know all the possibilities of the laboratory. In addition, they cannot be aware of the accountability of certain tests, or how much informative they are.

No one asks what he should do before doing it.

Ordering doctors should have continuous exchanges of information with laboratory doctors, since many doctors order unnecessary tests or miss the necessary ones.

Dozens of approaches emerge for diagnosis of the same condition – some better than others.

The correct diagnosis may be achievable promptly, but it is missed or very commonly delayed, with adverse clinical consequences to the patient and/or adverse financial consequences to the institution

One important example is chronic Plavix therapy. Plavix is an anticoagulant drug widely used to counteract the risk of thrombotic events. There are low and high responders who need different doses of the drug to achieve the result; obviously, the dose administered should be differentiated according to the responsiveness.

Without adapting the dose, low responders are not protected against thrombotic events, while high responders are.

Pharmacogenomics is able to assess the responsiveness to Plavix based on the functionality of the alleles involved, but the alleles involved are a number and the assessment may be difficult. And a pharmacogenomics team, costs.

However, with a brief analysis of the cost of an incorrect dosage, performed in a university hospital in USA, we see that if only 1% of stented patients are poor metabolizers, with more than 6000 patients under treatment, it means 60 adverse events avoided per year. Since the cost of an adverse event is 25000 USD, 1.5 million of total expense are much more that the setting of pharmacogenomics (Matetzky et al, 2004; Simon et al 2009).

The conventional approach is that clinicians order, laboratory performs tests and returns simple results. Clinician has to interpret results, but often without a real competence on many tests. The consequence is the increase of cost due to unnecessary tests and the difficulty to interpret results.

According this approach, tests are ordered and these bits of data are "tossed over the wall" to the physician who orders the tests. He is responsible for synthesizing clinical and laboratory data to achieve a diagnosis, often in a limited timeframe.

Someone at Vanderbilt University (Graber et al, 2017; Wright Pinson et al, 2016) have proposed a smart possible solution, by the institution of a Diagnostic Management Team (DMT).

An example of how the DMT works is the following: a physician has a patient with a prolonged PTT and must order the correct test to explain it preoperatively, but without ordering unnecessary tests. What to do? The available tests are many, some of which expensive, including Anti F Xa, VWF antigen, FII, PTT Mix, Ristocetin Cofactor, D-Dimer, Lupus Anticoagulant, Platelet Functional Test, FIX FVIII inhibitor, FXI, FXII, FX, FVIII, FXII, H.I.T. (Heparin Induced Thrombocytopenia), Association Ab, Thrombin Time, Fibrinogen, FVIII, FV, Platelet Count, PT, PTT, PT Mix.

If the treating physician fails to select the correct test to complete the diagnosis, the puzzle remains still incomplete and delayed diagnosis increases the expenses.

This is a wonderful chance for the action of the DMT. The Approach is: Physicians order tests by requesting evaluation of abnormal screening test or clinical sign or symptom.

The expert physician and colleagues in the DMT synthesizes the clinical and laboratory data and provides a narrative interpretation based upon medical evidence – not only when requested - but for every case. The role of the DMT is to develop the right pattern of diagnostic tests and to create a single comprehensive report. In the example of the elevated PTT, only six tests are needed to complete the diagnosis for the PTT Elevated and the results are FVIII Normal, FIX Normal, FI Normal, PT Normal, FXII Very Low, and PTT Mix Corrects to Normal.

This patient has Factor XII deficiency to explain the prolonged PTT value. There is no predisposition to bleeding with deficiency of this coagulation factor. There is no need to transfuse fresh frozen plasma prior to surgery.

4. Institution inadequacies

The problem is the failure of Institutions to recognize the clinical and financial benefits of advice on test selection and result interpretations on the total patient encounter.

Professional fee is $0 and the savings from a more rapid and more accurate diagnosis is $3000

$200,000 must be invested to develop teams of experts in an academic medical center.

However, the investment of $200,000 never happens because the return to the institution is in budgets other than the laboratory budget and not precise enough for many hospital administrators.

Now, some achievement of the DMT:

DMT decreases unnecessary tests. Following the number of tests before and after the institution of DMT, in 12 months tests have been reduced by 70%

DMT reduces omission of essential tests.

With reflex testing there are significant savings: 284USD for each test and a total of 0.8 million in one year only in one center.

DMT reduces costs. Over one year the annual saving has been calculated between 500.000 and one million USD on a volume of 1800 bone marrow.

The results of a pilot experiment to test the efficiency of DMT in coagulation tests show that there is a savings of 3000 USD per week for elimination of unnecessary tests, 9000 USD per month for earlier discharge. A total of more than 250.000 USD per year.

DMT helps clinicians in the choice of the correct, informative, test.

In fact, before DMT the clinician had to choose from a huge number of available tests, then interpret results; after the institution of DMT, the clinician chooses from a panel according to the clinical suspicion and results are evidenced in clear terms of a comprehensive report. The main problem in Countries is how to save money in public health. If the total budget of a hospital is 3 billion, with 3% of healthcare lab tests, there are two possible directions: 1) one third reduction in lab tests, leading to 2% of the expense for lab tests, that reduces the hospital budget to 2,97 billion; or, 2) increase lab tests by using useful tests that allow a more rapid and accurate diagnosis. This increases the expense for the lab to 4%, but reduces the budget of hospital to 2.5 billion with an important general saving (Van Horn et al, 1997).

This is inherent in the concept of appropriateness: To Do What Is Useful When It Is Useful.

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