Editorial

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Laboratory economics. Risk or opportunity?

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Health care expenditure is one of the leading economic drivers in most countries, second only to the amount of money spent on retirement. Public and private health care funding comprises between 6% and 12% of expenditure in many countries, with some notable exceptions such as the US where the share of the economy devoted to health care spending has recently surpassed 17%, or China and other African and South-East nations where the health care expenditure is much lower than 6% of the gross domestic product (GDP) [1]. These evocative figures may lead one to assume that the constant increase of public health care spending which has been recorded over the past decade has been paralleled by enhanced effectiveness in terms of both quality and quantity of life. Unfortunately, this is not the case, wherein the amount of money spent on health care in both the European Union and the US is not producing comparable health benefits (e.g. no correlation seemingly exists between reduced mortality and increased spending on patient care) [2]. The obvious consequence is that future interventions should be tailored on spending better rather than spending more. As health care expenses continue to increase around the globe, the implementation of novel, cost-reducing strategies must be considered to prevent reaching the tipping point where many national health care systems will fail to bend the cost curve.

It is not surprising that one of the emerging challenges of many (virtually every) public health services around the globe is to establish what types of services should be made available to the patients in a world with limited resources, just now recovering from an unprecedented economic crisis. Considering that a direct relationship exists between the GDP (which is still not recovering in many countries) and the parallel health care expenditure, the actual issue is to establish which would be the most appropriate threshold where benefits generated by any health care intervention may be ultimately worth. Many efforts are ongoing to accurately define the willingness to pay for health care interventions. After thoughtful analysis, for example, the UK National Institute for Health and Care Excellence (NICE) recently concluded that the cost/effectiveness threshold becomes evident in a range of expenditure comprised between £20,000 and £30,000 per quality adjusted life year (QUALY) [3], which exceeds by several orders of magnitude the cost of conventional diagnostic testing. A paradigmatic case is that of troponin testing, wherein the diagnosis of non-ST elevation myocardial infarction (NSTEMI) is now almost entirely based on this biomarker, the cost of which slightly exceeds €1 in most clinical laboratories [4].

There is widespread perception that the actual health care cost for in vitro diagnostics (IVD) is set to a sizeable 5%, thus putting it under fire by many health care administrators seeking to save money by constraining laboratory budgets [5]. However, recent statistics attest that the real spending for laboratory diagnostics is comprised between 1.4% and 2.3% of the overall health care expenditure [5, 6]. Therefore, even if IVD is just the tip of the iceberg of the overall health care spending, a tidal wave of reforms have been catalyzed to reduce its costs around the globe.

In this issue of *Clinical Chemistry and Laboratory Medicine* we publish an interesting study about the costs and income of clinical laboratory testing in Taiwan [7]. The leading take-home message of this article is that the cost per test was found to be constantly lower than the National Health Insurance (NHI) payment. Notably, most laboratory tests were found to have revenues with a medium profitability approximating 10%, and achieving a considerable +29% and +19% for clinical chemistry and immunochemistry testing. This evidence is not so different from previous studies which used cost-benefit, cost-effectiveness and cost-utility analyses, and also pinpointed the added economic value of diagnostic testing for individual facilities [8]. Intuitively appealing through this holistic view, IVD should be no longer seen as a simple cost for the public health care system, but also as a profitable business for hospital administrators. This was clearly highlighted by Charles M. Strom, who pragmatically concluded that '…the hospital laboratory became a cash cow with potential to generate large profits' [9].

Indeed, such a cultural sea change entails that laboratory professionals should be more committed to

laboratory organization and not discount the increasing importance of health care economics to prevent that unjustified IVD costs, mainly attributable to inadequate organization of their services, may erode potential values. Clinical utility and cost-effectiveness analyses are valuable supports for better use of care resources, for enhancing quality and intensifying the focus on patient-centered care [10, 11]. After all that is said, however, some critical issues remain in this orthodox economic dimension.

We should bear in mind that laboratory professionals are ordinarily committed to provide health care measures that may efficiently translate into better clinical outcomes, but not always the "cost-effectiveness paradigm" can be fulfilled. In the rather long history of laboratory diagnostics, many examples testify that the willingness to pay should not be seen as an insurmountable boundary inasmuch as some very expensive tests have virtually revolutionized our approach to diagnose and treat human disorders [12]. Would this still be possible in an entirely "cost-containing" or "return-of-investment" driven scenario? Probably not. Patient safety is another leading issue [13]. A growing body of evidence demonstrates that the downstream costs due to poor quality and errors in laboratory medicine account for unjustified expenses much higher than those due to the direct costs of laboratory tests [14]. Despite innovation and advances in laboratory technology have been clearly recognized as drivers of spending in the long term, they often achieve a breakeven point. Therefore, a spasmodic chase towards enhanced affordability by lowering the cost for single (diagnostic) test, purchasing low-cost analyzers or developing huge tenders (due to the misleading perception that "one size fits all"), may only herald perilous scenarios, characterized by lack of innovation, shortage of personnel, acquisition of low-quality equipment, but also by the risk of overlooking basic quality requirements (i.e. systematic quality control performance).

These considerations bring us back directly to the notion that return on investment is possible and technically viable in laboratory medicine, as clearly demonstrated by Su et al. [7]. However, this should be paralleled by reengineering the whole system according to a pay-for-quality and pay-for-performance strategy, thus blunting the sharp edge of shortage of public and private health care funding for IVD [15]. With the awareness that inequity is a major challenge of modern health care systems [16], the concept that "better (diagnostic) care, at lower cost, and with real economic revenues" is not necessary an oxymoron for those who have not seen and yet have believed in the real value of laboratory diagnostics [17].

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References

1. The World Bank. Health expenditure, total (% of GDP). Available at: http://data.worldbank.org/indicator/SH.XPD.TOTL.ZS. Accessed: 12 April 2016.
2. Lippi G, Mattiuzzi C, Cervellin G. No correlation between health care expenditure and mortality in the European Union. Eur J Intern Med 2016. doi: 10.1016/j.ejim.2016.02.025. [Epub ahead of print].
3. Appleby J. Crossing the line: NICE's value for money threshold. BMJ 2016;352:i1336.
4. Lackner KJ. High-sensitivity assays for cardiac troponins. Clin Chem Lab Med 2015;53:631–3.
5. Rohr UP, Binder C, Dieterle T, Giusti F, Messina CG, Toerien E, et al. The value of in vitro diagnostic testing in medical practice: a status report. PLoS One 2016;11:e0149856.
6. Lippi G, Mattiuzzi C. Testing volume is not synonymous of cost, value and efficacy in laboratory diagnostics. Clin Chem Lab Med 2013;51:243–5.
7. Su B-G, Chen S-F, Yeh S-H, Shih P-W, Lin C-C. Cost evaluation of clinical laboratory in Taiwan's National Health System by using activity-based costing. Clin Chem Lab Med 2016;54:1753–8.
8. Barletta G, Zaninotto M, Faggian D, Plebani M. Shop for quality or quantity? Volumes and costs in clinical laboratories. Clin Chem Lab Med 2013;51:295–301.
9. Strom CM. Changing trends in laboratory testing in the United States. Clin Lab Med 2012;32:651–64.
10. Lippi G, Mattiuzzi C. The biomarker paradigm: between diagnostic efficiency and clinical efficacy. Pol Arch Med Wewn 2015;125:282–8.
11. Lippi G, Plebani M. Personalized medicine: moving from simple theory to daily practice. Clin Chem Lab Med 2015;53:959–60.
12. Lippi G, Plebani M. Laboratory medicine does matter in science (and medicine)… yet many seem to ignore it. Clin Chem Lab Med 2015;53:1655–6.
13. Lippi G, Plebani M, Graber ML. Building a bridge to safe diagnosis in health care. The role of the clinical laboratory. Clin Chem Lab Med 2016;54:1–3.
14. Plebani M, Panteghini M. Promoting clinical and laboratory interaction by harmonization. Clin Chim Acta 2014;432:15–21.

15. Plebani M. Clinical laboratories: production industry or medical services? Clin Chem Lab Med 2015;53: 995–1004.
16. Deaton A. On death and money: history, facts, and explanations. JAMA 2016;315:1703–5.
17. Plebani M, Lippi G. Is laboratory medicine a dying profession? Blessed are those who have not seen and yet have believed. Clin Biochem 2010;43:939–41.

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