Streamlining laboratory expenditures through direct to consumer testing and reference prices: first do not harm

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The almost overwhelming increase of healthcare expenditure is one of the major obsessions troubling many policymakers and healthcare administrators around the globe, especially now that the whole world is still plagued by an unprecedented economic crisis. The constant growth of healthcare budgets has many and rather reasonable explanations, such as the increasing demand for (quality) care, the enlarged coverage beneath national reforms, the gradual ageing of the worldwide population, indirect costs of managing the system of care, along with the introduction of innovative diagnostic and therapeutic technologies, which never come with cheap prices.

Despite several lines of evidence were brought in support to the fact that the cost of diagnostic testing represents only the tip of the iceberg for a national healthcare system (i.e., between 1–2% of the total budget) (1,2), this essential area of science and medicine has been the focus of a large number of too frequently shortsighted political interventions, mainly aimed to reduce the net expenditure rather than targeting inappropriate testing. The application of so-called "linear" rather than "targeted" cuts is commonplace around the world, often disregarding that the overemphasized enticement towards personalized ("precision") medicine underpins the correct use of diagnostic testing (1).

For whatever kind of bizarre extraterrestrial creature accidentally landing on the Earth, the scenario would seem rather paradoxical, if not crazy. On one hand, many governments are putting national directives into action to reduce coverage and/or reimbursement of diagnostic tests, with the unspoken expectation to cut down budgets (healthcare expenditure is the second highest public expenditure in the vast majority of western and developing countries) (1). On the other hand lays a number of ongoing initiatives attempting to driving patient choice towards low-cost diagnostic testing. A recent study, published by Robinson *et al.* (3), showed that the introduction of reference pricing for laboratory testing was associated with the choice of low-cost facilities, along with decrease of prices and payments by both employer and employees. Overall, the out-of-pocket cost was also reasonably reduced. It is hence not really surprising that we are now virtually incapable spectators of a deregulated expansion of direct to consumer testing around the globe, which refers to different types of laboratory analyses directly offered to the "patients-consumers" through several marketing venues, but with no direct or active involvement of health care professionals (4). Practically, each patient can order, without medical counseling or supervision, dozens or hundreds (depending on money availability) of conventional or molecular tests, regardless of health status and clinical rationale. Many doubts have been recently raised over the quality and safety of the methodologies used by some of these laboratories, as well as over the real (clinical and psychological) impact of data generated by some consumer healthcare technology companies (5). What is rather clear to everybody, however, is that deregulation of *in vitro* diagnostic testing ends up to impose extra burden on the pocket of the consumers, but may also have unpredictable consequences on health and wellbeing. Just think at a false positive diagnostic test for establishing the risk of future cancer. Without appropriate counseling, this would inevitably trigger additional possibly invasive (and often expensive) investigations, not mentioning the psychological distress that may even lead to the questionable conclusion that preventive surgery will always be the best way to save lives [i.e., preventative double mastectomy for breast cancer 1 (*BRCA1*) cancer gene polymorphism].

It is hence not so bizarre to suspect that our extraterrestrial acquaintance would be assailed by a rather reasonable doubt: and what about the analytical quality? "Best test at the lowest cost" is seen as the most desirable aspiration by both governments and "patients-consumers" but—regrettably—the quality never comes for free. Offering deregulated "on-demand" (low-cost) diagnostic testing or providing reference prices (more or less like supermarkets do for attracting costumers) have very little to share with quality of care. Still in the search for the magic wand, we should always bear in mind that a patient-centered vision of care entails adopting tools that maintain the quality of care services at their highest possible level, compatibly with the limited availability of resources. Some reliable options have been put forward to limit unnecessary or inappropriate testing (e.g., the adoption of health technology assessment or computerized alert systems among others) (6,7), which were found to be paradoxically more effective than the so-called "linear" and indiscriminate cuts to reduce diagnostic expenditures while preserving a high level of quality throughout the testing process. So, whenever implementing new strategies for controlling the total spending of diagnostic testing, do not discount that price should not be the main driver and that… whatever the final strategy to reducing costs, first do not harm!

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Footnote

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