

# Chapter 7

## Innovation in Laboratory Medicine

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### ABSTRACT

*Laboratory medicine has a unique capability to evaluate the correct management of a medical test, its results, and the decisions it can determine. Therefore, laboratory medicine should try to improve patient outcomes, while improving quality and productivity, so that innovation in healthcare may proceed. Innovation in laboratory medicine demands an adequate identification of the unmet clinical need, evidence of clinical and cost-effectiveness of laboratory tests, and a managed implementation that takes into account the process change, appropriate resource management, and monitoring of outcomes. The main objectives of this chapter are to elucidate the role of innovation in laboratory medicine, identifying its main issues and the barriers it faces; to define a value proposition for laboratory tests and to point out several outcome measures that can be adopted in laboratory medicine.*

### BACKGROUND

In healthcare, nowadays, costs tend persistently to rise and services to be restricted, well short of recommended care (The Economist Intelligent Unit Healthcare, 2014). We also observe that there is a huge gap in quality and judgment across providers and geographic areas, with innovation being restricted to some contexts. In this context, a number of initiatives has been proposed to take a more value-based approach to healthcare (Kaplan & Porter, 2011). This has led to the call for a shift in emphasis from the volume of services to outcomes delivered for patients (Porter, 2014). Much of the total cost of caring for a patient involves shared resources, such as physicians, staff, facilities and equipment. To measure true costs, shared resource costs must be attributed to individual patients on the basis of actual resource use for their care, not averages. Cost-measurement approaches have obscured value in health care and led to cost containment efforts that are incremental, ineffective and, sometimes, even counterproductive. Until now, healthcare organizations have been measuring and accumulate costs around departments, physician specialties, discrete service areas and line items, such as drugs and supplies — a reflection of the

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organization and financing of care. On the other hand, measuring total costs over a patient's entire care cycle and weighing them against outcomes will enable structural cost reduction, through steps such as reallocation of spending among types of service in the appropriate settings, elimination of non-value-adding services, better use of capacity, provision of services in the appropriate settings, and so on. The large cost differences among medical conditions, and among patients with the same medical condition, reveal additional opportunities for cost reduction. The failure to prioritize value improvement in health care delivery, and to measure value, has slowed innovation, led to ill-advised cost containment, and encouraged micromanagement of physicians' practices. Aligning reimbursement with value in this way rewards providers for efficiency in achieving good outcomes, while creating accountability for substandard care.

## **INNOVATION IN HEALTHCARE**

Innovation has been generally defined as "...the intentional introduction and application within a role, group, or organization, of ideas, processes, products or procedures, new to the relevant unit of adoption and designed to significantly benefit the individual, the group, or wider society..." (Price & St. John, 2014). Innovation in healthcare undergoes invention, adoption and diffusion, this one is related with the facilitation and widespread adoption of the new test or device (Price, 2012). In order to innovation take place in healthcare, there has to be the identification of an unmet need, the determination of the effectiveness of a certain process, the application of the evidence-based knowledge at the time, and an audition to the application in the field. There are several drivers that impact on success of the innovation including process quality, effectiveness, efficiency, patient aspiration, the change observed in the care pathway and the impact on the stakeholders involved in healthcare delivery, as their flexibility to change (Omachonu & Einspruch, 2010).

Innovation can, thus, be classified as sustaining or disruptive (Christensen & Oversdorf, 2000). Sustaining innovation is the one that makes an incremental improvement. It allows that a product or service performs better in ways that customers already value. On the other hand, disruptive (also described as radical or transformational) innovation creates an entirely new market through the introduction of a new product or service (Hogan, 2005). Sustaining is incremental, while disruptive is truly transformational — having a major and durable impact. Sustaining innovation will take one existing concept and push it further; disruptive innovation takes several concepts and combines them into one seamless advance. Disruptive innovation improves a product or service in ways the market does not expect, for example, by lowering price or design change to address a different set of consumers. Innovation that involves impacts on more than one stakeholder is more likely to be disruptive. This disruption is achieved through significant changes in the interactions between different stakeholders, or even in the nature of the client-provider contract. Clearly, this would involve significant process change across the care pathway. This, however, is one of the most important features of innovation, since achieving a better outcome results mainly from doing something different, often radically. Very often, like in Laboratory Medicine, there is a substantial number of sustaining innovations that are then punctuated with disruptive innovations. Although sustaining innovation steadily drives progress, paradigm shifts usually occur only with disruptive thinking. Some examples of disruptive innovation in laboratory medicine include continuous flow analysis, dry reagents on dipsticks, pregnancy home testing, PCR, point-of-care testing, and use of MALDI-TOF mass spectrometry for pathogen identification (Rifai, 2015). With the escalating cost of healthcare, bold measures and disruptive approaches in delivering effective and economical clinical

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