



Invited critical review

# Innovation in healthcare. The challenge for laboratory medicine



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## ABSTRACT

The delivery of healthcare is the product of a complex organization and it is not entirely surprising that innovation is not always considered to deliver on the expectations generated by invention. As policymakers and payers seek to improve the quality and value-for-money of healthcare, more attention is being directed at the barriers to innovation, and the challenges of translating inventions into outcomes. Laboratory medicine is one facet of healthcare that has generated considerable levels of invention but, while showing increasing volumes of activity over the past decades, it has not been recognized for generating the benefit in outcomes that might have been expected. One of the major reasons for this position has been the poor quality of evidence available to demonstrate the impact of laboratory investigations on health outcomes. Consequently an absence of evidence stifles the opportunity to develop the business case that demonstrates the link between test result and improved outcome. This has a major influence on the success of innovation in laboratory medicine. This review explores the process of innovation applied to laboratory medicine and offers an insight into how the impact of laboratory medicine on health outcomes can be improved.

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## 1. Introduction

Invention and innovation are acknowledged as being major influences on the evolution of clinical medicine and the delivery of healthcare; laboratory medicine is an important part of this evolution. However it has also been suggested that “technological innovation” has been responsible for 20 to 50% of the growth in expenditure of healthcare over the last few decades [1–3]. At the turn of the century in the United States, the Institute of Medicine concluded that one of the reasons for the errors found in the

healthcare system was the increasing complexity of science and technology, one implication being that it was not being utilized appropriately—another being that innovation was not working [4]. In laboratory medicine there have been major advances in the repertoire of biomarkers and investigations available, as well as the technology to aid delivery, e.g. automation, biosensors and nanotechnology. Again, however, there have been many claims of too many (unnecessary) tests being requested [5,6], as well as slow adoption of new tests [7].

## 2. Invention and innovation

Invention has been defined as “an idea made manifest” [8] where the idea may be in the form of a piece of technology, a process, or an

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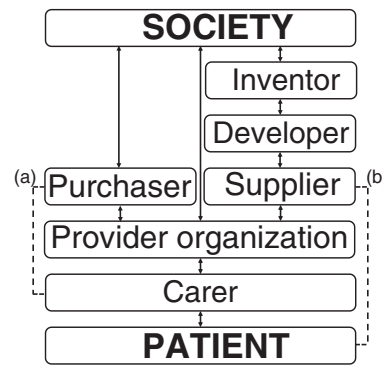
intervention. However, an invention of itself is not necessarily innovative. Rifai et al. introduced six “inventors” in a paper on “advancing laboratory medicine through innovation”, noting that the inventions changed the practice of laboratory medicine [9]. Rifai et al., in defining innovation as “inventiveness put to use” were highlighting the culture of biomedical technology innovation that already exists in laboratory medicine, supporting the idea of teaching innovation in context, advocated by Yock et al. However the latter’s description of innovation did not extend to the successful application in a clinical setting, except perhaps in the eyes of the inventor [10]. May observed that “innovation is almost never a thing-in-itself” although there may be a tangible beginning, which could be an invention or the recognition of an unmet need—both drivers recognized by Rifai et al. [11]. However in a complex organization, such as healthcare delivery, he points out that an innovation has first to be considered in relation to its social, technical and spatial contexts, then the crucial role of the stakeholders needs to be recognized, i.e. those who will be impacted by the innovation and the choices they make, and lastly, recognition of the importance of the process of implementation. These issues have been debated on many occasions in relation to innovation in healthcare [e.g. 12–14].

Innovation has been broadly 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” [15]. Simple, generic attributes of innovation include (i) an idea applied successfully in practice, (ii) the introduction of a new method or process, (iii) a new idea made useful, and (iv) a new idea that enhances value. Important practical characteristics include (i) novelty (i.e. something new), (ii) application, (iii) benefit and value, driven by (iv) addressing an unmet need, with (v) a willingness to adopt new practices, and (vi) delivering an improved outcome [16].

Omachonu and Einspruch described innovation in healthcare as “the introduction of a new concept, idea, service, process, or product aimed at improving treatment, diagnosis, education, outreach, prevention and research, and with the long term goals of improving quality, safety, outcomes, efficiency and costs” [16]. Thus innovation offers the possibility of a wide range of benefits to all stakeholders in healthcare, as well as to society as a whole.

### 3. Stakeholders and innovation in healthcare

Much has been written about the complexity of healthcare, and the number of stakeholders involved; when viewed from the perspective of innovation the stakeholder groups can be differentiated into those related to the care provided to patients, and those that invent, develop and provide the technology used in the delivery of care to patients. Each of these stakeholders interacts with others through some form of “provider–client” relationship or contract, each with their own expectations from innovation. The stakeholder groups most associated with innovation in the care delivered to patients include (i) the patient, (ii) the carer, (iii) the care provider organization, (iv) the purchaser of the care service (sometimes referred to as the healthcare commissioner/insurer/payer), and (vi) society. The stakeholders involved in the technology employed in the delivery of care to patients include (a) the inventor, (b) the researcher/developer, (c) the manufacturer/marketing/sales organization, and (d) the healthcare provider organization. The stakeholder landscape is shown in Fig. 1, indicating the most common “contractual relationships” found in healthcare, as well as less common examples, or opportunities for the future. Stakeholder expectations (benefits) are discussed later in the section on outcomes. In healthcare it is important to recognize all of the stakeholders involved in any care pathway as, invariably, the benefits of an innovation will be seen in a number of stakeholder domains, other than the domain in which the new technology (or treatment, etc.) is delivered. This can create significant tensions between stakeholders as it will involve



**Fig. 1.** An illustration of the key stakeholders in the delivery of healthcare, and the relationship between these stakeholders. On the left are the stakeholders directly related to the care given to patients, while on the right are the stakeholders involved in the process from invention to innovation through a contribution to patient care. Potential alternative relationships are denoted by the broken lines (a) services directly provided by the carer, e.g. a general practitioner, and (b) a test or device is directly purchased by the patient.

disinvestment in some stakeholder domains, e.g. delivering more care in primary care will reduce activity in secondary care.

While the Omachonu and Einspruch [16] definition of innovation in healthcare might be seen as a description that focuses on the societal level and the realms of the purchaser and provider, it is also relevant to all of the stakeholders who will be involved in the process of innovation that delivers the overall service. All such stakeholders can identify unmet needs within their immediate area of responsibility and are potential recipients of innovation, and it is important to recognize the responsibilities and accountabilities of those that contribute to, and impact on, the “clinical team” caring for the individual patient.

Different stakeholders will have differing needs or expectations of the healthcare service [17], and its component parts, and there are likely to be tensions or differences of views between stakeholders. The purchaser (commissioner/insurer) can be seen as the patient’s advocate and an important starting point for innovation, by understanding (and articulation in strategic planning) of the patient’s unmet needs—albeit most commonly expressed on a population basis. Similarly treatment guidelines are commonly based on evidence generated in a large cohort of patients. However it is acknowledged that what is best for the individual may not be best for the group, and the practicing clinician is left to individualize the care for each patient under his/her care. There are, therefore, a number of challenges or tensions between stakeholders. A common tension today is where specialist services are centralized either to ensure the critical mass of expertise required, or to save money—resulting in the possibility of many patients having to travel long distances to obtain care. Another example is the tension between what the supplier might want to charge for a new biomarker assay and what the purchaser or society is willing to pay. Thus you can consider the stakeholders in Fig. 1, each with their specific unmet needs and expectations, and the innovation challenges that can arise. The patient will expect the best outcomes at reasonable cost, the purchaser having the same aspirations on a population basis. The provider will seek to provide the service expected by the purchaser that is both clinically and cost effective. This is probably the point at which greater emphasis on costs begins to play a role with patients being offered choice in terms of access to services, and competitive tendering for services. Thus one can begin to see the impact of different approaches to the organization and management of healthcare on innovation.

For laboratory medicine important relationships (contracts) include those that exist between: (a) the researcher and the manufacturer, (b) the manufacturer and laboratory service, (c) the laboratory service and the patient, (d) the laboratory service and the carer, and (e) the carer and the patient, (f) the laboratory and the healthcare service

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