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Invited critical review

The future of laboratory medicine — A 2014 perspective

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ABSTRACT

Predicting the future is a difficult task. Not surprisingly, there are many examples and assumptions that have proved to be wrong. This review surveys the many predictions, beginning in 1887, about the future of laboratory medicine and its sub-specialties such as clinical chemistry and molecular pathology. It provides a commentary on the accuracy of the predictions and offers opinions on emerging technologies, economic factors and social developments that may play a role in shaping the future of laboratory medicine.

Contents

Abbreviations: ACO, Accountable Care Organizations; AEC, Atomic Energy Commission; ASCP, American Society for Clinical Pathology; ASIMO, Advanced Step in Innovative Mobility; BNP, brain natriuretic peptide; BRCA, breast cancer antigen; CAP, College of American Pathologists; CLIA, Clinical Laboratory Improvement Amendments; CMV, cytomegalovirus; DNA, deoxyribonucleic acid; eMERGE, Electronic Medical Records and Genomics; FACS, fluorescence-activated cell sorting; FDA, US Food and Drug Administration; GC, gas chromatography; GDP, gross domestic product; HER2, human epidermal growth factor receptor 2; HIV, human immunodeficiency virus; HIPAA, Health Insurance Portability and Accountability Act; HITECH, Health Information Technology for Economic and Clinical Health Act; HPLC, high performance liquid chromatography; HPV, human papillomavirus; IOM, Institute of Medicine; ISO, International Standards Organization; IT, information technology; IVDMIA, In Vitro Diagnostic Multivariate Index Assay; MALDI, matrix-assisted laser desorption ionization; MEMS, micro-electromechanical; mRNA, messenger RNA; MS, mass spectrometry; NCI, National Cancer Institute; NICE, National Institute for Health and Care Excellence; NIH, National Institutes of Health; NMR, nuclear magnetic resonance; PBMs, Pharmacy Benefit Managers; PCR, polymerase chain reaction; RFID, radio-frequency identification; RNA, ribonucleic acid; RT-PCR, reverse transcription PCR; SNP, single nucleotide polymorphism; TOF, time of flight; USB, Universal Serial Bus.

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1. Introduction

Attempting to predict the future or being dogmatic about what may or what may not transpire in the future is a risky business, and history provides numerous examples of predictions and assumptions that have proved to be wrong.

Spectacularly inaccurate predictions abound in the field of consumerism and computing. In 1966, *Time* magazine stated, "Remote shopping, while entirely feasible, will flop" [1]. In 2012, the US online retail sector had total revenues of more than $200 billion, with a compound annual growth rate of 11.0% between 2008 and 2012 [2]. The launch of the iPod drew the following comment from the founder of a major consumer electronics company in 2005: "Next Christmas the iPod will be dead, finished, gone, kaput" [3]. By January 2007, the iPod US market share of digital music player sales had reached 72.7% [4]. In 2007, the CEO of Microsoft advanced the opinion that "There's no chance that the iPhone is going to get any significant market share. No chance" [5]. By the end of fiscal year 2010, a total of 73.5 million iPhones had been sold [6].

The early days of computing also produced some famously erroneous predictions. In 1943, the chairman of IBM said, "I think there is a world market for maybe five computers" [7]. Another highly respected member of the early computer industry, the president, chairman and founder of Digital Equipment Corp., explained in 1977, "There is no reason anyone would want a computer in their home" [3]. Despite these predictions, a US Department of Commerce survey from 2011 showed that 75.6% of households in the United States reported having a computer [8]. In fact, computer makers shipped more than 85 million computers in the second quarter of 2012 [9], and the worldwide PC, tablet and mobile phone combined shipments were approximately 2.2 billion that same year [10].

The prognosticator usually bases predictions on contemporaneous information and perceived trends. Picking the relevant trends and identifying transformative technologies is generally more of an art than a science. For example, an emerging and ultimately successful technology can be at any of a number of stages of development, and these can influence the perception of its influence and contribution to future developments. These stages, characterized by the Gartner Hype Cycle, include "a peak of inflated expectations", "a trough of disillusionment" and end with "a plateau of productivity" [11]. Clearly, greater weight likely will be attributed to the future influence of a technology when it is at the peak of inflated expectations, compared to when it has descended into a trough of disillusionment.

Many authors have offered predictions regarding the future of laboratory medicine and its subspecialties. This article reviews the literature that prognosticates on the future of laboratory medicine and provides a 2014 perspective of the future of laboratory medicine.

2. Predictions for the future of laboratory medicine

There is no shortage of predictions about the future of laboratory medicine. These fall into two categories; the first category includes general predictions for the future while the second represents predictions for specific dates in the future (Table 2) [12–48].

An interesting starting point is the Inaugural lecture, titled "A view from a bridge," given in 1969 by Tom Whitehead, the first Chair of Clinical Chemistry at the University of Birmingham [16]. He identifies five eras of clinical chemistry: The *complicated era* from 1920 to 1940 when testing was manual and laborious, the *simplified era* from 1940 to early 1950s when test procedures were simplified, the *crisis era* in the late 1950s when the test workload doubled every 4–5 years, the *sophisticated era* in the late 1960s based on new automation and computing technology, and the *profile era* in the 1970s when tests were bundled together as profiles in order to improve laboratory efficiency and to detect biochemical abnormalities that would not have been detected by clinical examination (Table 3). He also points to the continuing importance of computers and automation, in addition to the emergence of preventative medicine and pharmacogenetics.

There is merit in each of these predictions. For example, profiling has re-emerged in clinical testing in the form of protein, tissue and nucleic acid arrays (e.g., cytokine profiles, array comparative genomic hybridization analysis) [49–52]. Computers and automation have played an increasingly important role in improving the efficiency and effectiveness of testing. More recently, pharmacogenetics, popularized by the slogan "right patient, right drug, right time" [53], has moved into mainstream testing (e.g., *CYP2C9* for warfarin dosing) [54].

Since 1969, there have been many predictions and views of the future development of laboratory medicine and its sub-specialties. A summary of these predictions is provided in Table 1 [12–48]. A number of common themes and buzz-words can be identified in the prognostications such as nanotechnology, biosensors, microchips, genomics, and proteomics. These topics, together with the more specific predictions, are discussed in greater detail below.

2.1. Laboratories, laboratory organization and staffing

Early publications predicted "as many as two workers in the laboratory" at large medical centers and specified that the roles of laboratorian and pharmacist would be combined [15]. By 1989, the emphasis had shifted to concerns about the impending shortages of pathologists [24], a concern that has continued into the 2000s [33].

In more recent times, futurists have predicted a world dominated by large supra-regional tertiary centers or laboratory networks formed by laboratory consolidation [35,46]. Contraction in the number of laboratories would be driven by out-sourcing of laboratory services, competition between laboratories for hospital work, and the commoditization of laboratory tests [28,34,35]. A positive trend would be possible growth due to refocusing of clinical laboratory services due to changing demographics (e.g., emphasis on diseases of the elderly and reassessment of location of services) [28]. Within laboratories, integrated services staffed by clinical laboratory scientists may lead to further contraction (e.g., hematology, transfusion medicine, biochemistry and immunology merged into a unified "blood sciences") [46]. Staff would be responsible for demand management, greater components of user education and the provision of additional consultative services related to laboratory testing. In the context of increased point-of-care testing, the future role of laboratorians would be reduced to maintaining equipment and performing quality control [19]. Other predictions focus on the challenges of global harmonization of in vitro diagnostic tests, reducing laboratory errors and eliminating unnecessary testing [33].

Early predictions for the scale and scope of clinical laboratories (e.g., a total of two workers in the laboratory) were off the mark (see Fig. 1 that contrasts a clinical laboratory in 1904 and 2014). However, predictions about a combined laboratorian pharmacist may have been accurate 100 years later with the advent of personalized medicine [55]. More importantly, predictions on laboratory consolidation have