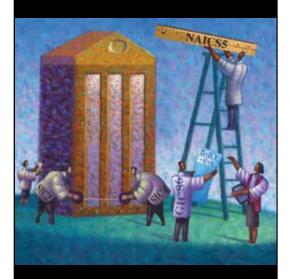
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#### VALUATION

# The Four Pillars of Healthcare: Part IV TECHNOLOGICAL ADVANCEMENTS IN THE HEALTHCARE INDUSTRY

By Robert James Cimasi, MHA, ASA, FRICS, MCBA, CVA, CM&AA; and Todd A. Zigrang, MBA, MHA, FACHE, ASA

he term "technology" has a broad meaning in the healthcare industry. It can range from the tangible tools, pharmaceuticals, and software that healthcare providers utilize when providing care and managing patient records, to the procedures that standardize the course of care.

This article, the fourth and final article in the series "The Four Pillars of Healthcare," will broadly discuss some of the recent technological advancements in the healthcare industry, addressing both management technology and clinical technology. The article will also discuss the changing demand for various aspects of healthcare technology, including demographic and access differences, and the advanced capabilities of healthcare research to develop rapidly developing areas of medicine.

#### MANAGEMENT TECHNOLOGY

The patient demand for healthcare services is increasing at a rapid rate, due to: improved access to care; the growth of the general population;<sup>1</sup> the enlarged number of individuals over the age of sixty-five;<sup>2</sup> and, the worsening physician manpower shortage.<sup>3</sup> Particularly due to the recent influx for previously

uninsured individuals (an estimated twenty million adults have gained insurance since the implementation of the Patient Protection and Affordable Care Act [ACA]),<sup>4</sup> providers will have to implement methods of managing added patient throughput. This growth in demand for healthcare services is a significant driver of more sophisticated patient management technologies, as well as the infrastructure for gathering and interpreting quality and outcomes data to support evidencebased performance metrics as the foundation for value-based reimbursement. The demand for management technology *vis à vis* the current U.S. healthcare delivery system was characterized in the 2012 *Futurescan Report*, to wit:

The healthcare industry cannot bend the cost and quality curve without relentless technologyenhanced innovation—a constant stream of new ideas, new methods, and new ways of providing and payment for care. Such innovations will be most effective if it comes from healthcare executives and clinicians 'in the trenches' who are no longer willing to do things in ways that clearly have been shown not to work.<sup>5</sup>

<sup>1 &</sup>quot;Population" in "Statistical Abstract of the United States: 2015" U.S. Census Bureau, Washington, DC, 2014, p. 9.

<sup>2 &</sup>quot;Why Population Aging Matters: A Global Perspective" National Institute on Aging, National Institute of Health, the United States Department of Health and Human Services, http://www.nia.nih.gov/sites/default/files/ WPAM.pdf (Accessed 05/14/12).

<sup>3 &</sup>quot;Physician Shortages to Worsen Without Increases in Residency Training" Association of American Medical College, 2010, https://www. aamc.org/download/286592/data/physicianshortage.pdf (Accessed 8/2/12).

<sup>&</sup>lt;sup>4</sup> 20 Million People Have Gained Health Insurance Coverage Because of the Affordable Care Act, New Estimates Show" U.S. Department of Health and Human Services, HHS Press Office, March 3, 2016, https:// www.hhs.gov/about/news/2016/03/03/20-million-people-have-gainedhealth-insurance-coverage-because-affordable-care-act-new-estimates (Accessed 1/24/17).

<sup>5 &</sup>quot;Chapter 1: Healthcare Reform: The Transformation of America's Hospitals: Economics Drives a New Business Model" in "Futurescan 2012: Healthcare Trends and Implications 2012–2017" By Kenneth Kaufman and Mark E. Grubs, Irving, TX: VHA Inc. (2012), p. 8–9.

Management technologies include: the processes and procedures through which providers organize patient encounters, charge entry, and the billing process; and the software and devices that support these activities. While there are myriad methods through which a healthcare enterprise may choose to approach management, the most publicized involve the interoperable exchange and consolidation of patient data and treatment standards. Most of the current management systems are implemented as a single package, and many contain:

• electronic health records (EHRs)

DEFINITION OF TERMS

Typically, the term "medical technology" conjures images of large, industrial machines or complex computer programs used to organize and track patient data. While this article focuses on management and clinical technologies, the term healthcare technology goes beyond the hardware and software utilized by providers, and includes intangible concepts such as healthcare processes.

Process technologies can affect the manner and structure by which healthcare is delivered and measured on both a clinical and management level, including treatment protocols, care mapping, and case management. For example, a three-year study of a pediatric intensive care unit found that more rigorous hand hygiene, oral care, and central-line catheter care protocols reduced hospital-acquired infections (HAIs) and associated healthcare costs, as patients spent, on average, 2.3 fewer days in the hospital.<sup>6</sup>

Management protocols, on the other hand, aim to reduce the cost of healthcare without lowering the level of quality care delivered by establishing protocols that allow providers to appropriately identify those procedures in which the expected treatment benefits to the patient are outweighed by the costs of delivering such care,<sup>7</sup> including early prostate cancer detection testing, routine EKGs, or annual Pap smears.<sup>8</sup> In addition to the utilization of such management technologies by providers, payors may also influence providers in this regard. For example, in 2008, Medicare began withholding payments for the treatment of conditions arising from twenty-eight "never events," <sup>9</sup> defined by the National Quality Forum (NQF) as: serious medical errors, such as performing the wrong surgical procedure; product or device events, such as contaminated drugs or devices; and criminal events, such as abduction of a patient.<sup>10</sup>

6 "Strict Hand Hygiene and Other Practices Shortened Stats and Cut Costs and Mortality in a Pediatric Intensive Care Unit" By Bradford D. Harris, et al., Health Affairs, Vol. 30, No. 9 (September 2011), p. 1751.

8 "Let's (Not) Get Physicals" By Elisabeth Rosenthal, The New York Times, June 2, 2012.

9 "Strict Hand Hygiene and Other Practices Shortened Stats and Cut Costs and Mortality in a Pediatric Intensive Care Unit" By Bradford D. Harris, et al., Health Affairs, Vol. 30, No. 9 (September 2011), p. 1751; "State Medical Director Letter" By Herb B. Kuhn, Centers for Medicare & Medicaid Services, To State Medical Director, July 31, 2008, http://downloads.cms. gov/cmsgov/archived-downloads/SMDL/downloads/SMD073108.pdf (Accessed 10/07/12).

10 "Never Event Fact Sheet" By The Leapfrog Group, March 2008, http://www.leapfroggroup.org/ media/file/Leapfrog-Never\_Events\_Fact\_Sheet.pdf (Accessed 2/8/11). • computerized physician order entry (CPOE)

• billing components

Although the 2012 Institute of Medicine (IOM) report entitled, *Best Care at Lower Cost: The Path to Continuously Learning Health Care in America*, did not specifically define the concept of technology as process, it nevertheless recommended several steps to facilitate the development of relationships between technology and providers if the U.S. healthcare delivery system is to learn from its past errors, asserting that:

"...[t]o help achieve a learning healthcare system, digital technology developers need to play the following roles:

- Ensure that electronic health record systems and other digital technologies capture and deliver the core data elements needed to support knowledge generation.
- Partner with patients, the delivery system, insurers, researchers, innovators, regulators, and other stakeholders.
- Collaborate in the development of core data sets for different diseases and conditions to support clinical care, improvement, and research.
- Develop tools that assist individuals in managing their health and health care and that provide opportunities for building communities to support patient efforts.

<sup>7 &</sup>quot;Is Health Spending Excessive? If So, What Can We Do About It?" By Henry J. Aaron and Paul B. Ginsberg, Health Affairs, Vol. 28, No. 5 (September/October 2009), p. 1273.

• Consider interoperability and integration in clinical workflows in designing digital health systems."<sup>11</sup>

Further, the 2012 IOM report emphasized the importance of maintaining a "digital infrastructure" as the backbone for U.S. healthcare delivery, and recommended that the U.S. healthcare system: "Improve the capacity to capture clinical, care delivery process and financial data for better care, system improvement, and the generation of new knowledge. Data generated in the course of care delivery should be digitally collected, compiled, and protected as a reliable and accessible resource for care management, *process improvement*, public health, and the generation of new knowledge."<sup>12</sup> [Emphasis added.]

The digital infrastructure utilized by some U.S. healthcare entities may include EHRs, CPOE, and billing components. An EHR is an electronic version of a patient's medical history, maintained by the provider over time, and may include all of the key administrative clinical data relevant to that person's care under a particular provider.<sup>13</sup> EHRs usually include: demographics, progress notes, problems, medications, vital signs, past medical history, immunizations, laboratory data, and radiology reports.<sup>14</sup> This automated access to information has the potential to streamline the clinician's workflow, support other care-related activities, and reduce the incidence of medical error.

CPOE allows physicians and providers to electronically order laboratory, pharmacy, and radiology services, with the objective of minimizing error by eliminating the difficulties and ambiguity associated with handwritten orders.<sup>15</sup> CPOE can help reduce errors related to poor handwriting or transcription of medication orders; for instance, one study published in the Journal of the American Medical Informatics Association found that CPOE lowered the chance of an error occurring on that order by forty-eight percent.<sup>16</sup> Implementation of CPOE has been highly encouraged by CMS, as it is a major requirement for the achievement of meaningful use under the Health Information Technology for Economic Clinical Health (HITECH) Act, which requires Medicare providers to obtain "meaningful use" of EHR by the end of 2014 to avoid reimbursement penalties and provides both financial incentives and programmatic support to overcome obstacles that have previously kept providers from adopting some form of an electronic record system.<sup>17</sup>

Billing components are also typically used in conjunction with EHRs in managing healthcare entities, and generally allow for automated billing processes.<sup>18</sup> These components allow staff to enter, among other items, prices for services, insurance discounts, and additional charges.<sup>19</sup> Each charge is typically matched with a service or treatment performed on a patient, and then the charge is entered using certain codes, which codes have associated fees.

#### TECHNOLOGY

In addition to the development and utilization of healthcare management and process technologies and management protocols, there have also been advances in the development of clinical technology, which have led to numerous treatment discoveries and innovations. Clinical technology encompasses any method or device used in patient treatment procedures, e.g., pharmaceuticals, surgical devices, and minimally invasive techniques. Notably, in an effective and efficiently operated healthcare enterprise, management and clinical technologies complement each other and may, in many cases, overlap.

One significant effect of clinical technology advancements is the transition to more procedures being offered in outpatient

11 "Best Care at Lower Cost: The Path to Continuously Learning Health Care in America" By Mark Smith et al., Institute of Medicine, Washington, DC: The National Academics Press, 2012, p. 10–21 (prepublication copy-uncorrected page proofs).

13 "Electronic Health Records" Centers for Medicare and Medicaid Services, March 26, 2012, https://www.cms.gov/Medicare/E-Health/ EHealthRecords/index.html?redirect=/ehealthrecords (Accessed 1/25/17). 16 Ibid.

<sup>12</sup> Ibid.

<sup>14</sup> Ibid.

<sup>15 &</sup>quot;Computerized Physician Order Entry (CPOE)" By Alex DelVecchio and Brian Eastwood, HealthIT, November 2014, http://searchhealthit. techtarget.com/definition/computerized-physician-order-entry-CPOE (Accessed 1/25/17).

<sup>17 &</sup>quot;Computerized Physician Order Entry (CPOE)" By Alex DelVecchio and Brian Eastwood, HealthIT, November 2014, http://searchhealthit. techtarget.com/definition/computerized-physician-order-entry-CPOE (Accessed 1/25/17); "American Reinvestment and Recovery Act, Sec. 13101," Pub. L. 111-5, 123 Stat 115 (February 7, 2009), p. 231; Paul Tang, "Meaningful Use of Health Information Technology: From Public Policy to Changing Care," Future Scan 2011: Healthcare Trends and Implications 2011–2016, 2011, p. 33.

<sup>18 &</sup>quot;What are the Important Components of Medical Practice Management Software?" Top Master's in Healthcare Administration, 2017, http://www. topmastersinhealthcare.com/faq/what-are-the-important-componentsof-medical-practice-management-software/ (Accessed 1/25/17).

<sup>19</sup> Ibid.

settings.<sup>20</sup> Specifically, advancements have resulted in less invasive procedures, shorter recovery times, and lower probability of complications; all of which have allowed for procedures that have traditionally been performed in an inpatient setting to be offered on an outpatient basis. Outpatient growth is projected to grow by seventeen percent from 2013-2023, while inpatient projections remain much more modest and even shrink in some service lines.<sup>21</sup> The increased costs associated with inpatient care, as well as the overall increase in healthcare demand, have contributed to increased outpatient service utilization from 366 million visits in 1993 to over 677 million in 2013,22 a growth pattern that will likely continue in response to persistent cost containment pressures<sup>23</sup> and the advancements in technology that have facilitated the shift from inpatient to outpatient.

As technology has advanced, so too has the way patient care is viewed, leading to technological developments related not only to the treatment setting (e.g., movement from inpatient to outpatient), but also how diseases are understood and treatments are managed by providers. Recent developments regarding genetics, gene therapy, and personalized medicine have largely been made possible by the science of genomics.

# THE GATEWAY: GENETICS, GENOMICS, AND GENOME TECHNOLOGY

The term personalized medicine has been used in several venues, such as customized pharmaceuticals and customized diagnoses. The landmark discoveries accompanying the advent of genome sequencing was the first step toward much of the technological advancement that served as the basis for a new genre of pharmaceutical and therapeutic medicine. In 2003, the Human Genome Project at the

National Institutes of Health completed the initial mapping of the human genome, a milestone that fueled interest in the field of genomics.<sup>24</sup> The technological advancements that followed served as the foundation for a new genre of pharmaceutical and therapeutic medicine. Biotechnology and biopharmaceuticals are influential drivers in today's market, accounting for the highest valued mergers and acquisitions in healthcare in 2016.<sup>25</sup>

24 "Human Genome Project: Fact Sheet" By National Institutes of Health, October 2010, http://report.nih.gov/NIHfactsheets/Pdfs/ HumanGenomeProject(NHGRI).pdf (Accessed 3/19/15), p. 1.

25 "US M&A News and Trends" BY FACTSET, Flashwire US Monthly, January 2017, https://www.factset.com/mergerstat\_em/monthly/US\_ Flashwire\_Monthly.pdf (Accessed 1/24/17), p. 6.

#### WHAT IS GENOMICS?

Genomics is the evaluation of the hereditary information provided by an organism's DNA and the application of research findings to the fields of genetic engineering and enhancement, cloning, stem cell research, and eugenics.<sup>26</sup> The National Center for Human Genome Research Institute (NCHGRI) is comprised of more than fifty researchers who are dedicated to specific facets of genetic and genomic research and contribute accordingly to one of seven branches of the NCHGRI: 1) Cancer Genetics; 2) Genetic Disease Research; 3) Genetics and Molecular Biology; 4) Genome Technology; 5) Inherited Disease Research; 6) Medical Genetics; and 7) Social and Behavioral Research.<sup>27</sup>

Several areas of genomics, cell-based therapies, and molecular targeting therapies also seem to hold promise for future advancements in the treatment of cardiac disease.<sup>28</sup> For example, pharmacogenomics applies the "genetic variability in patients' responsiveness to a drug in order to inform clinical decisions about dosing and

<sup>20 &</sup>quot;ASCs: A Positive Trend in Health Care" ASCA's Campaign for Advancing Surgical Care, http://www.ascassociation. org/advancingsurgicalcare/aboutascs/industryoverview/ apositivetrendinhealthcare (Accessed 1/25/17).

<sup>21 &</sup>quot;The New Normal? Shift to Outpatient Care, Payer Pressure Hit Hospitals" By Beth Kutscher and Melanie Evans, Modern Healthcare, August 10, 2013, http://www.modernhealthcare.com/article/20130810/ MAGAZINE/308109974 (Accessed 1/25/17).

<sup>22 &</sup>quot;Table 3.4: Outpatient Utilization in Community Hospitals, 1993-2013" in "Trendwatch Chartbook 2015: Trends Affecting Hospitals and Health Systems" American Hospital Association and Avalere, 2015, retrieved from http://www.aha.org/research/reports/tw/chartbook/ch3.shtml (Accessed 3/26/15), p. A-29.

<sup>23 &</sup>quot;Payments to Hospitals for Inpatient Hospital Services" 42 U.S.C. § 1395(ww)(b)(2) (2010).

<sup>26 &</sup>quot;Talking Glossary of Genetic Terms: Genomics" By National Human Genome Research Institute, http://www.genome.gov/Glossary/index. cfm?id=532 (Accessed 3/19/15); "Biomedical Research Issues in Genetics" By the National Human Genome Research Institute, January 6, 2009, http://www.genome.gov/10001740 (Accessed 6/29/09).

<sup>27 &</sup>quot;Overview of the Division of Intramural Research" By National Human Genome Research Institute, August 27, 2009, http://www.genome. gov/10001634 (Accessed 11/25/09).

<sup>28 &</sup>lt;sup>a</sup>A Tale of Coronary Artery Disease and Myocardial Infarction" By Elizabeth G. Nabel and Eugene Braunwald, The New England Journal of Medicine, Vol. 366, No. 1 (January 5, 2012), p. 61.

selection."<sup>29</sup> A "broader vision for personalized medicine extends beyond the development of individual treatment [plans] to individualized [disease] prevention [and early intervention] strategies, e.g., Type 2 diabetes."<sup>30</sup>

29 Ibid.

30 "Personalized Medicine to Identify Genetic Risks for Type 2 Diabetes and Focus" By Allen M. Spiegel, and Meredith Hawkins, Health Affairs, Vol. 31, No. 1 (January 2012), p. 44; "Improving Health by Taking It Personally" By Ralph Snyderman, and Michaela A. Dinan, Journal of the American Medical Association, Vol. 303, No. 4 (January 27, 2010), p. 363.

One means of achieving the vision of personalized medicine may be by mobile medical applications (m-health apps), which may be downloaded on smartphones and computer tablets. It is hoped that these m-health apps, which have expanded rapidly in the marketplace, will allow healthcare providers to efficiently develop and distribute "best-practice" standards and treatment protocols to providers.<sup>31</sup> Additionally, m-health apps are beginning to be utilized by patients to monitor chronic conditions by reporting such information as blood pressure levels or sugar levels to their physicians.<sup>32</sup>

Genomic understanding has given pharmaceutical companies new therapeutic targets, as well as the ability to improve existing drugs.<sup>33</sup> It is possible that genetic composition may be at least partly responsible for some adverse drug reactions, and understanding that composition may allow pharmaceutical companies to design more compatible drugs or to identify those patients who should not be given particular therapies.<sup>34</sup> In recent years,

certain genes have been associated with an increased risk of developing particular diseases or conditions, and the identification of such genes may allow individuals to take preventative measures against such conditions, particularly various forms of cancer. However, other findings indicate that such unsubstantiated information may present more harm than good,<sup>35</sup> e.g., stress on the individual being diagnosed, or unnecessary medical procedures such as premature mastectomies.

As the market for personalized medicine expands, and additional research related to genetic diagnoses saturates consumer driven healthcare channels, several companies offering personalized genetic mapping, known as genotyping, have appeared, e.g., 23andme.com. These direct-to-consumer genetic testing companies sell genetic kits that take a small sample of cells, typically via a cheek swab, and generate a genetic profile for the customer, which may indicate any diseases to which the individual may be prone.<sup>36</sup> The FTC and CDC have warned that some of these at-home genetic testing kits lack scientific validity and caution against reviewing test results without a doctor's counsel.<sup>37</sup> Some states, such as California and New York, have intervened in the distribution of an individual's genetic profile and potential future diseases without physician direction, and have sent cease and desist letters to several companies.<sup>38</sup> Additionally, four states, i.e., California, Nevada, Nebraska, and Pennsylvania, have passed legislation prohibiting misleading advertisements for genetic tests.<sup>39</sup>

<sup>31 &</sup>quot;Chapter 1: Healthcare Reform: The Transformation of America's Hospitals: Economics Drives a New Business Model" in "Futurescan 2012: Healthcare Trends and Implications 2012-2017" By Kenneth Kaufman and Mark E. Grubs, VHA Inc., Irving, Texas (2012), p. 8; "Beyond UX: Best Practices for Medical App Development" By Mithun Sridharan, Innovation Insights, August 4, 2014, http://insights.wired. com/profiles/blogs/beyond-ux-best-practices-for-medical-appdevelopment#axzz3UleZE3Fn (Accessed 3/18/15).

<sup>32 &</sup>quot;5 Critical Technologies Health Systems Should Require" By Michelle McNickle, Healthcare IT News, July 30, 2012, http://www. healthcareitnews.com/news/5-critical-technologies-health-systemsshould-require (Accessed 9/21/12).

<sup>33 &</sup>quot;Technology and the Boundaries of the Hospital: Three Emerging Technologies" By Jeff Goldsmith, Health Affairs, Vol. 23, No. 6 (2004), p. 150.

<sup>34</sup> Ibid.

<sup>35 &</sup>quot;Letting the Genome Out of the Bottle: Will We Get Our Wish?" By David J. Hunter, et al., New England Journal of Medicine, Vol. 358, No. 2 (January 10, 2008), p. 106-107.

<sup>36 &</sup>quot;How does 23andMe genotype my DNA?" 23andme Customer Care, https://customercare.23andme.com/entries/21263328 (Accessed 9/26/12).

<sup>37 &</sup>quot;Direct-to-Consumer Genetic Tests" Federal Trade Commission: Consumer Information, January 2014, http://www.consumer.ftc.gov/ articles/0166-direct-consumer-genetic-tests (Accessed 3/18/15).

<sup>38 &</sup>quot;Federal and State Responses to Dangers of At-Home Genetic Testing" By Sara Hoverter and Danielle Perlman from Georgetown School of Law, Memorandum to Steve Sakamoto-Wengel, Maryland Office of the Attorney General Paul Ballard, Maryland Office of the Attorney General, February 4, 2011.

<sup>39 &</sup>quot;Federal and State Responses to Dangers of At-Home Genetic Testing" By Sara Hoverter and Danielle Perlman from Georgetown School of Law, Memorandum to Steve Sakamoto-Wengel, Maryland Office of the Attorney General Paul Ballard, Maryland Office of the Attorney General, February 4, 2011; West's Annotated California Business & Professional Code § 17508(a); Nevada Revised Statutes Annotated § 598.0925(1)(a); Nebraska Revised Statute § 87-302(a)(14); 18 Pennsylvania C.S.A. § 4107 (a)(10).

The realities of personalized medicine produce a multitude of regulatory and reimbursement issues. Although the Health Insurance Portability and Accountability Act of 1996 (HIPAA) was designed to protect individual health information, the advancement of genetic testing has surpassed the regulatory standards as set forth under HIPAA. Subsequent legislation has attempted to protect an individual's genetic information while allowing for the furtherance of personalized medicine.<sup>40</sup> Similar to HIPAA, The Genetic Information Nondiscrimination Act of 2008 (GINA), enacted on May 21, 2008, was promulgated to protect against the misuse of their personal health information.<sup>41</sup> GINA prohibits the use of genetic information for discriminatory purposes by employers and health insurance companies, and amends both the Employee Retirement Income Security Act and the Internal Revenue Code.42

#### STEM CELL RESEARCH

Within any living organism, each cell is specialized to a specific biological system. Stem cells are "unspecialized cells capable of renewing themselves through cell division, sometimes after long periods of inactivity", and adapting their function to accommodate a certain type of tissue or organ under the proper conditions.<sup>43</sup> The unique regenerative capacity of stem cells has the potential to change the way health problems, e.g., diabetes and heart disease, are treated. As such, efforts to advance reparative medicine (therapies that heal the body's natural tissue) by developing efficacious cell therapies are at the forefront of medical research.<sup>44</sup> In June 2011, the first completely synthetic human organ (a trachea) was successfully grown from human stem cells and transplanted.<sup>45</sup> However, synthetic organs only function at a fraction of their natural

42 Ibid.

counterparts, e.g., a synthetic lung grown from stem cells functioned at approximately five percent of the effective rate of a natural lung when tested in rats at Yale University.<sup>46</sup>

On January 23, 2009, the first human embryonic stem cell (hESC)-based therapy was approved for clinical trial when Geron Corporation announced the clearance of their Investigational New Drug (IND) application for the clinical trial of GRNOPC1, which manipulates the growthstimulating properties of nerve cells to aid in rehabilitating acute spinal cord injuries.<sup>47</sup> Stem cell research is also being used to investigate the causes of birth defects, enhance drug development by providing molecular insight, and expedite the drug approval process through the facilitation of preliminary drug testing.<sup>48</sup> Additionally, understanding the differences between embryonic and nonembryonic stem cell proliferation may be the key to understanding-and treating—cancer.49 Recent trends and advances in stem cell technology have proved promising, with approximately fortyeight adult stem cell clinical studies completed, eight actively underway, another ten currently recruiting volunteers, and four approved for conducting a clinical study but not yet recruiting volunteers as of January 2017.<sup>50</sup>

#### DIAGNOSTIC MEDICINE AND TECHNOLOGY

Diagnostic medicine is utilized in both acute and chronic care for the purposes of prevention, screening, monitoring of health conditions, and disease detection and management. This staple of healthcare claims that, "A penny of prevention is worth a pound of cure...The pharmaceutical industry has long been focused on treatment of disease but it will be far more cost-effective to prevent disease than cure it, and this will be

<sup>40 &</sup>quot;Personalized Medicine-Part 2: Ethical, Legal, and Regulatory Issues" By F. Randy Vogenberg, et al., Journal of Pharmacy and Therapeutics, Vol. 35, No. 11 (November 2010), p. 629.

<sup>41 &</sup>quot;Genetic Information Nondiscrimination Act" Pub. L. No. 110-233, 112 Stat. 881 (May 21, 2008).

<sup>43 &</sup>quot;Stem Cell Information: Stem Cell Basics" National Institutes of Health, U.S. Department of Health & Human Services, April 28, 2009, http:// stemcells.nih.gov/staticresources/info/basics/SCprimer2009.pdf (Accessed 3/19/15), p. 1–2.

<sup>44 &</sup>quot;Stem Cell Information: Stem Cell Basics" By the National Institutes of Health, U.S. Department of Health & Human Services, April 28, 2009, http://stemcells.nih.gov/staticresources/info/basics/SCprimer2009.pdf (Accessed 3/19/15), p. 2.

<sup>45 &</sup>quot;World's First Synthetic Organ Transplant" Discovery News, July 8, 2011, http://news.discovery.com/human/first-artificial-organtransplant-110708.html (Accessed 3/19/15).

 <sup>46 &</sup>quot;Scientist Are Solving Our Donor Crisis with Lab-Grown Organs" By Jennifer Welsh, Business Insider, August 28, 2012, http://www. businessinsider.com/lab-grown-organs-2012-8?op=1 (Accessed 3/19/15), p. 2.

<sup>47 &</sup>quot;Geron Receives FDA Clearance to Begin World's First Human Clinical Trial of Embryonic Stem Cell-Based Therapy" Geron, Press Release, January 23, 2009, http://ir.geron.com/phoenix.zhtml?c=67323&p=irolnewsArticle&ID=1636192 (Accessed 4/1/15), p. 1.

<sup>48 &</sup>quot;Stem Cell Basics" National Institutes of Health, U.S. Department of Health & Human Services, April 28, 2009, http://stemcells.nih.gov/ staticresources/info/basics/SCprimer2009.pdf (Accessed 3/19/15), p. 2, 14.

<sup>49 &</sup>quot;Stem Cell Basics" National Institutes of Health, U.S. Department of Health & Human Services, April 28, 2009, http://stemcells.nih.gov/ staticresources/info/basics/SCprimer2009.pdf (Accessed 3/19/15), p. 14.

<sup>50 &</sup>quot;List of Studies for Adult Stem Cell" National Institutes of Health, January 25, 2017 https://clinicaltrials.gov/ct2/results?term=%22adult+stem+c ell%22 (Accessed 1/25/17); Author looked up current status of clinical trials at the U.S. National Institutes of Health website, ClinicalTrial.gov, by searching "Adult Stem Cell".

a driver of innovation."<sup>51</sup> Recent diagnostic advances support an attitude of prevention that, though inherently accepted, has not been practiced sufficiently in healthcare to date.

In addition to diagnostic medicine, diagnostic technology is the backbone of much technological advancement, including, but not limited to: 1) minimally invasive surgery; 2) preventative procedures; 3) telemedicine; and 4) therapeutics. Diagnostics may also play an important role in the advancement of current quality metrics reporting and associated value-based purchasing initiatives. While these characteristics provide clinical benefits to providers, patients, and payors, the economic value metrics of diagnostic imaging is unclear, as the technology is also associated with patterns of overuse and increased healthcare costs.<sup>52</sup>

#### THERAPEUTIC TECHNOLOGY

The range of prescripted use for therapeutic technologies has grown substantially over the last century, and innovation in the arena continues to lead to groundbreaking medical discoveries for therapeutic treatment in the fields of molecular pharmacology, radiation therapy, robotics and surgical technology, e.g., minimally invasive surgery, transplant technologies, home infusion therapy, and pain management.

#### HOME HEALTH TECHNOLOGY

In 2013, approximately 4.9 million patients (roughly 1.5 percent of the U.S. population) were discharged from home health agencies.<sup>53</sup> Additionally, the growing segment of older Americans will invariably contribute to the increased use of home infusion therapies. Although the U.S. Census Bureau predicted in 2014 that, between 2015 and 2035, the U.S. population would increase by fifteen percent,<sup>54</sup> the number of Americans age sixty-five and older is anticipated

51 "Biomarket Trends: Pharmaceutical Industry Undergoing Transformation, Companies Must Start Preparing Now for Changes to Come in 2020" By Steve Arlington and Anthony Farino, Genetic Engineering and Biotechnology News, Vol. 27, No. 15 (September 1, 2007), http://www.genengnews.com/articles/chitem.aspx?aid=2197 (Accessed 2/2/10). to reach 88.5 million in 2050, with the "oldest old," those age eighty-five and older, expected to triple from "6.3 million in 2015 to 17.9 million in 2050, accounting for 4.5% of the total population."<sup>55</sup> Approximately sixty-nine percent of those receiving home care services are older than age sixty-five.<sup>56</sup> In addition, the aging baby boomer population will continue to inflate the number of candidates for home healthcare as they become eligible for Medicare, with the first cohort of that population reaching eligibility in 2011.<sup>57</sup>

#### CONCLUSION

The scope of medical technology has changed dramatically since the origins of medical practice in ancient Greece. Technological advancement began slowly at first, and then more rapidly upon the commencement of the Industrial Revolution. Following World War II (WWII), the U.S. healthcare delivery system saw the rapid advent of new medical technologies, through the "arms race" in which providers engaged to develop and adopt the latest technology before any of its competitors, resulting in higher levels of health and an increased life expectancy, accompanied by a significant increase in medical costs.<sup>58</sup> Associated with these rising costs has been a decline in infant and child mortality and increased longevity, which, in turn, led to an increase in the overall population and the number of individuals needing care and treatment.<sup>59</sup> Postwar discoveries of new medical therapies, such as sulfa drugs and penicillin, quickly reduced infectious disease rates, with these rates decreasing to current levels within two decades.<sup>60</sup> Similarly, longer lifespans resulted in a more aged population, and shifted the focus of medicine toward expensive treatments

60 "The Determinants of Mortality" By David Cutler, et al., Journal of Economic Perspectives, Vol. 20, No. 3 (2006), p. 103.

<sup>52 &</sup>quot;Expanding Use of Imaging Technology and the Challenge of Measuring Value" By Laurence C. Baker, et al., Health Affairs, Vol. 27, No. 6, November/December 2008, p. 1467–68, 1471–72.

<sup>53 &</sup>quot;Long-Term Care Providers and Services Users in the United States: Data from the National Study of Long-Term Care Providers, 2013-2014" Vital and Health Statistics, Centers for Disease Control and Prevention, Series 3, No. 38 (February 2016) https://www.cdc.gov/nchs/data/series/sr\_03/ sr03\_038.pdf.

<sup>54 &</sup>quot;Table 1: Projections of the Population and Components of Change for the United States: 2015 to 2060" U.S. Census Bureau, 2014.

<sup>55 &</sup>quot;The Next Four Decades – The Older Population in the United States: 2010 to 2050" By Grayson K. Vincent and Victoria A. Velkoff, U.S. Census Bureau, May 2010, https://www.census.gov/prod/2010pubs/p25-1138.pdf (Accessed 1/25/17).

<sup>56 &</sup>quot;Basic Statistics About Home Care, Updated 2010" National Association for Home Care & Hospice, Washington, DC: National Association for Home Care & Hospice, 2010, http://www.nahc.org/assets/1/7/10HC\_ Stats.pdf (Accessed 3/23/15), p. 6.

<sup>57 &</sup>quot;The Nation's Health Care Conundrum: Where Do We Go from Here" By David Kroitz, The Concord Coalition, May 15, 2009, http://www. concordcoalition.org/issue-briefs/2009/0515/nations-health-careconundrum-where-do-we-go-here (Accessed 12/10/09).

<sup>58</sup> Healthcare Valuation: The Financial Appraisal of Enterprises, Assets, and Services" By Robert James Cimasi, MHA, ASA, FRICS, MCBA, AVA, CM&AA, Hoboken, NJ: John Wiley & Sons (2014), p. 536.

<sup>59 &</sup>quot;Epidemiology in the United States After World War II: The Evolution of Technique" By Mervyn Susser, Epidemiology Reviews, Vol. 7 (1985), p. 149–150.

for degenerative age-related diseases, e.g., heart disease, stroke, cancer, and senile dementia, treatment of which increased overall costs due to the long-term nature of the care.<sup>61</sup>

In contrast to other industries in which technological advancements are generally associated with greater output and equal or lesser input, the wave of medical technological advances following WWII correlated with a steady increase in medical costs. It has been estimated that more than fifty percent of the total rise in real medical care costs may be attributable to technological advances.<sup>62</sup> Since the 1970s, the perceived excessive rate of growth of healthcare spending— attributed in part to technological investments—has been acknowledged as a serious problem by the government, insurers, employers, and individuals.<sup>63</sup>

The establishment of many certificate of need (CON) laws restricting the construction and expansion of healthcare technology, facilities, and services was driven in part by this perceived excessive rate of growth of healthcare spending, as well as the "Roemer Effect." <sup>64</sup> In their 1959 study, Roemer and Shain argued that hospital beds would be intentionally filled by providers who induce ill-informed patients into hospital stays.<sup>65</sup> While the basis of the argument for this set of circumstances, i.e., "supply and demand," may have been valid during the "cost-plus reimbursement era" before the implementation of the prospective payment system (PPS) for hospitals in 1983, it is widely asserted that it has not been demonstrated to be the case today, in a value-based reimbursement environment characterized by the shifting of financial risk to providers.<sup>66</sup>

Over the course of human history, healthcare trends have been driven by advances in our medical capabilities, which are largely dependent on our technological progress. Current

- 61 "Epidemiology in the United States After World War II: The Evolution of Technique" By Mervyn Susser, Epidemiology Reviews, Vol. 7 (1985), p. 149–150.
- 62 "The Dynamics of Technological Change in Medicine" By A. Gelijns and N. Rosenberg, Health Affairs, Vol. 13, No. 3 (1994), p. 29; "Medical Care Costs: How Much Welfare Loss?" By Joseph P. Newhouse, Journal of Economic Perspectives, Vol. 6, No. 3 (1992).
- 63 "Unfinished Journey—a Century of Health Care Reform in the United States" By Jonathan Oberlander, New England Journal of Medicine, Vol. 367, No. 7 (August 16, 2012), p. 585.
- 64 "Excess Capacity: Markets, Regulation, and Values" By Carolyn W. Madden, Health Services Research, Vol. 33, No. 6 (February 1999), p. 1653.
  65 *Ibid.*

total spending on healthcare is 17.8% of GDP and grew at a rate of 5.8 percent in 2015 to an estimated \$3.2 trillion.<sup>67</sup> This growth is driven in part by the perpetual technological advancement, dynamic availability of the most accelerated technologies, fear of potential malpractice suits, and efforts to procure economic gain that support the necessary supply factors to perpetuate this invincible expansion. With the current market demand for both chronic and acute services undergoing continuous growth, available technologies, as well as future technological developments, will augment the healthcare practice with the clinical and administrative tools necessary to provide efficient, effective, and affordable healthcare services.  $\underline{VE}$ 



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<sup>66 &</sup>quot;The U.S. Healthcare Certificate of Need Sourcebook" By Robert James Cimasi, ASA, CBA, AVA, FCBI, CM&A, CMP, Washington, DC: Beard Books (2005), p. 2.

<sup>67 &</sup>quot;National Health Expenditures 2015 Highlights" Centers for Medicare & Medicaid Services, December 6, 2016, https://www.cms.gov/ research-statistics-data-and-systems/statistics-trends-and-reports/ nationalhealthexpenddata/nationalhealthaccountshistorical.html (Accessed 1/25/17).

# Coming in 2017

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