

## Medical Innovations Potentially Impacting Healthcare in 2015

In October 2014, the Cleveland Clinic convened its 12<sup>th</sup> Annual Medical Innovation Summit to unveil their “*Top 10 Innovations for 2015*.”<sup>1</sup> The top innovations were determined based on interviews with more than 110 Cleveland Clinic experts in all major medical specialties, asking each interviewee, “*What innovations are ‘game changers’ in your field?*” This vetting process yielded almost 150 emerging technologies, which were then pared down to a final list of ten innovations that may have an immediate impact on health in 2015.<sup>2</sup> In addition to the innovation summit hosted by Cleveland Clinic, the 2014 TedMed Conference also explored medical innovations, seeking to “*seed the innovations in health and medicine of today, making the breakthroughs of tomorrow possible*.”<sup>3</sup> In this forum, both well-known and undiscovered leaders, innovators, and explorers converged to discuss the possibility of a healthier future and the innovations that may advance that ideal.<sup>4</sup> This article will discuss some of the top innovations that were showcased at these two conferences, which innovations may impact the healthcare sector throughout 2015.

A notable innovation garnering attention from both the Medical Innovation Summit (where it ranked third) and TedMed is a new blood collection technology from a company called Theranos.<sup>5</sup> This technology requires only a small, nearly painless pin prick, producing just a drop of blood, and then runs more than 250 laboratory tests faster and cheaper than traditional methods.<sup>6</sup> It is also able to run multiple tests on one sample, giving healthcare providers the ability to order follow up tests without the need for another blood draw, and the results, on average, are received in less than four hours.<sup>7</sup> For patients fearful of needles and bloodwork, this new testing technology dramatically improves the phlebotomy experience, and may increase patient compliance rates for prescribed lab work.<sup>8</sup> In November 2014, Theranos released this blood-testing service to select Walgreens pharmacies, with plans to expand nationwide.<sup>9</sup> Theranos plans to charge less than 50% of the standard Medicare and Medicaid reimbursement rates for the tests,<sup>10</sup> and even lists the specific prices of each laboratory test on its website, with most charges listed at just a few dollars.<sup>11</sup>

The growing movement toward patient autonomy and transparency is influencing medical innovations outside of Theranos laboratories.<sup>12</sup> For example, *mobile health* (mHealth) technologies, which allow consumers to track their own vital signs, monitor chronic conditions, manage their weight, and care for loved ones, are increasing in popularity and usage.<sup>13</sup> One particular innovation is the STEMP™ Smart Temperature Patch, a thermometer that can provide continuous temperature readings via a patch resembling a Band-Aid.<sup>14</sup> The temperature measurements are then sent directly to the wearer’s smartphone for monitoring or to alert him or her of a rise in temperature. STEMP™ can also monitor multiple individuals, allowing family members to be alerted if anyone begins to experience a rise in temperature.<sup>15</sup>

Similarly, another company is offering a medical device kit “*designed to reduce cost, expand patient reach, and provide a method of immediate feedback for preventive care*,” through the @HomeVitals™ Medical Kit. This device may be prescribed by a physician so that the patient can record necessary vitals measurements from the comfort of their home, and upload this information to various *medical capture devices* and *wearables*, as well as EHR systems and secure health exchanges.<sup>16</sup> This technology could be particularly important for those patients living in rural areas or with limited mobility, enabling the physician to accurately monitor the patient’s health status without necessarily requiring a visit to the provider’s office.<sup>17</sup>

Other significant innovations for self-monitoring include those for diabetes and glucose monitoring. Gone are the days of logging glucose measurements with pen and paper; now, most patients utilize a number of applications or compatible devices which can automatically track their blood sugar levels. For example, iBGStar® is a glucose monitor that can be used separately or connected to a phone, where it can manage and track diabetes information.<sup>18</sup> The discreet device, which is about the size of a USB drive, can directly read glucose test strips and log the results on your phone.<sup>19</sup> This ensures that the patient has an accurate and reliable way of tracking their readings in a convenient location, with the ability to integrate their diabetes monitoring with other health monitoring systems, e.g., carbohydrate and calorie intake.<sup>20</sup>

Applications like The Macaw™ Mobile Manager for Diabetes and The WellDoc® DiabetesManager® integrate fitness and nutrition trackers, along with health coaching, to help diabetic patients more comprehensively manage their disease by not just focusing on their glucose levels, but their overall health as well.<sup>21</sup>

Drug innovations are some of the biggest leaders in innovations for 2015, with prominent advancements made in heart conditions, pulmonary fibrosis, and cancer treatments. Cleveland Clinic highlights some of these innovations, such as the PCSK9 Inhibitors, which present a novel method for reducing cholesterol.<sup>22</sup> This treatment is particularly useful for individuals who do not see sufficient improvement in their low-density lipoprotein cholesterol (LDL-C) from statins alone, or for those with a rare genetic mutation, hypercholesterolemia, which causes high LDL cholesterol levels.<sup>23</sup> Other drugs that hold promise are pirfenidone and nintedanib, which are used to treat Idiopathic Pulmonary Fibrosis (IPF), a serious disease with a typical life expectancy of only three to five years after diagnosis.<sup>24</sup> Pirfenidone has been shown to dramatically reduce the risk of mortality by 48%, while nintedanib was able to reduce lung function decline by the same percentage.<sup>25</sup> These improvements are dramatic for those afflicted by IDP, particularly since there is no cure for the disease which gradually decreases lung capacity due to scarring, leading to shortness of breath and eventual respiratory failure.<sup>26</sup>

New cancer technologies are also progressing in 2015, specifically in the form of antibody-drug conjugates and immune checkpoint inhibitors. Antibody-drug conjugates can specifically target certain proteins found within or around tumor cells, allowing these conjugates to bind to and destroy the harmful cells, while leaving healthy cells untouched.<sup>27</sup> This landmark innovation allows for precision killing of cancer cells with significantly fewer side effects.<sup>28</sup> This technology is becoming a more accepted approach to targeted cancer treatment, with more than two dozen new antibody-drug conjugates currently in clinical testing, and FDA-approved drugs already available for the treatment of Hodgkin's Lymphoma and HER2-positive breast cancer.<sup>29</sup> In addition to antibody-drug conjugates, immune checkpoint inhibitors, another new cancer technology, are being used individually or in combination with other cancer treatment mechanisms as a way of boosting the body's own defense mechanism against cancer.<sup>30</sup> The inhibitors work by removing an immune system "brake", which cancer cells utilize to hide from the body's immune system, keeping white blood cells from mobilizing against the cancer cells.<sup>31</sup> With the use of the immune checkpoint inhibitors, the T-cells are released and can mount an attack against the invading cancer cells, as well as remain in place ready to attack any recurring cancer cells well after treatment has been completed.<sup>32</sup> This is having a dramatic effect

on long-term cancer remissions, and increasing the level of tumor shrinkage in some patients.<sup>33</sup>

The Cleveland Clinic Innovation Summit's top two innovations for 2015 are: (1) a vaccination for dengue fever; and, (2) Mobile Stroke Treatment Units. The dengue vaccine, which has been 20 years in the making, helps protect vulnerable populations against four different serotypes of dengue fever that can cause high fevers, joint and muscle pain, and other symptoms, typically for a period of two weeks.<sup>34</sup> Those afflicted with dengue fever sometimes require hospitalization, and children can develop hemorrhagic fever as a severe, life-threatening complication.<sup>35</sup> With the development of a vaccine, those countries persistently plagued by the disease, e.g., the tropical communities in Southeast Asia, Africa, and Latin America, may be able to experience some relief as the number of afflicted individuals could drop 50% to 60% from the current levels of 50 to 100 million.<sup>36</sup>

The Cleveland Clinic awarded the top innovation for the year 2015 to the developers of the mobile stroke treatment unit. Strokes are the fourth leading cause of death in the U.S., typically causing permanent nerve and brain damage if not treated promptly.<sup>37</sup> The effectiveness of stroke treatment, specifically tissue-type plasminogen activator (t-PA), which can break up a blood clot in ischemic strokes, is time dependent, with best results seen when the drug is administered within an hour of arrival to the hospital.<sup>38</sup> Since time is such a critical factor, some hospitals are now using mobile stroke treatment ambulances to bring the diagnostic capabilities and treatment options to the patient faster. These units have a paramedic, EMT, critical care nurse, and a CT Technologist on board, with a neurologist available via telemedicine technology.<sup>39</sup> They utilize a mobile CT scanner to quickly scan images of the patient's brain while assessing symptoms.<sup>40</sup> The neurologist is immediately sent the scans, which can quickly yield a diagnosis, allow the neurologist to determine the best treatment option, and send the patient to the appropriate hospital for their condition. This combination of technology and providers allows some patients to be treated as soon as 11 minutes after arrival on scene, a dramatic improvement over current treatment standards, allowing most survivors to recover fully and suffer minimal side-effects from the stroke.<sup>41</sup>

Overall, 2015 looks to be the year that some of these medical innovations come to fruition. While many of the innovations described in this article still require regulatory approval before entering the market,<sup>42</sup> increasing utilization of "big data" in healthcare and declining costs in building new medical technologies will likely provide incentives to encourage continued innovation for medical devices.<sup>43</sup> These forward thinkers have the great potential to improve the health status of patients and contribute to the increased efficiency of healthcare delivery in the near future.

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**Robert James Cimasi**, MHA, ASA, FRICS, MCBA, CVA, CM&AA, serves as Chief Executive Officer of **HEALTH CAPITAL CONSULTANTS (HCC)**, a nationally recognized healthcare financial and economic consulting firm headquartered in St. Louis, MO, serving clients in 49 states since 1993. Mr. Cimasi has over thirty years of experience in serving clients, with a professional focus on the financial and economic aspects of healthcare service sector entities including: valuation consulting and capital formation services; healthcare industry transactions including joint ventures, mergers, acquisitions, and divestitures; litigation support & expert testimony; and, certificate-of-need and other regulatory and policy planning consulting.

Mr. Cimasi holds a Masters in Health Administration from the University of Maryland, as well as several professional designations: Accredited Senior Appraiser (ASA – American Society of Appraisers); Fellow Royal Institution of Chartered Surveyors (FRICS – Royal Institute of Chartered Surveyors); Master Certified Business Appraiser (MCBA – Institute of Business Appraisers); Accredited Valuation Analyst (AVA – National Association of Certified Valuators and Analysts); and, Certified Merger & Acquisition Advisor (CM&AA – Alliance of Merger & Acquisition Advisors). He has served as an expert witness on cases in numerous courts, and has provided testimony before federal and state legislative committees. He is a nationally known speaker on healthcare industry topics, the author of several books, the latest of which include: "[Accountable Care Organizations: Value Metrics and Capital Formation](#)" [2013 - Taylor & Francis, a division of CRC Press], "[The Adviser's Guide to Healthcare](#)" – Vols. I, II & III [2010 – AICPA], and "[The U.S. Healthcare Certificate of Need Sourcebook](#)" [2005 - Beard Books]. His most recent book, entitled "[Healthcare Valuation: The Financial Appraisal of Enterprises, Assets, and Services](#)" was published by John Wiley & Sons in 2014.

Mr. Cimasi is the author of numerous additional chapters in anthologies; books, and legal treatises; published articles in peer reviewed and industry trade journals; research papers and case studies; and, is often quoted by healthcare industry press. In 2006, Mr. Cimasi was honored with the prestigious "[Shannon Pratt Award in Business Valuation](#)" conferred by the Institute of Business Appraisers. Mr. Cimasi serves on the Editorial Board of the Business Appraisals Practice of the Institute of Business Appraisers, of which he is a member of the College of Fellows. In 2011, he was named a Fellow of the Royal Institution of Chartered Surveyors (RICS).



**Todd A. Zigrang**, MBA, MHA, ASA, FACHE, is the President of **HEALTH CAPITAL CONSULTANTS (HCC)**, where he focuses on the areas of valuation and financial analysis for hospitals, physician practices, and other healthcare enterprises. Mr. Zigrang has over 20 years of experience providing valuation, financial, transaction and strategic advisory services nationwide in over 1,000 transactions and joint ventures. Mr. Zigrang is also considered an expert in the field of healthcare compensation for physicians, executives and other professionals.

Mr. Zigrang is the author of the soon-to-be released "[Adviser's Guide to Healthcare – 2nd Edition](#)" (AICPA, 2014), numerous chapters in legal treatises and anthologies, and peer-reviewed and industry articles such as: [The Accountant's Business Manual](#) (AICPA); [Valuing Professional Practices and Licenses](#) (Aspen Publishers); [Valuation Strategies; Business Appraisal Practice](#); and, [NACVA QuickRead](#). Additionally, Mr. Zigrang has served as faculty before professional and trade associations such as the American Society of Appraisers (ASA); the National Association of Certified Valuators and Analysts (NACVA); the Physician Hospitals of America (PHA); the Institute of Business Appraisers (IBA); the Healthcare Financial Management Association (HFMA); and, the CPA Leadership Institute.

Mr. Zigrang holds a Master of Science in Health Administration (MHA) and a Master of Business Administration (MBA) from the University of Missouri at Columbia. He is a Fellow of the American College of Healthcare Executives (FACHE) and holds the Accredited Senior Appraiser (ASA) designation from the American Society of Appraisers, where he has served as President of the St. Louis Chapter, and is a current member of the ASA Healthcare Special Interest Group (HSIG) committee.



**Matthew J. Wagner**, MBA, CFA, is Senior Vice President of **HEALTH CAPITAL CONSULTANTS (HCC)**, where he focuses on the areas of valuation and financial analysis. Mr. Wagner has provided valuation services regarding various healthcare related enterprises, assets and services, including but not limited to, physician practices, diagnostic imaging service lines, ambulatory surgery centers, physician-owned insurance plans, equity purchase options, physician clinical compensation, and healthcare equipment leases.



**John R. Chwarzinski**, MSF, MAE, is Vice President of **HEALTH CAPITAL CONSULTANTS (HCC)**. Mr. Chwarzinski holds a Master's Degree in Economics from the University of Missouri – St. Louis, as well as, a Master's Degree in Finance from the John M. Olin School of Business at Washington University in St. Louis. Mr. Chwarzinski's areas of expertise include advanced statistical analysis, econometric modeling, and economic and financial analysis.



**Jessica L. Bailey**, Esq., is the Director of Research of **HEALTH CAPITAL CONSULTANTS (HCC)**, where she conducts project management and consulting services related to the impact of both federal and state regulations on healthcare exempt organization transactions and provides research services necessary to support certified opinions of value related to the Fair Market Value and Commercial Reasonableness of transactions related to healthcare enterprises, assets, and services. Ms. Bailey is a member of the Missouri and Illinois Bars and holds a J.D. and Health Law Certificate from Saint Louis University School of Law, where she served as Fall Managing Editor for the Journal of Health Law and Policy.