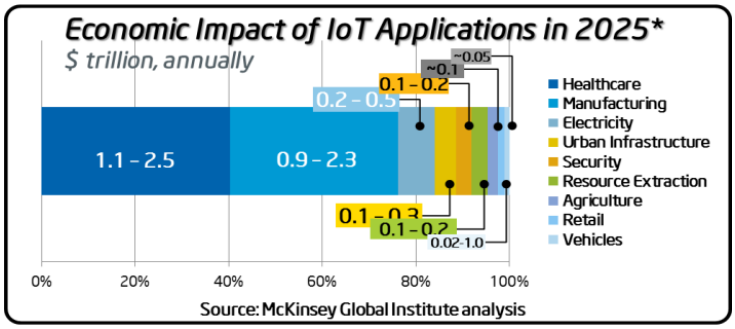
The Internet of Things and Healthcare
Policy Principles

Background

Within the next ten years, we envision that half of all care will be delivered virtually, with providers paid based on their teamwork and quality. We expect 24x7 diagnostics monitoring from phones, wearables, and even implantables with dramatic growth in sensing technologies from the hospital to the home. The integration of device data (inpatient, outpatient, and home- or mobile-based) into medical records will be a major push for the foreseeable future. In large part because of widespread wastefulness in service delivery and need for virtual care models, McKinsey forecasts that 40 percent of the global economic impact of the IoT revolution will occur in healthcare, more than any other sector.[1] Mobile healthcare devices will be used to track everything from fitness goals to surgical rehab faster, more convenient, and at reduced costs. Two distinct factors have the potential to make dramatic changes in U.S. healthcare: consumer engagement and payment for outcomes. These are crucial to meeting the needs brought by shifts in demographics.

Emerging 21st century care platforms require titanic shifts in thinking, business models, and infrastructure. The old "mainframe health" paradigm (*i.e.*, centralized, hospital-centric, expert-driven, reactive, costly) is giving way to a new "personal health" paradigm *(i.e.*, distributed, data-rich, preventive, home- and consumer-centric, and efficiency-driven). Demographic and economic drivers to a personalized healthcare shift include:



Population aging – a shift from younger to older population. Only 3 years from now, the human population will hit a crossover point for the first time in history. There will be more people over age 65 than under age 5. "No other force is likely to shape the future of national economic health, public finances, and policymaking than the irreversible rate at which the world's population is aging," according to Standard & Poors.[2] By 2030, China will have more people over age 60 than the total current U.S. population.[3]

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[1] *Big Data at Center of Disruptive Technologies*, McKinsey Global Institute (May 2013), http://www.mckinsey.com/insights/business_technology/disruptive_technologies.

[2] *Global Aging 2010: An Irreversible Truth*, Standard & Poors (Oct 2010), http://www.ebrd.com/downloads/research/news/Session_II_Mrsnik.pdf.

[3] *No Country for Old Age*, The New York Times (Feb 2013), http://www.nytimes.com/2013/02/19/opinion/no-country-for-old-age.html?_r=0.

Chronic diseases – a shift from predominantly infectious disease threats to predominantly chronic diseases, often exacerbated by lifestyle. Population aging increases the number of patients with heart disease, cancer, diabetes, lung and kidney disorders, Alzheimer's, and overweightness. These issues hinder productivity and are expensive and difficult to treat, requiring behavior changes. Today, 63 percent of the world's deaths are from non-communicable diseases (non-infectious; not transmitted by humans).[4] Low- to middle-income countries now carry roughly 80 percent of the burden of diseases like cardiovascular disease, diabetes, cancer, and chronic respiratory diseases.[5]

Global shortage of healthcare workers. The U.S. alone is projected to face a shortage of 124,000 physicians by the year 2025, yet this pales in comparison with the needs in Asia and Africa.[6]

On top of demographic and workforce problems, the healthcare sector is dramatically *in*efficient. Even if healthcare services were delivered efficiently, it would be extraordinarily difficult for a shortage of medical professionals to care for greater numbers of sicker people over the next several decades. Yet by all accounts, there are hundreds of billions of dollars in wasteful spending that need to be squeezed out of healthcare systems worldwide.

With the rise of the internet culture, there is a shift from passive to active patients. Patients and families are more engaged and digitally monitored by a growing array of apps and devices. The Intel Healthcare Innovation Barometer, an eight-nation, 12,000-adult survey last year,[7] revealed:

- 80 percent are optimistic about healthcare through innovation and technology.
- 70 percent are willing to see a doctor via video conference for non-urgent appointments.
- 70 percent are receptive to using toilet sensors, prescription bottle sensors, or swallowed health monitors.
- 50 percent believe the traditional hospital will be obsolete in the future, and would trust a test they personally administered as much or more than if performed by a doctor.

Health apps, social networks, and collaboration tools are growing rapidly. Enterprise and consumer health apps will continue to proliferate, shake out. Parks Associates indicates that 28

[4] *Death from NCDs,* World Health Org. (2014), http://www.who.int/gho/ncd/mortality_morbidity/ncd_total/en/.

[5] *The worldwide rise of chronic noncommunicable diseases: a slow-motion catastrophe,* World Health Org. (2014), http://www.who.int/dg/speeches/2011/ministerial_conf_ncd_20110428/en/.

[6] *Forecasting the global shortage of physicians: an economic-and needs-based approach*, Bulletin of the World Health Org. (July 2008), http://www.who.int/bulletin/volumes/86/7/07-046474.pdf.

[7] Intel Global Innovation Barometer: www.intel.com/newsroom/healthcare.

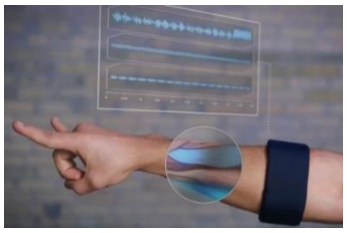
percent of U.S. broadband households have used some type of virtual care communication tool, and estimates the figure will grow to 65 percent by 2018.[8]

Three categories are emerging for IoT healthcare: Person to Person, Person to Computer, and Person as a Computer.

Person to Person: Dulcie Madden of Mimo developed an infant monitor that sends parents real-time information on their baby's breathing, skin temperature, sleeping position, and activity level. Mimo sends the baby's sleep data straight to her parents' smartphones.

Person to Computer: Vigilant, a Swiss company, has developed a smart insulin injection tracker to help diabetic patients manage their health. The injection tracker, called Bee+, is an electronic cap that fits most insulin pens on the market. It wirelessly transmits a diabetic's insulin injection data to a smartphone app.

Person as Computer: Myo (pictured right) uses the electrical activity in your muscles to wirelessly control your computer, phone, and other favorite digital technologies. With a wave of your hand, Myo will transform how you interact with your digital world. The technology is by Thalmiclabs, an Intel Capital investment.



Policy Principles

The potential for IoT and consumer engagement to dramatically improve health status/outcomes is limited by policies defined by face to face transactions. The shift is beginning and we urge Congress and the Administration to embrace new healthcare models by tackling difficult policy decisions.

Require Data Standards for Connectivity and Interoperability

- IoT in healthcare has the potential to aggregate data from patient records, wearable sensors, labs, diet, the environment, and social networking in real time, but only if the data can be analyzed. This takes standardized data formats. Policymakers should strengthen current requirements for data exchange among EHR's and the emerging IoT devices/solutions.

Regulate Smartly/Don't De-Innovate

- The regulation of software as a medical device has created confusion and missteps for health IT entrepreneurs. Today, Congress, regulators, and industry are collaborating to find the best regulatory framework through initiatives like the Food and Drug Administration

[8] *More than one-fourth of U.S. broadband households have used some type of online healthcare communications,* Parks Associates (Feb 2014), https://www.parksassociates.com/blog/article/feb2014-digital-health-webinar.

Safety Innovation Act (FDASIA) to better define what attributes of technology are subject to FDA device regulation.

- Regulatory pathways should be refined to reflect health technologies that are not medical devices. This will require alternative frameworks to ensure functionality and safety.

Re-Think Reimbursement

- IoT provides a new platform for capturing daily biometric data that shows trends and changes in health status in real time. However, this rich and actionable data is not being used today because our health systems are unprepared to incorporate the data into the fee for service payments, or shared savings models. Even the Accountable Care Organizations which have incentives to offer innovative services, are restricted by outdated Medicare regulations which dictate that payment for virtual services is only for patients living in rural areas (20 percent of U.S.), and will not pay for services at home and certainly not "on the go."

- Healthcare IoT solutions poised to change access and outcomes for chronically ill patients are now delayed not by technology, but by the lack of payment where virtual care is substituted and enhanced over face to face visits.

Virtual Care Improves Quality & Reduces Costs

With funding from a federal Beacon Community grant, St. Vincent Health worked with Intel-GE Care Innovations™ to test a remote care management program designed to reduce readmissions. Findings of the study, which concluded in 2012, ***show a 64% reduction in hospital readmissions*** compared to the study control group. Through daily telemonitoring of patients' biometrics (blood pressure, body weight, and oxygen saturation) and periodic videoconferencing, patients and their nurses were able to recognize any "red flags" and help address health problems before they became serious enough to require re-hospitalization.

Capture Patient Generated Health Data (PGHD) as a Vital Part of the Patient Record

- The $27B investment made by the U.S. Government in electronic medical records has spurred unparalleled adoption rates – 78 percent of physicians and 66 percent of our nation's qualifying hospitals have been certified. Yet, the real time data from sensors, tablets, smartphones, and peripherals are not captured in the EHR. Physicians can now diagnose a patient's medical condition from daily feeds provided by IoT devices noting changes in environment, diet, exercise, and medications, giving more accurate and longitudinal data rather than through readings from occasional office visits. HHS should address the issues of liability and data overload associated with PGHD and then recommend best practices for all future EHR regulations, to include PGHD.

Privacy and Security Required for IoT solutions

- According to the Office of Civil Rights in HHS, 199 PHI breaches were reported in 2013 affecting 7 million patient records. The need for security today in HIPAA covered entities is pervasive and as health information transfers between consumer and enterprise devices, message-level data encryption, API management, and data tokenization will become essential. HHS should continue to work with the healthcare industry to achieve agreement on a universally accepted health IT security standard or principals that can be enforceable and agree on criteria that deems organizations "HIPAA Security Rule Compliant."