Digital transformation is a term used to describe the holistic effect created by the application of digital technologies and how that application fundamentally transforms a particular domain. Digital transformation has arrived in the healthcare industry, with examples including system integration of patient data systems and cybersecurity measures for networked medical devices.

With the manufacturing of microscopic sensors becoming less expensive and cloud computing enabling organizations to access computing resources, Internet of Things (IoT) technologies are primed to disrupt healthcare. Digital device proliferation will only increase as manufacturer trends in telemedicine, wearables, biometric sensors, clinical efficiency, and interoperability escalate. One report projected that the “Internet of Medical Things” will grow from $60 billion to $136 billion by 2021, with spending across all industries on digital transformation projected to increase to $2.1 trillion through 2021.

Healthcare technology management (HTM) professionals operate as technical specialists for healthcare facilities, providing technical expertise to clinical staff and overseeing medical equipment throughout its life cycle. They also act as integrators of health technology, with the ability to leverage those technologies to provide better, safer patient care.

Two of the major concerns facing HTM professionals are compliance and cost. Improved efficiency is required for HTM departments to operate. The IoT lends itself well to field service work in addressing both of these issues.

In a traditional field service workflow, an end user makes a service request, the technician arrives to diagnose the problem, and, at a later time, the technician addresses the problem. With an IoT approach, the device experiencing the issue would autonomously contact the technician, providing contextual information. Then, the technician would be able to arrive with the required knowledge and resources to address the problem immediately. This connectivity would allow for real-time information for inventory management, reduced inspections, and a change to pre-emptive support.

As reimbursement models begin to transition from volume- to value-based programs that target the triple aim of improved care, improved outcomes, and lower costs, digital services can help in realizing the need for new revenue streams and cost-efficient operations. The success of a healthcare organization in the digital economy will depend entirely upon its adoption strategy of digital technologies.

Digital Health and the FDA
Evidence of the recognition being given to digital transformation can be found in the activities of regulatory bodies. The Food and Drug Administration (FDA) Center for Devices and Radiological Health (CDRH) has developed a Digital Health Program to foster collaboration and help develop and implement regulatory strategies for digital health technologies. In its Digital Health Innovation Action Plan, the FDA CDRH outlines the program’s approach to digital health products through the issuance of new guidance for implementation; reimagining product oversight through a recognition of the continuous, iterative innovation cycle of digital products; and describing the agency’s in-house efforts to increase its expertise.

The FDA also is building the National Evaluation System for health Technology (NEST) as a way to generate evidence for medical device evaluation and regulatory decision making. According to the agency, “NEST will generate evidence across the total product life cycle of medical devices by strategically and systematically leveraging real-world evidence and applying advanced analytics to data tailored to the unique data
needs and innovation cycles of medical devices.”

How are these technologies being applied to healthcare? The FDA has several criteria for digital health, including mobile health and the wireless technologies (e.g., Wi-Fi, Bluetooth, near-field communication) that enable it. Health information technology, wearables, telehealth and telemedicine, and personalized medicine are other examples. The agency also lists several other applications of digital health:

- Software as a medical device
- Advanced analytics and artificial intelligence, including machine learning, neural networks, and natural language processing
- The cloud for Internet-based computing and data storage resources
- Cybersecurity and interoperability, where devices can securely exchange and use information through an electronic interface with another device or system
- Medical device data systems, which are centralized systems for collecting medical device data (e.g., the electronic health record)

Digital health also includes novel applications of technology, such as the use of virtual reality and gaming applications in clinical settings, as well as medical body area networks, which include wearable and implanted wireless devices. In an interview with Vlastimil Cerny, chief information officer at the General University Hospital in Prague, Czech Republic, he discusses how the facility has used digital health in migrating data to a cloud-based system, machine-learning algorithms used in developing three-dimensional modeling of tumors, and the business intelligence tools used to access and analyze the hospital’s 21 petabytes of data. In an episode of the AAMI Podcast, Carolyn McGregor, the Canada Research Chair in Health Informatics at the University of Ontario Institute of Technology, discusses a big data application where the heart beats of premature babies (at 7,000 bph) are monitored for variability as an indicator of wellness. Although this continuous monitoring raises ethical concerns around privacy...
and security, having such detailed data may enable clinicians to pinpoint health risks that were missed previously.

**Understanding Digital Health**

To understand digital health, one must look at the different technologies that make something digital. Big data, analytics, cloud computing, mobile technologies, and more fall under the overarching concept of Industry 4.0. Industry 4.0 is considered the next industrial revolution, defined by cyberphysical systems such as the IoT or, in the case of healthcare, the Internet of Medical Things. The main attributes of Industry 4.0 can be summarized as follows:

1. Interoperability, or the ability for systems, machines, devices, and sensors to communicate via the Internet
2. Information transparency, where virtual models are created and enriched with sensor data, creating a “digital twin” of the system or device
3. Technical assistance to human counterparts, with aggregation and visualization of relevant data and automation of repetitive or unsafe tasks
4. The ability of the cyber-physical system to make decentralized decisions

Many of these technologies have already been developed and applied in other industries (e.g., automotive, aeronautics, manufacturing). These industry applications can provide insights and direct correlations that can be carried over to HTM. The use of scheduled and predictive maintenance, for which sensor data are continuously monitored and reported back, provides evidence on the state of given devices, allowing the system to forecast failures and reduce unplanned equipment downtime.

Data have become ubiquitous, and valuable insights can be drawn from many sources, including computerized management systems, many of which already have built-in predictive capabilities. Creating a data-driven culture promotes moving from a reactive to a proactive approach. Analytics can be applied to address regulatory compliance by measuring preventive/corrective maintenance completion rates and percentages, tracking equipment uptime, and using labor metrics to evaluate operational efficacy. Data can be used to provide an overall cost of operations, measure in-house cost-of-service ratio compared with that of an independent service organization or manufacturer, or use mean time between failure data combined with financial data for capital planning and asset management.

In the case of achieving 100% preventive maintenance inspection completion, evidence-based medical equipment management plans can be made to create personalized alternate equipment maintenance procedures unique to the device, facility, and department structure of a given healthcare network. Having the data to identify which devices need closer monitoring and those for which maintenance procedures have shown little effect can reduce workload greatly, freeing up resources to address critical needs. We’ve been fumbling around in a dark room, and analysis of available data finally has given us a flashlight.

**Future of Healthcare**

The smart hospital of tomorrow is a fully connected, cognitive hospital. The hospital infrastructure is able to continuously self-monitor and alert technicians with a forecast of failing parts while automatically purchasing the soon-to-fail part and customizing the equipment’s scheduled maintenance. The technician then is provided accurate contextual information and able to pre-emptively replace the part before failure. The hospital that can predict and react to the constant change of state in its environment is an autonomous enterprise.

With the advancement of interoperability and communication technologies, this autonomous organization also is capable of connecting to other autonomous entities that have built-in health monitoring systems, including smart clinics, smart hospitals, smart
cars, or any number of smart devices that have built-in biometric sensors, thereby effectively enabling the decentralization of healthcare.

To imagine such a hospital, having a few assumptions is necessary. The architects of this smart hospital have done their due diligence and built in the necessary infrastructure to capture the data while maintaining data integrity. Policies and standards have been established to create a common language on networked devices, therefore allowing data capture among all vested parties. Data have been aggregated on a centralized platform with built-in features that ensure applicable governance and security of the data. This centralized platform is easily scalable and provides appropriate end user accessibility. Workflows embedded with analytics have been developed using dynamic visualizations and automated reporting mechanisms to create data-driven business processes. The designers of this smart hospital have leveraged big data, cloud computing, and machine learning to create an artificial intelligence-based solution to optimize their hospitals operational efficiency.

In the smart hospital’s IoT platform, data are captured from several sources. Networked devices stream sensor data with near-real-time information and edge computing and analytics assist clinicians with faster diagnosis and alert users of any abnormal machine functions. Data from the CMMS provide performance and repair metrics with advanced analytics capable of finding failure patterns in work orders. With the use of natural language processing, these analytics are able to identify trends in technician labor notes, revealing previously disconnected insights. External data from other health networks and open data sets also are collected to provide a broader scope of product life cycle, failure, and performance data. After the data have been collected and transformed and analytics have been applied, cognitive models with autonomous functionality and self-learning capabilities are created. Meanwhile, computations are carried out in the cloud.

Management at the smart hospital is able to enhance its operational efficiencies by having a clear picture of asset and labor use based on productivity efficiencies, labor accountability, and the ability to identify solutions to low performance metrics. The data also allow them to make comparative calculations across facilities, manufacturers, models, or technicians.

Senior management is provided with predictive analytics to forecast costs, allowing informed technology roadmaps to be built and new technologies to be integrated into the healthcare ecosystem.

**Conclusion**

The preceding section provided a vision for the attributes of a smart hospital. Although the assumptions made address some of the infrastructure challenges that need to be overcome before a truly autonomous operation can be achieved, other external factors can inhibit an analytics platform. Communicating the return on investment to upper management related to establishing a data platform can be an obstacle due to the high cost of building the necessary infrastructure and the time needed to realize the benefits. Perhaps more importantly, until an open dialogue exists on establishing standards for data integration, HTM professionals are at the mercy of manufacturer trends. Challenges to adoption, including those related to infrastructure, data integrity, interoperability, and cybersecurity, will need to be addressed.

To achieve a Level 3 HTM program, as defined by the Association for the Advancement of Medical Instrumentation, bringing these Industry 4.0 technologies into the healthcare environment will be necessary. For good reason due to the nature of the industry, healthcare traditionally has been behind the curve in terms of adopting technology. This reality can benefit health professionals, providing a unique opportunity to leverage the technologies developed through other industries. However, we
cannot delay in establishing the vision and foundation needed to be able to use data and the predictive insights that can be drawn from them.

HTM professionals are the stewards of health technology, and we have reached a defining moment in the evolution of our discipline. Digital transformation is coming to healthcare, and HTM is unique in its technical expertise and intimate knowledge of clinical processes. This positions HTM professionals to be the champions of the digital transformation in healthcare, fostering the integration of these technologies. The alternative is remaining complacent—and if this happens—instead of bringing efficiency to the healthcare environment, we’ll find ourselves replaced by those who have adapted to the digital age.

References


