Abstract
An analysis of 8 change drivers and their implications for healthcare delivery professionals, healthcare technology developers, manufacturers and other related vendors

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Executive Summary

In 2015 AAMI established an environmental scanning program to anticipate important changes in healthcare technology design, development, manufacturing, implementation and management. What AAMI learned about eight change drivers may be as relevant for your planning as it is for AAMI.

AAMI’s scanning program is an attempt to make sense of the changing landscape and use those insights to make informed strategy decisions about priorities, programs and services. Trends and issues research is plentiful in this industry; the research methodology for this scan report began by assembling this rich stream of data. The patterns of change emerging from this data tell a story about the future. This story is plausible and convincing; however, the future can only be anticipated, never predicted. Once leaders decide to act or not, the trajectory of trends and issues can and do change. If you anticipate these changes, you will be better equipped to create your preferred future amid these possibilities.

The Future Story through Change Driver Forecasts, 2015-2025. Healthcare systems and payers are engaged in a decade-long drive to demonstrate accountability for patient outcomes and quality while driving efficiency up and costs down. Data collection, analytics and data-driven decision making will be central to healthcare technology management in the next five years. Systems thinking will evolve as a core competency, evolving from today’s troubleshooting for interoperability and cybersecurity into anticipating risk and leading performance improvement.

Marketplace dynamics will continue to favor mergers and consolidations as well as new information technology-based entrants, all striving for profitable buyouts or achieving hyper-scale in the trillion dollar healthcare industry. While solutions to accelerate development and harmonization of standards and regulations for emerging devices and systems of devices remain challenging, the preconditions for open, effective and efficient development and adoption are snapping into place.

The Internet of Things, connecting devices and other inanimate objects, is fast becoming the Internet of Everything connecting people, computers, sensors and digitized products to generate trillions in new value for everyone. Game-changing healthcare technologies are coming out of R&D labs to disrupt how and where medicine is practiced, putting intense pressure on healthcare technology and information technology managers to link these new capabilities into healthcare delivery. As machines become smarter and maintenance more automated, tomorrow’s healthcare technology job opportunities will go to leaders with the competencies to deliver patient and business outcomes through interdisciplinary teams inside, across and outside their organizations.

Three Horizons Methodology for Understanding Strategy & Change. One of the most difficult aspects of foresight is anticipating how quickly or slowly systems will change. An event can accelerate everything and complexity will slow things down much more than anyone might forecast. To pierce through this fog of uncertainty, AAMI is using the Three Horizons Methodology to represent the scan’s findings. This methodology attempts to characterize when changes may have their greatest impact and how organizations may have to adjust their strategic fit to achieve a preferred future. According to our analysis, five change drivers are already having a significant impact in Horizon 1 and continue to be significant in Horizon 2. The other three are likely to yield more profound changes in system capabilities, roles and relationships in Horizon 2 when they will be critical. Horizon 3 always describes a preferred future. What is your organization’s preferred future in Horizon 3? How can you respond to these change drivers in ways that will help you achieve that outcome?
# 3 Horizons Analysis of Change Drivers and Strategic Opportunity

<table>
<thead>
<tr>
<th><strong>Horizon 1</strong></th>
<th><strong>Horizon 2</strong></th>
<th><strong>Horizon 3</strong></th>
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<tbody>
<tr>
<td><strong>2015-2017</strong></td>
<td><strong>2018-2024</strong></td>
<td><strong>2025 &amp; Beyond</strong></td>
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- Quality, affordability and patient outcomes accountability
- Data collection, data analytics & data-driven decision-making
- Systems thinking for interoperability, cybersecurity and risk management
- Changing marketplace with new entrants, consolidations and product and service diversification
- Global relevance of standards & regulations for patient safety and quality assurance
- Value creation through increased connectivity
- Game-changing technologies in development, manufacture & healthcare delivery
- Tomorrow’s healthcare technology jobs and competencies

What is your organization’s preferred future? Insert it here.

### Today’s Significant Changes

What are the near term implications of these significant shifts now underway?

### Transition Period of Uncertainty and Change

What great challenges will our customers, clients and stakeholders face?

What are the strategic opportunities in this time of transition?

What capabilities will we need?

### Preferred Future: Our Vision & Desired Outcome

Are we taking strategic advantage of the opportunities to achieve our vision?

If not, why? What must change?

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**Additional Guidance in Using This Report.** Each change driver description opens with a forecast followed by key trends and issues. The scan included an extensive literature search; citations are included for distinctive facts and forecasts. General trends found in multiple sources are paraphrased. Interviews with 16 thought leaders (listed on the final page) confirmed the significance of these change drivers and possible implications. A summary of our research methodology is also included.
Change Driver 1: Accountability for Patient Outcomes, Quality and Affordability

**Forecast:** Healthcare systems and payers are engaged in a decade-long drive to demonstrate accountability for patient outcomes and quality while driving efficiency up and costs down.

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<tr>
<th>Trends</th>
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<tr>
<td>CMS and private payers in the US are moving to valued-based payments; similar cost control measures are being implemented globally.¹</td>
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<tr>
<td>Consolidation and mergers of hospitals, clinics, and healthcare technology companies and even insurance companies are booming.²</td>
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<td>Easy win cost savings are coming to an end and healthcare facilities now face a growing backlog of postponed investments and maintenance.</td>
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<tr>
<td>Price pressures from commoditization are growing; physicians have less autonomy to pick many diagnostics and devices.</td>
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<td>Healthcare technology vendors are moving from a product to a solution focus becoming partners in patient outcomes, quality and affordability.³</td>
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<tr>
<td>Data-driven analysis of device utilization could become the focus of future accountability measures.</td>
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<tr>
<td>Large healthcare organizations are negotiating corporate level service and supplier agreements to cover multiple locations.</td>
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<td>HTM services will use centralized logistics to deploy fewer, more mobile employees to multiple sites.</td>
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**Potential Implications**

This intense focus on accountability for quality and value affects everyone. Profit margins on commoditized healthcare technologies will be tight.

Change Driver 2: Data Collection, Analytics and Data-Driven Decision Making

**Forecast:** Data collection, analytics and data-driven decision making will be central to healthcare technology management in the next five years.

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<th>Trends</th>
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<tr>
<td>Experts estimate analyzing data will save hundreds of billions a year in healthcare and help predict adverse outcomes before they occur.⁴</td>
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² Healthcare Finance [http://www.healthcarefinancenews.com/blog/key-tips-successful-hospital-merger-or-acquisition](http://www.healthcarefinancenews.com/blog/key-tips-successful-hospital-merger-or-acquisition). Also maintains a running list of healthcare mergers as does Modern Healthcare News.

³ Premier Economic Outlook Survey. Fall 2014.


Also GE/Accenture report, *The Impact of Big Data in Healthcare for 2015*
Predictive modeling will be used to manage staff resources and equipment maintenance.

Most devices, except those too tiny to tag, must have a UDI code within the next five years.\(^5\)

Software companies and manufacturers are offering data analytics tools and services.

Major healthcare delivery organizations and independent service organizations that can collect data across multiple facilities have a deepening trove of data to analyze.

Debate is shifting from information ownership to information stewardship to balance the need to share data among stakeholders with the patients’ right to privacy.

Interest is growing in using data for benchmarking and comparable analysis.

Healthcare systems are becoming data rich and information challenged leading to a growing need for meaningful analytics, data visualization, and user centered design at the point of care.

Healthcare technology management needs standards and best practices in data collection, integrity, governance and analytics.

National tasks forces propose a coordinated registry network that could improve device evaluation and data collection to improve benefit/risk and safety knowledge from innovation to obsolesce.\(^6\)

### Potential Implications

Healthcare delivery professionals and healthcare technology developers, manufacturers and related vendors are all going up the data analytics learning curve; leading suppliers are likely to be a step or two ahead and well positioned to offer solutions.

#### Change Driver 3: Systems Thinking for Interoperability, Cybersecurity and Risk Management

**Forecast:** Systems thinking will evolve as a core competency in healthcare technology design and management, evolving from today’s troubleshooting for interoperability and cybersecurity into anticipating risk and leading performance improvement.

#### Trends

Healthcare faces a huge cybersecurity challenge now and the risk will grow as more devices move out of controlled environments into remote and home locations.

Today’s challenge is getting the data to and from the device into other systems for analysis in patient care and operations.

The push for greater accountability is making process improvement and change management a top priority.

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The demand for human-centered design is growing in tandem with requirements to work across organizational units.

National interest and investment is increasing in systems engineering education, training and innovation to improve healthcare performance.\(^7\)

Given the potential risks, some experts forecast that hospital networks will eventually be regulated and monitored by an external agency.

**Potential Implications**

Healthcare delivery professionals and healthcare technology developers, manufacturers and related vendors have an even greater need for cooperation and communication to create and share knowledge and competency in systems thinking if both sectors are to achieve success.

**Change Driver 4: Changing Marketplace with New Entrants, Consolidations and Product & Service Diversification**

**Forecast:** Marketplace dynamics will continue to favor mergers and consolidations as well as new information technology-based entrants, all striving for profitable buyouts or achieving hyper-scale in the trillion dollar healthcare industry.

**Trends**

Consolidations and mergers continue to occur at a brisk pace as hospitals, other provider organizations and healthcare technology companies reposition themselves to diversify, claim more scope and coordination of patient care, and achieve economies of scale.\(^8\)

Information technology companies are moving into healthcare; money is pouring into start-ups targeting digital health, privacy, transparency and work flow management.\(^9\)

Hyper-scalable companies are moving toward consumer-oriented, technology-enabled business models offering access to centralized service.\(^10\)

Growing foreign leadership is occurring in the design, development and manufacture of healthcare technologies.

The pendulum is swinging somewhat from globalizing markets toward more protectionism and regionalism; with trade and regulatory constraints, companies can find it easier to develop and manufacture where they want to market.

With the rise of additive manufacturing/3-D printing and other alternative production methods, companies are considering distribution infrastructure and customer intimacy in locating future facilities.

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\(^7\) President’s Council of Advisors on Science and Technology. Better Healthcare and Lower Costs: Accelerating Improvements through Systems Engineering.

\(^8\) Healthcare Finance [http://www.healthcarefinancenews.com/blog/key-tips-successful-hospital-merger-or-acquisition](http://www.healthcarefinancenews.com/blog/key-tips-successful-hospital-merger-or-acquisition). Also maintains a running list of healthcare mergers as does Modern Healthcare News.


Potential Implications

In this time of flux and consolidation, organizations in this field need guidance to help them navigate new relationships, adapt to changes in their environment, and explore new opportunities and capabilities.

Change Driver 5: Global Relevance of Standards & Regulations for Patient Safety and Quality Assurance

Forecast: While solutions to accelerate development and harmonization of standards and regulations for emerging devices and systems of devices remain challenging, the preconditions for open, effective and efficient development and adoption are snapping into place.

Trends

- Global harmonization of standards development, regulatory convergence and acceptance of third party compliance assessments are increasing to enable a global marketplace.
- More international participation in standards development is occurring especially from China.
- Standards are becoming less prescriptive and more descriptive of necessary process and performance/outcomes.
- Systems thinking is becoming a mindset in standards development with a rising need to incorporate practitioner and patient perspectives to achieve human-centered design.
- Standards development organizations and aggregators are adopting subscription models, integrating interactive data into workflow systems, and offering value added training events.\(^{11}\)
- As technologies converge into systems, standards developing organizations will compete with each other to determine who should have the development lead.\(^{12}\)
- Patient safety is the primary driver behind global regulation of healthcare technologies with priority given to higher risk devices and expedited approval offered to breakthrough technologies for underserved medical conditions.
- New approaches to streamline and update accreditation processes, such as DNV’s blending of ISO 9001 and CMS compliance, will emerge to facilitate accountability and systems thinking.

Potential Implications

With more global participants in standards and regulatory processes and fewer organizations able to commit knowledgeable people to these tasks, the few that can participate will have greater influence.


\(^{12}\) Outsell.
**Change Driver 6: Value Creation through Increased Connectivity**

**Forecast:** The Internet of Things, connecting devices and other inanimate objects, is fast becoming the Internet of Everything connecting people, computers, sensors and digitized products to generate trillions in new value for everyone.

**Trends**
- eHealth and mHealth adoption are moving from promise to implementation after a rough start-up phase plagued by interoperability and security challenges.
- As medical devices are digitized and networked, many will be remotely monitored and repaired.
- Original equipment manufacturers are developing closer relationships with users to diagnose problems, exchange data, and provide solutions.
- Patients will assume a greater role in monitoring and managing their health through connected systems of diagnostics, devices and information exchange.
- Hospitals of the future are likely to be bed-less data surveillance centers for remote patient monitoring except for the ICU, OR and ER rooms.\(^\text{13}\)

**Potential Implications**

Everyone will be learning to work in new ways and collaborate across systems, including exchanging operational and outcomes data.

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**Change Driver 7: Game-Changing Technologies in Development, Manufacture and Healthcare Delivery**

**Forecast:** Game-changing healthcare technologies are coming out of R&D labs to disrupt how and where medicine is practiced, putting intense pressure on healthcare technology and information technology managers to link these new capabilities into healthcare delivery.

**Trends**
- Patient-facing technologies, including wearable sensors and app-based diagnostics for routine labs, are the precursors to moving prevention and treatment into a virtual environment.\(^\text{14}\)
- Miniaturization of imaging and other medical devices is helping move more procedures out of the hospital and into satellite offices, clinics and the home.\(^\text{15}\)
- Medical devices are becoming more capable of self-diagnosis and remote recalibration.\(^\text{16}\)
- The convergence of IT and diagnostic/ therapeutic devices and drug delivery systems coupled with advances in genomics & pathways research holds great promise for personalized therapies.

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\(^\text{14}\) ECRI Institute. 2015 Top 10 Hospital C-Suite Watch List

\(^\text{15}\) ECRI Institute. 2015 Top 10 Hospital C-Suite Watch List

Automation of decision making, especially clinical decision support systems, is making diagnosis and treatment more systematic and reliable.

Additive manufacturing/3-D printing offers new capabilities for designing and producing customized solutions to repair and strengthen human bodies; prototyping new design approaches, and manufacturing commoditized products in new, more cost efficient ways.\textsuperscript{17}

Developing markets are becoming a disruptive testbed for innovative healthcare technology solutions.\textsuperscript{18}

Interest and investment in healthcare technology innovation is strong with initiatives like the proposed 21\textsuperscript{st} Century Cures Act, Qualcomm Tricorder X Prize, and venture capital for start-ups.

Robots and healthcare technologies have the capacity to work in different and smarter ways than humans, creating opportunities for people to move into new roles with judgment-based authority.

### Potential Implications

Healthcare technologies are shifting out of more regulated and better controlled environments and into more distributed and remote locations where safety practices are not yet well tested. The pressure to innovate and implement these game-changing technologies will be intense.

### Change Driver 8: Tomorrow’s Healthcare Technology Jobs & Competencies

**Forecast:** As machines become smarter and maintenance more automated, tomorrow’s healthcare technology job opportunities will go to leaders with the competencies to deliver patient and business outcomes through interdisciplinary teams inside, across and outside their institutions or companies.

### Trends

- Healthcare technology and information technology management are converging with more HTMs reporting to CIOs.
- HTMs are getting more opportunities to interact with healthcare management teams on capital management, facility planning and risk management.
- Healthcare technology management is becoming more interdisciplinary with competencies in IT, systems thinking, data analytics and clinical outcomes.
- Healthcare technology management is evolving into distinct roles that may evolve into different positions and career pathways in larger organizations: technician, clinical engineer, technical equipment planner and personnel manager.
- Healthcare technology designers, developers and manufacturers increasingly need both technical and client-facing skills to develop collaborative solutions.

\textsuperscript{17} Master Control. Five Trends Transforming the Medical Device Industry, 2015. Available at:  
http://mastercontrolinc.blogspot.com/2014/06/five-trends-transforming-medical-device.html

\textsuperscript{18} PWC. Global Health’s New Entrants, Meeting the World’s New Consumers, 2015. Available at:  
Industry leaders estimate a shortage of clinical engineers at a time when their competencies and skills in systems thinking and healthcare technology management are most needed.\(^{19}\)

A growing number of people are employed as contingent workers as more organizations strive to run lean and adapt to changing conditions; companies are retaining a small core of critical employees and outsourcing for specialized expertise and projects.

**Potential Implications**

The field of healthcare technology management is undergoing a major retooling of knowledge, competencies & skills with roles for preparatory schools, continuing education and user group training. Industry vendors need solutions-oriented professionals adept at meeting client needs.

**AAMI Environmental Scanning Methodology**

The scanning research flowed in this manner:

1. AAMI collected relevant trends reports. Signature i also collected association scans. Signature i reviewed these resources to assemble potential trends, issues and new developments.
2. AAMI staff reviewed, discussed and prioritized an initial matrix of trends and issues.
3. Signature i identified potential change drivers and conducted additional research.
4. Sixteen industry thought leaders participated in interviews (see below). They reviewed and discussed the change drivers and helped in identifying any missing trends and issues.
5. Informed by this input, the change drivers were updated for this report.
6. Signature i briefed AAMI senior staff on the research findings and led a discussion of their implications and insights.
7. AAMI used the draft report to inform its strategic planning and budgeting.
8. The AAMI board reviewed and discussed this report November 7 and recommended the scan findings be adapted for release to AAMI members and stakeholders.

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Sue Schade  
Matt Weinger

\(^{19}\) Issue Analysis for AAMI Board, 2014. Also one-day issue analysis by selected leaders, March 2014 with findings reported in Paving a Path Forward for Clinical Engineers in Healthcare, April 2014. And internal correspondence in support of strategic plan objective, 2.3. More definitive data on supply/demand unavailable.