Understanding the tipping point for healthcare innovations: five key findings

A literature review and analysis
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The U.S. has the largest medical device market in the world with a market size of around $148 billion. Expectations are for the market size to reach $155 billion by 2017 *(6)*. There are more than 6,500 medical device companies in the U.S. and over 80% of them employ fewer than 50 people *(6,9)*. Many of these companies currently report little-to-no sales revenue *(6)*. As medical device companies push forward wondering when the infamous "tipping point" will come, the following key findings derived from scholarly research, expert opinions and case studies may provide guidance.

The concept now widely referred to as the tipping point (the point at which an idea, trend or product produces a domino effect spreading it exponentially through a social system) originates from studies on Diffusion Theory. Everett Rogers, one of the pioneers of this field of study, states that diffusion "is the process by which an innovation is communicated through certain channels over time among the members of a social system." Other research defines diffusion as "the passive adoption by individuals and organization" and calls dissemination "the active attempt to influence the rate and success of adoption" *(2)*. Therein lies the question of how companies turn diffusion of their innovation into active dissemination and thereby increase the speed of adoption.

While there are no clear answers, models, or best practices broadly applicable to all healthcare innovations, the following five key findings were consistently observed throughout research to-date.

1. Innovation in healthcare is notoriously slow and difficult to predict
2. The healthcare landscape plays a large role in diffusion rate
3. Empirical research helps but is not enough
4. There is not an agreed upon model of diffusion
5. Invest in change and allow opinion leaders to take ownership

Key finding 1

Innovation in healthcare is notoriously slow and difficult to predict

The rate of adoption for evidence-based healthcare innovations varies widely, and slow adoption rates are said to contribute to inefficiencies in the health sector *(1)*. One suggested reason for slow adoption rates is that there is no centralized resource in the healthcare industry that tracks emerging innovations or assesses their impact(s) on hospital service-line demand and capacity requirements *(1)*.

Diffusion is not simple, nor does it happen in a logical, linear order of operations. A substantial body of literature says, "innovative biomedical technology is assimilated in a complex, non-linear, dynamic pattern, often contingent upon a mix of factors. These factors can originate from the attributes of the technology itself, from the context within which the new procedure is meant to operate, or from the interaction between the specific technology and the context in which the device operates" *(2)*. In short – it's complicated, and solutions that work well for some innovations fail miserably for others. Gerald Nadler's Uniqueness Principle states, "No two problems are the same." Donald Berwick adds, "Neither are any two solutions" *(3)*. Recent studies posit that it is not possible to take the strategies of successful innovations and apply general rules to facilitate diffusion *(1)*.

To make matters more complex, there are instances where medical breakthroughs were made in one part of a hospital and still not adopted in other areas of the same hospital. Studies state that, "Even when an evidence-based innovation is implemented successfully in one part of a hospital or clinic, it may spread slowly or not at all to other parts of the organization." Donald Berwick gives examples of nurses successfully reducing cesarean delivery rates and surgeons saving millions of dollars while drastically reducing errors – neither of which caught on in other areas of those respective hospitals *(3)*.

> The assimilation of innovation is **complex, iterative,** & frequently beset by **shocks, setbacks, and surprises.** *(2, 13)*

So what do we know about adoption rates? Figure 1, shows a widely cited innovation adoption curve. This graph breaks up the total population into groups based on how early they adopt a new innovation. When dealing with medical device and healthcare innovations, it helps to think about the people who make up these groups not as the customers using your device, but rather as the doctors, hospitals and other healthcare professionals who must adopt the innovation for it to succeed. It's important to note that each group of adopters watches the one before them. Therefore, if your innovation is in the stage where Early Adopters are experimenting with it, it's important to make the results they're seeing observable to the Early Majority who is next in line *(3)*.

The S-shaped line shows the rate of adoption over time, with full market saturation being reached once all of the laggards have adopted. Research states that, "changes appear to acquire their own momentum (tipping point) somewhere on the ascending portion of the adoption curve, often between 15% and 20% adoption" *(3,15)*.

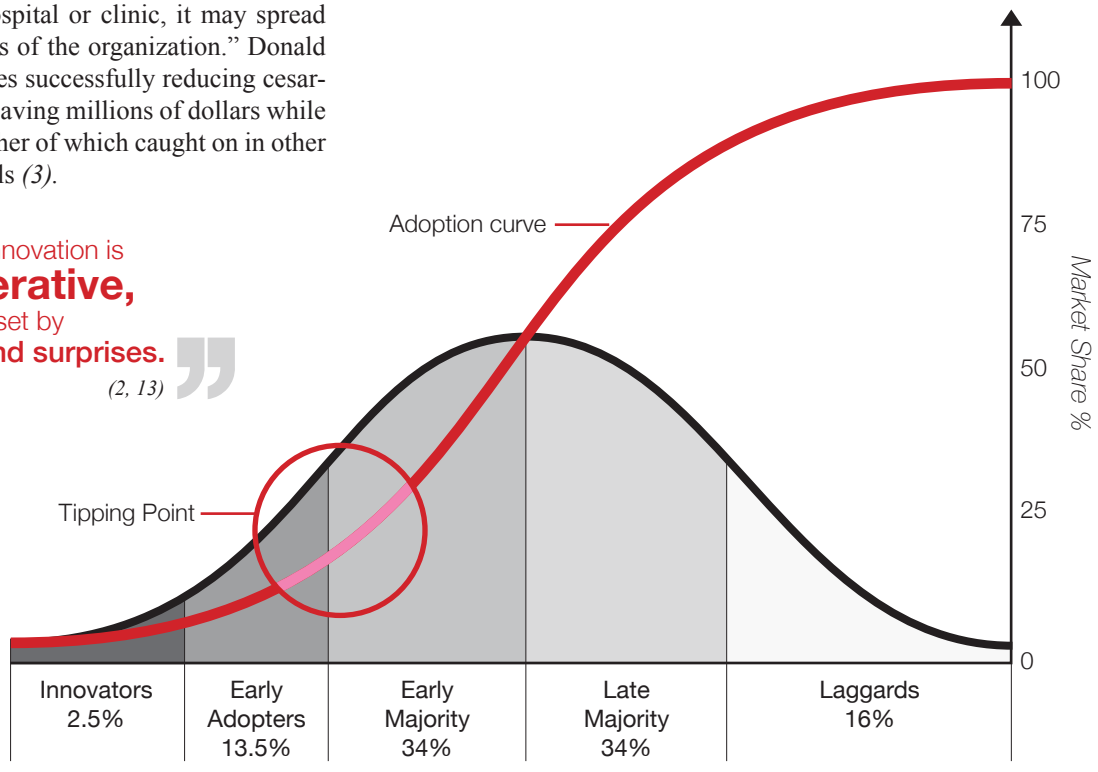


Figure 1

Adapted from published graph by Everett Rogers

Key finding 2

The healthcare landscape plays a large role in diffusion rate

Reimbursement landscape

In nearly every publication studying the barriers that hinder adoption rates, reimbursement is the first barrier mentioned *(2)*. It should be noted that while reimbursement can be a barrier, it could also be a driver depending on the level of reimbursement the innovation can obtain and the changes in the financing and delivery of healthcare *(2)*. The shift to value-based payment structures lends hope for innovations that can increase patient outcomes and quality of care at a lower cost.

Innovations that improve quality of care but also threaten to disrupt standard healthcare processes, economic relationships, and cultural patterns face high barriers to adoption. Research suggests that these types of innovations need equally disruptive drivers such as Malcolm Gladwell's "Mavens, Connectors, and Salesmen as individual agents of change, or as healthcare delivery systems and health plans organizing change" *(1)*. That leads us to the next landscape that must be considered - the role of hospitals and "physician champions" (often referred to in research as "opinion leaders").

Hospital landscape

These days, a large number of physicians are employed by hospitals and other healthcare organizations as opposed to owning their own practice – a shift that has changed innovation diffusion dynamics. Hospital groups and payers have more influence than ever in medical device buying decisions *(7)*. For hospitals to decide to adopt an innovation and assist in its diffusion, certain criteria should be met. First, it's critical for the hospital to be willing to invest in information technology *(1)*. Second, the organization must nurture innovators (in this instance the term "innovator" refers to the doctors/opinion leaders who are in the first group to adopt an innovation). The organization must offer praise, resources, and security for the inevitable failures that will occur or they run the risk of discouraging innovators and falling behind their competition *(3)*. "Researchers have attributed hospitals' acquisition of technology to multiple motivations, including the desire to improve clinical care, competitive pressure from neighboring hospitals, profit seeking in an environment of favorable insurer reimbursement, and availability of capital needed to adopt these technologies" *(4,16,17,18)*.

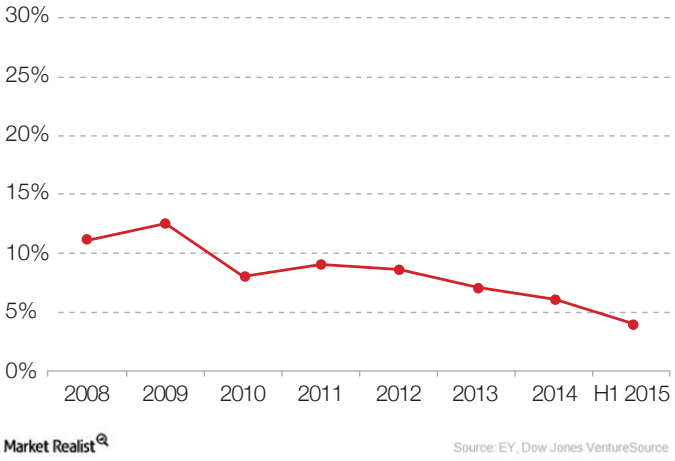
It's true that nowadays, non-clinicians such as hospital administrators and patients have more power than ever to influence diffusion; however, clinicians still hold the power to block by refusing to change behavior *(2)*. For instance, there was an evidence-based standard of care for diabetes set back in 1989 called the St. Vincent Declaration. Primary Care doctors felt that the standards were appropriate mainly for acute cases of diabetes and weren't relevant to their patients in primary care. As a result, the innovation did not find wide acceptance. It shows that "new knowledge can be ambiguous and interpreted according to particular contexts, which can affect the degree of translation into daily use" *(2)*. So, while non-clinicians hold much of the deciding power needed to adopt an innovation, clinicians hold the power to keep an innovation from diffusing.

Funding landscape

Early-stage companies backed by venture capital firms drive the healthcare innovation ecosystem. "Over the years, a disruptive industry landscape and a shift to value-based healthcare have led to a reduction in the interest of venture investors due to entailing risks and uncertainties. Venture financing deals decreased from 449 deals in 2014 to 409 deals in 2015, according to EY Lifesciences' 2015 report, which is a significant decline from the six-year average of 438 financing deals from 2009 to 2015" *(10)*. Figure 2 shows the decline in venture capital investment in the U.S. medical device industry. Just as reimbursement and hospital-acceptance will affect the rate of innovation diffusion, it reasons that funding, or lack thereof, will have an impact, as well.

Figure 2

Medical device industry share of U.S. venture capital



Key finding 3

Empirical research helps but is not enough

While empirical research is important for securing credibility for an innovation, research consistently shows that evidence alone is not enough for a successful diffusion *(2)*. When considering the type of research to conduct, one study noted that, important study elements that interest Centers for Medicare and Medicaid Services, and payers in general, are: *(1)*

1. eligibility or patient entry criteria
2. duration of follow-up
3. subgroups in which the technology may be effective
4. the extent to which effects on health outcomes can be generalized beyond narrow study populations
5. substitution effects
6. technology increasing effects

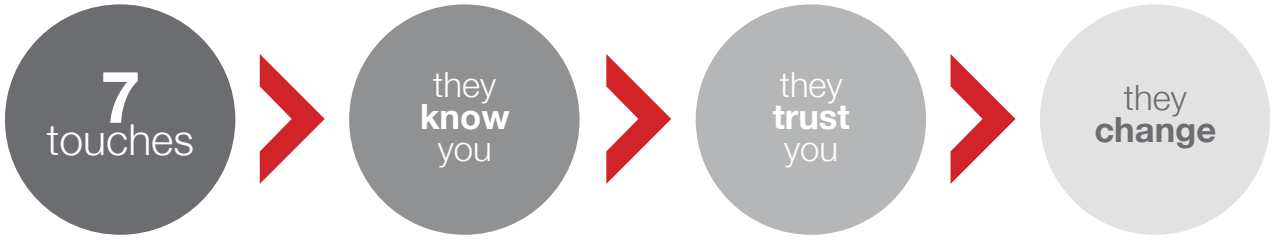
Beyond evidence

If evidence of effectiveness isn't enough to diffuse an innovation, what else is needed? Opinion leaders or "change agents" whose leadership is trusted play important roles in adoption as a way of influencing others through conformity and imitation *(2,14)*. These opinion leaders often come in the form of "physician champions" who fall into the first group of adopters from Figure 1, known as "innovators." These innovators are often chosen as elected leaders of clinical groups and are watched by the early adopters who catch on next *(3)*. Gaining the adoption of opinion leaders is a driver to speeding adoption; however, these innovators must employ methods of change to alter behavior and not just assume that everyone will follow along. As previous stated, making the results of the innovation observable to the next group of early adopters is helpful. So, how do we get the innovator physicians to hop on board?

The author of the New Yorker article entitled *"Slow Ideas"* asked a pharmaceutical rep how he persuades doctors, who are notoriously stubborn, to adopt a new medicine. The rep replied, "Evidence is not remotely enough, however strong a case you may have. You must also apply the 'rule of seven touches.' Personally 'touch' the doctors seven times, and they will come to know you; if they know you, they might trust you; and, if they trust you, they will change." The author goes on to point out that "human interaction is the key force in overcoming resistance and speeding change" *(5)*.

The use of ultrasounds in cardiology provides an example of opinion leaders successfully speeding the adoption rate. The idea of cardiology ultrasounds began in the early 1960s and to this day reports are showing that full market saturation has not yet been reached. In 1963 the first American article was published lending scientific credibility to the device; however, it wasn't until other valued opinion leaders began publishing articles in 1969 that acceptance started to grow. It was around the same time that academic institutions began incorporating echocardiography into courses *(12)*. "By the mid to late 1970s this technology had taken the American scene by storm, with a proliferation of publications exploring the use of echocardiography in all forms of cardiac disease" *(12)*. Today, cardiology and radiology are highly saturated segments of the ultrasound equipment market. "However, due to advances in 3D and 4D imaging, as well as elastography and combined MRI/ultrasound imaging techniques, growth rates in these markets are expected to remain in the mid-single digits until at least 2020" *(11)*. Though full market saturation has not yet been reached, the tipping point around the early 70s is assumed to have been a result of opinion leaders publishing their own research and incorporation into medical academics.

> **Evidence is not remotely enough,**
> however strong a case you may have.
> You must also apply the
> **'rule of seven touches.'**
> *(5)*



Key finding 4

There is not an agreed upon model of diffusion

Though Roger Everett seems to be deemed the godfather of diffusion research, to this day there are no agreed upon models of diffusion for companies to follow. As noted in key findings 1 and 2, healthcare innovations are slow, unpredictable, and at the mercy of the current landscape. However, there are some findings and suggested models that seem fitting to share.

Drivers and barriers

A 2003 paper about the tipping point and health care innovations had an interesting chart listing 11 barriers & drivers along with the strategic potential of each. "Drivers are events or circumstances that will foster a technology's adoption and diffusion; barriers are events or circumstances that will hinder or halt a technology's adoption and diffusion" *(1)*. The chart can be found in Appendix 1. Most notable are the only three barriers/drivers that are considered to have high strategic potential:

1. **Coverage:** Inclusion of a service or product utilizing a new technology as an insurance benefit.
2. **Reimbursement:** The amount paid to providers for services or products using the new technology, and the structure of reimbursement.
3. **Workforce:** Changes in and availability of the skills, competencies and workers required to utilize a new technology, and the impact of that technology on workforce performance and satisfaction.

Six critical dynamics of innovation diffusion

Another theory of how to predict or speed the rate of adoption comes from Roger Everett. To summarize, innovations perceived to have more of the following six dynamics are more likely to diffuse successfully, while innovation with less may diffuse slower or not at all *(1)*.

1. Relative advantage
2. Trialability
3. Observability
4. Communications channels
5. Opinion leaders
6. Infrastructure

Explanations of each of these can be found in Appendix 2.

Perceptions and contextual factors

Along the same lines of the previously listed six critical dynamics of innovation diffusion, other research states, "Perceptions of an innovation predict between 49% and 87% of the variance in the rate of spread" *(3,15)*. Most powerful is perceived benefit of the change; essentially, if people think an innovation can help them, they're more likely to adopt it. This is a bit more complicated than expected because it's a relative "balance between risk and gains and of risk aversion in comparing the known status quo with the unknown future if the innovation is adopted" *(3)*. The more understanding and knowledge that they can get about the expected results, the more likely they are to adopt the innovation. The research goes on to point out that the innovation cannot be perceived as too complex. Simple innovations are said to spread faster than complicated ones.

Additional tips collected from published studies:

1. The Institute of Medicine Chasm report suggested that strategies to advance the adoption of innovations should be focused on the healthcare organizations more than on strategies to change individual behavior *(1)*.
2. "Innovations are more likely to be adopted by organizations if, compared to other innovations, they require less skill to use, expose patients and doctors to fewer risks, and are more observable" *(2)*.
3. "Technologies are more likely to be adopted in organizations that are large, complex, and eager to penetrate new markets. There are better prospects to diffuse in organizations where chief executives have long tenures and high levels of education, and where physicians have been recently trained" *(2)*.
4. "Innovations are more likely to translate into practice in organizations where the new technologies are compatible with medical specialization and where CEOs are influential proponents" *(2)*.

Key finding 5

Invest in change and allow opinion leaders to take ownership

Even with patents in place to protect intellectual property, market competition is inevitable. According to the U.S. Patent & Trademark Office, "the total number of patents granted has increased by approximately 169% from 7,443 in 2009 to 19,992 in 2014" *(8)*. With rapid advances in technology like apps and 3D printing, it's easier than ever to develop ways of competing in a market without infringing on existing patents. In fact, studies show that competition is evolutionary in the sense that multiple product designs often are phased out over time. At the end, many competitors have virtually identical products. For instance, beginning in the 60's we saw many device designs for total knee replacements that would look bizarre by today's standards. Now, while there are still competitors making TKR devices, they are virtually indistinguishable from each other. Furthermore, in the auto industry, researchers believe the SUVs of today are going through a similar evolutionary period and in the future they will have figured out the best design and will all look similar *(1)*.

> "In innovation, new concepts usually must **come from outside the current system,** but new processes - the things that make the concepts live - must **come from inside or they will not work.**" *(3)*

One of the most interesting findings was that, "Individuals who develop an innovation often are not its best salespeople, because they usually are at least as invested in its complexity as in its elegance. They tend to insist on absolute replication, not adaptation. However, innovations are more robust to modification than their inventors think, and local adaptation, which often involves simplification, is nearly a universal property of successful dissemination" *(3)*. The study goes on to point out that, "In innovation, new concepts usually must come from outside the current [hospital] system, but new processes – the things that makes the concepts live – must come from inside or they will not work" *(3)*. This concept is intriguing, as it seems to encourage the companies that launch medical innovations to relinquish control of the treatment process to the opinion leaders and health systems that adopt the innovation. The assumption is that without allowing the early adopters to test, study, and ultimately make the innovation their own that diffusion will be stifled or extinguished altogether.

Appendix 1 (1)

Drivers and Barriers Affecting the Diffusion of Technology
Strategic Potential to Advance Diffusion

DRIVERS AND BARRIERS	DEFINITION	STRATEGIC POTENTIAL	EXAMPLES
Technology Breakthroughs	Critical advance in science and technology that supports product development.	Low	▪ Thrombolytic therapy for acute myocardial infarction ▪ Laparoscopic cholecystectomy ▪ Inhaled pharmaceuticals ▪ Remote chronic disease monitoring
Target Conditions	Diseases or conditions to which a technology will be applied based on scale, cost, severity.	Low	▪ LVAD for CHF ▪ Inhaled insulin for diabetes ▪ Monoclonal antibody radiopharmaceutical diagnostic scans for prostate cancer metastases
Convergence of Technologies	The combination of two or more technologies to enable novel diagnostic or therapeutic solutions.	Low	▪ Power management and In sensors ▪ Image guided surgery
Competing and Substituting Technologies	New products used to diagnose or treat the same conditions as an existing technology.	Low	▪ Minimally invasive procedures (Mid-CAB vs. PTCA with stents) ▪ Multidose vs. continuous subcutaneous insulin infusion (CSII) for diabetes ▪ Drug-eluting stents vs. brachytherapy for CAD ▪ Cardiac diagnostics, PET, other scans ▪ Imaging for spinal disease
Liability	Institutional liability and individual practitioner malpractice liability; privacy; confidentiality; fraud and abuse.	Low-Medium	▪ Electronic fetal monitoring ▪ Autologous bone marrow transplantation for solid tumors ▪ Vaginal birth after caesarean section ▪ OIG audits of pacemaker implants in Medicare ▪ HIPAA

Appendix 1 (1) *(cont.)*

DRIVERS AND BARRIERS	DEFINITION	STRATEGIC POTENTIAL	EXAMPLES
Regulatory Approval	Authorization to market a new technology, for use in specified populations and diseases or conditions.	Low – Medium	▪ Bioartificial liver ▪ Hybrid drug-device products ▪ Hybrids of cultured epidermal cells and scaffold products
Coverage	Inclusion of a service or product utilizing a new technology as an insurance benefit.	High	▪ Autologous chondrocyte transplantation for knee cartilage defects ▪ IDET for herniated lumbar intervertebral discs ▪ Implantable pressure monitors for heart failure ▪ LVAD as destination therapy for CHF
Reimbursement	The amount paid to providers for services or products using the new technology, and the structure of reimbursement.	High	▪ Autologous bone marrow tranplantation ▪ Pediatric immunizations ▪ Intensive insulin therapies ▪ Remote monitoring of chronic disease
Workforce	Changes in and availability of the skills, competencies and workers required to utilize a new technology, and the impact of that technology on workforce performance and satisfaction.	High	▪ PACS ▪ Angioplasty for acute MI ▪ Laparoscopic cholecystectomy ▪ Minimally invasive surgery ▪ Ultrasound in primary care setting ▪ Centralized reading of digitized images ▪ Telemedicine ▪ Service robots for hospital supplies
Cost	Operating costs of utilizing the technology once acquired, and cost to purchasers, payors, and society for the enhanced intervention.	Low	▪ IT Security ▪ Sensors for remote monitoring ▪ Cochlear implants ▪ Bioartificial liver ▪ LVAD as destination therapy
Capital Requirements	Capital costs of acquisition of a new technology.	Medium	▪ PACS ▪ PET ▪ Gamma knife ▪ Interventional robotic suites ▪ Sensors for remote monitoring

Appendix 2 *(1)*

According to Rogers, the characteristics which determine an innovation's rate of adoption are:

Relative Advantage
Relative advantage is the degree to which an innovation is perceived as better than the idea it supersedes. The degree of relative advantage may be measured in economic terms, but social prestige, convenience, and satisfaction are also important factors. It does not matter so much if an innovation has a great deal of objective advantage. What does matter is whether an individual perceives the innovation as advantageous. The greater the perceived relative advantage of an innovation, the more rapid its rate of adoption will be.

Compatibility
Compatibility is the degree to which an innovation is perceived as being consistent with the existing values, past experiences, and needs of potential adopters. An idea that is incompatible with the values and norms of a social system will not be adopted as rapidly as an innovation that is compatible. The adoption of an incompatible innovation often requires the prior adoption of a new value system, which is a relatively slow process.

Complexity
Complexity is the degree to which an innovation is perceived as difficult to understand and use. Some innovations are readily understood by most members of a social system; others are more complicated and will be adopted more slowly. New ideas that are simpler to understand are adopted more rapidly than innovations that require the adopter to develop new skills and understandings.

Trialability
Trialability is the degree to which an innovation may be experimented with on a limited basis. New ideas that can be tried on the installment plan will generally be adopted more quickly than innovations that are not divisible. An innovation that is trialable represents less uncertainty to the individual who is considering it for adoption, who can learn by doing.

Observability
Observability is the degree to which the results of an innovation are visible to others. The easier it is for individuals to see the results of an innovation, the more likely they are to adopt it. Such visibility stimulates peer discussion of a new idea, as friends and neighbors of an adopter often request innovation-evaluation information about it.

In summary, then, innovations that are perceived by individuals as having greater relative advantage, compatibility, trialability, observability, and less complexity will be adopted more rapidly than other innovations.

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