

Handling Disruptive Innovation in Clinical and Research Settings

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Topic Relevance by Timeline

Summary

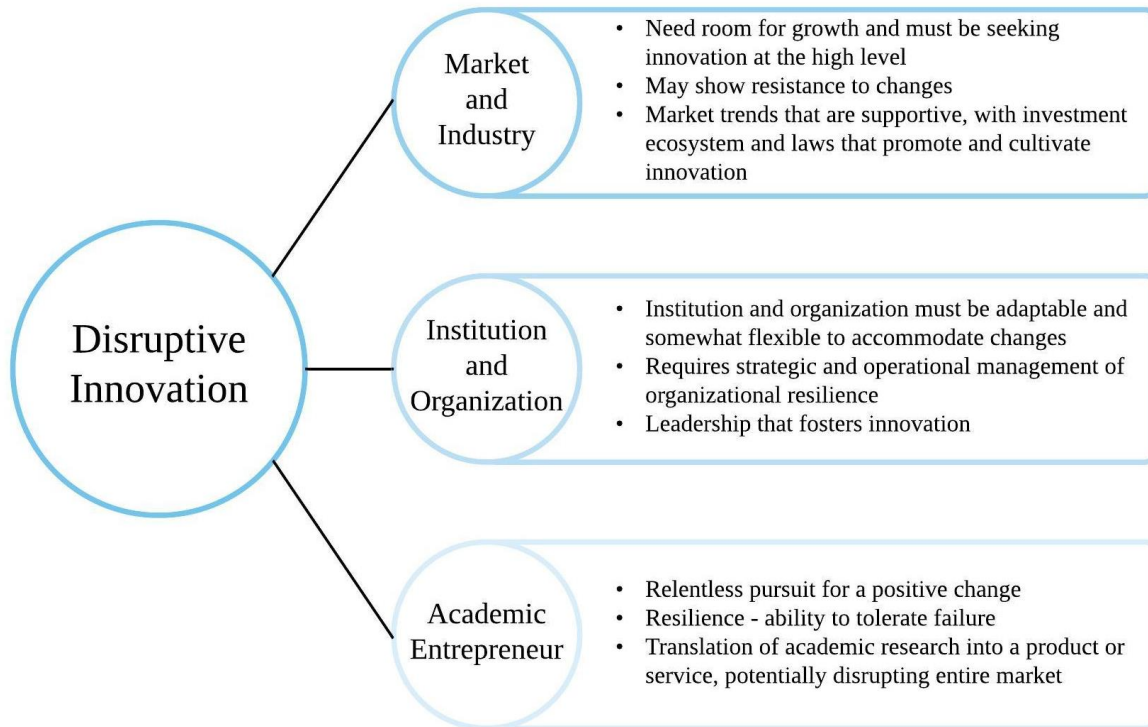
- The process of disruptive innovation is a driving force in making healthcare more affordable and effective.
- Building resilience through diversification of financial resources, networking, and focusing time/effort can help an academic entrepreneur tolerate setbacks and minimize risks.
- The sleep medicine case study highlights how fast a disruptive innovation can impact organizations on a micro and macro level.

Introduction

Disruptive innovation, defined as an innovation that creates a new market and network that eventually overtake established organizations, has brought about tremendous changes in several industries. It is an important facet of healthcare because it can minimize healthcare costs while simultaneously improving the quality of care. The convergence of innovation and healthcare within an academic (university) setting creates a distinct class of entrepreneur—the academic entrepreneur. To be able to make a sustainable impact in the healthcare industry, the academic entrepreneur has to learn to be resilient since they may face resistance as they seek to develop new technologies that ultimately can lead to disruptive innovation on the organizational and industry level as shown in Figure 1.

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Figure 1. Characteristics That Foster Disruptive Innovation.

Disruptive Innovation in Healthcare

In recent years, we have seen many efforts to transform the healthcare industry, yet performance, cost, and reimbursement issues remain problematic for the industry (see the chapter “Reimbursement Strategies and CPT Codes for Device Development”). Clearly, the healthcare industry is complex and interconnected, thus different stakeholders have to deploy innovative methods to alleviate issues that are prohibiting efficiency and care quality. Beyond providers and insurers, innovation in clinical and research settings is necessary to drive healthcare reforms forward. In healthcare, disruptive innovation is more specifically defined as the process of making changes, whether large or small, radical or incremental, to products, processes, and services that result in the introduction of a novel solution for an organization that adds value to the care received and contributes to the knowledge store within and across organizations (O’Sullivan and Dooley). An innovative idea brings change to the current healthcare landscape by introducing new or different roles for people, different workflows or processes, or new tools or modifications to existing ones, either through instant or long-term implementation (O’Sullivan and Dooley). By creating disruptive innovation, coupled with the resilience to handle the risks and uncertainty that comes along with it, an academic entrepreneur can create a positive impact in the ever-changing and uncertain healthcare sector.

The U.S. healthcare industry, worth \$3.3 trillion, represents almost 17.9% of the U.S. economy and involves millions of individuals from many disciplines. Different stakeholders, from healthcare payers to clinical researchers, are creating disruptive innovations that are transforming the United States' healthcare system. The role of innovation becomes increasingly important as demands for lower costs and better patient outcomes increase. In order for a disruptive innovation to be successful, it is necessary to create a solution that allows all players to thrive. To achieve this, academic entrepreneurs have to integrate their disruptive innovations into the existing models of healthcare. In addition, these institutions will have to adjust their care delivery approaches to accommodate these changes. For example, new research developments can lead to technologies that displace an existing clinical service line that is less pertinent and/or more costly. The resulting new clinical services may also reduce or alter an existing revenue stream for the healthcare institution. An example of disruptive innovation that will be discussed in detail later in the chapter is the change in the diagnostic procedures performed at the Sleep Medicine Program at the University of Pennsylvania in response to the advent of new portable sleep study technology.

Currently, stakeholders are mostly focused on minimizing costs in healthcare to make it more affordable and accessible by streamlining procedures and changing the payment model. While these costs can be reduced at several points in the system, the most effective and feasible solutions will 1) implement technologies that treat diseases that would have originally required a physicians' involvement, by enabling the procedures to be performed in a less expensive and more efficient way; 2) encourage innovative business models within and outside institutions to ease addition of value-adding procedures in an organized manner; and 3) establish a network that will allow different stakeholders in the healthcare system to share data and learn from each other (Christensen et al.; Hwang and Christensen).

Resilience as a Core Component of Disruptive Innovation

To achieve the promises of disruptive innovation, an academic entrepreneur must have not only the technical skill set to invent but also the resilience and adaptability to handle the invention. Disruptive innovations can be upsetting because they challenge the established norms and systems that exist in healthcare. These innovations can disrupt physicians' practices, hospitals' service delivery models, payers' payment systems, and more. Clinical innovations can further challenge the standards within an organization's operation and structure. Investments in equipment, technology, and staff will have to be reconsidered if practices change. This impact will often cause health systems to reconsider and develop new strategic plans to adapt to the internal changes brought about by disruptive innovations. Therefore, to foster innovation, an academic entrepreneur has to possess the ability to tolerate negativity and failure as well as to gather insights and recover from setbacks. This can be accomplished through applying the following three key lessons: 1) diversification of financial resources, 2) focusing time and effort, and 3) networking.

Diversification of financial resources

Existing/ongoing financial commitments, debt (heavily leveraged organizations), and overreliance on a few sources of income can reduce an organization's ability to tolerate disruption. In a similar way, this can apply for an academic entrepreneur if they rely on only one funding agency, or have numerous staff. It is, therefore, important to diversify services as well as financial resources to enhance tolerance of failure. Recently, academic funding has begun to rely more and more on industry support in addition to federal funding sources. For example, a research lab focusing on a specific pathway for an oncology treatment could obtain federal funds from the National Institutes of Health (NIH) as well as commercial funding from a strategic alliance with a biopharmaceutical company. In clinical settings, funding streams can come from multiple insurance payers and from a varied range of clinical services. In addition to diversifying financial streams and support, one has to plan ahead to avoid a lack of research funding brought about by delays in the federal funding approval process. Specifically, the academic entrepreneur will have to take into account the low funding rate of new grant applications and obtain funding far in advance since applications for federal funding may require a significant amount of time. Since industry partnerships can in some cases be approved more quickly than federal grants, these can be useful to create a balanced funding portfolio for a lab.

Focusing time and effort

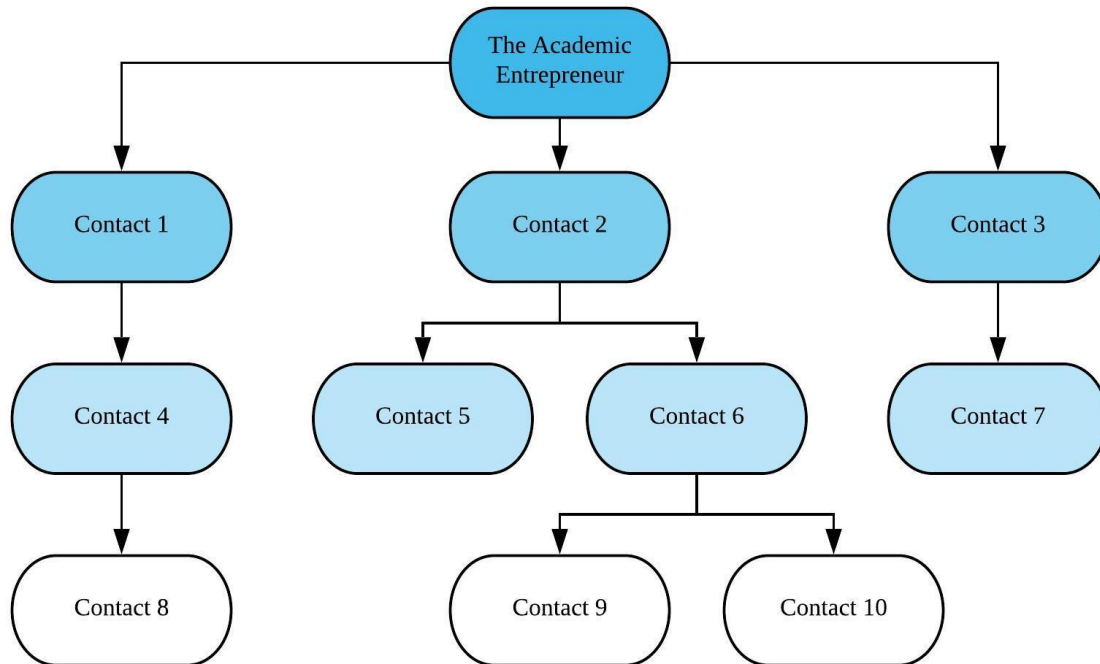
In order to drive a disruptive innovation into the healthcare system, an academic entrepreneur has to be able to focus their efforts and yet know when to disengage if necessary. Time is a finite resource. To make significant progress, one has to dedicate time and energy into the research projects they think will provide the most value. Assessment strategies that apply an objective lens are crucial in assessing and reviewing a project. An academic entrepreneur will have to compare current progress to objective benchmarks, set up an organized structure for external feedback, and reassess the project periodically, in order to know when to stay engaged, pivot, or end the project.

Networking

Networking—forming strategic alliances with individuals, experts, and organizations—can provide significant opportunities for an academic entrepreneur's idea to develop (see the chapter “Forming and Maintaining Meaningful Partnerships Between Academic Scientists and Corporations”). Fostering a large network of contacts with diverse expertise and complementary skills will enable one to gain different perspectives and approaches to their project, as shown in Figure 2. To maximize the value of one's network, it is also important to engage in face-to-face conversations with contacts rather than simply communicating online. A useful strategy is to identify two new potential contacts from each meeting by asking for suggestions on who else would be helpful in your network. In the example below, the meeting with Contact 2 led to two new contacts, Contacts 5 and 6, and was more productive than the meetings with Contacts 1 and 3. In addition, it is crucial to reach out beyond one's comfort zone and form partnerships with individuals in very diverse areas. It is typical to network primarily within one's division, or at an academic

conference with others in the same discipline. Yet the true potential for innovation is most effectively realized when one can engage with a collaborator in a completely different field. Seeking out these opportunities is not easy, but can offer the greatest reward.

Figure 2. Building a Diversified and Branching Network of Alliances.



Current State of Disruptive Innovation

While healthcare has been resistant to changes that may seem disruptive, there are several trends indicating that the sector is accelerating the emergence of disruptive innovations in clinical and research settings. The main trends are the shifting focus of services, the increase in cross-industry collaboration, and increasing tools and financial avenues to support such innovations.

On a larger scale, organizations are focusing more on providing value-based services for specific patient populations. The shift toward value-based healthcare opens up opportunities for the healthcare industry to use disruptive innovation to push for better outcomes, quality of care, and cost measures instead of pure volume (Hwang and Christensen). An example of an initiative that is investing in value-based healthcare is the Centers for Medicare and Medicaid Services (CMS)'s \$100 billion investment over ten years for innovation efforts to use value-based payment models, including the Bundled Payments for Care Improvement and the Medicare Shared Savings Program ("Bundled Payments for Care Improvement (BPCI) Initiative: General Information"). The market pressure from dominant payers enables the entire healthcare industry to focus on optimizing outcome and values. The move from a fee-for-service to a fee-for-value system will require

fundamental changes in the clinical settings. Thus, primary care providers, specialists, and hospitals are increasingly considering the end user, prompting a shift of focus to accountability for patient outcomes.

Zooming in to a more micro-level view, there is an increasing number of academic and industry collaborations through licensing or sponsored research agreements. These alliance partnerships between an academic institution and a dominant industry player can tremendously accelerate research and development to mature technologies into viable treatments for unmet needs (see the chapter “Identifying Unmet Needs: Problems that Need Solutions”). The CAR-T research and development alliance between the University of Pennsylvania and Novartis demonstrates this symbiotic partnership that accelerated the disruptive innovation of patient-oriented genetic therapy in oncology. Alliances foster and encourage more individuals to participate in academic innovation and entrepreneurship (see the “Post Alliance and Sponsored Research Agreements” chapter).

In addition, the introduction of programs, tools, and financial programs that support innovation in clinical and research settings has significantly eased the cost burden for an institution and/or the academic entrepreneurs themselves. The National Science Foundation’s Innovation Corps (I-Corps) program was created in 2011 and has been adopted by many top universities to offer scientists and engineers an opportunity to translate their research projects to commercialized goods or services that can demonstrate economic and societal benefits (see the chapter “I-Corps as a Training Tool for New Technology Development”). Utilizing I-Corps, an academic entrepreneur can gain insights and skills in entrepreneurship to support their innovations. Lastly, since capital is crucial in stimulating technological innovation, the increase in financing options and innovation investments makes it easier for academic entrepreneurs to follow through on their novel ideas. While previously there were limited options for an academic entrepreneur to finance their ideas and innovations as a startup, the number of private investments from angel investors, venture capitalists, and large biopharmas in the healthcare industry has increased significantly (see the chapters “Angel Investors” and “Seeking Venture Capital Investment”). Additionally, grants from the NIH such as the Small Business Innovation Research (SBIR) and Small Business Technology Transfer (STTR) grants (see the chapter “SBIR/STTR Grants: Introduction and Overview”) have facilitated the funding of studies and clinical trials to accelerate innovative ventures.

Case Study: Sleep Medicine—Dealing with a Paradigm Shift

While sleep is a fundamental part of our biology, the study of sleep and the field of sleep disorders medicine are relatively new. In 1991, the Center for Sleep and Circadian Neurobiology was established at the University of Pennsylvania. Over the course of seven years, studies conducted in the sleep lab network grew nearly sixfold, and the number of studies increased from 1,000 to 5,500 per year. While the great majority of these early studies were primarily in-lab (i.e., conducted in

the clinic or hospital), home studies were being developed and gradually adopted. New technology development, research validation of the technology, and standardization of the home sleep-study testing infrastructure, especially for sleep apnea, eventually accelerated. With the creation of portable sleep study units, diagnostic costs were reduced by approximately three- to fivefold relative to in-lab studies. Although less data was being collected from home sleep studies, results were sufficient to diagnose sleep apnea in patients, based on a growing body of research. While stakeholders knew about the potential disruptive innovation of home sleep studies for years, it always seemed on the distant horizon. Unfortunately, the actual transition itself happened within months, when insurance payers decided to implement pre-certification procedures for in-lab studies and instead to encourage the use of home sleep studies. This had a large impact on the revenue model for sleep labs due to the fixed costs for overnight in-lab facilities and the reduction in income. Several large sleep lab programs went bankrupt due to their debt load and lack of financing options and had to shut down entirely. The Penn Sleep Center was under significant pressure to revise its infrastructure.

In order to cope with this disruptive innovation—home sleep studies—the Penn Sleep Center made several fundamental changes (Pack). This included developing its capacity for home sleep studies, closing costly facilities (since the division had avoided long-term lease contracts, they were able to rapidly downsize facilities), and reducing the number of beds for in-lab studies. The size of technologist staff was also reduced, which can be a significant downside of disruptive innovation for the workforce. To minimize added staff stress, this was done quickly rather than prolonged over time. The pre-certification process was centralized, and staff were quickly informed about these initiatives. Some sleep technologists were moved into pre-certification to respond to the increased consult demand for home sleep studies. An overview of the change in models is described in Table 1 below. These changes to the clinical practice also had downstream consequences to the research program, such as the need to adapt to home sleep study data as well as in-lab sleep data.

Table 1. Clinical Models of Diagnosing Sleep Apnea.

Previous model	Innovative model
In-lab diagnostic: patient comes to sleep lab for an overnight diagnostic sleep study	Home diagnostic: portable sleep unit sent to patient's home by mail, is applied by the patient at home, then returned by mail.
Continuous positive airway pressure (CPAP) treatment data is collected using data cards that must be removed from the units by the patient, brought to the clinic, then downloaded for analysis in clinic	CPAP data is collected wirelessly and transmitted to a cloud repository for access by providers, and can also be viewed by the patient via a smartphone app or web browser.
Modification to CPAP device settings must be done via the physical data card which must be transported to and from the clinic or equipment provider	Modification of CPAP device settings can be done wirelessly via the web interface

Conclusion

As demonstrated by the sleep medicine case study, disruptive innovation is transforming the field of healthcare and the ways both academics and providers conceptualize it. A reimagining of healthcare is crucial because it allows for an improved system that can provide value-based care for patients as well as minimize costs for various stakeholders. Drawing from the different benefits of this new approach, the academic entrepreneur should be equipped with the skills and mindsets—such as the ability to network and manage risks, as well as the financial foresight—to further propel these innovations and help them reach fruition. Furthermore, the academic entrepreneur should develop resilience and tolerance for failure, as this will allow them to handle disruptive innovation. The changing paradigms that are becoming more patient focused create opportunities for academic entrepreneurs to move technological approaches into therapy.

Obtaining expert counsel

To learn more about disruptive innovations and develop the skills to handle them, an academic entrepreneur can seek out advice from peers in other divisions who may have experienced disruptive innovation in their workplace. Universities often have affiliated business schools, which may have faculty who are experts in the field. Additionally, innovation centers are becoming more common in universities, including within affiliated health systems (see the chapter “Resources at Academic Entrepreneurship Centers”). These innovation centers may have programs that assist and advise academic entrepreneurs in developing their ventures and address any unexpected challenges that may arise.

Practical Guides/Worksheets

A Nine-Point Checklist to Check Your Resilience for Academic Entrepreneurship: How Resilient Are You?

- Is your research funding coming from multiple sources?
- Would you be able to take a one-month sick leave and would your team be able to continue the research work?
- Do you have a network/contacts in multiple outside departments and/or divisions of the health system or other schools within the university or industry?
- From a clinical perspective, does your clinical success rely on several procedures?
- Does your role/job provide you with the flexibility to partner with other academic institutions or companies related to your field of research?
- Does your organization/institution allow you to dedicate sufficient time to your research/clinical project?
- Are you mentally comfortable shutting down a project that is not meeting the expected objectives or benchmarks?
- Can you participate in programs that assist and advise in innovation and entrepreneurship?

- Do you have a good work-life integration that allows you to have sustained engagement in your career?

If you can tick off most of these boxes, that is consistent with a relatively high degree of individual resilience.

Resources

1. “What Is Disruptive Innovation?”
 - a. This article by Christensen, Raynor, and McDonald, discusses how the term disruptive innovation was first coined by Clayton Christensen, based on his research in the disk-drive industry. The theory explores a phenomenon in which an innovation transforms an existing sector where high costs and complexity are valued through increasing simplicity and affordability. The new product or service grows and then takes over the industry as the new standard.
 - b. Article available at: <https://hbr.org/2015/12/what-is-disruptive-innovation>
2. *The Innovator’s Dilemma*
 - a. This book by Christensen is about how innovation occurs in various industries and how to embrace this for success.
3. “5 Ways to Drive Disruptive Innovation in Healthcare”
 - a. This article by Kaplan describes how the healthcare industry is in prime condition for disruptive innovation. The high costs and complexity of the system give room for improvements that can make it more efficient and more affordable.
 - b. Article available at: <https://www.inc.com/soren-kaplan/5-ways-to-drive-disruptive-innovation-in-healthcar.html>
4. *The Innovator’s Prescription: A Disruptive Solution for Health Care*
 - a. This book by Christensen and colleagues applies disruptive innovation to health care and discusses strategies to improve affordability.
 - b. Video summary about the book:
https://www.youtube.com/watch?v=tmKqt6jf_H0
5. “Building a Resilient Organizational Culture”
 - a. This article by Everly is about how organizational resilience can cultivate innovation and manage failure.
 - b. Article available at: <https://hbr.org/2011/06/building-a-resilient-organizat>
6. *One Mission: How Leaders Build a Team of Teams*
 - a. This book by Fussell, Goodyear, and McChrystal discusses strategies for unifying teams, especially those who are isolated and distrustful.
7. *Grit: The Power of Passion and Perseverance*
 - a. This book by Duckworth explores the hypothesis that what drives success is not “genius” but “grit,” which is a combination of passion and long-term perseverance.

8. *Option B: Facing Adversity, Building Resilience, and Finding Joy*
 - a. This book by Sandberg and Grant gives lessons on resilience that can be applied to diverse situations.

References

- “Bundled Payments for Care Improvement (BPCI) Initiative: General Information.” *Center for Medicare & Medicaid Innovation*, 17 Apr. 2019, <https://innovation.cms.gov/initiatives/bundled-payments/>.
- Christensen, Clayton M., et al. *The Innovator’s Prescription: A Disruptive Solution for Health Care*. McGraw-Hill, 2009, <https://www.hbs.edu/faculty/Pages/item.aspx?num=35729>.
- Hwang, Jason, and Clayton M. Christensen. “Disruptive Innovation in Health Care Delivery: A Framework for Business-Model Innovation.” *Health Affairs*, vol. 27, no. 5, Sept. 2008, pp. 1329–1335, doi:10.1377/hlthaff.27.5.1329.
- O’Sullivan, David, and Lawrence Dooley. *Applying Innovation*. SAGE Publications, 2009, doi:10.4135/9781452274898.
- Pack, Allan I. “Sleep Medicine: Strategies for Change.” *Journal of Clinical Sleep Medicine: JCSM: Official Publication of the American Academy of Sleep Medicine*, vol. 7, no. 6, Dec. 2011, pp. 577–579, doi:10.5664/jcsm.1450.

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