Chapter 8

When patients become innovators

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Abstract

Patients are increasingly able to conceive and develop sophisticated medical devices and services to meet their own needs - often without any help from companies that produce or sell medical products. This "free" patient-driven innovation process enables them to benefit from important advances that are not commercially available. Patient innovation also can provide benefits to companies that produce and sell medical devices and services. In this article, we look at two examples of free innovation in the medical field - one for managing type 1 diabetes and the other for managing Crohn's disease. We will set these cases within the context of the broader free innovation movement that has been gaining momentum in an array of industries and apply the general lessons of free innovation to the specific circumstances of medical innovation by patients.

Keywords: Free innovation; Medical innovation; Medical devices; User Innovation; Patient Innovation

1 Introduction

Patients are increasingly able to conceive and develop sophisticated medical devices and services to meet their own needs - often without any help from companies that produce or sell medical products. This "free" patient-driven innovation pro-cess enables them to benefit from important advances that are not commercially available. Patient innovation also can provide benefits to companies that produce and sell medical devices and services. For them, patient do-it-yourself efforts can be free R&D that informs and amplifies in-house development efforts. In this article, we will look at two examples of free innovation in the medical field - one for managing type 1 diabetes and the other for managing Crohn's disease. We will set these cases within the context of the broader free innovation movement that has been gaining momentum in an array of industries (von Hippel, 2016) and apply the general lessons of free innovation to the specific circumstances of medical innovation by patients.

1.1 Managing type 1 diabetes

In 2013, Dana Lewis, a professional in health communications in her 20s, joined forces with a software engineer and a few other individuals with type 1 diabetes to develop for themselves what the medical device industry had been promising to deliver for decades: an artificial pancreas. As patients, they sought to solve the problem of low overnight blood sugar levels, a

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common occurrence that can be deadly. They wanted to design a system that could automatically monitor blood sugar levels every few minutes and provide the right insulin dose to keep the number in a healthy range.

Within months, Lewis and her co-innovators designed an artificial pancreas that used computer code they wrote themselves and off-the-shelf hardware to connect commercially available continuous glucose monitors with commercially available insulin pumps. The device significantly improved Lewis's ability to manage her own blood sugar levels. She and her colleagues decided to make the design available to others online and make their software open source. This was the start of the Open Artificial Pancreas System (OpenAPS) movement (https://openapps.org). Today, multiple communities participate in this movement, multiple noncommercial DIY artificial pancreas designs are being shared, and thousands of individuals with diabetes use these DIY systems daily to monitor, manage, and improve their health.

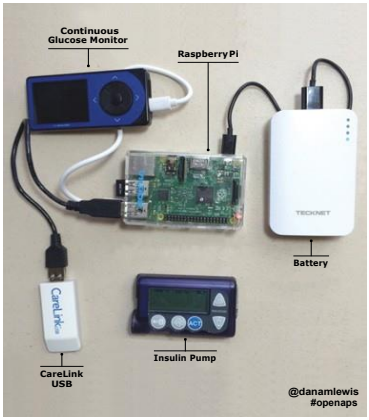

Figure 13: A DIY artificial pancreas

1.2 Managing Crohn's disease

Sean Ahrens, a computer science and business graduate from the University of California, Berkeley, became frustrated in his early 20s that there wasn't any detailed medical information on what he could do to minimize debilitating flare-ups from Crohn's disease. Although several drug treatments for Crohn's existed, all of them had significant toxicities and none was effective for every patient. As a result, many people tried to manage and reduce their symptoms through dietary choices. To fill a resource gap for patients, Ahrens, who was diagnosed with Crohn's when he was 12, created a website in 2011 called Crohnology, where fellow patients were invited to share their experiences regarding interventions and outcomes through an online questionnaire. The site compiled the data so that everyone could see which factors others found troublesome and which were helpful (https://chronology.com). Today, the site has more than 10,000 registered users. Crohn's patients throughout the world have come to find the information invaluable for managing their chronic disease.

2 The general practice of free consumer innovation

What is striking about both of these cases is that neither commercial medical producers nor the clinical care system offered a solution that these patients urgently needed. Motivated patients stepped forward to develop solutions for themselves, entirely without commercial support (Lewis, 2018).

Free innovation in the medical field follows the general pattern seen in many other areas, including crafts, sporting goods, home and garden equipment, pet products, and apparel (von Hippel, 2016). Enabled by technology, social media, and a keen desire to find solutions aligned with their own needs, consumers of all kinds are designing new products for themselves (see "About the Research").

Consumers innovate and diffuse their innovations in ways that are very different from producers, and it is important to understand the differences (see "Consumer Versus Producer Innovation," p. 84). Unlike traditional producers, who start with market research and R&D, free innovation begins with consumers identifying something they need or want that is not available in the marketplace. To address this, they invest their own funds, expertise, and free time to create a solution. Rather than seeking to protect their designs from imitators, as commercial innovators do, we found that more than 90% of consumer innovators make their designs available to everyone for free. What's more, they let other people test and improve on the initial design and make the new version available for free as well. Once a design is fully developed, it gets diffused still further, allowing consumers to make their own noncommercial copies, and allowing producers to commercialize the designs without having to license them from the consumer innovators[1].

You might wonder why individuals would bother to invest time and money in innovations without any expectation of being paid foreither their labor or their product designs. The answer is simple: Consumers who innovate are attracted by the personal benefits, such as the opportunity to use their innovations and the fun and learning they gain from the process of developing them. They also get satisfaction from sharing their innovations with people with similar needs (de Jong et al., 2015). In other words, they are self-rewarded.

As different as the consumer and commercial paradigms are from each other, they are complementary rather than opposing. Indeed, research shows that consumers, producers, and society at large are best served when both paradigms are used simultaneously (Gambardella et al., 2017). Producers can benefit from consumer innovation by adopting consumer product designs developed and tested by consumers for free; consumers benefit from producer-developed modules for DIY projects such as Raspberry Pi microcomputers and also from producer-

[1] A small number of consumer innovators take steps to protect their innovations from free copying, using patents and other means, and then try to sell them. Surveys show that these innovators (making up less than 10% in our re- search sample) follow the "producer paradigm" path and become entrepreneurs. Both the entrepreneurs and pro- ducers look for unmet needs and then invest in R&D to develop products and services that are likely to become profitable.

developed innovations that serve mainstream needs. And, of course, society as a whole benefits when consumer and producer innovators focus on what they do best and most efficiently[2].

Table 1: Sharing Crohn's disease information globally; Source: chronology.com

TOP MEDICATIONS	**Remicade**	★★★★	2,698 people
	Prednisone	★★★★	4,783 people
	Imuran	★★★★	2,355 people
TOP DIETS	**No Beer**	★★★★	2,348 people
	No Dairy	★★★★	2,010 people
	No Spicy Food	★★★★	1,936 people
TOP SUPPLEMENTS	**Vitamin B12**	★★★★	2,536 people
	Vitamin D	★★★★	3,165 people
	Probiotics	★★★★	3,095 people

3 Applying the ideas of consumer innovation to health care

Surveys show that medical-device development by patients is taking place on a massive scale. In nationally representative surveys conducted from 2010 to 2015 in the United States, the United Kingdom, Japan, Finland, Canada, and South Korea, approximately 1 million individuals reported that they had developed medical innovations to serve their own needs in the three years preceding the surveys[3]. Although the basic practices underlying free consumer innovation apply across sectors, innovators must make adaptations for their own personal and market environments. In the case of patient innova- tion, the most important adaptations have to do with ensuring safety and supporting free diffusion.

When a medical product that meets patient needs is available on the market, patients often prefer to buy that product rather than developing their own or copying another patient's free design. However, if a solution isn't available commercially and the need is urgent, many try to design and build their own product. Things patients need may not be profitable to produce for reasons including the following:

[2] Consumers, being self-rewarded, tend to pioneer new products and appli- cations. Since they give away their designs for free, they are not concerned with how much demand they generate from others. In contrast, producers prefer to enter markets after consumers have pioneered prod- ucts. They can then evaluate the reactions of free adopters to consumer-developed innovations and better understand the likely extent of market demand (von Hippel, 2016).

[3] The country surveys used a standard definition for medical innovations. Each had to be a new or modified product for personal or family use, developed by patients or their nonprofessional caregivers, and provide improvements over products already available on the market. Innovations that individuals developed at home for their jobs or for sale, or were paid to develop, were not included. See C. von Hippel, "A Next Generation Assets-Based Public Health Intervention Development Model: The Public as Innovators," Frontiers in Public Health, Sept. 4, 2018.

- Thousands of rare diseases are chronic and challenging for patients to manage on a long-term basis. In many instances, the diseases afflict rela- tively few patients and represent markets that are too small for producers to profitably serve.
- Often, even when a large number of patients have the same need, producers don't have sufficient incentive to innovate because there's no good way for them to profit from the type of solution that's needed. Crohn's disease offers a case in point. As useful as it may be for Crohn's patients to manage and reduce their symptoms through diet, getting companies to invest in the clinical trials is a hard sell. They would want to recoup the costs via patented food products or other measures.
- Even if an innovation can be protected and is potentially profitable, the regulations governing clinical trials tend to make it costly and slow for producers to get approvals. For example, in the United States, getting Food and Drug Administration approval for a device of low or moderate risk takes an average of 10 months. Approvals for high-risk devices - such as an artificial pancreas - could take four to five years and cost $75 million (Makower et al., 2010). As demonstrated by the history of the patient-developed artificial pancreas, patient innovators (whose noncommercial activities are exempt from FDA regulation) may be able to develop and produce something in a matter of weeks or months, at very little cost.

One or more of these constraints can inhibit the commercial provision of many things that patients need. This makes the free patient innovation system a critical resource that must be recognized and supported.

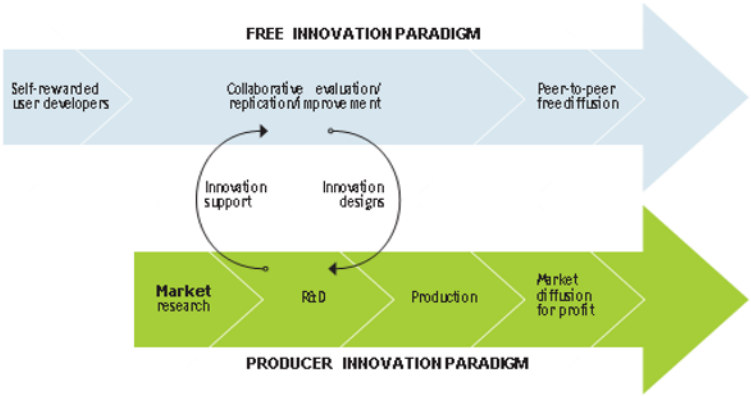

Figure 2: Consumer versus producer innovation; E. von Hippel, Free Innovation, 2017

4 Supporting patient innovation

Would-be patient innovators grapple with important questions about legality and safety, what the future of patient innovation looks like, and how the DIY system can be supported and improved. We address these questions here.

Is it legal for patients to develop and diffuse DIY medical innovations? Different countries have different laws regarding patient-developed innovations, although many Western countries follow similar guidelines. In the United States, freedom for patients to innovate is firmly rooted in the country's legal traditions. Under the U.S. Constitution's Fourth Amendment, which enshrines the right toprivacy, citizens may create medical innovations at home and use them on themselves. This right is protected whether others consider an innovation to be effective or ineffective or its use wise or unwise. The First Amendment, moreover, protects the right to free speech, thereby entitling people to tell the world about their innovations and to share details about designs and their use. In addition, the Commerce Clause of the U.S. Constitution and the governing statutes of federal regulatory agencies such as the FDA restrict agencies from regulating noncommercial activity.[4]

Is patient innovation safe? It's important to acknowledge that safety is not guaranteed. For example, a software coding error in the design of an artificial pancreas could lead to dangerous miscalculations in a patient's insulin dose. Such an error would be far more serious than, say, erroneously advising a Crohn's patient to avoid drinking beer. Offsetting this sort of risk is the fact that very few patient-created medical innovations fall into the highest FDA risk category.[5] Even in cases where there are significant safety risks, we think it would be a mistake for governments to limit patient innovation. In our view, there are two compelling reasons to encourage it.

First, the proper way to evaluate the dangers of patient innovation is to compare the risks patient DIY devices pose with the harm patients suffer when no such innovation exists. Consider again the artificial pancreas. Once building one became technically possible, it was hard to overlook the fact that the lack of an FDA-approved commercially available product contributed to the deaths from hypoglycemia of thousands of people with diabetes and a worsened quality of life for thousands more suffering from the disease (Seaquist et al., 2013).

In other words, when patients innovate to address medical problems unserved by commercial solutions, we may well see that their innovations provide a net gain rather than a loss in safety and quality of life for the whole population of affected patients. We expect safety will improve further as low-cost clinical trial methods are developed to enable patient communities to test their own innovations, utilizing similar ethical standards to those used by hospitals and universities for clinical research involving human subjects. (See "Low-Cost Clinical Trials by and for Patients.")

Second, as already noted, individual patients have the legal right to make their own choices, and these rights are very broad. By way of comparison, extreme sports are widely recognized as risky - those who participate in them can face injury or even death. Yet, in the name of personal freedom, society doesn't ban people from taking part in ex- treme sports. Similarly, some patient innovators will develop devices that could be seen as overly risky. But society shouldn't use that as an excuse for banning patient innovation.

[4] Sharing information about medical innovations for free is not a commercial activity. However, it is not legal for medical patient innovators to sell copies of their innovations to others without first receiving FDA clearance. See A.W. Torrance and E.A. von Hippel, "The Right to Innovate," Michigan State Law Review, no. 2 (2015): 793-829.

[5] According to the U.S. Food and Drug Administration, the devices (called Class III devices) "usually sustain or support life, are implanted, or present potential unreasonable risk of illness or injury."

What does the future of patient innovation look like? The ability of patients to develop new medical products to serve their own needs is growing, and we expect the system to become stronger over time for several important reasons. First, the DIY design tools that patient innovators need are becoming cheaper and increasingly capable. People with fairly rudimentary engineering skills can acquire powerful design software that can run on an ordinary personal computer either for free or for very little money. Second, the materials and tools used to build products from DIY designs are also becoming both cheaper and increasingly capable. For example, the original DIY artificial pancreas system design used a microcomputer that sells for about $30 today. Newer DIY solutions don't require a special-purpose computer at all, instead using smartphones and specially designed apps[6]. Third, the search and connection functions of today's internet enable patients - even those with extremely rare diseases - to find others with similar problems throughout the world. Patients and caregivers can collaborate online to build DIY projects. Indeed, thousands of patients have found their way to the OpenAPS and Crohnology websites, and many people have contributed their technical skills.

How can the free grassroots patient innovation system be supported and improved? We believe that patients, medical product and service producers, and government regulators should all support the patient innovation system and help it develop in medically and socially valuable directions. How can this be done?

At present, the early stages of the patient innovation process seem to be working well. It can leverage the same tools and systems used for consumer innovation in other fields - everything from open-source software development to hardware hacking in maker spaces. However, clinical testing and certain aspects of free diffusion are unique to medical innovation. These elements require special attention and improvement, and that's where innovating patients, commercial producers, and governments can all play a role.

4.1 Improving clinical testing

In the case of clinical trials, patient innovators cannot simply adopt FDA gold-standard trial designs. These designs - including randomized double-blind placebocontrolled trials - are generally too expensive for patient communities to conduct on their own. However, less elaborate designs can produce high- quality results at much lower cost and in less time[7]. Support for improvements here would involve creating websites and tool kits to provide guidance to patients who have little knowledge of trial design, appropriate privacy and safety standards for trial participants, and statistical analysis (much as other websites help software development newbies set up open-source projects with pretested tools and procedures). Such tool kits are being developed by DIY patient communities and offered by commercial sites like ProofPilot (https://proofpilot.com) to support both commercial and community experimentation.

4.2 Improving diffusion

Since patient innovations are exempt from FDA regulation only if they are diffused noncommercially, patients must make their own noncommercial copies from free designs. Given this

[6] An example is the RileyLink, "the communication highway between your insulin pump, CGM, and iPhone"; see "RileyLink."

[7] For example, n-of-1 clinical trial designs are applicable to many patient innovations; see "Low-Cost Clinical Trials by and for Patients."

restriction, how can noncommercial diffusion be simplified to make innovations more accessible to individuals who lack technical skills?

We see some promising opportunities in taking advantage of increasing openness of governmentapproved medical devices to DIY attachments and in the increased availability of commercial off-the-shelf, open-source components suitable for DIY projects. Consider the artificial pancreas project. In 2013 commercial medical devices such as continuous glucose monitors and insulin pumps were designed to protect the data these devices collected on patients, using encryption. Patients didn't have access to their data because the assumption was that only doctors would understand it and have use for it. As a result, innovators had to find ways to hack the devices to gain access to their own patient data, overriding the producer's intent. Today, device makers have incentives to make their interfaces open so that they can be a valued part of DIY systems[8].

As the benefits of patient-developed innovations become increasingly evident, many new types of specialized platforms and services to support free diffusion are likely to emerge. For example, Patient Innovation, a nonprofit online platform devoted to facilitating the evaluation and sharing of innovative solutions developed by patients with any disease, is available for free[9]. It complements special-purpose platforms like OpenAPS and Crohnology.

As the free patient innovation system expands and strengthens over time, we expect to see greater complementarity between it and the commercial medical innovation systems. Patients, medical product and service producers, and government regulators all have vital roles to play in supporting the free patient innovation system and helping it develop in medically and socially valuable directions. The economic reality is that commercial producers and medical service providers will never be able to deliver everything patients need. Innovative patients can fill many of the gaps if they are properly supported. A richer set of available medical innovation options will benefit patients, commercial medical caregivers, producers, and society at large.

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[8] South Korean insulin pump producer SOOIL Development has done this, and Dexcom, a producer of continuous glucose monitors based in California, has made a similar move. See M. Hoskins, "News: New Dana RS Insulin Pump Embraces #WeAreNotWaiting Open Design!" Diabetes Mine (blog), Sept. 12, 2017, www.healthline.com; and A. Tenderich, "News: Dexcom Opens API to Embrace Collaborative Diabetes Innovation!" Diabetes Mine (blog), Sept. 20, 2017.

[9] The Patient Innovation platform was recognized in 2016 by United Nations Secretary-General Ban Ki-moon for supporting the UN Sustainable Development Goals of promoting good health and well-being (SDG3) and fostering innovation and building resilient infrastructure (SDG9); the U.N. goal itself, however, is to "ensure healthy lives and well-being at all ages."

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