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The influence of risk classification and community affiliation on the acceptance of user-innovated medical devices

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Abstract

User innovation contributes significantly to societal advancement, particularly in developing novel products and services, offering substantial financial potential, and fostering the common good. This is particularly evident in medical science, where it addresses diverse needs and is often shared at minimal or no cost. However, the diffusion of user-innovated products remains limited and research on the perception of user-innovated products is rather scarce, reducing their potential contributions to the common good. This paper investigates end-users' perceptions of user innovation, a critical yet underexplored aspect of diffusion. Specifically, using a mixed-methods approach, we examine the influence of product risk classification and community development on the perception of user-innovated medical devices. This study combines qualitative research through semi-structured interviews (n=5) and quantitative research using a 2x3 (User Innovation vs. Producer Innovation; Product risk classification I, II, III) between-subject experiment (n=301). Our findings reveal that end-users evaluate user-innovated and traditionally-innovated products differently based on various criteria. User-innovated products are perceived as more pleasant and attractive, while traditionally-innovated products are viewed as safer and of higher value. This effect is more pronounced for products with higher risk classifications. However, the perceived lower safety and value of user innovation products result in a reduced willingness to purchase among end-users. Additionally, we find that community-developed user-innovated products consistently outperform in all evaluation categories compared to "pure" user-innovated products.

Keywords: User Innovation, Medical Engineering, Diffusion of Innovation, MMR, Consumer Acceptance

1 Introduction

When a company or individual innovates for their own benefit rather than for direct commercial gain, it is referred to as user innovation von Hippel (2005) and a central component of overall innovation activity.

Representative studies from the UK, US, and Japan show that in these states, an estimated 20 million people engage in user innovation activities, with budgets amounting to the equivalent of several billion euros (Ogawa and Pongtanalert, 2011).

Innovation occurring for profit rather than for personal use is considered the classic or traditional innovation paradigm, also often referred to as producer innovation. Even though Schumpeter formulated it as early as 1934, many guidelines and laws are still based on it today. However, a paradigm shift from classic to open and user-centered innovation has been underway for some time (Baldwin and von Hippel, 2011), with user innovation as a critical component. This shift is driven by increasingly heterogeneous needs and markets (Shah and Tripsas, 2007), the rising level of education among the population (von Hippel, 2005), and the growing ease of innovating on a small scale (Baldwin and von Hippel, 2011; Fuchs and Schreier, 2011).

User innovation generates significant social benefits. In addition to commercial aspects such as reducing deadweight loss (von Hippel, 2005), empathetic and altruistic motivations lead to free innovation, in which individuals with special needs support one another (Göldner et al., 2019). Moreover, user innovation holds substantial financial potential for user innovators, manufacturers, and end-users (Gambardella et al., 2017; Franke and Lüthje, 2020).

Despite its advantages, the diffusion of user innovation remains low. Only 5–17 % of user innovation is eventually shared with others, and the adoption rate is similarly low, ranging from 5–21 % (Ogawa and Pongtanalert, 2011; von Hippel et al., 2012).

As the barriers to innovation and commercialization of user innovation have been extensively studied, this paper focuses on the final step of diffusion: the acceptance of user innovation by end-users. The main research question is:

> *Do potential customers perceive user innovation as such, and how does this perception influence their product evaluation?*

In this study, we delve into an underexplored domain of user innovation, specifically focusing on "pure" user innovations (Ehls et al., 2020). While there is a rich array of studies examining market adoption of products with user involvement in innovation, as summarized by Cui and Wu (2018), the landscape of findings is somewhat fragmented. Notably, co-creation has been the focal point of many studies. For instance, research has shown varying degrees of customer willingness to pay for products that have been ideated or selected by users (Fuchs and Schreier, 2011; Schreier et al., 2012; Hautz et al., 2014; Franke et al., 2009; Dahl et al., 2015). However, this willingness does not always translate into market adoption (Dahl et al., 2015; Hautz et al., 2014; Franke et al., 2009).

These studies predominantly revolve around co-creation, where users have a partial role in the innovation process, and the producer retains control over manufacturing and sales. This leaves a gap in understanding the dynamics of pure user innovations, where users are at the helm of both innovation and diffusion.

Our research aims to shed light on the factors influencing the acceptance of user innovations in medical devices, where users drive both the innovation and its diffusion without producer involvement. Moreover, we explore the role of risk classification in adoption decisions, an aspect that warrants attention given the critical nature of medical devices. Lastly, we investigate the impact that community-driven innovation has on consumer perception. Specifically, we analyze how the knowledge that an innovation was nurtured and developed with the assistance of a community influences the way potential consumers view the innovation. This is significant as user entrepreneurs are often known to leverage community support in the innovation process (Shah and Tripsas, 2007).

2 Background

According to Schumpeter (1934), innovation is a process that combines "invention + exploitation," meaning a beneficial (usually financial) outcome derived from an invention. In his seminal work, "The Theory of Economic Development" (1934), he posits that economic progress and innovation are interdependent and mutually beneficial, implying that an unmet need would lead to capitalization through the provision of a solution, a concept underpinning "manufacturer-oriented innovation". In this classical view, companies capitalize on economic developments to innovate, customers purchase the product, thereby financing its emergence, and the innovation, in turn, fuels economic growth. This approach illustrates the classical innovation paradigm with a clear distinction between manufacturers and buyers. This paradigm has, however, undergone significant transformations since 1934.

2.1 Paradigm Shift from Classic to User-Centered Innovation

Future incumbents are poised to face more competition from individual innovators, user firms, and collaborative innovation groups (Baldwin and von Hippel, 2011). This shift is predominantly technology-driven, with digitalization, modular design, and innovative production practices taking center stage. Moreover, internet-based communication has significantly streamlined networking and drastically reduced costs (Baldwin and von Hippel, 2011; Fuchs and Schreier, 2011). With recent rapid advancements in generative AI, this trend might accelerate dramatically (Peres et al., 2023).

Von Hippel (2005) pinpoints a significant challenge in the innovation landscape: the information needed to create a significant innovation is widely distributed. Given the unpredictability of the next innovation source, traditional resource concentration might be less efficient. This inefficiency is addressed by the "democratization of innovation," a shift from innovation as a large corporation's monopoly towards a more accessible and lower-threshold approach to prototyping resources.

The term "democratized innovation", first coined by von Hippel (2005), outlines the foundational principles of user innovation. In this paradigm, the distinction between manufacturers and users is crucial. Manufacturers capitalize on selling a product or service and engage in classical innovation to benefit third parties. Conversely, user innovation is mainly motivated by the user's expectation of benefits from using the product. Innovation is considered both the development of new products as well as the modification of existing ones, and a manufacturer can simultaneously be a user. De Jong (2014) illustrates this concept using Sony, an electronic equipment manufacturer that also uses the machines it manufactures.

2.2 *Recent Advances in User Innovation*

The traditional "one-size-fits-all" paradigm, targeting the widest possible market, contradicts the concept of user innovation that addresses specific individual problems in increasingly diverse markets (von Hippel, 2005). Hence, user innovation often surfaces in markets with high heterogeneity (Shah and Tripsas, 2007; Franke and Lüthje, 2020). However, manufacturers avoid exploring niche markets with high demand volatility due to the associated financial risks (Ogawa and Pongtanalert, 2011).

Baldwin and von Hippel (2011) and Franke and Lüthje (2020) identify technological advancements and increased individual accessibility as catalysts for the rise of user innovation. They spotlight additive manufacturing, or "3D printing," as a tangible example. Von Hippel (2005) extends this argument, attributing the rise of user innovation to the evolution of computer software and hardware and the accessibility of user-friendly innovation tools and information databases. Such ease of access is expected to stimulate rapid growth in user innovation, irrespective of market heterogeneity and investment readiness.

The increasing prominence of user innovation is further boosted by corporate strategies that now incorporate user innovation into their production processes and even market products with explicit labels of user innovation (Schreier et al., 2012). But what aspects of the increasingly simplified user innovation process contribute to its upsurge?

Successful innovation requires two knowledge components: 'need knowledge,' or understanding a need, and 'solution knowledge,' the technical know-how to solve a given problem (von Hippel, 2005; Schweisfurth and Raasch, 2018). Typically, users possess 'need knowledge' but lack 'solution knowledge,' whereas manufacturers display the opposite trait (Hienerth and Lettl, 2017; Schweisfurth, 2017).

The problem with "need knowledge" is that it is typically much more unstructured and hidden at first glance, making it significantly more difficult to communicate (Schweisfurth and Raasch, 2018). This hurdle in information exchange is referred to as 'information stickiness' (von Hippel, 1994, 2005). Alongside, companies often exhibit a lack of 'need absorptive capacity,' a deficiency or lack of infrastructure to identify and meet articulated needs (Franke and Lüthje, 2020; Schweisfurth and Raasch, 2018). Consequently, it becomes easier for users to design products than to convey their specific needs to manufacturers.

Von Hippel 2005 introduces 'agency costs' as another impediment to user innovation. Agency costs encapsulate the effort required to ensure that a contracted manufacturer aligns its actions with the correct interests and understands the problem accurately. They also include the potential dissatisfaction with a product that fails to meet expectations.

Besides these aforementioned challenges, user innovators often cite self-reward, learning pleasure, curiosity, interest in the task, enjoyment of the work process, anticipation of a self-identifying product, and intellectual satisfaction as motivations for their innovation efforts. In community contexts, user innovators also mention increased recognition and a sense of belonging as benefits of innovating, potentially leading to financial gain or an increase in self-esteem (Franke and Lüthje, 2020; Pongtanalert and Ogawa, 2015; Ogawa and Pongtanalert, 2013; Baldwin and von Hippel, 2011; von Hippel, 2005).

The cost of innovation can also be lower for users compared to companies. For instance, users often bypass trial-and-error phases in product development, as an early product version might suffice to meet their needs Shah and Tripsas (2007). According to von Hippel (2005), every decision entails a cost-benefit consideration. An innovation occurs when the anticipated return surpasses the investment (Franke and Lüthje, 2020). Given the costs and benefits of user innovation, it seems to be a logical outcome for innovators. Franke and Lüthje (2020) further argue that in pre-capitalist times, all innovation was user-driven, borne out of personal necessity rather than financial incentive.

2.3 *The Prevalence and Significance of User Innovation*

User innovation remains a central facet of our innovation culture thousands of years into human history. In a study by Ogawa and Pongtanalert (2011), they found that 6.1 % of the UK population over 18 had participated in user innovation processes in the preceding three years. The adult population is approximately 47.4 million, which equates to about 2.9 million user innovators. An estimated £3.2 billion was invested in these processes, which surpasses the amount spent annually on research and development by UK consumer goods manufacturers by 1.4 times. In the United States and Japan, 5.2 % and 3.7 % of respondents, respectively, reported participating in user innovation processes over the same period, translating into 11.7 million people in the US and 3.9 million in Japan Ogawa and Pongtanalert (2011).

According to de Jong (2014), user innovation engages 15–20 % of companies, compared to 4–6 % of individuals. However, the prevalence of user innovation surges in specific niche markets. For instance, Shah et al. (2012) found that nearly one in four users of CAD software for printed circuit boards innovates for personal use. Similarly, in library information systems, the figure is 26 %, 19 % for users of Apache security software, and a substantial 38 % among "keen amateur sportsmen."

The extent of user innovation is, therefore, substantial, especially within niche markets. However, studies by de Jong et al. (2015) and Ogawa and Pongtanalert (2011) indicate that user innovation is prevalent across almost all fields (see table 1).

Both studies reveal the highest proportion of user innovation in crafts/tools and household domains (20–23 % of the innovations examined), followed by sports and hobbies (17–20 %). User innovation in medical devices and care is slightly lower but still significant. As wittily remarked by Henkel and von Hippel (2004):

> *Indeed, to paraphrase Solow's famous quip, user innovations appear everywhere but in the economic literature*

2.4 *User innovation in medical technology*

The pervasiveness of user innovation in even highly regulated markets such as medical technology can be quite startling. It has been argued that user innovators are primarily driven by non-financial incentives, making market entry barriers less significant for them (Shah and Tripsas, 2007). As proposed by Göldner et al. (2019) and Oliveira et al. (2015), the more pressing the need for a problem solution, the greater the effort an individual is willing to exert. Particularly in severe everyday life restrictions or chronic diseases, the pressure to alleviate suffering is substantially higher than in leisure areas such as hobbies and sports. The increasing trend of chronic diseases, an aging population demanding individualized medical care, and persistent exposure to risk factors intensifies societal suffering pressure (Goodman

Table 1: Prevelance of user innovation across different fields (Ogawa and Pongtanalert, 2011; de Jong et al., 2015)

Field	Ogawa and Pongtanalert (2011)	de Jong et al. (2015)
Craft / Tool	23%	20%
Sports and Hobbies	20%	17%
Household / Furniture	16%	20%
Food / Clothing	-	12%
Transport / Vehicle	8%	11%
Children / Education	10%	4%
Medical science / Nursing	2%	7%
Other	21%	9%

et al., 2013). Concurrently, the medical technology market is becoming increasingly diversified with specialized demands. Nonetheless, manufacturers' commercial interests limit the innovation domains they explore (Schiavone, 2020), whereas user innovation directly addresses problems, providing holistic rather than partial solutions (von Hippel, 2005).

The user's unique position in medical science also plays a part. The categorization by Schiavone (2020) into medical professionals, patients, caregivers, and non-directly involved individuals (like students or researchers) implies a significant portion of expertise in this field resides with users. For instance, 52 % of medical device startups that attracted venture capital investments from major medical device manufacturers between 1978 and 2007 were established by medical professionals themselves ?. Apart from these 'user entrepreneurs,' procedural innovations, particularly frequent in medical science, are carried out by highly skilled personnel (Hinsch et al., 2014).

Procedural innovations exemplify another challenge in medical science: the exceptionally high 'stickiness' of information. Pols (2014) describes the specific knowledge of patients as 'patient knowledge,' particularly 'messy.' Beyond the highly trained staff, numerous patients are also innovators in medical science. Their innovations are often frugal and technically straightforward, allowing them to bypass the stringent approval barriers for medical devices (Schiavone, 2020; Göldner et al., 2019; Shaw, 1985). This trend towards independent, innovative patients continues to grow (Pols, 2014; Oliveira et al., 2015; Carman et al., 2013).

Shaw (1985), Pols (2014), and Schiavone (2020) advocate for closer collaboration between patients and medical staff, echoing Carman et al. (2013) 's definition of 'patient engagement.' While the diffusion rate of patient innovation is only 5–17 %, more engaged patients are significantly more likely to share their innovations with others (Schiavone, 2020).

2.5 *Commercialization and Diffusion of User Innovation*

Kaminski (2011) characterizes the diffusion of innovation as the process whereby individuals adopt a new idea, philosophy, practice, or product. Typically, commercialization accompanies diffusion. Manufacturers commercialize their innovation 69 % of the time, contrasting with user innovation, where users commercialize only 17 % of the time (Preißner et al., 2017). User innovation can diffuse via establishing a startup or a manufacturer – two possible pathways for user innovation diffusion. Often, it also occurs non-commercially by voluntarily disseminating the information to peers (Halbinger, 2018; de Jong, 2014).

If you follow Schumpeter's 1934 postulation that innovation equals invention plus exploitation, user innovation can only be regarded as such if commercial exploitation exists. Suppose an innovation is not freely shared with peers. In that case, commercialization occurs either through the founding of a startup or a manufacturer, who acquires the information from the user either free of charge or for a fee. If an individual engaging in user innovation decides to commercialize the product independently, the term "user entrepreneurship" applies (Shah and Tripsas, 2007; Göldner et al., 2019).

Often, a user innovation is shared for a while free of charge until it gains commercial interest through the continuous improvement process within a peer group. User entrepreneurship is especially likely in areas where users have relatively low opportunity costs, there are narrow demand niches due to heterogeneous needs, and the market is characterized by uncertain, turbulent, and ambivalent demand. Furthermore, the benefit is not purely financial but brings intrinsic joy. The founding of start-ups often occurs without financial incentives. Instead, factors such as autonomy, control over strategic steps and decisions in product development, enjoyment of work, and the entrepreneurial lifestyle are crucial (Shah and Tripsas, 2007).

Besides founding one's own startup, commercialization via third parties is another common diffusion path for user innovation. Here, information about the innovation can be exchanged for a fee, for example, through licensing or without direct remuneration for the user. This process of collaboration between users and manufacturers was outlined in the 1980s by Shaw (1985) and von Hippel (1988) and is seen as a "user-dominated" innovation process.

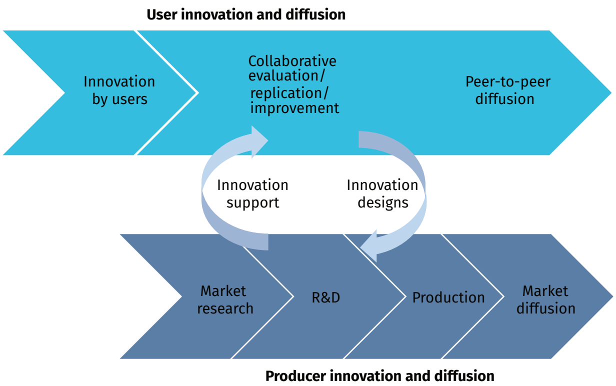

Figure 1: Interaction between user and manufacturer in the innovation process (Gambardella et al., 2017)

Gambardella et al. (2017) gathered four types of interaction from the literature (as well as a fifth hybrid solution of the previous four) between user innovators and manufacturers. The first two represent classic cases of collaboration in innovation and commercialization (Figure 1). The remaining two concern markets where user and classic innovation serve the same market independently or where user innovation replaces existing products, designs, or techniques.

Sharing information about innovation with peers for free is a common practice in user innovation. This form of innovation is difficult to accurately measure due to its lack of commercialization Franke and Lüthje (2020). However, a study by de Jong (2014) suggests that up to 30 % of individuals engaged in user innovation are willing to share their innovation freely or disclose information about it.

Notably, the willingness of companies to share information about their user innovations without compensation is twice as high compared to traditional product innovations. This is also evident in patenting: high-tech companies patent new products in 60.3 % of cases, while they protect only up to 13.6 % of their user innovations. This rate is even lower for individuals, ranging from 0.0 % to 8.8 % for patenting their own user innovation. This trend is also observed in the opposite direction: the larger a company is, the more likely it is to patent its innovation.

Oliveira et al. (2015) found in their study on patient innovation that 88 % of the sharing of solutions was directly patient-to-patient, followed by 25 % sharing their information via blogs or social media. The most significant indicator of whether an innovation is shared with others is the perceived improvement in quality of life due to the innovation.

Göldner et al. (2019) found that in user innovation, diffusion often serves an end in itself: users show empathy with other people with the same problems and therefore want to make their innovation as accessible as possible to as many people as possible. This pattern emphasizes what Ogawa and Pongtanalert described: users innovate for their own needs. Diffusion beyond this often occurs for non-commercial reasons and usually with peers. This phenomenon is known as "free revealing," and the subsequent innovation is referred to as "free innovation" (von Hippel, 2005; Schiavone, 2020; Baldwin and von Hippel, 2011).

2.6 *Diffusion Shortfall*

User innovation has been shown to benefit both society and those willing to incorporate it. For instance, it reduces the deadweight loss (price above margin costs) that arises when an innovation is shared very cheaply or entirely free of charge (free innovation). Imitators only have to pay the adoption costs, and competitors are encouraged to lower the price of their own innovation (von Hippel, 2005). Moreover, empathetic, altruistic motivations lead to free innovation, where people with special needs support each other (Göldner et al., 2019).

Henkel and von Hippel (2004) identify an increasing diversity of market offerings created by additional user innovation. This way, individual needs are better met since user innovation occurs in fields where manufacturers' innovation is not financially viable. User innovation thus complements the market alongside classic innovation. The two forms of innovation can benefit each other through their mutual complementarity, which reduces information stickiness. A so-called "welfare-enhancing internalization of spill-overs" benefits user innovation and manufacturers.

Financial benefits of user innovation for companies are also demonstrated Franke and Lüthje (2020); Gambardella et al. (2017). A company that actively integrates user innovation appears more customer-oriented, which improves its perception among customers who are not directly involved ("observers"). These customers represent the majority of the market. A positive attitude towards the company influences direct purchasing decisions (Fuchs and Schreier, 2011). Furthermore, behavior perceived as customer-oriented leads to increased customer loyalty (Sheth et al., 2000). Additionally, incorporating user innovation into a company increases perceived innovation, which boosts purchase intention, customers' willingness to pay, and the likelihood that the company will be recommended (Schreier et al., 2012).

Beyond integrating users in existing markets, user innovation can also open up entirely new markets. Shah and Tripsas (2007) cite the washing machine, the founding of "Yahoo!", some juvenile products and extreme sports such as canoeing, windsurfing, or snowboarding as prominent examples.

Despite these financial opportunities and social benefits, user innovation diffusion is low. Non-diffused innovation is difficult to measure, and Oliveira et al. (2015) state that only 22 % of the innovations that patients and caregivers used and considered new were new. von Hippel et al. (2012) find a diffusion rate of user innovation of 17 %, while Ogawa and Pongtanalert (2011) report a range of only 5–17 %.

Several reasons contribute to the low diffusion rate of user innovation, including the cost-intensive development of the product and market approval (particularly for medical products) and the high cost of patenting (Göldner et al., 2019). de Jong et al. (2015) describe that the patenting rate increases with the size of a company and is lowest for individuals. While some sources suggest that patenting in user innovation is low to increase diffusion through free revealing (Ogawa and Pongtanalert, 2011; Göldner et al., 2019; Pongtanalert and Ogawa, 2015), de Jong et al. (2015) demonstrate the coexistence of low patenting and diffusion rates.

Many user innovations are not even developed into marketable products Göldner et al. (2019). The diffusion and further development beyond one's own functional needs are perceived as an externality, and the effort is not seen in positive proportion to the benefit (de Jong, 2014). Halbinger (2018) supports this thesis, suggesting a negative correlation between the diffusion rate and the stated general interest and enjoyment in the innovation process. These users derive benefit from the enjoyment of the process and the altruistic motives of mutual support, so there is no perceived need for further exploitation of the innovation through commercialization.

The diffusion of innovation involves users and, in an intermediate step, manufacturers. However, the adoption rate of user innovation remains low. In a meta-study, de Jong (2014) shows an adoption rate of 5–21 % among consumers and 3–26 % among manufacturers. Keinz et al. (2012) suggest that the low adoption rate of companies is due to inadequate organizational structures. The not-invented-here syndrome (Katz and Allen, 1982) prevents openness to innovation, thus obstructing the adoption of potentially successful innovations from other users or companies.

The discrepancy between the potential benefits of user innovation and the low diffusion rate is considered a market failure (de Jong et al., 2015; von Hippel, 2005; Franke and Lüthje, 2020). Von Hippel 2017 dedicates an entire chapter to this phenomenon, which he calls "diffusion shortfall," in his 2017 book "Free Innovation." He describes that the market failure of free innovation occurs when the innovating and using parties would benefit more overall from increasing the diffusion rate of user innovation. Market failure occurs when innovators' resources are used inefficiently. This is the case when diffusion does not occur at all, and users with the same need independently develop very similar innovations (von Hippel, 2005). An inefficient use of resources is also present if the innovator could significantly lower adoption hurdles with a small effort.

In general, von Hippel (2017) describes three forms of behavior by the operators of free innovation that can lead to systematic diffusion shortfall. First, the user innovation has, by definition, been created for its own benefit, so its design may not create any added value for others. However, an innovation often gains value for third parties through simple modification. Second, even if the innovation is useful for others, its inventor often does not invest in further development to make it useful for third parties. Third, even when a useful innovation is available in a form that others can easily use, active investment in diffusion is often lacking. Despite a high willingness to freely reveal, there is a significant difference between this willingness and active investment in diffusion. Seventy-five percent of user innovators make no effort to diffuse their own innovation, even if they believe it has high added value for others.

The problem is that free innovation is intrinsic; there is no link between innovators and end-users via the market. Thus, market failure arises due to the perceived externality of diffusion, where even a small effort is perceived as a disadvantage, even if it creates a large advantage for others. This market failure was first described by von Hippel et al. (2016) in the context of medical technology.

2.7 *Reducing Diffusion Shortfall and Factors Influencing Diffusion Success*

To increase the prevalence of user innovation and realize its full potential, it is necessary not only to make innovation opportunities more accessible but also to actively reduce the diffusion shortfall (Franke and Lüthje, 2020). Acknowledging this market failure is only beneficial if addressed (de Jong et al., 2015). There are three possible strategies for this. First, the perception of benefits associated with diffusion can be enhanced through gamification. Second, the costs of further developing the innovation for diffusion can be reduced through makerspaces (von Hippel, 2017).

Legislation adaptation is another strategy to encourage user innovation. As user innovation can significantly benefit the common good, legislative authorities should promote it through appropriate amendments (von Hippel, 2017). Gambardella et al. (2017) argue that policies and laws facilitate user innovation and make it more attractive for companies to advance the common good. In contrast, strict patent laws and subsidies for traditional research and development can limit innovation openness, thereby reducing the contribution to the common good. Hence, legislative adjustment is overdue.

Apart from legislation, governments can promote user innovation in other ways, such as subsidizing specific user innovation projects or infrastructures that facilitate user innovation, like platforms (Koch et al., 2013) or makerspaces (Halbinger, 2018). These policies have proven successful in Sweden and Denmark (Svensson and Hartmann, 2018; Franke and Lüthje, 2020; Ogawa and Pongtanalert, 2011).

Kuusisto et al. (2013) describe the factors that influence diffusion success, which align with the reasons von Hippel outlines for diffusion shortfall. The innovation must provide added value for others, users must design their products so that others can use them, and they must actively promote diffusion. Furthermore, diffusion success depends on end-users' knowledge of the product and the risk associated with its use (Rogers, 1976). An affiliation of user innovators with a community also enhances diffusion (Shah and Tripsas, 2007).

2.8 *User innovation in communities*

Grabher and Ibert (2014) differentiate among three types of virtual communities, which are based on the degree of involvement of commercial operators on the one hand, and non-commercial users on the other. In addition to virtual communities, makerspaces for the co-creation of user innovation are particularly significant. These provide publicly accessible spaces where users can gather, exchange ideas, and collectively develop and share ideas for project work on topics such as technology, science, and art Halbinger (2018). The term 'community' is chosen over alternatives like 'networks' because these groups often possess a distinctive social structure that fosters identification with the group, thus enhancing the motivation to collaborate (Shah and Tripsas, 2007).

Collaboration within a group intensifies the effects of multidisciplinarity, thus boosting innovativeness (Shah and Tripsas, 2007). In the group setting, existing solutions can also be implemented more effectively due to a large pool of knowledge and skills and mutual support and feedback (Franke and Lüthje, 2020). In makerspaces, the innovation rate is 8 to 35 times higher than the population average, and the diffusion rate of innovation is 6 to 9 times higher (Halbinger, 2018).

For commercial diffusion, collaboration in groups during innovation is a stronger indicator than merely having commercial intentions (Halbinger, 2018). The adoption rate of community innovations significantly surpasses that of user innovations by individuals. A study by Ogawa and Pongtanalert (2013) shows that 86 % of innovations arising from communities were adopted by users, while the adoption rate for innovations from individuals was only 62.9 %.

Additionally, the commercial potential of a product is enhanced when it is developed within a community (Füller and von Hippel, 2008). This phenomenon stems from "user-generated brands," which are brands created by users. Although essential for adopting new products, marketing, and branding is typically time-consuming and cost-intensive and, thus, not particularly appealing to user innovators. In user communities, however, "user-generated brands" can emerge as a by-product of collaboration. Brands are defined by authenticity and "realness," which originate from passionate individuals motivated by the product rather than profit-driven actions. These attributes are inherent in user innovation Füller and von Hippel (2008); Füller et al. (2013).

Since successful collaborative work necessitates documenting all thoughts and steps, this information becomes readily available to others during development (Halbinger, 2018). Furthermore, innovations created through collaboration are less specific to one person's needs and are more focused on a general problem that binds these people, which enhances their commercial appeal (von Hippel, 2017). Apart from satisfying a broader range of needs, group collaboration also ensures that diverse types of people participate in the innovation's development. It has been demonstrated that various manifestations of the five key personality dimensions (the "Big Five") influence innovation, development, and diffusion success (Stock et al., 2016).

Alongside complementing personality types, the four interpersonal activities identified by Hargadon and Bechky (2006) are crucial for collective creativity and diffusion within communities:

- "Help-seeking", which is the active solicitation of support;
- "Help-giving", which involves committed, spontaneous, and sustained support of the help-seeker;
- "Reflective reframing", which occurs when people with different backgrounds and knowledge levels discuss a problem, question their approaches, and thereby redefine the problems; and
- "Reinforcing," which describes the social norms within a community that amplify the other three effects.

Another social norm within communities, besides free mutual support, is the free sharing of information and innovations among members (Franke and Lüthje, 2020). Only slightly over 7 % of participants surveyed in a study by Franke and Shah (2003) reported receiving payment for their community assistance. A majority, 92.6 %, believed that community members should support each other, with 74.1 % stating that providing free help within their community is the norm. The reasons community members cite for sharing information include the hope that their idea will be well received, the desire for acceptance and reputation within the community, the expectation that their innovation will be further developed, and gratitude for the ideas or free support they have received from others (Ogawa and Pongtanalert, 2013).

2.9 Reception of user innovation by end consumers

Crowdfunding shares many similarities with user innovation. The resemblance between Mollicks and Robbs paper "Democratizing Innovation and Capital Access: The Role of Crowdfunding" (2016) and von Hippel's influential 2005 work on user innovation "Democratizing Innovation" is no coincidence. Both user innovation and crowdfunding share aspects like transforming an idea into a marketable product that would otherwise be unavailable (Zvilichovsky et al., 2018)), as well as a robust involvement of investors during the project's creation.

Acar et al. (2021) show in their study that the perceived quality of a product increases when it has been realized through crowdfunding. A comparable effect was found in a study by Franke and Piller (2004) on the incorporation of user innovation in companies using the instance of toolkits for creating watches.

Moreover, people tend to favor a perceived "underdog" over a "big player." Thus, the evaluation of a smaller company improves, especially when its positioning is prominently promoted compared to a large corporation (Paharia et al., 2014). The authors argue that this effect occurs because end consumers attempt to bring fairness into the market. This finding is also confirmed by Acar et al. (2021) in their study on crowdfunding: Particularly, participants with a low tolerance for social injustice tend to prefer a crowdfunding project over a product from a large company.

Furthermore, people usually perceive nonprofit organizations as "warm," while profit-oriented organizations are viewed as "competent." User-innovated products are typically distributed as free innovations or at a very low cost. Therefore, companies and startups distributing these products fall under the nonprofit category. Without a "prime" or "bias," the willingness to buy a product is higher for profit-oriented companies. However, if a credible source promotes both companies, this preference tips (Aaker et al., 2010). The authors further argue that being perceived as warm or competent is not mutually exclusive, and a nonprofit company can more easily move into this "golden quadrant" where both dimensions are distinct. Füller and von Hippel (2008) and Füller et al. (2013) describe one such example, where user-generated brands play a pivotal role in customer perception and adoption of the product.

According to Acar et al. (2021), a high-risk classification of the product negatively impacts the advantage of crowdfunding. In such a case, like with medical products, crowdfunding is associated with a lack of expertise and professionalism and less preparation, planning, and testing.

2.10 Synthesis and Research Gap and Approach

While the benefits of user-innovated products are extensively discussed in the literature, there is a lack of research on the perception of these benefits by the broader population of end consumers. This gap is particularly evident in the case of "pure" user innovations. Additionally, the factors influencing perception and diffusion, such as the context of origin and risk classification of the product, have been mentioned without sufficient explicit, quantifiable, and empirical research. Therefore, this study focuses on investigating the acceptance of user-innovated medical products compared to products resulting from producer innovation within predefined risk categories and environmental factors.

Through a comprehensive literature review on user innovation, we identified significant research gaps. While the benefits of user innovation are widely recognized, there is insufficient research exploring potential consumers' perceptions of these innovations. Furthermore, the influence of these perceptions on the evaluation of user-innovated products remains unclear. This study aims to fill these research gaps by examining the acceptance of user-innovated medical products and understanding the factors that affect consumer perceptions.

Additionally, our investigation includes the aspect of community development in user innovation. By employing a mixed-methods approach, we explore the influence of product risk classification and community development on the perception of user-innovated medical devices.

3 Research Design

Our research question, *"Do potential customers perceive user innovation as such, and how does this perception influence their product evaluation?"*, is contextualized in the realm of medical devices. Our approach for exploring this question relied on a mixed-method research design, combining empirical investigation with qualitative and quantitative methodologies.

We initiated our exploration with an exhaustive literature review on user innovation. This informed the development of our interview guidelines, focusing on three main themes: the "history of the product's development," "the decision to distribute the product," and "the perceived acceptance and associated challenges of user innovation." A detailed account of each question and its source is provided in the appendix.

With the intent to scrutinize the acceptance of user-innovated medical products, we considered the perspectives of both innovators and customers, with a keen focus on the innovation environment and the level of risk associated with product usage. The qualitative phase involved in-depth interviews with experienced user innovators. The insights gleaned from these interviews, in conjunction with the literature review, informed our hypotheses, and played a crucial role in designing the subsequent experimental phase.

The quantitative phase involved testing the formulated hypotheses through an experimental design. This mixed-method approach not only lends empirical validation to our findings but also provides a holistic framework, offering a robust view of the intricacies surrounding user innovation (Schoonenboom and Johnson, 2017).

Further details about our methodology, including the qualitative interview process and quantitative experimental study, will be explicated in the subsequent sections.

4 Qualitative Data Collection and Analysis

4.1 Interview Structure

The interview structure aimed first to establish whether a classic user innovation was present. Next, we probed into the intent to diffuse and its impediments due to existing contradictions in the literature. Leveraging the experts' experiences, we asked about obstacles, support systems, customer interaction, and collective work in groups and communities. Queries regarding relations with larger companies and direct competitors were intended to elucidate user innovators' relationship with the conventional market and producer innovation. Lastly, we examined customer perceptions and the influence of user innovation on acceptance, gleaning from the experts' experiences to uncover potential strategies to boost customer-side acceptance.

4.2 Interview Methodology

Five interviews were conducted with the dual aim of probing deeper into topics identified from the literature review and extracting insights from experienced user innovators. The data collected informed the development of the questionnaire for the subsequent exeperimental study.

Five interviewees were selected based on their direct experience with user innovation and its distribution. The "Patient Innovation" organization (`https://patient-innovation.com`) served as a resource for identifying such user innovators. The chosen innovations for this study were of manageable complexity, a characteristic common in user innovations within the field of medical science (Schiavone, 2020; Göldner et al., 2019; Shaw, 1985). Interview durations ranged from 23:33 minutes to 47:21 minutes. These were conducted via video call, transcribed, and coded according to Braun and Clarke's guidelines (Braun and Clarke, 2006).

An overview of the interview partners, their nationality, their products, and the interview duration can be found in Table 2.

4.3 *Interview Insights and Hypothesis Development*

Analysis of the interviews revealed key insights as presented in Table 3). A dominant theme was the perceived advantage of user innovation narratives over products originating from traditional innovation approaches of larger companies. Based on these insights, we formulated two hypotheses:

H1: *User innovation is perceived more positively than producer innovation*

H2: *A product developed within a community is evaluated more positively than user innovations by individuals*

An additional hypothesis, derived from the literature review rather than the interviews, addresses the influence of product use-risk on the perception of user innovation, as compared to producer innovation (Acar et al., 2021; McKnight et al., 2002):

H3: *As the associated risk level of an innovation increases, the perceived value of a user innovation decreases*

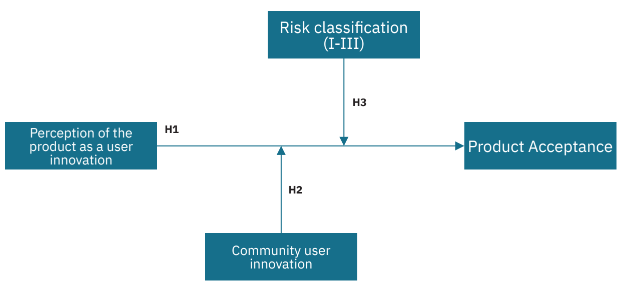

Figure 2: Schematic representation of research hypotheses

Figure 2 shows a schematic representation of our three hypotheses. The insights and hypotheses from our qualitative analysis and comprehensive literature review provide the foundational basis for our subsequent quantitative investigation. Drawing on these, we designed an experiment to test and further refine these hypotheses. The aim is to validate our qualitative findings and provide more generalizable conclusions about the perception and valuation of user innovations, especially within the context of varying risk levels and community development. We present the specifics of this experimental study and its outcomes in the following section.

5 Experimental Study

5.1 *Methodology*

To evaluate our hypotheses, we designed an experimental study, choosing products based on the risk classification from Regulation (EU) 2017/745 of the European Parliament and the Council on Medical Devices (Europäisches Parlament, 05.05.2017). This regulation sorts medical devices into risk classes I, IIa, IIb, and III.

To examine our third hypothesis, we specifically selected a product from each of three different risk classes: an FFP2 mask from Class I, a contact lens from Class II, and a pacemaker from Class III.

We constructed six different scenarios (2x3: User Innovation versus Producer Innovation x three risk classes) for our experimental design, aligning with a "between-subject design." Each participant was exposed to one of these scenarios where a product was depicted either as a user innovation or a producer innovation.

To test our second hypothesis, we employed a "within-subject design." Here, the same product initially introduced as a user innovation was presented again, but this time with a backstory of having been developed within a community.

Participants were asked to evaluate each product in terms of its appeal and their personal likelihood to purchase it.

5.2 *Assessing Product Acceptance, Willingness to Buy, and Control Variables*

Product attractiveness was assessed using a scale suggested by Laugwitz et al. (2008). We selected five items from their validated list: Good - bad, pleasant - unpleasant, attractive - unattractive, safe - unsafe, and high value - low quality. Participants rated these items on a 7-point Likert scale. To enhance validity, positive and negative ends of the scale were balanced

Table 2: Overview of Interview Partners, Their Products, and Interview Duration

ID	Nationality	Product	Duration minutes
I1	The Netherlands	Cane with lighting	47:21
I2	USA	App and smartwatch against PTSD	24:22
I3	USA	Shirt for people with restriction of fine motor skills	23:33
I4	New Zealand	Cutting board for people with restriction of fine motor skills	37:45
I5	Spain	Protection from blows or problems through movement for people with pacemaker	36:22

Table 3: Key insights from five semi-structured interviews

#	Citation	Topic
1	And the most important thing for me was that the existing things of which I [...] didn't really think, I just used it, but actually, it sucks [...] I was quite happy with it until I got hit by a car then I realized oh, but this design sucks. I have to improve it. [...] so, I started looking on the web, and there was no such thing. - I1	Innovation for your own benefit or that of a close attachment figure. The trigger was a specific moment
2	[...] zero market research. It was mostly to fix the problem of one single person. - I2	Diffusion only took place following the problem solution
3	[...] it was never going to be a company but while I was doing research trying to build the product for him, I just saw how many people on the internet have the same problem. [...] so, I created the product and patented the product which was probably key for me and then I launched. - I3	
4	And afterwards, when you use it, you see it can be useful for other people. So, that's when I started to create the startup and so on. But it was just for me in the beginning. - I5	
5	Oh, yeah, I think a lot of this is driven by the knowledge that this is user innovation. So, I know that like a lot of what they do is sold on like the story of me creating it and like my dad having PTSD. [...] that's how they get that kind of press. [...] We get tons of user feedback, which is super helpful. And most of them share their stories of their connection to why they need it [...], I don't know anyone that has had expressed a negative impact [of the User Innovation] [...] So, the story does bring them in, and it helps the transaction for sure. - I2	User innovation as a positive influence on diffusion success and acceptance
6	Yes, they love it, and it's going to work. It's going to help me spread the word. - I1	
7	NightWare just redid their webpage and so if you go to [the website] the whole thing is about "Our company is inspired by a young man's devotion to his father". And I think that's kind of the selling point like that's the reason they get big media. - I2	
8	You don't have a ton of people to brainstorm with which is a disadvantage for sure. You're kind of living in your own head it's very isolating. - I3	Disadvantages of working alone and advantages of the community/relevance of the work in the right team
9	One of my biggest faults is I don't move forward until I'm 100 percent comfortable of what I've got. [...] I really needed to have someone who pushed me, who was the exact opposite of me. - I4	
10	It is without the support of the Waag, I could have done but it would have been much harder, and much less fun. - I1	
11	It was surprising because I expected only to use it for doing some physical activity or doing some sport, but many people said that they would like to use it for other things. - I5	
12	The order of the items changed completely because I'm just one user. And I use in a particular way, but one of [the people I was working with] was blind, completely blind. - I1	
13	I would say building an effective team early on was a big obstacle. And I think a lot of our early steps took a lot longer than they needed to, just because I just didn't have the right people involved. - I2	

and alternated from left to right and vice versa (Ajzen, 2002).

Participants' willingness to buy (WTB) was also measured on a 7-point Likert scale (Ajzen, 2002).

We also introduced control variables, including participants' general attitudes towards mask-wearing during a pandemic (specifically for those who were presented the FFP2 mask), basic demographic characteristics, familiarity with user innovation (Schreier et al., 2007), trust in technology (McKnight et al., 2002), risk propensity (Filiz et al., 2018), and involvement in communities that drive innovation or share stories about it. These control variables helped us determine if factors such as familiarity with user innovation influenced its perception, or if general skepticism towards new technology created product aversion.

To avoid external influences, the questionnaires for each product were structured identically, apart from their origin story. All products in both scenarios underwent the same modifications and were presented with the same image and in the same order.

After an initial review of the data, we discarded six out of 301 responses that were identified as incomplete or incoherent based on our control questions. We analyzed the remaining data using non-parametric tests. Histograms of acceptance parameters and tests for the normal distribution of residuals can be found in the appendix.

The impact of demographic characteristics on product perception was examined using a Kruskal-Wallis test, as each category had more than two groups. Differences in perception of products within a risk group by innovation type were determined using a Mann-Whitney-U-test, as the samples were independent. Mean product perceptions for individual versus community user innovation were compared with a Wilcoxon test. Finally, individual acceptance parameters within each risk classification and innovation form were compared with a Kruskal-Wallis-test.

5.3 Results

Three responses regarding FFP2 mask acceptance during a pandemic were excluded based on a chosen criterion of less than four on a 7-point scale. Additionally, three incomplete or patterned responses (related to user innovation for the FFP2 mask, user innovation for the contact lens, and producer innovation for the contact lens) were excluded. The response count is summarized in Table 4.

Table 4: Comparison of responses in Classic and User Innovation

	Responses	Non usable	Usable
Classic Innovation			
Risk Class I	52	2	50
Risk Class II	51	1	50
Risk Class III	47	-	47
User Innovation			
Risk Class I	50	2	48
Risk Class II	54	1	53
Risk Class III	47	-	47
Total		6	295

Demographic data is presented in Table 5. The sample is not representative across all age and education categories, with the majority of respondents aged between 25 and 39 years (56.61 %) and holding a degree (69.49 %).

Specific personal characteristics of respondents are summarized in Table 6. We measured familiarity with user innovation according to Schreier et al. (2012), trust in technology to McKnight et al. (2002), risk tolerance to Filiz et al. (2018), and community affiliation in a way that fitted a similar logic.

To test our hypotheses, we examined two factors: product perception (pp) and willingness-to-buy (WTB). The results were used to compare acceptance of products across different risk classes and innovation forms.

Testing of residuals revealed a normal distribution only for risk class III product perception (Shapiro-Wilk, $p = 0.428$, significance level $p = 0.05$), hence an ANOVA test was performed for product perception comparison in this risk

Table 5: General Demographic Characteristics of participants

Category	Characteristic	Absolute Number	Percentage (%)
Total		295	100
Gender	Male	121	41.0
	Female	170	57.6
	Misc. Gender	2	0.7
	No Indication	2	0.7
Age	Younger than 25 years	106	35.9
	26 – 39 years	167	56.6
	40 – 60 years	18	6.1
	Over 60 Years	4	1.4
Education	No leaving qualification or	1	0.3
	Secondary school leaving certificate	6	2.0
	Abitur	78	26.4
	University degree	205	69.5
	Other	5	1.7

Table 6: Personal characteristics

	Total	Percentage (%)
Familiarity with innovation		
No	147	49.8
Low	70	23.7
High	78	26.4
Trust in technology		
1	1	0.3
2	6	2.0
3	24	8.1
4	59	20.0
5	90	30.5
6	100	33.9
7	15	5.1
Risk tolerance		
Low	207	70.2
Medium	11	3.7
High	77	26.1
Community affiliation		
No member	237	80.3
Passive	41	13.9
Active	17	5.8

class under different innovation forms. All other comparisons used non-parametric tests due to abnormal distribution from a high skewness and kurtosis (see Appendix).

Initial analysis compared mean values of perception and willingness-to-buy (WTB) for each stimulus, as detailed in Table 7. Notably, perception scores were consistently higher than WTB scores. A Wilcoxon test for two dependent samples confirmed this significant difference for all stimuli, except for the producer innovation of the contact lens and the community user innovation of the FFP-2 mask. Boxplots of perception and WTB are included.

Hypothesis testing required comparing perception and WTB mean values within risk classes and across innovation forms. Perception of products did not vary across producer, user, and community user innovation within risk classes. However, significant WTB differences emerged, where user innovation was significantly less appealing than producer or community user innovations, barring the exception of risk class I. Comparisons between producer and user innovation were performed using a Mann-Whitney-U-test, while user and community user innovation comparisons were performed using a Wilcoxon-test due to their presence in the same questionnaire.

Table 7: Influence of innovator and risk classification on prdoduct perception (pp) willingness to buy (wtb)

	PP	SD	WTB	SD	P
Producer Innovation					
Risk class I	4.84	1.48	4.40	0.92	<0.001
Risk class II	4.94	1.36	4.88	1.13	0.640
Risk class III	4.48	1.54	4.31	1.35	0.022
User Innovation					
Risk class I	4.84	1.13	4.26	1.41	0.003
Risk class II	4.97	1.48	4.16	1.37	<0.001
Risk class III	4.38	1.48	3.70	1.55	<0.001
Community-user Innovation					
Risk class I	4.97	1.31	4.85	1.22	0.540
Risk class II	5.04	1.20	4.75	1.08	0.005
Risk class III	4.69	1.37	4.30	1.40	<0.001
Total					
Producer Innovation	4.79	0.44	4.53	0.54	0.002
User Innovation	4.74	0.63	4.11	0.98	<0.001
Community-user Innovation	4.89	0.63	4.43	0.86	<0.001

Results are compiled in Table 8, with boxplots presented in the Appendix. Effect sizes were strong ($r > 0.5$) for WTB comparisons between user and community user innovations in risk class I, and moderate ($0.1 < r < 0.5$) in other cases (Cohen, 1988).

Further examination of the five individual acceptance parameters involved comparing each product and innovation form to identify variations in product rating across perception categories. These comparisons used a Kruskal-Wallis test and are presented in figures 3,4 and 5.

For producer innovations, "pleasant" and "attractive" ratings were consistently lower than "good" and "high value" across risk classes. Risk class-specific differences emerged in safety ratings. Conversely, user innovation products revealed significant rating differences across risk classes, with perceived safety decreasing as risk increased. For community user innovation products, acceptance parameters showed no significant differences across risk classes. Mean values, standard deviations, significances, and effect sizes are in Tables 9, 10 and 11.

Comparisons were also made for each acceptance parameter across innovation forms within each risk class. In risk class I, producer innovation products were rated significantly lower than community user innovation products for "pleasant" and "attractive". No significant differences emerged in risk class II, while safety was rated significantly lower for user innovation than producer innovation in risk class III.

6 Discussion

Only trust in technology influenced product perception and purchase intent in the demography and personal characteristics examined. Nonetheless, since there was no significant difference in the expression of this factor between the questionnaires (*Kruskal-Wallis test, asymptotic significance* = 0.074), it can be inferred that trust in technology doesn't substantively impact the validation of the hypothesis. All other characteristics did not have a statistically discernible influence on product perception or purchase intent. As purchase intent differed based on the product, other factors must be influential.

H1: User innovation is perceived more positively than producer innovation

Regarding this hypothesis, the qualitative and quantitative research yielded contrasting results. Despite the unanimity of the interviewed

Table 8: Comparison of perception and wtb within the risk classes, asked on a 7-point likert scale

Comparison	p	Z	r
	Perception		
User Innovation compared with			
Risk class I			
Producer Innovation	0.547	-0.60	-
Community-user Innovation	0.282	-1.08	-
Risk class II			
Producer Innovation	0.929	-0.10	-
Community-user Innovation	0.556	-0.59	-
Risk class III			
Producer Innovation	0.279	-1.08	-
Community-user Innovation	0.080	-1.75	-
	WTB		
User Innovation compared with			
Risk class I			
Producer Innovation	0.806	0.81	-
Community-user Innovation	<0.001	-3.54	0.51
Risk class II			
Producer Innovation	0.009	-2.62	0.26
Community-user Innovation	<0.001	-3.40	0.47
Risk class III			
Producer Innovation	0.037	-2.09	0.22
Community-user Innovation	0.013	-2.48	0.36

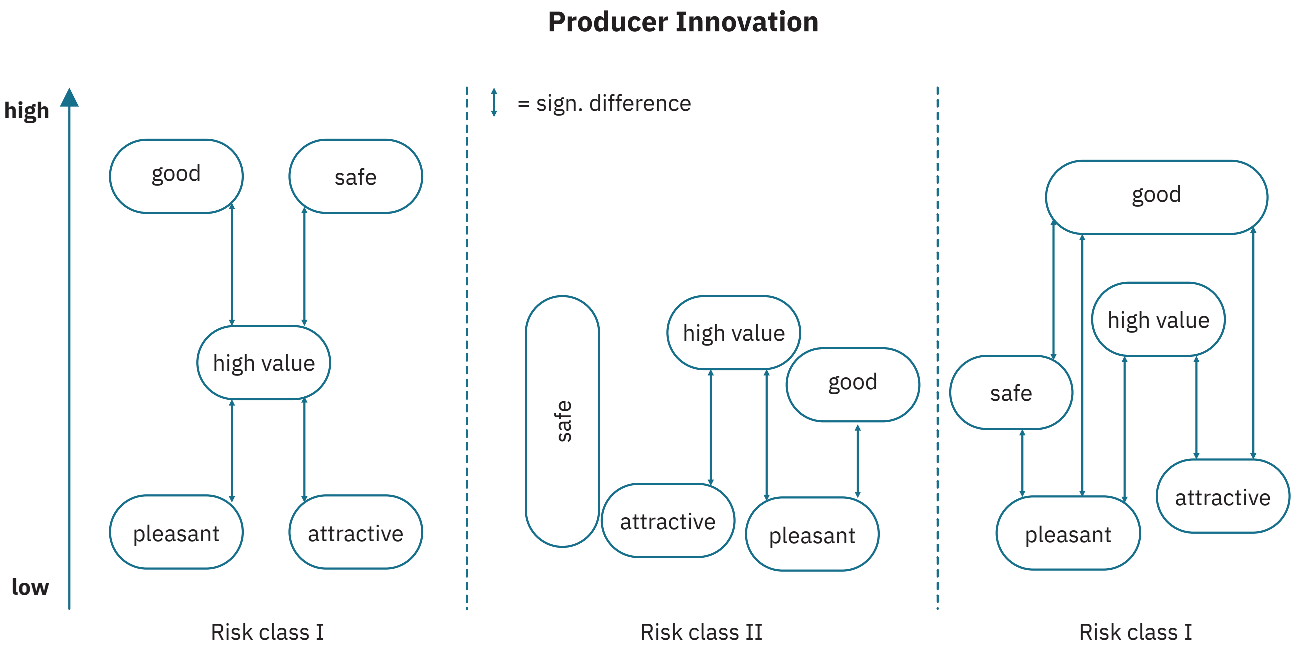

Figure 3: Acceptance parameters of producer innovation over the course of the three risk classes

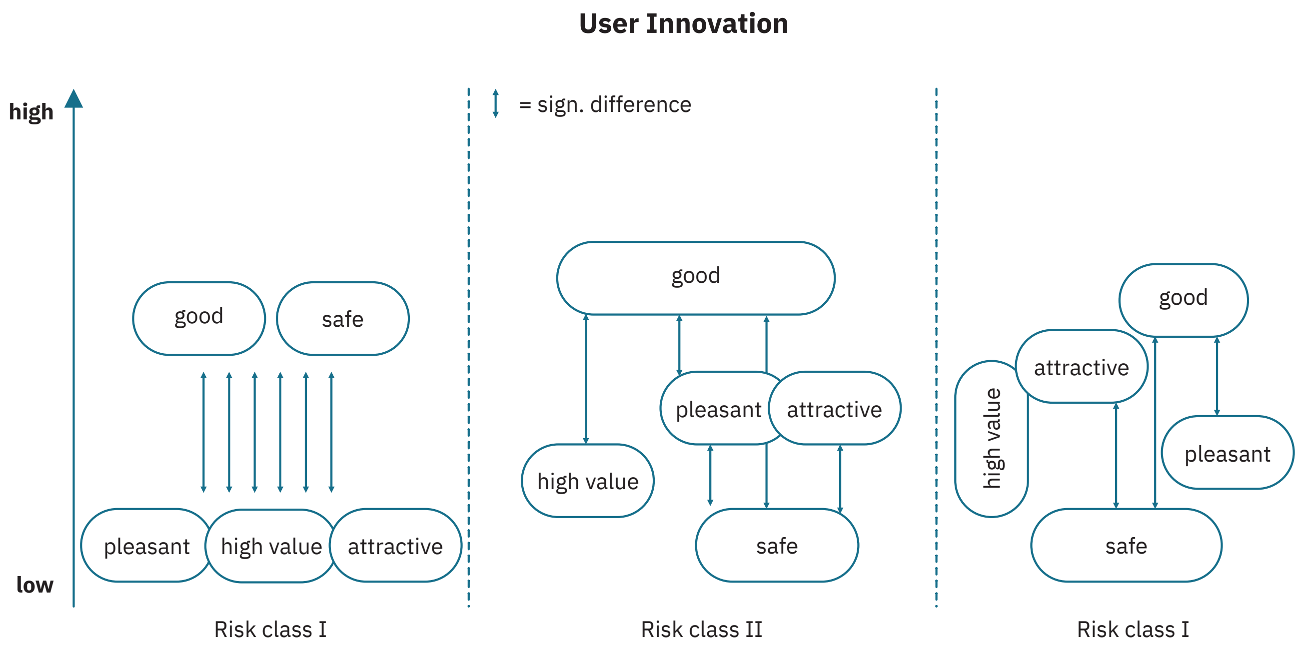

Figure 4: Acceptance parameters of user innovation over the course of the three risk classes

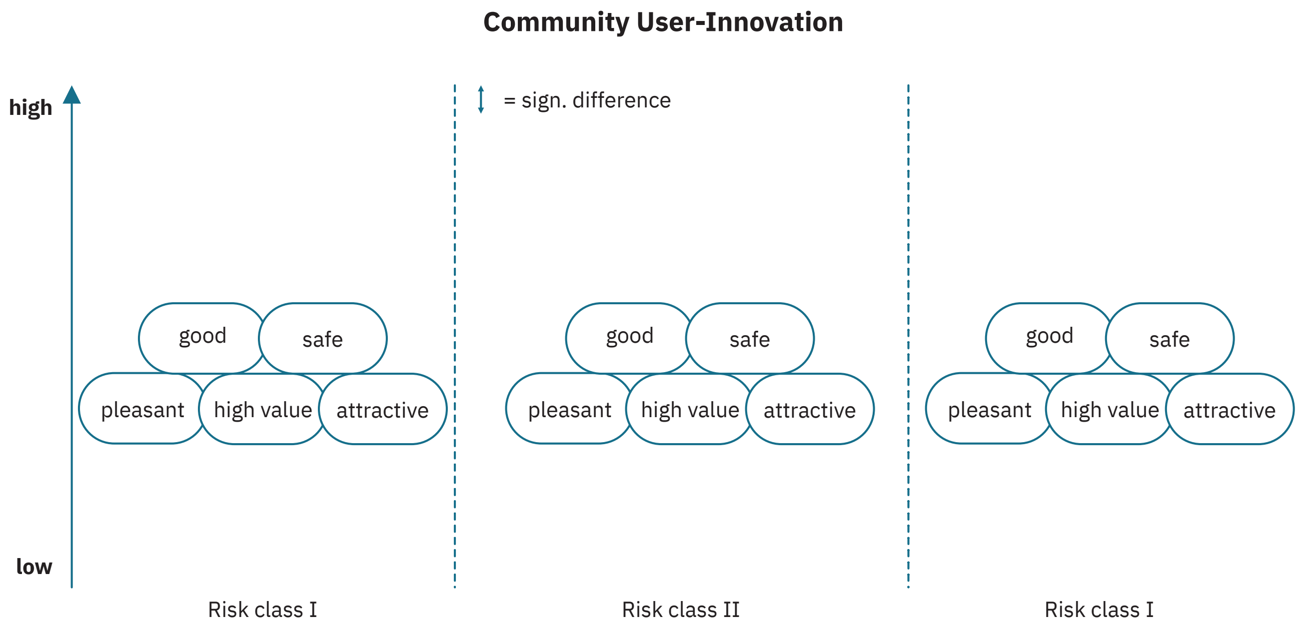

Figure 5: Acceptance parameters of community user innovation in comparison across the three risk classes. There were no significant differences within the parameters.

Table 9: Mean Values And Standard Deviation Of The Acceptance Parameters As Well As Significance, Effect Size And Standardized Test Statistics Of The Comparisons Of The Mean Values (Producer Innovation)

Parameter	Compared to	Z	p	r	M	SD
Risk class I						
Attractive					4.06	1.376
	Pleasant	0.12	0.904	-		
	High value	2.97	0.003	0.420		
	Good	5.40	<0.001	0.764		
	Safe	-6.23	<0.001	0.881		
Pleasant					4.18	1.201
	High value	2.85	0.004	0.403		
	Good	5.28	<0.001	0.747		
	Safe	-6.11	<0.001	0.864		
High value					4.9	0.909
	Good	2.43	0.015	0.344		
	Safe	-3.53	0.001	0.499		
Good					5.40	1.010
	Safe	-0.83	0.407	-	5.64	0.921
Risk class II						
Attractive					4.70	1.446
	Pleasant	-0.53	0.600	-		
	High value	2.17	0.030	0.306		
	Good	1.89	0.059	-		
	Safe	-0.98	0.325	-		
Pleasant					4.54	1.515
	High value	2.69	0.007	0.380		
	Good	2.42	0.016	0.342		
	Safe	-1.51	0.131	-		
High value					5.30	1.111
	Good	-0.28	0.782	-		
	Safe	1.18	0.23	-		
Good					5.16	1.299
	Safe	0.91	0.365	-	5.0	1.010
Risk class III						
Attractive					4.106	1.618
	Pleasant	-0.89	0.375	-		
	High value	2.70	0.007	0.394		
	Good	3.90	<0.001	0.569		
	Safe	-1.30	0.194	-		
Pleasant					3.915	1.396
	High value	3.58	<0.001	0.522		
	Good	4.78	<0.001	0.697		
	Safe	-2.19	0.029	0.319		
High value					5.0	1.268
	Good	1.20	0.231	-		
	Safe	-1.40	0.163	-		
Good					5.298	1.250
	Safe	2.60	0.009	0.379	4.596	1.313

Table 10: Mean Values And Standard Deviation Of The Acceptance Parameters As Well As Significance, Effect Size And Standardized Test Statistics Of The Comparisons Of The Mean Values (User Innovation)

Parameter	Compared to	Z	p	r	M	SD
Risk class I						
Attractive					4.40	1.69
	Pleasant	0.42	0.67	-		
	High value	0.07	0.94	-		
	Good	-1.87	0.06	0.41		
	Safe	-2.72	0.01	0.39		
Pleasant					4.58	1.54
	High value	-0.35	0.73	-		
	Good	-2.45	0.01	0.35		
	Safe	-2.30	0.02	0.33		
High value					4.67	0.98
	Good	-1.20	0.01	0.40		
	Safe	-2.65	0.01	0.38		
Good					5.31	1.27
	Safe	0.15	0.88	-	5.23	1.63
Risk class II						
Attractive					5.06	1.54
	Pleasant	-0.77	0.44	-		
	High value	-1.36	0.17	-		
	Good	-1.75	0.08	-		
	Safe	-2.75	0.01	0.38		
Pleasant					4.91	1.39
	High value	-0.60	0.55	-		
	Good	-2.62	0.01	0.36		
	Safe	-2.70	0.05	0.27		
High value					4.91	0.99
	Good	-1.20	0.28	-		
	Safe	-2.46	0.05	-		
Good					5.58	1.18
	Safe	-0.97	<0.01	0.63	4.40	1.42
Risk class III						
Attractive					4.64	1.63
	Pleasant	-1.75	0.08	-		
	High value	-0.47	0.64	-		
	Good	0.61	0.54	-		
	Safe	-2.41	0.02	0.35		
Pleasant					4.06	1.66
	High value	-1.28	0.20	-		
	Good	-2.35	0.02	0.34		
	Safe	0.66	0.51	-		
High value					4.51	1.28
	Good	-1.17	0.28	-		
	Safe	-2.47	0.05	-		
Good					4.83	1.52
	Safe	-1.20	0.00	0.44	3.97	1.44

Table 11: Mean Values And Standard Deviation Of The Acceptance Parameters And Significance Of The Comparisons Of The Mean Values (Community User Innovation)

	p	M	SD
Risk class I	0.14		
Attractive		4.83	1.31
Pleasant		4.77	1.46
High value		4.90	1.13
Good		5.02	1.23
Safe		5.31	1.37
Risk class II	0.39		
Attractive		5.04	1.40
Pleasant		5.02	1.22
High value		4.96	1.06
Good		5.28	1.15
Safe		4.89	1.17
Risk class III	0.40		
Attractive		4.94	1.36
Pleasant		4.57	1.36
High value		4.60	1.33
Good		4.87	1.42
Safe		4.47	1.38

user innovators in reporting positive feedback about their products and innovation narratives – even considering them as selling points in some cases (as with interviewee I2), data from the questionnaires (summarized in Table 8) depict a different scenario. The perception of the product does not differ between the types of innovation, and purchase intent decreases when associated with user innovation products compared to producer innovations. Hence, this hypothesis, H1, finds no support in its current form.

After comparing the overall perception of products across the mean of all five acceptance parameters, we conducted an internal comparison of these and individual parameter comparisons across risk categories. It was apparent that not all acceptance parameters were evaluated equally. Notably, user-innovated products' perceived safety declined with increasing risk class, while traditionally innovated products were consistently rated lower in attractiveness and pleasantness across risk classes. Furthermore, the "high value" parameter in user innovation scored lower than its traditional innovation counterparts. Although these parameters neutralize each other when considered an average value across all five acceptance parameters, they influence purchase intent in varying weights.

Aaker et al. (2010) study, which suggest that non-profit organizations are perceived as "warm" and profit-driven organizations as "competent", serves as a plausible explanation for these observations. Categorizing the attractiveness factors we utilized, "pleasant" and "attractive" align with "warm", whereas "high value" and "safe" are under the "competent" category (compare factors associated with warmth and competence as per Aaker et al. (2010): warm = generosity, honesty, sincerity; competent = effectiveness, skills, competitiveness). Thus, user innovation – often equated with non-profit organizations – can be compared to producer innovation, perceived as profit-oriented. Aaker et al. (2010) also argue that non-profit organizations' products have lower purchase intent than profit-driven ones. This finding elucidates the discrepancy in purchase intent despite seemingly equal product perceptions in this study. The observation further reinforces this interpretation that purchas intent for producer innovation products was higher only in risk classes II and III than for user innovation products, where perceived safety in risk class I remained comparatively high.

Upon reviewing the interviews, it is plausible to consider the perception of the interviewees as biased. It is more likely to receive positive feedback from a person about a product and its origin than to have them voice their dissatisfaction openly to the innovator. Additionally, people may be more prone to have the positive feelings they associate with user innovation products ("warm factors") at the forefront when asked for an assessment by the innovator than rational concerns about value and safety. Aaker et al. (2010) also indicate that purchase intent for a non-profit organization's product increases when a trusted source promotes it. Direct contact with the individual who invented and produced the product could boost trust and increase purchase intent. On H1, it can thus be concluded that user innovation products are not necessarily evaluated more favorably, but they are evaluated differently.

H2: A product developed within a community is evaluated more positively than user innovations by individuals.

As the participants only evaluated one product and no user-innovated competitors existed, qualitative research needs to answer this hypothesis. The questionnaires reveal no significant difference in product perception, yet mean values are marginally higher across all three risk classes for community user innovation than individual user innovation. Furthermore, the purchase intent for community user innovation products is significantly higher than for individual user innovation products across all risk classes. When examining the acceptance parameters, it is notable that there is no significant difference between individual parameters in community user innovation. Perceived safety does not significantly deviate from producer innovation even in risk class III, while the "warm factors" are still significantly higher in risk class I. Overall, community user innovation products performed better than all others across all domains, albeit occasionally only slightly. Therefore, this paper supports hypothesis H2.

H3: As the associated risk level of an innovation increases, the perceived value of a user innovation decreases.

The same conditions apply to the third hypothesis as to the second: since it involves comparing different forms of user innovation, it cannot be addressed by qualitative research. Comparing product perceptions of different risk classes within one form of creation is not viable, as it introduces another unknown influencing factor: the product. As shown in Table 7, product preference is consistent across all forms of innovation: the contact lens (risk class II) is rated highest, the pacemaker (risk class III) lowest, and the FFP2 mask (risk class III) falls in between. Consequently, the hypothesis must be tested by comparing it with the corresponding product from producer innovation.

Since no significant differences in product perception were confirmed, this hypothesis seems rejected at first glance, even based on the quantitative research results. However, examining purchase intent reveals that it remains the same for the product in risk class I. Still, for products in risk classes II and III, it is lower for user innovation products. Taken together, product perception and purchase intent support hypothesis three.

As elaborated in the paragraph regarding the first hypothesis, the product's perceived safety and value decline with increasing risk classification. One potential issue with user innovation is that respondents need help to imagine a private individual manufacturing a product of equal quality as a company. The fact that medical products must undergo a rigorous approval process and meet high standards does not alleviate this concern. This sentiment is underscored by a response in the questionnaire's free text field:

> *"The description of the text does not sufficiently emphasize for me that the pacemaker truly meets the technical quality requirements (it mentions that it has received approval), but I find it hard to imagine that a group of inventors actually carried out animal testing first, then human testing, and also had the funding to do it, which is a lot of money. To feel confident about the product, this process should be highlighted more." - from the questionnaire on user innovation, risk class III."*

This quote underscores that the respondent, despite being aware that it is a user innovation and that the product has received approval, still needs to work on believing that the product meets safety standards.

According to the findings of this study, user innovation tends to be perceived as "warm" while innovation by large companies is seen as "competent." In the context of Aaker, Vohs, and Mogilner's research on this phenomenon, there is a clear direction for user innovators. Aaker et al. (2010) argue that warmth and competence are not mutually exclusive but can coexist. For user innovation, increasing the perceived value and safety of the product is crucial in enhancing perceived competence. Collaborating in communities is one practical approach, among others, to achieve this goal. User companies and individuals can also emphasize security in their marketing efforts.

One example in medical technology is explicitly referring to the rigorous approval process for medical products. Brands offer another possibility. For instance, an established company can acquire the patent or license for the user-innovated product, further develop it, and promote and sell it under their brand name, which customers associate with competence. Simultaneously, the development history of user innovation can be emphasized. Another avenue is through "user-generated brands" (Füller and von Hippel, 2008). These brands are primarily created within user innovation communities and are characterized by high customer loyalty. McKnight et al. (2002) describe the connection between customer relationships and trust. Purchasing and using products involve "trust-related behavior" where trust in the seller is paramount. The importance of trust increases with the risk associated with the product, which is typically high for medical products.

6.1 Limitation and Outlook

The primary limitation of this study is the sample size of 295 usable responses from a non-representative group. Only four percent of the respondents did not have a high school diploma, and 92.54 percent were younger than 40. Future research should include a more extensive and diverse sample to ensure representativeness.

Moreover, it is essential to note that this study focuses specifically on user innovation in the medical product domain. Therefore, general caution should be exercised when drawing conclusions about user innovation. The generally high evaluation of product safety (evident in the case of the user innovation FFP2 mask, which received a higher rating than value, comfort, and attractiveness) can be attributed to the stringent approval process for medical products. The observed effect, where safety and value are rated lower for user innovation, maybe even more pronounced. Additionally, the medical devices examined in this study are not typically characterized by attractiveness and pleasantness, which may have contributed to lower ratings in these factors across all products compared to the average. The difference observed between individual and community user innovation products may have resulted from a "demand effect" since both were evaluated consecutively in the same questionnaire.

In reality, comparisons between different products are expected. Therefore, it would be beneficial for future research to include a comparative assessment, particularly between user innovation and producer innovation. Paharia et al. (2014) suggest that small companies can actively utilize such a comparison as a marketing strategy, as the "underdog" is typically evaluated positively in contrast to the "big player." A greater significance can be achieved by combining direct comparisons and isolated evaluations of individual products. To enhance external validity and better reflect reality, future studies should consider the frequently lower prices at which user innovation products are sold when examining willingness to buy. Exploring how lower fees or even free revealing of high-risk products influence product perception and willingness to buy would be interesting. Additionally, it would be valuable to investigate the influence of medical product characteristics on acceptance parameters to address the limitations above. Using actual existing products in surveys could enhance credibility and emphasize the products' development history.

In conclusion, potential end users perceive user and producer innovation differently. These differences must be considered to fully leverage the substantial potential of user innovation for the general public. Safety and value must be emphasized more strongly during the diffusion process, particularly for high-risk products. Simultaneously, companies are advised to integrate open innovation processes into their research and development efforts. Innovations created collectively tend to be evaluated more favorably. User innovators are encouraged not only to share their ideas and collaborate with others for a potentially more enjoyable innovation process, as described in the interviews but also to shape innovation collectively in the future.

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