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Considerations in the testing of a minimum viable product in healthcare

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Abstract

Introducing a Minimum Viable Product in the market and rapidly testing it proves valuable in assessing its value and potential. This involves experiments, gauging growth, and striving to diminish uncertainty in iterative cycles. The application of these approaches in healthcare, however, faces obstacles due to unique challenges including patient safety concerns and regulatory compliances. This paper undertakes a narrative literature review covering experiences of healthcare professionals and presents guiding considerations for medical startups to use in the market validation of their products.

Keywords: lean product development, biomedical design, co-design, user-centred design

1. Introduction

Prior to product development, the lean startup methodology emphasizes 'customer discovery,' involving the validation of business hypotheses through extensive interviews with potential customers (Blank, 2020). This process involves hypothesis testing related to customer segments, value propositions, and resources, aiming to ascertain customer needs, product viability, and potential willingness to pay. The lean startup framework hinges on three key concepts: validated learning, "get out of the building", and minimum viable product (Ries, 2011; Batova et al., 2016). Validated learning involves empirical validation of business models, helping startups understand genuine customer needs, thereby averting investment in unappealing products or services. The directive "get out of the building" urges entrepreneurs to counteract confirmation bias by seeking feedback from real customers in the initial phases to avoid investing in unwanted products (Batova et al., 2016; Reidl and Valtiner, 2021).

The concept of the Minimal Viable Product (MVP) as elucidated by Ries (2011), is what “helps entrepreneurs start the process of learning as quickly as possible. It is not necessarily the smallest product imaginable, though; simply the fastest way to get through the Build-Measure-Learn feedback loop with the minimum amount of effort”. It emphasizes a systematic approach to learning and innovation, particularly in nascent markets where uncertainty and ambiguity prevail. The MVP and its testing are an integral part of hypothesis-driven entrepreneurship associated with lean startup and focuses on learning customer values by rapidly testing value propositions with real customers (Garzinti and Golkar, 2020). Eisenmann, Ries, and Dillard (2012) highlight that each MVP aims to disprove hypotheses by presenting the smallest set of activities necessary. These iterations occur in short prototyping cycles. The primary objective of the MVP is twofold: to maximize learning and reduce uncertainty while decomposing customer needs for future product development (Dennerhy et al., 2019; Cook et al., 2023). However, much of the existing work on MVP processes remains practitioner-based, lacking theoretical definitions and testing of propositions (Anderson et al., 2017).

1.1. Current research gap

Startups operating in the healthcare sector face distinct challenges compared to other industries (Saadatmand, 2017). Unlike businesses such as Airbnb or food delivery services, healthcare startups frequently encounter regulatory hurdles directly affecting public interest (Burfield and Harrison, 2018). Persuading stakeholders—be it patients or government bodies—to embrace innovative healthcare technology demands a unique approach due to the inherent complexity involved. Patients may struggle to grasp the intricate nuances of healthcare products and regulatory requirements, underscoring the startup's responsibility to effectively educate and engage them. Given the heightened public interest, stringent regulations impose a greater burden of proof on healthcare startups. Navigating these challenges entails active stakeholder engagement, proficient communication, public education, and emphasizing the tangible benefits of their solutions in enhancing healthcare accessibility, quality, and outcomes for individuals and communities (Burfield and Harrison, 2018). Consequently, the approach to designing and developing medical devices necessitates a distinct strategy, extending to the realm of minimum viable product creation and testing.

The complexities inherent in drugs and medical devices differ significantly from the consumer-centric smartphone market for example. Unlike Apple, whose goal is primarily to market iPhones as desirable without the need to prove substantial life enhancements, healthcare startups face a different landscape (Berezkina, 2022). This difference significantly impacts the MVP testing phase for healthcare device development, which remains largely unexplored in literature, constituting a substantial gap in knowledge. Asmar et al. (2018) present a framework for agile development of innovative Product-Service-Systems in physical rehabilitation, emphasizing the conception, quick prototyping, and validation of an MVP device. This work can be extended to other areas of health care; however, the framework does not explain the selection of MVP techniques and the considerations inherent in this decision-making process.

This paper starts by capturing the different techniques available for MVP testing in various industries, then delves into the experiences of medical device startups and professionals from the healthcare industry through a narrative literature review, and then elucidates the considerations essential for MVP testing in the medical space. These considerations may act as a succinct base guideline for entrepreneurial teams to further develop strategies and take decisions to help their startups assess the viability of their market in the healthcare sector.

2. Techniques for testing of a minimum viable product

The MVP process involves various techniques (Ries, 2011; Bank, 2014; Blank, 2020; Blank and Dorf, 2020; Alonso et al., 2023; Cook et al., 2023), ranging from ad-words to early prototypes, which are crucial for validating both technical aspects and business hypotheses, guided by lean startup methodologies. Some of the techniques can be applied to either physical or virtual product representations, while others are versatile and can be employed across both platforms. They have been categorized accordingly and listed below, with a brief description.

Careful selection and utilization of MVP techniques are crucial before investing substantial time and resources in the testing phase. The choice between a physical or virtual representation should be made based on the specific objectives of the MVP testing exercise (Ries, 2011).

2.1. Techniques for physical product representations

a) Paper Prototypes: Physical representations, sketched or pattern-based, showcase product ideas physically. This method is particularly useful for physical product development.

2.2. Techniques for virtual product representations

a) Landing Page: The landing page serves as the primary point of interaction for visitors and potential customers. It acts not only as a marketing opportunity to highlight product features but also as a means to collect visitor analytics using tools like Google Analytics. It is essential to view landing pages beyond just email capture pages, leveraging them extensively to test new products and ideas.

b) Crowdfunding: Platforms like Kickstarter, Gofundme, and Indiegogo are crucial tools for MVP testing. These platforms serve as ecosystems where early adopters, driven by financial contributions, validate their interest in a product or business idea. Crowdfunding not only aids in validated learning but also provides access to early adopters for feedback and potential word-of-mouth promotion.
c) Pre-order Pages: Similar to crowdfunding, pre-order pages help gauge customer interest by offering products or business ideas for purchase even before their production. These pages serve as indicators of demand, offering insights into whether to continue or discontinue a project. However, customers backing a project often expect guaranteed delivery, and creating a challenge if product promises are not met.
d) Digital Prototypes: Mockups, wireframes, and prototypes demonstrate product functionality resembling the actual user experience. These range from low-fidelity representations to more advanced prototypes, aiding in clear communication of product ideas among team members.
e) Explainer Videos: Videos showcasing a product's intended functionality are invaluable in validating market interest. Dropbox's success story is a testament to how an explainer video garnered significant interest and sign-ups without the actual product.
f) Blogs: Blogging platforms serve as a low effort means to validate ideas within the target market. Platforms like Ghost and App.net started as blog ideas, fostering communities, and gathering customer input during the MVP development process.
g) SaaS and PaaS: Leveraging cloud platforms and services like WordPress, Heroku, and Google Forms expedites the MVP development process. These platforms accelerate product development, reducing the time required to bring an MVP to market.

2.3. Techniques for both physical and virtual product representations

a) A/B Testing: A/B testing is instrumental in evaluating the effectiveness of product or marketing modifications. By utilizing various analytics tools, it becomes easier to gauge visitor reactions to design improvements. This method allows for testing two versions of a page or marketing campaign to determine visitor preferences. In cases of physical product representations, A/B testing can involve creating variations of the product's packaging, display, or physical attributes and testing them with different group of customers to determine which version leads to better sales or customer satisfaction.
b) Ad Campaigns: Ad campaigns serve as a valuable means of conducting market surveys. Platforms like Google, Facebook, and Instagram enable targeting specific customer segments, providing insights into which product features or business hypotheses attract more attention. Setting up demo stations or pop-up shops in high-traffic areas allows consumers to interact with physical products directly, fostering engagement. The data obtained from ad campaigns, such as conversion rates or click rates or sign ups, help in shaping product features and strategies.
c) Wizard of Oz: This strategy involves presenting a seemingly complete product or service while carrying out the operational aspects manually behind the scenes. For physical product representations, this could involve presenting the MVP device to users in a controlled environment, such as a user testing session or a demonstration event - users interact with the product as they would with a fully automated version, unaware that human operators are managing it. Similarly, for virtual representations, human operators could, for example, control the content and guide users step by step through an otherwise automated purchase process. Companies like ZeroCater and Zappos initiated their operations in this manner before transitioning to automated systems.
d) Concierge MVP: Similar to the Wizard of Oz approach, Concierge MVP involves manual delivery of highly customized services to specific customers. Companies like Rent the Runway tested their services by offering in-person dress rentals to college students, providing valuable insights into the customer experience.
e) Piecemeal MVP: The Piecemeal MVP method involves creating a functional demo of a product using existing tools and services instead of developing proprietary infrastructure.

Developing prototypes using off-the-shelf, repurposed products is an example of a piecemeal MVP. Companies like Groupon initially utilized a blend of WordPress, Apple Mail, and AppleScript for order processing, avoiding extensive investment in infrastructure development.

f) Single-feature MVP: Focusing on a single feature within an MVP helps save development time and keeps customers focused on the primary product function. Companies like Foursquare and Buffer began with minimal features, concentrating on core functionalities before expanding.
g) Customer Interviews: Customer interviews involve exploratory discussions with users to understand the problems the product aims to solve. These interviews provide valuable information for refining the product's value proposition.

By leveraging these diverse MVP testing techniques, startups can gather valuable insights, refine their products, and validate their business hypotheses effectively. Each method offers unique advantages in obtaining customer feedback, validating market demand, and shaping product development strategies.

3. Experience of startup founders and other experts in healthcare

In accordance with the World Health Organization (2021), a medical device encompasses a wide range of instruments, machines, software, or substances designed for medical purposes, distinct from regular devices due to their specific intended use. These devices span from simple tools like tongue depressors to complex implements such as surgical lasers and pacemakers. Generally, medical devices serve one or more of the following five functions: diagnosis, prevention, monitoring, and treatment of diseases or the observation of human body conditions (Therapeutic Goods Administration, 2020). Arandia et al. (2023) outline three primary phases in the development of medical devices. The first phase focuses on development feasibility, identifying and validating various ideas and solutions while minimizing risks through prototype development. Subsequently, incremental, and iterative prototyping aims to refine the device's functionality by creating integrated prototypes. Finally, during medical product consolidation, the prototype transitions into a fully-fledged product, ensuring compliance with regulatory standards through verification, validation, and documentation.

The principles of lean startup methodology used in such development processes are well-known, particularly among those venturing into startup creation: understanding the customer, developing, and launching a minimum viable product, collecting customer feedback, analyzing, and iterating continuously. While these tactics excel in constructing photo-sharing apps or driving ad clicks, their application to revamping clinical workflows in a hospital or defining how individuals make decisions about investing in medical devices offers only a partial solution (Burfield and Harrison, 2018).

The application of lean startup methodologies as elucidated by Ries (2011) to the healthcare domain, is already underway. For instance, in hospital pharmacies, the shift from delivering large batches of medications once daily to smaller, more frequent batches every four hours has proven to reduce workload and prevent unnecessary rework or disposal of medicines due to changing patient orders or movements. Similarly, hospitals have adapted by collecting blood specimens in smaller, more frequent batches to improve turnaround time and maintain test quality, even if it means hiring additional staff. This shift is justified by the overall cost reduction in the system (Ries, 2011). However, these implications are on a very local scale. To scale a healthcare device successfully at a national or international level, one must not only demonstrate market potential and business success but also prove genuine improvements in patient health outcomes, enhanced accessibility, and/or cost reductions. Healthcare founders must present rigorous data to healthcare providers, investors, media, influencers, and regulatory bodies like the FDA, often necessitating years of trials and experiments for approval, far beyond the demands of a typical commercial enterprise (Burfield and Harrison, 2018).

The Customer Development methodology may not be suitable or necessary for all types of industries. In specific sectors such as biotechnology, there are scenarios where the aphorism "build and they will come" holds true, particularly in cases where groundbreaking drugs or critical solutions are developed to address pressing medical needs, like curing a specific cancer. In such a startup, the primary risk

lies in the initial stages of product development, especially in transforming a research hypothesis into an effective and successful drug. Success or failure isn't primarily about understanding customer needs or adoption; rather, it hinges on the company's ability to develop a functional product and navigate the rigorous approval process. In such cases, if a company can successfully create a working product and secure approval, there's a high likelihood of significant end-user demand due to the critical nature of the solution. The key challenges shift from understanding end-user needs to identifying appropriate partners, devising licensing strategies, and establishing effective distribution channels. However, it's crucial to note that this "build it and they will come" approach might apply to a select few ventures rather than being the norm for most startups (Blank, 2020).

In the realm of healthcare, the primary objective of almost every product or service is to ultimately benefit patients, whether the target audience is doctors, hospital administrators, or insurers. However, the purchase decision in a significant portion of these healthcare offerings is not directly by the patients themselves. This discrepancy between the beneficiary, the actual user, the provider, and the payer creates a complex interplay, wherein understanding these intricate relationships is crucial.

For healthcare startups, credibility amplifies, for example, when a prominent research hospital funds a study on the product's impact on their patient community (Batova et al., 2016). The significance of credibility for a regulated startup is paramount. Any assertion or endorsement from the startup's founder that serves their interests might understandably be met with skepticism. Even with a compelling narrative or robust data, statements from the founder alone lack the same authority. For instance, in 1776, when Philip Morris, the manufacturer of Marlboro cigarettes, proposed funding a health startup program, the association raised concerns. While some health startups might consider participation, most would prefer not to be linked with Philip Morris in any capacity (Burfield and Harrison, 2018). Contrast this with the credibility expectations faced by founders of healthcare startups. They must persuade hospitals and health systems that their technology can improve cost efficiency. Simultaneously, they need to assure patients and advocacy groups that the technology leads to better or at least neutral health outcomes. Convincing healthcare professionals like doctors and nurses that their solution simplifies their tasks is another challenge. Additionally, gaining approval from regulators at various levels regarding safety and security is crucial. This daunting task becomes more manageable with credible advocates supporting the startup's claims (Berezkina, 2022).

In a column published in TechCrunch, Dr. Nancy Markley, founder, president, and CEO of MPowrx, a health and medical products startup in Alberta, Canada, highlighted the importance of data transparency and external validation, stating that having their technology undergo clinical trials and peer-reviewed assessments contributed to the company's credibility. She stressed the necessity of being open to due diligence and the scrutiny of potential investors, urging founders to welcome the opportunity to prove their product's effectiveness through scientific validation. The ability to demonstrate scientifically validated applications becomes a critical factor in securing investor trust and market acceptance for a new healthcare product (Burfield and Harrison, 2018).

In 2011, Pepe established Mamotest, a telemedicine startup dedicated to offering free or low-cost mammograms to women residing in rural regions of Argentina. The initiative involved conducting screenings at their locations and transmitting images via the internet to a centralized facility for analysis by licensed radiologists. This innovative approach aimed to tackle one of Argentina's most critical healthcare challenges: the high mortality rate due to breast cancer, with twenty women succumbing to the disease daily, often due to late detection. However, Pepe faced a dilemma. In Latin America, there exists a bias against entrepreneurs operating in the healthcare sector, often perceiving their efforts as profiting from people's health problems. Recognizing this sentiment, Pepe strategically framed Mamotest's narrative around the women whose lives were saved by their service, emphasizing the commitment to saving lives over profit-making motives. To counteract biases and gain support, Pepe took an extreme approach by launching Fundación Telmed alongside Mamotest. This non-profit organization aimed to expand telemedicine use in underserved areas, focusing on early disease diagnosis. By partnering with like-minded nonprofits, Fundación Telmed promoted routine testing and heightened awareness of available services, such as Mamotest. Pepe strategically highlighted

Fundación Telmed's social mission while positioning Mamotest as a technology-driven enterprise, adapting his messaging depending on the audience (Burfield and Harrison, 2018).

3.1. Insights from interviews

Multiple startup founders and experts in the field of healthcare have been interviewed by other research groups (Burfield and Harrison, 2018; Nguyen-Duc et al., 2019; Berezkina, 2022). These groups have primarily collected data from industry practitioners and experts having technical experience of two to more than 10 years in the field of healthcare technology and healthcare entrepreneurship (Nguyen-Duc et al., 2019; Berezkina, 2022). These range from the then very early-stage startups like Matt Angle's Paradromics, to that of Markley, which was then selling its product in more than eighty-five countries (Burfield and Harrison, 2018).

Questions asked covered their understanding of the lean methodology process, MVP testing methods, and about their experiences in MVP testing. Based on insights gathered from healthcare startups and industry experts, the development of minimum viable products (MVPs) has been segmented into three distinct types: piecemeal MVPs (Type 1), functional MVPs (Type 2), and non-functional MVPs (Type 3). Type 1 MVPs simulate the user experience of the final product but lack actual functionalities, often serving as simulations due to resource limitations. They frequently employ rapid prototyping, local contractors, and off-the-shelf components. Type 2 MVPs involve comprehensive hardware unit designs integrating sensors, chips, and circuitry, focusing on functionality and final product quality. Hardware designs are typically done internally or through outsourcing, and extensive functional testing is conducted at various levels. Type 3 MVPs transition from hardware to software development post-validation of core hardware aspects. These MVPs concentrate on software components, prioritizing quality attributes and non-functional testing (Nguyen-Duc et al., 2019).

A shared perspective among these experts is that creating an MVP prototype is pivotal for every business owner. The primary aim of the prototype is to offer stakeholders a tangible understanding of the product's functionality, crucial for its success. They emphasized the importance of aligning business model development with initial phases to ensure resonance with customer needs. The complexity of navigating regulations, customer understanding, and trust-building emerged as key challenges in the medical device market for startups (Burfield and Harrison, 2018).

One respondent underscored the significance of mapping target customers as the initial step, identifying four distinct groups: individuals facing current issues, employers aiming to enhance productivity, hospitals seeking swift patient solutions, and proactive individuals concerned about future health issues. Essential considerations encompass whether it's an entirely new market, required device numbers, market size, existing presence, and whether it replaces an existing product (Nguyen-Duc et al., 2019; Berezkina, 2022). Emphasizing the need for early customer involvement in testing and piloting, the respondent highlighted the product's value proposition. However, the respondent cautioned against exclusively describing a Customer Value Proposition (CVP) for a non-existing product to customers. Hypothetical information might lead to confusion, lack of credibility, or misguidance, potentially causing unreliable customer responses (Berezkina, 2022).

Another respondent highlighted the importance of early brand establishment, likening it to strategies employed by prominent companies like Apple, aiming to build anticipation before product availability. In contrast, another respondent cautioned against immediate aggressive marketing for medical devices, stressing safety, regulatory compliance, piloting, customer feedback, and feature development before licensing and marketing strategies. They warned against aggressive pricing and discount strategies that could harm trust in the brand (Nguyen-Duc et al., 2019; Berezkina, 2022).

Respondents highlighted the importance of having a tangible prototype accessible for customers to interact with, expressing that customer inquiries during this phase provide invaluable insights, propelling product development. While one respondent stressed the urgency of creating an MVP at the earliest, another suggested exploring existing market solutions before focusing on the prototype's details (Berezkina, 2022).

The creation of a prototype involves more than just physical construction; it's imperative to ensure its functionality across diverse conditions and for all users. Appearance, material, and extra features become secondary, with the prototype's primary role being to simulate the real product and attract

attention. While customers seek a functional product, user experience, usability, and design hold utmost value. Presenting something concrete to the customers, even if initially in the form of a picture or mock device, aids in better customer understanding, emphasizing the necessity of an active, functional device over an aesthetically pleasing design at this stage. Best practices advocate for a comprehensive test plan, enabling customers to physically engage with the demo product, followed by detailed interviews to gather nuanced feedback. This iterative testing and refining process ensures optimal results, emphasizing the prototype's role as a time-saving asset due to swift feedback collection (Burfield and Harrison, 2018; Berezkina, 2022).

Startups encounter distinctive challenges in hardware development compared to software. Hardware projects face longer development timelines and struggle with frequent product releases due to the intricacies of physical unit production. Cases revealed complexities in sourcing components adhering to medical standards, particularly when dealing with international suppliers, impacting deadlines and product showcases. Some startups invest in in-house facilities like 3D printers to expedite prototyping, mitigating delays from external suppliers. Hardware prototyping might experience pauses due to component unavailability, interrupting the iterative process. Moreover, feature creep in multifunctional product designs poses complexities in managing and extending these functionalities during the design phase (Nguyen-Duc et al., 2019).

Respondents highlighted the common practice of piloting without licenses among startups, especially in low-risk medical device development. This approach aims to create solutions for patients and customers, both locally and internationally. They stressed the necessity of having a readily available product for testing purposes. Additionally, engaging with potential users through surveys and communication helps identify essential functions that might be needed. Another respondent emphasized the critical need for a startup team to establish clear targets and goals for their device. They underscored the significance of calibration and validation to ensure the device's ongoing performance, even if its initial price might be higher (Nguyen-Duc et al., 2019; Berezkina, 2022).

During the testing phase, a respondent highlighted the importance of building relationships with hospitals or regulatory bodies. They advocated for early data collection during testing to provide evidence to regulatory authorities, stressing the benefits of establishing customer relationships before the device's readiness (Burfield and Harrison, 2018).

In the healthcare sector, regulatory compliance and stringent quality-focused requirements contribute to the complexity of hardware development for startups. Adherence to ISO certification and standards requires structured process management tools and adherence to defined processes. However, the dynamic nature of product development and regulatory standards often makes it challenging to anticipate future complications or requirements. Consequently, quick decision-making becomes necessary despite extensive planning. Understanding these complex regulations, although challenging for newcomers, holds the potential to save substantial time and establish competitive advantages for manufacturers by ensuring compliance from the outset (Nguyen-Duc et al., 2019).

4. Results: Considerations for testing of the MVP in healthcare

In the selection of a technique or combination of techniques for MVP testing, the general criteria used includes: low resource requirements, diverse customer data acquisition, ease of conduct, applicability to a broad range of products, testing the willingness to pay and generate sales, and easily definable metrics for evaluation. Each MVP technique undergoes a scoring process based on these predefined attributes, resulting in a score for each technique against every criterion, thus guiding the selection (Saadatmand, 2017). While prior research has outlined general criteria for selecting tests in MVP testing processes, it is important to underscore the intricacies and specific requisites involved within the healthcare sector.

Following a comprehensive review of experiences shared by startup founders and experts from the healthcare domain, we have compiled a set of considerations (Table 1) that hold significant relevance within the healthcare industry. These unique considerations account for the specific demands and complexities inherent in healthcare product development and testing methodologies.

Table 1. Considerations for testing of the MVP in healthcare

#	CONSIDERATION	DESCRIPTION
1	Safety and security	Unlike other industries, it is crucial here to ensure robust safety and security measures before deploying any device on patients.
2	Compliance with regulatory medical standards	It can be financially draining and time consuming for multiple MVP iterations of a newly developed device to undergo compliance testing with each iteration. Workarounds include the use of an approved predicate device for partial testing and testing of only the look and feel of the device.
3	Privacy and Ethics	For MVP testing, a comprehensive test plan is required in accordance with the best ethical practices. Ensuring privacy of the participant with anonymization and encryption techniques should be considered.
4	Product positioning	The startup's alignment with its positioning strategy, such as care-focused branding should reflect in the customer's experience, ensuring that they feel nurtured and valued right from their initial interactions. This is critical towards building trust.
5	Credibility	Establishing credibility is paramount as it ensures patient confidence in the product's reliability and safety, fostering long-term relationships, trust, and acceptance within the community. Addressing this right from the initial customer interactions builds a strong foundation, essential for adoption, especially in a sector where reliability is critical for patient well-being and satisfaction.
6	Perceptions	Validating the device's value propositions through MVP testing is crucial, but it is equally important to recognize and address patient apprehensions. For example, the perception of signals from a home-based device, despite being similar to in-clinic therapeutic electrical stimulation, might trigger concerns akin to shocks, demanding careful design consideration.
7	Clinical data	Focusing on clinical data, efficacy, health outcomes, and transparency is very important. In the absence of internally validated clinical data, leveraging data from reputable scientific publications or similar devices, or recommendations from clinicians, aids in substantiating the device's reliability.
8	Patient education and community	Patient education and community engagement foster informed decision-making among patients and enable a supportive environment. Providing access to such avenues directly or indirectly during customer interaction is useful to gauge their understanding and acceptance.
9	Prototyping issues	Issues in physical production capabilities due to unavailability of medical standard components and interruptions should be planned for in advance.

The guidelines presented here are based on both referenced research and practical experience gained from involvement in numerous medical development projects. This work draws on experiences from both startups and larger, established companies, gathered through a narrative review of insights shared by professionals from both backgrounds. One of the ways in which this work can be used is to provide guidance for addressing specific challenges in medical device and system testing, and to present an overall guideline for thinking about them. Rather than rigidly adhering to every point outlined, it is important to understand the context, timing, and rationale behind the adoption of these considerations in MVP testing for healthcare products. They should be viewed as prompts for critical thinking rather than strict rules.

5. Discussion

The insights provided in this paper regarding MVP testing in medical devices may offer valuable guidance for startups and device development teams working in the healthcare sector. These insights can potentially empower them to engage in customer development process effectively, validate market demand, and shape their business strategies, while taking into account the intricate nuances specific to the sector. For instance, they could consider incorporating clinician testimonials, educational session links, or community engagement information on landing pages. They could consider the company's standing before finalizing an A/B testing for an exercise product to be positioned as a treatment solution

versus a preventative measure. They might explore a Piecemeal MVP by utilizing approved, marketed predicate medical devices. They may plan to leverage blogs for patient education or employ explainer videos to demonstrate product usage as well. Medical device startups may use the considerations outlined in this paper to design and conduct effective MVP testing, ensuring that their product meets the needs of all stakeholders involved in the ecosystem.However, an important aspect to ponder is the impact of a patient's health outcomes on their feedback during the MVP testing phase. Consider a scenario where a patient seeks an extremely user-friendly solution for their 20-week prescribed treatment process. At the outset, their expectations may be based solely on their imagination as they haven't experienced the treatment before. But would their expectations evolve over time? For instance, around the 15-week mark of the treatment, would they become frustrated and seek even simpler options? Alternatively, would they be content with the improvement in their condition and be willing to compromise further on ease of use, as long as the improvement continues? Such evolving demands in the market are challenging to predict, especially in the healthcare sector where gestation periods and usage periods can be very lengthy sometimes.

While startups can glean similar insights from extensive texts, detailed encounters, and long interviews with experienced professionals, this time-consuming process may overwhelm startup systems with limited bandwidth. By studying such narratives and summarizing learnings derived from them, this work holds the potential to serve as an essential guide. At the same time, this work can be useful in developing a framework to assist startups in navigating MVP testing in the healthcare sector. For example, the framework could include steps for conducting user research, defining MVP criteria, designing MVP experiments, and analyzing results. It could also provide guidance on addressing ethical, regulatory, and safety considerations throughout the MVP testing process. By following the framework, the startup can make informed decisions that maximize their chances of success in the healthcare market. In this sense, this work has descriptive as well as prescriptive value.An important limitation of the current study is that the considerations were drawn based on secondary interviews. First-hand interviews specifically tailored for their own experiences in the healthcare domain would be valuable for deeper insights. We aim to address this in future research work, while also developing strategies to address these considerations and test them, ultimately leading to a framework or potentially a design methodology tailored specifically for market-validated medical products.

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References

Alonso, S., Kalinowski, M., Ferreira, B., Barbosa, S.D. and Lopes, H., 2023. A systematic mapping study and practitioner insights on the use of software engineering practices to develop MVPs. Information and Software Technology, 156, p.107144.

Anderson, E., Lim, S.Y. and Joglekar, N., 2017. Are more frequent releases always better? Dynamics of pivoting, scaling, and the minimum viable product. https://doi.org/10.24251/hicss.2017.705

Arandia, N., Garate, J.I. and Mabe, J., 2023. Medical Devices with Embedded Sensor Systems: Design and Development Methodology for Start-Ups. Sensors, 23(5), p.2578. https://doi.org/10.3390/s23052578

Asmar, L., Rabe, M., Low, C.Y., Yee, J., Kühn, A. and Dumitrescu, R., 2018. Framework for the agile development of innovative Product-Service-Systems for existing physical rehabilitation systems. Procedia Manufacturing, 24, pp.147-152.

Bank, C., 2014. 15 Ways to Test your Minimum Viable Product. URL: https://thenextweb.com/news/15-ways-test-minimum-viable-product

Batova, T., Clark, D. and Card, D., 2016, October. Challenges of lean customer discovery as invention. In 2016 IEEE International Professional Communication Conference (IPCC) (pp. 1-5). IEEE.

Berezkina, E., 2022. Developing a Roadmap How to Bring a New Product to the Market: a low risk medical device.

Blank, S., 2020. The four steps to the epiphany: successful strategies for products that win. John Wiley & Sons.

Blank, S. and Dorf, B., 2020. The startup owner's manual: The step-by-step guide for building a great company. John Wiley & Sons.

Burfield, E. and Harrison, J.D., 2018. Regulatory hacking: A playbook for startups. Penguin.

Cook, D.A., Bikkani, A. and Poterucha Carter, M.J., 2023. Evaluating education innovations rapidly with build-measure-learn: Applying lean startup to health professions education. Medical teacher, 45(2), pp.167-178.
Dennehy, D., Kasraian, L., O'Raghallaigh, P., Conboy, K., Sammon, D. and Lynch, P., 2019. A Lean Start-up approach for developing minimum viable products in an established company. Journal of Decision Systems, 28(3), pp.224-232. https://doi.org/10.1080/12460125.2019.1642081
Eisenmann, T.R., Ries, E. and Dillard, S., 2012. Hypothesis-driven entrepreneurship: The lean startup. Harvard business school entrepreneurial management case, (812-095).
Garzaniti, N. and Golkar, A., 2020, October. Performance Assessment of Agile Hardware Co-development Process. In 2020 IEEE International Symposium on Systems Engineering (ISSE) (pp. 1-6). IEEE.
Nguyen-Duc, A., Khalid, K., Shahid Bajwa, S. and Lønnestad, T., 2019. Minimum viable products for internet of things applications: common pitfalls and practices. Future Internet, 11(2), p.50. https://doi.org/10.3390/fi11020050
Reidl, C. and Valtiner, D., 2021. Using MVP in Hardware Industry–Reduce "Time to Market" by Taking Risks. Journal of Advanced Management Science Vol, 9(4). https://doi.org/10.18178/joams.9.4.83-87
Ries, E., 2011. The lean startup: How today's entrepreneurs use continuous innovation to create radically successful businesses. Currency.
Saadatmand, M., 2017. Assessment of minimum viable product techniques: A literature. Assessment.