Most Regrettable Business Decisions

ERRORS - MISSED OPPORTUNITIES - PITFALLS - TAKEAWAYS

Why Do So Many Healthcare Innovation Initiatives Fail

Successful healthcare innovation requires more than technical and clinical expertise; it demands a deep understanding of the ecosystem, including regulatory requirements, reimbursement systems, and organisational dynamics. Embracing a holistic approach, fostering continuous feedback, and engaging stakeholders early are crucial for overcoming barriers and achieving scalability and sustainable, impactful growth in patient care.

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key points

- Complex Systems: Understanding the healthcare system's complexity and adopting a holistic approach are crucial for successful innovation.
- Economic Hurdles: Engage early with payers and validate economic models to overcome reimbursement challenges.
- Regulatory Compliance: Collaborate with regulators and strategically manage approval processes for efficient compliance.
- Evidence and Validation: Build robust clinical and economic evidence, including real-world validation, to gain stakeholder trust.
- Scaling Innovation: Address organisational resistance and integrate new solutions with existing practices and technology for successful scaling.

As an innovation leader, I was involved in a major project aiming to revolutionise at-home patient monitoring. The product development was carefully planned, and the team possessed the necessary technical and clinical expertise. The organisation had already been successful in producing products for monitoring patients in intensive care units (ICUs) around the world, which put it in a strong position in hospitals globally. Everything appeared to be in place for this to be a resounding success. However, it ended up being a failure. What went wrong?
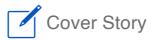
Today, I am involved with several promising healthcare ventures in behavioural health, mental health, advanced diagnostics, and cancer treatment. Each of these ventures has identified real and urgent patient needs and designed feasible solutions to tackle significant challenges in healthcare. However, they have encountered obstacles at various stages that have prevented them from progressing as planned and making the impact they had hoped for. Even powerful consumer platforms like Amazon have faced setbacks. My experience with the patient monitoring venture taught me to proceed with caution.

Adopting an Ecosystem Mindset and System Thinking for Success in Healthcare Innovation

Healthcare systems are complex. The industry has strict regulations, rigorous quality standards, complicated reimbursement mechanisms, many stakeholders, and many vested interests.

As we did with many products before, we approached this venture as a regular pipeline development: We designed a product with what we believed were compelling features

and functions fulfilling a real need: supporting patients at home, where they tend to recover or stabilize faster than in the hospital, at a much lower cost. However, the complexity of the healthcare system requires a different approach than the regular linear product pipeline prescribes.

Our first mistake was taking too mechanical a view of the world. As we learned along the way, the secret to mastery of complex programmes is adopting system thinking—a holistic approach that uncovers the interconnections and dynamic forces driving outcomes. This approach works from the perspective of the ecosystem and its most important players: it identifies the influence networks, barriers, and system dynamics.

While the solution succeeded in getting better patient outcomes at lower cost, we didn't take a couple of crucial things into account. The most important one was the economics for the hospital: the reimbursement model didn't reward a better solution. The insurer would reimburse a night in the hospital for thousands of dollars but not the monitoring of a patient at home for a fraction of those costs. The other significant barrier was that most care providers were reluctant to change their working methods and relationships.

In this case, the solution impacted different departments, how they worked together, and the relationship with referring general practitioners. We should have validated and approached our concepts from the payers' and various care providers' economic, cultural, and clinical perspectives. Early feedback would have given us insights that would have prompted a different proposition.

Cultivating a culture of continuous feedback, learning, and adaptability is crucial. This environment encourages teams to engage deeply with stakeholders, innovate, and experiment with solutions

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that must be viable from all perspectives to succeed. Understanding the broader context is paramount. It differs from driving tight schedules and project plans and focusing on revenue.

We concluded that we had to delve deep into the nuances of the ecosystem and conduct thorough customer feedback sessions and risk assessments. Creating scenarios to tackle unforeseen roadblocks ensures that the organisation is prepared for any eventuality, turning potential setbacks into opportunities for growth.
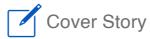
Transformative leadership hinges on the active engagement of all stakeholders. Fostering open communication channels where concerns and challenges are explicitly discussed and addressed builds trust and collaboration. This inclusive approach ensures that every voice is heard and valued, paving the way for collective success.

While strategies will evolve and the solution adjusted to the user needs, an unwavering commitment to the original vision and goals is essential. Leaders must remain flexible in their approach, adapting to changing circumstances without compromising quality. This steadfast dedication to excellence sets the standard for outstanding solutions. Large cohorts of patients will ultimately be monitored from home, but much water will have flowed under the bridge.

By embedding system-thinking principles into their leadership approach, leaders can significantly increase the odds of success in even the most ambitious endeavours. System thinking is not just about managing projects but gradually transforming organisations and driving sustainable, long-term growth.

Innovation Capabilities in Healthcare Ecosystems: A Holistic Approach to Diagnostics and Therapy

Several innovations in diagnostics and therapy have been developed in the last decades. But most have been point-solutions, solving specific problems for specific diseases. Unfortunately, many solutions never reach scale because their scope is too narrow, and they don't seamlessly integrate into existing systems and workflows.

In our case, we developed a clinically sound solution that needed to be better designed for integration into healthcare ecosystems. We also compromised the technical design, assuming hospitals didn't want to put their data in the Cloud, which would have made the solution more scalable.

This obstacle can be overcome by combining clinical, operational, technical, and economic capabilities to jointly design for the broader care flow and all the stakeholders instead of just the point solution. Innovation is way more than invention. Attention should be paid to fitting the innovation into existing economic models and clinical operational processes. This implies a team of brilliant clinicians or technologists will not cut it. You will have to bring the entrepreneur, the user-experience designer, the legal expert, and the data/ tech specialist together to craft a solution that could see the light of day. The design should start with the needs of the ultimate beneficiary of any healthcare solution: the patient. But more is needed. Each stakeholder's value (and monetisation) must be assessed, measured, and articulated.

An ecosystem approach can be pursued by partnering with complementary players to share insights, data, and technology and jointly create a more impactful proposition for all stakeholders. Technology choices will impact the solution's functionality, manageability, and cost. Cloud-based solutions and connected devices (IoT) allow solutions to be delivered and distributed at substantially lower costs than on-premises alternatives. Access to high-quality data is critical for all tech-based solutions, as AI will become progressively important in identifying and quantifying disease and personalisation of care pathways.

Leveraging Scientific Evidence to Overcome Clinical and Economic Validation Challenges

While our solution could prove that patient outcomes and experience were better and cost lower, based on baseline studies, hospitals asked for peer-reviewed studies with randomised trials.

So, another obstacle to success is the general requirement for clinical and economic evidence that the innovation will work as claimed, is safe, and delivers the promised benefits. Again, the standard is high, and there may be a need for randomised clinical trials, preferably double-blind ones. And even if you have successful, peer-reviewed evidence, your potential customers will ask for real-world evidence, which you will not have because you still have to take that hurdle. However, the requirement is valid: just having data from the isolated world of a clinical trial does not guarantee that the solution works in the complexity of the real world.

An approach that builds evidence for claims and hypotheses is valid for any business. It is part of an agile mindset. You experiment, continuously test, and rebuild to shape a solution that stands up to deep scrutiny. Working with the academic world has advantages, and many universities are eager to bring their methods, findings, and inventions to the market. An agile approach will also guide you towards bringing solutions to life early to create the feedback loops necessary to build a solid solution. Exposing the solution to actual patients and care pathways early will give you the required feedback. Leveraging existing clinical data, trials, and appro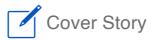vals helps speed up the solution. A collaborative, win-win approach will get you more than a zero-sum one. Many studies still live in splendid isolation.

Navigating Regulatory Approvals: Strategies for Efficient Compliance and Integration

With our solution, we recognised the need for regulatory approvals but had insufficiently isolated the components, like monitoring algorithms, that require regulation from those that don't. This means that any significant changes require revalidating the entire system rather than just those parts. This is a very costly and time-consuming aspect of the lifecycle cost of a healthcare solution.

Any new clinical solution will need to get the regulatory approvals (FDA and CE-mark) to validate patient safety and efficacy of the solution. If you have a genuinely innovative, new-to-the-world solution, this may take substantial time and effort. Every future-proof solution should aggregate data about users (patients and providers), engagement, and workflows. There are privacy hurdles to overcome. While GDPR and HIPAA provide clear frameworks, you will have to deal with variations of the different regions where you plan to deploy, which need to be baked into the design.

Working closely with regulators helps you better understand goals, requirements, and guidelines. In some areas, like AI-based clinical algorithms, regulatory approvals are still a work in progress, and you can influence how regulation is shaped. Your contractual agreements must take current and future rules into account. For instance, ask for patient consent upfront so you can start aggregating those critical longitudinal data sets.

It is essential to design for the different approval levels of Class I, II, and III devices. Platform software typically is not regulated, but algorithms that impact clinical outcomes are. Separating the parts allows for faster approvals.

Reimbursement Challenges: Navigating Payer Systems and Codes

As mentioned, the reimbursement system was one of the biggest hurdles to acceptance. In most Western countries, healthcare services are reimbursed by payers (health insurers) based on reimbursement codes. If the solution fits an existing code, you must apply for payer support based on clinical and economic evidence and regulatory approvals. You may be in for a lengthy process if it requires a new code. Working with selected payers early in the process may give you a better handle on what to expect regarding reimbursement. And beware, each country has different approaches to healthcare reimbursement, and value-based healthcare has yet to take off.

Scaling Innovation: Overcoming Organisational Resistance

While we secured a handful of strong backers to pilot the solution, scaling it was a significant challenge. Acceptance of innovation in a running organisation is the other big hurdle. Changing an organisation's way of working requires considerable effort to get users behind your system. While getting the backing of KOLs (Key Opinion Leaders) and hospital administrators is critical, it is no guarantee. Existing guidelines, processes, care pathways, protocols, and routines take time and substantial effort to change. That you bring clinical and economic improvement evidence is insufficient to transform your potential user's practices. Risk avoidance and downside protection are expected behaviours.

While great strides have been made in diagnosing and treating many diseases, we haven't seen much progress on the healthcare system level. Generally, hospitals still look the same, and despite a spike in virtual care during the pandemic, it has returned to face-to-face in brick and mortar. Care is fragmented and episodic rather than integrated and continuous. Prevention is still an orphan. There is incumbent inertia, with players holding on to their positions and unwilling to rock the boat, as this may have a potential downside. EMR and technology vendors hoard the data in their systems. Then there is the innovator's dilemma: it makes more sense to tweak the existing services than risk disrupting new systems and services that take advantage of new technologies, like AI.

Many hospitals will have the budgets and capabilities to pilot, but most of those will never scale up. As a hospital administrator told me, "We have more pilots than American Airlines." Innovation must be an integral part of the strategy, with clear stage gates, committed scale-up budgets, and an organisational drive to deploy a validated solution widely.

A multi-stakeholder approach will be necessary to bring everyone along. This requires a careful balance between fitting into the existing practices and workflow before being able to make the required change toward better outcomes. So, every solution should embrace the old while quickly showing the benefit of the new. There will be many design trade-offs, not just in user interfaces, workflow, and data management but also in change management. And the solution has to be flexible, as each provider will have specific processes and practices. Lastly, every solution must address safety, quality, and privacy upfront to get through the door.

Conclusion

Failure is a great teacher. This initiative changed my perspective on successfully deploying innovative solutions in healthcare. Navigating the intricate landscape of healthcare innovation requires more than just technical and clinical expertise. It demands a comprehensive understanding of the ecosystem, including regulatory requirements, reimbursement systems, and organisational dynamics. The lessons learned from our patient monitoring venture underscore the importance of adopting a holistic, system-thinking approach, engaging stakeholders early, and building robust evidence to support claims.

Healthcare leaders can overcome barriers and drive sustainable, long-term growth by fostering continuous feedback, collaboration, and adaptability. Embracing these principles will pave the way for impactful, scalable solutions that genuinely transform patient care.

Conflict of Interest

None