Barriers in Medical Device Innovation

Abstract
Every day, innovative new technologies can and do transform industries, and due to the massive technological innovations like the web, smartphones and communication technology, the rate of change has increased. But not all companies are created equal as regards creativity. The healthcare industry is extremely complex and due to rising costs and patient demands, the medical care delivery environment is under growing pressure. Such stresses and the industry's inherent existence itself make healthcare development more complex than it is in the consumer products market. To break through the complexities of medicine and drive science forward, inventors and medical testing and production firms must first resolve the many obstacles to the creation of healthcare products. Knowing how medical devices interact with humans is a critical problem that influences both the design and acceptance of innovative new technologies and their regulation.
The FDA classifies medical devices in three classes. The first two classes do not have many regulatory requirements, but class 3 has many hurdles to passing the regulatory requirements for marketing of the product. During the early generations, the regulatory requirement for marketing of medical devices was much less compared to the present situation: now they need to pass many regulatory hurdles, which is a very big barrier for medical device innovation because there is no proof that will it pass through the regulatory hurdles.

Key Words: Medical device, Innovative Barrier

Introduction

A medical device is described as a medical product which, via pharmacological, immunological or metabolic means, achieves its primary intended effect in or on the human body; or a tool intended for internal or external use in human or animal disease or disorder, diagnosis, treatment, mitigation or prevention.[2]

Example

Substances used for *in vitro* diagnosis and surgical dressings, surgical bandages, surgical staples, surgical sutures, ligatures, blood and blood component collection bags with or without anti-coagulant, and substances like mechanical contraceptives (condoms, intrauterine devices, tubal rings), disinfectants and insecticides.

History

The first "medical device" invented was the thermometer in 1603 by Galileo. In 1819 the stethoscope (wooden) was invented by Rene, and the real breakthrough was the discovery of X-rays in 1895, then the invention of the ECG in 1903, which is still used in all hospitals. There are more than 14,000 different products, according to Global Medical Device Nomenclature.

There are four types of classification of medical devices in India and Japan:[4]

CLASS	RISK	EXAMPLE
Class A	Low risk	Thermometer
Class B	Low -moderate risk	Hypodermic needle
Class C	Moderate- high risk	Lung ventilator
Class D	High risk	Heart valves

But according to some countries like Europe and the USA, there are only three classes:[1]

CLASS	RISK	EXAMPLE
Class A	Low risk	Thermometer
Class B	Medium risk	Lung Ventilator
Class C	High risk	Heart valves

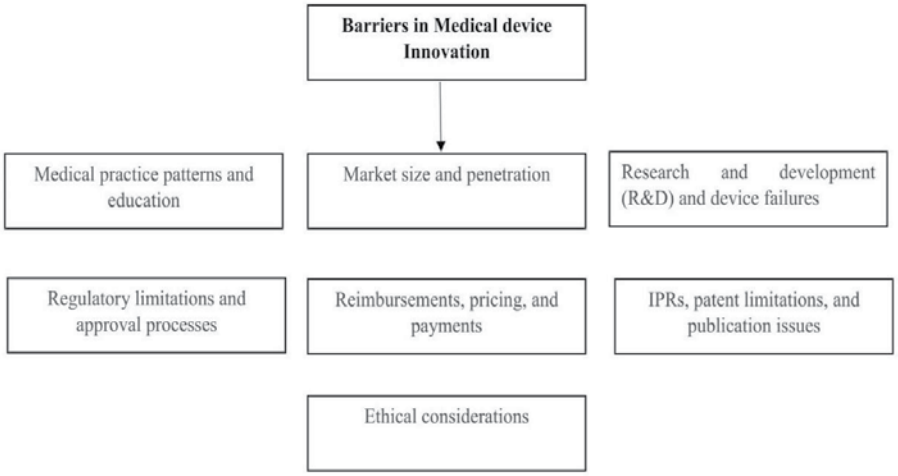
Innovation is not only about introducing something new but also adding value to it. It should be useful and feasible. Innovation and new product development are the lifeblood of the R&D department of an industry.

Ideas for change also come from consumers and experts who are most familiar with the issues that need to be addressed. Most ideas are received from clinicians and healthcare providers to solve their problems by innovating new products.

Barriers to innovation of medical devices cause a massive problem globally. For example, if a medical device is not on the market and the treatment for some disease or disorder is not available, most barriers relate to medical efficacy review, distribution of the product, and manufacturing of the medical device with good quality, regulatory oversight.

Another hurdle is questions relating to intellectual property rights (IPRs). The extensive testing that the US Food and Drug Administration (FDA) or the European Notified Bodies require represents large and risky financial commitments. The final financial outcome of investments may be uncertain even after positive clinical testing, as payments for products and services are not assured by reimbursement mechanisms. Reimbursements may require more research, recording a beneficial cost / benefit analysis for patients, healthcare providers, or even for the broader society. The cost of such studies is often the liability of the fabricators of products.[5]

Barriers in Medical Devices:[6]
The following topics will be discussed herein in an attempt to give a brief overview of barriers in medical device innovation:



Medical Practice Patterns and Education
While medical practice is changing rapidly, there is an underlying tradition in medicine which supports the status quo. New methods are often, and often correctly, adopted only after the "medical establishment" has completed and accepted controlled studies. Randomised trials and meta-analysis are needed for new procedures and technologies to become a standard of care. Even upon completion of such studies, years can pass before a tool or procedure is commonly used. This is a challenge for designers of devices who spend enormous resources to sell a product. The duration of the new product's high-income potential may be short, making it less desirable for new technology to be the first out. The method of introducing new technologies in hospitals is often difficult and relies on physician-administrative consensus.

Market Size and Penetration
The global market for medical devices is rising, but substantial maldistribution exists between rich and poor countries. The disparity is apparent and important as applied to the consumer technology industry such as mobile phones. Although cell phones are available to most people, there are few cardiac pacemaking agents, and the number of patients killed each year by a lack of pacemaker and defibrillator care is estimated at 1–2 million. While ordinary Africans can afford a cell phone and pay the subscription services, a lifesaving pacemaker and the requisite charges for implantation and monitoring cannot be managed. This can be partially understood as an inefficiency for medical devices firms in emerging markets and a lack of healthcare services and skills. Device manufacturers may be hesitant to offer the emergent market lower-priced products, believing their own goods could be cannibalised and profit margins eroded.

Research and Development (R&D) and Device Failures
Medical device R&D and sales are high-risk projects. It's a long and expensive process from proposal to practical medical implementation. Traditionally, early research is conducted in educational institutions, while in the corporate environment software creation, evaluation and development occur. Systems are expensive and often drag on for years. Despite extensive product evaluation both *ex vivo* and *in vivo*, the manufacturer's risk of later failure of new products will cause severe medical problems for the consumer and economic disaster. The Christiansen hip prosthesis and the "Björk–Shiley" heart valve, as well as the silicone breast implants in France, are leading examples of failed products. The future legal and financial consequences of such failures represent a major investment risk. As an example, with the problem of the "Björk–Shiley valve", where welded valve struts split and caused embolisation of the leaflet, the production company went bankrupt because of allegations of personal injury. The "Björk–Shiley" experience has resulted in more stringent testing practices and medical follow-up for heart valve products, which is helpful to patients, but acts as an innovation barrier as new claims will emerge more than 20 years after medical devices barriers to product development implantation. Initial acceptance and successful implantation of a device is definitely not a guarantee against future complications. It may be unrealistic for developed and poor countries to assume the same degree of complexity and safety features of medical devices as those requested by Western regulatory bodies. Most poor countries' gross domestic product could not afford the implantation of costly implants even for life-threatening diseases for the people, and it may be fair to permit simple, perhaps even less stable devices in such markets. At present, advanced computer therapy is open only to wealthy and government leaders in poor countries. Implantable devices pose risks to patients and are known as Category III products requiring premarket approval. In the US, the FDA, a government agency, oversees this procedure.

IPRs, Patent Issues, and Publication
New medical technologies are often the product of academic-commercial collaboration. This may create contradictions between the willingness to publish and the interest in patenting and obtaining IPRs. Previously, researchers and healthcare employees' IPRs may have been poorly secured, leaving the scientist with the choice of keeping or publishing an invention secret, risking the latter's loss of privacy. Technology transfer organisations, while increasing this obstacle, promote collaboration between companies and institutions. Small businesses, creating new technologies, may be in an adverse position to protect their IPR from the enormous legal and financial assets of corporations. Big companies often use large and general patents to protect their goods and services, preventing new development. Medical professionals are essential contributors to product innovation, and insufficient IPR regulations pose yet another obstacle to advanced innovative development unless technology transfer organisations actively help protect IPRs. A double-edged sword may be the question of patent law and practice. Gaining a patent will promote creativity by granting exclusivity to the patented item for the length of the patent. Patents, on the other hand, raise product costs

dramatically and may reduce creative efforts in the relevant field. Gold *et al*. provide a careful analysis of the importance and drawbacks of existing patent law practices. The consumer limitations on modern devices or drug therapies in the developing world is a particularly serious problem that has been proposed as an alternative to the current patent procedure.

Reimbursement and Pricing

Healthcare service fee is based on clinical classification in many countries and may not include the cost of new advanced tools. Methods involving new devices for healthcare providers can pose a financial pressure or loss. The lack of innovative technology payments will hamper the implementation of new technologies and thus product innovation. Legislation can vary considerably in different countries, and the lack of predictability is an apparent obstacle to innovation. Reduced payment options on emerging markets are seriously obstructing the introduction of new technologies. As noted earlier, patent regulations may further hinder the growth of low-income countries, even though these countries may be able to use the reversing design technique to manufacture out-of-patent products.

Ethical Considerations

The World Health Organization considers access to healthcare to be a human right, but this right remains a myth for most of the global population. Although the health problems are different, the richest countries are also struggling with delivery and access to care. Transplantation and use of existence-support equipment, such as dialysis and circulatory aid devices, should be in theory open to everyone in need, but provision, in fact, is severely restricted globally. In many countries, insurance may not cover existence-supporting devices such as pacemakers, and treatment is thus restricted to monetary rather than clinical indications.

Conclusion

As the world is moving very fast, innovation of medical devices will provide better lifestyles for patients. Innovation in medical devices has given enormous benefits to patients, particularly in the developed world, while there has been much less benefit to the population in emerging and poor countries. Because of the obstacles to technology, the production and adoption of novel medical devices was slower than for some consumer goods. The combination of medical and technical expertise will contribute to faster and more efficient growth, thereby enhancing investment capital availability. Early R&D will take place across consortia like education, manufacturing companies, and government agencies, thus increasing shareholder aversion to risk. Streamlining clinical trials, including a more consistent method to the process of evaluating health technology, can accelerate the implementation and spread of price-effective devices. While the current business model for computer manufacturers may be threatened by lower prices, increased sales may make up for them economically by establishing a real global market. Medical devices often have excessive pricing and it is undoubtedly true that this innovation will make it much easier for the medical field to stick to its basic moral principles when interacting with medicine and technology. Changes in patent laws and the way such laws are practised may decrease cost and increase competition.

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