Additional peculiarities of medical devices that should be considered in their development process

Authors:

- Isa C.T. Santos
  Instituto de Engenharia Mecânica e Gestão Industrial, Faculdade de Engenharia, Universidade do Porto
  Rua Dr. Roberto Frias, s/n 4200-465 Porto, Portugal
  isa.santos@fe.up.pt

- João Manuel R.S. Tavares
  Instituto de Engenharia Mecânica e Gestão Industrial, Departamento de Engenharia Mecânica, Faculdade de Engenharia, Universidade do Porto
  Rua Dr. Roberto Frias, s/n 4200-465 Porto, Portugal
  tavares@fe.up.pt
  (corresponding author)

Summary

Medical devices are peculiar products: their definition varies from country to country, they are used to treat diseases, and their different from pharmaceuticals. In 2012, we began to describe the complex and demanding environment of the medical device industry. In this paper, our previous research is extended with additional peculiarities of medical devices such as recall, pricing, and adoption factors.

Keywords

Characteristics, recall, reimbursement, pricing, adoption, ethics, redesign

Expert commentary

More often than not, crises are associated with unstable and dangerous situations, and the general public tends to miss their constructive sides: crises question the status quo and are a driver of change. The recent world crisis has exposed many dramatic situations, but it also put in the spotlight the efficient use of resources. In healthcare, that was translated in the recognition of the importance of health technology assessment.

By having to demonstrate the value of their medical devices, manufacturers have to develop solutions that really matter, and also optimize their processes. Product development methodologies, specifically those dedicated to medical devices, can help manufacturers to address
the enhancement of their performance. In order to develop such methodologies it is essential to understand what makes medical devices unique.

**Five-year view**

A recent study showed that, since the 1990s, the number of publications on product development methodologies dedicated to medical devices has been increasing. In the near future, and considering the need to optimize the processes related with healthcare, including those involving medical devices, the demand for more and better methodologies will increase. In order to develop such processes, the understanding of the peculiarities of the medical devices is essential.

**Key issues**

- The definition of the term ‘medical device’ besides being broad varies from country to country.
- Medical devices have particularities that affect their development process and, hence, should be addressed.
- Previously, Santos et al. reviewed some of the specificities of medical devices; this paper, aims to extend that work in order to develop such devices more efficiently.
- After a medical device enters the market, manufacturers have two obligations: post-market surveillance and adverse event reporting. In case of a defect or a possible defect, its manufacturer or distributor may take actions to recall or correct the device.
- The recall procedures vary from country to country.
- The diffusion and adoption of medical devices go beyond science; it also involves ethics and economics issues.
- Each entity, country, and economic region has specific rules to determine coverage and reimbursement of a medical device.
- In the development of medical devices, there is a constant potential for ethical conflicts. In an early stage, it is important to define a set of basic principles to follow and guide decision making.
- In the medical device industry, as well as in healthcare, price is a very sensitive topic.
1 Introduction

The term ‘medical device’ refers to any apparatus, software, material, or other similar or related item intended to be used in the diagnosis, prevention, monitoring, treatment, or alleviation of a disease or an injury. However, the exact definition of medical device varies from country to country as well as the regulatory framework it has to comply with. This is one of the peculiarities of the medical devices that Santos et al. [1] identified in their work; here, we complement their work by describing additional features, such as pricing and reimbursement, to help design a more efficient new-product development process dedicated to medical devices.

Like the information compiled by Santos et al. [1], the data presented here was scattered in several web pages, peer-reviewed journals, books, standards, and regulations, and is organized as follows. After a summary of the medical devices peculiarities described by Santos et al. [1], it is presented a definition of recall and its associated procedures. The factors affecting the adoption of medical devices are listed and considerations on pricing, reimbursement, and ethics are made. Thereafter, are presented reasons for redesign. Finally, conclusions are presented as well as the impact of the peculiarities identified in the development process of medical devices.

2 Peculiarities of the medical devices

The peculiarities of medical devices identified by Santos et al. [1] are summarized next.

Each country or economic region has its own regulatory framework that includes a definition of the term ‘medical device’ as well as a classification system according to the risk associated. The classification system relates with the procedures that must be accomplished in order to market a device. And once a device is in the market, the obligations of the manufacturers continue in the form of post market surveillance and adverse event reporting. As regulatory frameworks vary, if manufacturers wish to enter more than one market, they have to master all regulations and (probably) make additional investments to comply with them.

The development process of medical devices has several difficulties and challenges. For example, as medical devices have multiple users that use the devices differently and with distinct expectations, the process of capturing the customer’s expectations, preferences, and aversions – voice of the customer – is longer and complex resulting in additional costs, incomplete design requirements, and/or trade-offs. Another challenge lies in composition of the design team: medical devices are developed by multidisciplinary teams (from engineers to physicians) with each member having its own jargon and, thus delaying or even hindering the comprehension of the problem being addressed, the actual needs, and potential solutions.
To overcome the difficulties inherent to the development of a novel medical device, companies may require higher investments. However, as the device’s lifecycle is short, companies have little time to recover them.

3 Recall

A recall refers to any action taken by its manufacturer or vendor to either remove a product from the market, correct it, or to notify its owners about the defectiveness or potential defectiveness of a product. Any product can be recalled, for example, consumer goods, food, and child safety seats, and some industries, such as aviation and medicine, have clearly defined regulatory guidelines for the procedure.

As far as the impact of a recall is concerned, besides lowering the revenues resulting from the loss of sales, a company has costs to implement the recall process, to correct or replace the product, with the unsold inventory, and with eventual fines and legal disputes [2]. In addition to the financial costs, the company’s reputation and the physical and psychological well-being of the consumer are affected. Nonetheless, recalls are common.

As medical devices involve human safety, one would expect that recalls would be rare. However, the opposite occurs. According to the Food and Drug Administration (FDA), between 2007 and 2011, across the USA, there were at least 160 recalls, that is, approximately one recall every 11 days. In Europe, as there is no centralized authority for approvals and tracking of medical devices, it is difficult to trace the number of recalls, but a 2011 report from the Boston Consulting Group shows that the number of recalls in Europe is similar to the one in the USA [101].

Medical device recalls can either be voluntary or imposed by a regulatory body (e.g. competent authorities in Europe or the FDA in the USA). Their motives are assorted and include, but are not limited to, malfunction, microbial contamination or such a possibility, violation of regulations, quality failures like manufacturing defects, packaging and labeling errors, software glitches, and the device giving incorrect results. Depending on the severity of the defect detected, the company has to adopt a suitable recall strategy which comprehends the depth of the recall (Figure 1); communications through press releases, website of the manufacturer, trade journals, and newspapers; notification of the users; timeliness; and progress reports.

The removal of a medical device from the market can be done resorting to recalls, market withdrawals, and corrections. While a market withdrawal refers to the removal or correction of a distributed product, a correction refers to repairs, modifications, adjustments, and relabeling of the devices while they are still under the control of the manufacturer and do not need to be physically removed to some other location. These actions should not be confused with stock
recovery, which is not considered as a recall, and refer to the removal or correction of a device that has not been distributed or that has not left the direct control of the company.

According to the FDA, recalls are classified into three classes considering the relative severity of the health hazard presented by the product (Table 1), are subject of FDA news release, and are listed at the FDA webpage [102].

In Europe, there is no harmonized definition of recall. The term is often used as a synonym of a Field Safety Corrective Action (FSCA) which is defined, in the guidance document MEDDEV 2.12-1 from December 2009, as ‘an action taken by a manufacturer to reduce a risk of death or serious deterioration in the state of health associated with the use of a medical device that is already in the market’. FSCAs may include the return of a medical device to the supplier, a device modification, exchange or destruction, or an advice given by the manufacturer regarding the use of the device. These actions should be notified via a Field Safety Notice (FSN), and copies of the document should be sent to the competent authorities (CA) of the countries where they are applicable as well as the CA in the country where the notified body (NB) which made the attestation that led to the CE (of the French ‘Conformité Européenne’ meaning ‘European Conformity’) marking is situated.

In spite of recalls being negative surprise events, they act as catalysts of learning and research [2]. By adopting design tools such as failure mode and effects analysis (FMEA) or design philosophies like ‘safety by design’ [3,4], it is possible to reduce the probability of a recall. Nonetheless, to reduce the impact of such event, during the development of a new device one should prepare the recall procedures.

4 Adoption factors for medical devices

The factors affecting the diffusion and adoption of healthcare technologies go beyond scientific evidence. In this context, the term diffusion refers to the process by which a healthcare technology is communicated through certain channels over time among healthcare professionals, patients, caregivers, and people with special needs [5]. The concept of adoption is similar to the one of diffusion, but differs from it in the sense that includes the psychological processes an individual goes through in order to use a technology.

The diffusion process is typically represented by a graph representing the adoption rate, i.e., acceptance over time. Most innovations have an S-shape curve in which the slope indicates the speed of adoption (Figure 2). In healthcare, this slope is influenced by varied factors, namely opinion leaders, communication channels, potential value of the innovation relative to the current
practice, ability to try the innovation, and infrastructures or other technologies that cluster with the innovation [6], [103].

Medical devices can be bought specifically for a patient and/or medical procedure or in a bundle as medical supplies. The buyer can either be individuals (e.g. patients), or organizations (e.g. hospitals). Depending on the device and the buyer, the adoption criteria change, but, due to the complex nature of medical knowledge, buyers place trust in the physicians, which are supposed to advice according to the clinical need, free of bias, and financial inducements. It should be noticed that, in spite of the existence of diagnosis and treatment guidelines, such as the NICE clinical guidelines [104], physicians often adopt different medical approaches or protocols, and the human nature makes people’s perspectives change depending on whether they are dealing with abstract statistical populations or with their own family [7]. In addition, it is difficult to test products before consuming them and ‘shop around for the best deal’.

Overall, the acquisition of a medical device depends on its features (what it does), if it conforms with the legislation, its efficacy (ability to produce the intended result), performance (ability to fulfill the intended purpose), safety (risks to users during clinical practice), and reliability (consistency of performance and safety) [8]. The awareness of the technology’s potential, the adaptability to the user, the ease of use, the existence of appropriate training [9], and the customer support are other influencing factors. Biomedical ethics principles, namely beneficence, non-maleficence, respect for autonomy and justice, can also affect the adoption of novel medical devices [10].

Economics is important in the dynamics of the adoption of a medical device but is not crucial. Buying a device simply because is cheap may be an error; one should consider who will pay (e.g. patient, healthcare provider, or insurance company), how costs will be allocated (e.g. as consumables or as capital goods), and the device’s life cycle costs and cost-effectiveness [11,12]. Although frequently patients pay for their medical treatments, is more common to find insurance companies and governments in the role of payers, thus, without coverage or reimbursement, many patients would be unwilling or unable to pay for their treatments [13]. In addition, reimbursement tariffs, by setting the prices that can be paid, not only influence the use of medical devices by the healthcare providers and the demand, but also impact the revenues of the manufacturers and incentives to develop novel solutions.

The increasing pressure to reduce healthcare spending makes it difficult to conciliate cost-containment with access to healthcare technologies, since new technologies are in general more expensive than the ones they aim to replace. In this scenario, health technology assessment (HTA)
is used to set priorities on the use of resources. For governments and regulators, HTA has the additional role of helping to create policies that ensure the safety of the public and social equity. HTA evaluates systematically the properties and effects of healthcare technologies investigating their attributes, specifically performance characteristics, safety, efficacy, effectiveness, social, and economic impacts [14]. The economic analyses are used to compare the resources consumed with the health outcomes obtained. While the inventory of resources and its expression as monetary units is similar across most economic evaluations, the consequences from each alternative may differ considerably. Hence, three types of economic analyses can be considered: cost-effectiveness analysis (CEA), cost-utility analysis (CUA), and cost-benefit analysis (CBA) (Table 2).

In CEA, the consequences of different interventions are measured and compared using a single outcome; for example, life-years gained, number of deaths avoided, millimeter of mercury (mmHg) drop in diastolic blood pressure, or number of cases detected [15,16]. In spite of the limitations of this type of analysis and the public’s perception that decisions are based solely on costs, it can be a driver for the development of solutions that really matter. CUA is a type of cost-effectiveness analysis in which consequences or outcomes are measured in utilities [15], usually, quality-adjusted life years (QALYs).

In CBA, the consequences are valued in monetary units [15]. This represents an advantage since it can be conducted for just one technology, and the net benefit can be calculated immediately determining if a technology is worthwhile or not.

Considering the diversity of medical devices, further studies are needed to determine which economic analysis is more suitability to each medical device. In addition, additional studies are needed to understand the impact of HTA on both pricing and reimbursement.

Figure 3 summarizes the factors that influence the adoption of medical devices. By considering these factors during the development of a new device, it is possible to increase its diffusion and adoption.

5 Pricing
Like any other industry, in the medical device sector, each manufacturer has its own method to determine the price of its products. Sellers can either set their prices or bargain with the buyer. In either way, manufacturers generally aim to recover the costs associated with the research and development process, cover the operating costs, which include fixed and variable costs associated with production, marketing, and sales departments, and obtain a profit margin. In addition, variables such as reimbursement, price elasticity, market share, competition, and brand identity are also considered.
Devices like needles and blood bags are sold in competitive commodity markets; as they are essentially uniform across producers, price usually plays the most important role. On the other hand, more expensive and specialized devices, like magnetic resonance imaging (MRI) machines and artificial knees, operate in oligopolistic markets, i.e. the market is controlled by a small number of sellers [17], or to be more exact, in ‘differentiated oligopolistic markets’, because although the products available are similar they not always are perfect substitutes.

In healthcare, price is a delicate issue because few are willing to accept that health is a consumer good, that is, it is possible to attribute a price. Thus, it is commonly accepted prices not being disclosed, and manufacturers charge distinct prices to different buyers [17–19]. However, this scenario may change with the spreading of initiatives such as Peto [105], an information portal that, since January 2012, allows buyers from the UK’s National Health Service (NHS) to compare both supplier and product information.

Hutchings [20] studied the factors that influenced the effective price of medical devices and identified the following features:

→ clinical and other benefits;
→ health economic and social benefits;
→ manufacturer investment in a particular country;
→ investment in product research and development;
→ cost of goods and profit margin;
→ technological advancement;
→ patent and marketing exclusivity;
→ comparator product price;
→ budget impact;
→ equity; and
→ rarity and burden of the disease.

6 Reimbursement

‘Reimburse’ is defined as to repay someone who has spent or lost money. In healthcare, healthcare providers or patients pay for treatments at the time of their delivery but later, either the national health fund or a private health insurer, repays the costs in whole or in part. Reimbursement systems do not aim to fund healthcare; by setting the levels of reimbursement, they are used to control and reduce healthcare spending.

Table 3 lists organizations involved in the reimbursement process in the 8 countries with the highest health expenditure in 2009. Each entity has its own mechanism to determine the
reimbursement values [21] but often private insurers follow the decision taken by government bodies. The adopted requirements seem to change and evolve over time [22]; overall, data on clinical efficacy, risks, benefits, and costs are evaluated. Many government bodies, as France, Germany and Italy, have adopted reimbursement systems based on diagnosis-related group (DRG) coding [23]. In this system developed in the late 1960s by a team of the Yale University, similar and related procedures are grouped together, and then it is attributed a code that corresponds to a given value that is the set amount of money that is reimbursed.

Medical devices can be reimbursed after being recognized that they either provide a health benefit in its own (e.g. in France), or as a resource used in a procedure that provides a health benefit (e.g. in Germany and Italy). In the latter, the payment of the medical device comes within a budget, while the first modality removes the temptation of using a cheaper device when a more expensive is clinically more appropriate.

Commonly, there are two types of reimbursement lists: a positive and a negative one. The later comprises devices and procedures to which reimbursement is prohibited from either public or private funds. In general, an item is included in this list after a bad outcome of HTA; the decision is generic, not brand specific. In some countries, such as in Spain, being in the negative list also means that the device and/or procedure cannot be sold in that market.

A positive list includes medical devices and procedures that can be reimbursed along with the value of reimbursement. To be included in such a list, a code has to be attributed to the device or procedure, and then they have to be approved and officially listed. The approval process can be long, usually around 3 years [106], and, consequently, affect the adoption and implementation of medical technologies.

Reimbursement lists vary from country to country, public and private healthcare providers, hospital and outpatient care and, in some cases, then even vary by geographical region, as in Germany.

The value of the reimbursement is determined by the payer, that is, the government body or the healthcare insurance company. If the value of the reimbursement is not enough, the manufacturer has to demonstrate that the extra benefits are worth the additional reimbursement. Like a process to claim reimbursement, adjustments to the reimbursement value take around 3 years to conclude, and in the meanwhile, the device should not be commercialized in order not to compromise the request made.
7 Ethics

‘Primum non nocere’ or ‘primum nil nocere’ are two phrases in Latin that mean ‘first, do no harm’. Every physician knows them because is one of the fundamental principles of biomedical ethics that are taught in medical school. Those involved in the development, manufacture, regulation, and approval of medical devices should also be familiar with them because, like physicians, they play a role in the diagnosis, prevention, monitoring, treatment, or alleviation of a disease or an injury. However, this role is hidden because the contact with patients occurs during the development process (voice of the customer and prototype testing), market entrance (clinical trials), commercialization (advertising), and post market activities (HTA and reimbursement clinical trials).

In the medical field, there are four ethical principles that are commonly accepted: beneficence, non-maleficence, justice and respect for autonomy. The two first principles are inter-related; while beneficence is the obligation to provide benefits to patients, non-maleficence refers to the obligation to not inflict harm on patients, unless that is outweighed by potential benefits. In both cases, one has to ensure that treatments and/or medical devices are effective and able to provide safe treatments. These principles are supported by the following specific rules [10]:

- Protect and defend the rights of others;
- Prevent harm from occurring to others;
- Remove conditions that will cause harm to others;
- Do not kill;
- Do not cause pain or suffering.

The principle of justice concerns how social benefits and burdens should be distributed; it may be interpreted as fair, equitable, and appropriate treatment in light of what is due or owed to persons, i.e. to provide a fair access to the treatment.

Respect for autonomy refers to the right to hold views, to make choices, and take actions based on personal values and beliefs. Hence, choices should be made by those that have decision making capacity (are competent), are free of controlling constraints (voluntary), and are adequately informed. This principle is supported by a number of specific rules, including [10]:

- Tell the truth;
- Respect the privacy of the others;
- Protect confidential information;
- Obtain consent for interventions with patients;
- When asked, help others make important decisions.
The nature of medical devices makes them prone to financial, non-financial, individual, organizational, and societal conflicts of interest (Table 4 and Figure 4); i.e. a set of conditions in which professional judgment concerning a primary interest, such as a patient’s welfare, tends to be unduly influenced by a secondary interest, such as financial gain [24].

Ethical dilemmas may appear at any stage of the development process, since the identification of a need until post market activities. For example, when designers interact with users during the voice of the customer or prototype testing, they have to evaluate if users are able to understand and process information, and if they are volunteering for research without coercion, manipulation, or undue influence from others. This happens because among medical device users are vulnerable subjects, that is, individuals with limited capacity or voluntariness such as children, people with special needs, and individuals with incurable or fatal diseases or going through emergency situations.

The absence of regulations to guide companies to develop their advertising is another ethical challenge for manufacturers: in the one hand, it is immoral to impose product, but companies have to teach physicians to use their products and need their feedback to understand the problem and development future versions.

The basic principles of ethics presented here help to define a behavioral code of conduct that can be used to support decision making when such conflicts occur. Nonetheless, associations, such as Advanced Medical Technology Association (AdvaMed), MEDEC (Canada’s Medical Device Technology Companies) or TÜV Rheinland, have code of ethics on interactions with healthcare professionals [107, 108], namely gifts, product training and education, consulting arrangements, and research grants. To address the situations that are not mentioned in the codes, it is possible to resort to variant of the Bolam test; that is, ask a responsible body of colleagues if they would support the decision.

To prevent ethical conflicts, it is important, in an early stage, to define a set of basic principles to follow and guide decision making.

8 Redesign

Redesign refers to the process of designing something again or in a different way. It includes some of the tasks of an original design (e.g. voice of the customer, concept generation and prototyping), but it starts with and emphasis reverse engineering, i.e. the observation, disassembly, analysis, testing, and documentation of a product in terms of its functionality, form, physical principles, manufacturability, and assemblability [25]. It can be a good way of developing new products since it allows to reuse knowledge and machinery reducing development time and costs.
Redesigns can either be simple and subtle, or alter completely a product. There are several justifications for it, for example, it is part of the growth strategy of a company, it aims to homogenize a heterogeneous product portfolio into a family of products [26], simplify manufacture, and others (Figure 5). In the medical device sector, redesign is part of most companies’ growth strategy. In fact, companies launch their products with the assumption that further refinements will be incorporated in subsequence versions to keep customers excited about the devices and to overcome both time and technological constraints. Redesigns allow companies to gain market share while further research and development are still being carried out.

9 Conclusions

Both here and in the work of Santos et al. (2012) were presented several features that distinguish medical devices from other products. We inferred that these features impact the new-product development process and justify the development of a dedicated methodology to medical devices. However, experimental data is needed to support the claim that such methodology would contribute to save costs and the launch of new devices more quickly, effectively and efficiently. Among the characteristics identified, health technology assessment requires further studies. For example, it is important to understand how entities select HTA procedures, why they vary and which ones are more suitable to each type of medical device. Additionally, further research is needed to understand how HTA impacts pricing and reimbursement decisions.

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References


**Website references**


ABBREVIATIONS

AdvaMed – Advanced Medical Technology Association
CA – Competent authorities
CBA – cost-benefit analysis
CE – of the French ‘Conformité Européenne’ meaning ‘European Conformity’
CEA – cost-effectiveness analysis
CUA – cost-utility analysis
DRG – Diagnosis-related group
FDA – Food and Drug Administration
FSCA – Field Safety Corrective Action
FSN – Field Safety Notice
HTA – Health technology assessment
MEDDEV – Commission guideline relating to medical devices directives
MEDEC – Canada’s Medical Device Technology Companies
MRI – Magnetic resonance imaging
NB – Notified body
NHS – National Health Service
NICE – National Institute for Health and Clinical Excellence
QALYs – Quality-adjusted life years
FIGURE CAPTIONS

Figure 1: Supply chain of medical devices. The recall depth refers to the level of distribution from which a device is recalled (wholesale, retailer or consumer)

Figure 2: The diffusion process and description of technology adopters

Figure 3: Factors influencing the adoption of medical devices

Figure 4: Players in the development of medical devices, their interest and interactions; and conflicts of interest that may occur when there are adverse interests of both parties

Figure 5: Common reasons to redesign a product (adapted from [27])
TABLE CAPTIONS

Table 1: Classification of the recall of medical devices according to FDA
Table 2: Types of economic analyses and measurement units
Table 3: Organizations involved in the reimbursement process in the 8 countries with highest health expenditure in 2009 (the list is not exhaustive)
Table 4: Players in the development of medical devices and their roles in potential conflicts of interest (adapted from [24])
# TABLE 1

<table>
<thead>
<tr>
<th>Class</th>
<th>Description</th>
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<tbody>
<tr>
<td>I</td>
<td>A situation in which there is a reasonable probability that the use of or exposure to a violative product will cause serious adverse health consequences or death.</td>
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<tr>
<td>II</td>
<td>A situation in which use of or exposure to a violative product may cause temporary or medically reversible adverse health consequences or where the probability of serious adverse health consequences is remote.</td>
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<tr>
<td>III</td>
<td>A situation in which use of or exposure to a violative product is not likely to cause adverse health consequences.</td>
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<tr>
<td>Type of economic analysis</td>
<td>Cost measure</td>
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<td>monetary units</td>
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<td>cost-utility analysis (CUA)</td>
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<td>Canada</td>
<td>Patented Medicine Prices Review Board (PMPRB)</td>
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<td>Common Drug Review (CDR)</td>
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<td>France</td>
<td>Commission Nationale d'évaluation des Dispositifs Médicaux et des Technologies de Santé (CNEDIMTS)</td>
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<td></td>
<td>Comité Economique des Produits de Santé (CEPS)</td>
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<td>Germany</td>
<td>Institut für das Entgeltsystem im Krankenhaus (InEK)</td>
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<tr>
<td>Italy</td>
<td>Agenzia Italiana del Farmaco (AIFA)</td>
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<tr>
<td>Japan</td>
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<td>Institution</td>
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<td>Consultant</td>
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FIGURES

Figure 1

- **Laggards**
  - $\approx 15.0\%$
  - Traditional
  - Relatively isolated
  - Precarious economic situation
  - Suspicious

- **Late Adopters**
  - $\approx 34.0\%$
  - Skeptical
  - Responsive to economic necessity
  - Responsive to social norms
  - Limited economic resources
  - Low tolerance for uncertainty

- **Early Adopters**
  - $\approx 34.0\%$
  - Deliberate
  - Highly interconnected within peer system
  - Just ahead of the average

- **Opinion Leaders**
  - $\approx 13.5\%$
  - Well-respected opinion leadership
  - Well integrated in social system
  - Judicious and successful use of innovation

- **Innovators**
  - $\approx 2.5\%$
  - Ventreuese
  - Cosmopolite
  - Geographically dispersed contacts
  - High tolerance to uncertainty and failure

Figure 2