Study on Visualization of Ventricular Assist Device Development Process using System Dynamics

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Abstract

The purpose of this study is to identify the major factors that impact medical device development. Through the interviews with the person involved with ventricular assist device EVAHEART, we created a SD model. There are at least six stages in the device development process, including interactions with academia and the government. Through a simulation and comparison to Novacor, it was determined that the satisfaction of academia leads to government action in the subsequent measures.

Keywords

Ventricular assist device(VAD), EVAHERAT, Novacor, MHLW (the Ministry of Health, Labour and Welfare), Screening criteria, Regulatory Science

Introduction

The Japanese medical device industries are considered to have advantage for high technology though many items are large excess of imports over exports over twenty years. One of the major factors contributing to the uncertainty related to development especially approval by the government. [1] In order to clarify and visualize unclear relationships in the development of devices, we studied VAD EVAHEART and created the SD model. By simulating the SD model, an understanding for complex system was gained of the important factors in device development.

1. Material and methods

An System Dynamics model was created for the purpose of clarifying the development of the VAD EVAHEART. EVAHEART is ventricular assist device produced by Sun Medical Technology Research Corp. (SunMedical; Suwa, Nagano, Japan; Fig.1); The simulation period was 23 years according to the facts obtained for EVAHEART. For comparison purposes, we chose another VAD, i.e., Novacor. Novacor was a production by Baxter (IL, USA), approved in Japan in April 2004.



Fig. 1 EVAHEART ventricular assist device

1.1 Six stages of EVAHEART development

Prior to developing the SD model for EVAHEART, interviews were conducted with stakeholders based on inquiries made to three people from the manufacturer, three people from academia, five people from the government, and one cardiac surgeon. Interviews were conducted on a face-to-face basis or using e-mail or phone calls. In this study, the development of the model was limited to factors directly concerned with development. Other factors, such as budgetary and financial considerations, public opinion, and different environments, are excluded.

We estimated that there were at least six stages in the development of EVAHEART (Fig. 2). The development order does not apply to the stage order.



Fig. 2 Development model for EVAHEART

1.1.1 Collaboration between medical doctors and engineers

At this stage, cardiac surgeons and engineers meet to resolve problems. The human resource ratio is one surgeon to 4 engineers

1.1.2 Clinical evaluation

As the clinical trial progresses, data from patients are gradually provided. For EVAHEART, there were 16 patients from May 2005 through April 2008.

1.1.3 Academia and government

In academic societies, there are two types of member: those who do not know or trust EVAHEART and those who believe in EVAHEART. Before clinical trial information is made public, fewer members trust EVAHEART. The flow of trust is initiated by academics themselves and a few influential authorities who are satisfied by data. (Fig. 3).

1.1.4 Review for approval

Review for approval is accelerated by screening criteria. Some screening items may need to be reworked because of a lack of information. The review process continues until all screening items have cleared.[2]

1.1.5 Supply of materials

The behavior of companies that supply materials differs across the pre-clinical and clinical stages. Many companies have difficulty supplying materials at the first clinical

stages, but they gradually start becoming suppliers as they follow the lead of other companies.

1.1.6 Increase of clinical users

Three factors affect increases in clinical users: certified physicians, certified hospitals, and patients. It is estimated that 30 cardiac surgeons and 12 hospitals are certified every year and that there are 3,000 eligible patients.



Fig. 3 Model for academic and government satisfaction in relation to EVAHEART

1.2 Degree of progress

Degree of progress shows how medical device considered to be confident before clinical use. It is determined from the value of problems that need to be overcome, solved problems, ratio contributing solving problems, contributing ratio of companies, solved problems, ratio of companies that decided to supply and supplying companies until clinical use. (Fig.4) By interview from main manufacturer, we define relations between two technical breakthrough and its rise degree of progress. (Table 1) In this model, degree of progress behavior is almost same to actual EVAHEART's one.



Fig. 4 Model for degree of progress

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Time(from initinal)	Incident (technical breakthrough)	Degree of progress
24 month	Resolution of small size pump	Rise to 1/3 of whole
72 month	Hit an idea of cool seal unit	Rise to 2/3 of whole

1.3 Novacor

Novacor's development model is almost identical to EVAHEART's. The conditions of the simulation in Academia and government model are presented in Table 2 below.

	EVAHEART	Novacor	
Initial members who trust each VAD	10 people	2 people	
Number of authorities	5 peole	2 people	
Authority's initial influence	(2005)	(1996)	
Authority's initial initialice	17*12 month	17*12 month	
Authority's ultimate influence	(2008)	(1999)	
Authority's ultimate influence	20*12 month	20*12 month	
Number of academic seminars held	2 times	0 times	
Communication starts	17*12 month	15*12 month	

Table 2 Setting value in Novacor model

2. Results

A simulation and comparison between EVAHEART and Novacor shows that there is a

difference in terms of government credibility. (Fig.4)Both devices start to earn the satisfaction of academia after beginning their clinical trials (192 months for EVAHEART, 312 months for Novacor). However, the process occurs more slowly for Novacor. It takes approximately 223 months for EVAHEART to gain academia's full satisfaction and achieve the government behavior of issuing the Artificial Heart Guidelines. Novacor's satisfaction speed is slow, and it must wait 372 months for government action.



1:Full satisfaction (The point that the government decides to transfer its jobs and responsibilities to academia)

Fig.4 Simulation of government credibility in relation to academia

3. Discussion

This study shows that SD allows visualization of medical device development. The collaboration between medical doctors and engineers allows the progress of the device to increase through their joint problem resolution efforts. When the progress level reaches its maximum, clinical evaluation begins. With the data from the clinical evaluation, the approval of academia improves the chances of EVAHEART's government approval. In addition, Sun Medical's efforts to secure materials contribute to the level of progress. After the review process has been concluded, the number of certified physicians and hospitals increases through the qualification process based on the criteria for practice, which is prepared by academic societies upon request from MHLW. With certified physicians and hospitals, patient treatment and operations to introduce EVAHEART can begin. SD allows for simulations of over 23 years. This

attempt to reduce the uncertainty related to development will help newcomers understand the entire medical development process.

In this study, financial factors are excluded from the model. In Japan, medical device prices are deeply dependent on reimbursement from the government. To discuss the relationship between development and reimbursement, a discussion on the national budgetary system must be developed. We prefer to focus on device development and consider financial factors not to be part of this system.

Yamane explains the two guidelines issued by MHLW and METI in Japanese Guidance for Ventricular Assistance Devices/Total Artificial Hearts [3]. In this article, the author suggests the importance of collaboration among academia, industry, and government. Our research shows how academia and government were involved in the authorization of EVAHEART. This collaboration will lead each individual to determine what actions can be taken in relation to future political priorities.[4]

4. Conclusion

Our simulation of EVAHEART suggests that it has the potential to clarify unclear relationships in the development of devices. Our results can help those who are considering developing medical devices because the six stages of development can provide initial guidance on how to formulate their strategies. This also applies to the authorities that support the medical industry as they consider individual development policies.[5]

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