Surg Today (2011) 41:1182–1183
DOI 10.1007/s00595-010-4529-0

SURGERY TODAY

Review Article

Medical Care Issues in Japan Highlighted by the Regulatory Approval of the da Vinci Surgical System

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Abstract
Twelve years have passed since the emergence of the da Vinci Surgical System in the medical field, and highly advanced medical technology continues to develop rapidly. Surgeons are on a mission to provide better medical service every day. Yet, the Japanese Ministry of Health, Labour, and Welfare is taking a conservative stance against medical advancement. Two major issues that puzzle surgeons are the time-consuming process and delay in approval of medical devices, and limitations on health insurance coverage. The author of this article insists that now is the time to speak up for the reality that the more medical technology develops, the higher the costs that are necessary. He believes that all who are involved need to come together to share values for a better perspective.

Key words Medical care · Regulatory approval · Advanced medical technology · da Vinci surgical system

Introduction

The da Vinci Surgical System was developed by Intuitive Surgical (Sunnyvale, CA, USA) in 1994 and has been marketed since 1998. Twelve years have elapsed since its initial release. Originally a venture enterprise in the United States, Intuitive Surgical is now listed on the US stock market and is advancing on a steady track. By the first quarter of 2010, the company had sold 1200 da Vinci systems worldwide, approximately one-half of which were the older model "da Vinci Standard." The "da Vinci S" model was launched 3 years ago and has evolved further, with the "da Vinci SI" model released last year.[1] In Japan, Intuitive Surgical received the long-awaited regulatory approval at the end of 2009 to market the "da Vinci S Surgical System." This news has been welcomed by surgeons engaged in robotic surgery, who await great progress in robotic medicine in the near future. Furthermore, with robotics acquiring formal acceptance and a legitimate place in clinical medicine, it is expected that the systems will be used widely in the Japanese clinical setting. However, we had high hurdles to overcome before regulatory approval was granted, which highlights the difficulties we are encountering in trying to promote advanced medical technology using robotics. They include the high expectations from the distributor who applied for approval, the Ministry of Health, Labour and Welfare, as well as the external Pharmaceuticals and Medical Devices Agency (PMDA). As of April 1, 2008, the PMDA had only 426 staff including 277 who conducted scientific reviews of pharmaceuticals and medical devices, and 65 who analyzed quality and safety. Even with the support of the Ministry of Health, Labour and Welfare, the PMDA has too few workers. On the other hand, the US Food and Drug Administration and the European Medicines Agency have approximately 2900 and 3540 staff, respectively (Table 1).

Under rigorous monitoring by the Ministry of Health, Labour and Welfare and in accordance with the interest of the manufacturer, we were obligated to use the device within the Japanese health insurance system. During my involvement in the process, I perceived some issues of medical care in Japan, which were highlighted by the process of regulatory approval of this device.

Device Lag

Compared with other countries in the developed world, there is a much longer device lag in Japan: the approval process for a new device in Japan takes at least 3 years,

Reprint requests to: G. Watanabe
Received: June 16, 2010 / Accepted: October 5, 2010

Table 1. Staffing numbers of government bodies researching new medical devices for approval in Japan versus United States and Europe

Japan	USA	Europe
Total: 426 (Drug and medical device reviews: 277[a]; postmarketing safety: 66)	Total: 2900	Total: 3540

As of April 1, 2008
[a]310 including supporting staff from the Ministry of Health, Labour and Welfare[5]

and in some cases as long as 5 years. During this time lag, new models or devices are constantly being developed. With a 3–5-year time lag from the appearance of a new device to its approval, Japan is always using devices that are at least 3 years old. Even with the inauguration of the PMDA and the introduction of the "fast-track" system, a significant reduction in the length of the approval process is unlikely.

How Can We Introduce New Expensive Devices?

I believe that accelerating the process is the first step toward overcoming the problems associated with approval of new expensive devices. The PMDA needs more staff to increase productivity and allow easier transaction if a newer version of an approved device is released. The PMDA should also exclude testing that has already been done for original versions of an approved device, or shorten the process by consulting specialists on the old version. To make the most advanced medical equipment accessible, the PMDA should reduce the costs of clinical trials or permit the joint provision of insurance-covered and insurance-excluded treatments for cutting-edge medical devices.

Recently, health insurance companies have been advertising new products. By adding a special contract for advanced medical care, the health insurance can be extended to cover the use of advanced medical technology not normally covered by general health insurance. This reflects the fact that current health insurance does not adequately cover the cost of highly specialized treatments.[2] In countries such as the United States, where only about 60% of the people join a health fund,[3] the concept of receiving medical care at one's own expense is well established and people may elect to pay for advanced medical technology. In Japan, both the medical care providers and the population are so used to the national health insurance, which started in 1955, that they may have the misconception that medical care is a public service. Since some patients will have to pay additional high fees to receive treatment with advanced medical technology in the future, the Japan Medical Association and other organizations are criticizing this mixed medical care system.[4] However, if we consider the future of Japan and the prospect that it will have to join other countries in realizing border-free medicine, the Japanese people must be informed that medical care is expensive and that they might have to pay high costs to receive necessary treatments with advanced medical technology.

These two issues surrounding advanced medical technology, such as robotic surgery, represent only the tip of the iceberg of the problems of medical care in Japan. I hope that the readers of this article, especially surgeons, will contemplate a new the roles and working conditions of surgeons who constitute a valuable resource for society, in the context of medical care in the twenty-first century.

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