Commentary

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# Japan's advanced medicine

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**Summary** **Like health care systems in other developed countries, Japan's health care system faces significant challenges due to aging of the population and economic stagnation. Advanced medicine (*Senshin Iryou*) is a unique system of medical care in Japan offering highly technology-driven medical care that is not covered by public health insurance. Advanced medicine has recently developed and expanded as part of health care reform. Will it work? To answer this question, we briefly trace the historical development of advanced medicine and describe the characteristics and current state of advanced medical care in Japan. We then offer our opinions on the future of advanced medicine with careful consideration of its pros and cons. We believe that developing advanced medicine is an attempt to bring health care reform in line rather than the goal of health care reform.**

***Keywords:*** Advanced medicine, universal health insurance, health care

## 1. Introduction

After taking power last December as Prime Minister of Japan, Shinzo Abe implemented a bold new approach known as "Abenomics" - a portmanteau of Abe and economics - to reinvigorate Japan's economy. Indeed, Abenomics is a "quiver" of policies featuring "three arrows": monetary relaxation, fiscal stimulus, and economic growth strategies (*1*). The first two arrows were fired during Abe's early days in office and have already hit their marks. The overvalued yen has fallen sharply and the stock market has surged, both spurring corporate profits. Although the two strategies did not result in real changes in the economy, these signs of economic recovery did lead to hope and skepticism around the country. Seeking to boost Japan's long-term economic performance, the keenly awaited third arrow of Abenomics was just recently released (*2*). It focused on structural reform and creating special rooms within the public sector, including the energy industry, medical care, and infrastructure, to revitalize the private sector. As a result, innovations in medical technology and health care reforms represent a stepping stone towards achieving further economic growth, primarily in the health care field.

Advanced medicine (*Senshin Iryou*) is the frontier of innovations in medical technology and health care reform. Advanced medicine is a unique medical care system in Japan offering highly technology-driven medical care that is not covered by health insurance along with conventional medical care that is covered by health insurance (*3,4*). Advanced medicine has received a great deal of public attention. National debates among professional health workers, local governments, and policymakers concerning the practice, implications, and theory of advanced medicine have also been refueled by Abenomics' growth strategies (*5,6*). Here, the basic concept of advanced medicine in Japan will first be explained. Next, its origin and history will be described. The current state of advanced medicine around the country will then be documented. Last, the future of advanced medicine will be predicted.

## 2. Basic concept of advanced medicine

Advanced medicine literally means to practice medicine by integrating the best of alternative medicine and conventional medicine to diagnose and treat patients. This term often appears in the medical literature and the media (*4,6*). In Japan, however, the term "advanced medicine" commonly refers to the

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use of newly developed medical devices, drugs, or technologies that have been authorized by the Ministry of Health, Labor, and Welfare (MHLW) but have not yet been covered by health insurance (*3*). Actually, this term is used more frequently in health care than in medicine. Here, advanced medicine is considered to be a Japanese version of off-label use of technology-driven medications and medical devices. In order to better understand this concept, one first needs a brief introduction to the history of advanced medicine and the health insurance system in Japan.

The current public health insurance system in Japan was established in 1961 and subsequently revised several times (Figure 1)(*7,8*). This system is universal health coverage called *Kaihoken*. Based on *Kaihoken*, everyone in Japan is able to choose his/her desired medical facility at which to receive the same medical care for sickness or injury at the same cost by making a co-payment of 10-30% of the cost depending on his/her age and/or income. If that monthly co-payment exceeds the maximum co-payment limit, the patient can apply for the High-Cost Medical Care Benefits (*Kougaku-Ryouyohi*) (*9*). This national system of additional benefits ensures that the patient pays only medical costs capped at the maximum co-payment. To ensure equity and equality in health care, the health care system has combined varied health care delivery systems with a nationally uniform payment system known as the Medical Fee Schedule (*Shinryou-Housyuu-Seido*) (*10*).

The Central Medical Council on Social Insurance, appointed by MHLW, revises this fee schedule every two years to individually set appropriate fees for all drugs, medical devices, and procedures. The medical fee schedule is uniformly applied to all medical facilities being reimbursed by public health insurance. To control health care costs, the public health insurance system excludes some health care services, such as those for routine childbirth and cosmetic surgery, and special forms of medical care, including cutting-edge medicine. In principle, conventional medical care would qualify for coverage by public health insurance, but public health insurance will not cover any medical care, in whole or in part, that involves the usage of any cutting-edge drug or device that is not listed in the medical fee schedule. In other words, patients receiving a new medicine that is not covered by health insurance along with other care that would normally be covered by insurance must pay for both forms of medical care out-of-pocket. This provision is known as the ban on combining medical care covered by health insurance and medical care not covered by health insurance (*Kongou-Shinryou No Kinshi*) (Figure 2) (*11*).

Japan's universal health care system has led to excellent health of the population as a whole at a low cost over the past half century (*7, 12*), but this system also faces challenges in terms of improving the quality of medical care while controlling cost (*7,9*). The ban on combining medical care covered by health insurance and medical care not covered by health insurance has resulted in delayed development or use of cutting-edge treatments (*13,14*). To meet the growing demand for good care and newly developed drugs and treatments, the Government revised the health insurance system

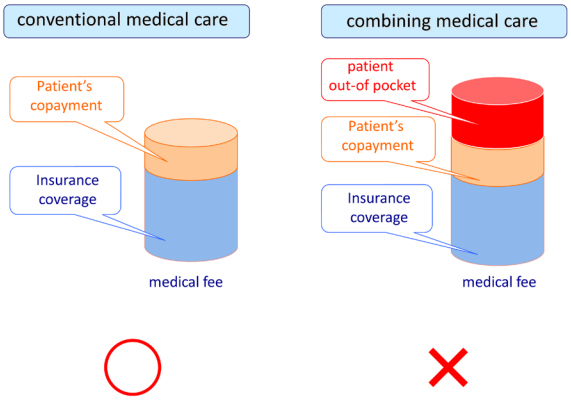


**Figure 2. Ban on combining medical care covered by health insurance and medical care not covered by health insurance.**

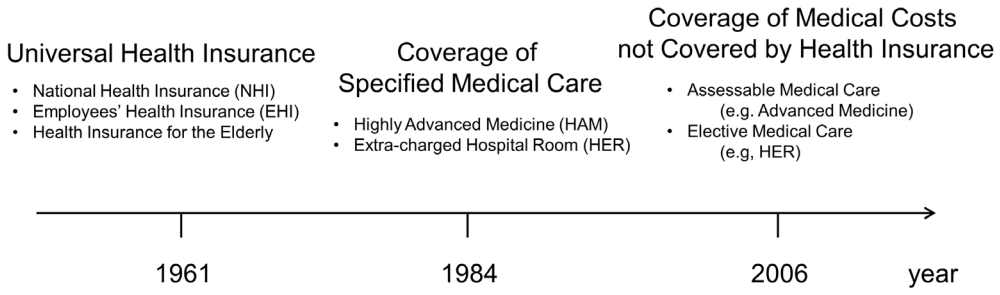


**Figure 1. Timeline of the history of advanced medicine.** Universal Health Insurance is also called public health insurance in Japan and consists of three parts: Health Insurance (for employers and their dependents), National Health Insurance (mainly for agricultural workers, the self-employed, and retirees), and Health Insurance for the Elderly (for those over the age of 75). Coverage of Specified Medical Care is an older system that reimburses specified medical expenses. Coverage of Medical Costs not Covered by Health Insurance is a new system that reimburses medical expenses not covered by health insurance. Assessable Medical Care refers to medical care that has to be assessed as appropriate to be covered by health insurance while Elective Medical Care refers to medical care that the patient has chosen to receive.

in 1984 (Figure 1). The Government introduced a new system called the Coverage of Specified Medical Care (*Tokutei Ryouyouhi*) that makes some exceptions to the ban on combined medical care covered by health insurance and not covered by health insurance. The new system potentially allows health insurance to cover highly advanced medical care while still disallowing patient preferences, such as a private hospital room (*9*). If, under the new system, a patient receives a MHLW-approved cutting-edge treatment at a specially authorized medical facility, then the portion of medical care that would have been covered by health insurance is in fact covered, and the patient pays only for the portion of care that is not covered by health insurance (*4,9*). To keep pace with the emergence of new medical technologies and drugs in some fields, like cancer therapies, and to meet the diverse needs of patients, the Government accelerated reforms and partially relaxed the ban on combining medical care covered by health insurance and medical care not covered by health insurance. The Government amended the Health Insurance Act in 2006 and replaced the system for coverage of specified medical care with another system known as the Coverage of Medical Costs not Covered by Health Insurance (*Hokengai-Heiyou-Ryouyouhi*) (Figure 1). Under this new system, the definition of advanced medicine was revised. Advanced medicine consists of two parts, one of which is highly advanced medicine (as mentioned earlier) and the other of which is advanced medical care (*Koudo Iryou*) (*3*). Advanced medical care includes certain new drugs or state-of-the-art medical technologies that have not been approved by the Pharmaceutical Affairs Act (PAA). This revision has led to more technology-driven medications and medical devices than ever being covered, regardless of the status of their approval by the PAA, when medical care combines care covered by health insurance and care not covered by health insurance as long as those medications or medical devices are proven safe and effective and are authorized by the MHLW.

### 3. Current state of advanced medicine

Since its emergence, advanced medicine, together with relaxing the ban on combining medical care covered by health insurance and medical care not covered by health insurance, has become a controversial issue in the area of health care reform (*4,15*). The Japan Medical Association (JMA) opposed the proposed reform, primarily from the perspective of equity, whereas the Government intended to promote advanced care planning in response to the rapid rise in health expenditures and increased demand for innovative drugs and medical devices. Abenomics seeks to encourage companies developing advanced medical technology as part of its growth strategy. To encourage exports of advanced medical technology and hasten approval of new drugs and devices, the MHLW recently announced its reclassification of advanced medicine into Parts A and B, and revised the approval process (*3*). Advanced medicine A represents highly advanced medicine (as mentioned earlier) while Advanced medicine B includes most of the advanced medical care just mentioned. According to the latest data from the MHLW (*16*), Advanced medicine A includes 65 types of diagnostic tests and treatments while Advanced medicine B includes 45 types. In total, 791 diagnostic tests and treatment approaches falling under Advanced Medicine A and 505 diagnostic tests and treatment approaches falling under Advanced Medicine B were performed in clinics, hospitals, or medical centers across the country. The current state of advanced medicine in Japan is as follows (*3*):

*1*) The total number of medical facilities providing advanced medical services and total expenditures on advanced medicine have both been steadily increasing. The number of types of advanced medicine, however, has not changed significantly, partly because of the strict approval process in which each previously approved advanced medical technology or drug has to be periodically evaluated to decide whether to continue or revoke its status based on its efficacy and safety. One example of advanced medicine from 2011, da Vinci Surgery – surgery with a multi-armed robot and a magnified 3D high-definition vision system – was recently removed from the list because it was approved by the Central Medical Council on Social Insurance for coverage by health insurance in 2012.

*2*) Most currently available advanced medical solutions are newly developed medical devices, technologies, and drugs used in regenerative medicine and cancer treatment such as homografts and heavy ion radiotherapy. However, some advanced medical solutions relate to diagnosis, such as genetic testing for resistance to chemotherapy and genetic testing for sensitivity to antiviral therapy.

*3*) Advanced medicine has been provided to outpatients as well as inpatients.

*4*) The cost of advanced medical care varies widely, ranging from 10,000 yen for genetic testing for drug intolerance (*e.g.*, CYP2C19 genotyping for tailored treatment of *H. pylori* infection) to several million yen for one round of cancer immunotherapy or radiotherapy (*e.g.*, heavy ion radiotherapy).

*5*) Although medical facilities providing advanced medical care are found in every prefecture, their numbers vary quite widely among the different prefectures (Figure 3).

*6*) In concert with the government's decision to hasten approval of new drugs and devices, major university hospitals are rushing to establish a center or facility to provide various forms of advanced medical care.

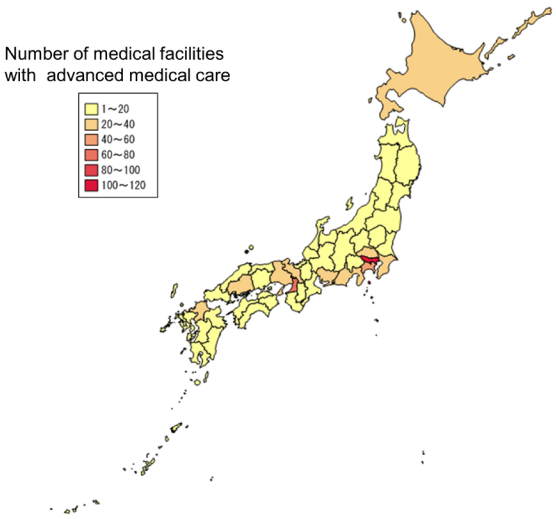


**Figure 3. Nationwide distribution of medical facilities offering advanced medical care.** Source: Ministry of Health, Labor, and Welfare. List of medical facilities offering advanced medical care (in Japanese). *http://www.mhlw.go.jp/topics/bukyoku/isei/sensiniryo/kikan02.html*. This map was drawn by HAKUCHIZU II software (ver. 2).

## 4. Prospects for the future

Given Japan's rapidly aging population and continuous budget deficits, there is no doubt that the current health care system faces significant challenges (*17,18*). Without substantial reform, the system's sustainability will be called into question. Advanced medical care has developed and expanded since it emerged as part of proposed health care reform. This has been especially true since Abe announced his economic growth strategies (*1,2*). Nonetheless, one must not forget that advanced medicine itself cannot solve fundamental problems that the health care system faces, such as aging of the population. Reaching the ultimate goal of health care reform – controlling costs, improving quality and ensuring equity – will also be extremely difficult.

On the positive side, the expansion of advanced medical care will increase the availability of innovative drugs and cutting-edge medical devices, and thereby keep up with growing demand and also improve the quality of care. It will also encourage advances and innovation in basic and translation research, which in turn will promote exports of advanced medical technology and accelerate economic growth. Moreover, most advanced medicine is not covered by public health insurance, so expanding advanced medical care will indirectly reduce healthcare expenditures (*4,11*). That said, expanding advanced medical care will probably widen the healthcare gap between the rich and poor, particularly, if the ban on combining medical care covered by health insurance and medical care not covered by health insurance is totally lifted (*15*). This may reduce equity in medical care, thereby contravening the fundamental principle of universal health coverage. In addition, there are also concerns about how to ensure the safety and efficacy of new drugs and highly technology-driven medical care (*17*).

The problems facing Japan's health care system are multi-dimensional (*7,17*). Expanding advanced medicine is an attempt to address these problems but is not a magic bullet. Despite growing awareness of advanced medicine, there is still little consensus about what to do or how to make things better. Advanced medicine cannot be implemented politically, nor must it be implemented all at once. Indeed, it should be debated in more detail and be implemented in accordance with evidence-based practices.

***Note:*** *The opinions expressed here are solely those of the authors and do not necessarily reflect the views of Yamagata University Graduate School of Medical Science.*

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