

Inclined Trends in the Telemedicine Policies of Japan

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Abstract

This paper reports on the findings of an investigation of the status of Japanese telemedicine laws, social insurance medical fee payment fund systems, and their effects from 1997 to April 2003. Basic telemedicine classifications are also defined in this paper and in Japanese laws; funding and actual cases in operation were examined based on the aforementioned classifications. Furthermore, analyses of telecommunication fees, which will have a significant impact on the future of telemedicine, were made with eventual liberalization in mind. Finally, this paper discusses the feasibility of a Japanese version of “Universal Service,” by predicting when a shift toward a liberalized market will be implemented by the Japanese Ministry of Posts and Telecommunications.

Key words: Telepharmacy, Direct patient care, Home-care, Aging society

Objective

“Telemedicine” refers to the utilization of telecommunication devices to support medical treatment and/or to examine patients through the use of telecommunication devices. This paper discusses the ramifications of telemedicine laws enacted through bureaucratic policies (policies developed by administrative officials and selected research specialists who create the original draft). This method of policy-making is quite uncommon in Europe and the United States. We will also provide our views on new business, i.e., telepharmacies and the Japanese version of “Universal Service.”

Background

The field of telemedicine is in fact quite old. The U.S. National Aeronautics and Space Administration (NASA) first began to conduct research on it in coordination with the startup of the Gemini project. Telemedicine eventually developed into a phase of serious practical testing and research in the Apollo project, with its objective of putting a man on the moon. The Apollo project utilized telemedicine technology to monitor the astronauts’ life-support systems and to ensure their security and safety. After the Apollo project, the technology was directed toward the welfare of those on earth, leading to the development of various technologies, as well as operational testing. In recent years, this old yet new telemedicine technology has gradually gained practicality in Japan, and this report attempts to analyze recent trends and activities in the field by examining current Japanese laws and regulations on telemedicine.

Classification of Telemedicine

There are many classification methods for telemedicine. This paper simplifies the classification of telemedicine operators into four types. This classification is suitable for our purposes from the standpoint of the relationships between medical business operations and applicable laws.

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|---------------------------|---------------------|
| 1. Physician to Physician | Second Opinion |
| 2. Nurse to Physician | Teleconsultation |
| 3. Patient to Physician | Direct Patient Care |
| 4. Patient to Nurse | Telehomecare |
| 5. Patient to Pharmacist | Telepharmacies |

Here, the term “Second Opinion” used refers to physician’s inquiries for advice and consultation with a medical specialist through the use of telecommunication lines. Telepathology and teleradiology would also fit this description. “Second Opinions” can be included in the broader sense of the term “consultation.” However, it is distinguished from other types of consultation (i.e., medical staff to physician) by the fact that it is in its own category, as it requires special billing and payment systems, along with divisions based on licensing-related matters. Using a direct telecommunication line to examine patients is defined as Direct Patient Care (DPC) or Remote Medical Observation (RMO). DPC in Japan is considered legal medical treatment when the following two conditions apply: (1) A patient in stable condition with a chronic disease is re-examined. (2) Patients reside on remote islands or in isolated areas or the situation is an emergency and there is no alternative. The basic rule applied in examinations and the patient-physician relationship is that a physician conducts examinations of patients face-to-face. Therefore, DPC through the use of telecommunications lines is considered to compliment face-to-face examinations. In addition to the two classifications specified above, a nurse or public nurse attempting to determine the health status of a “home-care patient” is classified as telehomecare, and services relating to all aspects of the prescriptions and home delivery of drugs are classified as telepharmacy services [1-5].

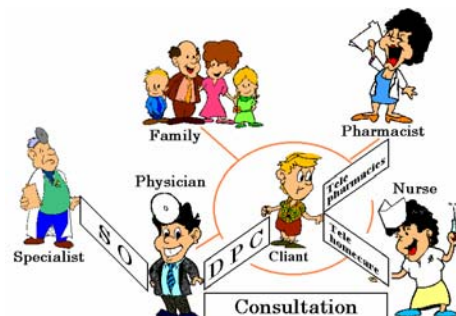


Figure 1 Classification of Telemedicine

Medical Expenditures and Deregulation in Japan

There are two potential dynamics at work in the trends and activities of Japanese telemedicine. The first is increasing medical expenses, and the second is deregulation intended to simplify the structure of our society.

Consider the first force, medical expenditures. Medical expenditures account for 7.3% of the Japanese national budget, and this figure is increasing at an annual rate of 5%. In recent years, halting or slowing soaring medical expenses has become a matter of national urgency. Consequently, telemedicine has received a great deal of attention, as it is viewed as a means by which the efficiency of medical systems can be increased.

In regard to the second force, individual ministries and agencies have been reviewing deregulation measures since the beginning of the 1990s. A substantial effort was made to implement deregulation, in an attempt to increase the efficiency of medical treatment and reduce medical expenses. In the field of home medical care or DPC/RMO, the “face-to-face examination principal” (Article 20, Medical Practitioners’ Law) was revised. Acts prohibiting home-delivery services for prescriptions (Article 37, Pharmaceutical Affairs Law) and those prohibiting home services for nurses and physicians were also revised.

Investigation of the System

Direct Patient Care

HPB #1075 (Official notice issued by the Director General of the Health Policy Bureau, Ministry of Health and Welfare)

On December 24, 1997, a history-making notice in the Japanese medical industry was issued to all prefectural governors plus the governors of Tokyo, Hokkaido, Osaka, and Kyoto by the Director General of the Health Policy Bureau. The official notice describes the Bureaus’ basic position regarding the “face-to-face examination principal” of Article 20 of the Medical Practitioners’ Law and on telemedicine. This new notice was announced in response to a report submitted by the Telemedicine Research Group (Ministry of Health and Welfare), which has been studying the issue since 1996. The noteworthy points of the official notice are summarized in the 10 items below (see attached information). The most significant point is the Bureaus’ approval of the use of DPC, particularly in emergency situations.

1. Telemedicine utilizing telecommunication and IT (Information Technology) devices does not infringe on Article 20 of the Medical Practitioners’ Law.
2. Telemedicine complements “face-to-face examinations” and should be administered to patients with chronic diseases who are in stable condition.
3. Telemedicine should be administered in accordance with patients’ requests, and must be beneficial to the patient.
4. Telemedicine can also be administered to patients who are otherwise unable to have a “face-to-face examination” with a physician, such as patients in isolated areas and bedridden elderly patients. (DPC approval)

5. Not only does Telemedicine enable sufficient explanations to be provided by attending physicians, it also clearly defines the responsibilities of the patient.

Telepharmacies

Official notice #90 issued by the Division Chief, Pharmaceutical and Medical Safety Bureau, Planning Division. An official notice pertaining to the matter of the “Receiving of prescriptions by fax and the home delivery of prescriptions to patients” was issued on December 25, 1998 by the Division Chief of the Pharmaceutical and Medical Safety Bureau’s Planning Division, Ministry of Health and Welfare. This notice was intended to provide information on the Pharmaceutical Safety Bureau’s activities, and was written in response to another notice issued to various ministries and agencies pertaining to “Initial views on deregulation,” dated December 15, 1998. This does not mean that there were no instances of pharmaceuticals being delivered to patients’ homes prior to official notice #90. For example, there have been cases in which peritoneal lavage fluids were delivered to CAPD (continuous ambulatory peritoneal dialysis) patients, as the fluid is very heavy. In such cases, the pharmaceutical manufacturer used a parcel delivery service to deliver the fluid to the patient’s home. Official notice #90, however, makes it legal to receive prescriptions through telecommunication lines and to send prepared prescriptions by mail, provided that the service satisfies the conditions specified below. It should be added here that Article 9 of the Mail Law stipulates that a patient’s privacy must be strictly guarded and that delivery personnel are responsible for doing so.

- 1) Patients must agree to receive deliveries made by persons other than a pharmacist.
- 2) Delivered prescriptions must be verified as being identical to the prescription order transmitted by fax.
- 3) Said pharmacy must have records of the drugs dispensed to said patient.

Payment of Telemedicine Fees (corresponding actions by the Social Insurance Medical Fee Payment Fund)

Actual funding for telemedicine by the Social Insurance Medical Fee Payment Fund began in Japan in April 2000. More specifically, the Fund for the payment of medical expenses approved that “telediagnosis using pathological images during surgery” can add points in the table of points for fees. However, the conditions were limited in this case, as described below.

- (1) Facility standards subject to prior notification and approval (In general terms, must be highly advanced medical treatment centers: consultation recipient)
- (2) Medical institution with a clinical engineer on staff with more than five years of experience in the field of pathology (consultant)

In the future, telediagnosis utilizing x-ray images or endoscopic images may gradually be incorporated into the medical billing system, but it is not clear when this will come about.

Observation

Prospects for Home Medical Care in Japan

First, let's look at the prospects for Japanese home medical care by introducing an example in which DPC and telepharmacies are combined. A case in point is the "Multimedia Village Project" in Katsurao village in Fukushima prefecture, in which telecommunications and IT networks were installed through subsidies from the Ministry of Posts and Telecommunications' "Municipality Networking Facility Development Project" of 1997. There were three main objectives of the "Multimedia Village Project." The first was to promote communication between villagers, the second was to compensate for the various disadvantages of rural living, and the third objective was to eliminate disparities with urban areas. In order to achieve these objectives, "Reexamination via interactive TV phones with ISDN (Integrated Services Digital Network) connections and drug delivery service by mail" were implemented. This system is currently in operation primarily for patients with chronic disease, but TV phones (Phoenix mini) have been installed in all village households (500 in total). Furthermore, medical institutions (outside of the village) —as many as nine hospitals, including those villagers' regular hospitals —were connected to the network of TV phones. Based on this network between patients and hospitals, the system works in the following manner. First, Hospitals administer DPC to patients with chronic diseases based on data (i.e., electrocardiograms) obtained from their bio-data-retrieving terminal (NEC product: Sukoyaka-mate). Second, upon completion of the examination, the prescription is sent to the pharmacy. The prescription is then filled and sent from the pharmacy to the post office. Finally, the medicine reaches the patient by regular mail, and telepharmacy Service is complete (Figure 2). All medical and prescription bills can be paid through the use of postal money orders.

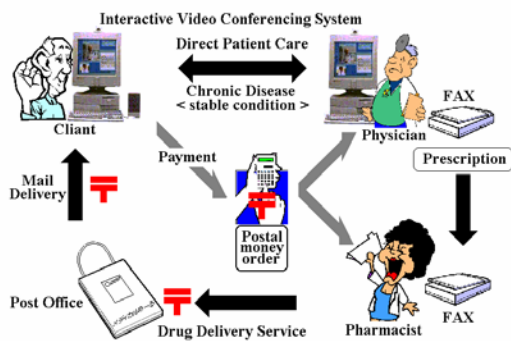


Figure 2 DPC and Delivery of Drugs by Mail

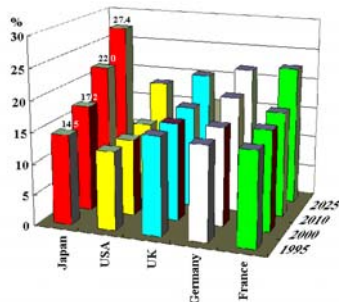


Figure 3 Transition of Senior Citizen's Ratio in Japan

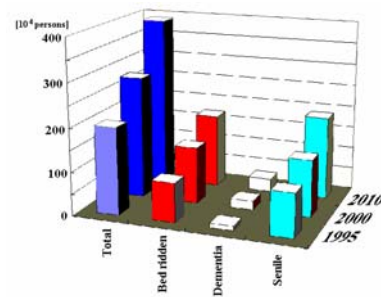


Figure 4 Number of elderly in need of support

Here, we would like to elaborate on the prospects for home medical care. Figure 3 shows the estimated transition of the senior-citizen's ratio. It is predicted that by the year 2010, Japan will be second to none in terms of its drastically reduced childbirth rate and the consequent aging of society, with 22.0% of the population being senior citizens 65 years of age or older.

In the year 2000, the elderly in need of care —1) Bedridden, 2) Dementia, 3) Senile —will total 2,800,000 people. However, special nursing homes in the year 2000 will only accommodate up to 692,000 people. Therefore, 2,100,000 people will be receiving care at home, either from their family members or a home helper. By the year 2010, the total number of elderly in need of care is expected to increase to 3,900,000. The maximum capacity at that point would only total up to 800,000, and it is estimated that 3,100,000 elderly will be potential candidates for home-care. We feel that DPC utilizing interactive TV conferencing systems through ISDN (Integrated Services Digital Network) lines, in tandem with telepharmacies, would effectively enhance the quality of home medical care. This is due to the fact that most patients in need of home medical care or home-care are those who have a chronic disease but are in stable condition, and for whom DPC would therefore be a viable option. To patients in stable condition, the administration of medication through mail delivery is not regarded as having a high risk potential in comparison with that to patients who are in serious condition or are under immediate intensive care. There is another reason that DPC and telepharmacies may spread and be widely accepted: the ability of a patients' family members to consult a physician in their homes. This would be a great help to family members who must provide long-term care for their loved ones. Due to Japan's unique background, it may become a huge telemedicine market for home medical care and home-care.

Outsourcing and Telemedicine in Japan

Rationalization within the medical field is progressing at a rapid pace due to stagnant economic growth, low birth rates, and our aging society. Japanese hospitals, which formerly functioned as "stand-alone" (self-sufficient) entities, are resorting to a similar course of action as hospitals abroad. That is to say, they are outsourcing linen supplies, meals, clinical testing, and the filling of prescriptions in order to rationalize the business-administration aspects of hospital management. "Filling prescriptions" refers to the

preparation of medication in which the amount and combination of drugs is adjusted based on a patient's age, weight, and the like. It should be mentioned here that the three largest profit margins (profits derived from the difference between wholesale prices and patients' retail prices), which may or may not put hospital business administration in the black, are as follows: 1) drugs, 2) clinical testing, 3) artificial dialysis. The current Japanese prescription-drug market totals 21.4-billion dollars (\$1.00 = ¥100). It is expected to achieve an annual growth of 12% within the next five years, and the market is expected to total approximately 37.6-billion dollars in the year 2005. In spite of the large market, most pharmacies are individually owned small businesses. We believe that the telepharmacies created by official notice #90, issued by the Division Chief of the Pharmaceutical and Medical Safety Bureau's Planning Division, will be effective in the field of pharmaceutical outsourcing in the future. The integration of small pharmacies and large corporations is also likely.

On the other hand, there are no legal barriers on the outsourcing of image diagnoses in Japan. However, the authors of this paper believe that inter-hospital "Second Opinions" (X-ray images, specialized image diagnosis, pathological images) will not progress to the extent that the pharmacies mentioned above (The telepharmacies) will. This is due to the fact that the Japanese medical funding system is fundamentally different from its American counterpart, in that the Japanese system does not take into account the "evaluation (experience or track record) of the examining physician" in its payments. Put more simply, the same number of billable insurance points (money) is calculated for payment by the medical funding system, regardless of who interprets an X-ray image. Insurance points do not reflect whether a specialist or an intern just out of medical school with minimal experience is interpreting an X-ray image. Moreover, there is no "ranking of physicians" or "ranking of hospitals" in the Japanese medical system. That is to say, communication may occur between hospitals seeking or providing a "Second Opinion" in Japan, but only due to the humanitarian spirit and the belief in community service. This is due simply to the fact that there is no advantage whatsoever to such communication to the business-administration side of the hospital. The authors of this paper believe that inter-hospital telecommunications for "Second Opinions" will not initially represent a large market, due to Japan's current insurance policies and billing system.

If there could be a market in which "Second-Opinion Centers" would be viable businesses, it would have to be a case in which a hospital has no choice but to recover the initial costs for very expensive medical equipment, specifically special imaging devices (MRI, CT-SCAN, Electronic endoscope, etc). In addition, hospitals would be forced to operate and transmit images so that they could accumulate billable insurance points, simply to pay the initial costs for the equipment purchased. This may be regarded as a viable application of telemedicine, but strictly from the standpoint of business administration. This case illustrates the point that immediate growth in image-diagnosis outsourcing is not possible without some

advantage or incentive attached to its implementation. To cite an example, in April 2000, the Social Insurance Medical Fee Payment Fund approved the use of insurance points as payment for the remote diagnosis of pathological images during surgery. However, the annual number of consultations regarding the remote diagnosis of pathological images during surgery is considered to be extremely small in terms of

market size, totaling some 2000 consultations nationwide in 80 Japanese medical schools (one to two schools/month). A second factor in "Second Opinions" encountering difficulty in the initial stages is barriers within the medical education system. Strong factions and affiliations between Japanese universities remain, and it is considered taboo for most universities to request a consultation or "Second Opinion" from medical institutions outside of their own faction or affiliation.

Telecommunication Fees (Free Market vs. Management Policies)

The state of Japanese national finance is extremely severe, with the national deficit constituting 10% of the GDP, and total accumulated debt amounting to 108% of the GDP. This current state of national finance is worse than that seen in New Zealand in 1984. In addition, current government policy on public enterprises (including the telemedicine project) requires that not only the central government but also the local government pay (up to 25%-50%) for the enterprise. Finances at the local government level are also becoming an extremely serious problem. There is reason for optimism concerning the widespread use and application of telemedicine in terms of the legal framework and basic technology. However, the implementation of telemedicine-related projects involving local government is in fact at a standstill. This is due primarily to the fact that Japanese local governments nationwide are in a state of virtual bankruptcy due to insolvency. In view of this situation, there is no choice but to limit the implementation of such projects. The implementation of telemedicine in Japan must, for the time being, be limited to operations at individual hospitals and private corporations. At this level, the key to the widespread use and application of telemedicine is minimizing telecommunications fees, which represent the majority of running costs. Generally speaking, there are two ways to minimize telecommunication fees. One is to create a free market and reduce fees through competition. The other is to adopt a management policy (Universal Service) and lower the fees on specific charges.

Conclusion

Trends and activities regarding telemedicine were analyzed through a review of the relevant laws and the medical funding system during the period between 1997 and April 2000. A milestone in the telemedicine field occurred in April 2000, when the medical funding system approved the use of billable insurance points for the "remote diagnosis of pathological images during surgery." This date essentially marks the commencement of telemedicine in Japan. In the near future, it is predicted that we will see huge and rapid growth in drug delivery services and the outsourcing of

pharmacies. However, inter-hospital telemedicine (Second Opinion) will experience difficulties until the implementation of the Japanese version of "Universal Service."

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