Japanese Case Study on Monitoring and Developing Quality of Health Care

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1. Provision and Financing of Care

- Japan's health care system is characterised by private ownership on the supply side and mainly public finance on the demand side. It is mainly private providers that supply medical services, although for-profit enterprises are prohibited from running hospitals. More than 70% of beds are found in premises owned by private medical care providers.

- Medical care providers are classified into clinics, which have fewer than 20 beds (including none), and hospitals, which have 20 or more beds. The relationship between doctor's clinics and hospitals is partly complementary and partly competitive. Both offer ambulatory care. A fifth of the doctor's clinics have beds, although the number of beds per doctor's clinic is as small as 12 on average. Japanese patients can go to any physician or hospital, with no difference in cost, and physicians are in principle free to treat or prescribe as they see fit (Ikegami, 1999).

- With the intention that the function of medical institutions should be differentiated more clearly, "special function" hospitals were established in 1992, which provide advanced inpatient care for referred patients. Also, a system of "local medical service support" hospitals was introduced in 1998, which act as a hub for support of and

cooperation with local clinics. Currently, 81 " special function " hospitals and 55 " local medical service support " hospitals exist. Since 2001, measures have also been underway to assist the functional specialization of medical institutions. These include the division of " other beds " (i.e. beds excluding tuberculosis, psychiatric and infectious disease beds) into " long-term care beds " primarily for hospitalized patients requiring long-term care, and " ordinary beds ", which are principally for acute patients. Different rules of reimbursement are applied to each type of bed.

- Japan has mandatory social health insurance with broad benefits and only modest cost sharing by patients (OECD, 2001). There are more than 5,000 insurers in total and membership is determined by occupation and residency. The medical insurance system, broadly speaking, breaks down into the Employees Health Insurance (EHI), and the National Health Insurance (NHI). The latter is mainly for the self-employed and unemployed people, and is managed by municipalities, in principle. The EHI is further divided into (1) Government-Managed Health Insurance (GMHI), managed by the Social Insurance Agency, which covers employees of small and medium-sized enterprises and (2) Society-Managed Health Insurance (SMHI), managed by health insurance societies established independently or jointly by businesses in the same industry, which covers employees of large companies, and (3) Mutual Aid Associations (MAAs), which are mainly for public employees.

- The insurance premiums of employees are proportional to their remuneration. The insurance premiums of national health insurance are proportional to the incomes and the number of households. A redistribution scheme accounts for some of the differences in the assessment base and the age structure of the different insurance funds. The co-payment rate is currently 30 percent, but it is lower for the elderly. The total co-payment burden on households is capped, bringing the average effective co-payment rate to about 15 percent.

- Medical institutions are paid on a fee-for-service basis with regulated medical fees. A

variable payment system, which reflects the disparate level of technical ability of medical personnel and the functional differences of medical care institutions, has been introduced. Since 1998, a Diagnosis Related Group/Prospective Payment System (DRG/PPS) has been piloted in 10 hospitals. In addition, a system of global assessment by Diagnosis Procedure Combination (DPC) was introduced in 2003 at "special function" hospitals. Also, a fixed-sum payment system was established for patients in long-term care beds. Two organizations oversee auditing and payment; the Social Insurance Medical Fee Payment Fund (Payment Fund) for the EHI; the Federations of the National Health Insurance Associations (NHI Federations) for the NHI.

2. Political and Institutional Background

- The central government of Japan plays the central role in regulating the health care sector. The main health care policy in Japan has been to develop the framework for delivery of medical services and improve provision through the Medical Service Act and the Medical Practitioner's Act, while at the same time creating a universal medical care insurance system (achieved in 1961) with the Health Insurance Act (enacted in 1922) and the National Health Insurance Act (enacted in 1938). In addition, central and local governments themselves act as insurers which cover two thirds of all the insured and as providers through their own hospitals.

- Major reforms to the health care system are typically drafted by the Ministry of Health, Labour and Welfare (MHLW), and finally come into effect through amendments of the acts mentioned above. Many stakeholders, including the ruling party, are involved in the decision making process, but the thrust of the reform is usually not altered by this process.

- Traditionally, quality of care has been regarded as a professional responsibility and has thus remained under the control of the medical profession. Moreover, quality

control was left to individual physicians, whereas collective and standardized approaches such as clinical practice guidelines have just started to develop. This is partly explained by the distinct training styles of the different Japanese medical schools, and partly by the fact that physicians ' hospital appointments are usually controlled by the department and are generally life-long. (Ikegami, 1999).

- In the past, patients in Japan have exhibited a strong tendency to leave the selection of treatments and all questions of judgment to the physician. Recently, however, public trust and confidence in medical care have declined. According to an opinion survey published in a newspaper in 2002, 74% of people are concerned about medical malpractice, and 26% do not trust physicians much (Asahi Research Institute report, 2002). Patients are beginning to assert their own medical service needs, calling on medical institutions and the government to actively disclose information to the public and demanding to be involved in debates on the quality of medical care. The spread of the concept of informed consent has led to patients demanding information from physicians, and the belief that physicians should not provide treatment without explanation and without obtaining the patient 's consent is starting to become widespread.

- Several cases of medical malpractice occurred in recent years which have raised doubts about the traditional self-regulatory approach. Most notably, a patient mix-up leading to an operation on the wrong patient at a university hospital in 1999, received much media attention and paved the way to certain new regulatory initiatives aimed at developing patient safety.

- The Japanese government has responded to the growing concerns about patient safety and quality of medical care in their recent reform plans. In 2001, a set of " Basic Principles of Medical Care System Reform " was agreed between the MHLW and the ruling party, which was aimed at guiding future reform strategy in the health care sector. These principles included proposals for strengthening respect for

patients ' perspectives and efficient provision of high quality of medical care services. Various initiatives for reforming the medical care delivery system and the medical fee system, aligned with these principles, were announced in April 2002.

3. Approach to Monitoring and Improving Quality of Care

1) Government Regulation

- Traditionally, the Japanese government attempted to maintain and improve quality of medical care by setting minimum requirements for the structures in which care is delivered. These included, for example, staffing ratios for patients, minimum space in hospital wards, and standards for medical equipment. Moreover, regulations stipulate that the administrator of a Japanese hospital has to be a licensed physician.

- The issuance and cancellation of physicians ' licenses are solely under the responsibility of the Minister of Health, Labour and Welfare. He issues licenses for those who graduate from medical school and who pass a national examination. Medical licenses are valid for life without any renewal procedure. The Minister of Health, Labour and Welfare may revoke a physician 's license or may suspend him or her for a fixed period in those instances where he or she is punished by more than a fine.

- Control of medical fees has been an important feature of government regulation in Japan. The MHLW has succeeded in containing medical expenditure growth through judicious adjustment of fees (OECD, 2001). However, that process has offered few financial incentives to improve quality of care. In particular, the exclusion from reimbursement coverage of hospital infrastructure and staff related to quality management such as medical record keeper and managers for quality assurance programs has done little to promote quality of care provided by hospitals (Ikegami, 1999).

- Recently, the government has begun to implement measures to raise the quality of medical services through providing economic incentives, improving hospital management and governance, and changing training requirements for physicians.

- Under the 2000 medical fee schedule revision, the MHLW would reduce a hospital's fees, if no explicit treatment plan for inpatients existed. Under the 2002 revision, the MHLW designated 110 technically demanding operations, for which a physician is required to perform a minimum number of operation cases per a year and to meet certain training requirements to qualify for full payment. The medical fees are reduced by 30% when these prerequisites are not satisfied.

- Following some cases of medical malpractice at a university hospital in 1999, emphasis is now placed on the development of safety control mechanisms. Measures have been taken to strengthen regulations, provide economic incentives, and disseminate information to consumers. In April 2000, the MHLW made it mandatory for the "special function" hospitals to have safety control mechanisms in place. In practice, these consist of the development of clinical practice guidelines, establishment of internal systems of reporting on medical malpractice and related incidents, organization of a patient safety committee, and improved staff training. In 2001, the "Medical Safety Countermeasures Research Council", whose members include representatives from care providers, consumers and universities was established. It recommended extending the above-mentioned measures to all hospitals, with a view to improving drug delivery and equipment design; making adverse events less likely; and enhancing education and training in medical safety. It also called for the foundation of a central agency for handling complaints and queries from patients. Steps have been taken to implement these recommendations since October 2002. Also, payments have been reduced for the hospitals which do not introduce safety mechanisms. Furthermore, the Japanese Council for Quality of Health Care (JCQHC), an independent body, has started to collect information on adverse events, in collaboration with hospitals, and the Prefectures have established "Medical Safety

Assistance Centers (MSAC)".

- From April 2004, physicians will be required to undergo at least two years of clinical training after graduation from medical school. During those two years, the physicians will be rotated among 7 major clinical departments with a view to their acquiring the basic clinical abilities required in primary care. Physicians who fail to complete this training may only open a practice, if they obtain a permission from the governor of the prefecture

2) Self-Regulation

- The Japanese Medical Association (JMA) is the key institution of professional self-regulation. As a voluntary membership organization, JMA represents about 60 percent of all Japanese physicians (JMA, 2002). A subsidiary of the JMA is the Japanese Association of Medical Sciences (JAMS), which comprises 96 specialist medical societies. Policy recommendations and guidelines of the JMA have a strong impact on the medical care provided by physicians on the frontline.

- The JMA established the Continuing Medical Education (CME) program in 1987, modelled after the Physician Recognition Award of the US. While participation is voluntary, certificates are issued to participants who have completed certain training requirements, which can be used for advertising purposes. A certificate of completion requires 50 CME hours per year, and a certificate of recognition is granted after three years of fulfilling the completion requirements.

- The medical specialty societies in fields such as internal medicine, have started to operate voluntary certification programs. The certification requirements vary by specialty. In general, candidates for specialty certificates are required to take tests which are in oral or written forms. Also, specialty societies require some volume of clinical activity or a certain number of operations performed by candidates. In 1994, a

triangular approval system was established among the JMA, the JAMS and Japanese Board of Medical Specialist (JBMS). The self-certification programs of 15 societies have so far been approved. Advertising the specialty of physicians is not allowed until the training programs of the society concerned obtain approval by the MHLW.

- In recent years, attention has focused on strengthening the role of Evidence Based Medicine (EBM) in the practice of medicine in Japan. Clinical practice guidelines, describing the standard treatment based on medical evidence, are being developed with the cooperation of the central government and medical professionals. In June 1998, the MHLW established the "Medical Technology Evaluation Promotion Taskforce" to review critical issues on EBM and clinical guidelines, and a research budget was provided for the development of clinical practice guidelines. It is intended to complete 47 guidelines. By 2002, 14 guidelines have been completed. Even though clinical practice guideline setting and implementation is voluntary, it has proved to be a useful instrument to ensure quality of care. In the questionnaire survey of 2003, some 60 percent of physicians in Tokyo responded that they used Japanese Guidelines for the Management of Hypertension (JSH) which were implemented in June 2000. Moreover, the proportion of physicians who would prescribe inhibitors of the angiotension conversion (ACEI or ARB drugs) as their first choice drug, increased by 30% from 70% in 2001 to almost 100% in 2003, following one of the recommendations in the guideline. From 2004, the Japanese Council for Quality Health Care (JCQHC) will provide information on EBM from a database, and clinical practice guidelines will be provided via media such as the Internet.

- Two distinguishing features of the practice of medicine in Japan are: the strong sense of identification of medical professionals with the medical institution to which they belong; and the degree to which medical institutions operate as a single organization. "Quality control (QC) activities" take a variety of forms, including: activities throughout institutions as a whole, under the leadership of the hospital

director; and measures taken by smaller groups in each ward and occupational category. There are around 200 medical institutions with "internal QC circles" of this kind. In recent years, some medical institutions have in addition introduced "total quality management" (TQM) systems in order to systematically and continuously improve the quality of medical care. Medical professionals active in this area have been independently developing their own ties, establishing in 1999 the "Medical TQM Promotion Council". This helps to foster mutual awareness and exchanges between medical institutions which are taking steps to improve the quality of medical care..

- Some medical institutions have started to conduct patient satisfaction surveys and to involve patients in the clinical decision process. There is also a growing trend to improve information technology systems, such as electronic medical records, and to use critical pathways for treatment decisions.

3) Third party regulation

- The Japanese Society for Quality in Health Care (JSQua), has 60 member hospitals and 50 individual members and has taken a pioneering role in the development of quality improvement activities in health care since 1990. For the present, JSQua has been paying more attention to outcome-based standards by developing measurable quality indicators which can be shared among its members (Hiroto Ito, et al, 1998).

- In order to provide a system of third-party accreditation of medical services, the Japanese Council for Quality Health Care (JCQHC) was established in 1995. The JCQHC has been engaged in evaluating and accrediting activities since 1997. Medical institutions are evaluated through examination of documentary evidence and visits, the findings of which are deliberated by an assessment committee and, provided that a certain level is reached, the institution is accredited. The number of accredited hospitals as of May 2003 was 935. Assessment covers six areas: 1. administration of the hospital's organization and role in the community, 2 patients' right and safety, 3.

care environment and service for patients, 4. quality of medical treatment, 5. appropriateness of nursing care, and 6. rationality of the hospital's administration and management. Hospitals can choose whether or not to be assessed, and the results are not publicly disclosed. However, consenting accredited hospitals are disclosed on the JCQHC's website, and accredited hospitals are also free to advertise themselves as such. Under the medical fee revisions of 2002, accreditation by an organization such as the JCQHC was required for payment by the insurer to the hospital of palliative-care ward inpatient fees and additions to fees for palliative care treatment and outpatient chemotherapy.

- Another method of third-party assessment of quality used in Japan is the independent acquisition by medical institutions of ISO9000s, which is the newly-established "International Organization for Standardization (ISO)" standard for quality systems in industry.

4) Patients and Purchasers

- While the insurers do not become involved in setting standards for medical care, they make an effort to ensure and develop quality of care by checking medical fee statements, and by collecting and providing information on the delivery of medical services by providers. The National Federation of Health Insurance Societies (NFHIS) is developing a hospital information-retrieval system through which the insured person can find a hospital fitting to his or her care needs.

- A recent development is an increase in patient advocacy and support groups and an increasing number of malpractice lawsuits (Takahashi, 1997).

- Advertising of health services is as a rule prohibited, except for certain items of information that are permitted in the interests of consumer protection. However, patients' demands for information on medical services are increasing, and articles on

hospitals and physicians with good reputations frequently appear in magazines and books. In 2002, the range of information that could be legally advertised was substantially expanded, and patients are now able to find out about matters such as the specialty of physicians, the average length of stay, the number of operations, and the provision of second opinions by providers.

- People are also increasingly interested in their own patient records, and there are growing calls for patients to be allowed to see medical invoices, medical records and test data, and where necessary to make copies. In 1997, a revision of regulations was made to allow the disclosure of medical invoices by an insurer when that is requested by an insured person. The JMA released in 1999 its own " Guidelines on the Provision of Treatment Information ", which stipulate that patients should as a rule be allowed to see and copy their own treatment records if they request, and these guidelines went into operation in 2000. Moreover, under the Act for Protection of Personal Information (2002), medical institutions were obliged to disclose certain medical information in principle in response to requests from patients.

- Partly as a consequence of the spread of the Internet, it has become increasingly common in recent years for patients to search for necessary information online. Some medical institutions and individual physicians actively publish information on methods of treatment and their performance using the Internet, The quantity of information accessible to patients via the Internet is expected to increase dramatically although it is difficult to assess the reliability of such information.