

A glimpse of pharmacy practice in Japan: Déjà vu

DONALD T. KISHI

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The Pharmacy Abroad section of AJHP features brief, informal, and topical communications related to pharmacy in other countries. Contributions are welcomed from pharmacists abroad or from pharmacists who have traveled abroad.

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During the past 10 years, I have had the opportunity to participate in various professional and education-related pharmacy meetings in Japan. Most have been 10-day to two-week stays. However, in the fall of 1998 I was able to spend three months in Japan as part of a relationship between the University of California School of Pharmacy and Tokyo University of Pharmacy and Life Sciences (formerly known as the Tokyo College of Pharmacy). Immersed in teaching pharmacy students; providing seminars to hospital and community-based pharmacists; participating in discussions with faculty, practitioners, and students; visiting hospital and community pharmacies; and surfing the Internet, I gained a *gaigin's* (foreigner's) perspective on pharmacy education, pharmacy practice, and health care in Japan.

Reflecting on the time I spent in Japan reminded me of my experiences with pharmacy education and practice in America in the late 1960s

through the 1970s, when clinical pharmacy was struggling for acceptance within and outside the profession. It also brought back thoughts of the mid-1980s to the present, when controlling health care costs has been the dominant force driving the U.S. health care system. Japan's health care system, pharmacy education, and pharmacy practice are now experiencing these health care, professional, and educational struggles and the changes that efforts to contain health care costs bring. *Déjà vu.*

The Japanese population

As in most other industrial nations, the population in Japan is aging.¹ In 1998, Japan led the world in life expectancy for men (77.16 years)

and women (84.01 years).² The five leading causes of death in Japan in 1998 were, in descending order: cancer, heart disease, cerebral vascular disease, pneumonia, and accidents or adverse events.³ The fertility rate in Japan is steadily declining.¹ In 1998, the fertility rate reached its lowest point to date, 1.38 births per 1000 women of childbearing age. This rate is lower than the 2.1 births per 1000 required for replacement of the existing population.⁴⁻⁶

There are several negative implications of an aging and non-self-renewing population for the economic, health care, and educational systems in Japan and potentially its stature among world powers. Both trends will lead to an older, smaller work force, a decrease in productivity, and less tax revenue to support Japan's National Health System (NHS). These changes come at a time when Japan is beginning to see increased utilization of health care resources.

In response to the declining fertility rate, the Japanese government has implemented the "Angel Plan," which attempts to address some of the factors hindering young couples from having a family, including inadequate income and cramped living quarters.^{4,6} Another government plan, the "Gold Plan," was announced in 1989 and is scheduled for implementation in April 2000.

DONALD T. KISHI, PHARM.D., is Clinical Professor of Pharmacy, Department of Clinical Pharmacy C-152, School of Pharmacy, University of California at San Francisco, San Francisco, CA 94143-0622 (dtk@itsa.ucsf.edu).

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Its objective is to provide support for families with elderly parents through home helpers, guidance and counseling, daycare centers, homes for the aged, nursing homes, and residential communities for the elderly.¹ The plan is to be funded through taxation (50%) and insurance contributions (50%).⁷ Given the fiscal problems being experienced by the Japanese Ministry of Health and Welfare (MHW) and the Japanese economy in general, funding this program may prove problematic. The development of public assistance programs for the elderly points to the needs being created by the changing attitudes in Japan about a child's obligation to his or her parents and by an aging population.⁷

Overview of the health care system

As I reflect on the Japanese health care system, I am reminded of the U.S. system before managed care became dominant. The Japanese system is hospital centered, is based on fee-for-service scheduled reimbursement, is physician dominated, involves preference-based rather than evidence-based decision-making, and is treatment oriented rather than prevention or health promotion oriented. Both health care-naïve and -dependent patients are served through a system that is highly regulated on the provider and supplier side and underregulated on the user side. The resultant unnecessary overutilization of health care resources may be the consequence of free medical services that existed for the elderly from 1972 to 1982.¹ In the mid-1990s, overutilization resulted in health care expenses that began exceeding the funds required to support the system.

Japan's health care system, however, differs from current and past systems in the United States in terms of financing and structure. Japan has a single payer: the government. Over 80% of Japan's hospitals and approximately 95% of physicians' offices

(clinics) are private. There are no for-profit hospitals and no multihospital systems in Japan; such practices are prohibited either by law or by practicality (a hospital's chief executive officer must be a physician). There is also a distinct separation between outpatient and inpatient care, since patients who cannot be managed in the clinic must be referred to a hospital and the care must be provided by physicians employed by that hospital.⁸ This arrangement may be similar to the "hospitalist" trend in the United States. Despite the existence of a single governmental insurer, the relationship among health care providers appears to be very similar to that in the United States, involving as it does uncoordinated and noncommunicating silos of health care. Exacerbating the lack of connectivity is the fact that Japanese patients have the freedom to use any health care provider they choose, even though they have no choice in selecting a health insurance plan.⁸

Health insurance

Health care in Japan is primarily paid for by the NHS, which is administered and regulated by MHW. Universal health insurance was established in 1961 and currently consists of three broad types: insurance for corporate employees; for farmers, the self-employed, and retired employees; and for the elderly. The program for the elderly covers bedridden patients who are over 65 years of age and all individuals over 70. The corporate employees' program is funded by an insurance premium or income tax. For example, an employee of a large corporation is assessed approximately 4.25% of his or her salary, which is matched by the corporation to yield a premium equivalent to 8.5% of the salary. The premium for farmers, self-employed persons, and retirees is dependent on the income and number of family members. Funding for the program for the elderly primarily comes from contributions from

the other two programs. Each of these insurance programs also receives varying support from local and national government.⁹ In 1997, the contributions to national medical expenditures were as follows: public funds, \$13.3 billion; medical insurance, \$134.5 billion; medical insurance for the elderly, \$92.15 billion; and patient out-of-pocket expenditures, about \$38 billion.¹⁰

The range of services covered by the NHS includes inpatient care, outpatient care, home care, dental care, prescription drugs, long-term care, and prosthetics. Herbal medications were recently added to covered medications. There are, however, exclusions to the products and services covered, such as prescription drugs not on the NHS formulary, nonprescription medications, physical examinations, and corrective lenses. Oral contraceptives were not approved for use in Japan until 1999; similarly, MHW prohibited organ transplantation until 1997. At that time, a law defining the circumstances under which an organ could be removed—brain death and concurrence of family—was enacted. While it is now legal, organ transplantation still has some cultural and religious barriers to overcome.

In addition to excluding some services and products, the NHS requires copayments for approved and covered products and services. Copayments for covered prescription drugs vary with the number of medications prescribed for a patient. Similarly, the government is decreasing reimbursement of the prescriber once the patient exceeds a specified number of drugs. In 1990, this limit was 10 drugs; it was reduced to 8 drugs in 1996 in an effort to decrease polypharmacy.¹ Copayments of 20–30% are required for inpatient and outpatient health care services, except for the elderly. For the elderly, there is a flat copayment of about \$11.40 per day for inpatient care and a maximum copayment of \$4.75 per outpa-

tient visit (a maximum outpatient copayment of \$19 per month).⁹ Once the patient's copayments exceed the set monthly maximum, the insurance pays. The health care provider is reimbursed for the various services provided on the basis of a detailed, nonnegotiable fee schedule set by the government. The fees for a given service are the same regardless of the health care setting in which it is provided. It is illegal for a provider to recoup the difference between the charge and set reimbursement.⁸

In 1997 the Japanese government reported that national medical expenditures exceeded \$275.5 billion, or \$2189 per person.^{11,12} This figure probably should not be used for comparison with other countries, since items included in health care expenditures may vary with each country's reporting standard.^{13,14} 1997 is about the time when national medical expenses exceeded revenue from premiums and other sources. The downturn in Japan's economy during the past few years and increased unemployment (currently at an all-time high of 5%) have resulted in decreased premiums and taxes to support the NHS. In 1997 approximately one third of the health system's annual national medical expenditures, or \$92.15 billion, was for the care of the elderly.^{10,11} It is projected that the cost of caring for the elderly will exceed 50% of all health care expenditures by 2025.¹⁵ How to fund this increasing health care cost is a question the government has not resolved. Even the health care plan for the elderly, the Gold Plan, may be at risk. Employers, employees, and other contributors to the health insurance fund appear to be increasingly unwilling to assume the level of financial responsibility necessary to make the Gold Plan work.

In addition to the difficulty of financing the NHS, there is the problem of growing overutilization of the health care system. This issue may have been hidden by the free flow of

yen during Japan's economic boom. The aging of the population has continued to increase demands on the system. The long history of "free" health care has created an expectation that health care is an entitlement. Incentives that have stimulated utilization of the system have not been effectively countered by the government. For example, there continues to be a financial incentive for physicians to prescribe and dispense medications. Although the government is trying to persuade patients to use a "home" community pharmacy rather than obtaining prescription medications from a physician, this habit is proving hard to break. Reimbursement of physicians on the basis of prescriptions written and dispensed provides an incentive for overprescribing, which results in increased costs associated with products, monitoring, and medication errors. There has also been a financial incentive to keep hospital beds occupied. This census-related incentive, the entitlement attitude of patients, the lack of skilled-nursing and extended care facilities, and the growing tendency for children to no longer provide care for their elderly parents may be contributing to an increase in medically unnecessary admissions and long hospital stays (~44 days in 1996).^{1,16}

In summary, the NHS appears to be headed down a financial path similar to that of Medicare in the United States. The NHS, however, must cope with a rapidly aging population, a troubled economy, increasing unemployment, a shrinking labor force, a public with an entitlement attitude, and misdirected provider incentives. These forces will continue to result in overutilization of the system in the face of a diminishing insurance premium revenue base—until providers and patients take more responsibility for correcting the underlying problems.

Patient rights and quality of care

Another major difference between the Japanese and U.S. health care sys-

tems relates to patient rights. In Japan's physician-dominated system, it was not until recently that the patient had protections or rights. For example, it was not until 1997 that MHW implemented a law requiring obtaining a patient's informed consent for use of an investigational drug. It was not until 1998 that MHW proposed that the patient has the right to know the contents of his or her medical record.^{14,17} This basic patient rights issue continues to be debated, with the major resistance coming from the medical community. It is not surprising that this is an issue, since traditionally physicians have not even disclosed the diagnosis to the patient.

Hospital pharmacy practice

There are approximately 9400 hospitals in Japan. Technically, a hospital in Japan is a health care facility that has more than 20 beds. A clinic or a physician's office can have up to 20 beds and not be classified as a hospital.¹⁸

Over 10 years ago, I observed a pilot system that included computerized physician order entry and drug information programs in operation at a university hospital in Japan. This particular program used a touch screen and provided the physician with a menu of drug, dosage, and regimen options; the ability to split the screen to view a monograph on the drug being prescribed; and the patient's medication profile. The computers on the hospital's wards were linked to a server in the hospital's pharmacy that was linked to unit dose or single-dose packaging, labeling, and dispensing equipment similar to Baxter's ATC 212 system. On my most recent trip, I saw the same type of setup in a large community hospital. I do not know how widespread computerized physician order entry linked with dispensing technology has become in Japan, but one might assume it is quite extensive, given the technology available in Japan.

With respect to other institutional

dispensing responsibilities, intravenous admixtures, including total parenteral nutrient solutions, are primarily prepared by nurses or are purchased from commercial sources. The pharmacy is responsible for procuring and distributing these solutions. In some hospitals, large pharmacy and i.v. solution compounding sections are still in operation. Another dispensing role of the pharmacist is the result of the use of herbal medications. The Japanese have developed technology that automates the preparation of herbal medications and the making of the powder-paper dosage forms used to dispense these medications.

Until recently, hospital pharmacies were responsible for dispensing discharge medications and for dispensing prescriptions originating from the hospitals' clinics. However, in 1998 MHW shifted this dispensing responsibility to community prescription pharmacies. Along with the shift in the workload associated with discharge and clinic prescriptions, a staffing ratio for public hospitals of 1 pharmacist to 75 hospital beds was set by MHW. This has resulted in the downsizing of pharmacist positions in most hospitals, particularly university hospitals. The increase in the workload of the remaining hospital pharmacists will decrease the number of potential hospital-based clerkship sites and preceptors. Further, the shift in responsibility for dispensing discharge medications will increase prescription volume and workload in community prescription pharmacies. These actions by MHW are consistent with attempts to decrease hospital costs and with the concept of patients using their "home pharmacy" for outpatient medication needs.

In Japan, pharmacy technicians are not utilized to any great degree. A major medical center hospital pharmacy that I visited employed only one technician, and his responsibilities were essentially those of a storekeeper, with no involvement in any

phase of medication dispensing. Discussing this situation with the hospital's pharmacists did not clarify whether the lack of technical personnel is a result of forces external or internal to pharmacy. Two pharmacists added that only a tenth of hospital pharmacy practitioners appear to be motivated to practice clinically. Put another way, 90% of hospital practitioners may be content with just dispensing. Perhaps this hanging on to the dispensing role and the sparse use of technicians may be a result of physicians' dominance of the clinical arena and the relative lack of clinical education and training for pharmacy students and pharmacists. Furthermore, there is the possibility that MHW may have established the 1-pharmacist-to-75 beds ratio to indirectly pressure hospital pharmacies to begin to use pharmacy technicians to cope with the increased workload that is resulting from pharmacist job downsizing. Given the dispensing technology that exists and the underutilization of technicians, one might think that the unmotivated 90% of Japanese hospital pharmacy practitioners might become motivated to identify nondispensing roles for themselves.

Japan was introduced to clinical pharmacy concepts in the 1970s, and, as in the United States, the implementation of clinical pharmacy services has progressed slowly. This has been true despite MHW-promulgated financial incentive programs that have rewarded and made it easier for a hospital pharmacy to develop cognitive services like drug information, pharmacokinetic assays, medication monitoring, and discharge medication counseling. Under these programs, MHW pays the institution on a per-patient-per-month basis if the service is offered.¹⁹ The pharmacokinetic services that have been developed appear to be more analytical than clinical (e.g., a pharmacokinetic assay is performed primarily to determine a drug's concentration, rather

than as part of collaborative drug therapy management with the patient's physician). MHW also provided an incentive for hospital pharmacists to counsel patients about their medications. While some hospitals have taken advantage of this incentive, many have not. Today, the counseling incentive may be moot, given the pharmacist-to-bed ratio and the resultant reduction in pharmacist availability.

In the United States, pharmacists have a significant decision-making role in drug therapy-related policies and formularies. In Japan, the hospital pharmacist's role on a pharmacy and therapeutics or formulary committee—if there is a committee—appears to take a back seat to the physician's. The physician's dominance extends to drug purchasing and negotiation of purchase prices.¹⁹

Another potential clinical activity for the hospital pharmacist is adverse-drug-reaction (ADR) reporting and analysis. The hospital pharmacist's role in ADR reporting in Japan was unclear until 1997. Up until that time, the system was based on reporting of ADRs by manufacturers and by hospitals that were selected to monitor for and report ADRs. In addition, there was a legal provision requiring community and nonprescription pharmacies to report ADRs related to nonprescription drugs. Since 1997, the reporting system has expanded to include all medical institutions and pharmacies and has required pharmacists, physicians, and dentists to file ADR reports. During my 1998 stay in Japan a number of hospital pharmacists were attempting to implement ADR-reporting systems in their institutions with or without staff physician involvement. Also, guidelines for pharmaceutical manufacturers' reporting of ADRs were expanded to include infections resulting from drug therapy. As the system currently exists, ADRs reported are analyzed by MHW, and, as warranted, the manufacturer is required to

appropriately revise its cautions for use. I could not determine whether there is a drug recall system or a health care provider ADR-alert system. However, an Organization for ADR Relief was established by MHW to provide financial and medical assistance to individuals who have had an ADR. This organization is funded by pharmaceutical manufacturers' contributions and penalties.²⁰

According to the literature, quality is a major area in the Japanese health care system that needs improvement.¹⁴ Japan has no equivalent to the Joint Commission on Accreditation of Healthcare Organizations.¹⁹ The National Institute of Health Services Management (NIHSM) in Japan consists of health policy, health economics, and facilities design and planning departments and lists hospital quality assurance and evaluation of the health care system as one of its responsibilities. However, it appears that NIHSM serves more of a consultative role than an evaluation or accreditation function with respect to these responsibilities. NIHSM performs health policy and administrative research and provides management training and continuing-education courses for health care personnel.²¹

The concept of postgraduate pharmacy residencies in Japan has been discussed periodically, but residency program implementation has progressed at a rate similar to the rate of implementation of clinical pharmacy practice and education. There does not appear to be a professional, educational, or organizational effort to advance the concept of pharmacy residencies; consequently, no standards or accreditation processes exist.

The rate of implementation of clinical pharmacy services may be attributable to a number of causes, including physician dominance, the nonutilization of technical personnel, the lack of clinical training, the lack of pharmacy residency programs, and pharmacists' lack of motivation.

However, these obstacles may be only superficial manifestations of deeper problems, such as acceptance of authority without question and resistance to change, that may be much more difficult to overcome.

Nonprescription pharmacies

Pharmacies in the ambulatory care setting in Japan can be divided into nonprescription pharmacies, prescription pharmacies, and combined nonprescription-prescription pharmacies. Many of the nonprescription pharmacies have no front door (to facilitate entry and increase shelf space), only a roll-down barrier for securing the pharmacy when it is closed. The nonprescription pharmacies are very noticeable as you walk through a metropolitan area. Open shelves and countertops display the various drug and nondrug products, much as in the nonprescription section of a smaller drugstore in the United States; however, in addition to display shelving in the store, displays may extend out onto the sidewalk. These nonprescription pharmacies may be independent or may belong to small local chains or a national chain. Government-designated and approved nonprescription drug products must be sold through a pharmacy and are not available in convenience stores or supermarkets. Some common products available in the United States, such as aspirin, are not available over the counter in Japan. Advertising of nonprescription products is legal, but prescription drugs cannot be advertised.²²

Community prescription pharmacy practice

The separation of physician prescribing and dispensing (*bungyo*) was first encouraged by MHW in 1985. Actual achievement of this separation has been very slow, despite the urging of MHW. The slow progress is attributable to a 10-centuries-long tradition under which physicians have supplemented their incomes by pre-

scribing and dispensing medications.^{13,14} This incentive stimulates polypharmacy, increases health care costs, and may unnecessarily expose patients to potential drug interactions and associated costs. When I discussed this issue with some Japanese pharmacists, they indicated that the generally lower dosages of pharmaceuticals used in Japan are based not only on the population's smaller physical size but also on this desire to use multiple-drug therapy rather than maximizing the dosage of a single agent.

In an effort to reduce costs and further encourage *bungyo*, MHW is promoting the concept of the home community pharmacy to patients. Ideally, patients would purchase nonprescription drugs and have their prescriptions filled only at a home pharmacy. This would allow pharmacists to detect drug interactions and monitor compliance by centralizing the patient's source of prescription medications.²³ MHW has basically eliminated the dispensing of discharge medications and clinic prescriptions at the hospital pharmacy in an attempt to further stimulate the patient's use of a home pharmacy. It is my understanding that MHW is also attempting to decrease the reimbursement for physician-dispensed prescription medications as a disincentive. MHW reported that 18.1% of the prescriptions in 1994 were dispensed through pharmacies,²⁴ and the Japan Pharmaceutical Manufacturers Association reported a 23% rate for this in 1996.²⁵

Another barrier to the patients' use of home pharmacies is the need to change the public's and pharmacists' perception of what the pharmacist's role in health care should be to optimize the appropriate use of medications and to minimize medication-related problems.

Once a prescription is written, it must be filled within four days or it is considered to have expired. Quantities allowed to be dispensed are limited to a

14-day supply, unless the medication is considered long-term therapy, in which case a 28-day supply may be dispensed. The concept of refills on prescriptions does not exist. The patient must revisit the physician to obtain another prescription. Similarly, phone-in prescriptions, orally transmitted prescriptions, mail-order prescriptions, and drug samples are illegal.^{13,22}

This system of limiting quantities and requiring new prescriptions may explain the often-heard complaint of how busy the physicians are and their reluctance to give up the reimbursement associated with dispensing medications. For patients covered by the NHS, the price of a prescription is fixed regardless of where the prescription is filled, and the patient's copayment is 30%.

As with hospital pharmacists, the government offers a financial incentive for community pharmacists to counsel patients about their prescription medications. For a pharmacist to provide this counseling legally, the pharmacist must know the patient's diagnosis. This is somewhat problematic and increases counseling-time requirements, since many physicians still do not tell the patient what disease or condition he or she has. A few of the community pharmacists I spoke with indicated that the financial incentive offered by the government is too low—that counseling takes time and they are too busy to take advantage of the incentive. On the other hand, I am aware of some pharmacists who provide this service to patients despite the government's requirements and low reimbursement. These factors, however, may prove to be major obstacles to the government's home pharmacy concept and its efforts to separate prescribing and dispensing and to increase pharmacist counseling in the ambulatory care setting.

There are approximately 30,900 dispensing pharmacies in Japan.²⁶ I had the opportunity to visit the prescription pharmacy of one of a

former University of California student. His family has been in the pharmacy profession since the early 1900s. He owns two pharmacies, which are state-of-the-art even by U.S. standards. The pharmacists use computerized profiles and have developed a computer-generated patient information program to supplement pharmacist-provided medication counseling. The two pharmacies are linked by fax and computer. Computers provide centralized billing of prescriptions, inventory control, and ordering of medications. The owner employs technicians and uses them for activities beyond those of a storekeeper. The pharmacy itself is appointed with antique fixtures and has very few nonprescription medications displayed. It reminded me of prescription-only community pharmacies in the United States in the 1970s.

Conclusion

Many of the barriers to advancing pharmacy practice in Japan are reminiscent of those that have been experienced by progressive U.S. pharmacists. The health care system in Japan is highly regulated, hierarchical, and bound by tradition and culture. Physicians resist change, dominate health care, and exercise formidable political clout. Standards are poorly enforced, and accreditation processes are lacking. Culturally, the *shukumei* or *shigatani* attitude (acceptance of fate or destiny) may ultimately underlie what appears to be complacency in pharmacy practice. It seems that substantive change in pharmacy occurs only when the government mandates it. Perhaps, in the face of the rising cost of health care, MHW will mandate more opportunities for extending pharmacists' involvement in the health care system beyond selling nonprescription products and dispensing prescription medications. Whether Japan's pharmacy profession will be willing to respond to such opportunities remains to be seen. Déjà vu.

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