Asia-Pacific
Economic Cooperation

2010/SOM3/LSIF/023

Healthcare System Innovation for Aging Society - Issues and Direction

Submitted by: University of Tokyo

JAPAN 2010

Life Sciences Innovation Forum
Sendai, Japan
18-19 September 2010

APEC members have shared common challenges such as promoting R&D of medical technology, delivering high quality of healthcare and increasing healthcare expenditure. In Japan, universal public healthcare insurance system has been accomplished and we the Japanese enjoyed high advanced healthcare under the system. However, Japan face crisis of the system by rapid increased cost with population aging as well as progress of medical technology. At the crisis, we should focus on healthcare innovation by deregulation as well as market mechanism, affordable healthcare insurance system, and optimal resource allocation for healthcare by meaningful use of IT. Aging society must be a challenge not only for Japan, the first runner in aging but the other Asian members in APEC. We should engage in collaborated research for seeking uncertain solutions in the near future.

Healthcare System Innovation for Aging Society
-Issues and Direction-

APEC Life Sciences Innovation Forum
Health Financing Mechanisms & Options
Sep. 19, 2010

Prof. Akira Morita
University of Tokyo

(C) 2010 Policy Alternatives Research Institute, University of Tokyo

1. Introduction

- APEC members face Common Challenges on Healthcare Policy listed below as discussed at the Singapore Session, "Healthcare in Asia of 2010":
  - Healthcare costs continue to rise faster than general inflation.
  - More doctors have not necessarily led to price reduction.
  - Greater health care spending has not always led to better health.
  - Patients' expectations continue to rise.
  - Employers and taxpayers are increasingly reluctant to pick up the bill.
- In the face of these challenges, how can we deliver equally high quality of healthcare and keep fiscal stability?
- What is the best financial combination for healthcare delivery between public spending and out of pocket including private insurances?

2

2. Basics of Japanese Healthcare System (1)

- Main Features in finance and delivery of healthcare
  - In Asia, Japan is one of the pioneers to accomplish universal public healthcare insurance in 1961.
  - The Japanese people have access to high quality healthcare service in exchange for low financial burden.
  - Under the public healthcare insurance, Medical Fee, universal price scheduled by Japanese Government, is paid for healthcare services. Minimum quality of healthcare service is uniformly regulated throughout Japan as well.

- Healthcare Insurance System

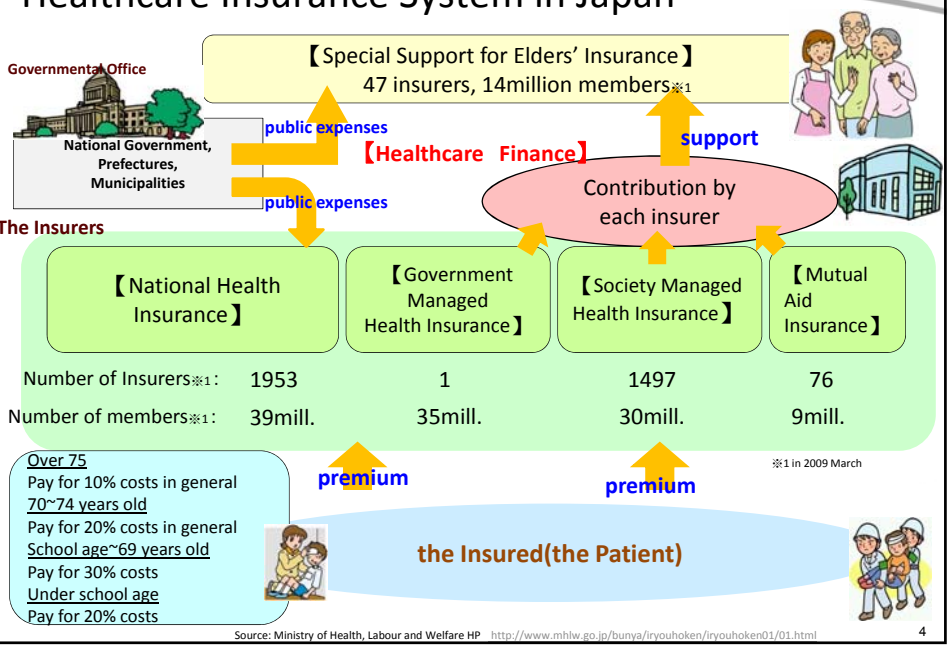
  There are five kinds of Insurance:

  1) National Health Insurance (managed by municipal governments for unemployed and self-employed)
  2) Government Managed Health Insurance (for small company employee)
  3) Society Managed Insurance (managed by unions for company employee, and premium paid by both employer/employee equally)
  4) Mutual Aid Insurance (for public servants and private school teachers etc.)
  5) Special Support for Elders' Insurance (for over 75 years old)(1/2 public expenditure)

- *We, the Japanese people, on the condition of monthly insurance premium paid, generally get healthcare services in any hospitals and clinics throughout Japan.*

3

Healthcare Insurance System in Japan



Source: Ministry of Health, Labour and Welfare HP http://www.mhlw.go.jp/bunya/iryouhoken/iryouhoken01/01.html

4

2. Basics Japanese Healthcare System (2)

- Coverage Decision Making, Medical Fee Scheduling, and Payment Structure

- Medical Fee (including drug price) and covered service under public healthcare insurance is *uniformly scheduled* by the "Central Social Insurance Medical Council", an advisory committee for Minister of Health Labour and Welfare.

- Council board consists of three groups and twenty members; seven representatives for insurers, seven for doctors, dentists, and pharmacists, and lastly six for public.

- Medical Fee is merely an official price for insurers to pay for covered healthcare services provided by hospitals and clinics. Then, *Patients generally have to pay for 30% of healthcare service costs* under each healthcare insurance (10 or 20 % for over 70 years old). The price scheduled by the Japanese Government is *not mandatory but referencial* in market, so hospitals and clinics can purchase drugs and devices etc. by market price.

5

2. Basics Japanese Healthcare System (3)

- *Incentive mechanism for efficiency in healthcare has been weak* because payment for service is calculated by cost based, not prospected based with some exceptions.

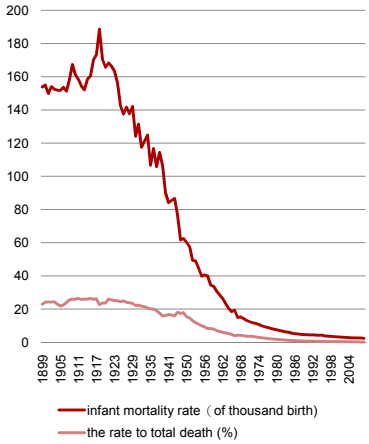
- *Healthcare system had worked until about 1990*, though healthcare cost increased by rapid progress of medical technology and widespread use of healthcare service. Healthcare system kept secure since the number of working age population were more compared with the other in population pyramid and rapid economic growth continued for long term.

- *In the end, health condition of Japanese People became dramatically better than before and top ranked high life expectancy has already been accomplished.*

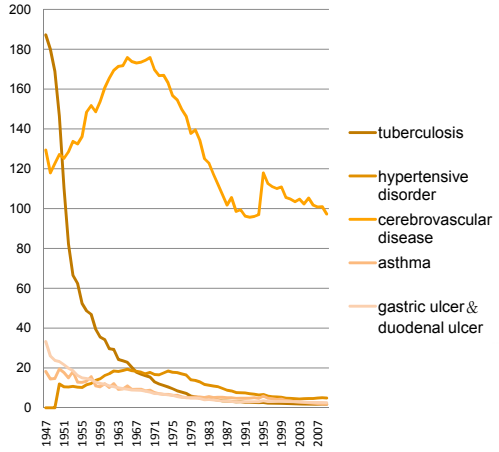
6

Improving the Health Condition

infant mortality rate
(of thousand birth,%)



Transition of Mortality Rate by Cause
of Disease
(of 100 thousands person)



Source: Vital statistics(2009)

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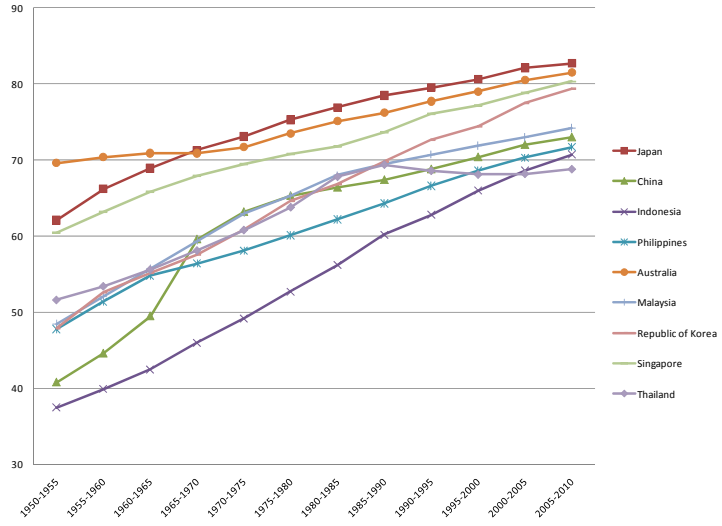
Life Expectancy at Birth, Both Sexes Combined (years)



Population Division of the Department of Economic and Social Affairs of the United Nations Secretariat, World Population Prospects: The 2008 Revision, http://esa.un.org/unpp, Wednesday, August 25, 2010; 4:28:54 AM.

8

3. Aging and Crisis in Healthcare System (1)

- Population age structure has rapidly changed toward a large older generation since 1990 (especially over 65 years old). In Japan, aging has been accelerated by the universal public insurance program, progress of healthcare technology and downward trend in the birthrate with modernization.
- *With populations aging, growth rate of healthcare cost exceeds economic growth rate and existing healthcare system is at risk of failure.*

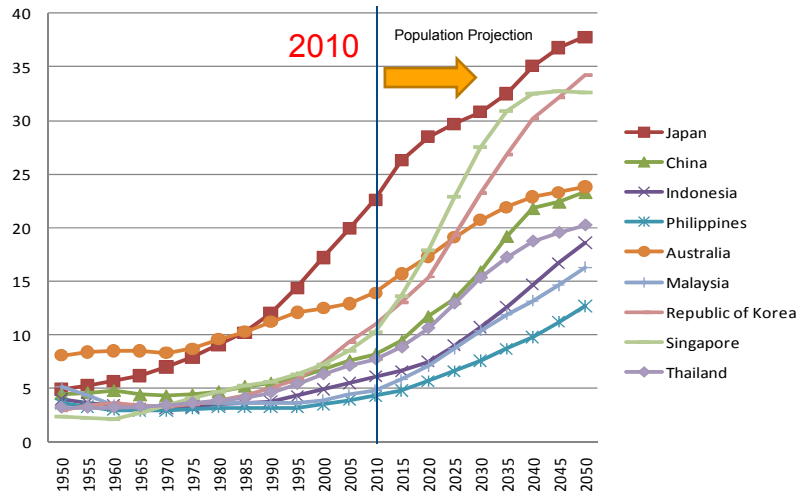
- Components of Crisis

  1)More people in aging
  - Structural change in disease from infectious to chronic.
  - Living for longer time with complicated diseases thanks to advanced medicine.

  2)Population decline
  - Local healthcare became weak because of gap between demand and supply to healthcare services in thinly populated rural areas, advanced medical technology and hospitals aggregated for affording the technology.
  - In rural areas, physicians are shortly supplied because burden for physicians working in hospitals has been increased in delivering high advanced medical technology.

9

Percentage aged 65 or over (%)



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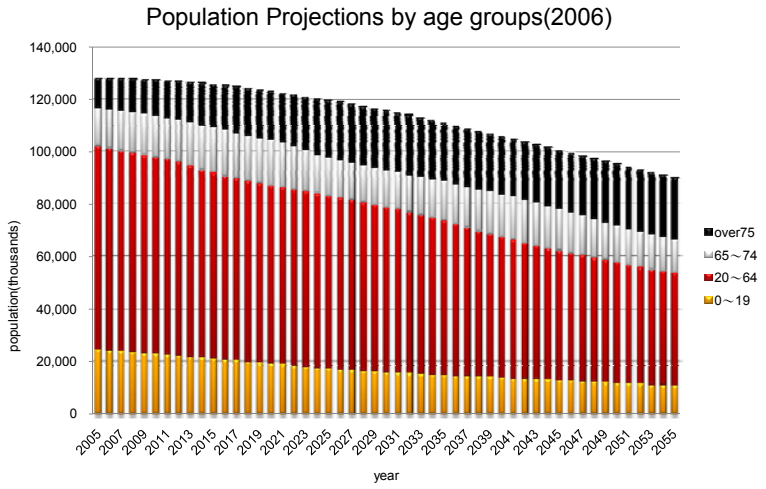
10

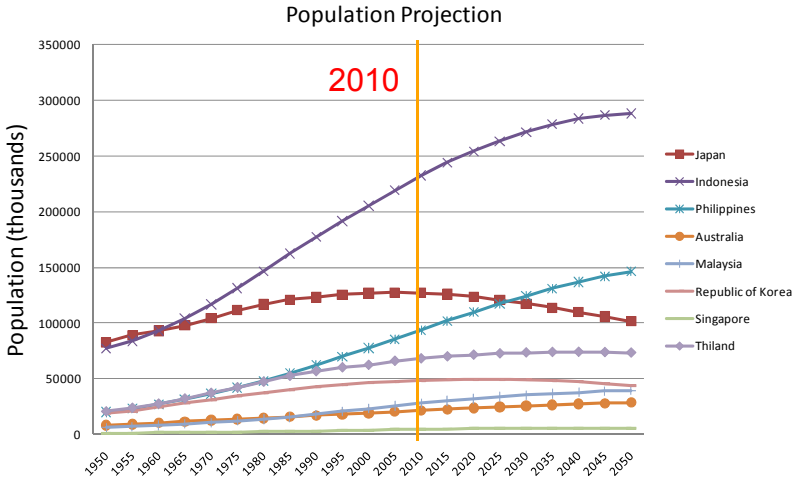
Population Decline in Japan



Source: National Institute of Population and Social Security Research Population Projection for Japan: 2006-2050

11

Population Decline in APEC



Source: Population Division of the Department of Economic and Social Affairs of the United Nations Secretariat, World Population Prospects: The 2008 Revision, http://esa.un.org/unpp, Wednesday, August 25, 2010; 4:28:54 AM.

12

3. Aging and Crisis in Healthcare System (2)

3)Increasing Medical Cost

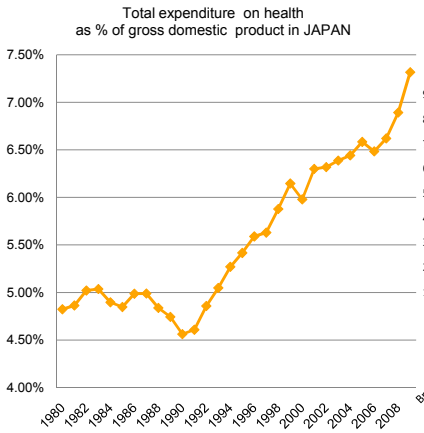
- Absolute amount of cost grows; $350 billion in 2009 and 7.32% of GDP in 2009.
- Rapid increasing cost in recent years; growth rate impossible to cover in the near future.
- Financing ratio between out of pocket and public spending (including both insurance and the other public expenditure) is around 20% to 80%.

4)Crisis in healthcare insurance

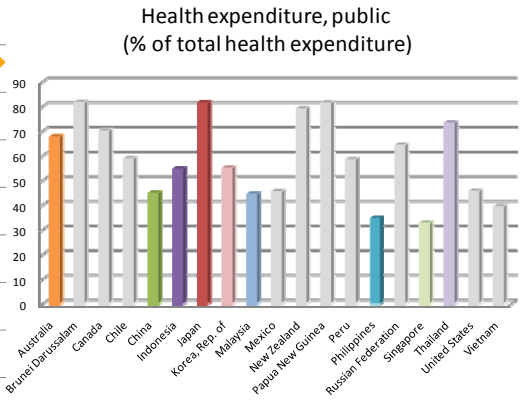
- *Extreme difficulty of National Health Insurance* (managed by municipal governments for unemployed and self-employed including increasing retired, less paid, and poor health elders).
- *Much public fund has been used for covering the deficits of the National Health Insurance*. The other insurance such as Government Managed Health Insurance, Society Managed Insurance and Mutual Aid Insurance also faces heavy deficits for increasing insured elders. In addition, budgetary restraint became more heavier than before.

13

Increasing Healthcare Cost



Source: Estimates of National Medical Care Expenditures (2009) and System of National Accounts(2008) and the 2nd Quarterly Preliminary Estimates of GDP (Percent changes in Nominal GDP,2010)



Source: World Health Organization National Health Account database 2010

14

3. Aging and Crisis in Healthcare System (3)

5)Deficiencies in Healthcare system

- *Gap became huge between the system and rapid change of demand for healthcares.*
- Effective primary care delivery/function of general practitioners has not been accomplished.
- More connected healthcare is needed between clinics and advanced hospitals, among clinics and among hospitals.
- Separated regulations for delivery and financing between healthcare and longterm nursing care as well.
- Time lag for access to new drugs and medical devices between Japan and U.S./EU continued in spite of action plan of MHLW and Pharmaceuticals and Medical Devices Agency, PMDA.

- *Present payment system of scheduled medical fee lacks any incentive mechanism for efficient allocation of healthcare resources.*

15

3. Aging and Crisis in Healthcare System (4)

- In the end, we have to face unavoidable dilemma that assuring quality of healthcare services would be difficult with tight budget restraint if we keep universal public healthcare insurance secure; more burden of future generations would be charged if we depend on more public expenditure.

- Disparity in access to healthcare services would widens among Japanese People if co-payment or out of pocket for high advanced medical technology services is allowed.

- At present, *dual use of public healthcare insurance for covered service and out of pocket for uncovered service is not allowed* with some exceptions. In other words, if we want to combine covered services with a uncovered service, we have to owe 100 % of healthcare cost for the all services provided. To soften this kind of penalty for combined use of the public insurances and out of pocket for uncovered service is the most important issues in Japanese health.

16

4.Direction for needed Reforms (1)

- *It is primal to make healthcare service efficient. The strategies for efficient healthcare services are (1)introducing market mechanism by institutional changes and (2) efficient allocation of limited healthcare resources.*

1)-1 Systemic reforms by deregulations and more transparency in regulations etc.

- Giving companies incentive for innovation of medical technology and promoting competition.

- For example, introducing attractive price for R&D of innovative medical device and drug, and transparent and simplified approval process not only for shortening time lag for access to new drugs and medical devices between Japan and U.S./EU but reducing administrative cost.

- In addition to internal affairs, global harmonization in regulations should be promoted in accordance with growing global market.

(However, we face an unavoidable dilemma between safety assurance by post market surveillance and deregulated approval system.)

17

4.Direction for needed Reforms (2)

- Introduction of competition by fair evaluation to doctors and hospitals/clinics, and scheduling medical fee based on quality of healthcare services.

(There is some possibility to create disparity of services as well as unequal access to services throughout Japan and among Japanse People.)

1)-2 Reforms in healthcare insurance

- Making insurance administration/review efficient and transparent by advancing integration and reorganization of insurers.

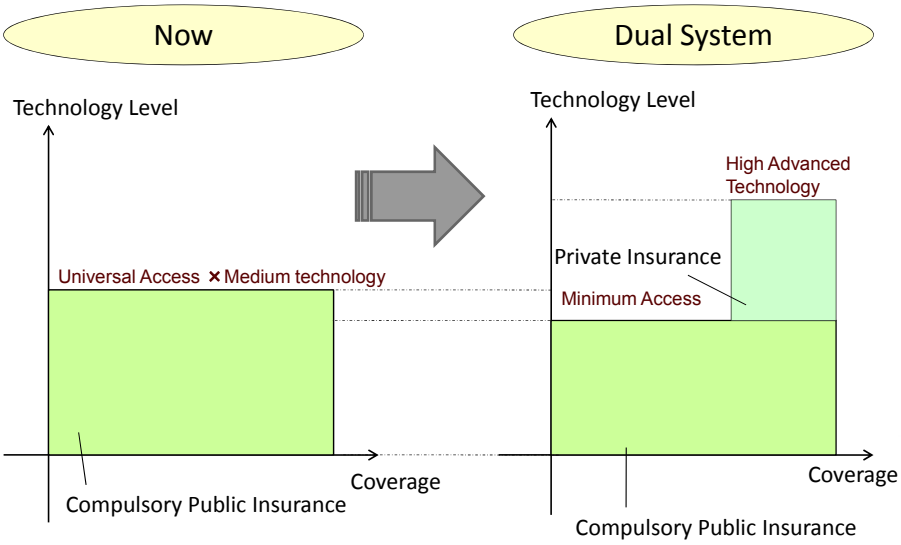
- Dilemma between universal equal access to healthcare and disparity in available services.

- Balancing public expenditure and out of pocket.

- One of the possible solutions is to establish a dual insurance system consisting of compulsory public insurance for minimum access to healthcare and private insurance for beyond the minimum access.

18

Reforms in Healthcare Insurance



19

4.Direction for needed Reforms (3)

2) efficient allocation of limited healthcare resources

- *Patients' choice to hospitals and clinics is unlimited throughout Japan but resources are not efficiently allocated such as personnel and material contributions needed for healthcare.* For example, disparity in doctors, hospitals and clinics, sub-optimal placement and use of medical devices, and unconnected healthcare between clinics and advanced hospitals, among clinics and among hospitals etc.

- One of the main reasons in inefficiency and the least used resource is medical information. To make meaningful use of medical information was not practical at all because of huge financial cost and much time for its introduction. *However, recent IT progress has already become a promising solution to the problems on cost.*

- We lag behind in application of IT throughout Japan as a reasonably alternative resource because:
  - First, privacy concern is big about establishing core infrastructure of patient ID.
  - Second, trustworthiness of IT is insufficient and cost of initial investment is very high for IT introduction.
  - Third, hospitals and clinics are inactive for IT introduction.

20

4. Direction for needed Reforms (4)

- Recently, it is seriously discussed to introduce ID system. We find trend toward meaningful use of IT based on ID infrastructure enable to (1) keep tabs on patients, hospitals/clinics, allied health professional, and healthcare resources, (2) record all medical practices, and (3) deliver effectively all needed information for optimal resource allocation.

- Positive Effects by Healthcare IT:

  1) Enhanced quality of care for patients by sharing personal health information in hospitals and clinics.

  2) Promoted research for building trust and effective medicine by disclosure of useful information as well as technology assessment based on all clinical data.

  3) Optimal resource allocation of personnel and material contributions throughout Japan.

  4) Efficient Management in each hospital and clinic through real time information on placements and operating rates.

- *Total effect by use of IT in healthcare is uncertain because higher quality of healthcare causes increasing healthcare demand though the IT accomplishes enhanced quality and effective allocation of healthcare resources. However, cost introducing IT in healthcare must bring us the biggest benefit if it is optimally used.*

21

Positive Effects by Healthcare IT

①Quality

Enhanced quality of care by sharing personal health information by hospitals and clinics.

②Research

Promoted research for building trust and effective medicine by disclosure of useful information as well as technology assessment based on all clinical data.

Healthcare IT

③Resource Allocation

Optimal resource allocation of personnel and material contributions throughout Japan.

④Management

Efficient Management in each hospital and clinic through real time information on placements and operating rates.

22

5.Conclusion

- Direction for needed Reforms in Japanese Healthcare System

  1)*We should keep universal healthcare insurance secure*.

  2)*Debate is needed to allow individual financial burden for only high advanced medical technology services in spite of gap between accessibility to healthcare among Japanese People.*

  3)*Reforms are needed to eliminate hurdles for effective healthcare system*: incentive should be given for private actors by deregulations and more transparency in regulations etc.

  4)We should make use of informative resources like clinical data for efficient allocation of limited healthcare resources by investing IT.

- *Aging society will be destiny for most Asian members in APEC after Japan, the first runner in aging. Speed in increasing cost is rapid with aging as well as progress of health technology. In Japan, universal public healthcare insurance contributes for life span extension. We are very happy If Japan could be a lesson for other APEC members. We should engage in collaborated research trials in Asia for seeking uncertain solutions.*

23

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Working Paper
Sep. 19, 2010

Prof. Akira Morita
With Chiaki Sato, Reiko Arami
University of Tokyo

(C) 2010 Policy Alternatives Research Institute, University of Tokyo

Healthcare System Innovation for Aging Society
-Issues and Direction-

Summary

This paper shows issues and a possible direction in healthcare system for APEC members with rapid future progress in aging. APEC members have shared common challenges such as promoting R&D of medical technology, delivering high quality of healthcare and increasing healthcare expenditure. In Japan, the universal public healthcare insurance system has been accomplished and we the Japanese enjoyed high advanced healthcare under the system. However, Japan faces crisis of the system by rapid increased cost with population aging as well as progress of medical technology. At the crisis, we should focus on healthcare innovation by regulatory reforms as well as market mechanism, an affordable healthcare insurance system, and an optimal resource allocation for healthcare by meaningful use of IT. Aging society must be a challenge not only for Japan, the first runner in aging but the other APEC members. We should engage in collaborated research for seeking uncertain solutions in the near future.

1. Introduction

With progress of aging, APEC members face common challenges on healthcare policy listed below as discussed at the Singapore Session, "Healthcare in Asia of 2010": 1) Healthcare cost continues to rise faster than general inflation, 2) More doctors have not necessarily led to price reduction, 3) Greater health care spending has not always led to better health, 4) Patients' expectations continue to rise and 5) Employers and taxpayers are increasingly reluctant to pick up the bill.

In the face of these challenges, we must find solutions for aging society through "Healthcare System Innovation". However, how can we deliver equally high quality of healthcare and

keep fiscal stability? What is the best financial combination for healthcare delivery between public spending and out of pocket? The task to find the solutions must be a difficult and unavoidable challenge for APEC members.

This paper shows issues and a possible direction in Japanese healthcare system for APEC members with rapid future progress in aging. The article proceeds in five parts. After the introduction, Part 2 explains basics of Japanese healthcare system in light of finance and delivery. Here, both equal access to healthcare under universal public insurances and minimum quality of healthcare services under uniform regulations throughout Japan are specified as distinguished features.

Part 3 explores crisis in healthcare systems with progress of aging. In this part, next five factors are focused on as components of the crisis: 1)more people in aging, 2)population decline, 3)increasing healthcare cost, 4)crisis in healthcare insurances, and 5)deficiency in healthcare systems. Here, unavoidable dilemma will be presented that assuring high quality of healthcare service would be difficult with tight budgetary restraint if we keep the universal public insurance system secure; more burden of future generations would be charged if we depend on more public expenditure.

Part 4 presents primal reforms needed for making healthcare service efficient. The strategies for efficient healthcare service are 1) introducing market mechanism by institutional changes and 2) efficient allocation of limited healthcare resources.

Finally, Part 5 shows a possible direction in Japanese healthcare system: 1) keeping universal public insurances secure, 2)needed debate allowing individual financial burden for only high advanced medical technology services in spite of gap between accessibility to healthcare among Japanese People, 3)needed reforms eliminating hurdles for effective healthcare system: incentive should be given for private actors by deregulations and more transparency in regulations etc., and 4)making use of informative resources like clinical data for efficient allocation of limited healthcare resources by investing IT.

In this paper, as one of the first runners in aging, we propose for APEC members that we should engage in collaborated research trials for seeking uncertain solutions to future healthcare system innovation.

2. Basics of Healthcare System in Japan

Japanese healthcare system has two features in finance and delivery, with accomplishing some great outcomes: universal public healthcare insurance and uniform regulations for minimum quality of healthcare throughout Japan[1]. In Asia, Japan is one of the pioneers to accomplish universal access to healthcare under public insurances in 1961. Under the public insurance system, the Japanese people have access to high quality healthcare services in exchange for low financial burden. Then, Medical Fee, universal price of health care scheduled by Japanese Government, is paid for healthcare services. In addition to setting medical fee uniformly, Japanese Government has assured minimum quality of healthcare services by uniform regulations throughout Japan as well.

2.1 Financing System

2.1.1 Kinds of healthcare Insurance Program

Japan has a universal health insurance system based on mandatory employment based insurance and residence based insurance. The insurance system consists of four principal insurance schemes and a special supporting scheme for elders' insurance.

There are three kinds of employment based insurance. First is Society Managed Health Insurance. The insurance is managed by unions for company employee, and its total premium is paid through pay roll tax by both employer/employee equally. In March 2010, there are 1473 insurers for company employees. Second is Government Managed Health Insurance. The insurance is managed for employees working in relative small companies. Third is Mutual

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[1] For Basics of Japanese healthcare system, see, e.g., Naoki Ikegami, The Japanese Health Care System: Its Success and Challenges for the Future, HARV. HEALTH POL'Y REV. 2008; 9:110-118.

Aid Insurance. The insurance covers mainly public servants and there are 76 insurers for each public sector.

The National Health Insurance is not an employment based insurance listed above but residence based insurance. The insurance managed by over 1900 municipal governments etc. as each insurer covers for the unemployed and self-employed.

Finally, the elderly over 65 years old are covered by a special supporting system.[2] The system is financed through contributions from the other three insurance schemes, as well as contributions from the central government. Contribution from the elderly is paid to the plan they were enrolled in while employed.

[Figure 1] shows the overview of healthcare insurance system in Japan. One noticeable point is that the healthcare system has a flexible adjusting mechanism to each insurance scheme by public expenditure indicated on [Figure 3]. The mechanism works as some compensation to much deficit in the insurance funds including National Health Insurance, Government Managed Insurance, and Society Managed Health Insurance. In fact, the mechanism keeping the national public insurance system secure has pressured the national budget restraint for recent years.

2.1.2 Benefits

Benefits provided by the public healthcare insurance program covers basic health services indicated on [Figure 2], such as physician or dental care, and hospitalization. Prescriptive drugs are also included in the benefits. Then, the insured have right to select freely hospitals or physicians among Japan. For the covered services, about 30% of healthcare service costs are charged to the insured as co-payments. We, the Japanese equally have universal access to healthcare without difference among kinds of insurance. .

2.1.3. Medical Fee Schedules, Pricing and Reimbursement Structure

In Japan, the central government uniformly schedules Medical Fee (including drug price) and covered services under the public healthcare insurance system. The "Central Social Insurance Medical Council", an advisory committee for Minister of Health Labour and Welfare has the authority to set medical fee. The council board consists of three groups and twenty members; seven representatives for insurers, seven for doctors, dentists, and pharmacists, and lastly six for public. Medical Fee is merely an official price for insurers to pay for covered healthcare services provided by hospitals and clinics. Then, Patients generally must pay for 30% of healthcare service costs under each healthcare insurance (10 or 20 % for over 70 years old). The price scheduled by the Japanese Government is not mandatory but referential in market, so hospitals and clinics can purchase drugs and devices etc. by market price.

Fee for service reimbursement for hospitals and clinics is the main scheme in Japan. Incentive mechanism for efficiency in healthcare has been partly weak, because payment for service is calculated by cost based, not prospected based with some exceptions. Payment based on Diagnosis and Procedure Combination, (DPC), Japanese version of Disease Related Groups, DRG has been introduced as an exception but it works only for all advanced hospitals.

2.2 Delivery System

Japanese Government mainly regulates hospitals and clinics, which are most privately owned, on safety issues except for bet numbers. In the healthcare sector, more strict regulations can easily be justified for minimum quality of care than in the other sectors because of information gap between service providers and recipients. For example, Medical Service Act passed in 1948 has governed practice requirements on personnel, building structures, advertisements and number of bets etc. Medical Practitioners Act has regulated on qualification as a doctor and other Acts have governed other medical professionals such as

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[2] Ministry of Health Labour and Welfare, MHLW is dealing with some reformation on the supporting system on the elderly over 75 years old. In the meanwhile, the system has been separated from the system for the elderly over 65 to 74 years old, available at http://www.mhlw.go.jp/bunya/shakaihosho/iryouseido01/dl/info02d_e.pdf

dentist, pharmacist and nurse etc. Code of ethics for medical professions has blocked activities for efficiency to some extent. In addition to these regulations, the approval system before selling pharmaceuticals and medical devices works for protecting people from unreasonable risks.

Besides stringent safety regulations, there is not an approval but notification procedure in opening clinics. Then, the regulations to hospitals and clinics work less in both funding and investment aspects than in safety. In other words, incentive mechanism for physicians managing hospitals and clinics has been dominated by medical fee schedules, which leads to some inefficiency in healthcare.

A less regulatory feature is also applied to selecting physicians and hospitals by the insured. Unlimited choice by the insured disturbs effective division of roles among hospitals and clinics.

2.3 Outcome

Under the system explained above, health condition of Japanese People became dramatically better than before and top ranked high life expectancy has already been accomplished. Infant mortality rate is an outstanding example for one of our accomplishments. As [Figure 4] says, it was 76.7 per 100 thousands (18% in total death) in 1947 but in 2009 it improved up to 2.4 per 100 thousands (0.2% in total death).

[Figure 5] and [Figure 6] are other great examples for Japanese healthcare system. According to [Figure 5], mortality rate of diseases has drastically declined since the postwar, such as tuberculosis, high-blood pressure disease, asthma, gastric ulcer/duodenal ulcer, and cerebrovascular disease. Indicated on [Figure 6], life expectancy became over 80 years in late 1990s and Japan has been the country with the longevity

In spite of this kind of great outcomes, increasing healthcare cost became a big concern for Japan in recent years. Healthcare cost increased by rapid progress of medical technology and widespread use of healthcare services, though the Japanese healthcare system had worked until about 1990. The system kept secure since the number of working age populations was more compared with the other in population pyramid and rapid economic growth continued for long term.

3. Crisis in Healthcare System with Progress of Aging

The existing healthcare system is at risk of failure with populations aging, growth rate of healthcare exceeding economic growth rate, and budgetary restraint. Population age structure has rapidly changed toward a large older generation since 1990 (especially over 65 years old). In Japan, aging has been accelerated by the universal public insurance program, progress of healthcare technology and downward trend in the birthrate with modernization. Then, we faced healthcare crisis with very slowed economic growth and rapidly increasing cost. There are five components for the crisis: 1)more people in aging, 2)population decline, 3)increasing healthcare cost, 4)crisis in healthcare insurance, and 5)deficiency in healthcare system.

3.1 More People in Aging

First is increasing demand of healthcare for chronic diseases by aging. Aging makes structural transition in diseases from infectious to chronic. For example, as [Figure 8] shows, tuberculosis like infectious diseases decreased, though cancer, heart failure, pneumonia, and lifestyle-related diseases increased at a great rate. Not only structual change in diseases but longer living time is one of the features of aging. People live longer with complicated diseases thanks to advanced medicine. In fact, [Figure 9] indicates that the rate of over 65 years old suffering from lifestyle-related diseases is more 10% than that of 0-64 years old.

Both of structural change in diseases and the more elderly people with complicated diseases affected strongly increasing healthcare cost. The cost especially for the elderly with chronic and complicated deseases has become a major part of in total amount of healthcare cost. For example, the cost by age tends to grow drastically after 55 years old. Then, the averaged cost for over 75 years old was $7.9 thousand as three times as that for all generations, $2.6

thousand (1$=100 yen). Moreover, hospitalization expenses for the elderly over 75 years old was 7.4 times as many as that for 0-64 years old.[3] See [Figure 10] and [Figure 11].

3.2 Population Decline

Second factor for the crisis is malfunction in the healthcare delivery system with population decline and low birth rate. The present total fertility rate in Japan is 1.27 in 2005. Then, Japan must be a depopulating society because the rate is below 1.5, even slightly increased, on the assumption that no changes in present systems and social-economic environment. See [Figure 12], [Figure 13], [Figure 14] and [Figure 15].

In 2045, projected population in Japan will be less 100 million according to National Institute of Population and Social Security Research. It means that 100 workers support the 79.4 elders over 65 years old in 2055 based on calculation of "dependent population ratio".[4]

Malfunctions in the helthcare delivery system will be worse in rural areas through population decline. There are problems such as division of roles between clinic and hospital, among clinics and among hospitals. Then, indicated on [Figure 16], staffs are not sufficiently allocated in primary care, the number of doctors/nurses is smaller than that of the international standard, and all staffs in hospitals are scarece.

There are two related problems with malfunctions in the healthcare delivery system: falling of local healthcare and shortage of physicians. First of all, local healthcare became weak because of gap between demand and supply to healthcare services in thinly populated rural areas, advanced medical technology and hospitals aggregated for affording the technology. Second, physicians are shortly supplied in rural areas because burden for physicians working in hospitals has been increased in delivering high advanced medical technology. For example, with growing litigation risks, the problem of doctors' shortage in some specialties including obstetrics and pediatrics became familiar in general.

3.3 Increasing Medical Cost

Third is increasing medical cost accelerated by population aging. In 2009, national healthcare expenditure was $353 billion ($1=¥100),[5] though the expenditure in 2008 was $341 billion, increased by 3.5%. The expenditure per capita became $2760 in 2009 increased 3.6% compared with that in 2008. Then, the proportion rate in GDP must be higher. The rate of expenditure per nominal GDP was 7.32%.[6] In light of national income, the rate of expenditure per national income became 9.11% in 2007 (8.87% in 2006). In 2050, the rate of expenditure per nominal GDP will be 10.76% and the public expenditure rate will be over 50% on the condition of present systems by calculating estimated data in 2007 and 2008. See [Figure 17] and [Figure 18]. It is clearly evident that both of aging and low birth rate will cause deficit in premium paid for benefit under the public insurance system. More public expenditure will also be unavoidable though Japan has already depended on relatively more public expenditure than the other members.

3.4 Crisis in Healthcare Insurances

Fourth, not only National Health Insurance but Government Managed Health Insurance, Society Managed Insurance and Mutual Aid Insurance have faced heavy deficits for increasing the insured elders with tight budgetary restraint. Firstly, National Health Insurance covers

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[3] MHLW, Features of the Healthcare Cost for the Elderly, available at http://www.mhlw.go.jp/bunya/iryouhoken/database/zenpan/roujin_tokusei.html

[4] "Dependent Population" means populations consisting of over 65 years old and less 14 years old. In addition, "Dependent Population Rate" is (over 65 years old + less 14 years old)/15-64 years old.

[5] MHLW, Estimates of National Medical Care Expenditures (2009).

[6] Until 2007, data is based on Estimates of National Medical Care Expenditures (2007). About 2008 and 2009, data are estimated figures based on "Transition of National Medical Care Expenditures". For calculating Nominal GDP, data is based on "System of National Accounts" until 2008. Then, Nominal GDP in 2009 is computed by multiplying data in 2008 by data from the 2nd Preliminary Estimates (Percent changes in Nominal GDP) in 2009.

less earning, relatively older and more risky in diseases. It has been also operated for all of uncovered people under the employment based insurance system. In fact many people applied for National Health Insurance and benefit given to the insured also increased because the number of the elder in sick has been growing with aging, economic depression, and lower income after retirements or due to unemployed etc.[7] See [Figure 19]. The rate of insures with deficit balance in the fiscal year 2007 was 71.1% (1283 insurers). Compared with the rate in the fiscal year 2006, 18.9% was added (333 insurers) as with deficit balance.

In addition to National Health Insurance, the other insurances faced similar financial problems. For example, Government Managed Insurance had generally deficit balance by $2.290 billion in the fiscal year 2007 as well. 80% of insurers had deficits under the Society Managed Insurance and total current-account deficit was $5.235 billion.[8] The reason they are facing financial problems is adjusting among the insurances and supporting the elderly. All and all, it must be difficult to solve financial crisis because both of National Health Insurances and Society Managed Insurance have been pressured by tight budgetary restraint.

3.5. Deficiency in Healthcare System

Fifth, failure of health care in aging became apparent by huge gap between the system and rapid change of demand for healthcare. There are three kinds of deficiencies in Japanese healthcare system. First of all, present payment system of scheduled medical fee lacks sufficient incentive mechanism for efficient allocation of healthcare resources. We need medical fee schedules for more effective use and allocation of medical resources.

Second, we need a health insurance system which allows balancing between equal access to healthcare and financing by out of pocket payments. Not only ratio between public and private expenditures but introducing market mechanism to a part of the system will be our challenge.

Third, data use infrastructures for patients' choice and optimal allocation of resources have been under construction in planning, practicing and evaluating of healthcare. At present, effective primary care delivery/function of general practitioners has not been accomplished. More connected healthcare is needed between clinics and advanced hospitals, among clinics and among hospitals. Separated regulations for delivery and financing between healthcare and long term nursing care as well. IT has some potential for solving these issues as showed below.

In this way, prompt healthcare reforms are needed for the existing system at risk of failure. We have faced unavoidable dilemma that assuring quality of healthcare service would be difficult with tight budgetary restraint if we keep the universal public insurance program secure; more burden of future generations would be charged if we depend on more public expenditure. Then, disparity in access to healthcare service would widens among Japanese People if co-payment or out of pocket for high advanced medical technology service is allowed.

4. Primal Reforms needed for Making Healthcare Service Efficient

For healthcare system reforms, it is primal challenge to make healthcare services efficient at population aging. The strategies for efficient healthcare services are (1)introducing market mechanism by institutional changes and (2) efficient allocation of limited healthcare resources.

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[7] Compared with other employment based insurances like Society Managed Insurance, National Health Insurance gets preferential treatments. For example, maximum out of payment for the insured is $5900 ($1=¥100) under National Health Insurance and $7927.92 under Society Managed Insurance, especially in Hokkaido, the area of highest premium rate 9.42%. See Japan Health Insurance Association, Premium Schedules in 2010, available at http://www.kyoukaikenpo.or.jp/8,0,120,584.html

[8] National Federation of Health Insurance Society, Society Managed Insurance Accounting Outlook of the Fiscal Year 2009, Sep. 10, 2010, available at http://www.kenporen.com/press/pdf/20100910172618-0.pdf

4.1 Institutional Reforms

We, Japanese People will not get sustainable access to high quality of healthcare without healthcare innovation. For promoting the innovation, two institutional reforms are needed: medical fee scheduling and approval system. Not only more transparent regulations on clinical trial and approval but medical fee scheduling procedures properly evaluating innovative drugs and medical devices will be needed.

Japanese Government has already started several reforms for new growth by healthcare and delivery of the latest drugs and medical devices used in the world. For example, "5-Year Strategy for the Creation of Innovative Pharmaceuticals and Medical Devices" has been agreed among Ministry of Education, Culture, Sports, Science and Technology (MEXT), Ministry of Health, Labour and Welfare (MHLW) and Ministry of Economy, Trade and Industry (METI) on April 26, 2007.[9] The annually revised strategy targeted for supporting companies from the stage of R&D to marketing of drugs and medical devices through cooperated policies. It also focused on "Drug Lag" and "Device Lag/Gap" which mean existing time lag for access to new drugs and medical devices between Japan and U.S./EU.[10] Under the 5 Year Strategy, attractive prices will be set in next years for innovative medical devices and drugs, and more transparent approval process not only for shortening time lag for access to new drugs and medical devices between Japan and the other members.

In addition to the 5 year strategy, Cabinet has just scheduled "[11]New Growth Strategy" in 2010. According to the New Growth Strategy, centered sites for clinical trial and speeding approval process up are listed as improved until 2020. In this way, Japanese Government makes efforts to evaluate healthcare innovation through approval process and fee schedules with taking deficits in public insurances into consideration.

4.1.1 Medical Fee Schedules and Drug Pricing System

Giving incentive to companies and inviting more market competition will be needed for healthcare innovation in medical fee scheduling and drug pricing system. It is challenging that we should place a priority on the appropriate valuing innovative new drugs in possible pricing schemes that allow for the steady replacements of off-patent pharmaceuticals with generics. We need to introduce a process for evaluating innovation in medical devices based on efficacy etc., as well.

We will improve the pricing system with global perspectives. R&D by companies like international clinical trials is common and launching strategies are heavily affected by each member's pricing system. In other words, the pricing system in Japan is not isolated from but interacts with that of the other members. In the long run, it will be effective to support R&D in harmonized schemes to some extent.[12] Growing harmonization in Intellectual property is an example.

4.1.2 Approval System

In approval system, challenges for us are regulatory transparency and shortening review time. Showed on the Figures below, approval process in drugs[13] and medical devices[14]

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[9] MEXT, MHLW, and METI, 5-Year Strategy for the Creation of Innovative Pharmaceuticals and Medical Devices April 26, 2007, available at http://www.mhlw.go.jp/bunya/iryou/shinkou/dl/03.pdf

[10] MHLW, Supplements for the 1st Meeting on Prompt Delivery of Effective & Safety Drug, Oct. 30, 2008 at 2, available at http://www.mhlw.go.jp/shingi/2006/10/dl/s1030-8c.pdf (according to data in 2004, 1416.9 average days for access in Japan and 504.9-915.1 average days for access in EU/US from the first launching in all over the world).

[11] Cabinet Decision, The New Growth Strategy Blueprint for Revitalizing Japan, June 18, 2010, available at http://www.kantei.go.jp/foreign/kan/topics/sinseichou01_e.pdf See also Prime Minister of Japan and his Cabinet, Timetable for 21 National Strategic Projects under New Growth Strategy, available at http://www.npu.go.jp/policy/policy04/pdf/20100618_shinseityou_gaiyou_eigo.pdf

[12] See, e.g., OECD, Pharmaceutical Pricing Policies in a Global Market 179 (2008).

[13] Id. at 65.

required more time from application to launching compared with that of U.S., Canada, U.K., Switzerland, Sweden, Australia, Netherlands, France, Germany, Spain, and Italy. Though Japanese Government has already started several reforms, clarifying approval review and standard, effective consulting and preliminary review before applications by Pharmaceuticals and Medical Devices Agency, PMDA, and expansion and improvement of review staff will be gradually introduced according to "5 year Strategy" and "New Growth Strategy". In addition to regulatory transparency and shortening review time in approval process, it is very important how effective post market surveillance we should apply for patient safety.[15] Regulatory trade off between the premarket and post market stage in light of time, cost and stringency should be take highly into consideration. In next years, risk benefit approach like a balanced policy between speedy and safety in approval should be promoted by science in regulations, international harmonization and efficient review with sufficient resources. See [Figure 20], [Figure 21] and [Figure 22].

4.1.3 Healthcare Insurance System

The system we need is assuring Japanese People universal and equal access to healthcare as fair and reasonable as possible. To reform the insurance system toward healthcare innovation must be uneasy challenges. It will be clear after we realized dilemma such as between tight budgetary restraint and universal access to high quality of care, between allowing more out of payment and unequal access to healthcare among Japanese People, and between delivering high advanced healthcare technology and deficits in insurance funds. In the end, the problem is how we should introduce healthcare innovation, which can not always reduce cost with tight budgetary restraint.

A possible solution is allowing combination use of public and private insurance: public universal insurance for basic healthcare services and private insurance for additional uncovered services. By the combination use of public and private insurance, we can introduce market mechanism among private insurance policies for only additional uncovered services with equal access to basic services under the public insurances. Here, we wil also face other difficult issues such as what is covered basic healthcare services, how to deliver sufficient useful information for selecting physicians and hospitals, how to establish more transparent decision making process on service's coverage and medical fee schedules, how to allow pricing competition and practice in private insurances, and how to regulate unfair practices in a private insurance especially related with discriminations based on a pre-existing condition.

Most important here among the issues listed above must be a process to decide what are basic healthcare services or not. Without a transparent procedure, we can not get trust from Japanese People to the insurance system and any benefit from innovation through market competitions in additional uncovered services. There have been many examples that public insurance or pay roll tax systems cannot always provide people all and latest services including high advanced medical technologies. In other words, people having access to healthcare assured by a public insurance or pay roll tax system, services they get have some unavoidable limitations.[16] In EU members, Health Technology Assessment, HTA has been going on since 1990s for balancing approach between introducing healthcare innovation and considering tight budgetary restraint.[17]

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[14] See, e.g., U.S. International Trade Commission, Medical Devices and Equipment: Competitive Conditions Affecting U.S. Trade in Japan and Other Principal Foreign Markets (Christopher Johnson & Heather Sykes eds., March 2007), table 6-7 and 6-8.

[15] MHLW, New Medical Device & Technology Industry Vision, Sep. 19, 2008, at 36-37, available at http://www.mhlw.go.jp/houdou/2008/09/dl/h0919-2b.pdf

[16] See, e.g., Michael Tanner, The Grass Is not Always Greener: A Look at National Health Care Systems Around the World, Cato Institute Policy Analysis, Mar. 18, 2008, at 7-33 (international comparison).

[17] See, e.g., Dana Goldman, Darius Lakdawalla, Tomas J. Philipson, Wesley Yin, Valuing Health Technologies at Nice: Recommendations for Improved incorporation of Treatment Value in HTA, Health Econ. 19: 1109–1116 (2010). See also EUnet HTA, Joint Action 2010-12, Feb. 23, 2009 (for putting into

4.2. Effective Use System of Medical Resources

Optimal resource allocation can be accomplished by recent progress of Health IT. In the meanwhile, resources needed for healthcare has not been allocated efficiently. Patients' choice to hospitals and clinics is unlimited throughout Japan but resources are not efficiently allocated such as personnel and material contributions. For example, there is disparity of allocations in doctors, hospitals and clinics.[18] In addition to connecting healthcare, medical device allocation and use is sub-optimal as well. One of the main reasons in the inefficiency and the least used resource is medical information. To make meaningful use of medical information was not practical at all because of huge financial cost and much time for its introduction. However, recent IT progress has already become a promising solution. Now is the time to change healthcare systems with IT.

Recent progress of health IT solved cost and time issues in use of information to some extent. For example, MHLW has published "Ground Design to Information age in Healthcare, Health Service, Longterm-care, and Public Welfare" in 2007.[19] It was based on big change in Japan that many people easily accessed and used information everywhere with high advanced information technology and broadband infrastructure. The goal of the "Ground Design" was for building societies where Japanese People get access to high quality connecting healthcare services though IT.

Introducing IT to health is a strong trend in the world. One of the most attracting news was investments for use of EHR in U.S. U.S. Congress passed a new federal statute named by American Recovery and Reinvestment Act, ARRA of 2009.[20] According to one of the part of this statute, Health Technology for Economic and Clinical Health, HITECH Act, use of electronic health information throughout 50 states and introducing proper information security protections are goals and the act established regulations on selling personal health information and a compensation scheme after collecting charges in statutory violations.[21] In this way, meaningful use of health IT has just started throughout U.S. though it has some longer histories in several states like Massachusetts.[22]

In Japan, it is seriously discussed to introduce ID system. We lagged behind in application of IT throughout Japan as a reasonably alternative resource because of three reasons: 1) privacy concern has been big about establishing core infrastructure of patient ID. 2) trustworthiness of IT was insufficient and cost of initial investment is very high. 3) hospitals and clinics were inactive for IT introduction. It has been changing, however and we find trend toward meaningful use of IT based on ID infrastructure. For example, The "New Growth Strategy Blueprint for Revitalizing Japan", schedules on introducing ID in next a few

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practice an effective and sustainable HTA collaboration in Europe that brings added value at the European, national and regional level).

[18] National Security Council, Supplements for Final Report, Nov. 8, 2008, at 4-5, available at http://www.kantei.go.jp/jp/singi/syakaihosyoukokuminkaigi/saishu/siryou_3.pdf

[19] MHLW, Ground Design to Information Age in Healthcare, Health Service, Long term Care, and Public Welfare, Mar. 27, 2007.

[20] Health Information Technology for Economic and Clinical Health Act, HITECH in the American Recovery and Reinvestment Act, ARRA of 2009 (Pub. L. No. 115-5, 123 Stat. 115 (2009)).

[21] See, e.g., American Medical Association, H.R. 1, the American Recovery And Reinvestment Act of 2009 Explanation of Privacy Provisions (2009); C. Stephen Redhead, The Health Information Technology for Economic and Clinical Health (HITECH) Act, CRS Report R40161, Feb. 23, 2009.

[22] See, e.g., Allan H. Goroll, Steven R. Simon, Micky Tripathi, Carl Ascenzo, David W. Bates, Community-wide Implementation of Health Information Technology: The Massachusetts eHealth Collaborative Experience, J. Am. Med. Inform. Assoc. 2009;16:132–139; Ashish K. Jha, Catherine M. DesRoches, Peter D. Kralovec & Maulik S. Joshi, A Progress Report On Electronic Health Records In U.S. Hospitals, Health Affairs; 29:10, August 26, 2010; Ashish K. Jha, Catherine M. DesRoches, Eric G. Campbell, Karen Donelan, Sowmya R. Rao, Timothy G. Ferris, Alexandra Shields, Sara Rosenbaum, David Blumenthal, The Use of Electronic Health Records in U.S. Hospitals, N. Engl. J. Med. 2009;360:1628-38.

years.[23] The Cabinet Office of Japan also has published "A New Strategy in Information and Communications Technology" in May 2010.[24] Both New Growth Strategy" and "A New Strategy" show our hopes to possible ID systems.

Health IT seems a very useful tool for optimal allocation of medical resources[25]. Here, Health IT is suposed as a tool to 1) keep tabs on patients, hospitals/clinics, allied health professional, and healthcare resources, 2) record all medical practices, and 3) deliver effectively all needed information for optimal resource allocation for patients, doctors, and the others. In practice, there will be four kinds of use:

(1) Enhanced quality of care for patients by sharing personal health information in hospitals and clinics.

(2) Promoted research for building trust and effective medicine by disclosure of useful information as well as technology assessment based on all clinical data.

(3) Optimal resource allocation of personnel and material contributions throughout Japan.

(4) Efficient Management in each hospital and clinic through real time information on placements and operating rates.

The total effect of IT healthcare is unclear but cost introducing IT in healthcare must bring us the biggest benefit if it is optimally used for listed above. We should be cautious higher quality of healthcare sometimes causes increasing healthcare demand though the IT accomplishes enhanced quality and effective allocation of healthcare resources.

5. Conclusion

Summary about a direction for needed reforms in Japanese healthcare system is as follows:

1)We should keep universal healthcare insurance secure.

2)Debate is needed to allow individual financial burden for only high advanced medical technology services in spite of gap between accessibility to healthcare among Japanese People.

3)Reforms are needed to eliminate hurdles for effective healthcare system: incentive should be given for private actors by regulatory reforms and more transparency in regulations etc.

4)We should make use of informative resources like clinical data for efficient allocation of limited healthcare resources with sufficient privacy protections by investing IT.

Aging society will be destiny for most Asian members in APEC after Japan, the first runner in aging. Speed in increasing cost is rapid with aging and progress of health technology. In Japan, the universal public insurance system contributes for life span extension. We are very happy If Japan could be a lesson for the other APEC members. We should engage in collaborated research for uncertain solutions.

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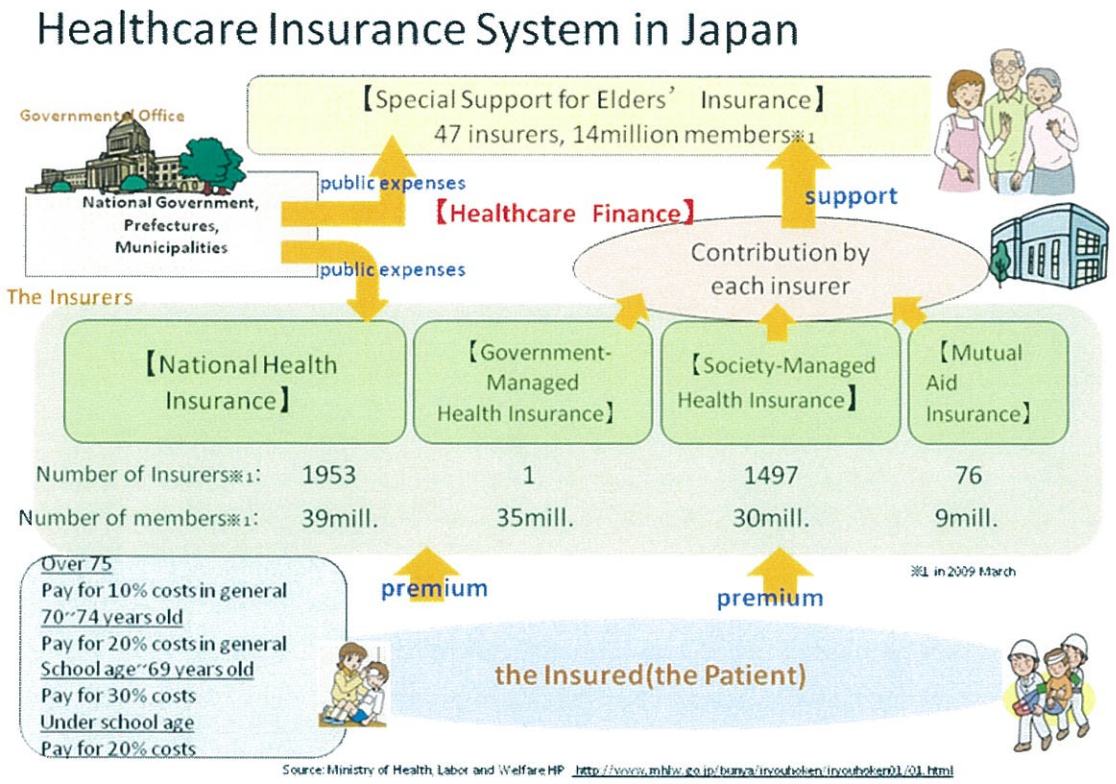
[23] Cabinet Decision, supra note 11, at 39 and 62.

[24] IT Strategic Main Division at Cabinet Office of Japan, A New Strategy in Information and Communications Technology" in May 11, 2010.

[25] See, e.g., Panel Discussion on Mar. 5, 2010 at Policy Alternatives Research Institute, PARI at University of Tokyo.

【Appendix】Chart

[Fig1]



[Fig2]

National Health Insurance & Health Insurance Benefits

(From October 2009onwards)

Payment		National healthcare insurance (local authority)		Healthcare insurance
Healthcare payments	Healthcare Benefits Visiting nursing healthcare	Until the entry into primary school ; 80% After junior high school to 74years: 70% 70~74years: 80% (70% for those with an income comparable to working persons*)		※From 2008 Apr to 2011 Mar, self-pay for 70~74years remains 10%.
	Meals during hospitalization expenses	Standard amount borne for meals: ¥260 per meal Low income persons after the 90th day of hospitalization: ¥160 per meal		Low-income persons: ¥210 Persons of particularly low income (70 years old and over): ¥100 per meal
	Living care during hospitalization	Living care standard fee: ¥460 per meal (meal cost) + ¥320 (residential cost) Particularly low-income persons: ¥130 per meal (meal cost) + ¥320 (residential cost)		Low-income persons: ¥210 per meal (meal cost) + ¥320 (residential cost) Persons receiving senior citizens welfare benefits: ¥100 per meal (meal cost) + ¥0 (residential cost) * The amount borne by patients with serious diseases will be the living care standard fee
	High-cost medical care expenses (with individual limit)	Young people (High income) ¥150,000 + (medical expenses) × 1% (¥83,400) (General) ¥80,100 + (medical expenses) × 1% (¥44,400) (Low income) ¥35,400 (¥24,600) (figures in parenthesis are for the fourth month onwards)		Senior Citizens Hospitalization / Outpatients (per person) (Working income level) ¥80,100 + (medical expenses) × 1% / ¥44,400 (General) ¥44,400 / ¥12,000 (Low income) ¥24,600 / ¥8,000 (Particularly low income) ¥15,000 / ¥8,000
Cash payments	Lump-sum allowance for childbirth	Contents of benefits are decided by separate regulations. (Most insurers pay ¥420,000)	Lump-sum allowance for childbirth Lump-sum allowance for childbirth and nursing	¥420,000 paid in the instance of the insured person or their dependent giving birth
	Lump-sum funeral allowance, burial costs	Contents of benefits are decided by separate regulations. (Most local authorities pay at a rate between ¥10,000-50,000) Practiced by most local authorities	Burial costs	Fixed amount of ¥50,000 paid in the instance of the insured person or their dependent dying
			Family burial costs	Fixed amount of ¥50,000 paid in the instance of the insured person or their dependent dying
	Invalidity benefit	Voluntary benefit (Not practiced by any local authorities)	In the case that the insured person becomes unable to work because of medical treatment being received for a cause not related to work, an amount approximate to two thirds of that persons standards daily wage will be paid daily for a maximum period of 6 months.	
	Maternity allowance		During the maternity leave taken by the insured person, an amount approximate to two thirds of that persons standards daily wage will be paid daily for a maximum period of from 42 days prior to the birth to 56 days after the birth.	

*Persons with an income comparable to that of a working person are those persons with a taxable income of around the same level as that of the average taxable income for a person currently working (approx. 14.5 million yen)

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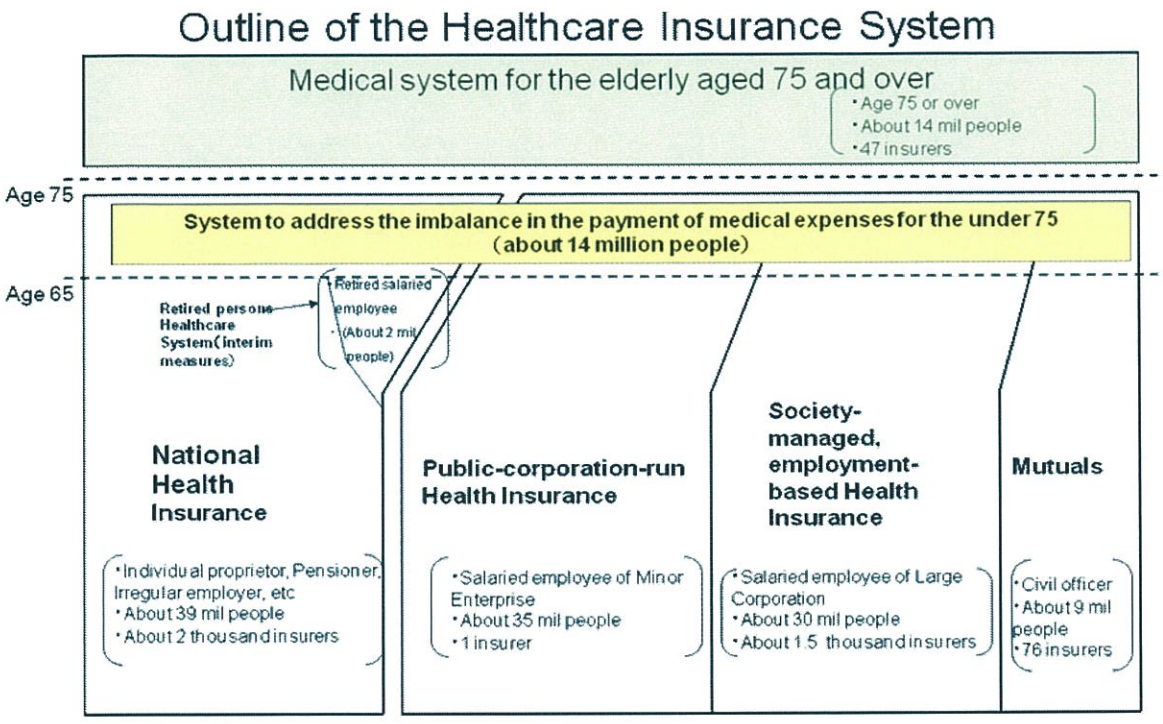
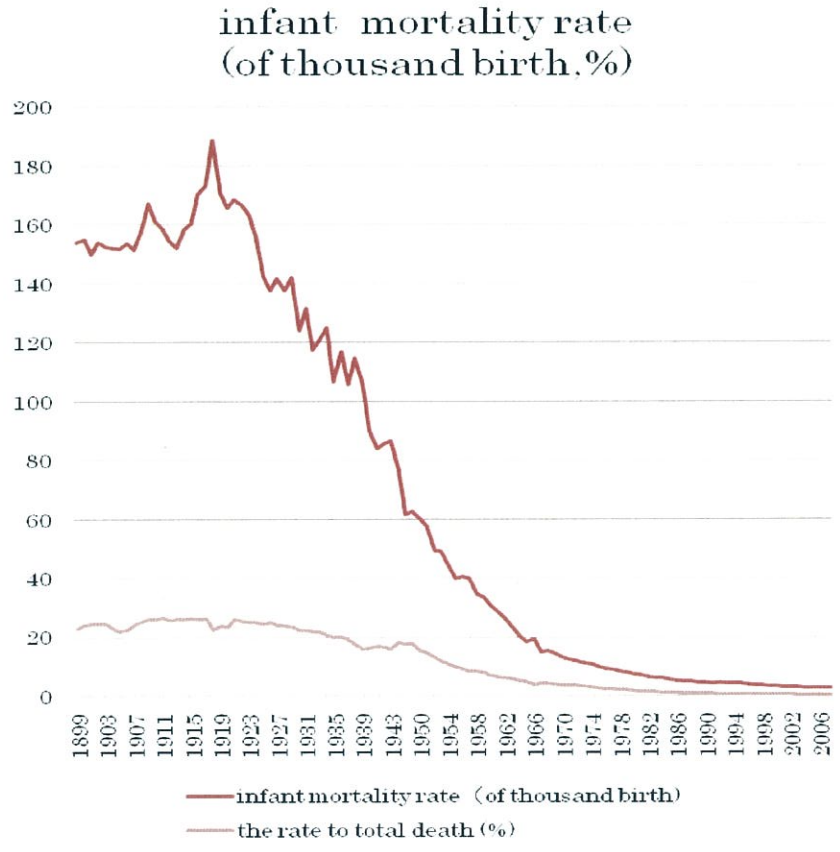
Source: Health Insurance Bureau-Ministry of Health, Labour and Welfare, "Japanese Health Insurance System"

[Fig3]



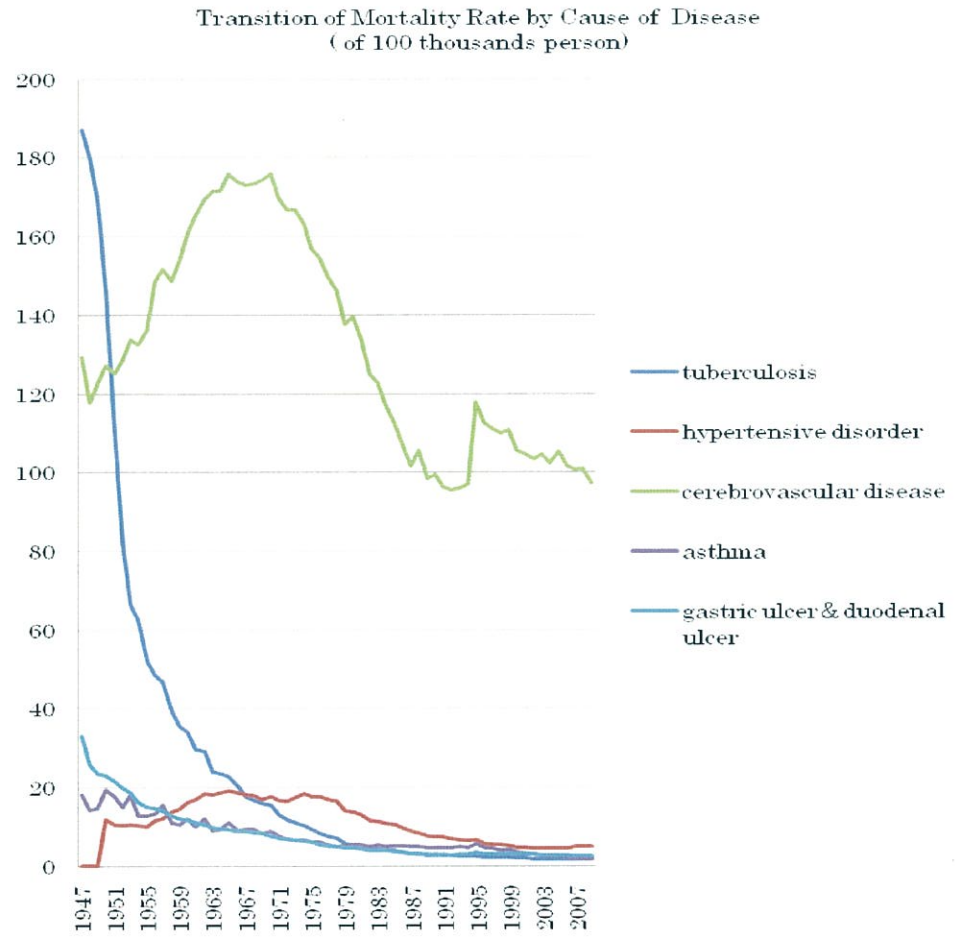
※ Numbers of enrolled members are the quick estimation as of the end of March 2009
Source: Health Insurance Bureau-Ministry of Health, Labour and Welfare,
"Japanese Health Insurance System" ,Revised Version

[Fig4]



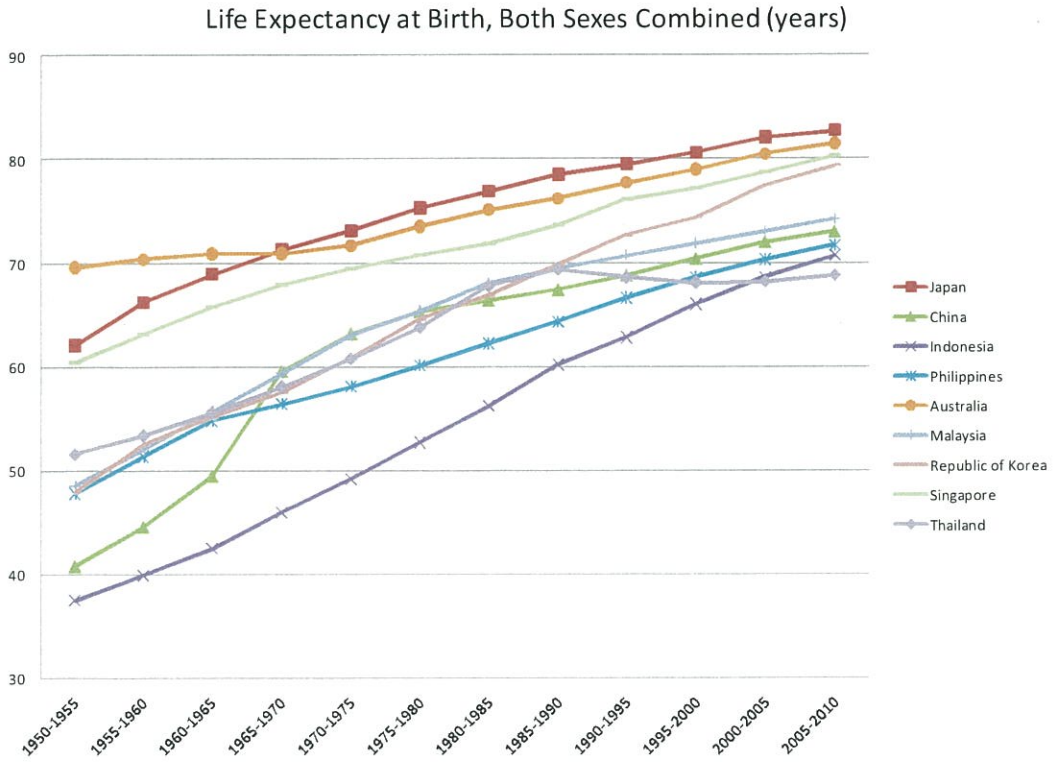
Source: Vital Statistics (2009)

[Fig5]



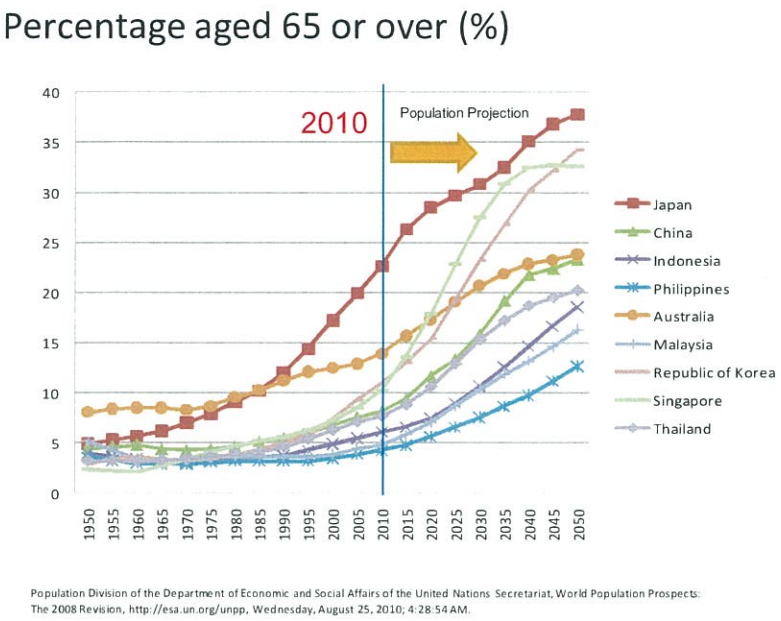
Source: Vital statistics (2009)

[Fig6]



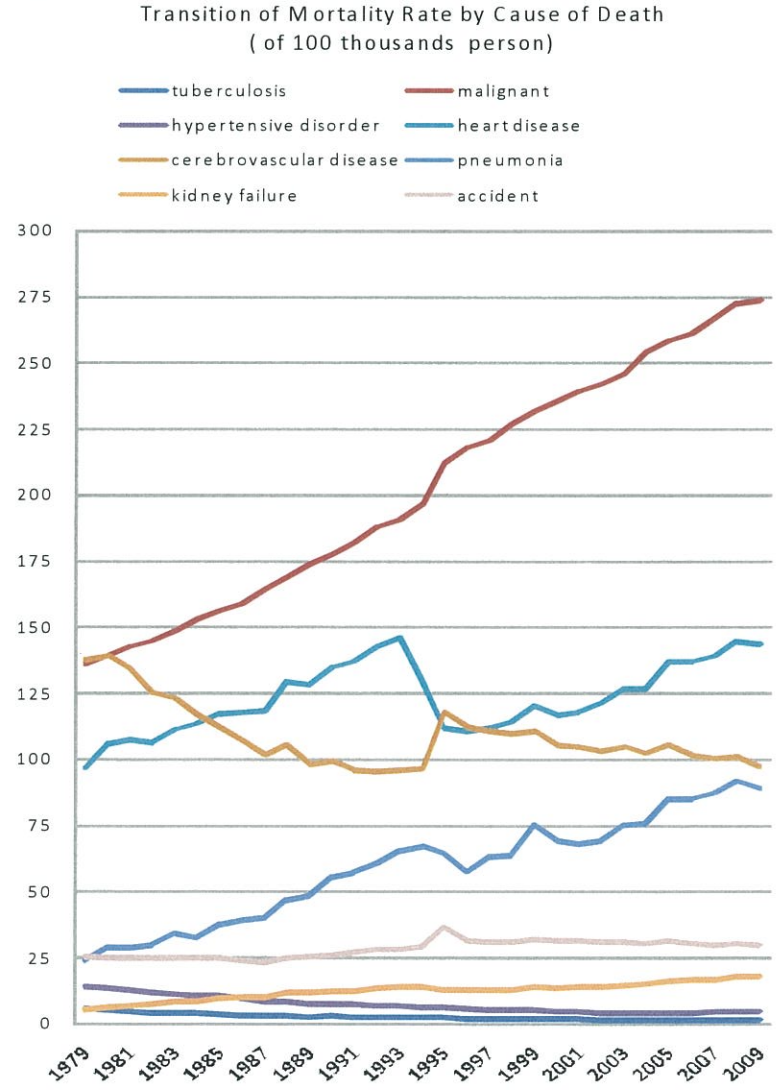
Source: World Population Prospects: The 2008 Revision

[Fig7]



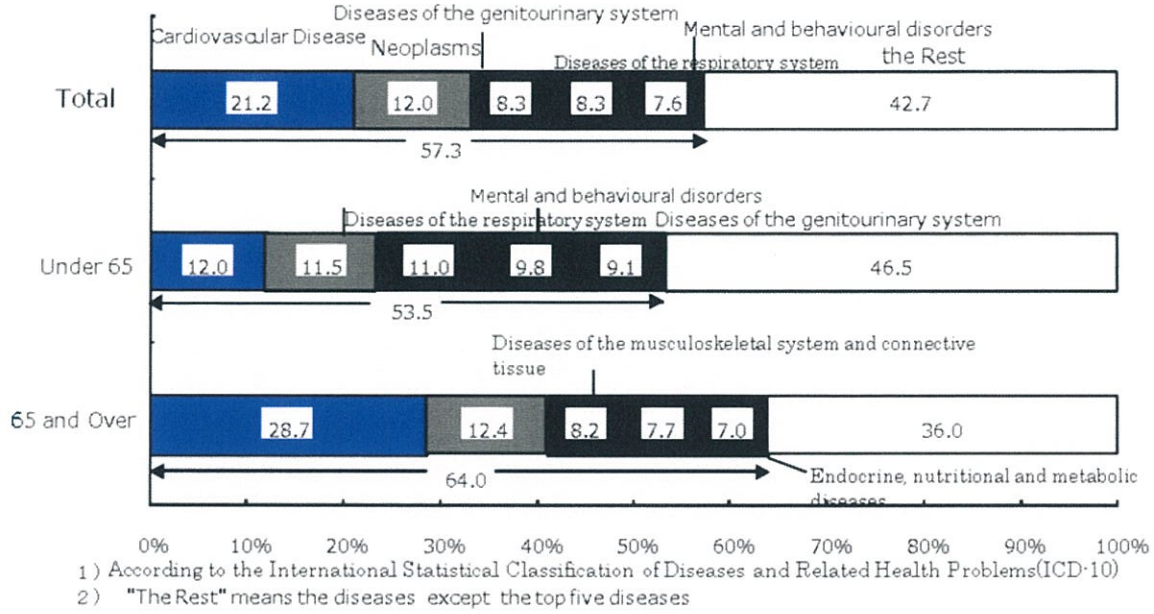
Source: World Population Prospects: The 2008 Revision

[Fig8]



Source: Vital Statistics (2009)

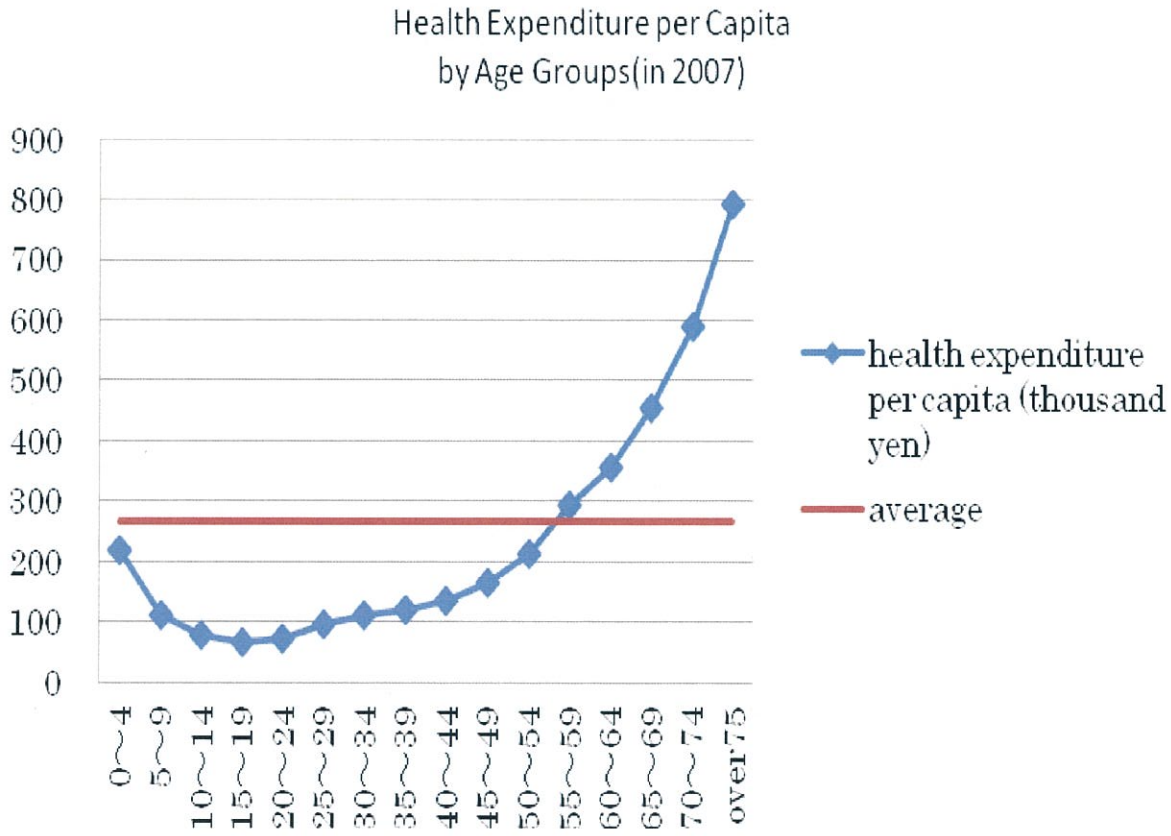
[Fig9]



1) According to the International Statistical Classification of Diseases and Related Health Problems(ICD-10)
2) "The Rest" means the diseases except the top five diseases

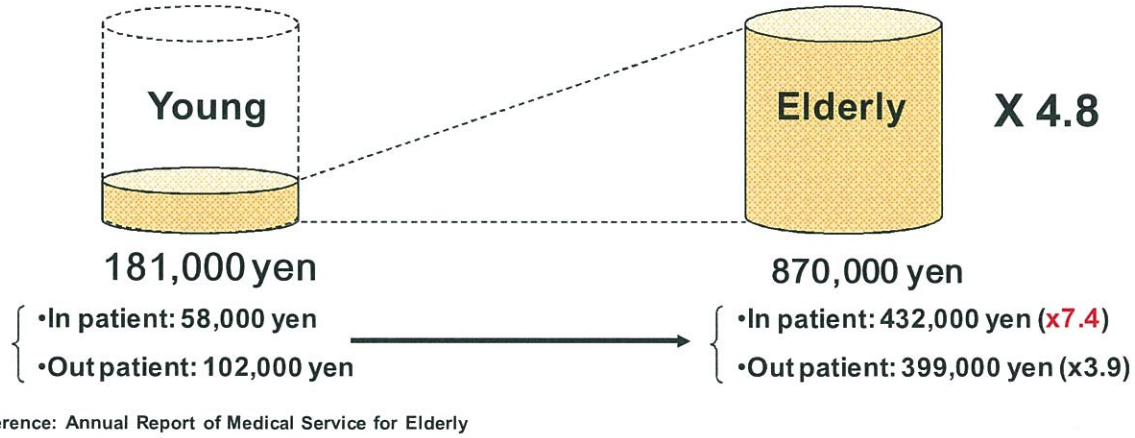
Source: Estimates of National Medical Care Expenditure(2007)

[Fig10]



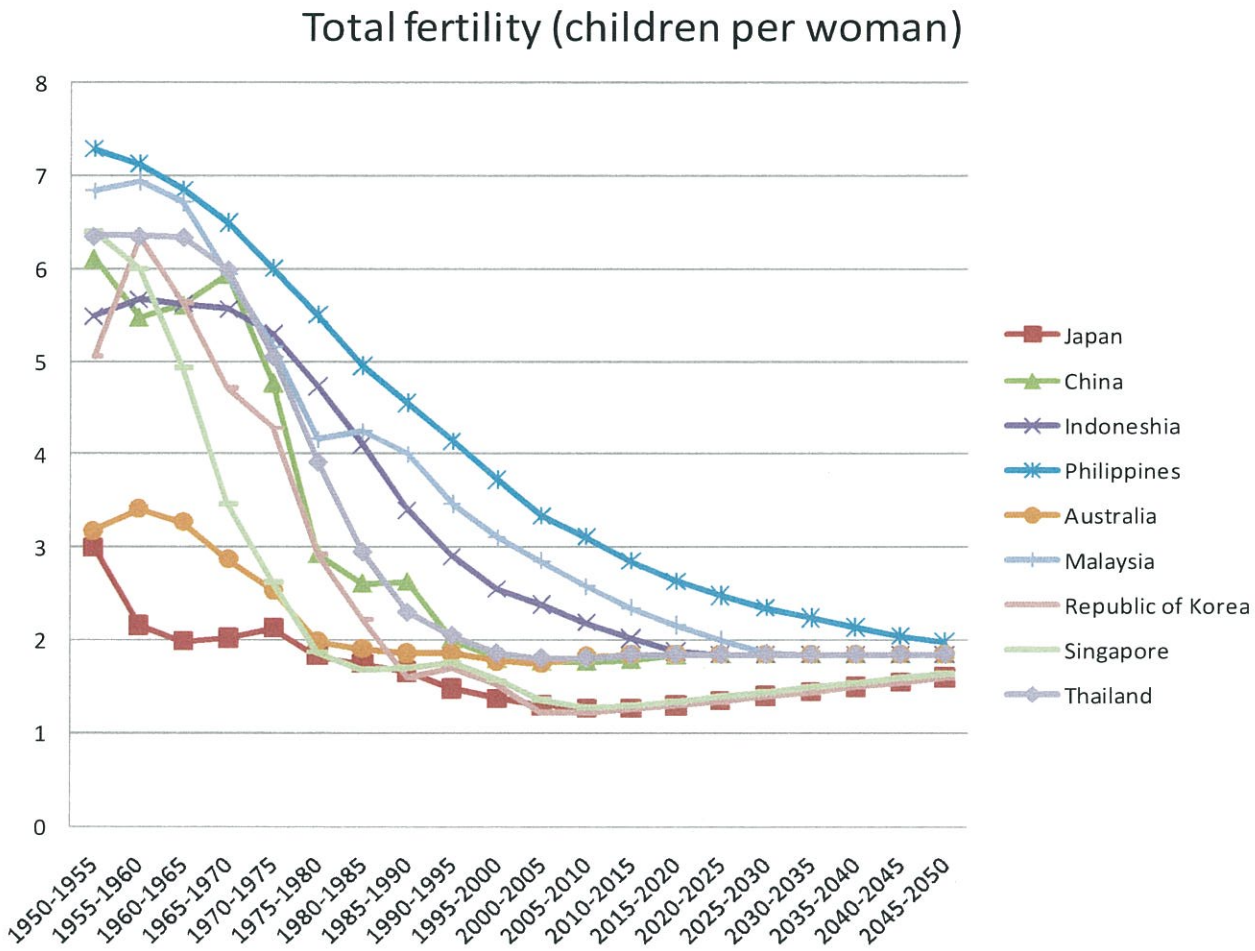
Source: Estimates of National Medical Care Expenditure(2007)

[Fig11]Comparison of Health Expenditures per capita (2007)



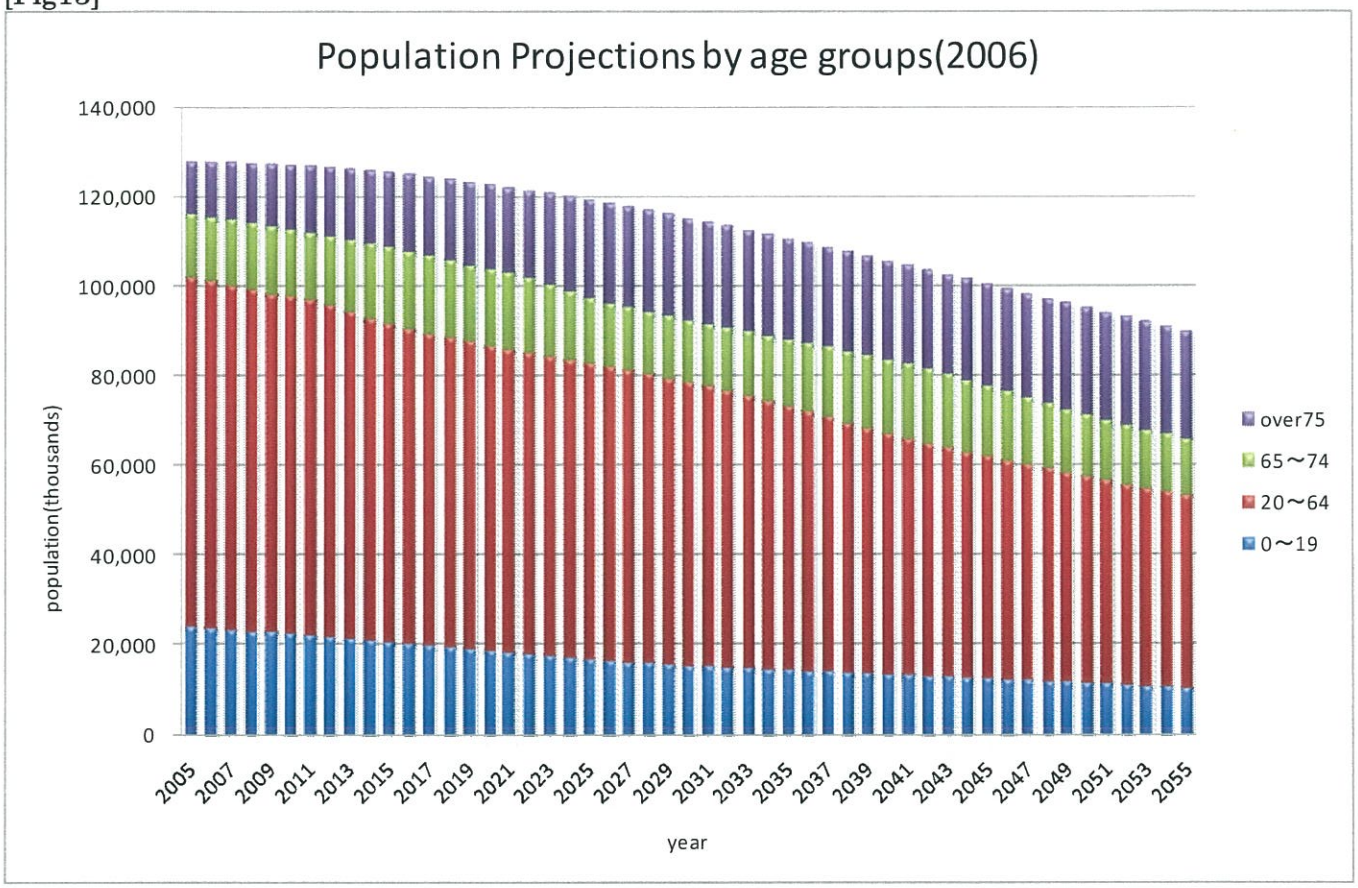
Source: Health Insurance Bureau-Ministry of Health, Labor and Welfare, "Japanese Health Insurance System"

[Fig12]



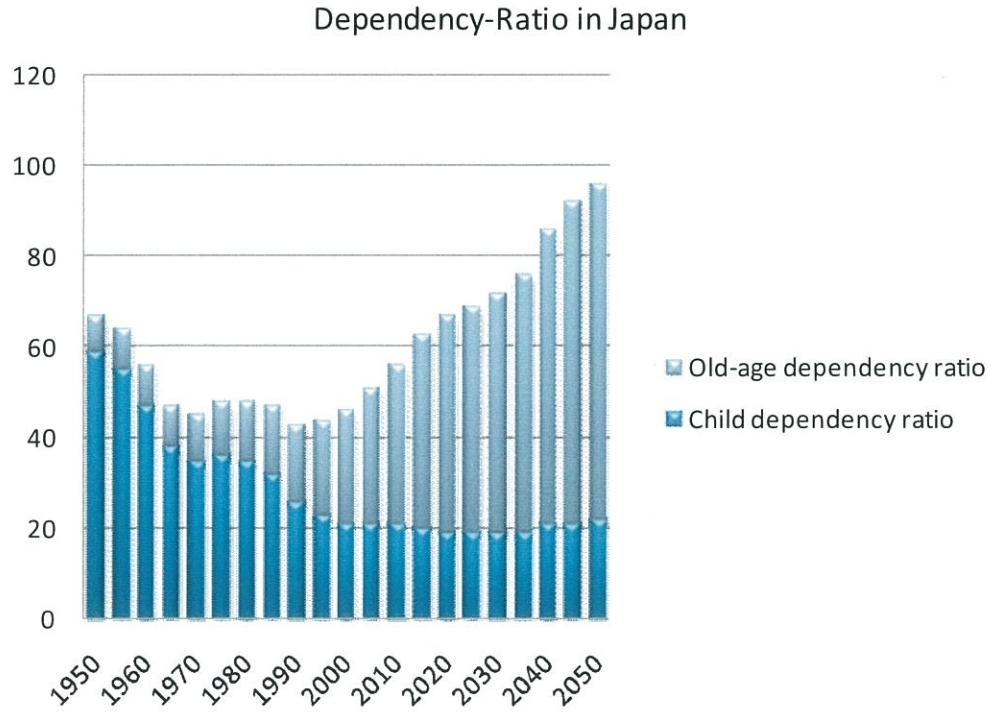
Source: World Population Prospects: The 2008 Revision

[Fig13]



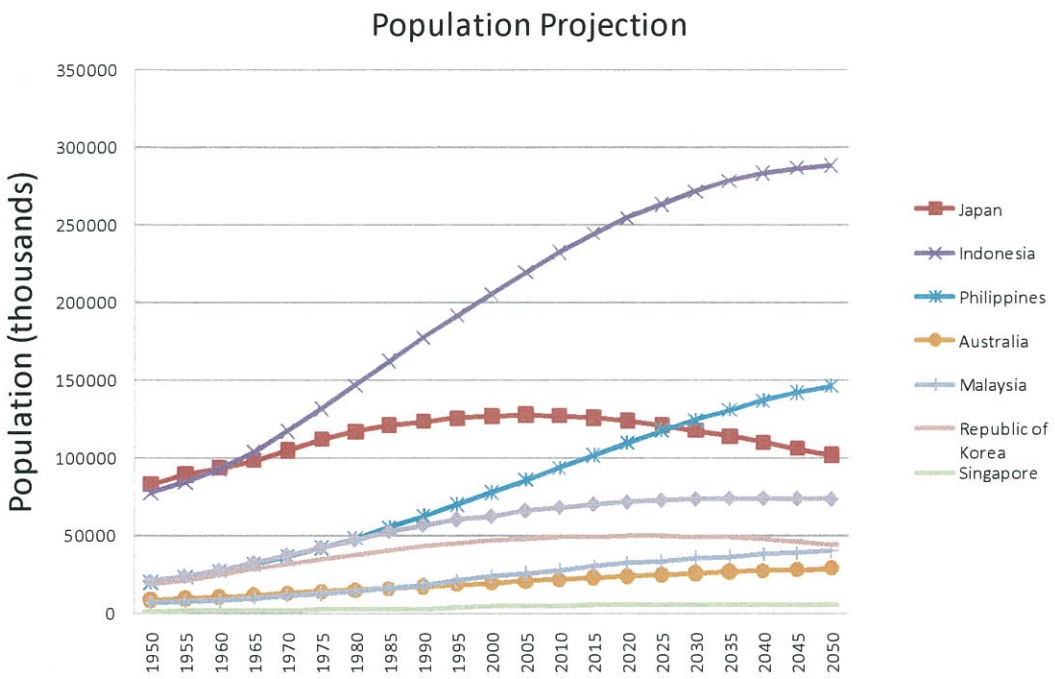
Source: National Institute of Population and Social Security Research Population Projection for Japan: 2006-2050

[Fig14]



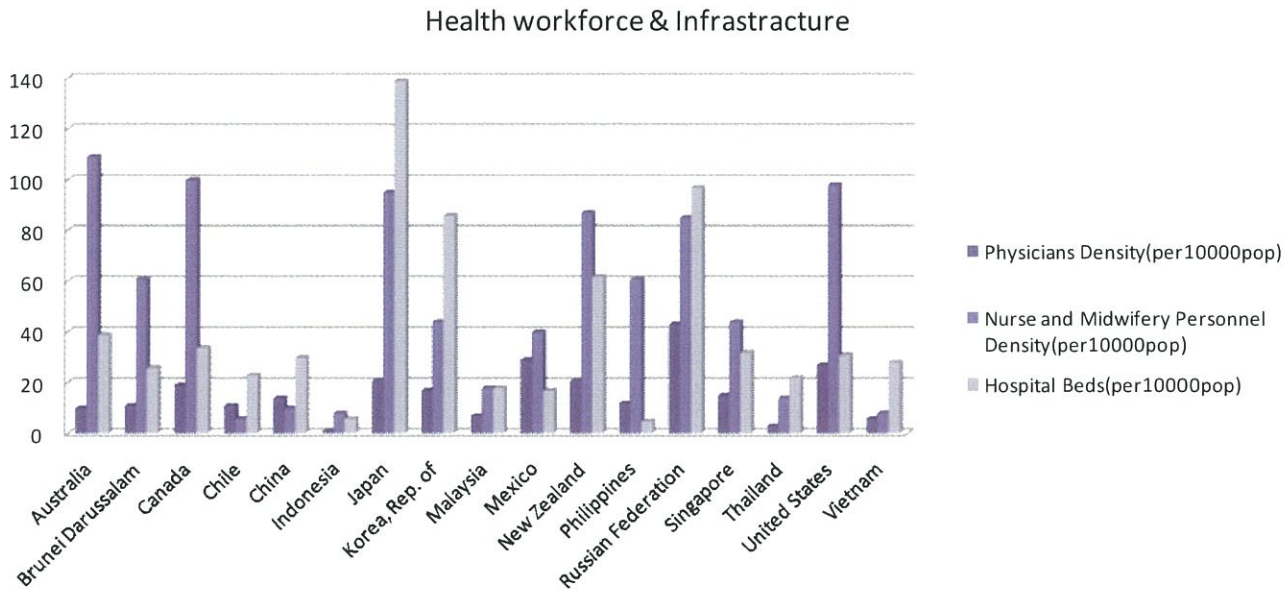
Source: World Population Prospects: The 2008 Revision

[Fig15]



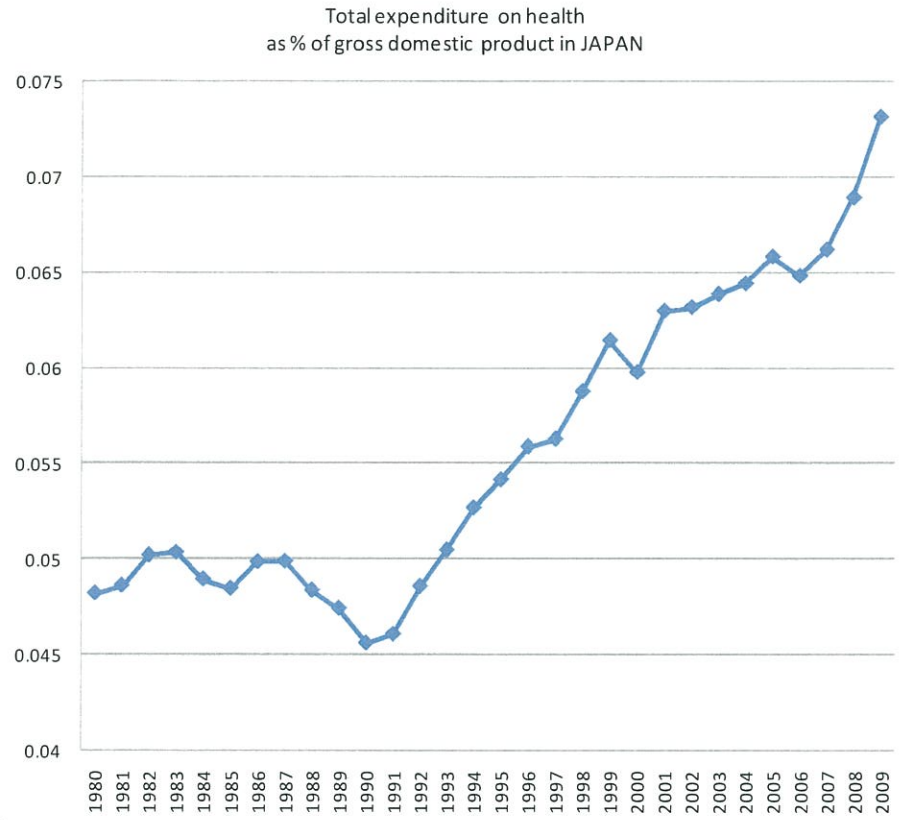
Source: World Population Prospects: The 2008 Revision

[Fig16]



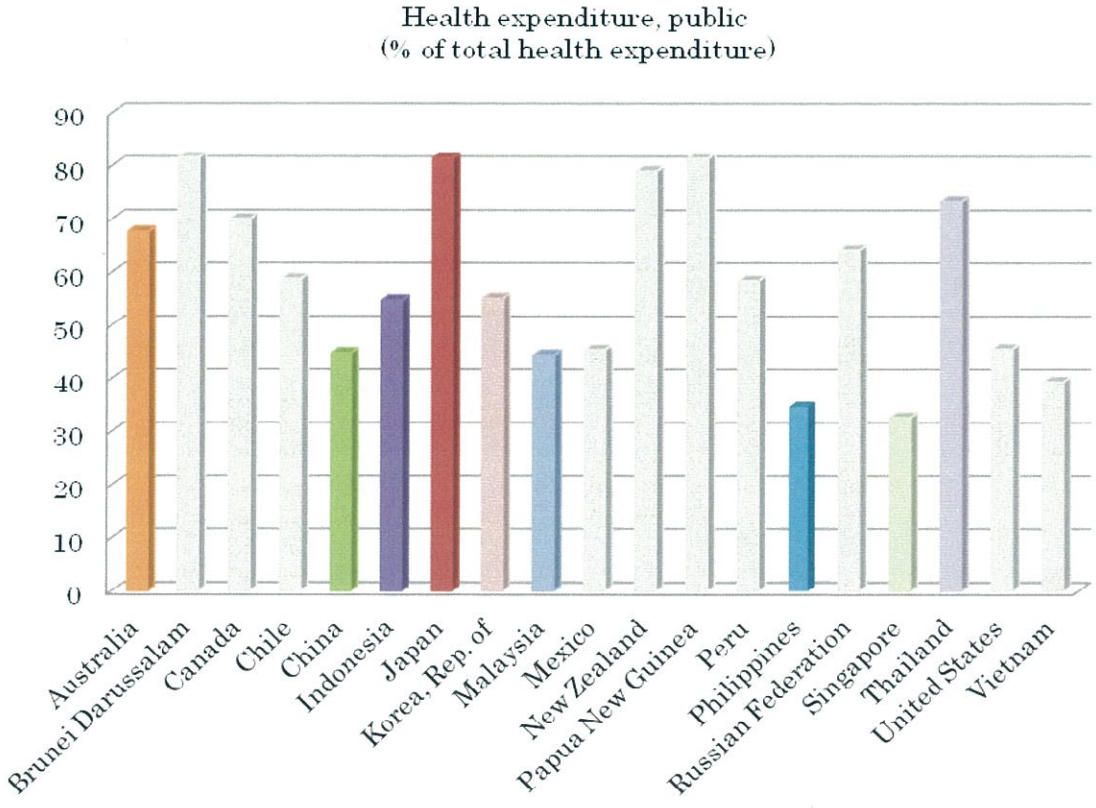
Source: World Health Organization National Health Account database

[Fig17]



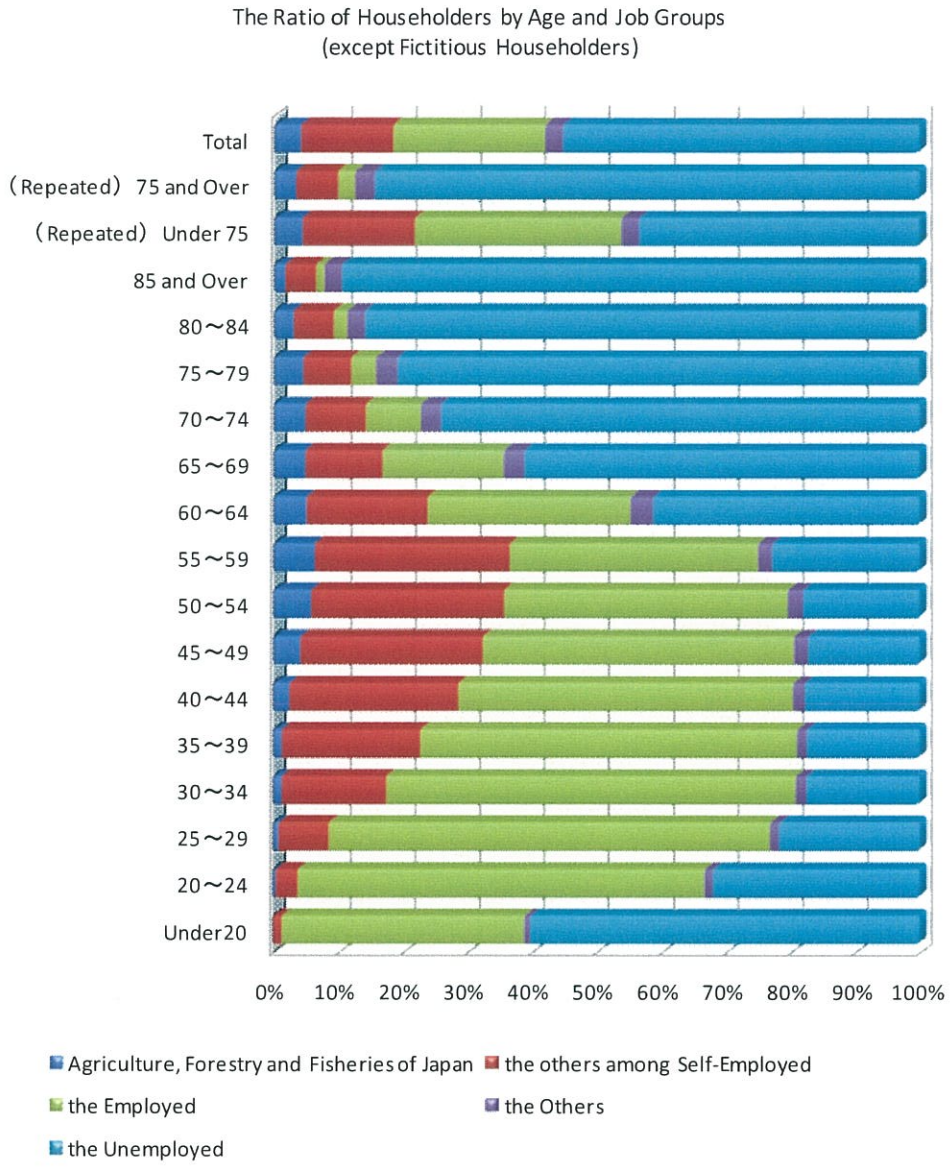
Source: Estimates of National Medical Care Expenditures (2009) and System of National Accounts (2008) and the 2nd Quarterly Preliminary Estimates of GDP (Percent changes in Nominal GDP,2010)

[Fig18]



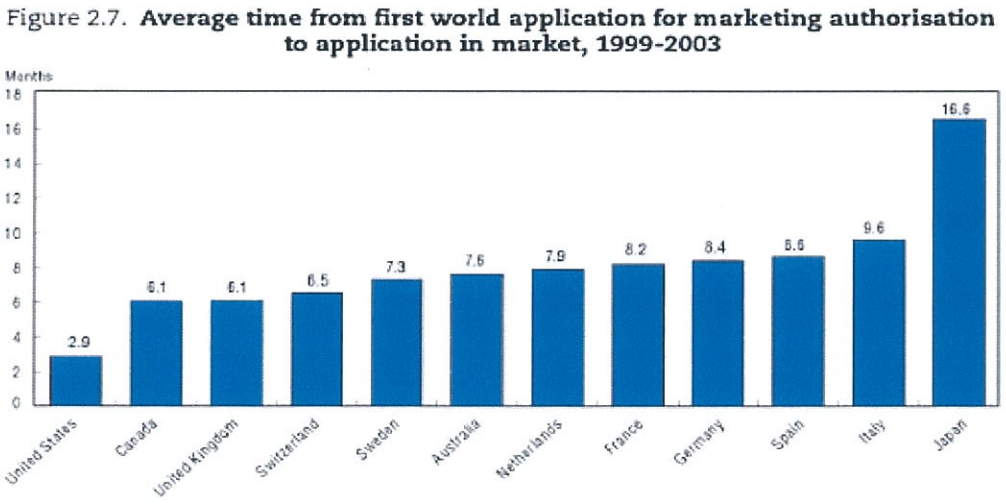
Source: World Health Organization National Health Account database 2010

[Fig19]



Source: Survey on the Insured of National Health Insurance (2007)

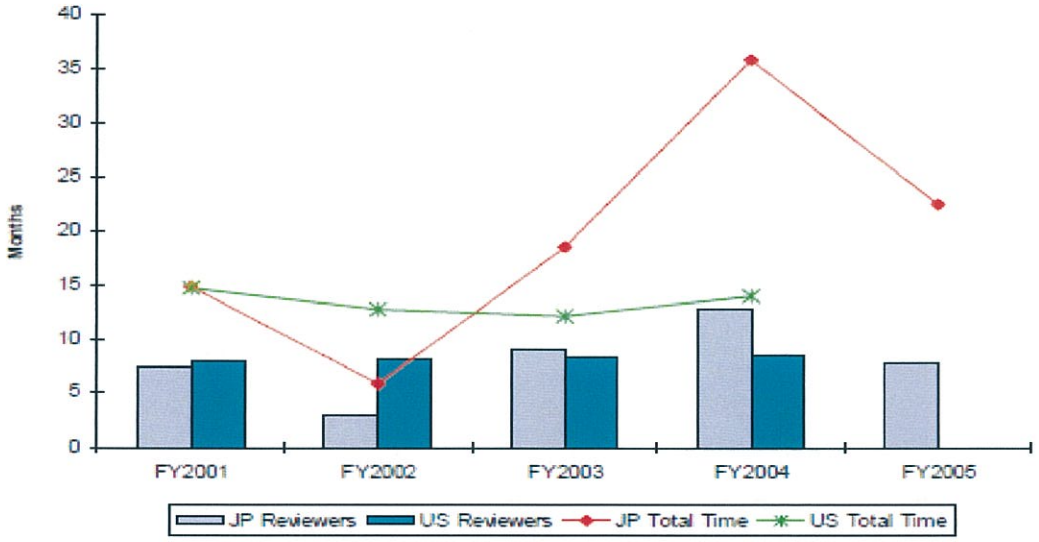
[Fig20]



Source: OECD, Pharmaceutical Pricing Policies in a Global Market 65 (2008)

[Fig21]

Figure 6-7 Comparison of reviewer times and total review times for new medical device applications between Japan (median) and U.S. (mean), 2001–5



Source: U.S. International Trade Commission, Medical Devices and Equipment: Competitive Conditions Affecting U.S. Trade in Japan and Other Principal Foreign Markets (Christopher Johnson & Heather Sykes eds., March 2007), table 6-7.

[Fig22]

Table 6-8 PMDA new medical device approvals and median PMDA review * processing time, 2002–5

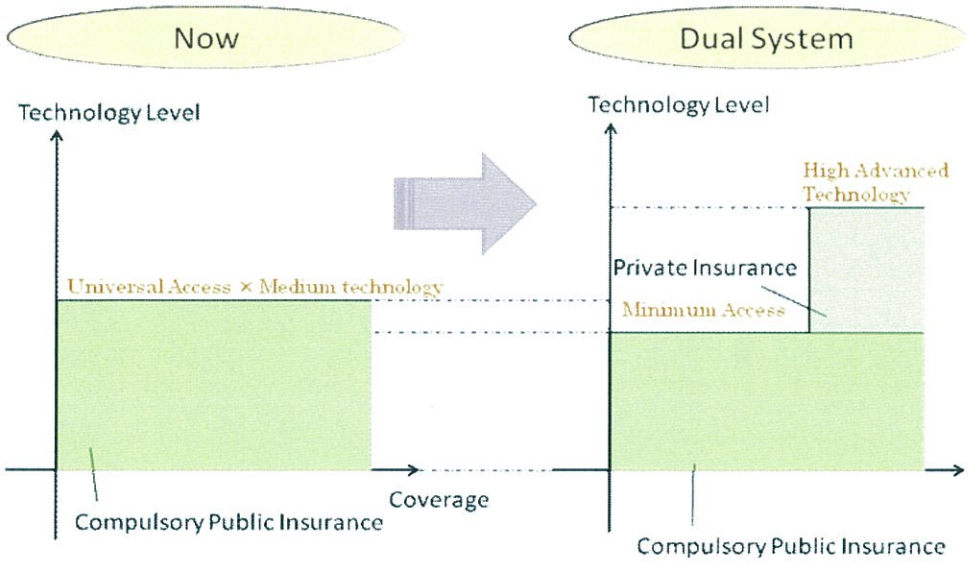
Fiscal Year	2002	2003	2004	2005	Filed in and after FY 2004, but approved in FY 2005 *
Median PMDA review time*	88 days	284.5 days	386 days	232 days	55 days
Total review process time	176 days	564.5 days	1,083 days	678 days	308 days

Source: Japan Pharmaceuticals and Medical Devices Agency (PMDA), Annual Report FY2005

Source: U.S. International Trade Commission, Medical Devices and Equipment: Competitive Conditions Affecting U.S. Trade in Japan and Other Principal Foreign Markets (Christopher Johnson & Heather Sykes eds., March 2007), table 6-8.

[Fig23]

Reforms in Healthcare Insurance



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