The social insurance systems in foreign countries and pricing of medical devices

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Abstract: In this aging Japanese society, the demand for ensuring a healthy life and improving the quality of life is on the rise. The government declared “Health Japan 21” and dental health has been identified as one of the most important issues. At the same time, national medical care expenditure is increasing year by year. As such, efficiency in dentistry is required, and the quality, efficacy, and safety of medical devices have been standardized. As one of the steps toward introducing new medical devices and technology, this report contains a collection of data, research, and studies on the social insurance system and pricing of medical devices in foreign countries.

Keywords; dentistry, medical devices, pricing, social insurance system, western countries

Introduction
As regards the system providing dental services, there are many historical backgrounds and differences, which include the process of establishment in each country. However, the remarkable rise in medical expenditure is common to many countries and this rise exceeds the economic growth in each country. The ultimate goal is to improve medical efficiency while securing medical quality in each country, and various methods are constantly being tried to achieve it. Anderson classified dental care systems in different countries into three types: 1) Government management type (using tax), the United Kingdom (UK), Sweden; 2) Social insurance type, Germany, 3) Private enterprise insurance type, The United States of America (USA) [1].

Dental expense insurance system in UK
In UK, nations were able to get the medical services of the National Health Service (NHS) for free in general, and also had dental services free of charge in the past. After 1952, patients had to foot their own bills for dental treatment, and after 1999, patients had to cover 80% of their expenses for a while. Under the Blair Administration, after 2001, the NHS was reformed to expand medical expenditure to 1.5 times the previous value, but dental expenditure was rather reduced. In 2006, the greatest reform of the NHS was carried out. Before, a score was set on each dental treatment, and according to the score dental costs were calculated, but the system on a piecework basis was abolished. After the reform, dental treatment was classified into three categories, and patients have to pay a fixed amount of money accordingly. Payment for dental clinics was shifted to the total sum contract system (Table 1). Also, England was divided into 10 areas, independent institutions called Primary Care Trusts (PCTs) were installed, and PCTs started to carry the NHS. The budget of the PCT was determined by the total population of the area. Medical, dental, and drug costs were covered.

Dental expense insurance system in Sweden
As for the dental expenditure in Sweden, how expenses are assisted varies with the age of the patients. For people 24 years or older, the benefit in kind is provided by the dental insurance system. For people under the age of 24, free public dental treatment is provided by each local government (Landsting). The upper limit of coverage of one’s own medical and dental expenditure is 900 SEK (1 SEK = 0.10 USD on April 02, 2020) per year. Dental clinics are classified into private ones and public ones which are run by each local government. Ninety percent of dentists working in private clinics are in collaboration with insurance, and they provide dental care for people 20 years or older, whose dental costs are covered by the insurance. Medical expenses can be decided by the dentist, and patients have to cover any cost over their insurance.

Dental expense insurance system in Germany
In 2000, the German statutory insurance scheme (GKV) was enforced, and in 2003, and GMG (GKV modernization legislation) was carried out. In this system, a combination of various medical expense insurance is financed, and the costs are covered at a premium. While its not health insurance enrolling all people, almost all nations are joining some kind of medical insurance. About 87% were enrolled in public medical insurance in 2016 (https://www.mhlw.go.jp/wp/hakusuyo/kaigai/18/dt3-04.pdf). All the employees whose income lies below a threshold amount are obliged to go for public insurance, and those who earn above the threshold amount can choose either a public or a private one. Patients must pay for medical expenses that are not covered by the insurance, and combining insured and uninsured care is allowed. People under the age of 18 do not have patient’s copayment.

Dental expense insurance system in the United States of America (USA)
As for public medical insurance in USA, discussions about universal health insurance coverage have been repeatedly controversial. In 2010, the Patient Protection and Affordable Care Act, which was at the center of the Obama Care was enforced, and joining in insurance was required of all nations from 2014. A penalty was imposed on nonmembers, but it was abolished because of tax reforms as of 2017. Originally, realizing universal health insurance coverage was difficult. Medicaid, which is for the low-income earners is run by each state government. Medicare, which is for the elderly and people with disabilities is run by the federal government. In both these systems, around 25% of the nation is covered. The remaining 75% will take out private insurance policies, but their taking it out is voluntary. It costs much, as such 13% of the nations do not have any insurance.

American dental insurance is divided into five types (Indemnity insurance, Preferred Provider Organization [PPO], Health Maintenance Organization [HMO], Point of Service [POS], and High Deductible Health Plan [HDHP]). In indemnity insurance, the same benefits can be available at any dental clinic, but an insurance premium is expensive, and patients have to pay all the medical treatment fees first, and then they will be reimbursed by the insurance company. The PPO has a similar function as indemnity insurance, and it reduces the burden of the members. The PPO is a network that links an insurance company to medical institutions. In the PPO network, patients can get a discount on medical expenses. When a PPO member sees the network-linked doctors, the patient does not have to pay their medical treatment fee. In an HMO plan, the members choose one primary care physician from the list that is provided by the insurance company, and the physician indicates suitable medical service. Without a referral by the physician, patients cannot be seen in another medical institution. The POS is a midway plan between PPO and HMO. In this plan, members choose one primary care physician as with the HMO and can see another medical institution without a referral by the primary care physi-
A comparison of basic medical insurance plans

| Plan Type         | Indemnity | PPO       | POS       | HMO       |
|-------------------|-----------|-----------|-----------|-----------|
| Primary Care Physician (PCP) | Not required | Not required | Required | Required |
| Health care providers where insurance benefit is paid | Not limited | Not limited, and medical cost is discounted in the network | The providers that PCP referred, and other providers | Only the providers that PCP referred |
| Premium           | High      | Medium-high | Medium-low | Low       |
| Convenience       | High      | Medium-high | Medium-low | Low       |

Table 3 Official price systems of medical devices in several countries

| Country         | Official price system | How to determine official prices |
|-----------------|-----------------------|---------------------------------|
| USA             | No official price system | -                                |
| UK              | No official price system | -                                |
| Germany         | No official price system | -                                |
| France          | LPP system            | CNEDSMTS is a cell of HAS. It evaluates each medical device technically. Based on the results, CEPS (comité économique des produits de santé) negotiates official prices with applicants and determines official prices with referring prices in other countries. The Prostheses List Advisory Committee’s (PLAC) belongs to the Department of Health and Aged Care. PLAC deliberates on official prices, and the minister determines official prices. Clinical experts evaluate and classify medical materials into groups (functional classification). For medical materials in the same group, the official price of the group is applied. If innovation is accepted, a premium official price is applied. |
| Australia       | Prostheses list system | The Prostheses List Advisory Committee’s (PLAC) belongs to the Department of Health and Aged Care. PLAC deliberates on official prices, and the minister determines official prices. Clinical experts evaluate and classify medical materials into groups (functional classification). For medical materials in the same group, the official price of the group is applied. If innovation is accepted, a premium official price is applied. |

Table 1 The sum contract system for dentistry in England

| Band | Cost (USD) | Description |
|------|------------|-------------|
| 1    | 22.70 (28.12 USD) | An examination, diagnosis, and advice. It also includes X-rays, a scale, polish, and planning for further treatment |
| 2    | 62.10 (76.93 USD) | Treatment such as fillings, extractions, root canal treatment |
| 3    | 269.30 (333.63 USD) | Treatment such as crowns, dentures and bridges |

Pricing of medical devices in foreign countries

According to documents of the Ministry of Health, Labor and Welfare, the national medical care expenditure in 2016 was 42 trillion yen, and its proportion of the Gross Domestic Product was 7.8% (https://www.mhlw.go.jp/toukei/saikin/hw/k-iroyohi/16/dl/kekkka.pdf). About 10 years ago, the dispensing costs were high, but now, they are decreasing because of the rise in generic drug prices. Also, the price calculation rules for medical materials covered by medical insurance are revised step-by-step, and price differences between Japan and countries overseas are corrected.

The medical insurance system in France is a social insurance system. It consists of several different systems for employees (general system and special system for civil officers) and self-employed workers (system for self-employed workers and agricultural workers). There exist several insurers running those systems, and an association called Union Nationale des Caisses d’Assurance Maladie (UNCAM, National Union of Health Insurance Funds) promotes cooperation between these insurers. The government has transferred authority to determine which medical act is covered by insurance or the rate of reimbursement to UNCAM. The Couverture Maladie Universelle (Universal health coverage) was introduced, and the French have health insurance enrolling all nationals including those who are the target of medical aid, its similar to the system in Japan. Then, standards for pricing medical devices and materials are similar to those in Japan too. Manufacturers have to submit 1) outlines of the application, 2) medical technical documents, 3) economic document to HAS (Haute Autorité de Santé). The economic document has to include estimations of the market share, sale, cost-reduction gained from using the product, comparisons with other treatments, and prices of similar products in other countries (https://www.mhlw.go.jp/file/05-Shingikai-12404000-Hokenkyoku-Iryouka/0000101309.pdf).

Just for information, official price systems for medical devices in several countries are shown in Table 3.

Discussion

This report contains a collection of data, research, and studies concerning the social insurance system, and the pricing of medical devices in foreign countries. Medical care insurance systems in each country differ with the history and culture (social value) of each country. Since the range of healthcare services covered by each public insurance differs, its necessary to note this point enough when systems are compared across nations.

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Conflict of interest

The authors declare no conflict of interest.

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