"Needs Survey" under the Governmental Commission on the Projects for ODA Overseas Economic Cooperation in FY2012

Summary Report

Kingdom of Thailand
Republic of India
Republic of South Africa

Dialysis Technique Network Development Plan

March, 2013

System Science Consultants Inc.

This report is a summary of a needs survey conducted by the contractor, under the Governmental Commission on the Project for ODA Overseas Economic Cooperation, commissioned by the Ministry of Foreign Affairs of Japan in Fiscal Year 2012. It does not necessarily represent the official views of the Ministry of Foreign Affairs of Japan.

Introduction

Change of lifestyle due to rapid modernization and economic development has led to health problems such as high prevalence of non-communicable diseases (NCDs). The main factors for NCDs are high blood pressures and hyperglycemia, which have the possibility of resulting in renal disease. Generally, hemodialysis (HD) treatment is expensive in the country where the social security system is not well developed, despite the fact that that the only medical treatment of end-stage renal disease is dialysis or renal transplantation. On the other hand, in fact, the wealthy and upper-middle class population has been increasing in the surveyed countries, and the demand for HD treatment must be increasing. To respond to increasing dialysis demands, the Japanese HD treatment system, which is 1) having team patient care system in the hospital, 2) maintaining high water quality management, and 3) high quality of medical equipment and consumables, is able to make a contribution on this demand. This system has resulted in the best quality HD treatment in the world.

Currently in Japan, the East Kyushu area from Oita to Miyazaki Prefecture is the area where the minor and major companies that manufacture the blood and vascular medical devices are concentrated. The area has the number one market share in Japan for artificial kidneys, blood circuits, and catheters for blood vessels. The area, so called "East Kyushu Medical Valley Framework (EKMV)", is establishing a place of research and clinical training for performing overseas medical personnel training in association with universities, hospitals, companies and prefectural governments. The network, centered in the EKMV, will contribute to conducting effective personnel training for expansion of dialysis related services among training centers in Japan and the dialysis-medical-base hospitals overseas. Furthermore, the manufacturing companies in the area will also get future market development opportunities through technical cooperation on HD treatment.

Thus, the objective of the survey is to investigate the needs for better HD treatment in hospitals, based on the analysis of the issues on HD treatment through collecting information including the country's health system, health insurance system, HD treatment system, patient needs, the distribution market, and so on. The survey team also analyzed whether Japanese HD treatment is accepted and, what kind of cooperation should be implemented for establishing better HD treatment system through a Japanese Official Development Assistance (ODA) scheme.

The survey was conducted from November 2012 to January 2013, including visiting the target countries (Republic of South Africa, Republic of India, and Kingdom of Thailand).

I. Description of the current situation and development needs of the concerned development issues in the surveyed countries

According to the World Bank list of economies 2011, South Africa and Thailand are categorized in the upper middle income countries and India is categorized in the lower middle income countries. All three countries are economically developing, and therefore, the problem of high prevalence of NCDs has been looked at more closely and has become a serious social issue.

The survey revealed that the needs of accelerating HD treatment is high since the number of renal failure patients is increasing. Current numbers of renal failure patients are 70,000 (estimated) in South Africa, 800,000 (estimated) in India, and 330,000 (based on the statistics data) in Thailand. On the other hand, the current number of patients who are accepted to be involved in HD treatment is only 10% in these three countries. The survey also confirmed that the potentials in terms of policy priority, infrastructure information system, social security system for the patients, and human resources of Thailand have advantages in relation to those of South Africa and India. The details are explained as below.

- Policy prioritization of prevention and control of NCDs are clearly stated in the health policy, particularly in Thailand, which recognizes renal diseases as one of the major health problems. Furthermore, health policy prioritization is associated with the budget of medical insurance. The National Health Security Office of Thailand secures the budget for renal diseases treatment as a specific disease and it accounts for 3.4% of the total reimbursement budget in 2013.
- Although the average annual rate of increase is 10% in the recent years in Thailand, the total number of dialysis facilities is still insufficient.
- The information system on HD treatment in Thailand is established and well maintained by the Nephrology Society. Their annual report has been published since 1998.
- Human resources in terms of medical doctors and nurses are sufficient at the tertiary level hospitals, and there is an established training course for nurses to become dialysis nurses in the whole country.
- In Thailand, since the patient clinical profile, such as difficulties of transplantation due to aging and having diabetes, is similar to that of Japan, the demand for maintenance HD is high.

However, there are some challenges to improve the quality of HD treatment in Thailand. One of the biggest challenges is that the clinical engineer (CE) does not participate in the HD treatment, while CEs are responsible for management of dialysis machines and water quality which play a crucial role in the quality of the treatment in Japan.

On the other hand, the policy priority on renal diseases in South Africa and India is not necessarily high at present, since there are so many other health issues in the both countries. However, it is true that the number of renal diseases patients is increasing; hence, the needs for HD treatment should increase as well in the near future. To expand HD treatment in South Africa and India, the establishment of a health insurance scheme and information system are necessary. There is no national health insurance scheme in the both countries, which results in difficulty maintaining HD treatment for the vulnerable people. In addition, due to the undeveloped information system, it is impossible for both countries to know the actual situation on HD treatment, such as demographic data, economic data, and management of complications in treatment.

It is emphasized that the HD treatment guidelines that the three countries use are the European and American ones as a reference. Unlike these well-known countries' guidelines, the Japanese guidelines are not very well known by the medical personnel in those countries. Furthermore, the survey revealed that the level of cleanliness of dialysis water in the three countries is lower than that of Japan, so it is difficult for the Japanese products to adapt their dialysis system to those levels immediately because the Japanese products are designed for good performance in conditions of good water quality.

II. Analysis on the products and technologies developed by the Japanese SMEs

The Japanese endoscopic and image diagnostic technology business in the field of medical equipment (ME) has been expanding to the world, and the next most potential market to be expanded is HD treatment technology, especially to the developing countries.

In Japan, HD treatment has been implemented for more than 40 years, and the current number of HD patients is over 300,000, the highest number relative to population in the world.

Recently, it has emerged that the quality of Japanese HD treatment is the number one in the world. The Dialysis Outcomes and Practice Patterns Study (DOPPS) in 2002 revealed that the mortality rate of Japanese HD patients was the lowest (6.6%), comparing with that of American (21.7%) and European (15.6%) patients.

The outcome is a result of accumulating the improvements in the Japanese HD system, which combined the "hard" part (ME) and the "soft" part (personnel and management). In addition, factors such as establishment of governmental social security for the patients, shortage of kidney donors, the majority of patients who are incompatible with kidney plantation due to aging and having diabetes supported the improvement of HD treatment of Japan.

The "hard" part (hardware-related aspects) of HD treatment, which includes the combination of the technologies of purification of dialysis water and dialyzers with high

performance membranes (HPM), contributes to longer life and improved quality of life (QOL) of patients by eliminating the risk of microbial contamination. Recently, it is recognized that purification of dialysis water, in which water treatment and development of dialysis fluid is conducted centrally for patients, is one of the most important factors in HD treatment, and the standard of those processes of Japanese treatment has become the world-wide standard.

As for the "soft" (non-hardware related aspects) part, the teamwork of HD medical personnel such as physicians, nurses, CEs, dietitians, and social workers contributes to improving treatment safety and patients' QOL. Among them, especially, the CE has an important role in terms of HD system management such as water quality and maintenance of ME.

The dialysis machine consists of a lot of materials and parts. Major corporations assemble materials and parts which are provided by small and medium-sized enterprises (SMEs), and sell the products. There is no Japanese company which produces the whole portfolio in-house in this field.

The costs of dialysis machines and equipment are relatively lower in the surveyed countries than in Japan. Re-using the dialyzer is one of the important factors for reduction of the total dialysis treatment cost. For instance, the number of re-uses of dialyzers is from 10 to 15 in Thailand at the moment, which suggests the possibility that sales of dialyzers will be expanded if the dialyzer becomes single-use.

III. Possible applicability of the SME's products and technologies to the future ODA projects

Possible applicable products for HD treatment for participating in the HD market of the surveyed countries include HPM dialyzers and dialysis machines which are compact and high-performance. However, there is a precondition to introducing these products, which is to improve dialysis water quality. Technologies such as purification of dialysis water for indispensable to make maximum use of the products as well as to prevent pyrogens (fever-inducing agents) from entering the body. Besides, products related to purification including disinfectant, reagents for monitoring the purified level, and establishment of the manual and guideline are also important.

In the all of the surveyed countries, it was found that 1) Japanese HD treatment is surprisingly little known for its outcomes such as low mortality rates, 2) there is a relatively low quality of dialysis water, and 3) there is an inadequate system of water quality management and safety control. Moreover, expanding of role of the CE should be considered.

The advantage of the EKMV is to have a well-established total quality management

system of HD treatment since it is established by industry, government and academia. In particular, the following items are able to contribute to improving the dialysis treatment according to the needs of the countries; 1) dialysis water purification technology, 2) HPM dialyzers and dialysis machines, and 3) control of infectious diseases and safe treatment by good coordination of personnel.

Therefore, the EKMV will take the initiative in the following steps to tackle the above issues of the surveyed countries in the medium-term of the framework.

1) Inviting and showing Japanese HD treatment to demonstrate the advantages to the policy-related governmental officials and physicians of the surveyed countries

2) Conducting a detail survey on the problems and plans for improvement of dialysis water quality in the targeted health facilities, and conducting training for CEs on preparation of dialysis water and its supply, maintenance of water processor apparatus, management of water quality, piping design, and so forth in Japan to improve dialysis water quality in the surveyed countries

3) Preparing for the development of a training system in the surveyed countries on water quality and for formulating a technical cooperation project

4) Implementing the technical cooperation project to improve the water quality in the country as well as to establish the training network

Projects to be addressed in the mid-term

Time	Project Name	Contents	Possible ODA Scheme
1-2 year (s)	Decision Makers Training	Inviting and showing Japanese HD treatment to demonstrate the advantages to government officials and physicians.	Training in Japan
	Survey on improvement of dialysis water quality	Conducting detailed survey on the problems and plans for improvement of dialysis water quality in the targeted health facilities, and conducting training on preparation of dialysis water and its supply and management.	Experimental Survey
	Technical Training for improvement of dialysis water quality	Implementing training for CEs and nurses regarding water management (Training of Trainers).	Training in Japan
1 year	Feasibility Study	Conducting preparatory survey on the development of training systems in EKMV and the surveyed countries.	Feasibility Study
	Technical Cooperation Project formulation	Drawing the road map to develop training systems with local governments, target hospitals, and other hospitals/clinics.	Project Formulation Survey, Detailed Planning Survey
3-5 years	Project for improvement of dialysis water quality	If the system in which private companies can directly propose technical cooperation projects can be strengthened, implementing the technical cooperation project to contribute to human resource development in the relevant countries targeting the development of CEs, etc.	Technical Cooperation Project
	Research Network for HD treatment	Conducting research to develop a model to introduce Japanese HD treatment and to narrow global/ regional gaps of HD treatment in future.	Science and Technology Research Partnership for Sustainable Development (SATREPS)

IV. Possibility of business development by utilizing the SME's products and technologies in the surveyed countries

The survey revealed that the HD systems in the surveyed countries are not currently prepared for the introduction of Japanese products, although there were needs for improving HD treatment in the all of the surveyed countries, especially in Thailand. It is indispensable to improve the dialysis water quality first and foremost, so that the Japanese products can provide their best performance.

In the mid-term, as described in the Chapter III, The EKMV needs to be supported by the ODA scheme to allow the surveyed countries to realize the good quality of HD treatment in Japan, and to conduct training to improve dialysis water quality in the countries. Ultimately in this term, the aim is to develop HD training networks among health facilities in the countries as well as developing them between the country and Japan. In addition, CEs and industries in the EKMV will participate in the whole process of the survey and the technical cooperation to modify the design of the products to adapt them to the situation of the country.

In the long-range outlook, Japanese products such as HPM dialyzers are introduced through the HD treatment networks because the physicians and CEs tend to utilize the MEs that are familiar to them.

The Cabinet of Japan approved the "Emergency Economic Measures to Revitalize the Japanese Economy", which is the nation's top priority, in January 2013. It states that the government should back up Japanese SMEs to accelerate their overseas operations and to enable the investment income to flow back from abroad smoothly to vitalize the domestic economy.

According to the 2010 white paper on SMEs, internationalization of SMEs by direct investment overseas is effective for the SMEs to increase sales, build new business, build name recognition of the company, and new development of new suppliers. Although the opinion is often heard that domestic industry is hollowed out as a result of shifting production overseas, and the phenomenon accelerates the impoverishment of the regional economy, it is reported that shifting production overseas increases not only productivity of labor but also domestic employment. It is extremely important for SMEs and their regional economy to develop the next business plan by utilizing this survey results and analysis through being supported by the Japanese government.

Needs Survey
Dialysis Technique Network Development Plan

SMEs and Counterpart Organization

- Name of SME : System Science Consultants Inc. and East Kyushu Medical Valley Framework (EKMV)
- Location of SME : Oita and Miyazaki prefectures
- Survey Site・Counterpart Organization : Kingdom of Thailand, Republic of India and Republic of South Africa

Concerned Development Issues

- Rapid modernization and economic development have led deaths from non-communicable diseases.
- The demand of hemodialysis (HD) treatment is increasing due to Chronic Kidney Disease caused by high blood pressure and diabetes.

Products and Technologies of SMEs

- The area of the East Kyushu has the largest market share in Japan for artificial kidneys, blood circuits and catheters.
- Strengthen of global competitiveness and improvement of HD treatment are the targets based on the HD system in association with prefectural governments, universities, hospitals and companies in the EKMV.

Proposed ODA Projects and Expected Impact

- JICA training: EKMV is inviting related personnel to demonstrate the good quality of HD treatment in Japan and to develop relationship among governmental officials and hospitals of the target countries.
- JICA survey: EKMV will 1) Improve quality of dialysis water, 2) Implement technical personnel training, 3) Prepare training centers in the target countries
- Technical cooperation: EKMV will export Clinical Engineer training to expand Japanese-type of HD treatment.

Future Business Development of SMEs

- Japanese products and techniques is introduced in the target countries.