

Resolving Healthcare Challenges through Innovation and Improving Access to Healthcare

Special Feature: Quest to Provide Safe, High-Quality Healthcare to All

Medical systems and infrastructure can vary by country and region, leading to an array of issues being faced in different medical settings. As a global provider of medical devices, the Terumo Group seeks to ensure that everyone has constant access to safe, high-quality healthcare. Accordingly, we earnestly address the medical issues faced in specific countries and regions, collaborating with medical institutions, government agencies, international institutions, and nonprofit and nongovernmental organizations, to resolve these issues.

CASE 1

Transradial intervention (TRI): percutaneous coronary intervention via the radial artery in the wrist

Transradial intervention (TRI) training for physicians in Latin America conducted through public-private partnership to contribute to improved patient quality of life and reduced healthcare expenditures



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CASE 2

Pathogen reduction technology system for safer blood transfusions

Public-private partnership to advance measures for infection control of blood used for transfusions in Ghana



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Oxygenators supporting cardiovascular surgeries

Support for first open heart surgery in Zambia performed by Zambian surgeons



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Training for medical professionals underpinning safe, high-quality medical services

Planning and implementation of practical training programs based on the needs of Japan's medical settings



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CASE 1 Quest to Provide Safe, High-Quality Healthcare to All

Transradial intervention (TRI): percutaneous coronary intervention via the radial artery in the wrist
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TRI’s Contribution to Patient Quality of Life and Reduced Medical Spending

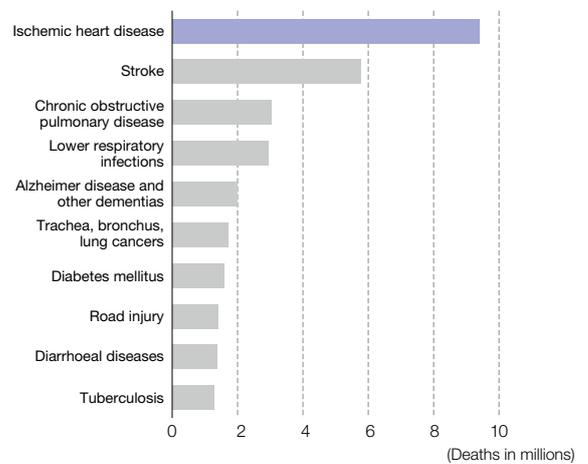
According to a survey*1 by the World Health Organization, of the 56.9 million deaths around the world in 2016, the leading cause of death was ischemic heart disease, such as angina pectoris and myocardial infarction. These diseases claimed the lives of 9.4 million people and accounted for 17% of deaths in that year. Percutaneous coronary intervention (PCI) using catheters is a widely used method of treating ischemic heart disease.

A common PCI procedure used to treat ischemic heart disease is transfemoral intervention (TFI), which entails inserting catheters through the femoral artery in the groin. Recently, however, the use of TRI, a procedure in which catheters are inserted through the radial artery in the wrist, has become more common out of consideration for its ability to contribute to higher patient quality of life and reduced medical spending. TRI does not require hemostasis procedures around the groin, and patients are generally able to walk sooner after TRI procedures than after TFI procedures, resulting in shorter hospital stays. Furthermore, the rate of bleeding complications at the site of catheter insertion after procedures is said to be lower, and a U.S. clinical study*2 has indicated that the cost of TRI is roughly ¥90,000 less than TFI per procedure.

Promotion of TRI Use in Various Countries through Product Development and Training

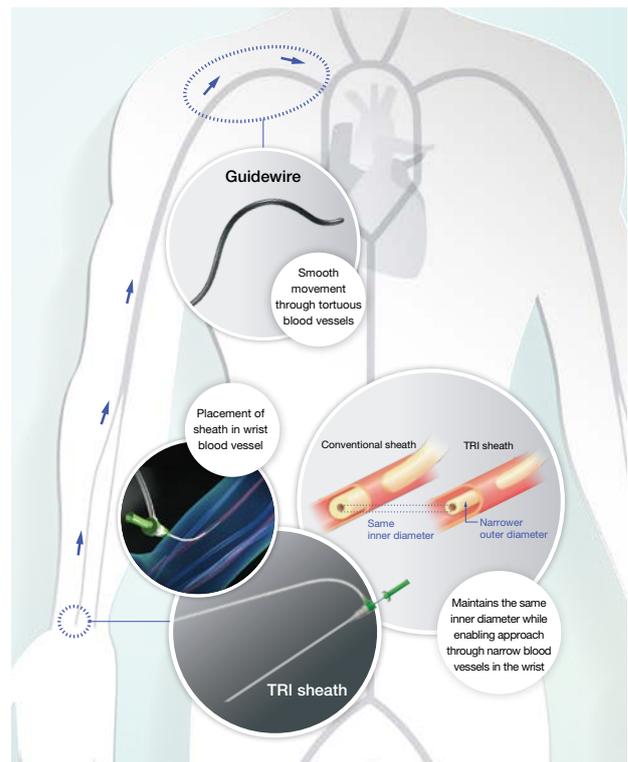
Although TRI boasts these benefits, it is also more difficult to perform than TFI as it can be hard to insert catheters into the narrow blood vessel (radial artery) and the access to the coronary artery is tortuous. Terumo is seeking to remove these obstacles by developing and supplying refined and improved devices for use in TRI procedures. At the same time, we are working together with highly talented Japanese physicians to develop training programs and educational tools while creating opportunities for techniques to be transferred between physicians. We thereby aim to spread understanding of the value of TRI along with the techniques for performing this procedure. As a result of these ongoing efforts, the percentage of PCI procedures for ischemic heart disease represented by TRI has been found to be around

Top 10 Global Causes of Death, 2016



Source: Global Health Estimates 2016: Estimated deaths by age, sex, and cause, World Health Organization, 2016

TRI Procedure
 (Accessing lesion site in coronary artery via wrist blood vessel)



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90% in China, 70% in Japan, and 40%–50% in Asia and Europe. Moreover, the rate of use of this procedure has risen to roughly 35% in the United States, despite being less than 10% a decade ago.*³

Support for Spreading TRI in Latin America through Public–Private Partnerships

The spread of TRI in Latin America has been slower than in other regions, despite ischemic heart disease rating high among the causes of death in this region. Actual rates of usage varied from country to country but were estimated to range from 10% to 30% five years ago.*³ Medical infrastructure is being installed in these countries as their populations grow and age, but there is still a lack of equipment and physicians, creating a need for efficient, low-cost medical services.

To address this issue, Terumo is supporting the spread of TRI in Latin America through public–private partnerships to contribute to improved quality of life for patients, higher medical efficiency, and reduced medical costs. In 2011, Terumo together with Japan International Cooperation Agency (JICA) invited five young physicians from Mexico to Japan to undergo TRI training. This training was performed through cooperation with Dr. Shigeru Saito of Shonan Kamakura General Hospital, a leading authority on TRI in Japan who actively promotes the spread of TRI around the world. In addition, we participated in a public–private partnership project organized by JICA over a two-year period beginning with 2014, during which we provided TRI training for approximately 40 physicians from national hospitals in Mexico, Colombia, Brazil, and Argentina. In these training programs, physicians were invited to Japan to observe procedures at hospitals including Shonan Kamakura General Hospital and to take part in simulation training at the Terumo Medical Pranex comprehensive medical training facility. Follow-up training was also held in the respective countries of participants upon their return to check their level of proficiency at performing TRI procedures. Post-program surveys indicated a large increase in the number of TRI procedures performed at the hospitals with which participants were affiliated along with a boost in the portion of PCI procedures represented by TRI. These results confirmed a steady rise in the understanding and use of TRI. Terumo anticipates that the physicians who took part in this training program will help train other physicians in their countries as instructors.

Recognition for this program has led to its evolution into the Project for Promotion of Minimally Invasive Techniques Focused on TRI Method, a technical cooperation project

that was part of Japan's official development assistance and was promoted by JICA. Launched in 2015, this project is being advanced by the Japanese and Mexican governments. One facet of this project included the establishment of a TRI training center inside the National Institute of Cardiology of Mexico, which was completed in July 2016. Terumo is supporting this project through the provision of training apparatuses and technical instruction.

Further Promotion of the Spread of TRI through Collaboration with Various Countries' Governments and Other Organizations

Terumo plans to continue to collaborate with medical institutions, academic associations, and government bodies in various countries to promote the spread of TRI. Through the ongoing provision of the products and training support necessary based on the circumstances and issues faced in medical settings in each country, we hope to help disseminate high-quality healthcare.



Latin American physicians undergoing TRI training

*1 Source: *Global Health Estimates 2016: Estimated deaths by age, sex, and cause*, World Health Organization, 2016

*2 Source: Amin AP, House JA, Safley DM, et al. Costs of transradial percutaneous coronary intervention. *JACC Cardiovasc Interv.* 2013. (U.S. dollar amounts translated at the rate of ¥110 to US\$1)

*3 Percentage of PCI procedures represented by TRI in each country or region estimated by Terumo Corporation

CASE 2 Quest to Provide Safe, High-Quality Healthcare to All

Pathogen reduction technology system for safer blood transfusions

Public-private partnership to advance measures for infection control of blood used for transfusions in Ghana

Reduction of Infection Risks Associated with Blood Transfusions in Africa

Various safety measures are taken for blood products to prevent infections caused by bacteria, viruses, and other pathogens as well as side effects from transfused white blood cells. Currently, however, no method of testing or pathogen reduction can completely eliminate the risk of a transfusion-transmitted infection (TTI). In middle- and low-income countries, blood donors have more infections than in high-income countries.*1 In fact, sub-Saharan Africa has the highest rate of HIV and malaria infection in the world, so reducing the risk of infection from blood transfusion is an important medical issue. In a survey conducted in the Republic of Ghana, TTIs from malaria are estimated to occur in up to 28% of blood donation recipients.*2

Public-Private Partnership Project to Advance Measures for Infection Control of Blood Transfusions in Ghana

To improve this situation and others like it, the Terumo Group partnered with Japan International Cooperation Agency (JICA) and since 2017 has been conducting a program through public-private partnership for preventing disease transmission through blood transfusions in the Republic of Ghana.*3 Using the Mirasol Pathogen Reduction Technology (PRT) system developed by Terumo's Blood Management Company (Terumo BCT), Terumo is working with the Ministry of Health and the National Blood Service, Ghana, to promote the routine use of the Mirasol PRT system for whole

blood. A total of four Mirasol devices have been installed in the National Blood Service blood banks in both of Ghana's main cities, Accra and Kumasi. After the pathogen reduction process, transfusions are given to the most vulnerable patients, including postpartum hemorrhage patients as well as child and adult oncology patients. A haemovigilance system to monitor safety of blood transfusions is also being implemented to accumulate data acquired throughout the entire process, from blood donation through preparation to the post-transfusion condition of the patient.*4 This will enable the analyses and assessments needed to keep adverse events from occurring.

Mirasol PRT System Supporting Safe Transfusions

Mirasol uses UV light and riboflavin (vitamin B₂) to inactivate a broad range of pathogens, including bacteria, viruses such as HIV, parasites such as malaria, and white blood cells in blood products, reducing the risks of disease transmission and side effects from blood transfusions. It received the CE mark for platelets in 2007 and for plasma in 2008, and it is now sold in more than 20 countries, mainly in Europe, the Middle East, and Africa. Unlike in high-income nations, patients in middle- and low-income countries often receive transfusion of whole blood, rather than blood components. Therefore, Terumo sought the possibility of using Mirasol for whole blood. In 2014, the African Investigation of the Mirasol System (AIMS) clinical trial performed in Ghana was the first and only clinical trial to demonstrate that a pathogen reduction technology, specifically Mirasol, can

Pathogen Reduction Process for Whole Blood Using Mirasol® PRT System



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effectively reduce the incidence of TTI of a bloodborne pathogen. The results of the AIMS trial were presented at the 2015 congress of the AABB (formally known as the American Association of Blood Banks) and were also featured in the medical journal *The Lancet*. That same year, Mirasol received the CE mark for whole blood treatment, marking the availability of the first and only PRT treatment for whole blood.

Training of Local Staff to Promote Smooth Introduction in Ghana

Training the local staff is essential for the smooth implementation of the PRT process and implementation of a haemovigilance program. In addition to the training performed in Ghana, Terumo also enlisted cooperation from the Japanese Red Cross Society to invite doctors and nurses from hospitals and the National Blood Service in Ghana to Japan. They were given training in haemovigilance as well as tours of blood collection and processing centers and hospitals. The visiting dignitaries were also given a tour of the Terumo

comprehensive medical training facility, Terumo Medical Pranex. During this visit, there were opportunities to share, discuss, and exchange opinions on how Terumo may be able to further contribute to societal and healthcare development in Africa. These efforts are supported by the global collective strengths of Terumo, with associates from the Head Office, Terumo BCT, Inc., and Terumo Europe NV going beyond the boundaries of organizations and regions to cooperate and coordinate the ongoing activities.

Continued Effort to Ensure Routine Use of Mirasol PRT System in Ghana

This public-private partnership project with JICA will conclude in December 2018, but the Terumo Group will continue working to ensure the routine use of Mirasol in Ghana. Beyond this, Terumo also plans to use the experience and expertise gained from this project to help develop the infrastructure for an adequate, safe, and sustainable blood supply in Africa.

*1 Source: *Global Status Report on Blood Safety and Availability*, World Health Organization, 2016

*2 Source: Freimanis G, et al., "Investigating the Prevalence of Transfusion Transmission of Plasmodium within a Hyperendemic Blood Donation System," *Transfusion* 2013; 53 (7): 1429-1441

*3 Terumo applied and was selected for "Collaboration Program with the Private Sector for Disseminating Japanese Technology for the Social and Economic Development of Developing Countries" by JICA and has been conducting this program on an outsourced basis from JICA.

*4 For haemovigilance, AABB Consulting Services, an affiliate of AABB (formerly the American Association of Blood Banks), is contracted to formulate and conduct facility assessment and implementation training programs as well as auditing and feedback.



AIMS clinical trial being performed in Ghana



Mirasol® PRT system used in Ghana

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Comments from Members Involved in CASE 1, CASE 2 (Public-Private Partnership Projects)

CASE 1

Transradial intervention (TRI): percutaneous coronary intervention via the radial artery in the wrist
 Transradial intervention (TRI) training for physicians in Latin America conducted through public-private partnership to contribute to improved patient quality of life and reduced healthcare expenditures

Through a JICA public-private partnership project, we worked toward the lofty goal of resolving the medical issues faced in four Latin American countries by spreading use of TRI. To this end, we offered a training program that included hands-on training using models as well as opportunities to observe the masterful techniques of Japanese physicians and to speak with these individuals. I am confident that this experience deepened participant understanding of TRI and the techniques needed to perform it. Surveys conducted after the program showed a drive to use these techniques in clinical settings in all countries, something I would say represents a massive success. I hope to help contribute to the spread of TRI through public-private partnerships with medical institutions, academic associations, and government bodies going forward. It is our goal to tie such efforts to improved health for people, lower medical costs, and consequently business growth for Terumo.



Naofumi Okajima

Manager, Innovation Marketing
 Terumo Interventional Systems
 Division, Cardiac and Vascular
 Company
 Terumo Corporation

CASE 2

Pathogen reduction technology system for safer blood transfusions
 Public-private partnership to advance measures for infection control of blood used for transfusions in Ghana

The Mirasol system would act as a major leap from our current status of blood safety with a high residual risk. It would afford a safer blood supply because it reduces bacteria, viruses, and parasites, and we do have quite a large number of these pathogens in our blood. Mirasol also inactivates white blood cells so it would afford the recipients less reactions in terms of transfusion adverse events.



Dr. Shirley Owusu-Ofori

Head of Transfusion Medicine
 Komfo Anokye Teaching Hospital
 Kumasi, Ghana

CASE 1

CASE 2

JICA collaborates with private sector companies with the aim of transmitting the superior products, technologies, and expertise of Japanese companies to developing countries through public-private partnerships in order to contribute to their social and economic development. The project for promoting treatment of ischemic heart disease through TRI in four Latin American countries as well as the project for preventing infections during blood transfusions in Ghana in which we partnered with Terumo were both judged to be applicable under this program. These projects entailed using Terumo's products, technologies, and expertise in the coronary intervention and blood transfusion fields, respectively. Utilizing JICA's wealth of local information and interpersonal networks as well as the trust JICA projects enjoy in these countries, we were able to facilitate the smooth introduction of these products, technologies, and expertise into local medical settings. The results have already begun appearing.

JICA is also proactive in its efforts to support businesses that help resolve the issues faced by developing countries to contribute to the accomplishment of the United Nations Sustainable Development Goals. These efforts are advanced in the form of projects for supporting dissemination, verification, and commercialization efforts and feasibility studies. I hope Terumo will engage in public-private partnerships to continue contributing to the resolution of medical issues in developing countries by utilizing its products, technologies, and expertise in a wide range of medical fields to help spread TRI, prevent infections from blood transfusions, and address other medical issues.



Takashi Baba

Director, Private Sector Investment
 Finance Division,
 Private Sector Partnership and
 Finance Department, Japan
 International Cooperation Agency
 (Formerly Director, Private Sector
 Partnership Division)

CASE 3 Quest to Provide Safe, High-Quality Healthcare to All

Oxygenators supporting cardiovascular surgeries

**Support for first open heart surgery in Zambia performed by
Zambian surgeons**

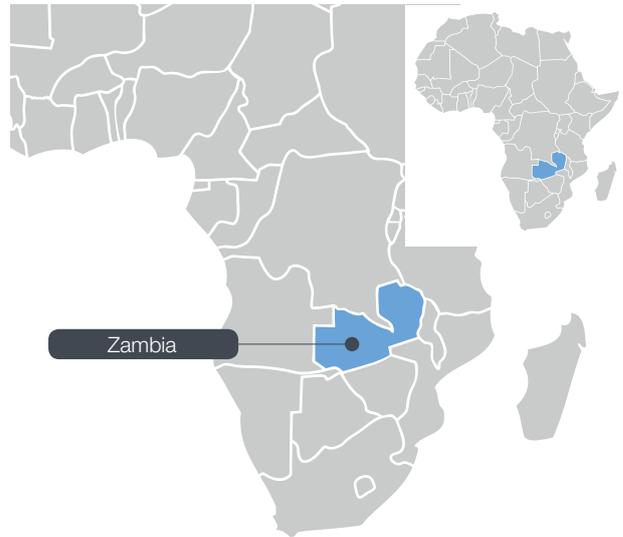
Children with Heart Diseases on Surgery Waiting Lists

Zambia, located inland on the southern portion of the African continent, suffers from lagging development of medical infrastructure coupled with a lack of medical professionals capable of providing advanced medical services. For these reasons, patients requiring treatment are constantly unable to receive adequate medical services.

University Teaching Hospital (UTH), the national hospital that provides Zambia’s most advanced and specialized medical services, is also faced with a severe lack of medical professionals. UTH is the only hospital in Zambia at which patients can undergo cardiovascular surgeries. In the past, these surgeries have been performed purely by teams of foreign surgeons or visiting surgical teams and only in small numbers, and the necessary surgical techniques were not transferred to Zambian surgeons. As a result, over 200 children with heart diseases are still on waiting lists for surgery.

**First Open Heart Surgery Performed by
Zambian Surgeons**

Tokushima International Cooperation (TICO) is a nonprofit organization that has been providing medical support to Zambia for a number of years. Seeking to address this situation, TICO partnered with UTH in 2017 to commence a program for cultivating a cardiovascular surgery team comprising Zambian surgeons. As part of this program, TICO invited surgeons from Japan to provide intensive training for Zambian surgeons and nurses beginning in September 2017. The goal of this training was to endow these individuals and



other Zambian medical staff with the skills needed to perform open heart surgeries.*1 In February 2018, the first surgery for treating atrial septal defect**2 to be conducted by Zambian surgeons took place at UTH. Such surgeries have already been conducted on three female patients aged nine, 10, and 18. These three open heart surgeries were performed over a period of four days by a Zambian surgical team consisting of four surgeons, two nurses, and one clinical engineer. Support was provided by Japanese surgeons invited by TICO. The surgeries took longer than normal, but they were able to be completed safely through coordination among the Zambian team and the guidance of the Japanese surgeons.



Surgery in progress



Zambian medical staff, TICO surgeons, and Japanese medical staff invited by TICO that took part in the surgery

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Support for Open Heart Surgeries through Provision of Oxygenators

Terumo supported this project by supplying, free of charge, the oxygenators and cardiovascular circuits needed for training medical professionals as well as the syringe pumps that are used after surgeries. We also provided the oxygenators and cardiovascular circuits required for the actual surgeries. Oxygenators are used to temporarily provide the functions of the lungs in cardiovascular surgeries and other surgeries that entail stopping the heart. Today, hollow fiber oxygenators*³ are commonly used. These oxygenators were first developed by Terumo. Since the initial launch of hollow fiber oxygenators in 1982, we have proceeded to implement refinements and improvements to realize more stable gas exchange performance and more compact designs, innovations that have led to Terumo hollow fiber oxygenators being used in medical settings worldwide.

Ongoing Provision of Necessary Products to Support Medical Activities

TICO is continuing its efforts to cultivate Zambian surgeons to ensure that such surgeries can be performed in Zambia reliably and consistently in the future. Similarly, Terumo will keep supporting the activities of TICO through the supply of oxygenators and other initiatives with the aim of making cardiovascular surgeries more readily available in Zambia and other African countries.



Oxygenator with integrated arterial filter

*1 Open heart surgeries are surgeries for treating heart diseases that entail making incisions into the heart of the patient. Heart-lung machines are used during these surgeries to temporarily provide the function of the heart and lungs.

*2 Atrial septal defect is a type of congenital heart disease in which a hole is present in the muscle wall between the left and right atriums of the heart at birth. Congenital heart diseases are said to occur in one in every 100 people and atrial septal defects are estimated to represent between 7%–10% of these diseases.

*3 Hollow fiber oxygenators are oxygenators that use hollow fiber membranes, which are equipped with gas exchange functions primarily made of microporous polypropylene materials. Oxygen is supplied to the blood flow and carbon dioxide is removed through the numerous tiny holes, which only allow for passage of gas and not blood, in these materials to sustain the life functions of the patient during surgery. (Terumo's oxygenators currently employ a design in which oxygen gas flows through the inner channels of the hollow fiber membrane and blood flows through the outer channels.)

Comment from Tokushima International Cooperation (TICO)

CASE 3

I would first like to thank Terumo for their ongoing support of our activities.

We are currently working to train cardiovascular surgery teams at University Teaching Hospital with the goal of saving as many people suffering from heart disease as possible. There are many tasks that need to be tended to if cardiovascular surgeries are to continue. These tasks include enhancing the overall capabilities of the hospital, training Zambian surgeons and perfusionists,*⁴ and ensuring smooth distribution of surgical equipment within Zambia. We will be steadfast in our efforts to address these tasks. I am exceptionally grateful for the various equipment Terumo has provided, especially those that were donated to us. In January 2019, we plan to begin performing coronary angiography, and the support of Terumo will be all the more important as a result. I hope this good cooperative relationship will continue on into the future.



Dr. Osamu Yoshida

Director, Tokushima International Cooperation (TICO)
Director, Sakura Medical Corporation

*4 Perfusionists are responsible for operating and managing the extracorporeal circulation equipment (heart-lung machine) that provides the function of the heart and lungs during cardiovascular surgeries. In Japan, these duties are included in the roles of clinical engineers.

CASE 4 Quest to Provide Safe, High-Quality Healthcare to All

Training for medical professionals underpinning safe, high-quality medical services

Planning and implementation of practical training programs based on the needs of Japan's medical settings**Non-Technical Skills Garnering Attention in Medical Settings**

Medical progress is giving rise to more sophisticated and complex examination and therapeutic techniques, which in turn is requiring medical professionals to acquire a wider range of increasingly more specialized knowledge and skills. In conjunction with this change in the medical landscape, a trend toward the practice of team approach to healthcare is emerging in Japan's medical field. This practice entails various medical professionals, including physicians, surgeons, nurses, clinical engineers, pharmacists, and nutritionists, working together to support patients. The ability to provide safe, high-quality medical services as a team hinges on the specialized knowledge and skills of team members as well as on their so-called non-technical skills. Examples of non-technical skills include situational judgment capabilities, leadership, communication skills, and teamwork. These skills have been garnering a great deal of attention in medical settings as team approach to healthcare becomes more common. A recent survey reported that more than half of all medical accidents are the result of a lack of non-technical skills.*1

Support from Dedicated Team for Planning and Implementing Training Programs

As a medical device manufacturer, Terumo works to address such issues in medical settings by devoting efforts to planning and implementing medical training programs on the

proper use of medical devices, among other topics. At medical institutions, various training programs are conducted, even as medical professionals go about their busy clinical activities. These programs target specialized professionals, such as residents undergoing clinical training, nurses, and clinical engineers. Several hospitals have requested support in planning and implementing these training programs. Terumo rose to the call by providing support for these tasks and by jointly developing educational tools with hospitals. In 2004, we established a dedicated team for planning and implementing training programs for medical professionals. Since then, we have been carrying out proprietary Terumo training programs on matters such as intravenous injections and safe operation of infusion pumps and syringe pumps for nurses and residents undergoing clinical training.

Fostering of Propensity for Autonomous Thought and Action

Training programs planned by Terumo focus on teaching appropriate use of medical devices and fostering a propensity for autonomous thought and action in participants. Based on this policy, we seek to provide training programs that closely simulate the conditions found in clinical settings. For this reason, we utilize Terumo Medical Pranex, a comprehensive training facility that recreates the functions of actual hospitals. Through practical training at this facility, we



Intravenous injection training at Terumo Medical Pranex (both photos)

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seek to help medical professionals gain specialized knowledge and skills while nurturing their situational judgment capabilities, leadership skills, communication skills, and other non-technical skills. In recent years, we have also been focusing on the development of programs for cultivating trainers to allow other medical professionals to continue to receive training in their respective hospitals after they have completed our programs. Furthermore, 2017 saw the launch of a new training program based on the theme of preventing medical accidents. This program is aimed at hospital medical safety managers as well as the directors and vice directors of hospitals. In addition, medical representatives are dispatched to medical institutions to conduct training programs.

Ongoing Improvements and Revisions While Supporting Medical Professionals

Terumo has continued to conduct its training programs while implementing ongoing improvements and revisions. As a result, the aggregate number of medical professionals we have helped train over the past 10 years exceeds 30,000*2 when including Terumo-assisted programs planned and implemented by hospitals. These professionals largely consist of nurses and residents undergoing clinical training. Going forward, Terumo will continue to provide practical training based on the needs of medical settings to promote safe and appropriate use of medical devices and support the medical professionals responsible for providing safe, high-quality medical services.

*1 Information is based on reports (accident causes) from medical institutions registered with Japan Council for Quality Health Care over the period from January to December 2016 described in *Project to Collect Medical Near-Miss/Adverse Event Information 2016 Annual Report*.

*2 Figure represents the aggregate total of participants from fiscal 2008 to fiscal 2017.

Comment from an Associate

CASE 4

In the medical field, hospitals must work to cultivate talented human resources in order to attract patients. Fostering the trainers that conduct training at hospitals is therefore a matter of utmost importance.

Terumo's team of associates that have clinical experience as nurses and are well versed in education provides trainer-development programs that were created together with medical professionals. Recently, it has become common for training programs to focus on improving the overall capabilities of participants, including the ability to make judgments based on their insight and techniques as well as their attitude. Terumo has therefore developed programs based on the theme of fostering a propensity for autonomous thought and action centered on simulation training. We continually revise and improve these programs to ensure that they always match the needs of medical settings. These training programs have won praise from the managers of medical facilities that have undergone training, stating that our reliable programs offer instruction based on the fundamentals and that participants have been increasingly exercising flexible ingenuity in the guidance they provide at hospitals, as had been anticipated.

Moving forward, we will continue to provide training on the appropriate use of medical devices to cultivate medical professionals that can design training programs for preventing medical accidents and infections in hospitals.



Sanae Hoshino

General Manager, Clinical Support
Hospital Systems Division,
General Hospital Company,
Terumo Corporation