Assistive Device Revolution for the Independence of Older Adults in Japan

Care Robots and Other Technology Innovations

Yoko Crume, Ph.D.

August 2018

ILC-Japan

ILC (International Longevity Center) is a non-profit organization to study the trend of population aging with low-fertility from the international and interdisciplinary perspectives, to share the center's findings, to educate the public, and to make policy recommendations to the government.

17 centers have been established to date in the world: in the United States, Japan, France, the United Kingdom, Dominican Republic, India, South Africa, Argentina, Netherlands, Israel, Singapore, Czech Republic, Brazil, China, Germany, Canada and Australia. These centers constitute an alliance (called ILC Global Alliance) that promotes joint studies and symposia as well as country-specific activities within the context of this loose network.

ILC-Japan has been engaged in numerous studies concerning the ethos of productive aging, and we have actively sought to share our findings and educate the public since 1990. We aspire to serve as an international resource center and will continue to proactively initiate projects that contribute to an ideal aging society, where all generations will support one another and live happily.

ILC-Japan
KDX Nishishinbashi Buldg., 6th Floor,
3-3-1, Nishishinbashi, Minato-ku,
Tokyo 105-8446, JAPAN
URL: http://www.ilcjapan.org
E-mail: ilcjapan@mba.sphere.ne.jp

This report was first published in June 2018.

ABOUT THE AUTHOR

Yoko Crume received her B.S. degree from International Christian University in Tokyo, Japan, and her M.S.W. and Ph.D. degrees from the University of North Carolina at Chapel Hill in the United States. Her professional career includes working as a clinical social worker at John Umstead State Psychiatric Hospital, an administrator at the North Carolina Division of Aging, and an Associate Professor at the Joint Master of Social Work Program in North Carolina. Currently, she works as an aging service consultant and researcher, and she is an active community volunteer in Nashville, Tennessee. She can be reached at yokocrume@gmail.com.

Content

Acknowledgements

This research was supported by the Japan-United States Friendship Commission, the Northeast Asia Council of the Association for Asian Studies, and the International Longevity Center-Japan (ILC-Japan). The author also acknowledges ILC-Japan for its logistics assistance, photo acquisition, and publication. Finally, the author appreciates the insights and review comments shared by John Campbell and Richard Crume.

Introduction

Assistive technology (AT) is the field that addresses the needs of people with disabilities by integrating technological devices and services to restore, improve, and maintain their daily functioning. The idea of integrating devices and services was first introduced in the Individuals with Disabilities Education Act of 1990 (IDEA) in the United States. However, the history of assistive devices themselves can be traced back to the 5th and 6th centuries BCE in China and Greece. Today, the AT field is at the onset of a revolutionary transformation, where scientific and technological advancements in the robotics field will augment human functional deficiencies so well that human disabilities may cease to exist in the future, according to Herr (2014). With this ambitious goal in mind, robotics research and development programs in AT are well underway in Australia, Canada, China, Denmark, France, Germany, Japan, New Zealand, South Korea, Sweden, the United Kingdom, and the United States, and other countries (e.g., China, India, and Russia) are not far behind.

The focus and extent of engagement in AT varies among nations, depending on their interests and research capabilities, with some countries farther along than other. However, AT developments in Japan are especially interesting because of the country’s focus on disabilities among the older population and the strong linkage with Japan’s overall economic redevelopment strategy. In this regard, Japan is at the forefront of AT development—a number of new assistive devices for older adults are being tested for functional and commercial viability, and some have already been introduced into the marketplace.

This article describes the unique AT developments in Japan, examines the factors that have influenced the direction of Japanese AT development, and considers how the direction of research and development may help attain Japan’s goals of promoting the health, wellbeing, and independence of older adults while contributing to the restoration of national economic viability. Lessons learned from the Japanese experience are important because societal aging is a global issue and a major concern in many countries.

History of AT development

Today, Japan pursues one of the most active AT programs in the world. However, Japan has not always been a leader in the field, and much of the recent progress has been built upon the accomplishments of other nations, especially the United States and several European countries. Further, continuing interactions with the international community is important for future developments in the AT field in Japan. Understanding the history of AT adds perspective for the direction of future AT development in Japan.

The earliest recorded examples of AT use come from ancient Chinese stone slates and Greek vases, which depict people with disabilities being transported in wheeled furniture. (Kamenetz, 1969) Making a device specifically designed for people with disabilities comes much later, perhaps in the Middle Ages, as exemplified by the three-wheeled wheelchair invented in 1655 by a German paraplegic watchmaker, Stephen Farffler. Another key development in the history of AT, the Braille system, was invented in the mid-19th century for people with visual impairments, and an updated version of the original Braille system is still in use today.

In the early- to mid-20th century, the emergence of disability as a social concern triggered systemic responses in the United States and Europe. In particular, the disabilities prevalent among young, wounded soldiers returning from a succession of wars and conflicts attracted attention, stimulating the development of more advanced assistive devices, such as the Hoover cane (white canes designed to be used as mobility devices) and motorized wheelchairs.

More recently, the Independent Living Movement, which started as a grassroots, civil rights movement in the 1960s advocating for the rights of people with disabilities, was highly influential in subsequent AT development. The movement was instrumental in passing the Rehabilitation Act in 1973 and the Americans with Disabilities Act in 1990. These complementary U.S. laws not only established the norm for nondiscrimination based on disability, but they also set the stage for future AT innovations by requiring auxiliary aids to ensure people with disabilities could benefit from the services they receive.

Two other pieces of legislation that were influential from this period were the Technology-Related Assistance for Individuals with Disabilities Act of 1988 (commonly called the Tech Act) and the aforementioned IDEA. The former act clarified the American government’s intention to actively encourage the application of advanced technology to assistive devices and services to support the daily functioning and learning of people with disabilities, and the latter act focused attention on the role of AT in educating school children with disabilities.

Legislation and resulting AT developments in the United States had a significant influence on the international community, including publication of the International Classifications of Functioning, Diseases, and Health (referred to as the ICF) by the World Health Organization (WHO) in 2001, replacing the older and out-of-date International Classification of Impairments, Disabilities, and Handicaps system. The ICF redefined a person's disabilities from the perspective of daily functioning and identified the important role of assistive devices and technology as well as overall improvements in the physical environment that can benefit everyone, regardless of age or disability.

In 1950, shortly after the end of World War II (WWII), Japan enacted the People with Physical Disabilities Law as the first national program to provide assistive devices to people with disabilities, primarily focusing on wounded soldiers returning from the war. This legislation was followed in 1963 by the Welfare Law for the Aged, which mandated program development to provide assistive devices to older adults who meet the service requirement. Since then, many Japanese municipalities have also initiated their own assistive device programs. Today, the Program to Subsidize the Cost of Wearable Devices under the Law to Comprehensively Support Daily and Social Living of Persons with Disabilities (commonly called the Persons with Disabilities Comprehensive Support Law) is the main governmental vehicle to provide assistive devices in Japan, primarily to people of all ages with severe disabilities.

Assistive Device and Care Robot

In Japan, the term "kaigo robotto" (long-term care or simply care robot) is often used to describe the new group of innovative assistive devices currently under development or recently entering the marketplace. The term is used loosely and can mean both robots and other innovative assistive devices that may not necessarily meet the current definition of robot. (Honma, 2017) While people often use the term robot, many people have difficulty explaining exactly what it is. This is not surprising given that the New Energy and Industrial Technology Development Organization (NEDO), a Japanese agency founded in 1980 to coordinate industrial research and development activities, declares in its 2014 White Paper on Robot that "there exists no perfect consensus definition of robot." (NEDO, 2014)

The field of robotics is in constant flux, and the definition is constantly shifting. However, for the purpose of this article, the functional definition of a robot is "an intelligent machine that combines sensing, thinking/controlling, and acting technologies." (Ministry of Economy, Trade and Industry [METI], 2008) "Sensing" refers to simulating the human senses, such as seeing, hearing, smelling, and touching, and it has become increasingly common for robotic systems to also be equipped with "super-human" sensors, such as global positioning system technology. Robotic system computers perform "thinking" and controlling duties that include recognizing incoming information from the sensors, developing an action plan, and coordinating actions. And an actuator transforms the energy created by a motor or other mechanical device into the desired motion. Japan particularly excels in sensing and controlling technologies.

The International Federation of Robotics (IFR, 2016) classifies robots into two categories, industrial and service, where a service robot is defined as a "robot, other than industrial robot, that provides useful services to people autonomously (or semi-autonomously)." The IFR further classifies service robots into two use groups: professional and personal/domestic. Care robots belong to the personal/domestic group, while robots used in medical and rehabilitative services belong to the professional group. (The professional group also includes disaster response robots, like those used at the Fukushima Nuclear Power Plant following the historic 2011 earthquake and tsunami.)

Factors Affecting AT Innovations in Japan

Japanese AT innovations today are fueled by the following four factors: (1) the global phenomenon of societal aging, particularly the aging trend in Japan; (2) incentives created by Japan's existing programs for aging services; (3) Japan's search for a new industrial niche to bolster its economic recovery; and (4) international influence and trade barriers. These factors are described below.

Global Societal Aging and Japan. Societal aging is a global phenomenon. The worldwide aging trend gained momentum in the mid-20th century, and between 1950 and 2000, the global average life expectancy increased 20 years, according to the United Nations (2002). This trend is expected to continue, and by 2050, the global average life-expectancy is projected to reach 75 years. Several countries known for longevity are expected to attain an average life-expectancy of 90 years even sooner. (Salomon et al., 2012)

The global aging trend has been especially apparent in Japan, where the combined effects of longevity and low fertility have accelerated societal aging at an unprecedented rate in recent decades. (Cabinet Office of Japan, 2017) In 2016, 34 million people, or 27.3% of the total Japanese population, were already age 65 and older, and nearly half of them (17 million people, or 13.3% of the total population) were 75 and older. Further, it is projected that the 65-and-older and 75-and-older populations will increase to 38.4% and 25.5%, respectively, of the total population by 2065. The rapid increase in the oldest segment of the older population is particularly notable in Japan as well as in a number of other countries, mostly in Europe and parts of Asia, where the proportion of older adults is already high. (Salomon, 2012)

Many people believe that today's older adults are healthier and maintain their daily functioning longer than any time in the past, as illustrated by popular slogans like "today's 70-year-old is yesterday's 50-year-old." These claims are supported by the Health-Adjusted Life Expectancy (HALE) statistics, which show an increase in the average number of years people live in good health. However, because HALE statistics are increasing at a slower rate than overall life expectancy, the years people live in less than good health (or with disabilities) are also longer. (Salomon et al., 2012) These statistics further support projections of a continuing expansion in the demand for assistive devices.

Japanese Programs for Aging Services. In Japan, heightened concern over the increasing need for caregiving for older adults began to emerge as early as the 1960s, when the original Welfare Law for the Aged was established. (Campbell, 1992) Since then, Japan has developed numerous older adult policies and programs, often inspired by the "best practice" examples in Scandinavia and other countries. The two most prominent Japanese policies and programs were the Elderly Health and Welfare Promotion 10-year Plan of 1989 (commonly known as the Gold Plan) and the mandatory public Long-term Care Insurance Program (LTCIP), started in 2000. The primary purpose of the Gold Plan was to expand the capacity of services for older adults, focusing on the development of home- and community-based care services and, to a lesser extent, to expand facility services to reduce the burden on family caregivers. The primary beneficiaries of the LTCIP are adults age 65 and older who become eligible for services once their service need level is determined. Of particular interest is the inclusion of the Welfare Equipment Rental Program (WERP) in the LTCIP, the first nationally administered assistive device rental program directly linked to older, home-residing beneficiaries. Other government programs also make assistive devices available, although Ohashi (2014) notes that accessing these programs can be confusing and difficult for older adults who had not used them previously, and they rarely take advantage of these programs.

The WERP was the first large-scale national program specifically designed for the older population in Japan. The program rents out assistive devices in 13 categories (e.g., wheelchairs, walkers, and hospital beds) to program beneficiaries who have met the care-need criteria. The monthly out-of-pocket cost of renting a device is either 10% or 20% of its commercial rental cost, depending on the beneficiary's income. Today, this rental program requires a plan of use to accompany each rental agreement to ensure that the appropriate device is provided and properly used to preserve and enhance the user's residual functional capacity. (Ohashi,

2013) The Association for Technical Aids (ATA) has initiated a training program for assistive device planners who work with beneficiaries to develop individualized assistive device use plans, and roughly 13,200 planners had been trained through 2015.

A concern raised about the WERP is that it does not offer individual rentals to beneficiaries living in residential facilities. The LTCIP provides a lump sum to these facilities, which, in turn, purchase assistive devices as a part of the standard equipment shared by their residents. Although the facilities are free to purchase devices that meet the functional needs of each individual resident, little economic incentive exists under the current reimbursement system to provide individually fitted assistive devices. As a result, the facilities tend to purchase the more cost-effective, one-size-fits-all devices. This funding mechanism is a carryover from the pre-LTCIP days, and Ohashi (2014) points out that because of this funding mechanism, the need for individually fitted assistive devices has not been met for many residents in care facilities.

Despite the limitations described above, the WERP is considered the primary mechanism to make assistive devices accessible to older adults in Japan. Although the process of adding innovative assistive devices to the WERP list of available rentable items has been slow, recent changes to the review process may expedite the listing of devices in the future.

Economic Recovery. Since the end of WWII, the Japanese economy has experienced remarkable growth, followed by contraction and slow recovery. The 70-year history of the post-WWII economy can be characterized in three phases (1) economic recovery following WWII, leading to a high growth rate (1945 to the early 1970s); (2) becoming a leading industrial power and then moving into an overheated state known as the bubble economy (mid-1970s to mid-1990s); and (3) a prolonged period of deflation, stagnation, and slow recovery (mid-1990s to the current time). Today, many are concerned about the economic future of Japan in an environment of intensifying international industrial competition while the nation is experiencing both an increasing older population and overall population decline.

Japan's current policies and programs for major economic revitalization were first initiated in the 1990s, and there have been renewed efforts since then to update these policies and programs, as exemplified in the Strategy for Japan's Revitalization. (The Prime Minister's Office, 2013) An interesting recent elaboration upon this strategy involves the Society 5.0 vision, where Japan would be able to solve a wide range of societal needs and create a "society centered around human beings where they live comfortably . . . and pursue active life," by mobilizing cyber technology. (Japanese Business Federation, 2017; Cabinet Office of Japan, n.d.*a*) The Japanese government has started implementing tasks aimed at this vision, including (1) establishing program leadership at METI; (2) removing administrative barriers among the ministries and agencies; (3) encouraging collaboration among industry, academia, and government; (4) establishing fewer regulations that stifle development; (5) providing large-scale governmental investment; (6) promoting open innovation; (7) partnering with foreign companies and organizations; and (8) recruiting talent globally. It is important to note that some of these tasks may not be easy for Japan, with its history of success through strong internal bonding and emphasis on its uniqueness. After all, it was not long ago when Japan was both admired and ridiculed as “Japan Inc.” Nevertheless, these tasks highlight Japanese ambition to become an international powerhouse again in robotics in general, and specifically in the AT field, with special attention to the country’s aging population.

International Influence and Trade Barriers. Japan has a strong tradition of incorporating important, interesting, or useful aspects of other developed countries into the fabric of Japanese society, often with substantial adaptations. Innovations in AT are no exception, and this explains how some AT innovations in both technology and policy got started in Japan.

In 1993, five years after the passage of the Tech Act in the United States, Japan passed similar legislation called the Social Welfare Device Law to promote innovations in assistive devices. The influence of the Tech Act on the subsequent Japanese legislation is undeniable, as Japanese policy-makers recognized the U.S. approach as a solution for both its aging population and struggling economy. At the same time, the new Japanese law incorporated several new features specifically addressing the unique circumstances in Japan, such as (1) focusing on the AT needs of the aging population; (2) emphasizing the importance of interagency collaboration between METI and the Ministry of Health, Welfare, and Labor (MHWL); and (3) adding assistive devices as a focus area of NEDO.

Another important influence relates to the presence of a trade barrier caused by the way Japanese handle assistive devices differently from other countries, especially the European Union (EU), the United States, and China, which represent huge potential markets for Japanese AT in the future. These countries are similar in that they all treat assistive devices as medical devices and require formal approval before allowing marketing of the devices in their countries. This approval process often requires applicants to submit detailed efficacy and safety data as a part of the application packet. In contrast, Japan does not require such data for domestic marketing, and data on product efficacy and safety become necessary only when the product is marketed in countries where new assistive devices must be approved first. The data requirements for assistive devices in the EU, United States, and China are summarized below:

EU. In the EU, all assistive devices must first obtain a registration for medical devices called a "CE Mark," as required by a binding agreement among member nations. (Pelkmans, 1987) Depending upon the risks involved, CE Mark applicants are required to provide one of several levels of clinical and safety data to vouch for their product's efficacy, safety, and practicality. This requirement, in turn, promotes further development and enhancement of new product research, testing, and evaluation capacities. Of particular interest is the pioneering user-driven innovation method, where product users are involved with product planning through final clinical tests. The innovative products developed using this method are considered highly desirable because they are presumed to be closely aligned with the realistic needs of users. Denmark and Sweden, two of the leading nations promoting this approach, have supported promising user-driven innovations from around the world, including Japan. (Development Bank of Japan [DBJ], 2014; Organization for Economic Co-operation and Development [OECD], 2012)

United States. The American market is considered potentially the most profitable destination for care robots and other innovative assistive devices. However, to market an assistive device in the United States, it must first receive approval as a medical device from the Food and Drug Administration (FDA). There are three classes of approval, with the highest-class approval designated for high-risk devices. Normally, innovative assistive devices fall into the medium-level approval range, and such applications are often required to be accompanied by extensive clinical and production data. In addition to FDA approval, being included on Medicare's Durable Medical Equipment (DME) list is considered highly desirable. Medicare is a federal health insurance program primarily for adults age 65 and older, and the program pays 80% of the costs of approved DMEs. One caveat is that increasingly, a specific DME becomes available to beneficiaries only when it is on a list of equipment sellers who won competitive contracts from Medicare. To secure a coveted place on this list, it has become important to establish the product's desirability through ample supportive data prepared by a reputable third-party organization, preferably American.

China. The Chinese regulatory environment is similar to that in the United States and EU in that it also considers assistive devices as medical devices and requires approval from the China Food and Drug Administration (CFDA). While the CFDA application process is especially challenging for foreign applicants because of its complexity, the potential importance of the Chinese market, particularly in the coming years, is undeniable.

Japan has not changed its regulatory policy for assistive devices (except for hearing aids, which are now considered medical devices). In fact, some recent reports note that this Japanese approach (i.e., absence of regulatory control for assistive devices) has helped Japanese companies expedite the process of developing and marketing their new assistive device products. (Mouri, 2016*a*) Nevertheless, the importance of compiling data on a product's efficacy, safety, and practicality through clinical testing, as a part of the product development process, has been recognized, not only for marketing purposes, but more importantly, as a responsible practice for manufacturers to follow. In particular, the user-driven innovation approach, as it is practiced in countries like Denmark and Sweden, seems to be gaining traction. (DBJ, 2014)

Policies and Programs to Promote AT Innovations

Shortly after the passage of the Welfare Device Law, the Japanese government implemented the Program to Support Practical Application of Assistive Devices for Solving Challenging Issues (shortened as SPAAD in this article) in the 1993–1994 period. (NEDO, 2017*a*; NEDO, 2017*b*) Based on the premise that public-sector support is essential because of the high business risk and low profit margin associated with AT research and development, especially for smaller businesses, this program was conceived to provide subsidies to promising innovation projects of up to $200,000 per year for 3 years (based on the exchange rate of $1 US = ¥100 used throughout this article). Many, but not all, of the projects that have been funded under this program involve robotics and assistive devices specifically designed for older adults. According to NEDO (2017*b*), this program is still in place, and as of 2016, subsidies have been provided to a total of 222 projects, with roughly half of them (107) commercialized, as shown in Table 1. However, only 5% of total projects have reported commercial success so far.

Table 1. Summary of Innovation Projects Funded by NEDO (Through 2016)

Year	Applications		Subsidies (Unit: $ Million)	Status	
	Applied	Accepted		Marketed	Profit Reported
1994	118	19	2.88	0	0
1995	77	9	1.78	4	0
1996	128	13	1.67	8	1
1997	123	13	1.95	6	1
1998	123	15	2.06	13	1
1999	158	20	2.42	10	2
2000	183	21	2.43	6	0
2001	129	10	2.44	10	2
2002	121	10	1.57	7	1
2003	115	5	0.88	9	0
2004	131	10	1.14	4	0
2005	77	5	1.29	4	0
2006	43	5	1.5	4	1

Year	Applications		Subsidies (Unit: $ Million)	Status	
	Applied	Accepted		Marketed	Profit Reported
2007	34	5	1.07	2	0
2008	56	7	1.03	1	0
2009	45	4	0.93	2	0
2010	75	11	1.01	3	0
2011	29	11	0.54	4	1
2012	45	7	0.52	4	0
2013	58	7	0.33	4	0
2014	34	7	0.90	3	0
2015	33	3	1.15	0	1
2016	38	3			
Total	**1,973**	**222**	**31.49**	**107**	**11**

Source: NEDO (2017): 2017 SPAAD Plan

Early on, the Japanese innovation effort was concentrated in the areas of basic research and infrastructure development, attracting little public attention. The first robotic assistive device introduced to the domestic market was My Spoon in 2002, designed to help people with upper limb disabilities feed themselves by operating a joy stick. By the mid-2000s, new robots developed by some of the nation's most promising young "robot doctor" entrepreneurs began to emerge in the marketplace, attracting much media and public attention.

The government also stepped up its activities with the 2011 announcement of the Action Plan for Major Policies on Science and Technology by the Council for Science and Technology (CST), which later changed its name to the Council for Science and Technology Innovation (CSTI). The CST/CSTI is composed of the Prime Minister, cabinet ministers, and leading academics and experts and serves as the nation's control tower for science and technology policies. The Action Plan included the development of assistive devices with a focus on devices that can be operated easily by older adults and those with disabilities and that can help reduce the physical and mental burdens on family and professional caregivers. This part of the Action Plan was intended, by 2020, to (1) slow the growth of older adults needing caregiving; (2) increase opportunities for participating in community activities among older adults and people with disabilities; (3) reduce the caregiving burden while increasing the quality of care; and (4) enhance international economic and industrial competitiveness. In summary, the Action Plan included clarifications of the goals and expectations of assistive devices in achieving these goals. (CST, 2011)

Table 2 lists the most notable recent projects intended to (1) develop care robot safety features and safety evaluation methods; (2) strengthen clinical trial capabilities by linking care robot developers and long-term care facilities; (3) identify priority areas for care robot development; (4) provide subsidies to developers in priority areas and improve evaluation methods; (5) establish a national contest to identify projects focused on inexpensive care robot development; and (6) provide subsidies to long-term care facilities to purchase care robots.

Table 2. Recent Programs Designed to Promote Innovations in Assistive Devices

Projects	Content
Practical Applications of Assistive Devices and Care Robots	Started in 2009 to provide $60 million over 5 years to establish safety evaluation methods and develop care robots incorporating safety features.
Supporting Practical Applications of Assistive Devices and Care Robots	Started in 2011 with an annual budget of $8.3 million to support activities linking developers and LTC facilities and to conduct surveys and clinical trials. Consultation services by professionals started in 2013.
Identification of Priority Areas in Long-term Care Applications of Robot Technology	Beginning 2012, identified (1) transfer assistance; (2) mobility support; (3) toileting assistance; and (4) monitoring devices for dementia patients as focus areas for robot technology applications. In 2014, bathing assistance was added to the list.
Developing and Incorporating Robotic Devices in Long-term Care	Started in 2013 with an annual budget of $30 million to provide subsidies to companies and research organizations engaged in developing care robots in the focus area listed above. Also included was a project to cultivate an environment suited for evaluating the effectiveness and safety of new care robots.
5-Year Plan for Developing Care Robots	Adopted by the Cabinet in 2013 to conduct an annual national contest for developing inexpensive and marketable care robots. Also announced was early implementation of safety standards.
Subsidies for Care Robot Purchases	Started in 2014 to expand the market for robotic care devices by providing $500 million to help LTC facilities. Simultaneously, large-scale evaluation projects were planned at facilities using the robotic care devices purchased with funds from this program.

While innovations in assistive devices have never been limited to the application of robotic technology, the emphasis has always been on care robots, and in the 2013 5-year Plan, METI and MHLW jointly prioritized five types of care robots for development and market expansion as a component of Japan's larger revitalization strategy, as shown in Table 3. The table also shows the number of the projects supported by this program as of 2017. The types of support rendered by the program depend on need and range widely from technology application and clinical data collection to marketing strategy development. (METI, 2017*a*; METI, 2017*b*; MHLW, 2013)

Table 3. Care Robot Categories under Assistive Robot Development 5-year Plan

Equipment Type		Purpose	Conditions for Subsidies	Subsidized Cases and Examples
Transfer Assistance	Wearable	Assist transfer to/from bed, wheelchair, or commode	• Reduces caregiver load • Caregiver can put on without help	Approved cases: 5 Example: HAL® by Cyberdyne Co.
	Non-wearable	Assist transfer to/from bed and wheelchair	• Caregiver operates without help • Hanging type lift not included	Approved cases: 8 Example: SASUKE by Muscle Actuator Motor Co.
Mobility Support	Outdoor Use	Support outdoor walking and shopping	• User can operate without help • Supports maintaining walking ability • Safe power-assist on slope	Approved cases: 12 Example: RT.2 by RT. Works Co.
	Wearable Outing Assistance (2017 addition with no further information available)			
	Indoor Use	Support indoor activities (especially toileting)	• Supports maintaining walking ability • Operable by user or with no more than one person assisting • OK to combine with other devices	Approved cases: 7 Example: Cuddling Robot by Sanyo Homes Co.
Toileting Support	Disposal	In-room disposal of excretion	• Can be set up in a room • Prevents smell dispersion into the room	Approved cases: 10 Example: Wrappon by Japan Safety Co.
	Self-care Assistance for Toileting (2017 addition with no further information available)			
Bathing Support		Support getting in/out of bathtub	• Operable by bather or with no more than one person assisting • Can be removed when other family members bath • No renovation involved	Approved cases: 5 Example: Wells by Sekisui Homes Techno Co.
Monitoring	Facility Use	Monitors multiple residents simultaneously and alerts care providers when intervention is warranted	• Information sharing function among care providing team members • Operable 24/7 • Can be linked to other equipment and software	Approved cases: 21 Example: "non-touching, non-restraining monitoring bed" by Ideauest Co.
	Home Use	Platform for home use to	• Can monitor multiple rooms simultaneously	Approved cases: 14 Example: Imairumo

Equipment Type		Purpose	Conditions for Subsidies	Subsidized Cases and Examples
		monitor and alert for falling accidents at home	• Can be used in bathroom and dark rooms • Can be used by care recipient to alert family caregiver • Can be personalized to reflect care recipient's activity pattern	HI by SOLXYZ Co.
Provider Support	Use of Robotics to Enhance Service Provision (2017 addition with no further information available)			

Source: Nursing Robot Portal Site (2017): List of Robots

According to information available from The Japan Agency for Medical Research and Development (AMED, 2017), 68 care robot development projects received funding and support from the 5-year Plan. Of these, 11 are now commercialized in the market place, as shown in Table 4.

Table 4. List of Commercialized Care Robots Supported by Robot Care 5-year Plan

Priority Area	Product	Company
Wearable Transfer Assistance	HAL® Lumber Type for Care Support	CYBERDYNE Co.
	Muscle Suit Care Type	Kikuchi Seiskusho Co.
Non-wearable Transfer Assistance	Transfer Assistance Hug T1	Fuji Machinery Co.
	Rishone Plus (integrated electric bed/wheelchair)	Panasonic AgeFree Co.
	Robohelper Sasuke	Muscle Actuator Motor Co.
Outdoor Mobility Support	Robot Walker RT.2	RT. Works Co.
	Robot Walker Flatia	Kawamura Cycle Co.
Toileting Support	Portable Flush Toilet Kyuretto	Aron Chemicals Co.
Monitoring System for Care Facilities	Three-dimensional electronic mattress monitoring system	Noritsu-Precision Co.
	Silhouette monitoring sensor	King Securities Co.
	Owlsight monitoring system	Ideaquest Co.

Source: METI (2017): [METI/AMED Project to Promote Care Robot Development and Use: A list of Commercialized Products]

As new products started to appear on the market, regulators and developers increased their awareness of the need to address safety and efficacy issues. As discussed earlier, this was deemed necessary for expansion to the global market. Around the same time, the public's concerns over safety was heightened following the reports of injuries and deaths among older adults while using assistive devices. Although those cases were not directly caused by care robots or other new innovations, the public started demanding better accountability. The steps taken in response include (1) METI initiating the Assistive Device-specific Japan Industrial Standards (JIS) Mark program in 2008; (2) MHLW partnering with ATA to conduct the Project for Clinical Evaluation of Assistive Devices; and

(3) NEDO collaborating with other nations to establish ISO13482, the first international safety standard for personal care robots. (Aizawa, 2014; MHLW, 2017)

Both JIS Mark and the Project for Clinical Evaluation are voluntary testing programs. Unlike the international standards for other products already in place, ISO13482 is mostly qualitative rather than involving the quantitative testing of products, partially due to the newness of the field. For this reason, the reputation and credibility of the testing agency are important for confidence in the safety of the product. Two of the four case examples presented in this article, HAL® and RT.2, were among the first recipients of certification under ISO13482.

The national policies and programs in Japan have also impacted local policy and program development. Of special interest are two regional/municipal participants in the Comprehensive Special Zones for Local Revitalization Program: the Sagami Robot Industry Special Zone and the Okayama New Health Care Special Zone. Special zones are designated by the national government to implement pioneering initiatives that are designed to improve local conditions in a specific way envisioned by the locality. Once designated, special zones receive special privileges, such as regulatory exceptions, tax exemptions, and fiscal allocations for goal attainment. Sagami and Okayama are noteworthy because they have incorporated the promotion of assistive device innovations into their respective project scopes. (Cabinet Office of Japan, n.d. *b*)

The Sagami Robot Industry Special Zone implemented a rental program for innovative assistive products in 2010 to help expand their use in residential care facilities in the region and, at the same time, support local companies developing care robot products. Initially, seven assistive robots were selected for the rental project, including HAL® and Paro (discussed later in this article). In 2011, the Kanagawa Welfare Service Association (2011) published a report that included a set of recommendations from 28 participating care facilities, as summarized in Tables 5. Key recommendations were to (1) make the devices more affordable; (2) gain a better understanding of the frontline needs; (3) increase information on safety; (4) make the devices more user-friendly; (5) provide information on cases and use data; (6) reduce the preparation time before devices can be used with new patients; and (7) change the management style to be more open to new approaches. The report noted that some devices were viewed as “unnecessarily ostentatious,” and some interviewed expressed doubt about the appropriateness of “machine-assisted care.”

Table 5. Summary of Responses on Challenges for Introducing Robotic Support

Response Category		Main Concerns	Facilities Responding
Product-Specific Concerns	Cost	Too expensive	21
	Cost performance	• Lacking clearly demonstrated benefits	9
	Functionality	• Not sufficiently finalized as a practical product • Lacking sufficient understanding of the needs in care facilities • Too elaborate and too much preparation time needed for use	9
	Safety	• Not clear if safety is adequately addressed	8
	Ease-of Use	• Required staff time for use	5
General Information	Basic Information	• Too little information about care robot itself	6
	Case Examples	• Lacking information on evidence of utility and case examples	4
Management Attitude		• Lacking funds to invest • Lacking proactive stance to solve challenges facing care workers and clients	6
View toward Care		• Belief that robots cannot care for clients like humans	5

Source: Kanagawa Welfare Service Association (2011): [Report on the Model Project for Promoting Long-term Care and Medical Robots].

Okayama City's goal for its Special Zone project is to make Okayama an age-friendly place to live, and as a part of this effort, the City initiated an assistive device rental project for their older residents in 2014. The primary project goal is to promote innovative assistive devices, including care robots selected by Okayama City, such that they can be added to the list of the LTCIP's WERP, thus making the devices available nationally. The program also includes items from locally-based companies, such as Power Assist Gloves (designed to assist hand-grip by pneumatic power) by Daiya Industries to promote local innovations. In a way, the Okayama program seeks to serve as a trial-run for new promising products, and for this reason, the rental fees are set at 10% of the commercial rental fees, consistent with the national rental program. The city has been compiling and analyzing the findings from user surveys in collaboration with rental device makers, local universities, and the MHWL. Assistive devices are selected for this program by the city, and the monthly rental fees are shown in Table 6. (Okayama City, n.d.)

Table 6. Assistive Devices in Okayama City's Rental Program

Category	Product	Company	Monthly Rental Fee
Bathing Assistance	Shower Onyoku Chair	Sekisui Home	$5.00
Communication Robots	Paro	Intelligent System	$20.00
Hand Assistance	Power Assist Glove	Daiya	$17.00
Medication Assistance	Fukuyaku-shien Robo	Carepot	$15.00
	Okusuri-nondene	Kamiden	$8.00
	e-Okusurisan	Eisai	$10.00
Monitoring	Odayaka Time	F.S.C.	$16.00
Toilet Assistance	Wrappon	Japan Safety	$8.00
Walker	ACSIVE	Nanbu	$10.00
	Kaisoku Walker	Welfan	$3.50
Posture Correction	Trunk Solution	TSC	$14.00
Indoor Ramp	Heartful Slope	Nakashima	$8.50

Source: Okayama City (2018). [Okayama Special Zone Project: Cutting-edge Assistive Device Rental]

According to a report by Okayama City (2016), a total of 52 people, for example, used the program to rent Paro for an average rental period of 6.1 months in the two-year period between 2014 and 2016. The report concluded that a significant degree of reduction in problematic behaviors among the clients was observed by family caregivers. Also, the caregivers reported a reduction in psychological burden of caregiving. Further, the report noted that 32% of the clients discontinued the rental of Paro within the first two months, suggesting the importance of ensuring the device is appropriate for use by the client. For this reason, the report recommended improving the education and assessment process before renting out Paro.

In 2016, RT.2 (no longer available from the Okayama rental program) became one of the first robots to be included in the LTCIP's WERP, giving Okayama bragging rights about its role in securing AT equipment acceptance.

In general, the findings from both Sagami and Okayama, along with several other regions, are preliminary, and it remains unclear which new assistive devices may prove to be successful as commercially viable products. However, the commercialization of these products is progressing, and lessons learned from early innovations are influencing how policies and programs need to be strengthened in the coming years. In 2014, Prime Minister Shinzo Abe convened the Conference for Starting Robotic Revolution and set a domestic sales goal of $500 million/year for medical robots (needing official approval as medical devices) and assistive robots (needing no special approval in Japan) combined. (Honma, 2017) Of this amount, the sale of the care robots was projected to reach $150 million/year. (Mouri, 2016*b*)

Older Adult’s Views

According to the 2016 White Paper on Labor and Welfare by MHWL, 72.7% of older Japanese want to continue living independently in their homes as they grow older (MHLW, 2016), and another survey reports that 68% of older adults favor using assistive devices to make their daily living easier. (Cabinet Office of Japan, 2014) In another survey, this time not limited to older adults, 60% of the survey respondents favored the use of care robots. (Cabinet Government Public Relations Office of Japan, 2014) According to this survey, while the most frequently cited reason for favoring care robots was the expectation for “reducing caregiver burden” (64%), other reasons were associated with the hope of increasing independent lifestyle options, such as “being freed from pleasing caregivers” (42%), “increasing self-sufficiency” (36%), and “preventing physical and mental decline” (21%).

Surveys involving older adults and aging tend to focus on the frailty and economic hardships in later years, and more surveys are needed focusing on older adults’ views and plans toward independent living and the use of technology. It would be especially interesting to capture the shifting views of *dankai-no-sedai* (the Japanese baby boomers born between 1946 and 1949). Like their counterparts in the United States, this age group is known to be better educated, have more professional experience and willingness to explore new ways, and be more comfortable with technological shift. How this generation responds to care robots and other assistive device innovations as they approach their 7th decade is an important factor for the success of assistive device innovations in Japan. Although little information is currently available on this generation’s view toward care robots and other assistive devices, a survey report from the Cabinet Office of Japan (2013) supports this group’s proactive views toward their life and living as older adults.

A noticeable trend is the proliferation of the word “independence” in virtually every program, law, and regulation associated with aging and disabilities in Japan. Although the term is not new, caution is needed in using the term because independence has long been understood in Japan as the responsibility of a young person to become economically self-reliant. In contrast, the concept of independence has been nurtured in the United States and elsewhere as the right of older adults and people with disabilities to live independently. For this reason, experts (Kanbe, 1995; Ohashi, 2014) urge caution when using this term, particularly in Japan, in the context of older adults. Further discussion on the topic of independence is warranted, especially involving older adults themselves, to better understand what assistive device innovations are desirable and how they can be made available to and affordable for older adults.

Examples of Japanese Assistive Device Innovations

The SPAAD played an important role in the development of innovative assistive device products since 1993 (especially in its early days), with noticeable overlaps with the Care Robot 5-year Plan occurring later**.** Approximately half of the projects subsidized through the SPAAD have been commercialized, although only a few have reported profits to date. It is interesting to note that recently a new focus area has been added to this program that targets innovations for “older adults with manageable disabilities” who are experiencing disability-related inconveniences but do not meet the service criteria of the long-term care insurance program. This is an example of the new emphasis on developing assistive devices that are helpful for older adults in maintaining their daily functioning and community living. This recent development is consistent with the global trend, even though some critics have pointed out that there has been no concrete evidence so far that demonstrates the effectiveness of assistive robots in enhancing independent living among older adults and lightening caregiver burdens, according Mouri (2016*a*).

All four case examples discussed in this section (RT.2 , HAL®, Paro, and comuoon) have received technical and financial support through the SPAAD, highlighting the success of innovations involving public-private partnerships. Even though these four examples alone may not depict the entirety of AT development in Japan, each has attracted much public attention and are considered early successes. As the examples illustrate, many (but not all) new assistive devices adopt a name taken from English that seems to reflect a global ambition to convey a new direction away from traditional assistive devices. In this section, the spelling and capitalization of product and company names are those commonly used by the companies in their brochures. All photos used in this section are copyrighted and used with permission of the owners.

RT.2 Of the four examples presented in this article, RT.2, developed by RT.Works, is the most straightforward innovation. RT.2, along with its predecessor RT.1, were pioneers in the field of robotic walkers. Although their designs are different, both models share the same robotic functions, and for this reason, they are sometimes considered the same innovation. (RT.Works, as the Original Equipment Manufacturer or OEM, also provides the robotic component of Little Keypass, a robotic walker sold by another company Kowa.)

© RT. Works co.,ltd. Permission by RT.Works

Rt.2 is a 4-wheel walker with a big shopping basket in front that can serve as a seat. It weighs about 20 lbs. and can be collapsed for transportation. By adding robotic functions to the frame, RT.2 is designed to make outdoor walking easier and more comfortable for those with walking difficulties. Sensors send road information to its control system, which supplies power to the wheels to help users negotiate the ups and downs of streets so that walking is safer and less exhausting. The core robotic technology employed in RT.2 includes (1) a six-axis sensor to gather information on ground conditions and user movement; (2) handle grip sensors to collect information on user movement; (3) a real-time control mechanism responding to information sent from the sensors; and (4) a lithium ion battery as the power source. RT.2, as with RT.1, meets ISO13482, the safety requirement for personal care robots.

Fujii (2017), the lead developer for RT.2, noted that the core technologies used in RT.2 could have easily been applied to a robotic wheelchair instead, but he and his colleagues chose the walker because they liked the idea of a device that helps older adults maintain their ability to walk, and for that reason, they focused their attention on making their walker easy and safe to use and visually attractive. They believed these qualities might give users a sense of independence and confidence.

Additionally, Fujii (2017) noted in an interview with the author that RT.2 is a lighter and more practical version of the previous model, RT.1, with changes made to meet the specifications of the LTCIP. Further, he noted that although he is happy with the overall changes, the requested removal of Internet of Things (IoT) access embedded in the device was a disappointment. The IoT would have enabled RT.2 to automatically send an emergency alert in case of an accident, and it could have allowed daily walking data to be sent to a health care provider, as is the case with RT.1. Further, the walker could have easily checked directions and the weather forecast and even make phone calls without having to reach for a smart phone or iPad.

In the same interview, Fujii stated that the domestic demand for a walker is around 200,000, and sales of 10,000 units would be considered a huge success. However, the current rental total remains 500 to 600 units. (At the time of interview, RT.Works was finalizing an indoor model that would allow a user with walking difficulties to move around indoors rather than using a wheelchair or depending on a caregiver for walking assistance.)

The RT robotic walkers received the 2016 Robotic Award in the category of best small business venture along with the aforementioned Little Keypass. The Robot Award is an honor bestowed on promising development efforts from co-sponsors METI and the Japan Machinery Federation. The award noted, as the reason for selection, RT’s technological competence responding to clearly identified social needs.


© CYBERDINE INC.
Permission by CYBERDINE

<u>HAL®</u> HAL®, an abbreviation of Hybrid Assistive Limb, is a group of wearable robots from the CYBERDYNE Company, and they are perhaps the most talked about assistive robots today in Japan. Unlike RT.2, which had been commercialized in a relatively short period, the history of HAL® development overlaps the entire period of robotic applications in assistive devices in Japan.

HAL® research started in 1991 with the goal of developing an innovative medical device for people with mobility challenges, a primary goal that remains the same today. (CYBERDYNE, 2018) While maintaining his focus on medical devices, Yoshiyuki Sankai, HAL® developer and Professor at Tsukuba University, was able to expand the scope of his work to include the development of assistive devices for the older population. Doing so offered the most favorable environment to pursue his goal of developing HAL®, given the Japanese interest in combining solutions for the aging population and economic revitalization. Multipurpose functionality is the hallmark of HAL®, and the inclusion of assistive device development was well within reach for Sankai. Once HAL® was commercialized in Japan as an assistive device in 2008, Sankai moved quickly to arrange the clinical data collection necessary for HAL® to be approved as a medical device. This strategy worked well for HAL®, and it received approval as a medical device in a very short period, between 2013 and 2017, in Japan, Europe, and the United States.

Sankai claims that HAL® is the first cyborg-type robot in the world. (Lazarte, 2014; Tateyama, 2017) A cyborg robot, unlike a humanoid, does not make its own decisions for action. Instead, HAL® interprets the minds of the wearers from their movements and other information, helping them to carry out their intended actions, such as walking or lifting. As noted above, HAL® was first commercialized as an assistive device, and the rental program started in 2009 by CYBERDYNE, a venture enterprise for production and distribution of HAL®.

A key component of HAL® is a bioelectric signal sensor (BES) that includes electrodes attached to the wearer’s skin for detecting a minute amount of bioelectrical signal as a way of capturing the brain's intention for action, such as walking. HAL® also includes a *Cybernic* control system, which is a hybrid control system that integrates and controls HAL®’s movement. Cybernics is a new discipline founded by Sankai to "integrate human, robot, and information" (CYBERDYNE, 2018), and the use of Cybernic technology allows HAL® to assist human movement smoothly in accordance with the wearer's intention, according to Sankai.

Medical HAL® (Lower Limb Type) is the center of attention today. Treatment using Medical HAL® is based on Sankai's theory called interactive biofeedback, which involves the formation of a closed loop initiated by BES signals and is useful in the treatment of patients with certain types of diseases and related conditions. (Sankai and Sakurai, 2017*a*; Sankai and Sakurai, 2017*b*) Based on clinical trial findings that have demonstrated its efficacy and safety, Medical HAL® is now approved for use as a medical device for neurorehabilitation in Japan, the United States, and some European countries.

CYBERDYNE, along with other participating developers in NEDO's 5-year Plan for Developing Care Robots, is credited in helping the development and publication of the international safety standard for personal care robots, ISO13482. This opportunity also helped HAL® engineers make improvements to HAL®'s own safety features, becoming the first personal care robot in the world to receive the ISO13482 certification. (Furukawa, 2014)

Sankai has become a cultural icon in Japan. His talent and vision have garnered people's admiration as one of the best-known innovators representing the Japanese robotics industry. In 2009, the Japanese government invited him as one of 30 prominent scientists/engineers to participate in the Funding Program for World-Leading Innovation R&D on Science and Technology (or FIRST for short), providing a total of $100 million to share among the 30 participants to pursue their research and development projects identified as most promising. This funding, along with many other governmental funding awards along the way, has financed and boosted HAL®'s ambitious undertaking. Further, in the 2015 White Paper on Science and Technology, HAL® products as group were recognized as one of eight innovations that had impacted everyday life in Japan. (Ministry of Education, Culture, Sports, Science, and Technology [MEXT], 2015) These examples show Sankai's major contributions as one of the most talked-about innovators in Japan.

Today, of all robots, HAL® is probably best known. CYBERDYNE has a network of exhibit halls and showrooms and actively promotes the HAL® brand, attracting not only those who contemplate using HAL® as a medical or assistive device, but also a wide range of visitors and even groups of school children. In 2016, Medical HAL® was awarded the coveted Robot Award in the MHLW Minister category, and in 2017, an insurance company started to feature HAL® in its TV commercials, followed by an announcement of Medical HAL® receiving FDA approval for use in two treatment categories. With these successive attention-getting developments, anticipation continues to increase for HAL®'s commercial success.

Paro Like HAL®, Paro, a communication robot developed with older adults with dementia in mind, is considered an early international success story. Some may even argue that Paro is more successful than HAL® internationally because it has already been tested and used in more than 30 countries. Another similarity with HAL® is that Paro is increasingly pursuing its therapeutic (i.e., medical) potential, using its success as an assistive device as a springboard. The name Paro came from "Paasonaru Robotto," Japanese pronunciation of the term "personal robot."

© Intelligent System Co., ltd. Permission by Intelligent System

Paro looks like a stuffed animal resembling a harp seal baby. It is around 24 inches tall and weighs 5.5 pounds, and by design, it "feels soft and has the weight and size of an easy-to-hold baby," according to promotional publications. Internally, it is a communication robot with "feeling, thinking, and acting" functions. Takanori Shibata, a robotics engineer at the National Institute of Advanced Industrial Science and Technology (AIST), initiated his work with Paro in 1993, the year the Assistive Device Act was enacted. Then, in 2004, he founded a venture company named Intelligent Systems for production, marketing, and maintenance services for Paro. Paro received the coveted Robot Award in the service robot category in 2006, the award program's inaugural year, highlighting the hope it represented for the industry.

The core idea for Paro came from the kinship people develop toward animals, and Shibata proposed that an animal-like robot could be very useful to people with dementia if it can offer the same (or a similar) sense of connectedness with alive animal without the care and challenges real animals demand. In choosing a baby seal as the model, Shibata (2012) used the findings from a psychological experiment showing that people would be more accepting of an animal-shaped robot that is cute but less familiar than the ones that they know well, like dogs and cats. Shibata made sure that Paro is appealing to the visual, auditory, and tactile senses of the person who holds it by incorporating realness (e.g., using the recorded sound of a baby seal) and perceived desirability (e.g., softness of the snow-white fur). To achieve the desired assistive effects and also ensure its safety for users whose physical and mental functioning may have been compromised, close attention was paid to selecting the materials and sewing techniques.

Paro is equipped with several types of sensors, a computer that is twice the capacity of a common laptop, and quiet-type actuators that move seven parts of the body. The battery, once charged, lasts 5 hours. These components are integrated and programmed to approximate how a real pet animal might respond to a human. Paro even has the limited capacity to learn how to respond to certain cues, for example, responding to the name the user gives it.

Initially, Paro was marketed domestically as a pet alternative for older adults who do not have access to pets. Its price was set at around $4,000, taking affordability into consideration, according to Shibata (2012). The idea of using Paro in a setting similar to animal therapy caught the imagination of Danish. Specifically, the Dementia Center in Copenhagen offered Paro a spot in its care robot evaluation project, which received funding from a national project called “Be Safe” during the years 2006 to 2008. Animal therapy, developed in the United States in the early 1970’s, is a therapeutic method based on the idea that interactions between animals and humans are beneficial to humans physically, physiologically, and mentally. Since the 1980s, a number of researchers have published test results that support the efficacy of animal therapy, while some caution that animal therapy needs further structural development before it can be recognized as an established psychological treatment method. (Fine & Beck, 2010; Kruger & Serpell, 2010)

Shibata coined the term “robot therapy” to distinguish therapy using Paro from the animal therapy. The Danish expectation for Paro was high because although animal therapy is well accepted in Denmark, there have been concerns about the high costs and risks associated with using live animals. Paro was thought to have the potential to address these concerns.

The successful experience at the Dementia Center led to a dissemination offer from the Danish Technological Institute (DTI), a highly respected technological research center. However, Shibata and the Dementia Center were concerned about DTI’s lack of experience and expertise in the areas of dementia care and working with older population, and Shibata accepted the offer only after DTI had agreed to (1) recruit the Paro project director from the Dementia Center to lead the DTI project; and (2) partner with Shibata and his group at the AIST in Japan. Based on this agreement, in 2009, DTI embarked on activities to promote and sell Paro in Europe, including expansion to Germany, France, Holland, Scandinavia, and other countries. The joint promotional effort involved convening user conferences, developing training programs for Paro-based therapeutic activities, and building a network of Paro-using therapists and advocates. DTI named the combined activities the “Paro model” and applied the model to help promote other care robots, but these efforts were largely unsuccessful, according to Shibata (2018).

Paro's success in Denmark and other European countries enhanced its potential, and at the same time, it served as a wake-up call for Japan, whose approach to assistive device innovation had been characterized as technology-driven, where the primary motivation comes from developer's application ideas rather than user input, as noted by DBJ (2014). Concerns about the Japanese approach had already surfaced, as indicated in the Sagami report (Kanagawa Welfare Service Association, 2011). The concerns were not specifically directed to Paro, but its experience in Europe and later in the U.S. served as a catalyst for increasing Japanese awareness of the need for better data on the device's efficacy, safety, and practicality to make it more marketable. It was also instructive that even a highly regarded organization such as DTI in a country with advanced social welfare programs can benefit from the capacity-building brought about by the Paro project. Under Shibata's leadership, since 2012, AIST has hosted nine international symposia in Japan with professionals and practitioners interested in Paro and robot therapy, and it has expanded its scope to include children with learning disabilities and disaster survivors, such as those who experienced the historic 2011 earthquake and tsunami.

It has already been pointed out that with care robots and assistive devices the safety and practicality factors are just as important as the use of cutting-edge technology and eye-catching newness. From this perspective, it is interesting to note that the level of AI used in Paro is "appropriate" rather than cutting-edge. The Danish Council of Ethics (2016) has noted that high-powered AI is not necessarily required to create an emotional bond between human and robot, using Kismet (developed by MIT) and Paro as examples. The Council has also pointed out that the ethical questions raised in reviewing communication robots like Paro involve (1) whether the robot enhances or replaces human involvement; and (2) the nature of therapeutic benefits based on "deception." Recognizing that (1) risks always exists even when replacing human involvement is not intended, and (2) not all "deceptions" are bad or unethical, the Council recommended that Paro be used under the guidance of a responsible individual (care provider or caregiver) who is capable of protecting the dignity of the user.

Today, according to Shibata (2017), 5,000 Paro devices are in use in over 30 countries. In the U.S., the FDA approved Paro as a Class II medical device for symptom-management of people with dementia as well as for treating depression and pain. It is also approved for use in rehabilitation of stroke victims. Medicare and some private insurance cover biofeedback therapy with Paro, with a doctor's prescription. (In biofeedback therapy, the patients learn how to utilize their mind to alleviate headaches, pain, and other physiological and physical problems and has been gaining popularity in the United States.) The findings from a randomized controlled trial (RCT) using Paro at the University of Texas concluded that Paro was effective in the management of problem behaviors among patients with dementia. The same study also reported that Paro was effective in reducing the use of pain medications. (Peterson et al., 2016) Further, the cluster-RCT by Jones et al. (2018) found Paro effective in controlling low to moderate agitation episodes, and another cluster-RCT by Jøranson et al. (2016) reports a decreased need for using psychotropic medication. Lane et al. (2016) also found less need for medication in an 18-month study conducted among 23 veterans in a United States Veterans Admiration long-term care facility. Currently, the Chinese University in Hong Kong is conducting an RCT on Paro-based symptom management in cases of older adults with dementia. (Yu et al., 2015)

© universal sound design inc.

Permission by universal sound design

comuoon Although care robots are at the forefront of Japanese efforts for innovation in assistive device, other types of devices are also being developed. For example, a new listening device called comuoon focuses on improving the hearing environment by being placed at locations where important daily conversations take place. With comuoon, the innovation is in sound technology. According to Shinichiro Nakaishi (2017), the comuoon developer, the device is especially useful for older adults with presbycusis, a hearing impairment that is one of the most common age-related functional declines. The unusual name, comuoon, was made up from two English words, communication and cocoon, with the first letter “c” un-capitalized, according to Nakaishi (2017).

The comuoon unit is a two-part system that includes a small, vertical, microphone and an equally small, egg-shaped speaker. On a desktop, the microphone is positioned in front of a person with normal hearing, and the speaker faces the person with presbycusis. For example, at a doctor's office, the microphone should be placed directly in front of the doctor, and the speaker should face directly toward the patient. This configuration secures the most efficient collection and delivery of spoken words to the person with presbycusis, and thus, increases the likelihood of successful communication between the doctor and patient, Nakaishi (2017) notes. Other use locations may include clinics and hospitals, the customer windows at banks and government offices, the living room at home, or a classroom at school. The device can even be installed in a taxicab to aid driver-passenger conversation.

The central feature of comuoon is a small, innovative speaker that delivers clear sound to the listener during face-to-face conversation. This is achieved by reducing the use of noise-causing glue, incorporating a honey-comb shaped vibration plate capable of reproducing better conversation-range sounds, recessing the position of the vibration plate to prevent sound scattering, and providing an egg-shaped inside wall that reduces sound distortion. These features allow sounds that are loud and clear to be delivered to the person with hearing impairment but not to others in the vicinity. This is a departure from the concept behind hearing aids, which is to make incoming sound primarily by making it louder but not necessarily successful in making it clearer. Nakanishi's innovation focuses on reproducing clear sound.

The issue of hearing impairment among the older population is especially relevant in Japan. Ohashi (2014) points out that "Japan has neglected to support people's right to adequate hearing" because it has failed to designate the hearing aid as a medical device requiring personal fitting by trained professionals, and it does not provide a financial assistance program for hearing impairment, as the United Kingdom and some other countries have done. Ikeda (2017) notes that these factors have resulted in the low utilization of hearing aids in Japan and the equally low satisfaction rates among users. Japan started to ameliorate this problem in 2017 by adopting revisions to the Drug and Medical Device Law, designating hearing aids as medical devices for the first time. Masuda (2017), however, points out that even with a pair of well-fitted hearing aids, people with presbycusis hear only on average about 70% of the words spoken to them.

Recognizing the challenge of addressing the technical and social issues regarding hearing aid use, Nakanishi developed comuoon as a new approach to improve hearing by stepping away from the hearing aid and improving the hearing environment. Relieved from the constraints of the hearing aid, this new approach allowed Nakanishi to concentrate on reproducing clear sound in a way that he believes has not been accomplished with conventional hearing aids. (Nakaishi, 2017) His approach of seeking an environmental solution to disability is consistent with the ICF direction. Further, the primary focus on people experiencing minor to moderate hearing problems (in the range of 20–70 dB) is consistent with the recent Japanese government direction of paying closer attention to assistive devices that are useful for older adults with minor to moderate disabilities. Interestingly, Nakanishi noted during his 2017 interview with the author that his most recent development activities involve a new-generation hearing aid incorporating comuoon innovations. He indicated that when this developmental work is completed, people will have the option of relying on comuoon in the environment, wearing the new generation hearing aid, or using both, depending upon the degree of their hearing impairment.

While data supporting the efficacy and practicality of comuoon are still limited, the Tokyo Metropolitan Industrial Technology Research Institute (2016) conducted a sound pressure test and concluded that the comuoon speaker was superior in increasing the volume of conversation range sound (1000 Hz to 2000 Hz). And a study team from Kyushu University reported improvement in the mild-to-moderate range, hard-of-hearing outpatient population when they engaged in conversation using comuoon. (Noda et al., 2015) The most recent finding is from a magnetoencephalographic study that showed improved sound intelligibility when hearing-impaired study participants using comuoon heard easy-to-confuse pronunciations. The study, conducted by the Hearing Rehabilitation Study Group at Hiroshima University's Space Regenerative Medical Center and published in the NeuroReport journal, demonstrated the importance of sound clarity in improving conversational hearing. Based on these findings, Nakagawa et al. (2017) concluded that improving sound intelligibility using comuoon is beneficial to the hearing-impaired. Comuoon is currently in use in a study at a dementia group home in Japan to improve conversational frequencies among its residents with auditory impairment. If proven useful as a rehabilitative tool, the door may open for medical use, like HAL® and Paro.

Discussion

In Japan, 40 years have already passed since concern about the issues of an aging society first surfaced. When one looks back on this passage of time, it is hard to overlook the way Sawako Ariyoshi's 1972 bestseller, Koukotsu-no-hito (the title of its English translation is The Twilight Years), symbolized the public's focus on the plight of the daughter-in-law, the designated caregiver in traditional Japanese families. At a time when derogatory terms were used to describe the condition we now call dementia, the novel brought awareness and empathy to this illness, but more poignantly, it brought attention to the question, "who is going to care for them?" Then, in 1995, another bestseller, Kouraku, by Shuichi Sae, depicted the social confusion and fear appearing after traditional caregiver assumptions began to fall apart.

At about this same time, the Japanese government became very concerned about the country's future economic outlook. For example, the once-dominant Japanese industrial robot sector was starting to face serious competition from an increasing number of countries, and that affected the competitiveness of other major sectors, such as automobiles. Facing these challenges, Japan decided it was in its best interests to maintain its robot leadership and to work to assume a pioneering role in the up-and-coming service robot sector. The resulting Japanese service robot development strategy was multifaceted but included the importance of developing the care robot in meeting the caregiving needs of the older population. While the idea of applying advanced technology to innovate assistive devices had already been established in the United States five years earlier, choosing the aging population as the focus of its effort reflected Japan's domestic priority and formed the foundation for subsequent development.

The innovation activities focusing on care robots have been consistently led by the Japanese government since the enactment of the Welfare Device Law in 1993. The main features of this effort included linking the needs of an aging society with economic revitalization, promoting inter-ministry collaboration between METI and MHLW, and clarifying NEDO's active involvement, and these features continue as the programmatic framework today.

Initially, the care robot development effort was led by METI and robot engineers, with relatively limited influence from MHLW. METI's active involvement brought new resources and talent to the field of assistive devices, even though their understanding of the needs for assistive devices among the growing numbers of older adults and their caregivers was sometimes lacking. The critics labeled Japan's effort, especially in its early days, as technology-driven, with the primary focus on the application of robotics to create a new industrial venue.

Japan's developmental efforts were aided by its unique regulatory environment, where assistive devices are not subjected to the regulatory approval process, as are medical devices. This lax approach allowed assistive device innovators to expedite the development process, sidestepping the need to compile and publish data on efficacy, safety, and practicality, thereby saving time and money. However, in the case of Paro, Shibata and his colleagues have been placing an emphasis on collecting and publishing clinical data from early on in its development (Shibata, 2001; Saito, 2003; and Shibata, 2003). As innovations in assistive devices proliferate today, the experiences gained by them and others will be invaluable in developing a new process whereby consumers of assistive devices can be assured of their quality and benefit.

The need for collecting clinical data became apparent in the mid- to late-2000s. This is when the initial attempt was made to launch promising Japanese care robots into the global marketplace, first into the EU market, where a new assistive device must first receive a CE Mark as a medical device before it can be marketed. Marketing in the United States and China, two of the other major trading targets for the care robot industry, also required data collection because these countries also handle assistive devices as medical equipment and require governmental approval prior to marketing.

Facing this challenge, Paro had a lucky break, which was receiving an invitation from the Dementia Center in Copenhagen, Denmark, to participate in its care robot evaluation project, funded through the national Be Safe project. As a communication robot, Paro embodied Japanese creativity, sensitivity, and product quality, and the Danes quickly saw its potential as a therapeutic tool for older adults with dementia. This collaboration was highly successful, leading to a partnership with the highly regarded DTI that served as a focal point for establishing Paro as a therapeutic tool and increasing its brand recognition internationally. The arrangement was mutually beneficial for DTI, which gained valuable experience in working with the older population and dementia. However, the DTI's efforts to apply these methods to promote other care robots likewise has not been very successful.

The systemic implications presented by the overseas experiences of Paro and other care robots include (1) the value of collaborative partnerships with established research and evaluation organizations overseas to explore and secure marketing options; (2) the need to develop domestic assessment and evaluation capacities specifically targeting assistive devices; and (3) the timeliness of reevaluation of the technology-driven paradigm. The value of collaboration with overseas partners has been well recognized, and the trend to maximize the benefits of such collaboration is expected to continue and grow.

The most important outcome of the overseas experience with Paro and other care robots is recognition of the importance of developing domestic capacity to assess and evaluate the efficacy, safety, and practicality of the care robots and other new assistive devices. Consequently, since 2009, the national government has implemented a number of programs to promote and support data capacity building activities in collaboration with a wide range of organizations. These activities include developing evaluation methods at universities and research institutes, publishing voluntary standards focusing on the efficacy, safety, and utility of assistive devices, training evaluation professionals, and building new testing and evaluation facilities. The infrastructure for testing and evaluation, when fully developed, is envisioned to support a balanced approach to product development for assistive devices, benefitting both domestic users and overseas marketing initiatives.

Japan's extensive involvement in publishing the ISO13482 standard for care robots was intended to help Japan become an important destination for testing and evaluating the effectiveness and safety of new assistive devices, especially care robots. However, one obstacle for Japan in assuming this role has been the Japanese regulatory policy of separating assistive devices from medical devices, a distinction not practiced by other countries. Revisiting this policy is important for marketing considerations, but more importantly, because differences between the two types of devices have become increasingly murky, as demonstrated by the medical and assistive device versions of HAL®. Currently, however, there is little such discussion in Japan. Instead, the current strategy attempts to close the regulatory gap between Japan and other countries by instituting a series of voluntary standards by various organizations. It is yet to be seen whether this approach will work.

As the role of clinical testing and evaluation expands, so does the role and responsibility of MHLW in this and related areas to ensure that the effort and resources being poured into the development of care robots and other assistive device innovations result in making assistive devices more user-friendly, safe, and affordable. Especially, in the coming years, the WERP under the LTCIP will increase its role as the primary venue for care robot domestic distribution. Japan has already added five innovative products to the approved assistive device rental list—a toileting assistance device in 2012 and four robotic walkers, including RT.2, in 2016. The effectiveness of the WERP as a venue for new products will depend on the timeliness of the review process, which still needs much enhancement. The WERP also needs to be extended to older adults residing in the facilities to ensure they have the equal access to individually selected and fitted assistive devices, including care robots.

The roles the municipalities and local organizations have played are important, too. In addition to the two special district projects in Sagami and Okayama, a number of other cities and their partners have started their own programs to promote the use of care robots and collect user feedback. Unfortunately, the collection and dissemination of these data seem to lack coordination and, as a result, these efforts do not seem to cumulate effectively. Thus, it is important to further improve the coordination of collecting and sharing feedback from users.

This raises a fundamental question about the intended users and beneficiaries of innovations in care robots and other assistive devices. Historically, the primary burden of societal aging has been placed on the caregiver, particularly in Japan. As mentioned, Japan's focus was initially on the plight of family caregivers, and later, as professional care expanded, the concern began to shift to the physical and mental stress of the care workers. The timing of the care robot development in its early days roughly overlapped this period. Thus, it was natural to expect the focus of assistive device innovations, including care robots, to be on reducing care worker's physical and mental stress.

More recently, the policy focus has shifted again. Today, an increasing emphasis has been placed on policies and programs that are supportive of the independent living of older adults in the community. This emphasis is the reflection of many factors discussed in this article. Yet, in Japan, as some experts have pointed out, the concept of independent living is not necessarily clearly understood as a right older adults are entitled to or should expect. This may explain why today relatively little effort is evident to actively engage older adults having minor functioning issues with the process of developing care robots and other assistive device innovations. In this regard, a good starting point for Japan would be a thorough review of the user-driven innovation practiced in northern European countries, such as Denmark and Sweden, followed by Japan's unique contributions, as has been Japan's practice in the past with innovations originating overseas.

Conclusion

The Japanese government has led a national effort over the past 25 years to promote assistive device innovations centered around the development of care robots, under the premise that these devices can help solve the societal aging challenge while contributing to the restoration of national economic vitality. This article described the care robot's unique history in Japan, examined the factors that have influenced the course of development, and considered how these efforts may ultimately help Japan attain its dual goals. Today, Japan is in the process of rolling out the fruits of these initial efforts, with the four assistive innovations introduced in this article showcasing the breadth of ingenuity and technological strength of the Japanese effort. However, it is still unclear if these or other currently available devices will prove to be successful in the long run and able to contribute to one or both of the goals of aiding societal aging and the economy. The only certainty is that the future of older adulthood can no longer be imagined without the presence of care robots and other innovative assistive devices.

References:

Aizawa, K. (2014). [On JIS Mark for assistive device]. Retrieved January 15, 2018, from hcrjapan.org/hcrnews/pdf/2009-02/p2.pdf

Ariyoshi, S. (1972). [Kokotsu no Hito]. Tokyo, Japan: Shincho Bunko.

Cabinet Government Public Relations Office of Japan. (2014). [*Summary report on special survey on care robots*]. Retrieved December 2, 2017, from https://survey.gov-online.go.jp/tokubetu/h25/h25-kaigo.pdf

Cabinet Office of Japan. (2013). [*Director General's report on survey of views of Japanese baby boom generation*]. Retrieved June 15, 2018, from http://www8.cao.go.jp/kourei/ishiki/h24/sougou/zentai/pdf/cover-list.pdf

Cabinet Office of Japan. (2014). [*The Survey on older adults' views toward daily living*]. Retrieved December 2, 2017, from www8.cao.go.jp/kourei/ishiki/h26/sougou/zentai/index.html

Cabinet Office of Japan. (2017). [*The 2017 White paper on aged society*]. Retrieved May 29, 2018, from http://www8.cao.go.jp/kourei/whitepaper/w-2017/html/gaiyou/s1_1.html

Cabinet Office of Japan. (n.d.*a*). Realizing Society 5.0. Retrieved May 1, 2017, from https://www.japan.go.jp/abenomics/_userdata/abenomics/pdf/society_5.0.pdf

Cabinet Office of Japan. (n.d.*b*). Comprehensive Special Zones. Retrieved November 11, 2017, from http://www.kantei.go.jp/jp/singi/tiiki/sogotoc/siryou/gaiyoueng.pdf

Campbell, J. C. (1992). *How policies change: The Japanese government and the aging society.* Princeton, NJ: Princeton University Press.

Council for Science and Technology (CST). (2011). [2011 Action plan for major policies on science and technology]. Downloaded on July 7, 2018, from http://www8.cao.go.jp/cstp/output/20100708ap.pdf.

CYBERDYNE. (2018). Personal email communication.

Danish Council of Ethics. (2016). [Recommendations concerning social robots translated into Japanese by S. Yamauchi]. Downloaded from www.f.waseda.jp/s_yamauchi/robot/Danishi_Gov.html.

Development Bank of Japan (DBJ). (2014). [Challenge and outlook on development of Japanese long-term care robot industry: Importance of User-Driven Innovation approach of northern European nations]. *Health Care Industry Current, 11*. Retrieved

March 15, 2017 from http://www.dbj.jp/pdf/investigate/mo_report/0000015497_file4.pdf

Fine, A. H. and Beck, A. (2010). Understanding our kinship with animals: Input for health care professionals interested in the human/animal bond. In A.H. Fine (ed.), *Handbook on animal assisted therapy* (pp.3-16). London: Academic Press.

Fujii, H. (Interview, April 15, 2017, at RT. Works, Osaka, Japan).

Furukawa, K. (2014). [News release on February 5: ISO publishes an international safety standard for living-support robots]. Retrieved June 6, 2017, from http://www.nedo.go.jp/news/press/AA5_100247.html

Hamada, T., Yokoyama, A., and Shibata, T. (2003). [Robot therapy development]. *Keisoku to Seigyo* Vol.42, September Issue, 756-762.

Herr, H. (2014). *The new bionics that let us run, climb and dance.* Presentation at 2014 Ted Talks. Retrieved June 2, 2018, from https://www.ted.com/talks/hugh_herr_the_new_bionics_that_let_us_run_climb_and_dance

Honma, K. (2017). [Development and distribution of care and support robots]. *Aging and Health*, *81*, 6-13.

Ikeda, M. (2017). Hearing aid market in Japan. Document posted by the U.S. Federal Trade Commission. Retrieved June 7, 2018, from https://www.ftc.gov/system/files/documents/public_comments/2017/05/00087-140718.pdf

International Federation of Robotics (IFR). (2016). 1.2.1. Definition of service robotics. Retrieved June 19, 2018, from https://ifr.org/img/office/Service_Robots_2016_Chapter_1_2.pdf

Japan Agency for Medical Research and Development (AMED). (2017). *METI/AMED project to promote care robot development and use: A list of commercialized products*. Retrieved February 1, 2018, from http://robotcare.jp/wp-content/uploads/2017/04/List-of-commercialized equipment.pdf (In Japanese).

Japanese Business Federation. (2017). [Riviving Japan through Society 5.0]. Retrieved January 5, 2018, from http://www.keidanren.or.jp/policy/2017/010.html

Jones, C., Moyle, W., Murfield, J., Draper, B., Shum, D., Beattie, E., et al. (2018). Does cognitive impairment and agitation in dementia influence intervention effectiveness? Findings from a cluster-RCT with the therapeutic robot, Paro. *Journal of American Medical Directors Association*. [Electronic Version]. Retrieved May 15, 2018, from https://www.sciencedirect.com/science/article/pii/S1525861018301038.

Jøranson, N., Pedersen, I., Rokstad, A. M. M., & Ihlebek, C. (2016) Change in quality of life in older people with dementia participating in Paro-activity: A cluster-randomized control trial. *Journal of Advanced Nursing*, 72-12, 302--3033.

Kamenetz, H. L. (1969). A brief history of the wheelchair. *Journal of the History of Medicine and Allied Sciences, 24*-2, 205-210.

Kanagawa Welfare Service Association. (2011). 2011 [Report on the Model Project for Promoting Long-term Care and Medical Robots]. Retrieved May 30, 2018, from http://www.kaigo-robot-kanafuku.jp/image/CBDCCAD4__merged.pdf

Kanbe, J. (1995). [A study on independence and learning among older adults]. [Electronic Version] *Kyoiku Gakubu Kiyo, 263-45,* 263-270.

Kruger, K. A., & Serpell, J. A. Animal-assisted interventions in mental health: Definitions and theoretical foundations. In A.H. Find (Ed.) *Handbook on animal-assisted therapy: Theoretical foundations and guidelines for practice.* (pp. 33-48). San Diego, CA: Elsevier Academic Press.

Lane, G. W., Noronha, D., Rivera, A., Craig, K., Yee, C., Mills, B., et al. (2016). Effectiveness of a social robot, "Parp," in a VA long-term care setting. *Psychological Services, 13-3,* 292-299.

Lazarte, M. (2014). Enter first cyborg-type robot. Downloaded from https://www.iso.org/news/2014/09/Ref1882.html.

Masuda, S. (2014). [Hard of hearing among older adults]. *The Journal of Japan Geriatrics Society, 51-1*, -17. {Electronic Version] Retrieved October 15, 2014, from Downloaded from https://www.jpn-geriatsoc.or.jp/publications/other/pdf/review_51_1_1.pdf

Ministry of Economy, Trade and Industry (METI). (2008). [On the past industrial policies]. Retrieved on May 15, 2016, from http://www.meti.go.jp/committee/materials2/downloadfiles/g80919c05j.pdf

Ministry of Economy, Trade and Industry (METI). (2017*a*). [The priorities in application of robot technology in assistive device]. Retrieved May 1, 2018, from http://www.meti.go.jp/press/2017/10/20171012001/20171012001-1.pdf

Ministry of Economy, Trade and Industry (METI). (2017*b*). METI/AMED [Project to promote care robot development and use: A list of commercialized products]. Retrieved March 15, 2018, from http://robotcare.jp/wp-content/uploads/2017/04/List-of-commercialized equipment.pdf

Ministry of Education, Culture, Sports, Science and Technology (MEXT). (2015). [2015 White Paper on Science and Technology]. Downloaded from http://www.mext.go.jp/b_menu/hakusho/html/hpaa201501/detail/1358751.htm

Ministry of Health, Labor and Welfare (MHLW). (2013). [On the 5-Year Plan for Care Robot Development]. Retrieved January 15, 2018, from http://www.mhlw.go.jp/file/05-Shingikai-12301000-Roukenkyoku-Soumuka/0000034903.pdf

Ministry of Health, Labor, and Welfare (MHLW). (2016). [*The 2016 White paper on labor and welfare*]. Downloaded from www.mhlw.go.jp/wp/hakusho/kousei/16/dl/1-02.pdf.

Ministry of Health, Labor and Welfare (MHLW). (2017). [Report on clinical testing project for social welfare devices]. Retrieved June 15, 2017, from www.techno-aids.or.jp/gap/ifo/201706

Mouri, M. (2016*a*). [ARC Report: Advantageous Japanese position in developing robots for medical use]. Retrieved June 15, 2017, from www.asahi-kasei.co.jp/arc/service/pdf/1002.pdf.

Mouri, M. (2016*b*). [ARC Report: Improved practicality of care robots]. Retrieved December 8, 2017, from www.asahi-kasei.co.jp/arc

Nakagawa, K., Nakaishi, S., Imura, T., Kawahara, Y., Hashizume, A., Kurisu, K., et al. (2017) [Neuromagnetic evaluation of a communication support system for hearing-impaired patients]. [Electronic Version]. *NeuroReport. 28-12,* 712-719.

Nakaishi, S. (2017). (Interview, April 10, 2017, at , Tokyo, Japan).

New Energy and Industrial Technology Development Organization (NEDO). (2013). [HAL® received CE mark]. Retrieved June 7, 2017, from www.nedo.go.jp/AA5-100215.htm

New Energy and Industrial Technology Development Organization (NEDO). (2014). [*White Paper on Robot*]. Retrieved March 10, 2018, from http://www.nedo.go.jp/content/100567345.pdf.

New Energy and Industrial Technology Development Organization (NEDO). (2017*a*). [*Implementation plan for the Program to Support Practical Application of Assistive Device for Solving Challenging Issues*]. Retrieved September 5, 2017, from www.nedo.go.jp/content/100863800.pdf

New Energy and Industrial Technology Development Organization (NEDO). (2017*b*). [*The Program evaluation report: The Program to Support Application of Assistive Device for Solving challenging Issues*]. Retrieved September 10, 2017 from www.nedo.go.jp/content/100862099.pdf

Office of Prime Minister. (2013). Japan Revitalization Plan (Provisional), June 14, 2013. Retrieved June 10, 2018, from https://www.kantei.go.jp/jp/singi/keizaisaisei/pdf/en_new_senryaku.pdf.

Ohashi, K. (2013, September). [*Care management from ICF perspective and utilization of assistive devices*]. A printed copy of paper presented at the Yamanashi University, Kofu, Japan, on September 2, 2013

Ohashi, K. (Ed.). (2014). [*New social welfare devices and long-term care revolution: Guide for incorporation and implementation*]. Tokyo, Japan: Nihon Iryo Kikaku.

Okayama City. (2016). [*The survey report on the Assistive Device Rental Model Project*]. Okayama City, Okayama: Author.

Okayama City. (2018). [*About the Assistive Device Rental Model Project*]. Retrieved June 5, 2018, from http://www.city.okayama.jp/hofuku/hokenfukushiseisaku/hokenfukushiseisaku_ 00084.html

Organization of Economic-Cooperation and Development (OECD). (2012). *The robotics innovation challenge: Opportunities and solutions for a silver economy.* Retrieved July 1, 2017 from Downloaded from http://www.oecd.org/officialdocuments/publicdisplaydocumentpdf/?cote=DSTI/ICCP/IE%282012%296&docLanguage=En

Pelkmans, J. (1987). The new approach to technical harmonization and standardization. *Journal of Common Market Studies, 25-3*, 249-268. Retrieved June 1, 2017, from https://courses.washington.edu/eulaw09/supplemental_readings/Pelkmans_New_Approach_Harmonization.pdf

Saito, T., Shibata, T., Wada, K., and Tanie, K. (2002). Examination of change of stress reaction by urinary tests of an elderly before and after introduction of mental commit robot to an elderly population, *Proceedings of the Seventh International Symposium on Artificial Life and Robotics, Beppu, Oita, Japan, 16-18, January, 2002.* 316-319.

Sae, S. (1995). [Kouraku]. Tokyo, Japan: Shincho Bunko.

Salomon, J. A., Wang, W., Freeman, M. K., Vos, T., Flaxman, A. D., Lopez, A. D., et al. (2012). Healthy life expectancy for 187 countries, 1990–2010: A systematic analysis for the Global Burden Disease Study 2010. [Electronic Version]. *Lancet, 380*, 2144–2162. Retrieved May 1, 2016, from http://www.thelancet.com/pdfs/journals/lancet/PIIS0140-6736(12)61690-0.pdf

Sankai, Y. and Sakurai, T. (2017*a*). [Cybernics and future of treatment for neurological disorders: Functional regenerative medicine with HAL]. *Shinkei Naika*, 86-5, 596-603.

Sankai, Y. and Sakurai, T. (2017*b*). [Functional regenerative medicine: Dawn of Cybernics Treatment]. *Saisei Iryo*, 16-2, 10-21.

Shibata, T., Wada, K., Saito, T., and Tanie, K. (2001). Robot assisted activity for senior people at day service center. *Proceedings of the 1st*

International Conference on Information Technology in Mechatronics, Istanbul, Turkey, October 1-3, 2001. 71-74.

Shibata, T. (2012). [Research and development of therapeutic robot Paro and recent domestic and international activities Surrounding Paro]. In [*Symposium on Robot Therapy with Seal Robot Paro: Vol. 1*]. Retrieved December 15, 2016, from http://intelligent-system.jp/paro-therapy1

Shibata, T. (2017). [Development and dissemination of care robot, PARO: Innovations in non-pharmaceutical treatment for dementia]. [Electronic Version] *Joho Kanri 60-4,* 217-228. Retrieved December 30, 2017, from from https://www.jstage.jst.go.jp/article/johokanri/60/4/60_217/_pdf

Shibata, T. (2018). Personal email communication to the Author on July 6, 2018.

Tateyama, A. (2017). [Origin of creativity: Professor Sankai's formative years]. Retrieved September 1, 2017, from https://www.jsps.go.jp/j-pdab/data/sankai.pdf

The United Nations. (2002). *Second World Assembly on Aging*: *Political Declaration and Madrid International Plan of Action on Ageing*. New York, NY: Author.

Yu, R., Hui, E., Lee, J., Poon, D., Ng, A., Sit, K., et al. (2015). Use of a therapeutic socially assistive pet robot (PARO) in improving mood and stimulating social interaction and communication for people with dementia: Study protocol for a randomized controlled trial. *Journal of Medical Internet Research, 4-2*, e45. Retrieved February 3, 2017, from https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4433493/