

Results of an Opinion Survey on Healthcare and Advanced Medical Technology in Japan

July, 2011

American Medical Devices and Diagnostics Manufacturers' Association (AMDD)

Table of Contents

Introducti	ion1
Executive	Summary2
Recomme	ndations from AMDD4
Survey Ov	verview5
Part 1: On	Advanced Medical Technology6
	er 1: Awareness and Sense of Importance Regarding Advanced al Technology7
	Many members of the general public are aware of advanced medical technology and more than 80% have used it7
2.	Many people think advanced medical technology is important
	Advanced medical technology is important due to the "early detection and treatment," "lower invasiveness" and "accurate diagnosis" it provides
	The general public recognizes the value of advanced medical technology in terms of diagnosis and patient groups in terms of treatment10
	Respondents who are concerned about their health 10 years from now think advanced medical technology is more important11
	er 2: Diagnosis and Treatment Using the World's Most Advanced al Technology
1.	Many people want to use the world's most advanced medical technology
	Both patients and the general public want to use the world's most advanced medical technology even if it costs slightly more13
Chapte	er 3: Device Lag and Other Issues14
1.	More patients are aware of the device lag and other issues than the general public 14
	Many Japanese people expect early improvements in the device lag and other issues
Part 2: He	althcare Services in Japan17
	The most important point facing the Japanese healthcare services is an "improvement in the quality of medical services"
2.	Less than a half of those surveyed are satisfied with the current medical system $\dots 18$
	Many people are satisfied with the level of personal expenses and access to healthcare services
	Patients are dissatisfied with the unavailability of the most advanced treatments and the general public with the costs associated20

Introduction

The American Medical Devices and Diagnostics Manufacturers' Association (AMDD) is an industry group in Japan primarily consisting of U.S.-based advanced medical device manufacturers. The advanced medical technology provided by our members has contributed significantly to the early detection and treatment of cancer and other diseases, saving the lives of patients and improving quality of life (QOL) following surgeries. Our member's products include cardiac pacemakers and catheter-based treatments such as stents, artificial cardiac valves, artificial joints, medical devices for cataracts, such as intraocular lens, diagnostic imaging devices, including CTs and MRIs, in vitro diagnostics (IVD) that are indispensable for examination and diagnosis and many other technologies that are an integral part of healthcare services in Japan today.

As an industry group that provides these kinds of advanced medical technologies, we conducted a survey to gain insights into how Japanese patients and the general public feel about advanced medical technology and what they desire in the future from medical devices and the Japanese medical system. This survey comprises an online survey with 2,000 samples chosen from the general public and a survey mailed to representatives of various patient groups.

We believe that the real opinions and fresh voices from the Japanese public and patient groups gained through this survey about medical devices will contribute to the future of medical devices in Japan. We would also like to make the results of the survey available to administrative agencies, policymakers and the media in order to help raise awareness of the problems regarding medical devices in Japan.

Finally, I would like to take this opportunity to express my appreciation to the patient groups for their cooperation in this survey.

David W. Powell Chairman American Medical Devices and Diagnostics Manufacturers' Association (AMDD)

Executive Summary

The American Medical Devices and Diagnostics Manufacturers' Association (AMDD) conducted a survey in order to gain insights into how Japanese patients and the general public feel about advanced medical technology and what they desire in the future from medical devices and the Japanese medical system.

The survey consisted of two parts - an online survey that was conducted with 2,000 samples chosen from the general public and a mail survey that was carried out with representatives of patient groups. The first part – the online survey – was conducted between September 24 and 30, 2010. With 2,000 respondents (50% males and 50% females) aged 40 to 69 years old, this was the first large opinion survey conducted in Japan on medical devices and IVD. In the second part, we asked representatives from 136 patient groups related to medical devices about advanced medical technology and Japanese healthcare services from their perspective as representatives of patient groups. We received answers from 50 groups, among which 49 samples were valid.

The implementation of the survey was outsourced to IIC Japan and the final report was compiled by the AMDD.

This survey report is composed of two parts: "On Advanced Medical Technology" and "Healthcare Services in Japan." The first part is further divided into "Awareness and Importance of Advanced Medical Technology," "Diagnosis and Treatment Using the World's Most Advanced Medical Technology," and "Device Lag and Other Issues." In each of the sections a comparison was carried out between the survey results from the general public and those from the patient groups. The overall survey results and analyses can be summarized as follows:

- 1. Awareness and Importance of Advanced Medical Technology
 - 93% of the general public is aware of the advanced medical technologies mentioned in the survey. 81% answered that they have used advanced medical technology. [Refer to p.7]
 - A large majority (87%) of the general public thinks the use of advanced medical technology is "very important" or "slightly important" when they or a member of their family need diagnosis or treatment. 86% of patient group representatives also responded "very important" or "slightly important." This indicates that many Japanese people recognize the importance of advanced medical technology. [Refer to p.8]
 - More than 70% of the general public think that advanced medical technology is important because of the "early detection and treatment," "lower invasiveness" and "accurate diagnosis" it provides. Among patient groups, 88% acknowledge "lower invasiveness," 71% "faster and more accurate diagnosis," and 67% "early detection and treatment of diseases," as being important factors. This indicates that lower invasiveness, one of the most important characteristics of advanced medical technology, is highly appreciated. [Refer to p.9]
- 2. Diagnosis and Treatment Using the World's Most Advanced Medical Technology
 - 74% of the general public "definitely want to use" or "want to use" advanced medical technology when they or a member of their family require diagnosis or treatment either now or in the future, while as many as 86% of patient group respondents also think so. As a matter of course, patient groups have greater

expectations regarding the use of advanced medical technology. [Refer to p.12]
Among respondents who "want to use" advanced medical technology taken from the question above, 66% of the general public and 74% of patient group respondents answered "yes" to the question: "Would you want to use the world's most advanced medical technology even if it costs slightly more?" This result indicates that many Japanese people are willing to accept slightly higher medical costs in order to use the world's most advanced medical technology. [Refer to p.13]

- 3. Device Lag and Other Issues
 - Less than 20% of the general public was aware of the words "drug lag," "device lag," and "device gap," while more than 60% of patient group respondents were aware of them. This indicates that patient groups have greater awareness and understanding of medical issues in Japan. [Refer to p.14]
 - For "device lag," 85% of the general public and 90% of patient groups think "it should be improved immediately" or "it should be improved as soon as possible." For "device gap," 83% of the general public and 78% of patient groups believe so. This result shows that many Japanese people want early introduction of the world's most advanced medical technologies and in vitro diagnostics (IVD). [Refer to p.16]
- 4. Healthcare Services in Japan
 - Responses to "satisfaction with Japanese healthcare," 43% of the general public is "satisfied" with current Japanese healthcare services, 24% are "not very satisfied" or "completely unsatisfied." In the case of patient groups, 43% are "satisfied," while as many as 39% are "dissatisfied." [Refer to p.18]
 - Respondents who think "improvement in the quality of medical services" is "important" in Japanese healthcare services was 90% of the general public and 87% of patient groups [Refer to p.17]. 35% of the general public and as many as 53% of patient groups are "dissatisfied" with Japanese healthcare services because "many of the world's most advanced treatments are not available" in Japan. [Refer to p.20]

Recommendations from AMDD

Based on an analysis of the survey results, AMDD makes the following recommendations:

While Japanese are broadly aware of advanced medical technology and adequately recognize its importance, they currently desire a swift improvement in issues relating to healthcare services in Japan, such as a device lag and device gap. They also have a desire to better access the world's most advanced medical technologies. It was also revealed that more than half are willing to accept slightly higher medical costs for the use of it.

"Device lag" refers to new medical devices and IVD introduced into Japan much later than the U.S. and Europe, which is a significant issue on a medical front. Although governmental agencies are making efforts to solve this problem, fundamentally it is yet to be resolved. Therefore, it is expected that action programs will be further promoted. "Device gap" refers to medical devices used worldwide that are ultimately not introduced in Japan, which has hurt patients considerably from the perspective of improvements in quality of life and higher levels of secure protection.

The primary causes for the device lag and device gap are that Japan's pharmaceutical regulations and insurance systems that surround medical devices increase the amount of work and investment to collect additional data required by manufacturers. This creates difficulties in the decision making of appropriately timing the introduction to the Japanese market because of the difficulties in forecasting and framing of business plans. Other causes include, the fact that the value of innovation is inadequately reflected in the pricing system for new products; decreases in the price of existing products by each functional category based on the current market price and through FAP; and unpredictable pricing processes for new products (the timing of pricing and the price itself). Innovation here means novelty in medical devices, i.e. continuous efforts in development, upgrading and improvements to enable not only safer and more effective diagnosis but also faster and more accurate analysis, including early detection and treatment of diseases and less invasive and painful treatments, thereby helping reduce medical expenditures nationwide as well as contributing to better QOL for patients.

To cultivate the domestic medical device industry and eliminate the device gap, it is critical to assess the value of innovation in medical devices appropriately and reflect these results in insurance reimbursement prices. For designated insurance medical materials on the other hand, although the costs for introduction into the Japanese market and corporate management in Japan is higher than abroad, in many cases the price of new products is set lower than other markets, which has seriously hindered the promotion of introducing new devices into Japan. Also in the area of regulatory affairs, it is necessary to clarify the requirements by in Japan in light of international standards and to realize the least burdensome approach for both manufacturers and reviewers in the process of reviewing technology. In order to sufficiently meet the expectations of those who desire use of the world's most advanced medical technology, despite slightly higher medical costs, it is important to promote improvements in Japanese healthcare services and to contribute to technological innovation in the medical devices industry and IVD as a whole. It is required that FAP be abolished and the value of innovation be adequately reflected in the medical service fees, as well as the pricing processes be clarified.

Overview of the Survey

Objective:

To gain insights into public opinion about advanced medical technology and healthcare services among Japanese people aged between 40 and 69.

Approach:

The survey consisted of two parts - an online survey carried out among members of the general public and a mail survey carried out among representatives of patient groups.

1. Online Survey for Members of the Public

- Method: Online survey conducted September 24 30, 2010
- Sample conditions: Males and females aged 40 to 69 years old (Sample is 50% male and 50% female)
- Survey area: Nationwide
- Sample size of 2,000 respondents (chosen by area and age based on 2005 census results)

Age	Nationwide	Hokkaido Tohoku	Kanto	Chubu	Kinki	Chugoku Shikoku	
40s	626	74	212	116	100	54	70
50s	750	92	244	138	122	70	84
60s	624	74	204	116	108	56	66
Totals	2,000	240	660	370	330	180	220

- Margin of error: ±0.4 2.2% (in cases where 2,000 responses where gathered)
- Survey company: IIC Japan
- Survey panel company: CiM-Net Research

2. Mail Survey for Patient Groups

- Method: Mail survey conducted between October 29, 2010 and January 31, 2011
- Sample conditions: Representatives of 136 patient groups related to medical devices
- Sample size of 50 respondents (49 valid and 1 invalid)
- Survey company: IIC Japan

Part 1: On Advanced Medical Technology

This survey first inquired into the public's awareness and sense of importance regarding advanced medical technology; opinions about the characteristics of advanced medical technology; the extent of desire to make use of the world's most advanced medical technology and awareness of the device lag and other issues.

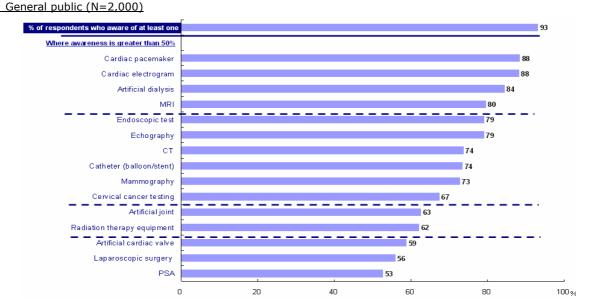
For purposes of this survey, medical devices and IVD are defined as "advanced medical technologies" as follows:

* List of medical devices and diagnee	ostic products (advanced medical technologies)*		
Cardiac pacemaker	Cervical cancer testing		
ICD	PSA		
AED	Echography		
Catheter (balloon/stent)	Endoscopic test		
Artificial cardiac valve	Breast cancer marker		
Intraocular lens	Cardiac infarction marker		
Artificial joint	Mammography		
Spinal implant	СТ		
Shunt	MRI		
Insulin pump	PET		
Artificial dialysis	SMBG		
Brain aneurysm coil embolization	CAD (computer aided design)		
Laparoscopic surgery	Cardiac electrogram		
Radiation therapy equipment			

Chapter 1: Awareness and Sense of Importance Regarding Advanced Medical Technology

1. Many members of the general public are aware of advanced medical technology, and more than 80% have used it.

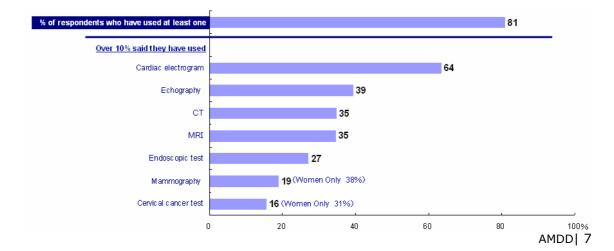
Regarding awareness of and experience with advanced medical technology among members of the general public, according to the survey more than 70% of respondents are aware of the following "medical devices/tests" that are defined as "advanced medical technologies": cardiac pacemakers, cardiac electrograms, artificial dialysis, MRIs, endoscopic tests, echography, CTs, catheters, and mammograms. As many as 81% of respondents have experienced these advanced medical technologies. (Patient groups were not asked this question because many of them have suffered from some form of disease and, as such, will be aware and have experienced medical devices/tests.)



Q. Please select all medical devices and/or diagnostic tests (advanced medical technologies) that you aware of. [Multiple Answers: MA]

Q. Please select all medical devices and/or diagnostic tests (advanced medical technologies) that you have used in the past. [Multiple Answers: MA]

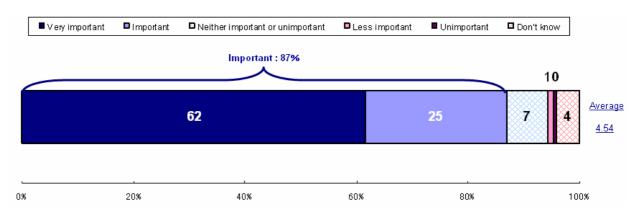
General public (N=2,000)



2. Many people think advanced medical technology is important.

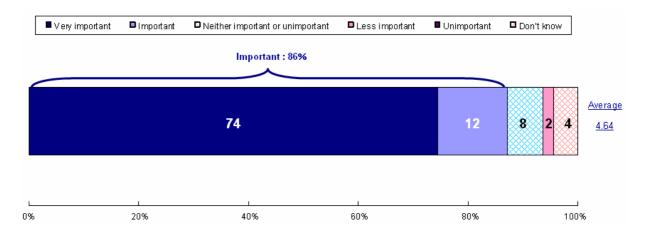
Asked how important these advanced medical technologies are when the respondent or a member of the respondent's family requires diagnosis or treatment, about 90% of both the general public and patient groups answered "very important" or "important." While 62% of general public think "very important," 74% of patient groups answered "very important". This indicates that patient groups have greater expectations regarding the use of advanced medical technology.

Q. Please indicate how important "medical devices and/or diagnostic tests (advanced medical technologies)" are when you or your family members require diagnosis or treatment (based on the list indicated previously). [Single Answer: SA]



General public (N=2,000)

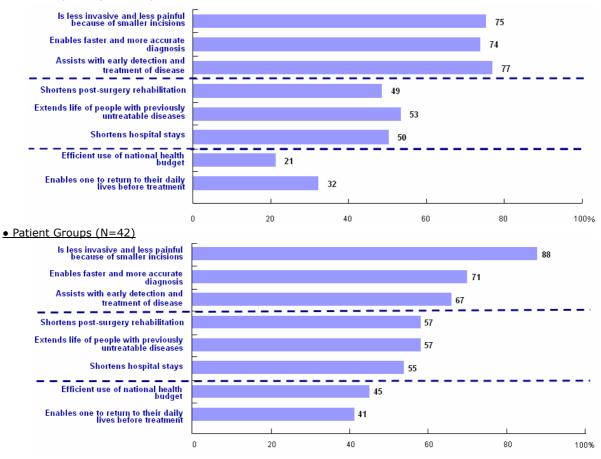
• Patient Groups (N=49)



3. Advanced medical technology is important due to the "early detection and treatment," "lower invasiveness" and "accurate diagnosis" it provides.

More than 70% of the general public thinks advanced medical technology is important for each of the following reasons: "It assists with early detection and treatment of diseases," "it is less invasive and less painful because of smaller incisions" and "it enables faster and more accurate diagnosis." Nearly 50% answered, "It extends the life of people with previously untreatable diseases," "it shortens hospital stays," and "it shortens post-surgery rehabilitation" as reasons for its importance. On the other hand, among patient group 88% replied that, "It is less invasive and less painful because of smaller incisions," 71% that "it enables faster and more accurate diagnosis," and 67% that "it assists with early detection and treatment of disease" as main reasons. This indicates that patients highly appreciate lower invasiveness, which is an important feature of advanced medical technology. According to these results, Japanese people recognize that advanced medical technology and IVD help improve the quality of life of patients and eases the burdens of diseases.

Q. Please indicate the reasons why you think advanced medical technologies are very important or important (as answered in the previous question). [Multiple Answers: MA]



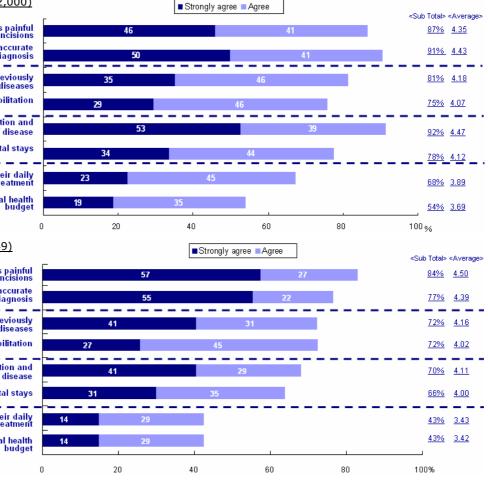
General public (N=1,740)

4. The general public recognizes the value of advanced medical technology in terms of diagnosis and patient groups in terms of treatment.

While the general public highly rated items related to diagnosis such as "it enables faster and more accurate diagnosis" and "it assists with early detection and treatment of disease" from responses to the question about the characteristics of advanced medical technology, many patient groups placed greater value on items related to treatment, including "it is less invasive and less painful because of smaller incisions." Whilst it is natural that appreciation depends greatly on whether or not respondents suffer from a disease, a major distinction is that responses from patient groups gave a higher ranking to the characteristics such as lower invasiveness and faster and more accurate diagnosis of advanced medical technology.

Advanced medical technology assists patients in improving their QOL, through early detection and diagnosis of diseases and shorter hospital stays, ultimately leading to efficient use of national medical expenditures. When responses by consumers and patient groups are compared recognition of this point is not high among either.

Q. Please indicate how much you agree with each of these characteristics of medical devices and diagnostics (advanced medical technologies), based on the list indicated previously. [Single Answer: SA]



General public (N=2,000)

Is less invasive and less painful because of smaller incisions Enables faster and more accurate diagnosis Extends life of people with previously untreatable diseases Shortens post-surgery rehabilitation Assists with early detection and treatment of disease Shortens hospital stays Enables one to return to their daily lives before treatment Efficient use of national health budget

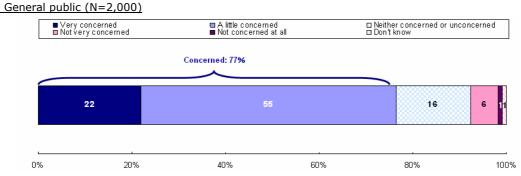
• Patient Groups (N=49)

Is less invasive and less painful because of smaller incisions Enables faster and more accurate diagnosis Extends life of people with previously untreatable diseases Shortens post-surgery rehabilitation Assists with early detection and treatment of disease Shortens hospital stays Enables one to return to their daily lives before treatment Efficient use of national health budget

5. Respondents who are concerned about their health ten years from now think advanced medical technology is more important.

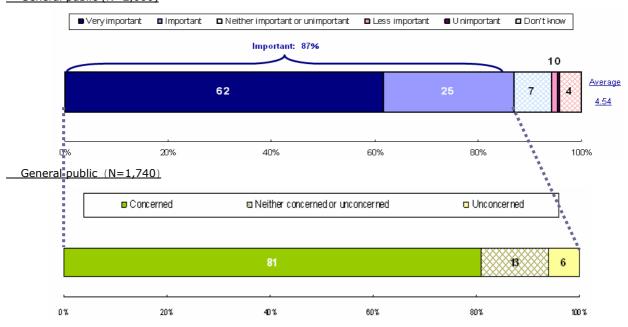
Members of the general public, assumed to currently be in good health, were asked about their concern regarding their health ten years from now. 77% of all respondents answered "very concerned" or "a little concerned", while only 7% are "not concerned." This shows that most respondents are concerned about their health.

Q. How concerned are you about your health ten years from now? Please select which best applies to you. [Single Answer: SA]



When cross-tabulating the respondents who acknowledged the importance of advanced medical technology on page 8 of chapter 1 -2 based on their answers regarding their health ten years from now, it can be seen that 81% of those respondents answered that they are "concerned" about their health ten years from now. This indicates that respondents who are concerned about their health in the future consider advanced medical technology to be more important.

Q. Please indicate how important "medical devices and/or diagnostic tests (advanced medical technologies) are when you or your family members require diagnosis or treatment (based on the list indicated previously). [Single Answer: SA]



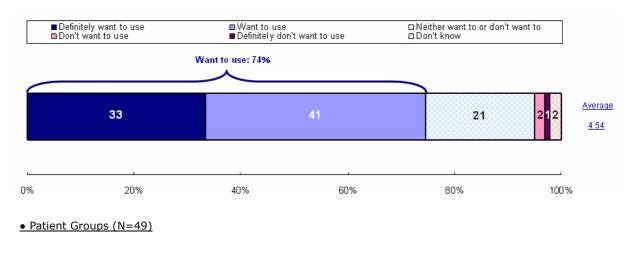
General public (N=2,000)

Chapter 2: Diagnosis and Treatment Using the World's Most Advanced Medical Technology

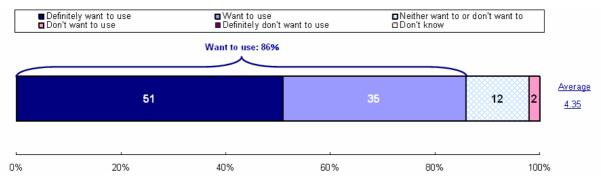
1. Many people want to use the world's most advanced medical technology.

When asked to indicate to what extent they want to use the world's most advanced medical technology when they or a member of their family requires diagnosis or treatment, 74% of the general public and 86% of patient group respondents answered "definitely want to use" or "want to use," which represents a strong inclination. The ratio of patient group respondents who replied "definitely want to use" was as much as 18% higher than that of the general public, which indicates a greater willingness among patient groups to want to use the world's most advanced medical technology.

Q. If you or a member of your family require diagnosis or treatment now or in the future, please indicate to what extent you want to use the world's most advanced medical technology. [Single Answer: SA]



General public (N=2,000)



2. Both patients and the general public want to use the world's most advanced medical technology even if it costs slightly more.

Respondents who answered they want to use the world's most advanced medical technology on the previous question were also asked to what extent they want to use it if it costs slightly more. 66% of the general public and 74% of patient groups answered, "I would definitely want to use it" or "I would want to use it" even if it costs slightly more. Their intense desire reveals that the general public or patient groups would want the world's most advanced medical technology even if it costs slightly more when treatment is required.

Q. To what extent would you want to use the world's most advanced medical technology for diagnoses or treatment even if it costs slightly more? [Single Answer: SA]



General public (N=1,492)

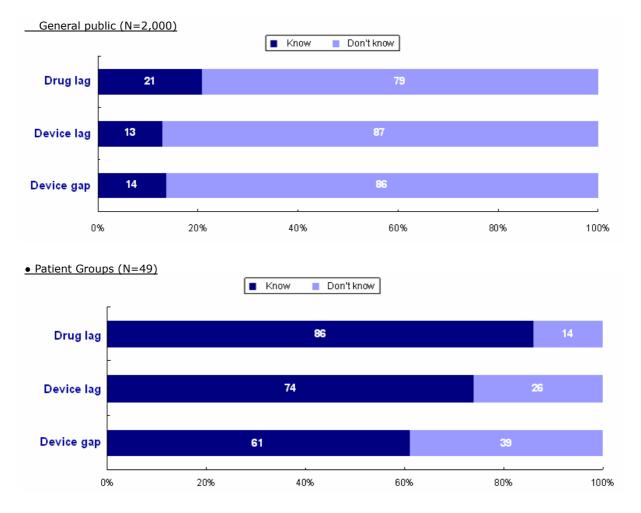
Chapter 3: Device Lag and Other Issues

1. More patients are aware of the device lag and other issues than the general public.

This survey also looked at awareness of the "drug lag," "device lag," and "device gap" as examples of current issues facing Japanese healthcare services.

On average less than 20% of the general public are aware of the words "drug lag," "device lag," and "device gap" while more than 70% of patient groups are aware of the terms "drug lag" and "device lag," and more than 60% are aware of the term "device gap." This would indicate strong awareness among patient groups who are directly affected by these issues.

Q. Have you heard of the following terms before? Please select all that apply and indicate your level of understanding of each one.



The survey described each of these four issues in detail and gauged respondents' knowledge about the facts. From the results among the general public 80% were aware of the term "drug lag" and 53% were aware of the term "device lag", which is a significant improvement in awareness, while awareness of the term "device gap" only slightly improved after describing the facts.

All patient group respondents (100%) are aware of the description of the term "drug lag," 84% of "device lag," which is a slight improvement, while awareness of the term "device gap" deteriorated after it was described, contrary to expectation. This may be because respondents are aware of the word "device gap" but do not understand it in detail.

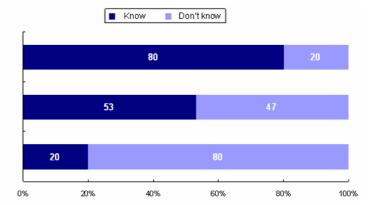
Q. Are you familiar with the issues below facing Japan? Please select all that apply to you.

General public (N=2,000)

The situation where patients in Japan cannot use world's most advanced drugs because they are not approved in Japan

The situation where patients in Japan cannot receive treatment with the world's most advanced devices and diagnostic tests because they are not yet approved in Japan

The situation where half of world standard medical devices are not available in Japan

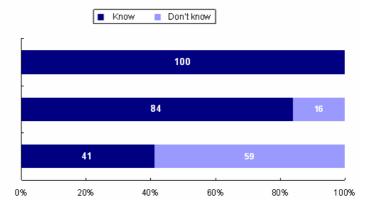


• Patient Groups (N=49)

The situation where patients in Japan cannot use world's most advanced drugs because they are not approved in Japan

The situation where patients in Japan cannot receive treatment with the world's most advanced devices and diagnostic tests because they are not yet approved in Japan

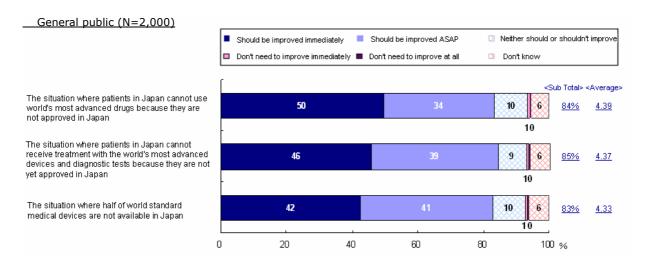
The situation where half of world standard medical devices are not available in Japan



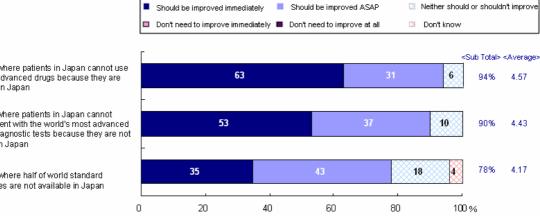
2. Many Japanese people expect early improvements in the device lag and other issues.

When asked the question about expectation for improvements, over 80% of both the general public and patient group respondents answered, "They should be improved immediately" or "they should be improved as soon as possible," which indicates a strong expectation for improvements in every issue.

Q. How much improvement is needed for each situation? Please select all that apply to you.



• Patient Groups (N=49)



The situation where patients in Japan cannot use world's most advanced drugs because they are not approved in Japan

The situation where patients in Japan cannot receive treatment with the world's most advanced devices and diagnostic tests because they are not yet approved in Japan

The situation where half of world standard medical devices are not available in Japan

Part 2: Healthcare Services in Japan

This survey also explored public opinion about current healthcare services in Japan. It investigated what respondents think important regarding the Japanese medical system, and to what extent they are satisfied with healthcare services in Japan, to find out specifically what they are satisfied and dissatisfied with.

1. The most important point facing the Japanese healthcare services is an "improvement in the quality of medical services".

Asked to select an issue they consider important regarding the Japanese medical system, both patient groups and the general public chose an "improvement in the guality of medical services" as their top response. In addition, general public put more importance on items related to costs, such as "the system to reduce the medical expense burden of individuals" and "efficient use of medical expenditures."

Q. How important do you think are each item? Please select those that apply to you.

General public (N=2,000)

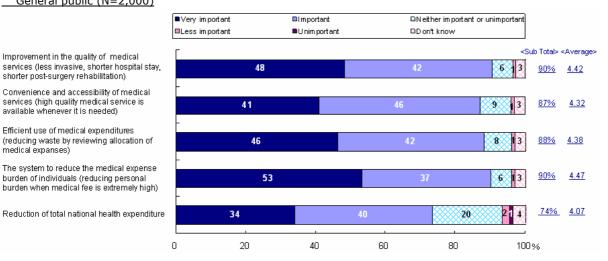
Improvement in the quality of medical

services (high quality medical service is

shorter post-surgery rehabilitation)

available whenever it is needed) Efficient use of medical expenditures

medical expanses)



• Patient Groups (N=49)

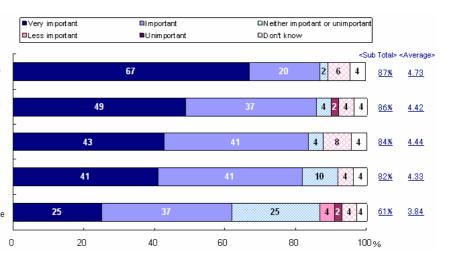
Improvement in the quality of medical services (less invasive, shorter hospital stay, shorter post-surgery rehabilitation)

Convenience and accessibility of medical services (high quality medical service is available whenever it is needed)

Efficient use of medical expenditures (reducing waste by reviewing allocation of medical expanses)

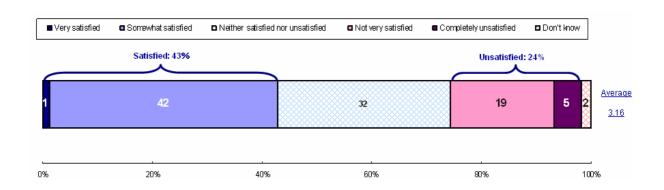
The system to reduce the medical expense burden of individuals (reducing personal burden when medical fee is extremely high)

Reduction of total national health expenditure



2. Less than a half of those surveyed are satisfied with the current medical system.

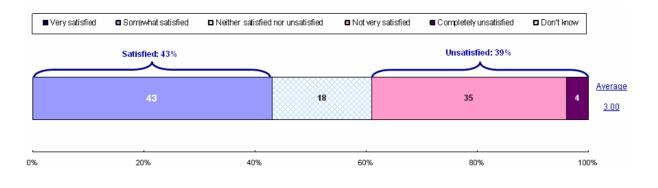
Asked about their satisfaction with healthcare services in Japan, about 40% of the general public and 40% of patient groups answered they are "satisfied." On the other hand, 24% of the general public and 39% of patient groups answered they are "not very satisfied" or "completely dissatisfied," clearly indicating that patient groups who answered "dissatisfied" is nearly 15% more than the general public.



Q. How satisfied are you with medical services in Japan? [Single Answer: SA]

• Patient Groups (N=49)

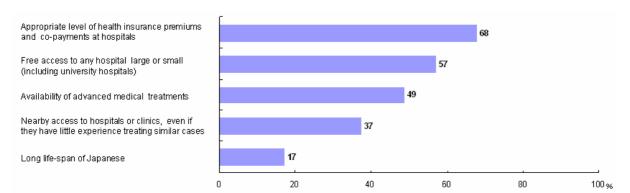
General public (N=2,000)



3. Many people are satisfied with the level of personal expenses and access to healthcare services.

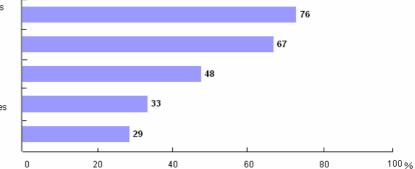
Respondents who answered they are "satisfied" with Japanese healthcare services on the previous question were asked about their reasons why they are specifically satisfied with the current Japanese medical system. The order of items they selected does not change between the general public and patient groups, and "appropriate level of health insurance premiums and co-payments at hospitals" and "free access to any hospital large or small (including university hospitals)" was supported by a majority of respondents.

Q. Please indicate reasons why you are satisfied with medical services in Japan. [Multiple Answers: MA]



General public (N=856)

• Patient Groups (N=21)



Appropriate level of health insurance premiums and co-payments at hospitals

Free access to any hospital large or small (including university hospitals)

Availability of advanced medical treatments

Nearby access to hospitals or clinics, even if they have little experience treating similar cases

Long life-span of Japanese

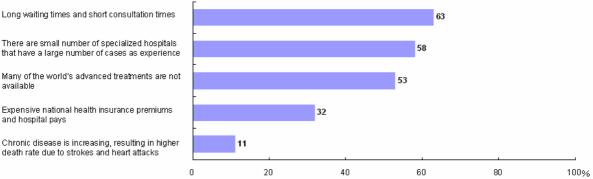
4. Patients are dissatisfied with the unavailability of the most advanced treatments and the general public with the costs associated.

On the other hand, respondents who answered "dissatisfied" with the Japanese healthcare services to the above question were asked what they are specifically dissatisfied with about the current medical system. While patient groups are dissatisfied with items relating to treatments, such as "there are a small number of specialized hospitals that have a large number of successful case studies" and "many of the world's most advanced treatments are not available," much of the general public are dissatisfied with "expensive national health insurance premiums and hospital co-pays." In particular, responses from patient groups who said that, "many of the world's most advanced treatments are not available" as a reason for their dissatisfaction, was nearly 20% more than the general public.

Q. Please indicate reasons why you are unsatisfied with medical services in Japan. [Multiple Answers: MA]

General public Long waiting times and short consultation times 81 There are small number of specialized hospitals 44 that have a large number of cases as experience Many of the world's advanced treatments are not 35 available Expensive national health insurance premiums 66 and hospital pays Chronic disease is increasing, resulting in higher 30 death rate due to strokes and heart attacks 0 20 40 60 100 % 80

Patient Groups (N=19)



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available

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