02 Leverage the Full Value of Advanced In Vitro Diagnostic Tests

Situation

Since the 1960s, advances in research and medical technology have led to the development of new diagnostic devices and measuring techniques that enable faster and more accurate diagnostic test results and provide healthcare practitioners with more useful information. Some of these new devices and techniques may cost more to perform than older tests, but they have become recognized around the world as essential in modern medical care because they contribute to improved treatment, faster recovery and greater peace of mind for patients. They can also lead to lower total healthcare costs because they can contribute to more successful treatment, faster patient recovery times, and shorter hospital stays.

Nevertheless, over the past 20 years, the full value of in vitro diagnostics (IVD) has not always been fully recognized in the Japanese healthcare system, particularly in the levels of medical reimbursement fees. As a result, Japanese patients have not always had timely access to the world's most advanced diagnostic testing.[1] In some cases, patients have undergone older diagnostic tests that are less expensive to conduct, but that may not be as accurate and speedy, or provide as much information as newer, more technologically advanced tests do.

The advantages of laboratory testing, including genetic testing, for accurate diagnosis and preventive medicine have been increasingly recognized by healthcare practitioners. In the 2008, 2010, 2012 and 2014 medical fee revisions, some fees were increased in recognition of the value provided by laboratory testing. However, there is still room for improvement.

Current Policy

In recent years, national medical care expenditure has grown, due to the increased health consciousness of the population, economic growth, the aging of society, and innovations in medical care technology.

Recently, medical service fees for diagnostic testing have been steadily reduced, despite significant advances in medical technology, including automation that reduces labor costs while increasing speed and accuracy.

Completely new diagnostic testing methodologies that are more sensitive and more accurate, and provide more useful information, have been developed. As one example, the fee for HIV testing has been steadily reduced, despite the introduction of increasingly advanced testing products that provide greater value. On the other hand, it can be very expensive to develop a new diagnostic testing agent, secure product approval, introduce it to the market, and maintain a system to ensure an uninterrupted supply and consistent high quality. As a result of not reflecting the value of improvements in diagnostic testing technology, Japan's low reimbursement fees for diagnostic testing can undermine research and development of new, effective diagnostic testing technology. There are no incentives for innovation. Low reimbursement rates for diagnostic testing can also result in a "diagnostic lag" that can delay Japanese patient access to new diagnostic tests for several years after they are available in other developed countries.[1]

Among the IVD systems currently available in Japan, there remain differences in basic product performance, such as in the sensitivity and accuracy of reagents. However, there are cases in which products with higher performance levels, in terms of accuracy and speed, are eligible for the same medical service fees (number of National Health Insurance points) as products with lower performance levels. National Health Insurance Reimbursement should be set in a way that reflects the true value of each diagnostic test and reagent, so that more effective (sensitive, accurate, speedy) ones are rewarded with higher fees.

One example can be found in the case of HIV/AIDS testing in Japan. Among advanced countries, the number of HIV/AIDS patients is rising only in Japan. Deficiencies in the existing testing system are a contributing factor in this rise. The testing system should be improved to allow testing of blood, tissue, and DNA samples at the appropriate time and in the most appropriate location. This means that some tests should be conducted quickly on site at the hospital or clinic, while other tests that are less urgent or require more sophisticated examination can be sent off-site to a testing laboratory. Such testing system reform should be conducted as a consistent national policy, rather than in different ways by different local governments.

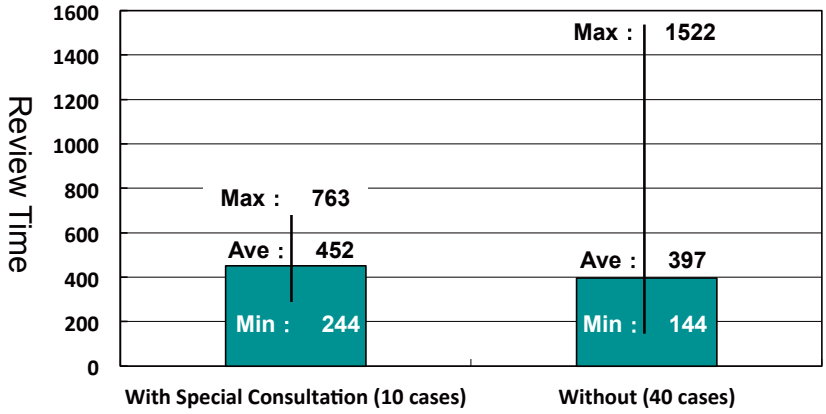
Recommendations

- Reduce the diagnostic lag through faster IVD product reviews. The period from submission until approval of innovative IVD technology in Japan is long. This increases development costs and slows patient access to the world's most advanced (more sensitive, speedy, and accurate) IVD technology. The Pharmaceuticals and Medical Devices Agency (PMDA) should cooperate with industry to effectively, efficiently and speedily implement "Collaboration Plan" for IVD review acceleration, which started from April, 2014.
- Establish a medical reimbursement pricing system that better reflects the clinical value and quality of IVD tests. Laboratory tests should be conducted at medical institutions when speedy diagnosis helps improve medical treatment or shorten hospital stays. An expert committee should be set up within the Central Social Insurance Medical Council that is capable of evaluating IVDs, similar to the existing expert committees for evaluating drugs and devices.
- Improve the overall quality of IVD tests available and commonly used in Japan. The medical reimbursement system should be revised to reflect differences in the clinical value of various IVD tests, so that healthcare practitioners have an incentive to use more advanced (sensitive, speedy and accurate) tests and so that manufacturers have an incentive to invest in research and development of new testing technology. A system for regular reviews (reevaluation) by a third-party IVD expert organization should be introduced to assess these differences.
- Establish a consistent national medical screening system to promote screening and follow up for key diseases like HIV/AIDS, cervical cancer, hepatitis B and hepatitis C in a way that enables early detection and treatment of disease. The system should be consistent nationwide, rather than leaving it up to each local government to implement independently. The system should also recognize that, although some newer, more accurate and speedy IVD tests may cost more than older generations of the same test, they can often help to improve cost efficiency by increasing the success rate of treatment and by shortening hospital stays.

Reference

1. L.E.K. Consulting LLC. 2014. IVD review time clock surveys conducted for the Japan Association of Clinical Reagents Industries and the American Medical Devices and Diagnostics Manufacturers Association's In Vitro Diagnostics Committee www.jacr.or.jp and www.amdd.jp.

2. Wide Disparity in IVD Product Approval Periods (New Product Review Time)



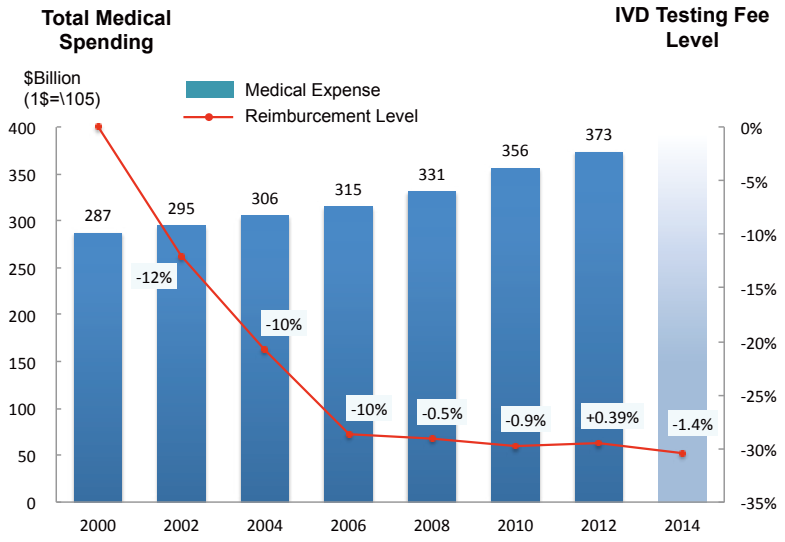
Collaboration Plan for acceleration of IVD product review should be effectively, efficiently and speedily implemented to provide more effective in vitro diagnostic products to clinical practitioners in a more timely manner.

Special Consultation	Number of Cases	Approval Period (Reviewer Time)	
		Within 6 months	
		Number of Cases	Achievement rate
With	10	1	10%
without	40	27	68%

Source: Japan Association of Clinical Reagent Industry Association and American Medical Device and Diagnostic Manufacturer Association Joint Time Clock Survey, 2014.

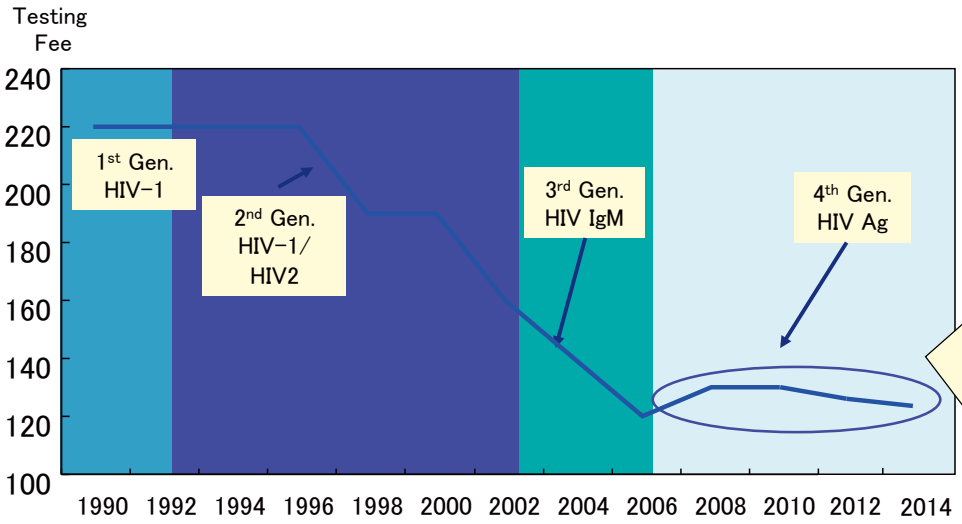
2. Positioning of Laboratory Tests in the Healthcare Insurance System

2014 Reimbursement Revision: Transitional Change of Total Medical Expenditures and In Vitro Diagnostic (IVD) Testing Fee Level



- **Recently, IVD testing fees were steadily cut to reduce costs.**
- **The true value of the contribution of IVD testing to healthcare has not been reflected.**
- **The result of the medical service fee revision from 2008 to 2014 better reflected the value of diagnostic tests.**

2. 2014 Reimbursement Revision: Full Value of Improved HIV Tests Not Reflected



Although the quality has improved in each new generation of test, the value of the most advanced tests has not been reflected in insurance reimbursement points.

Test Kit Type	HIV-1	HIV-1, HIV-2	HIV-1, HIV-2, Group O	HIV-1, HIV-2, Group O、Anti-Core Antigen Antibody
Antibody / Antigen tested	IgG	IgG	IgG, IgM, IgA	IgG, IgM, IgA, Core antigen

2. IVD Example: HIV Test Reimbursement Pricing Does Not Reward Innovation

	1st Gen.	2nd Gen.	3rd Gen.	4th Gen.
Year	1986	1992	2002	2006
Detected Ab/Ag	IgG	IgG	IgG IgM IgA	IgG IgM IgA Core Ag
Target of diagnosis	HIV-1	HIV-1 HIV-2	HIV-1 HIV-2 Group O*	HIV-1 HIV-2 Group O*
Window Period	50 days	50 days	32 days	28 days
NHI points	220	220 →190	160	120 →123**

* : HIV 1 Group O ** : 130 from 2008, 127 from 2012, 123 from 2014

New generations of HIV tests provide more information in a shorter time frame. However, old and new HIV Ab in vitro testing products with different performance receive the same reimbursement points.