

# Japanese system needs to evaluate “the true value of IVD”

The Japanese reimbursement system is failing to recognise the contribution made by technological advancements in the IVD field, Dr Isao Ikeda, chairman of the American Medical Devices and Diagnostics Manufacturers' Association's (AMDD's) IVD committee, tells *Clinica*



Dr Isao Ikeda

Clinical testing, especially in vitro diagnostics (IVDs), has evolved considerably since the late 1960s, with significant advance in the discovery and development of new tests, as well as improvements in medical technology. Clinical testing became such an essential part of medical practice that a new term of “laboratory medicine” was formed.

However, since the 1990s, the Japanese healthcare system has rarely carried out appropriate evaluations of the true value of

IVDs and its contribution to medical practice. For that reason clinical testing fees have fallen sharply since 1990, while healthcare costs continue to rise (see figure 1).

The 2008 revision of medical reimbursement fees in Japan made an effort to reflect the value of IVDs and indicated a more promising future trend.

While the need and importance of reviewing the value of IVDs for Japanese healthcare was acknowledged and partially reflected in the revision, it failed to differentiate the valuable contributions of technological advancements and of new clinical indications for existing biomarker tests.

The healthcare system in Japan faces many significant challenges including the advancement of medical and scientific technologies. In recent statements, government representatives have highlighted the need to correctly assess the following:

- How will these technologies improve the quality of medical care in Japan?
- How will they improve patients' quality of life (QOL)?
- How will they impact the overall medical cost, including longer term economic benefits?

In order to secure innovation and enhancement of IVDs for new, valuable contributions to the Japanese healthcare system, it is obligatory to revise the current reimbursement system.

A new reimbursement system needs to be created that will reflect the actual value of new technologies and biomarker tests with respective clinical indications to clinical care and overall healthcare cost. Furthermore, it needs to ensure that the right tests of appropriate quality will be made available to all people in Japan at the right time and place.

## Timing

Testing at the right time involves two dimensions: the timing of disease progression and the timing from test request to the availability of a result.

The use of IVDs should have an increasingly important role in earlier phases of disease progression and ideally identify early risk factors that will allow us to prevent a disease.

In that regard, the introduction of metabolic syndrome

screening tests in 2008 is a positive example. For better patient management in acute diagnosis and appropriate triage and treatment decision, it is important to make results available sooner, thus to shift appropriate testing from centralised locations to hospital-based laboratories.

## Price and value

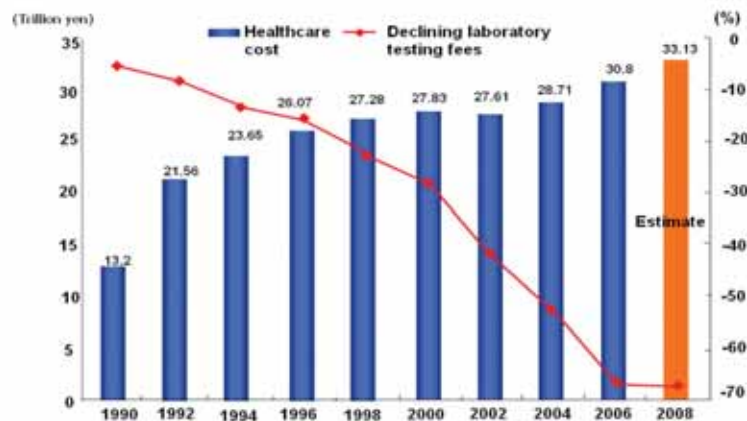
Clinical testing fees do not reflect the value of the products used, and provide no incentive, but rather a disincentive, for new product developments.

The current Japanese reimbursement system does not reflect the beneficial impact of advanced medical technologies compared to those based on older technologies.

The current reimbursement for HIV testing is a good example of such a mismatch in value recognition (see figure 2).

While new generations of test performance provide the opportunity to detect an increasing number of variations of the virus, and better sensitivity (thus allowing for earlier disease detection), there is no incremental reimbursement for these superior test generations available. Instead, reimbursement is lower for advanced tests today than it was for older generations a few years ago. All of this is being compounded by increasing regulatory requirements, which add to the cost of introducing new products into Japan. In many cases, such products have already undergone thorough tests and have been certified (CE mark).

Figure 1. Healthcare cost and clinical testing fees in Japan



**Place**

Providing appropriate access to testing is closely linked to the importance of the timing and priced value of testing as explained above. For example, today, hepatitis and HIV tests are made available at healthcare centres around Japan, but such centres are yet relatively few and very limited to specific geographic areas.

As a result, not everyone has easy access to these important tests. A reimbursement system should be introduced which considers the importance of testing locations as part of the clinical need and encourages appropriate availability of testing. In the example of hepatitis and HIV testing, this could involve testing carried out at healthcare facilities throughout Japan.

Clinical laboratory testing has, and will continue, to contribute to medical care and improving patients' QOL.

In order to continue enhancing its contributions and to

provide such healthcare solutions in a sustainable manner, it is imperative that the Japanese medical insurance system introduce and implement a reimbursement system based on actual value of new technologies.

In recent years, there has been a whole-range of new IVD advances; advances in rapid diagnostic assays, molecular testing systems for sexually transmitted diseases and healthcare-associated infections, liquid-based cytology systems for cervical cancer testing as well as biomarker tests with respective clinical indications for clinical care, all of which resulting in overall healthcare cost savings.

In Japan, we must create a medical reimbursement system

that rewards investments in R&D, and the development of new IVD technologies that have demonstrated evidence for their valuable contributions to healthcare, in order to provide high quality healthcare for people in the country.

**Figure 2. The decline in HIV testing fees as the testing method advances**

