MedTech Europe
from diagnosis to cure

The Value of Diagnostic Information

A comprehensive concept of "Value" for diagnostics

In Vitro Diagnostic (IVD)[1] testing has become an indispensable tool in clinical practice. It can provide critical information at every step of the patient pathway, from prognosis, screening, diagnosis to monitoring the progression of disease, and predicting treatment responses. IVDs also play an increasing role in driving personalized and cost-efficient healthcare delivery.

SOME FACTS AND FIGURES ABOUT IVDs

Results of in vitro testing influence as many as 70% of clinical decisions, while IVDs account for just 0,8% of total healthcare expenditure. When IVDs are reimbursed, the decision is typically based on the cost of the test kit itself, the equipment that analyses the sample (usually large laboratory machines) and the cost of staff performing the analysis, rather than on the value they bring. The reimbursement of IVD's varies widely across the continent, from €3.6 (Romania) to €43.5 (Switzerland) per capita per annum, which leads to large inequalities of access. Therefore, there is a major need for a new evaluation framework, that recognizes the comprehensive value of diagnostic information.

INFORMATION ON A WIDE RANGE OF OUTCOMES

The concept of value and its measurement for IVDs is different from that for therapeutic medical devices or pharmaceuticals. IVDs are complex interventions which can provide information on a wide range of different outcomes, depending on the contextual factors and the perspective taken:

- Improved clinical benefits for patients;
- Societal gains of early detection and prevention of disease progression;
- Value of knowing for individual patients;
- Economic savings and resource efficiencies for healthcare institutions and health systems;
- Improved patient management by health care providers;

Essentially, the information resulting from diagnostic testing, provides value by enabling the different users to make decisions on the expected best course of action with less uncertainty.

1) In Vitro Diagnostics are any medical device which is a reagent, reagent product, calibrator, control material, kit, instrument, apparatus, equipment or system, whether used alone or in combination, intended by the manufacturer to be used in vitro for the examination of specimens, including blood and tissue donations, derived from the human body, solely or principally for the purpose of providing information:
• Concerning a physiological or pathological state; or
• Concerning a congenital abnormality; or
• To determine the safety and compatibility with potential recipients; or to monitor therapeutic measures;
Source: The European Medical Technology Industry – in figures, 2016

CAPTURING THE COMPLETE PICTURE

To capture the full value of diagnostic information, and appropriately consider what matters to patients, society and to all other players involved in the healthcare delivery, both assessors as well as decision makers on funding and reimbursement should consider the full breadth of value that diagnostic information can provide, including:

- From a patient perspective, the direct and indirect impact on relevant outcomes;
- From a health system perspective, the impact on the use of resources by different actors, in different healthcare pathways and settings, and over time.

If the full potential of diagnostic information is explored, societal as well as individual health outcomes will improve in a sustainable way. To achieve that, it is necessary to define relevant and pragmatic assessment methods, which build the basis for rewarding the value of diagnostic information. Such assessment would go beyond technological criteria and would comprise the multiple dimensions of value and the multiple outcome measures, relevant for medical decision making.

Diagnostic Information Brings Multidimensional Value