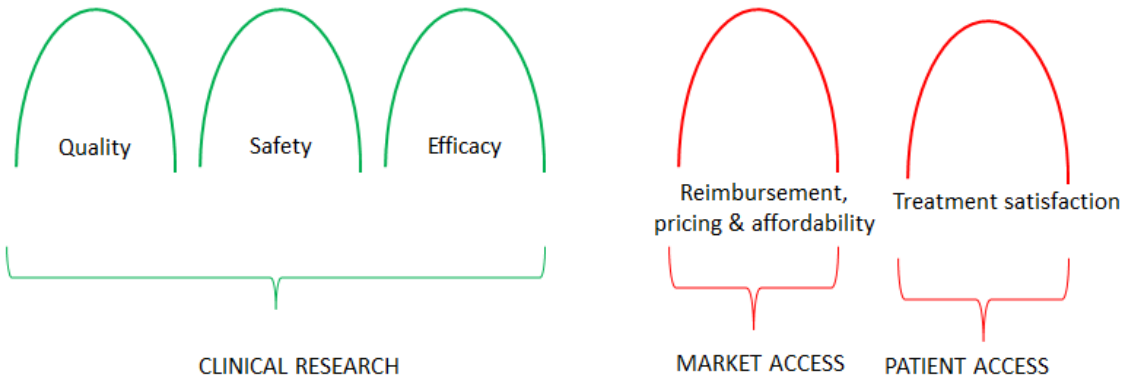
Articulating the value of diagnostics: challenges and opportunities

Diagnostics make a tremendous contribution to health by informing circa 70% of health care decisions at only a fraction of total health care spending (circa 2%) (1). Nevertheless, diagnostics face difficulties in current market conditions to obtain reimbursement and to enter the market efficiently, as health care policy makers and managers often struggle to separate and reward the value of diagnostics from the value of treatment. At the same time, providing information about the quality, safety, and efficacy of medical innovations including diagnostics is no longer sufficient to ensure acceptation and reimbursement (2) (figure 1). Indeed, an ever more important "fourth hurdle" is the need to provide evidence about the cost-effectiveness of an innovation to obtain (national) reimbursement (3). Fed by growing concerns about the high costs of new technologies, this "fourth hurdle" is applicable to an increasing range of technologies including diagnostics. However, the evaluation of diagnostic tests typically stops after assessing the test accuracy (4).

Various frameworks for the evaluation of diagnostics have been developed. The common feature of these models is that they emphasize the need of assessing patient and societal outcomes. The importance of providing evidence on the cost-effectiveness of the diagnostic innovation is also mentioned, and since this information is increasingly valued by various stakeholders, a need arose for methodological scrutiny in the economic assessment of diagnostics. For example, the National Institute for Health Care Excellence (NICE) in the UK, which acts on behalf of national payers, has set up a Diagnostics Assessment Programme (DAP) for proper evaluation of diagnostics to inform reimbursement decisions. Besides the need of health economic evidence for obtaining national reimbursement this evidence is highly valuable for informing decision-making and gaining market acceptance at local levels.

Figure 1 – Hurdles in articulating the value of diagnostic innovations (3)



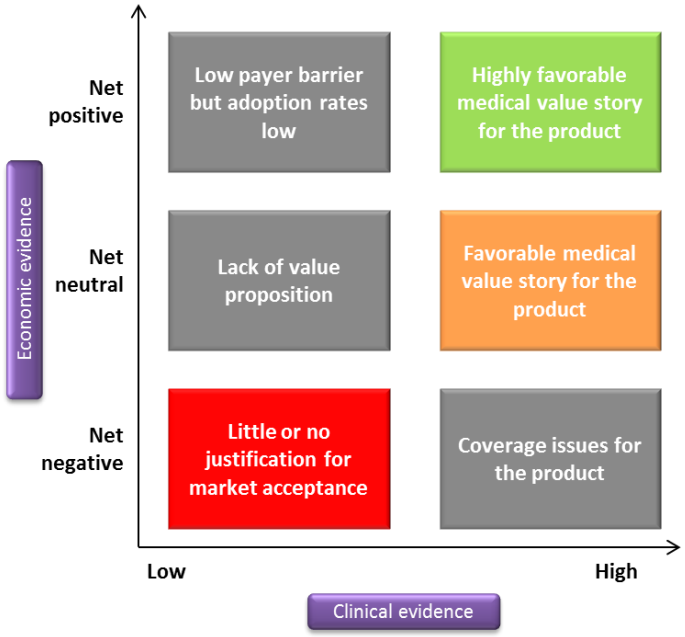
The finding that only a limited number of diagnostics enter the market can partially be explained by several trends related to possible negative effects of diagnostic tests. For example, there is growing concern about the overuse of diagnostics. The introduction of diagnostic tests can lead to the diagnosis of diseases that would otherwise not manifest symptoms or deteriorate the health of a patient. Furthermore, the diagnosis can cause anxiety in patients and may lead to the provision of unnecessary (and sometimes risky) treatments. Secondly, the availability of medical technologies is associated with sizable increases in spending (11). This is not burdensome if these technologies produce comparable societal benefits. However, it has been suggested that an increase in healthcare spending does not simply produce higher quality of care (11). Recent research found that the availability of a diagnostic imaging technique did not necessarily substitute the use of other imaging techniques. This drove up spending in other areas to the extent that these expenses exceeded the benefits generated by the new diagnostic test (11).

This raises the question how the added value of diagnostics can be convincingly and clearly demonstrated to support and accelerate market access. In this paper we will highlight the challenges and opportunities in articulating the value of diagnostics. We will furthermore argue that tailored health economic evidence is essential to make the value of diagnostics more compelling to stakeholders such as payers, users, clinicians and patients and to gain market and patient access.

CHALLENGES

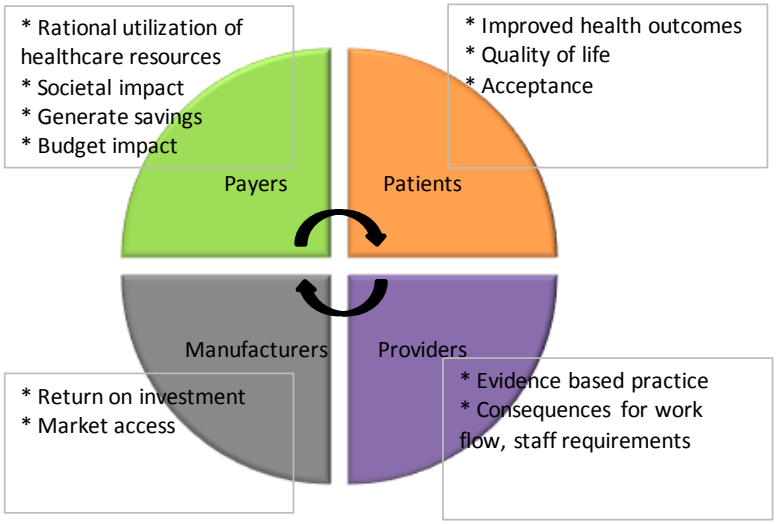
The value of a diagnostic test is determined both by its clinical and its economic value. These two types of evidence are essential to support acceptance, adoption and coverage of a new diagnostic test (figure 2). For many years, the clinical value of diagnostics was assessed on diagnostic accuracy as diagnostics have few direct patient outcomes. Over the last decades, the diversity and applications of diagnostics has expanded exponentially which has ensured that diagnostics now have the potential to influence various outcomes regarding disease management, patient outcomes, and patient wellbeing. Therefore, policymakers and potential users are increasingly requesting information about these various outcome measures to demonstrate clinical value (12). On the other spectrum, economic evidence includes information on how the use of a diagnostic innovation will affect budgets of users and stakeholders.

Figure 2 – Medical Value Map. Maximum value when both Clinical and Economic Value is demonstrated via compelling evidence (13)



The clinical value associated with the use of a diagnostic test follows from three sequential components: (1) test accuracy; (2) diagnostic thinking; and (3) effectiveness. A diagnostic test generates clinical value when the diagnostic accuracy of a test influences the therapeutic decisions of prescribing clinicians and this eventually impacts patient outcomes (12). The evaluation of clinical value can be quite complex because it requires detailed knowledge of existing and emerging steps in the care pathways after diagnosis (14). The clinical and economic value is thus determined by various outcomes which can be more direct and applicable to a single stakeholder (i.e. short-term utility and budget impact) or which can be indirect (i.e. final health outcomes and societal benefits). The differential timing of these outcomes means that stakeholders do not experience the same benefits or incur the same burden related to the diagnostic test. This is even complicated by the fact that stakeholders have different decision drivers and evidence needs (figure 3) (3). For example, patients and clinicians will value the use of a technology based on the patient's health and clinical experience (15). On the other hand, policy makers, management and payers will primarily take the budget impact of the new technology into consideration (both in the short- and in the long-term). All these differences should be taken into account by developers when articulating the value of diagnostics.

Figure 3 – Decision drivers and evidence needs of different stakeholders.



OPPORTUNITIES

Besides all the aforementioned challenges, there are also many opportunities for articulating the value of diagnostic innovations. Multiple methods have been developed that can help in acquiring this information to support and accelerate their introduction to the market.

Because of the current resource constraints in healthcare and the increasing need to allocate resources efficiently, private and federal payers have become critical in examining the value of diagnostic tests (16). Healthcare policymakers have long called on manufacturers to shift from a narrow technical or biomedical perspective (test accuracy) to a wider perspective considering final outcomes in the patient population (17). The ultimate goal of diagnostic tests is to provide information that aid health care providers in making clinical decisions that will eventually lead to improved patient health outcomes (15). Performing health economic analyses is a method where both the effect on clinical outcomes and the effect on costs can be studied, both on short- and on long-term. As such, these analyses are of great help when demonstrating the value of diagnostics to clinicians, payers and policymakers.

Health economic analyses

In comparative health economic analyses, a new (diagnostic) test is compared to the current standard of care. Particularly in the field of diagnostics this requires a detailed understanding of how a diagnostic test impacts clinical management (i.e. by starting, stopping, or modifying treatment, performing additional testing, or watchful waiting). The clinical pathways in both situations are studied, and the costs and health outcomes that result from each situation are assessed. A health economic model can be used to integrate data from various sources (i.e. epidemiological data, clinical trials, cost of illness studies, expert opinion etc.) to evaluate final patient outcomes. Depending on the availability of data, assumptions are used in health economic analyses which are evaluated by means of scenario and sensitivity analyses. For example, scenarios may include different assumptions regarding the disease prevalence, test performance, therapeutic efficacy or the costs of the test. Comparing the cost-effectiveness result in the different scenarios provides insight into important drivers of the cost-effectiveness of the diagnostic test.

Several guidelines have been drafted on how health economic evaluations should be performed when analyzing the value of diagnostics . Six general steps can be identified for this evaluation (figure 4).

Figure 4 – Steps in conducting health economic evaluations.

1. *Systematic literature search*
2. *Identify stakeholders*
3. *Involve Key opinion leaders (KOLs) and users in the process*
    a. *To articulate current clinical practices and true clinical value of the innovation*
4. *Draft decision analytical model*
5. *Test different scenarios depending on the availability of data*
6. *Translate into user-friendly interface for use at payer, clinician, laboratory directors* etc.

The involvement of KOLs is paramount in order to identify the model structure and evidence base, particularly regarding the application of the diagnostic test and the process that influences patient outcomes (see challenges).

Early economic evaluations are useful for timely decision-making during product development

The majority of health economic analyses are conducted during the last phases of the product development cycle. The information obtained from these analyses is useful for decision-makers and potential users. However, health economic analyses can also provide valuable information for manufacturers. Early insight in the potential cost-effectiveness of a new diagnostic test is useful to optimize product development. Early health economic evidence can be used to make adaptations during product development to beneficial the patient and societal impact of the innovation and to increase the return on investment (6). This prevents high spending of research and development budgets during late development for devices with limited value.

Early cycle economic evaluations evaluate technologies when they are still in development, which means that early evidence on the potential cost-effectiveness is provided. In medical product development, decisions with regard to future development have to be made during the product development cycle. To that end, the results of an early economic evaluation can be used for timely decision-making. Early cycle economic evaluations are conducted during several phases to either inform R&D decisions, investment decisions, or market strategies. R&D decisions are informed by identifying the product's advantages and by prioritizing the intended applications of the new technology including the target group and setting. This information substantiates the concept development of a new diagnostic test. Another example of an early cycle evaluation is the headroom analysis. With this method, the cost-effectiveness of comparators in the current care are reviewed to assess the room for improvement of the new diagnostic test given its expected benefits. The headroom can be assessed across different applications of the diagnostic test to inform product development, continuation decisions, and pricing of a new test. Another advantage of early health economic models is the ability to identify which information is most valuable to reduce uncertainty about the cost-effectiveness results. The evidence that is obtained by early modeling is useful to guide product development and market decisions at an early time point and to increase return on investment compared to the conventional analyses later in the product development cycle (23).
Even though evidence about the cost-effectiveness is provided and market access is obtained, this might not be sufficient to get the diagnostic introduced and embedded at the local level (24). On this level, potential users are primarily interested in how the adoption of a new diagnostic test will affect their budgets.

Budget impact analyses

Budget Impact Analyses (BIAs) address the expected changes in the expenditure of a health care system after the adoption of a new intervention. BIAs are used for budget or resource planning, but are also increasingly required by reimbursement authorities, along with cost effectiveness analyses (CEAs), as part of a listing or reimbursement submission. Those interested in BIAs include those who manage and plan health care budgets, such as administrators of national or regional health care programs, administrators of private health insurance plans, administrators of health care delivery organizations, or employers who pay directly for health care. Each stakeholder has a need for clearly presented information on the fiscal impact of the adoption and diffusion of new health care interventions. They may differ, however, in their requirements for particular time horizons and for the categories of costs in which they are interested .

Discrete choice experiment

When a new diagnostic test has entered the market and is available at the local level, the last hurdle is to obtain patient access. Prescribing clinicians have to take up the diagnostic test before patients have access to it. Manufacturers may be interested in the predictors of acceptance of new tests in order to prioritize product features during product development. For example, patients may take the emotional and cognitive effects associated with a diagnostic test into account in choosing one test over another (12). Patients can dislike a diagnostic test due to the discomfort of undergoing the test or due to anxiety experienced while waiting for the results. Such preferences are identified in a **discrete choice experiment** (DCE). In these studies the characteristics of a new technology and the relative importance of these characteristics are identified that play a role in the doctor and/or patients acceptance of the technology.

Conclusion

In the current market conditions, manufacturers face challenges in obtaining market and patient access of their diagnostic innovations. Assessing the value of diagnostics will become more challenging as the technical possibilities and potential applications of diagnostic tests are increasing. This paper highlighted the importance of tailored health economic evidence on diagnostic innovations to inform multiple stakeholders in various decision making processes. Health economic analyses, budget impact analyses, and discrete choice experiments are valuable methods for providing tailored evidence to several stakeholders such as potential payers, providers, and patients. In addition, methods of early health economic analyses were explained to illustrate the value for manufacturers to guide product development and to increase the return on investment of a new diagnostic test.

About Panaxea

PANAXEA is a University of Twente spin-off accelerating patient access to biomedical innovations by building scientific evidence to inform strategic development, pricing and reimbursement decisions. Our mission is: “Unlocking the value of biomedical innovations”. We combine health economic, health science and strategic expertise to provide a range of services. By means of this approach we support your company in identifying, building and articulating the clinical, humanistic and economic value of your product to inform local, national and international decisions makers. We collaborate with our clients to identify the critical success factors and articulate the added value of their biomedical innovations, even at the earliest development stages. We commit to tailor-made solutions to meet our clients’ needs along the biomedical product development pathway.

What sets PANAXEA apart from other consultancies is our science-based approach and high academic standards that are applied along the entire innovation development pathway. Herewith we provide you with a competitive advantage from the start.

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