Chapter 4

Application of Economics Concepts to Stratified Medicine: Use of Health Economics data to support Market Access for Stratified Medicine interventions

Hans-Joerg Fugel
Mark JC Nuijten
Eric Faulkner

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Abstract

**Background:** Stratified Medicine (SM), as opposed to empirical medicine, is the practice of using biomarkers or diagnostic tests to guide the choice of therapeutic treatments. The link between the diagnostics and therapy provides new opportunities for value creation and may strengthen the value proposition to pricing and reimbursement authorities. However, SM provides new challenges for the value assessment process, in particular health technology assessment (HTA) and pricing and reimbursement (P&R) decisions. Although health economics (HE) should be relevant for all stakeholders, not all stakeholders are comfortable with analysis/interpretation of economic data relevant to SM interventions as this approach is still in an early/emergent stage in most markets.

**Objective:** This article addresses how different stakeholders are using the health economic data in the overall value of information analysis to inform prioritization and reimbursement of SM interventions.

**Results:** Findings of an expert discussion outlines key challenges affecting various stakeholders when applying health economic data in the healthcare decision-making process for SM interventions.
1. Introduction

Stratified Medicine (SM) as opposed to empirical medicine is the practice of using biomarkers or diagnostic tests to guide the choice of therapeutic treatments. The SM approach stratifies the patient population into responders and non-responders using a predictive diagnostic test and hence defines a cohort of patients that shows a differential therapeutic response for a certain treatment, and as a consequence reduces the eligible patient population. Matching therapies to patient populations using diagnostic-based stratified medicine offers the prospect of enhancing patient care with safer and more effective drugs, delivered with a greater certainty of success to those in need. The link between the clinical biomarker and the therapy provides new opportunities for value creation, offers the potential to improve clinical practice and treatment pathways and to strengthen the value proposition to pricing and reimbursement authorities.¹

However, the application of biomarkers and companion diagnostics to drug development and commercialization is occurring in a complex legal, regulatory and reimbursement environment which does not currently fit with SM approaches. For example, diagnostics and pharmaceuticals are evaluated by different decision makers within the health authorities, whereas a holistic approach is required in order to assess the full health and economic value of stratified medicine from a health care system perspective. Third party payers in various healthcare systems have been rather resistant to paying for costly stratification diagnostics unless the diagnostic companies can demonstrate clinical utility and/or cost-effectiveness without endangering the various health care budgets. The concern regarding SM approaches among payers includes fears that the use of expensive tests for a large population and/or that the higher price for some biomarker-targeted treatments will wipe out any potential savings from targeting therapeutic interventions. However, in practice this depends on a number of factors including test cost, percentage of test responders anticipated in the target population, and the cost of the stratified treatment versus alternatives.

Stratified Medicine provides new challenges for the value assessment process, in particular health technology assessment (HTA) and pricing and reimbursement (P&R) decisions. Adding a diagnostic or testing element to pharmaceutical technology will increase treatment complexity and can complicate value assessment, including uncertainties around evidence assessment, gaps in the evidence supporting clinical utility and differences in the quality of medical management with the tests. In addition, there is an absence of implemented procedures, criteria and standards in generally assessing diagnostics/tests in SM.² In many markets, HTA of diagnostics remain nascent and evolving although in general most standalone tests are reviewed at local and regional level for reimbursement purposes) while globally HTA of diagnostics is highly heterogeneous with no clearly accepted standard.

Although health economics (HE) should be relevant for all stakeholders, not all stakeholders are comfortable with analysis/-interpretation of economic data relevant to SM interventions as this approach is still in an early/emergent stage in most markets. In addition, some stakeholders
may consider the specific ethical issues related to SM more important than health economic benefits. They may be concerned about stratification of patients associated with possible false positive/negative results which may have severe consequences for the patient leaving to inappropriate treatment. Furthermore, physicians must take an active role in applying SM approaches for this concept to be successful, but may require education on ‘how to use’ new technologies and appropriate financing systems including incentives to support appropriate use of the test. As more SM interventions reach the markets in the next years, payers will be making more coverage and reimbursement decisions that take into account the cost and value of these technologies.

This article will address how different stakeholders are using the health economic data in the overall value of information analysis to inform prioritization and reimbursement of SM interventions. Findings, derived from an expert discussion will outline key challenges affecting various stakeholders when applying health economic data in the health care decision making process for SM interventions.

**Expert meeting**

An expert meeting was organized (December 2011) with a panel of international experts in the field of both health economics and SM to discuss the main methodological issues in the health economic field of SM (manuscript of ‘Health Economic Assessments in SM’ is currently under review) as well as the application of these data in the healthcare decision making process of different stakeholders in EU countries and the US. The experts were sent before the meeting a set of published literature on health economics and stratified medicine as preparatory materials. The panel discussion was guided by statements drafted from key principles and best practices for health economics to address specifics of HE in SM. It was considered important to focus on SM in active disease populations, therefore SM as preventive tool in healthy people (e.g. screening for oncogenes) was not addressed. There was no specific disease focus during the discussions, however, the specialists participating in this meeting considered issues associated with conducting health economics research in SM for two scenarios: a) Diagnostic is used as a companion diagnostic test in a test-treatment combination (e.g. HER2/neu- Herceptin, KRAS/EGFR- Vectibix and Erbitux, predictive for efficacy); b) Diagnostic is developed as stand-alone test (e.g. Oncotype DX and MammaPrint prognostic tests for adjuvant chemotherapy).

**2. Use of HE-data for SM decision-making**

The following target users (stakeholders) have been identified as relevant for SM decision-making:

- Third party payers
- Advisory bodies (e.g. NICE)
Different health economic data are relevant to different health decision makers in various markets. Cost-effectiveness is relevant to some key health decision makers but is not the most useful form of economic information to others. To date, a few cost-effectiveness analyses (CEA) exist for SM interventions with inclusive results as the evidence for effectiveness is frequently preliminary at the time of product launch. Tests may lack conclusive evidence linking their clinical usefulness to health outcomes and without sufficient evidence addressing key dimensions of test value it is difficult to assess cost-effectiveness. The lack of reliable information to support SM cost-effectiveness has been reinforced by several systematic reviews on the topic.\textsuperscript{[3-5]} For instance, some stand-alone diagnostics (e.g. CYP2C9 testing to inform warfarin dosing or CYP2C19 testing to identify clopidogrel (Plavix) responders) have not achieved broad payer acceptance because evidence of the links between testing, treatment and health outcomes has not been sufficiently established.\textsuperscript{6} Because of complexities in CEA of SM, budget impact information (BIA) may be more relevant and actionable for most target users, especially third party payers. There is an expectation by payers that applying a test will lead to cost savings (cost-offset) by limiting care to effective regimens, and decreasing resource use by lowering the frequency of treatment complications. However, many tests that are used to stratify patients are still “below the radar” of decision makers, because they are either cheap, or used on small scale, and individual tests may not be easily differentiated by existing payment mechanisms in many markets.

Often, these tests are covered within the DRG (diagnosis related group) fee schedule in the inpatient (hospital) setting and a code-based fee schedule in the outpatient (ambulatory) setting, respectively, a technical procedural cost which does not consider clinical and economic value.\textsuperscript{7} Moreover, nonspecific coding issues (i.e., “code stacking”) for molecular tests makes it difficult for payers to track outcomes associated with diagnostics. Health economics is not an issue in such circumstances, until the prevalence of the conditions becomes high, at which point there may be perceived ethical issues associated with test accuracy or possible budget consequences. Under these circumstances, the choice between a SM treatment approach and traditional treatment becomes relevant and requires the assessment of opportunity costs of decisions about which health care intervention to use.

However, in many markets there is a lack of implemented procedures, criteria and standards in generically assessing tests in stratified medicine.\textsuperscript{2} For instance, stand-alone diagnostics follows a medical device technology evaluation process which has very different evidentiary requirements from medicines. Different types of test have different evidence requirements and diagnostic evidence assessment methods are still evolving in most major markets, although countries like the UK, France, Canada, Australia and the US have started to explicit developing criteria-/guidelines for more appropriate diagnostic value assessments.\textsuperscript{8} Historically, in a
The majority of markets diagnostic evidence has most frequently been submitted by test manufactures to individual budget holders assessing test performance and budget impact. While currently there is no consistent process for conducting HTA’s of companion diagnostic in EU and the US, payers are interested in evaluating the clinical utility (linking test use to change patient management) and economic impact of diagnostic testing (cost offsets throughout the test and treatment cascade) as part of coverage and reimbursement decisions.

At present, payers often do not differentiate between stand-alone and co-developed companion diagnostic tests in terms of acceptance criteria (economic or clinical). This may be problematic for stand-alone tests if criteria associated with companion diagnostics (i.e., drug/diagnostic combinations) are applied to stand-alone tests that do not operate with the same market and economic freedoms as pharmaceuticals. For companion diagnostics developed in tandem with the drug, this is often not an issue since the evidence developed will be more “drug-like” in nature and will more clearly link test use to clinical utility and health/economic outcomes.

Regardless of the criteria used in the actual decision-making, both CEA and BIA can be considered important in both companion and stand-alone diagnostic scenarios for the payer (including a wide variety of governmental and private organizations). An example is the Mammaprint test in The Netherlands, which shows that the evaluation depends on the type of stakeholder. The Dutch national health authorities are currently exploring the value of the Mammaprint test from a clinical and cost-effectiveness perspective (within a prospective clinical phase III trial - MINDACT1). However, payers (insurance companies) are already reimbursing this test, because the use of the test has demonstrated to realize cost savings and positively impact on the annual budget of the payers. This example shows that from a payer’s perspective, clinical utility and cost-effectiveness are not that important if budget impact and clinical consequences are clear.

**Inconsistent methodology for value assessments**

For central HTA bodies (e.g. NICE) incremental cost-effectiveness is an important health economic outcome in certain markets (e.g. UK, Sweden, Belgium and The Netherlands) although the cost-effectiveness estimates for recent SMs (e.g., HER2, EGFR and KRAS testing) have been highly variable among major HTA markets, suggesting that methods for incorporating test information into economic evaluations are inconsistent. Different evaluation approaches have been used within the EU to inform reimbursement and there is currently much ambiguity about whether SM interventions are or will be covered, by whom, and at what rates. For instance, while Herceptin (trastuzumab) in breast cancer and Erbitux (cetuximab) in colon cancer are widely reimbursed across the EU, reimbursement for the companion HER-2/neu testing and KRAS testing varies across Europe. In the UK, France, Germany and Italy both tests are publicly-funded and are reimbursed on cost-based formulae, hence not subject to a value-based payment negotiated based on its relevance to clinical decision making. In other countries (e.g. Spain), local/ regional market access for these diagnostic based therapies have been achieved only through subsidizations for HER-2 and KRAS testing (lower test prices / or free test) by pharmaceutical manufacturers. However, decentralization of HTA reviews

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1 MINDACT: (Microarray In Node-negative Disease may Avoid ChemoTherapy)
(regional/local) and lack of health technology assessment transparency makes a broad coverage of diagnostic tests within countries to a cumbersome and lengthy process. Questions remain about appropriate economic measurements and approaches towards more flexible reimbursement schemes, which would facilitate a broader market access of SM interventions.

**Increased complexity**

Assessment of the added value of SM interventions is complex and depends on many factors including the performance of the diagnostics, quality of labs and medical management practices. There are also relatively few mechanisms or incentives to assess economic value from a societal perspective because in many health care systems in EU and the US there is no longitudinal accounting to enable payers to capture long-term cost savings from near-term testing. However, anticipated health care costs savings from targeting drug therapy will remain theoretical until a more holistic perspective on healthcare may be followed. There is a need to clarify the evidentiary framework and to establish evaluations standards on how to evaluate diagnostic and test treatment combinations by leading HTA agency and payers. Organizations such as the Center for Medical Technology Policy (CMTP) and the Evaluation of Genomic Applications in Practice and Prevention (EGAPP) in the US as well as the European Personalized Medicine Diagnostics Association are working to explore evidentiary criteria for reimbursement of diagnostics and SM interventions.

**Ethical Aspects**

Governmental bodies (e.g. NHS/UK, Department of Health /US) will take a broader perspective beyond clinical and economic outcomes assessing SM intervention, including social values (equality) and ethical issues. The ethical issues are most closely related to the sensitivity/specificity of the diagnostic test in SM. On the one hand, SM is an improvement over empirical medicine, due to one treats only the right patient identified by the companion diagnostic instead of a broad population that includes also unknown non-responders. On the other hand, there is a risk to fail to treat the right patient because of the sensitivity of the test. For example, a number of patients will not receive the most optimal treatment after a false negative test, which may have severe consequences for the patient. Alternatively, following a false positive test, a cancer patient may not receive a SM treatment that will work and could die because alternative treatments were not used/ denied. Thus, if a SM program leads to a favourable incremental cost-effectiveness ratio, e.g. 20,000 Euro/QALY, but the sensitivity/specificity of the diagnostic test is only 50%, the SM program will probably not be accepted. The low sensitivity/specificity and its resulting ethical issues are unlikely to justify approval, despite the favourable cost-effectiveness. This example shows that balancing clinical, economic and ethical issues is key for SM interventions.

The weight of ethical issues related to sensitivity/specificity of the test makes the assessment of SM much more a multi-criteria decision than traditional pharmaceuticals. However, the relevance of ethical issues compared to health economic issues will vary significant by market- and cultural perceptions and may become especially important for severe diseases, like multiple sclerosis. It is more challenging to evaluate a biomarker for such a disease due to the large number of patients and the test required to be highly accurate (i.e., as close to 100% sensitivity
and specificity as possible) given the severity of the disease and the risk of withholding an appropriate treatment from someone. Likewise, the principles of equality and access should be applied ensuring that new SM interventions are equitable available to patients recognizing its willingness to pay and the ability/ scope of patient co-payment.

Within hospitals, the interest of health care providers is more towards budget impact data and financial savings related to more efficient use of healthcare resources than towards cost-effectiveness data which is not different to traditional pharmaceuticals. Providers may judge SM approaches based on limited short-term sensitivity and specificity outcomes of the diagnostic test and may not include the long-term treatment associated outcomes. The performance of an additional test is often included in an existing diagnosis-related group (DRG tariff) where hospitals are paid a predetermined fixed payment rate per case according to historical cost patterns that do not reflect additional cost of using tests. So the additional tests can be viewed as an extra expenditure for the hospital, creating a disincentive for adoption unless cost-offsets in other budget centers justify use of the test or the payment system is updated to account for extra costs. However, changing existing payment system is cumbersome and requires the demonstration of sufficient cost and volume-data associated with a new technology. To bridge introduction of new technology temporary funding instruments such as NUB\textsuperscript{2} in Germany may be used and new flexible infrastructure is emerging across Europe which may allow clinic budget holders to enable possible patient access to such new technology via specific market access schemes including risk sharing with manufactures to address uncertainty about performance of technology and budget impact. At the same time, development, adoption and use of new diagnostic tests will be influenced by health care provider competence in using these technologies. Efforts to educate physicians and other providers are critical for proper use of these technologies in treatment decision making.

Health care professionals are another important target user. The physician or health professional will mostly be interested in the clinical effectiveness of SM intervention rather than in the costs which is not different to traditional pharmaceuticals. Clinicians in Europe will think about whether it is good practice (also according to their clinical group) and if SM treatment is included in the clinical guidelines. However, considering the increasing pressure on health care budgets, physicians may well be willing to provide advice on possible economic benefits or even to contribute to net cost-savings (either immediate or in the future) of SM interventions provided robust and transparent economic outcomes are available and have been communicated to them. At the same time, physicians in many health care systems are not paid for applying test/diagnostic in daily practice and may require appropriate financing systems including incentives (e.g., fee by doing the test) to support SM approaches from the physician’s perspective. In the US, there are examples of Accountable Care Organization models where quality measures/clinical pathways may alter the incentive structure for selection of certain treatments which may support SM approaches in this context.

For Health care professionals and providers, legal issues are also important to consider given potential for false positive/negative results, especially in the US, but also increasingly in

\textsuperscript{2} NUB: Neue Untersuchungs- und Behandlungsmethoden, a new Diagnostic and Treatment Method Regulation
Europe. Providers (hospitals) may still use the test to avoid malpractice lawsuit risk that may follow from withholding the test to patients. The hospitals will incorporate this test into the guidelines to make explicit when the test can or cannot be used, including to defray potential legal risks associated with SM.

For employers in the US who subsidize employee health insurance, there may be a budget impact issue on the premium cost with the introduction of new SM technology. This is especially true for high prevalent disorders, where downstream costs in terms of the premiums will be based on excess costs of the prevalent group. For instance, the application of the Roche AmpliChip CYP450 test for depression could present an example for employers to be forced to increase premium cost, because of the high prevalence of depression in the professional population.

3. New challenges for HTA and P&R schemes

Stratified Medicine provides new challenges for the value assessment process, in particular health technology assessment (HTA) and pricing and reimbursement (P&R) decisions. Adding a diagnostic or testing element to pharmaceutical technology will increase treatment complexity and complicates value assessments. Furthermore, third party payers in public and private health care systems in EU and the US have adopted different pricing & reimbursement policies for drugs and diagnostics. While pricing & reimbursement of pharmaceuticals in many EU countries and the US can be characterized as somewhat “value-based”, the reimbursement of diagnostics is resource or cost-based.10

Reimbursement agencies across Europe have compiled lists of devices and procedures established which are generally based on a version of the DRG system (e.g. in France/GHS code; UK/HRG).11 In this system, similar and related medical procedures are grouped together. Each group is then coded and given a monetary value, which is the set amount of money that will be reimbursed for each procedure, frequently including diagnostics and drugs, unless they are separately payable in the system. Often, these lists vary by country, between public and private healthcare provider, between hospital and outpatient care and sometimes by geographical region. For example, in the US, all in vitro diagnostics must be assigned to CPT (Current Procedural Terminology) code in order to be reimbursed. Major payers and other health authorities will make an effort to link new diagnostics to the existing reimbursement levels of older tests involving similar effort and cost. This means, that payments must come from an existing budget set for this procedure based on DRG or CPT codes and tests outside of the DRG system are separately payable. In the US, payment techniques such as “cross-walking” and “gap filling” are used for this purpose. Many observers have emphasized the need for more flexible pricing & reimbursement schemes which stimulate and reward innovations and reflect the added value of diagnostics tests. Current reimbursement schemes for diagnostics do not reward value creation, which discourage diagnostic companies from investing in such research. Several government commissioned reports have recommended a re-evaluation of reimbursement rates for diagnostics12 by pursuing changes in diagnostic coding and payment systems to better reflect the value of diagnostic tests. However, changing standard coverage
principles and/or to establish new coding systems is a rather long and uncertain process in many EU countries and the US.

In the meantime, novel payment approaches, risk sharing and conditional reimbursement agreements with third party payers are being explored to overcome the tension between funding new but expensive technologies and obtaining value for money where traditional reimbursement is not deemed appropriate. These arrangements between a manufacturer and payer/provider can use a variety of mechanisms (e.g. pay-for-performance, value-based purchasing) to address uncertainty about the real performance of technologies in daily practice enabling certain market access. They present an opportunity to enhance the value of SM by measuring comprehensively both outcomes and cost over a full cycle of care (e.g. episode of care payment); thus may be more appropriate to align the incentives of various stakeholders involved in P&R decisions when realizing long-term patient benefits including associated funding. However, in practice such market access schemes present an administration burden and many organizational and implementation challenges need to overcome to ensure effectiveness of such agreements. There must be good research governance and such agreements may be difficult to negotiate, due to legal requirements and increased costs and bureaucracy.

Coverage with evidence development (CED) provides another opportunity to move diagnostic testing forward within SM interventions. CED is used to generate data to inform clinical usefulness of tests while enabling earlier financial rewards to test developers, helping to maintain the return of investment. CED is currently under consideration in several jurisdictions in the US and in Europe.

To foster a broader coverage of SM approaches within the healthcare systems will require a more centralized, holistic and consistent process for conducting HTA’s in Europe and the US. Given the general lack of the HTA-approach for SM interventions, commonly accepted standards and procedures on how to evaluate stand-alone diagnostics and test-treatment combinations need to be established in order to provide industry with a clear-cut pathway to market access and reimbursement for population-wide use. Although key principle and standards for HTA´s exist for traditional pharmaceuticals in general, there is a need for more specialized HTAs which take into account most reliable and available evidence and being tailored to the specificities of SM interventions. This involves a rather broad value definition including clinical, economic, ethical and social values when considering the full impact of using a SM approach on the whole treatment pathway of patients. At the same time, a more holistic approach to health care funding is required in order to realize the full clinical and health economic benefits of SM interventions. Because of silo mentality in many health care systems, national authorities may need to develop a central financial system specifically applied for SM interventions. Creative solutions, such as the approach to care integration through bundled payments in The Netherlands will need to be identified and tested. In this sense, there is an
opportunity for Europe with its primarily single payers systems to realize SM approaches in a more cohesive way compared to the rather segmented US system.

4. Discussion

In an area of cost-containment and limited health care resources there is a need to consider opportunity cost of decisions about which health care interventions to use. Health economic analyses represent a key factor to determine the uptake of SM into healthcare systems while third party payers must be apprised of the value-adding effects of stratified medicine interventions to better understand the benefits of using such technologies in establishing their payment and reimbursement plan. However, understanding of economics of SM is challenging because the available evidence is often inadequate to truly inform decision making at both the local and national levels. Adding a testing element to pharmaceutical technology will increase treatment complexity and complicates value assessment including uncertainties about evidence assessment, test performance and quality of labs or medical management. There is a clear need to clarify areas of uncertainties and to establish evaluations standards on how to evaluate diagnostic and test treatment combinations by leading HTA agency and payers. While cost-effectiveness data may or may not be considered by payers in their rationale for paying for high-value tests, for many payers in EU and the US the cost impact is influential, particularly if use of the test results in direct cost savings such as avoidance of inappropriate drug therapy.

Market Access of stratified medicine approaches depends much on the assessment process, in particular HTA and P&R decisions. Today, fragmentation of HTA data requirements and methodology but also of P&R systems for diagnostic testing which are primarily cost/procedure based are not necessarily structured to reward the added-value of using tests to improve health outcomes. Novel payment approaches and risk sharing agreements may help to enhance the value of SM interventions on a case by-case basis provided that clinical and health economics outcomes are transparent. Moreover, such forms of market access schemes may be more appropriate to align the incentives of various stakeholders involved in P&R decisions when realizing long-term patient benefits including associated funding. Generating high quality clinical and health economic evidence will provide the confidence that enables third party payers more rapidly to adopt tests. At the same time, payer decision making may need to become flexible enough to allow for short-term inefficiencies in order to understand and benefit from long-term value. However, anticipated health care costs savings from targeting drug therapy will remain theoretical until a more holistic perspective on healthcare may be followed. Fostering broader coverage of SM approaches within the healthcare systems will require a more consistent process for conducting HTA’s in Europe and the US. Although best practices and key principle exist for HTA’s of traditional pharmaceuticals in general, there are no commonly accepted standards for applying these principles & measurements to SM approaches. However, recent attempts for HTA’s in stratified medicine are increasing in defining pathways and evidence criteria for SM technologies in some markets (e.g. UK/NICE’s Diagnostics Assessment Program). Moreover, further methodology development through an inclusive dialogue which reflects and balances input from key stakeholders including payer, patients, providers, employers, and industry is needed.
5. Conclusions

As more SM interventions reach the markets in the next years, payers will be making more coverage and reimbursement decisions that take into account the cost and value of these technologies. This article outlined key challenges affecting various stakeholders when applying health economic data in the health care decision making process for SM interventions. These challenges include methodological issues in the economic assessment of SM interventions and the need to clarify uncertainties regarding clinical and economic evidence requirements. Stratified medicine raises also new ethical issues in the market access evaluation, which do not exist for traditional pharmaceuticals. The weight of ethical issues related to sensitivity/specificity of the test makes the value assessment of SM much more a multi-criteria decision than traditional pharmaceuticals. HTA methodologies will have to evolve to address the multiple components of value that a diagnostic and therapy can provide. It is likely that different mechanisms of evaluation will be developed that are appropriate to each scenario (i.e. test-treatment combinations vs stand–alone diagnostic). In addition, coverage and payment pathways must be developed to adequately capture the value of diagnostic and test-treatment combinations to incentivize future investments in new technologies. Finally, early–stage cost-effectiveness analyses models may be particularly useful in SM and can help manufactures to prioritize investment decisions, including whether or not to combine a test and a drug and to generate more evidence. Such approaches may play an increasingly important role in influencing drug/diagnostic portfolio decision-making.

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