

"HEALTH ECONOMICS WILL CHANGE THE DIAGNOSTICS LANDSCAPE"

Many words have been written and spoken about health economics. The discussion on how to spend healthcare resources more efficiently has many facets ranging from new models for reimbursement to significant changes in how new tests are being developed. In order to provide an overview on current viewpoints in health economics, these topics were discussed with three internationally well-known health economics experts: Prof. Lou Garrison, Department of Pharmacy, University of Washington, Seattle, USA; Prof. Adrian Towse, Office of Health Economics, University of York, London UK; and Ass. Prof. David Veenstra, Department of Pharmacy and Institute for Public Health Genetics, University of Washington, Seattle, USA.

What is your belief regarding the potential value of diagnostics for managing healthcare costs?

Towse: Diagnostics can provide potential value in various environments from prevention to targeted treatments. Identifying particular subgroups for tailored treatments is probably the greatest promise that modern diagnostics can give – even in terms of economic value.

Garrison: Diagnostics could help to make the healthcare systems more efficient overall – so that we obtain greater value for the money we spend. Targeting those patients with a better cost-effectiveness ratio can add value by avoided side effects in poor responders, improving compliance and reducing uncertainty.

Veenstra: The potential value is pretty clear, if you look at innovative solutions like biomarkers – they help physicians to treat patients more appropriately, which generally lead to a greater value for healthcare systems. But we should also mention that, particularly in the US, there hasn't been much incentive to create value given current lack of value-based reimbursement.

Do diagnostic products already provide significant economic value?

Garrison: Yes, they do – if we could not measure lipids in hyperlipidemic patients or viral loads in HIV patients, we would not be able to manage them as effectively and efficiently. At the same time, given the largely cost-based reimbursement system that is applied to diagnostics, it is apparent that manufacturers will have difficulties capturing any additional value they create above the offered price. Unlocking the full potential for diagnostics to contribute value would seem to depend on moving towards a value-based reimbursement – one that rewards value creation instead of paying flat rates. Things could be better in the future if diagnostic reimbursement is reformed.

Towse: Or take primary care settings for example, where diagnostics help identifying whether a patient is asthmatic or not and then adjust the appropriate medication. Screening of patients in general can provide significant economic value here.

Veenstra: ... Examples include testing for diabetes, where diagnostics already provide significant value. There are many treatments that basically depend on diagnostics, which are taken for granted today.

If you take a closer look on industry issues now - are there examples where the diagnostics industry has already provided value through health economics analysis?

Garrison: My impression is that there has only been a very limited use of health economics analysis for diagnostics specifically. Perhaps the value of screening tests for breast cancer, cervical cancer, and colorectal cancer are the best examples of where health economics has been used to evaluate diagnostic tests.

Towse: Health economics analyses weren't really provided in the past. One simple reason for that is that the economic value wasn't considered in price negotiations for diagnostics. That's one of the reasons why there is nothing like a broad 'health economic culture' in the diagnostics industry today.

If the diagnostics industry would put a stronger focus on health economics analyses – could that lead to more favorable reimbursement structures for tests?

Garrison: Yes, I think that making the case for the incremental value creation would be helpful, but there is also potential to find agreement with reimbursement authorities to carry out such analyses if they are willing to give greater weight to value creation in their reimbursement levels. Demonstrating both clinical utility and cost-effectiveness is going to cost companies some money for the additional studies. Paying them more for value creation would be a reasonable step forward to provide some incentive to do these studies, in my view.

Veenstra: Definitely. But I'd guess that it would take at least five years from now before we see consistent reforms in terms of reimbursement procedures. Perhaps ten years from now we'll probably see the incorporation of a value-based reimbursement as a standard. On the private-payer level however, this may happen sooner.

Does health economics analysis for diagnostics products require a new approach, e.g. in terms of levels of evidence, outcome measurements, follow-up times, etc.?

Garrison: I think that diagnostics companies should do more health economics evaluation, and I see some of this already happening. The evaluation approach is fundamentally the same as for other medical technologies. Appropriate types and levels of evidence will depend on the specific technology and the disease it applies to. In some instances, additional evidence may need to be developed.

Veenstra: The key difference between pharmaceuticals and diagnostics is that regarding regulatory requirements and acceptance by the clinical and scientific community, pharmaceuticals have much better evidence-based arguments when they hit the market. Diagnostics tend to be thought of as 'safer' in general, therefore up-front assessments requested are generally lower. For assessing the value of a diagnostic product this means that you simply don't have that much of information demonstrating its value.

Towse: But also higher requirements for proving efficacy will be up shortly – demonstrating the effectiveness in practice. The core will be indeed to show evidence in therapeutic work better, because without this evidence you simply can't contribute value. I think that this should increasingly become a part of the regulatory and licensing process. Independently of that I'd expect that customers will want to see more of that.

Which steps need to be done first?

Garrison: Work needs to begin on several fronts immediately, if it hasn't already started. Reimbursement reforms, standards for analysis or shifts in study design are good examples for that. Reimbursement reform is going to take a long time, but a first step would be to convince authorities to consider value creation through a kind of “exceptions process.” That would at last promote recognition that new diagnostics can create high value.

Veenstra: There needs to be a significant reform in the process of reimbursement from the legislation side. Vendors and industry associations have already started to address this in their conversations with political decision makers, using value as the essential criteria for reimbursement. The first step could be to get away from the current cross-walking where the price of one test is closely related to that of a similar one. On the other hand, private payers could start to ask manufacturers for value-based arguments regarding their products, which would lead to a certain pressure on the relevant authorities.

Towse: Yes, companies will obviously change their research and development portfolios to better reflect diagnostics as products with a high value – if reimbursement procedures become more value-oriented.

Regarding the conflict between best medical care and costs – can health economics help to draw the line?

Towse: It's essentially helpful to understand the origin of healthcare costs and the value of diagnostics. It gives a more constructive environment to decide in terms of cost effectiveness and budget impact.

Garrison: The issue is really obtaining the best health we can for the money we spend, and health economics can be a big help here. Measurement of health outcomes is important, as is the application of cost-effectiveness analysis, but it is only one of the factors that must be taken into account. For example, access to care and equity are also important.

Veenstra: Where to draw the line is more a question of local policies and public opinions. Generally, health economics helps to understand the implications of best care and its costs – but it doesn't decide where to draw this line.

What's the current state of health economics for diagnostics industry in your market? Is it required for market access?

Garrison: My understanding is that it is little used, but some other countries are beginning to request it. Today health economics is not generally considered as part of either approval or reimbursement processes for diagnostics in the US, Germany, or the UK.

Veenstra: Requirements for something like a 'proof for value' is fairly minimal in the US. There have been few value or economic assessments so far. Reimbursement especially for laboratory testing in the US is based on rather antiquated models. I think that this will change, but it's going to take some time. But there are also some on-going activities to develop an approach for diagnostic manufacturers in order to consider value better in the dialogue with payers.

Towse: Health economics in the diagnostics industry is not very relevant today here in the UK. But this will change over time. Politically there's a clear need to create a culture of a more value-based view on budget and payment decisions.

If you compare the contribution of pharmaceuticals and diagnostics to health economics today – how will it develop in the future?

Veenstra: Just look at approaches like personalized care that are enabled by new diagnostics – I think that developments like this will boost a more differentiated view on the contribution of diagnostics to medical success. In terms of contributing value we'll probably see a similar development with diagnostics as within pharma – and this process of gaining recognition will develop faster with diagnostics.

Garrison: Pharma uses it a lot more, but there has long been some analysis of the economics of diagnostics as well, but I think we will see a lot more of the latter in the future.

Towse: I'd agree – the significance of diagnostics will change as customers increasingly understand the relation between benefits and cost of diagnostics. Roche Diagnostics' AmpliChip CYP 450 Test is probably the best example for that. On the other hand manufacturers will have to demonstrate the value of their products in more detail if they want to get paid appropriately in the future.

What is the practical balance between use of cost-effectiveness and budget impact analysis from a policy point of view?

Garrison: We need to consider both, though generally more weight should be given to cost-effectiveness analysis, as long as we are talking about relatively infrequent medical problems. If diagnostics are applied to a broad population to find a significant subgroup to target, it will certainly be important to consider the total budget impact.

Towse: The budget impact is especially important on the institutional level, e.g. hospitals or centers of medical care. It's less clear here in the UK for the National Health Service [the national regulation body] although cost-effectiveness impact is considered to a certain extent. But as budgets remain tight, the budget impact may stay at the forefront.

How relevant are health economics results for patients, physicians, policy makers, insurers and/or payers?

Garrison: For patients, it might mean better response, fewer side effects and less uncertainty. Physicians will experience an easier management and better outcomes for their patients. From the insurers/payers view, it would bring benefits in terms of less risk and better value for the money spent. Politically, it is most relevant for setting guidelines. It would become more relevant if the US health insurance system provided stronger incentives to monitor value for money. In the US, the basic incentive for those in insurance plans is still to use more medical services as long as the marginal benefit is greater than zero regardless of the marginal cost.

Tiered co-pays for drugs are one of the tools being used to make patients more cost sensitive. Still, much of medical spending must be on patients who are seriously ill requiring high cost treatments. Decisions about what to provide in these circumstances are still a plan decision – that could and should consider health economics.

Towse: Cost efficiency and cost savings considerations will be beneficial for all of the above. It helps to identify the correct use of the appropriate diagnostic tool. It also protects patients from being over-medicated.

Veenstra: There are certain changes in diagnostics technologies that may spur a different approach to health economics and lead to a rising interest from the payers. For example, we are now seeing some first diagnostic solutions that can help guide expensive drug therapies. This will probably also help to raise the awareness for the value that modern diagnostics can provide.

Garrison: Additionally, most countries do continue spending a greater and greater share of national income on health care. This is not surprising – better health is one of the things we want to buy as our incomes rise. Nonetheless, given that medical care is not subject to all of the normal competitive market forces, health economics can be an important factor for policy makers, clinical leaders, and payers to optimize the use of resources. It will change the landscape for diagnostics significantly in the next years.