NEWSLETTER

No. 6 / December 2016

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VALUE FRAMEWORKS

What is the real challenge? Uncertainty about medical benefits, about costs or about decision-making? Value frameworks are widely believed to make coverage decision more transparent and more predictable than the existing global score systems with benefit categories or health-economic thresholds.

Different value frameworks have been developed by institutions and will be further optimized. Value is now debated quite extensively in the scientific and to a lesser extent in the public domain. This will lead to a more common understanding of value which will reduce uncertainty about decision-making.

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VALUE FRAMEWORKS – WHAT IS THE IMPACT?

Value discussions and assessments have escaped from the bilateral boundaries between manufacturer and decision-makers. Institutions and clinicians are now trying to balance drug prices and additional benefits by their own value frameworks. More than 20 valid criteria can reasonably be considered in MDCA's (multi criteria decision analysis). However, after a deliberative process, common ground is often found only for 4 criteria: effectiveness, safety, economics and a "wildcard" for additional benefits. It is interesting to note that the patients view has found no place so far!

Table 1: Value Frameworks – an overview

		ACC / AHA	ASCO	ICER	MSK Drug Abacus	NCCN	ESMO
Clinical	Benefit	x	x	x	x	x	x
	Toxicity	x	x	x	x	x	x
Economic	CEA	x		x			
	BIA			x			
	Affordability		Reported separately	x		x	
Innovation	Novelty				x		
Disease	Unmet need				x		
	Rarity				x		
	Burden				x		
Metrics		COR LOE LOV	NHB	Care Value Health System Value	Score multipliers	Evidence blocks	MCBS
Output		Level of value assessment	Score	Value based price	Value based price	Score (1-5) / block no synthesis	Level of value assessment
Perspective		Physician /Patient	Physician /Patient	Payers / Policy makers Physician / Patients	Payers / Policy makers Physician / Patients	Physician /Patient	Payers / Policy makers Physician / Patients
Conditions addressed		Cardiovascular	Oncologic	All conditions Focus on new drugs with high impact	Oncologic	Oncologic	Oncologic

Sources	Basic work from Neumann (2016) and Westrich (2016) - modified and extended by pharmaLevers GmbH Research
ACC/AHA	American College of Cardiology / American Heart Association
ASCO	American Society of Clinical Oncology
ICER	Institute for Clinical and Economic Review
MSK Drug Abacus	Memorial Sloan Kettering Cancer Center with Drug Abacus Calculation Tool
NCCN	National Comprehensive Cancer Network
ESMO	European Society for Medical Oncology
Reported separately	Acquisition costs, patient co-pay
COR	Class (Strength) of Recommendation : I, IIa, IIb, III - based on Benefit/Risk-Relation
LOE	Level of Evidence: Quality of Evidence
LOV	Level of Value: High value = < $ 50 K /Qualy; Intermediate value = $ 50 K to < $ 150 K; Low value > $ 150 K /Qualy
NHB	Net Health Benefit: Combining clinical benefit (Hazard Ratio), toxicity (vs comparator) and bonus points (e.g. QoL); score from -20 to 130
CER	Comparative Effectiveness Research
CEA	Cost-Effectiveness Analysis
Care Value	Comparative Effectiveness, Incremental Cost-Effectiveness, other benefits or disadvantages, contextual considerations (ethical, legal and other issues for relative priority)
Health System Value	Short term: Budget Impact (market uptake pattern, national Budget impact - threshold for NME); Long term: Health System Value
MCBS	Magnitude of Clinical Benefit Score: A,B,C level for curative approach, 1 to 5 for non-curative; adjustment +/- 1 for Toxicity and QoL

Interesting to note - the patients view has found no place so far.

4 out of the 6 most popular frameworks are dealing with Oncology. The ESMO assessment provides a policy advice whereas the ASCO score guides clinicians. The ICER probably reflects best the payers' and decision-makers' views as economic concerns are widely integrated. MSK Drug Abacus enables us to value different features and then check the own calculated price against the market price (http://www.drugabacus.org/drug-abacus/tool/). Finally ACC/AHA focus on risk/benefit assessment and quality of evidence.

Value Frameworks and Decision making

Decision-making in health care is very complex. Different types of decisions must be made requiring different factors (criteria) to be considered. However, some criteria are relevant for all decisions (Alonso-Coello 2016):

- Available Options
- Anticipated Effects
- Certainty of evidence
- Costs and feasibility

Clinical recommendations can either be strong, moderate or weak. This, however, is not feasible with coverage decisions; an intervention is either covered or not. Pricing is just a tool to counterbalance this dilemma e.g. price negotiation or restriction in use.

What we are facing today is the evolution of competing value frameworks. Basically, they are competing for criteria to be included in a framework. So we are still in the phase to decide on criteria.

Value frameworks and decision frameworks are not the same. The latter is final and requires an even more systematic, explicit and transparent approach considering the best available research evidence (Alonso-Coello 2016).

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REFRAMING VALUE ASSESSMENT?

Many of us see a Global Score with 5-6 benefit categories (e.g. HAS, IQWIG) as a difficult to follow process with a lack of transparency. The dream is to develop a value framework in order to calculate a universal score with a direct link to pricing. Payers and pharmaceutical companies would use the same tool and get almost identical results (see figure 2: right down corner – ideal situation). Such a system would increase long term planning security for all stakeholders.

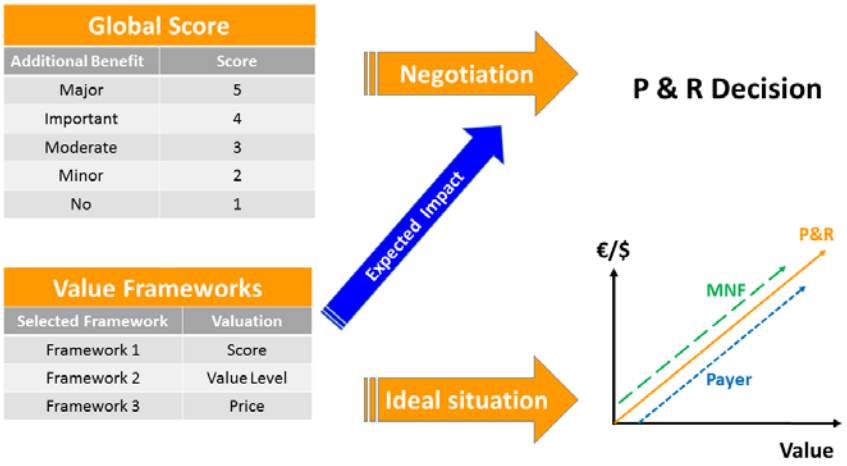

Figure 2: Impact of Value Frameworks

Unfortunately, current value frameworks cannot fulfill such desire. The outputs of the previously described value frameworks are different. It can be a score, a price, a value level or a value block. In oncology, however, the different frameworks ranked similarly, indicating convergent validity (Tanya 2016). In the near future we expect a wide range of additional value frameworks covering non-oncological conditions. At the end we will face a variety of specific value frameworks alongside a global score. Value frameworks will generally reflect a specific view and selection of criteria while leaving out some other aspects. This is in contrast to a global score which has the advantage that almost every aspect of value can be incorporated except opportunity cost under budget constraint (Drummond 2016).

So what is the impact of value frameworks? Value frameworks offer valid and reliable external value assessments with different focal areas and methodologies. Value frameworks will complement evidence and argumentation during the demanding negotiation phase with payers and decision-makers. Value frameworks may leverage a benefit category upgrade. They may also reduce the level of uncertainty as evidence is boosted by expert recommendations.

> Value Frameworks will strengthen the company's negotiating position rather than replace a current global score.

A comprehensive value framework should be based on an integral approach taking into account the different stakeholders and their key drivers for decisions. At the end the societal perspective should become the overriding principle. Let's face it – ethics are difficult to integrate into an index and cultural preference will lead to different value weightings. Again value frameworks will deliver different values across countries as for global scores.

Downplay or leave out economics is hardly promising

ASCO is reporting costs separately without integration into its score (Schnipper 2016). ESMO does not evaluate costs at all (Cherny 2015). ACC/AHA is proposing to integrate cost-effectiveness into clinical recommendation (Anderson 2014) but is ignoring overall budget impact. NCCN rates affordability on 1-5 scale without a clear explanation (Neumann 2015).

Only the ICER value framework is using cost-effectiveness and national budget impact systematically. On top of that the ICER framework is the only framework including some patient centric metrics (e.g. QoL) and some indirect benefits (e.g. productivity) which can be applied to all conditions (Westrich 2016).

Value means balancing clinical benefits with costs. What we are basically heading for is a single value score which correlates with subsequent pricing level, or which at least guides pricing.

Downplaying cost-effectiveness (value for money) and affordability (budget impact) will hardly lead to a common understanding of value. But all key stakeholders must agree on value criteria. If not we will not moving forward to a more transparent and reliable decision-making process.

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CLOSING THE VALUE GAP

Basically value is a tri-relation between Manufacturer, Patient and Payer. The pharmaceutical company is creating value by innovation. The patient has the specific need to use it and the payer is expected to pay the bill. The society is the observer to judge whether the Triangle works well. The Decision-Maker is acting as an agent for the society. They key issue is how to balance the patients' and payers' perspectives as they are different. Patients want to have immediate access to a new drug if its risk/benefit ratio is favorable. In contrast to the US, patients in most Western European countries are little price sensitive. On the other hand payers have to consider value for money and affordability for such drugs.

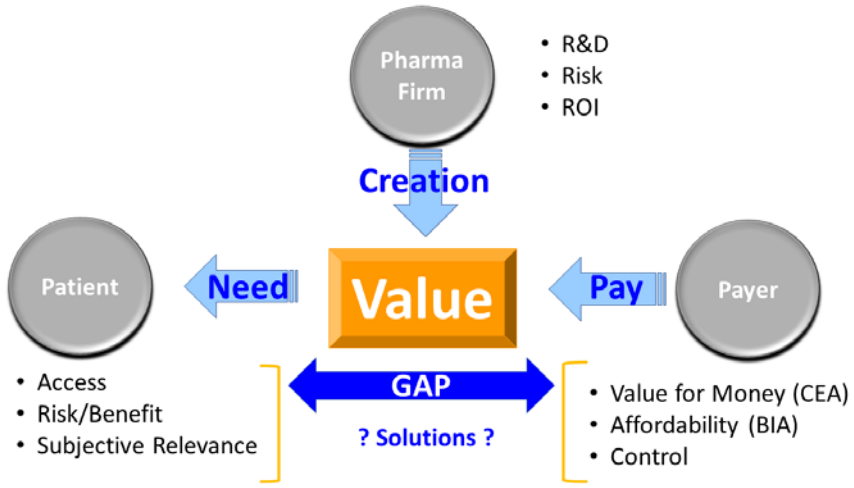

Figure 3: The Value Triangle

> "Clinicians are imperfect agents for patients and payers have an agency relationship with patients and with people who pay premiums" (Towse 2016).

Preference between patients and clinicians may vary substantially. In a MCDA-pilot study (Sussex 2013) patients rated clinical aspects much lower and social impact on daily lives much higher than clinicians. There is no doubt that the patient's view has to be taken into account. HTA bodies too often consider only costs and effects because there is no other evidence available (Towse 2016). Since 2010, Canada created opportunities for patient groups to contribute to HTA's in the Canadian Drug Review (CDR) process. Patients' insights can be incorporated as an outcome in HTA protocols and be used in the interpretation of evidence (Berglas 2016).

> "No decision about me, without me" is a basic democratic principle (Berglas 2016).

Obviously, patient insights are only one of multiple elements to frame value. Consequently, they may not change the outcome of reimbursement decisions. A key questions remains "Relevance to Patient": a minor benefit in the eyes of the society may make a huge difference in daily life for the illness-affected person. At the end it needs a societal consensus to judge fair balance of benefit and costs.

Encourage and integrate the Patients' perspective to convince payers

Payers basically value cost-effective innovations and offer them to their insured persons as long as evidence is obvious. The payers' population based view makes it difficult for them to appreciate individual benefits if they are marginal. A marginal additional benefit, however, may have a significant impact on patient's daily life. Today we face a significant lack of evidence in this area. Aggregating individual data to a population based cohort will generate the missing evidence. Another point is that payers' budgets have little room to consider non-clinical benefits as e.g. productivity. Health care needs the societal perspective; it's the society who finally decides of whether resources are fairly allocated to vulnerable groups.
This leads to the conclusion that the Beverage health care financing system has an advantage to include patients' views.

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CONSEQUENCES IN PRACTICE

Value Frameworks do not facilitate Pricing & Reimbursement. In addition to the existing different coverage decisions across countries we have to deal with mixed results from a variety of value frameworks. Of course this is helpful as we get valid insights from independent providers and institutions. It is just getting more demanding to create a consistent, clear "value story" but it offers a lot of improved possibilities to demonstrate the true value of a new intervention.

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REFERENCES

Alonso-Coello P, et al. GRADE Evidence to Decision (EtD) frameworks: a systematic and transparent approach to making well informed healthcare choices. 1: Introduction. BMJ. 2016 Jun 28;353:i2016. doi: 10.1136/bmj.i2016.

Anderson JL, et al. ACC/AHA statement on cost/value methodology in clinical practice guidelines and performance measures: a report of the American College of Cardiology/American Heart Association Task Force on Performance Measures and Task Force on Practice Guidelines. J Am Coll Cardiol. 2014 Jun 3;63(21):2304-22. doi: 10.1016/j.jacc.2014.03.016. Epub 2014 Mar 27. (see also Halperin JL, et al 2016).

Berglas S, et al. Patients' perspectives can be integrated in health technology assessments: an exploratory analysis of CADTH Common Drug Review. Research Involvement and Engagement (2016) 2:21, DOI 10.1186/s40900-016-0036-9.

Cherny NI, et al. A standardised, generic, validated approach to stratify the magnitude of clinical benefit that can be anticipated from anti-cancer therapies: the European Society for Medical Oncology Magnitude of Clinical Benefit Scale (ESMO-MCBS). Ann Oncol. 2015 Aug;26(8):1547-73. doi: 10.1093/annonc/mdv249. Epub 2015 May 30.

Drummond M. Value Assessment Frameworks in Europe. Can One Size Fit All? Presentation at ISPOR EU, October 29 – November 2, 2016, Vienna, Austria.

Halperin JL, et al. Further Evolution of the ACC/AHA Clinical Practice Guideline Recommendation Classification System: A Report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines. J Am Coll Cardiol. 2016 Apr 5;67(13):1572-4. doi: 10.1016/j.jacc.2015.09.001. Epub 2015 Sep 24.

Neumann PJ and Cohen JT. Measuring the Value of Prescription Drugs. N Engl J Med. 2015 Dec 31;373(27):2595-7. doi: 10.1056/NEJMp1512009. Epub 2015 Nov 18.

Neumann PJ. Drug Value Frameworks. International Society for Pharmacoeconomics and Outcome Research, Initiative on US Value Assessment Frameworks, Stakeholder Conference, Washington DC, September 23, 2016.

Schnipper LE, et al. Updating the American Society of Clinical Oncology Value Framework: Revisions and Reflections in Response to Comments Received. J Clin Oncol. 2016 Aug 20;34(24):2925-34. doi: 10.1200/JCO.2016.68.2518. Epub 2016 May 31.

Sussex J, Rollet P, Garau M, Schmitt C, Kent A, Hutchings A. A pilot study of Multicriteria Decision Analysis for Valuing Orphan Medicines. Value in Health 2013;16(8):1163-9. doi: 10.1016/j.jval.2013.10.002. Epub 2013 Nov 14.

Tanya GK, et al. A Novel Method for Evaluating Value Assessment Frameworks. Poster PRM107 at ISPOR EU, October 29 – November 2, 2016, Vienna, Austria.

Towse A. Is balancing Value Demonstration for Payers and Patient Interest a feasible Notion? A Health System Perspective. Presentation at ISPOR EU, October 29 – November 2, 2016, Vienna, Austria.

Westrich K. Current Landscape: Value Assessment Frameworks. National Pharmaceutical Council (NPC) 2016. Online available at: http://www.npcnow.org/publication/current-landscape-value-assessment-frameworks (visited Nov. 22nd 2016).