The Value of Diagnostic Tests When Treatment is Not Optimal: A Health Economics Perspective on Multi-Assay Molecular Diagnostic Panels for Infectious Diseases

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Disclosure/Disclaimer

- Cepheid provided support for my research to prepare this talk.

- The views expressed are my own.

Key Points

- In general, our—largely cost-based—coverage and reimbursement policies for diagnostic tests fail to reward value creation adequately.

- Specifically, coverage and reimbursement policies for multi-assay molecular diagnostic panels under-estimate their potential value to patients and society at large.

Key Features of Diagnostic Tests as Economic Goods

- Payment/reimbursement is often “cost-based” through linkage (”cross-walk”) to existing tests rather than “value-based.”
- A diagnostic test-drug combination creates greater value through the combination: but there is no set rule or practice for attributing the value share to the test vs. the diagnostic.
- Diagnostic tests provide information and thus reduce uncertainty, which is valuable in its own right.
- The diagnostic information on infectious diseases generated for specific individuals can have broader public health implications and thus societal value.

What is “Value”?

- From an economic perspective:
  - Value is what someone is (actually) willing to pay or forgo to obtain something (opportunity cost)

- Implications:
  - Varies across individuals and over time
  - Difficult to measure in health care because of insurance
  - In principle, we would ask a plan member about their willingness to pay the **incremental insurance premium (or taxes).** In practice, the amount is too small to be estimated reliably.

The Economics of Personalized Medicine: A Model of Incentives for Value Creation and Capture

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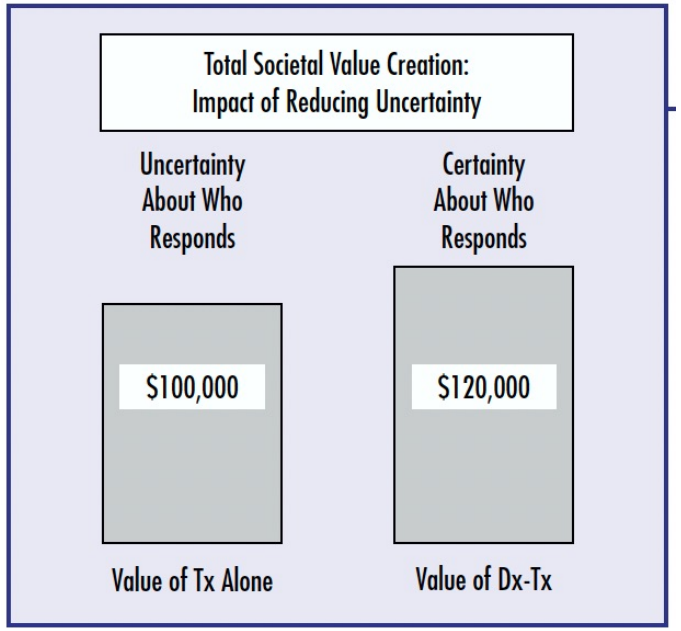
Personalized medicine is a concept promoted as a new paradigm for health care delivery, with particular emphasis on more tightly linking genomics-based diagnostics and therapeutics. Previous analyses focused on the pharmaceutical market; this analysis also addresses the incentives to develop linked genomics-based diagnostics and the broader public policy implications. Using a standard economic framework of an insurer-payer negotiating reimbursement with manufacturers of an innovative, targeted diagnostic and a companion patented therapeutic, several illustrative hypothetical scenarios are developed. The relative importance of the key economic factors is examined, including whether the reimbursement system is value or cost based, whether the therapeutic is already marketed, the strength of diagnostic intellectual property, and a current year versus longer time frame. The results suggest that health systems reforms that promote value-based, flexible reimbursement for innovative, patent-protected diagnostic and therapeutic products are critical to create stronger economic incentives for the development of personalized medicine.

Drug Information Journal, *Vol. 41, pp. 501–509, 2007*



Key Assumptions for the Five Scenarios

Key Assumptions

Scenario	Tx Price	Dx Reimbursement	Insurance Premiums	Dx After Tx on Market
Reference case	Fixed	Cost based	No increase	Yes, ex post
A	Fixed	Cost based	No increase	Yes, ex post
B	Flexible	Cost based	No increase	Yes, ex post
C	Fixed	Value based	No increase	Yes, ex post
D	Flexible	Cost based	Increase	No, ex ante
E	Flexible	Value based	Increase	No, ex ante

Results: Value Distribution for the Five Scenarios

Results

	Value Distribution (in thousands of dollars)				
Scenario	**Patient *P***	**Insurer *N***	***T* Manufacturer**	***D* Manufacturer**	**Total Value Creation**
Reference Case	0	0	100	0	100
A	20	70	20	10	120
B	20	0	90	10	120
C	20	0	20	80	120
D	0	0	110	10	120
E	0	0	60	60	120

1. **Value-based, flexible pricing in both Dx and Tx markets would provide a stronger incentive than currently exists for linked Dx-Tx innovation (ie, personalized medicine).**
2. **IP protection for Dx, coupled with value-based pricing, is an important factor in providing a financial incentive to develop the Dx needed to support personalized medicine.**
3. **The incentive for Dx and Tx companies to team up ex ante to develop a linked Dx-Tx could be affected by the relative IP protection in the two markets.**

PERSPECTIVE

Can and should value-based pricing be applied to molecular diagnostics?

Martina Garau*[1], Adrian Towse[1], Louis Garrison[2], Laura Housman[3] & Diego Ossa[4]

Personalized Medicine (2013) **10**(1), 61–72

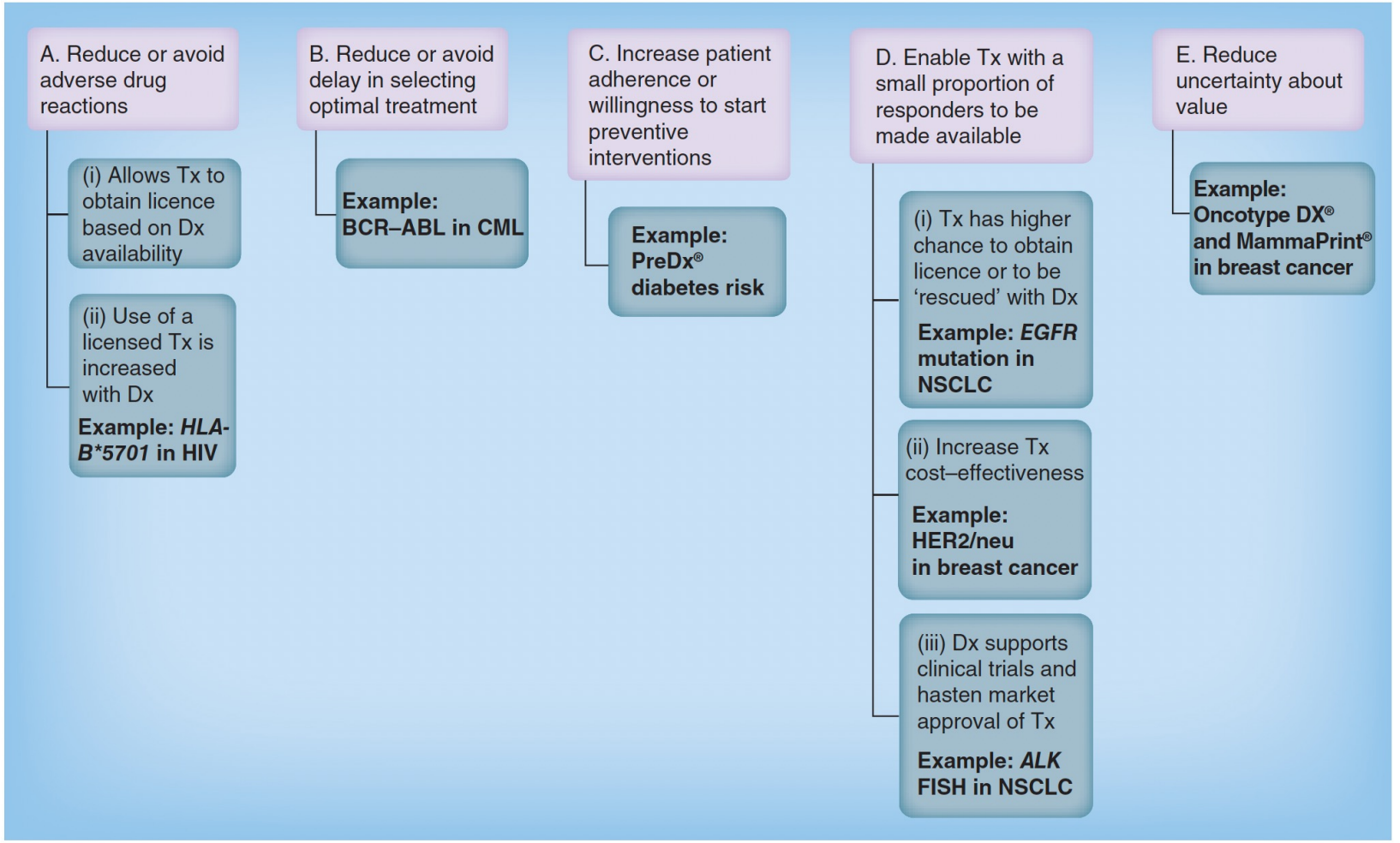


Figure 1. Pathways of value of molecular diagnostics and key examples.
CML: Chronic myelogenous leukemia; Dx: Diagnostic; NSCLC: Non-small-cell lung cancer; Tx: Treatment.

Office of Health Economics Research

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The Value of Knowing and Knowing the Value:

Improving the Health Technology Assessment of Complementary Diagnostics

WHITE PAPER

July 2016

WORKING GROUP AND EDITORIAL COMMITTEE

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2016

FIGURE 2

Elements of value for complementary diagnostics

Notes:

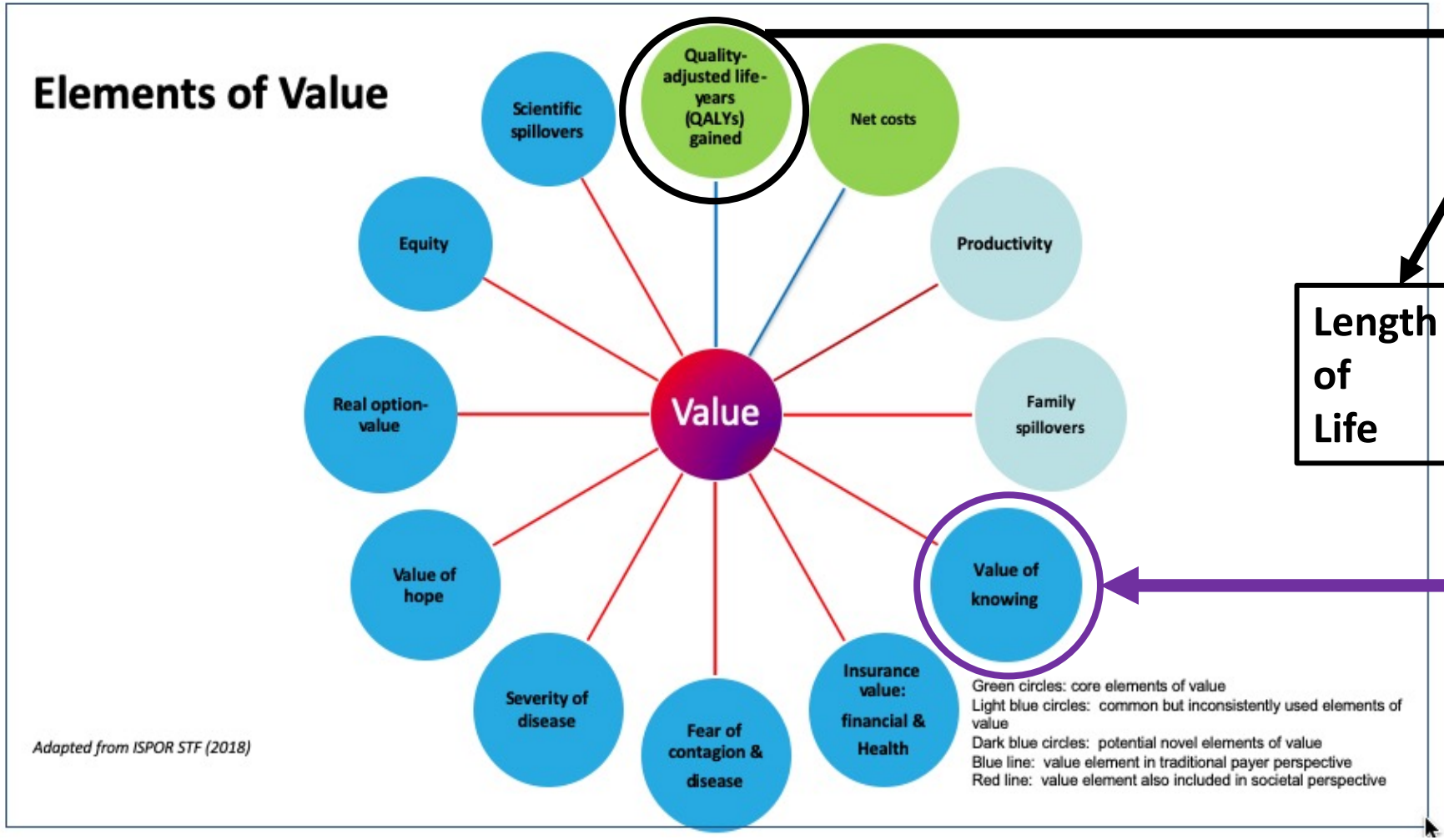
Light grey circle: traditional elements of value as considered by HTA

Dark grey circle: expanded value framework: elements not traditionally considered/measured

Green line: value from health system perspective

Red line: value also included in societal perspective

Elements of Value for Augmented Cost-Effectiveness Analysis (2018)



Length of Life

Health-Related Quality of Life

Reduction in Uncertainty

US Second-Panel Volume: Impact Inventory (October 2016)

Figure 1. Impact Inventory Template

Sector	Type of Impact (list category within each sector with unit of measure if relevant)[a]	Included in This Reference Case Analysis From...Perspective?		Notes on Sources of Evidence
		Health Care Sector	Societal	
Formal Health Care Sector				
Health	Health outcomes (effects)			
	Longevity effects	☐	☐	
	Health-related quality-of-life effects	☐	☐	
	Other health effects (eg, adverse events and secondary transmissions of infections)	☐	☐	
	Medical costs			
	Paid for by third-party payers	☐	☐	
	Paid for by patients out-of-pocket	☐	☐	
	Future related medical costs (payers and patients)	☐	☐	
	Future unrelated medical costs (payers and patients)	☐	☐	
Informal Health Care Sector				
Health	Patient-time costs	NA	☐	
	Unpaid caregiver-time costs	NA	☐	
	Transportation costs	NA	☐	
Non–Health Care Sectors (with examples of possible items)				
Productivity	Labor market earnings lost	NA	☐	
	Cost of unpaid lost productivity due to illness	NA	☐	
	Cost of uncompensated household production[b]	NA	☐	
Consumption	Future consumption unrelated to health	NA	☐	
Social Services	Cost of social services as part of intervention	NA	☐	
Legal or Criminal Justice	Number of crimes related to intervention	NA	☐	
	Cost of crimes related to intervention	NA	☐	
Education	Impact of intervention on educational achievement of population	NA	☐	
Housing	Cost of intervention on home improvements (eg, removing lead paint)	NA	☐	
Environment	Production of toxic waste pollution by intervention	NA	☐	
Other (specify)	Other impacts	NA	☐	

Public Health Genomics

Review Article

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The Value of Diagnostic Information in Personalised Healthcare: A Comprehensive Concept to Facilitate Bringing This Technology into Healthcare Systems

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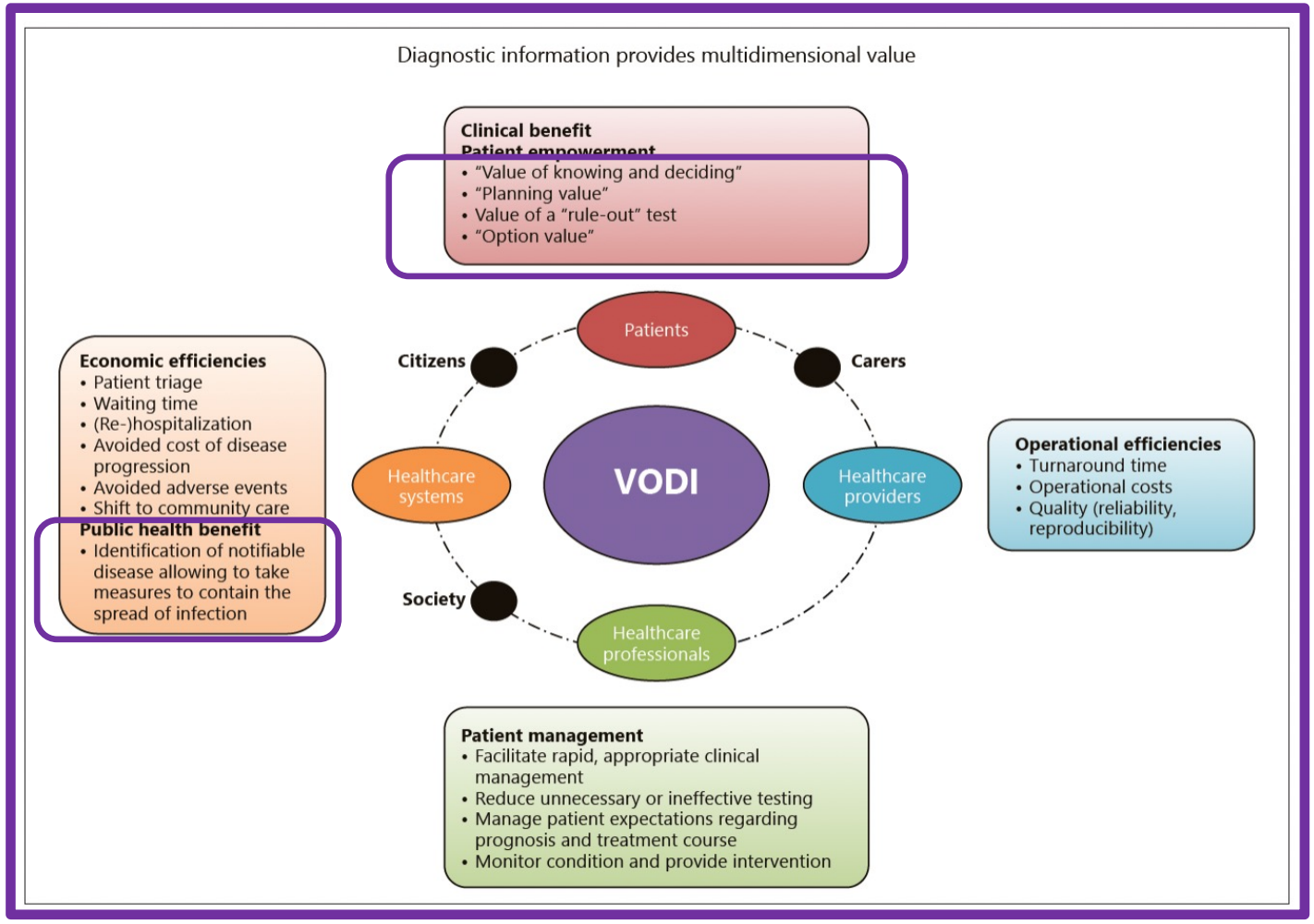

Challenges in Assessing Economic Value of Multi-Assay Molecular Diagnostic Panel: Simplified Example—Two-Assay Respiratory Test

- Suppose the cost of the dual-assay (A+B) is $40 and each would cost $20 as a single assay.
- What if payer will not pay for the dual but only for the single A?
- This implies a loss of:
  - Suppose COVID-19 is negative, patient will not know if he/she has B
  - Society will not know if patient has B. This affects public health policies such as social distancing.

Conclusion

- In evaluating the impact of multi-assay PCR panel tests on patients and on society, we need to take a broader perspective that considers the both value of knowing from diagnostic information as well as public health impacts.

- The current system of coverage and reimbursement is cost-based—not value-based—and thus does not provide adequate support for diagnostic test innovation.

Thanks!

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