ECONOMIC VALUE OF VACCINES

ISPOR Forum of the

Economic Value Assessment of Vaccines Designed to Prevent Infectious Disease Task Force

Monday, May 23, 2016

Outline for the Forum

- Task Force Leadership Group Members
- Presentation of draft framework for task force report
- Remaining critical points for guidelines for cost-effectiveness analysis of vaccines
- Guidelines for additional approaches
- Budget optimization modeling
- Financial services modeling
- General discussion (25 minutes)

ECONOMIC EVALUATION OF VACCINES

Moderator:

Baudouin Standaert, MD, PhD, Health Economics, GlaxoSmithKline Vaccines, Wavre, Belgium

Speakers:

Josephine A. Mauskopf, PhD, MHA, MA, Vice President, Health Economics, RTI Health Solutions, Research Triangle Park, NC, USA

Johan L. Severens, PhD, Professor of Evaluation in Health Care, Institute of Health Policy & Management, Institute of Medical Technology Assessment (iMTA), Erasmus University, Rotterdam, The Netherlands

TASK FORCE LEADERSHIP GROUP

Co-Chairs:

Josephine Mauskopf, PhD, Vice President, Health Economics, RTI Health Solutions, NC, USA

Baudouin Standaert, MD, PhD, Health Economics, GSK, Vaccines, Belgium

Leadership Group:

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Tony Culyer, CBE, BA, Emeritus Professor, University of York, York, UK

Lou Garrison, PhD, Professor, Department of Pharmacy, University of Washington, Seattle, WA, USA

Raymond Hutubessy, PhD, MSc, Senior Health Economist, Initiative for Vaccine Research, World Health Organization (WHO), Geneva, Switzerland

ECONOMIC EVALUATION OF VACCINES DESIGNED TO PREVENT INFECTIOUS DISEASE TASK FORCE

Leadership Group:

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Damian Walker, PhD, MSc, BSc, Deputy Director, Gates Foundation, Seattle, WA, USA

Framework for Economic Value Assessment of Vaccines: I

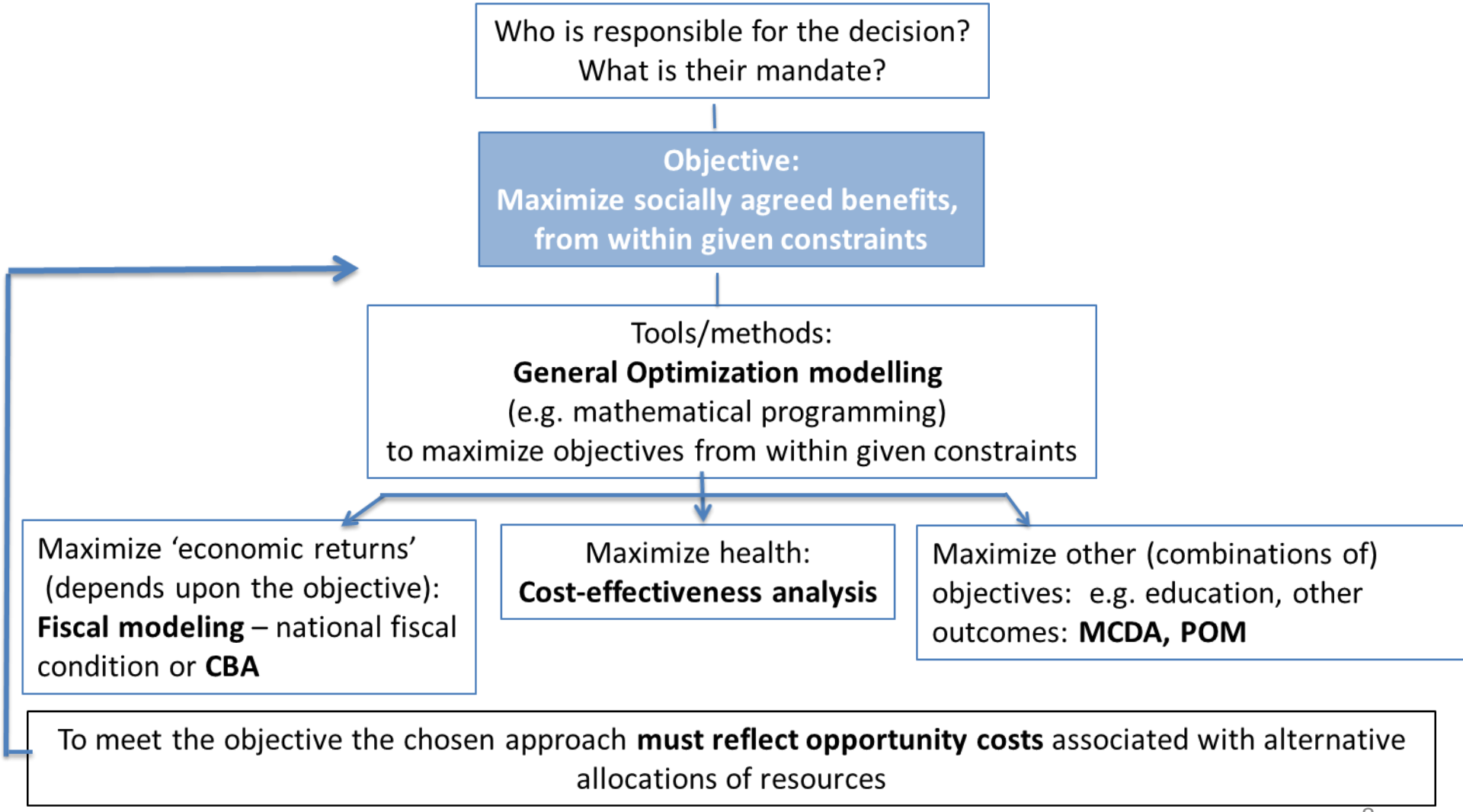
For any investment decision drawing upon collective resources, what do we need to know?

1. Agreed collective objective (measure of benefits)
2. Improvement in the agreed benefits from investing available resources in an investment (allocation to a sector, a healthcare program, an intervention, research, whatever..)
3. Opportunity costs of investing resources in alternatives in terms of benefits those resources could generate if used for other purposes

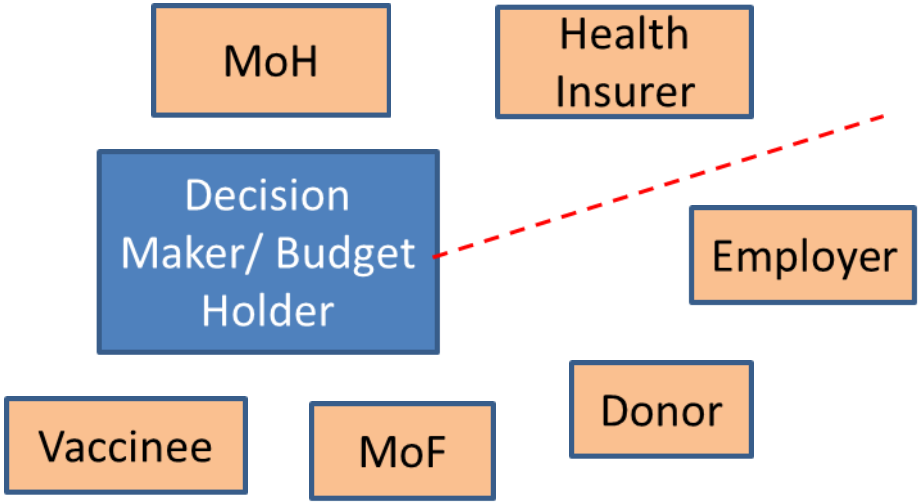
Framework for Economic Value Assessment of Vaccines: II

This raises challenging questions including the following:

1. Relating to objectives: Who defines? Can they be measured? Can they be valued? With multiple criteria how are they traded off? Can they be combined into a single measure?
2. Relating to costs: How measure? Good proxies for resource use? Whose resources? What resources? What if resources held by multiple stakeholders, perhaps with varying objectives?
3. Relating to methods: What methods may inform investments? What to do when we can't quantify and value everything of concern? How do we handle uncertainty? What's the role of process is allocating collective resources?


Who is responsible for the decision?
What is their mandate?
Objective:
Maximize socially agreed benefits,
from within given constraints
Tools/methods:
General Optimization modelling
(e.g. mathematical programming)
to maximize objectives from within given constraints
Maximize 'economic returns'
(depends upon the objective):
Fiscal modeling – national fiscal condition or CBA
Maximize health:
Cost-effectiveness analysis
Maximize other (combinations of) objectives: e.g. education, other outcomes: MCDA, POM
To meet the objective the chosen approach must reflect opportunity costs associated with alternative allocations of resources

Who is Assessing the Economic Value for Vaccines



Who's decision in what context?

	Advising	Buying	Providing	Regulating	Selling	Using
Employer	■	■	■			
Foundations		■	■			
GAVI		■	■			
Government		■	■	■		
Individuals		■				■
Manufacturer			■		■	
Ministry of Finance		■		■		
Ministry of Health		■	■	■		
NGOs		■	■			
NITAGs	■					
Professionals	■		■		■	■
Third party payers		■	■	■		
UNICEF		■	■			
WHO	■			■		
Worldbank	■			■		

Information need?

Input and Output Measures for Vaccines

Vaccine Price (pre-set or determined through competitive bidding) and vaccine program costs

Health gain (direct & indirect) using dynamic models

Better educational scores & work, fewer families in poverty trap, increased GDP/GNI, fiscal gain

Disease management cost

Other disease-related costs

Value for Money

NPV/IRR

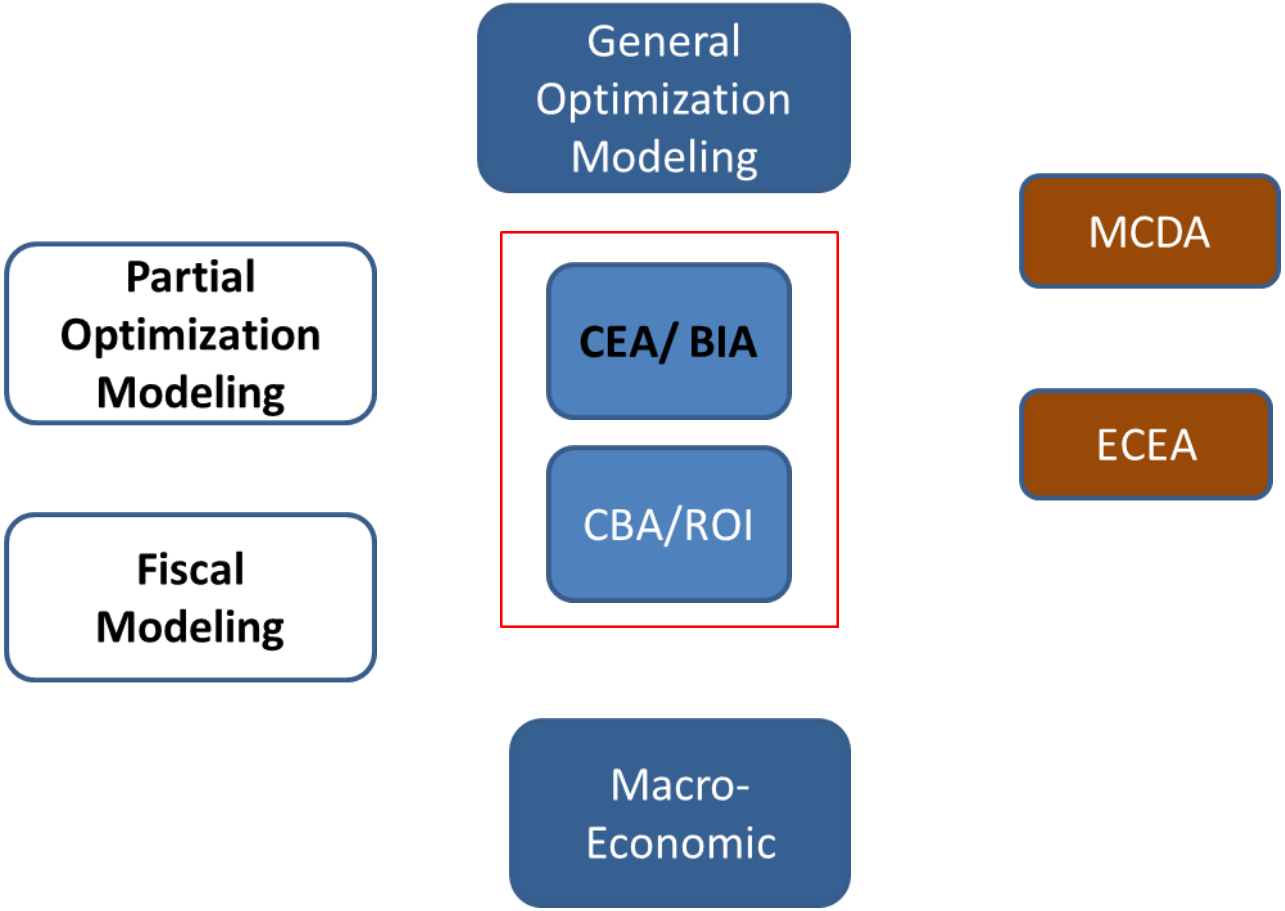
Budget impact (vaccine & Total)

Disease-related mortality - lost QALYs/DALYs

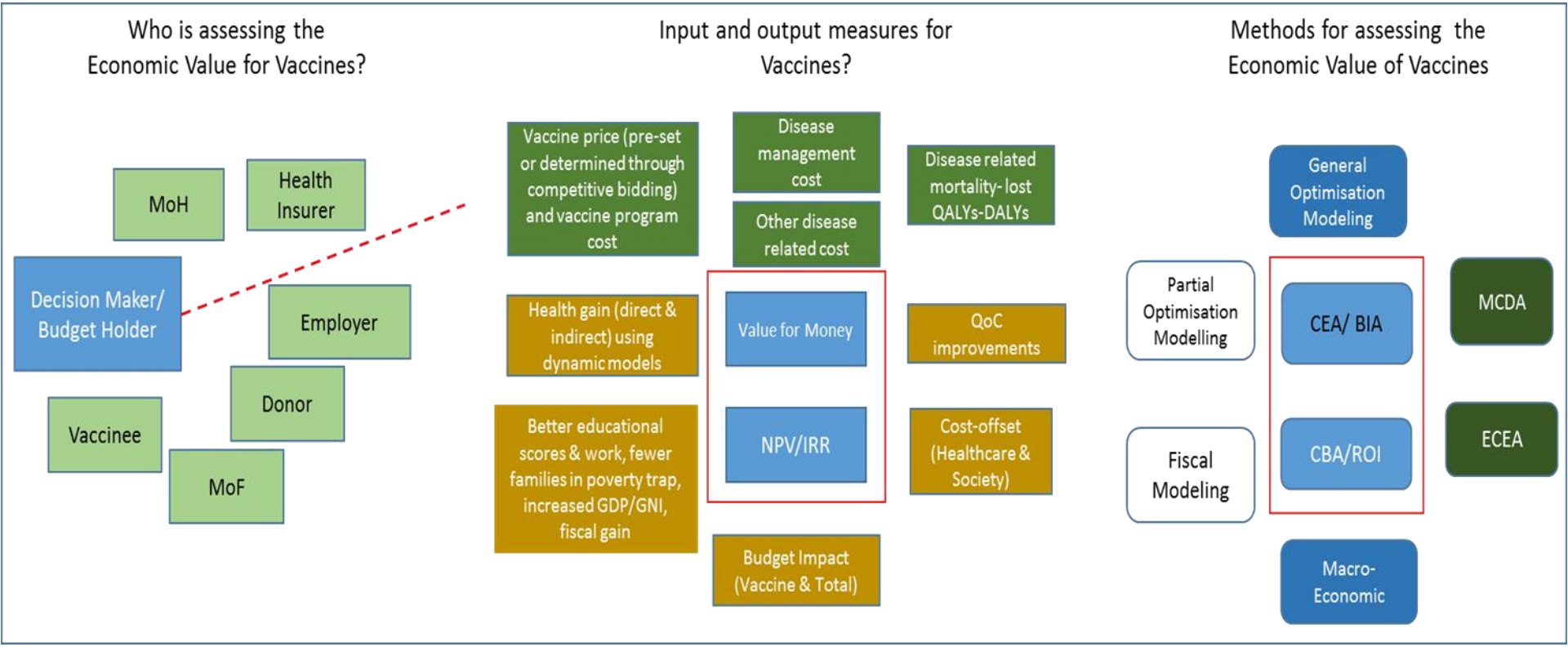
QoC improvements

Cost-offset (Healthcare & Society)

Methods for Assessing Economic Value of Vaccines



Overall View of Framework



Summary of Draft Framework

- Framework based on the following concepts
  - Multiple decision makers/budget holders with different responsibilities

  Evaluate efficiency of funding allocations using different metrics
  - Multiple methods to develop measures relevant for decision makers
- Task Force Report will present guidelines for three methods to develop measures for vaccines of interest to different decision makers
  - Guidelines for CEA – primary method used for presentation of value for money – Task Force will produce extension of currently available vaccine-focused guidelines using Gates Reference case as the baseline
  - Guidelines for optimization modeling – additional method for presentation of value for money – Task Force will produce initial guidelines
  - Guidelines for fiscal analysis modeling – method for presentation of return on investment – Task Force will produce initial guidelines for vaccines

COST EFFECTIVENESS ANALYSIS

European Guidelines on CEA (Ultsch et al, 2015) -20 criteria

- Approach: background, general statement, consensus, pro & con
- Model-specific: model type, time horizon, calibration, validation, natural history, evaluation method
- HE-specific: discounting, indirect cost, impact of care on QoL, perspective, QALYs, Cost
- Vaccine-specific: duration of efficacy, type of efficacy (symptom or infectious related), sequential or non-sequential, PP or ITT, indirect effect, target population, other externalities (- & +)
- Sensitivity analysis:

	Structure	Input	Output
One-way			
Multi-way			
PSA			
Scenario			

WHO-guidelines (D Walker, P Beutels R Hutubessy, 2010)

- Question to be answered
- Cost & especially cost of vaccination
- Vaccine impact
- Modelling
- Discounting
- Estimating, presenting, interpreting
- Practical use
- Other concerns (value for money or the 9 other criteria for priority setting)

Gates Reference Case, 2015

- Difficult to present generally applicable guidelines for CEA
- Reference case is more suitable: concrete example with all the different elements related to model, data-input, data-output, sensitivity analysis, perspective, a.o.
- However not vaccine specific
  - Externalities not covered
  - Population approach not selected

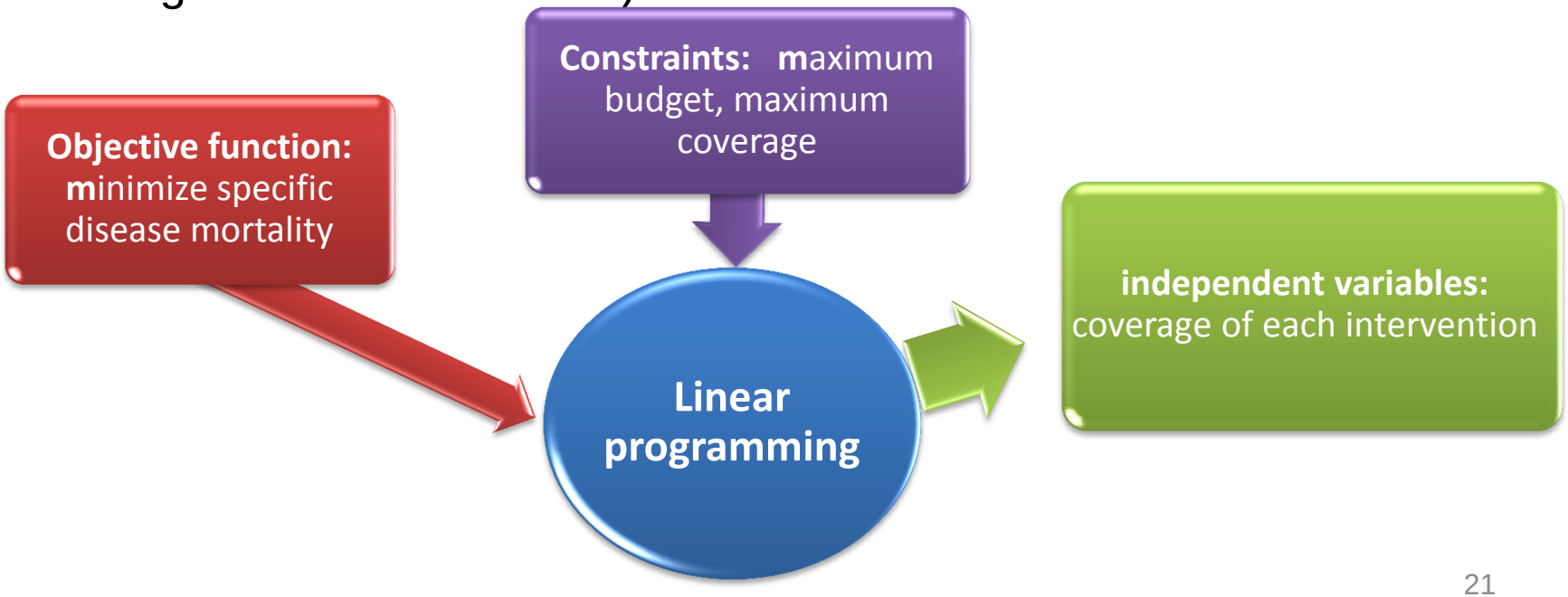
Areas of Focus

- Consensus on outcome result to present in order to be also comparative between models (cfr. population versus cohort)
- Discounting rules on short and long term with right justification of selection criteria
- Minimum sensitivity analysis to be developed and reported
- Outcomes selection on DALYs versus QALYs
- Choice of comparators
- Understanding the link between CEA and BIM with population models

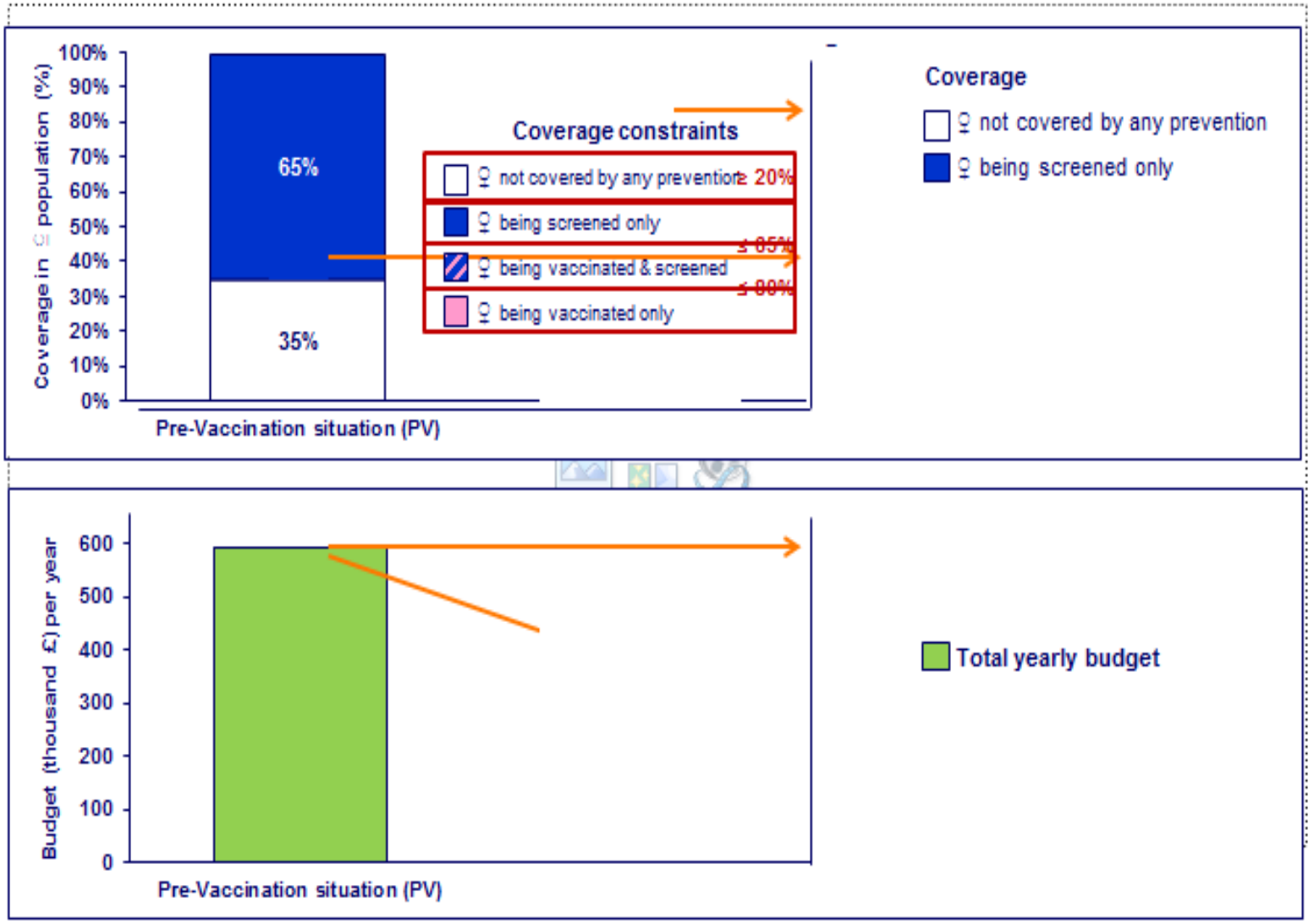
PARTIAL OPTIMIZATION MODELING

Partial Optimization Modeling in HPV/CC

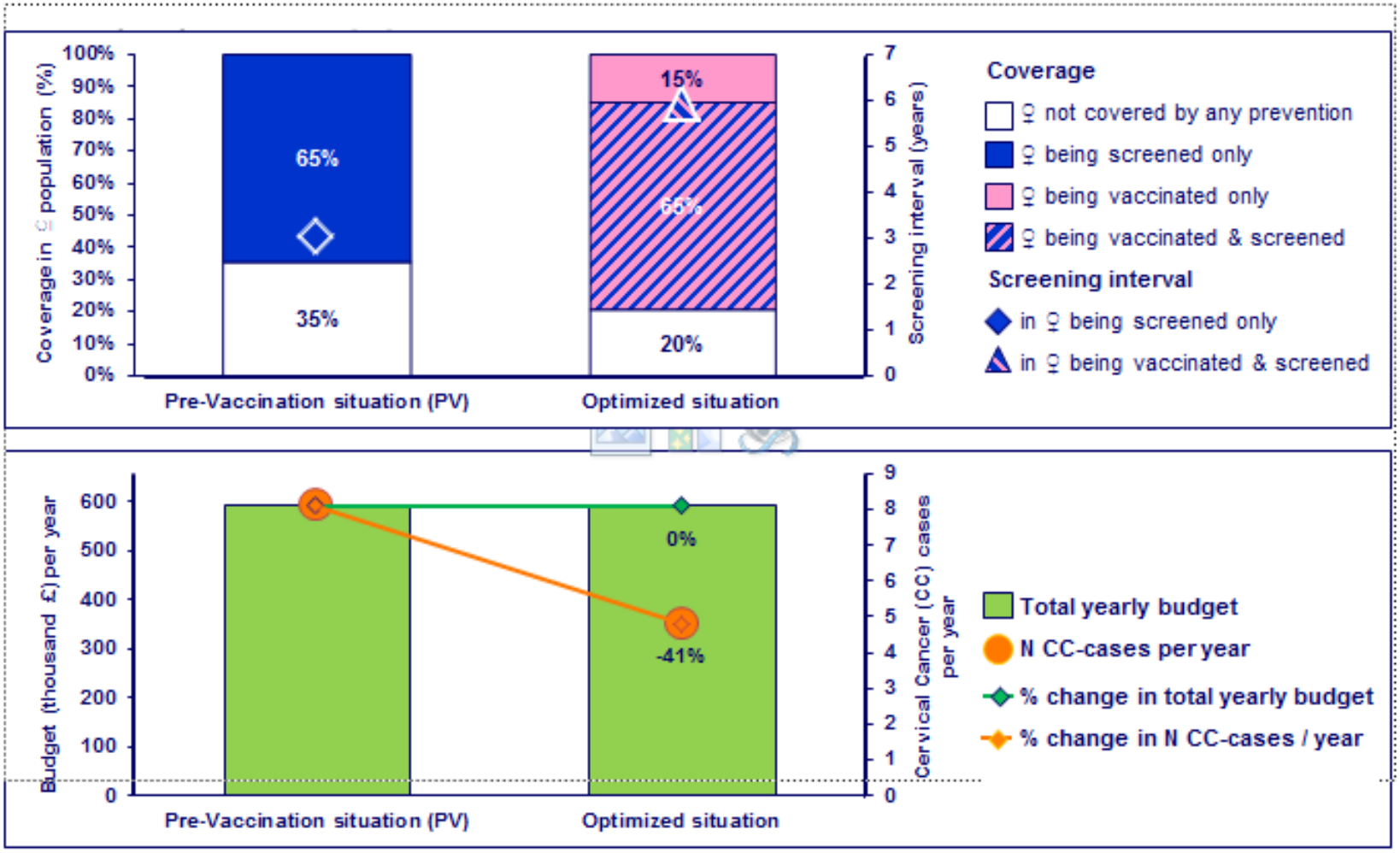
- With a fixed budget how to maximize cervical cancer (CC) reduction?
- What is the optimal mix of interventions (screening and vaccination) for a given budget to attain the objective?
- If budget increases, which intervention to select first (more screening or more vaccination)?



Optimize health gain in HPV?



Optimize health gain for HPV?

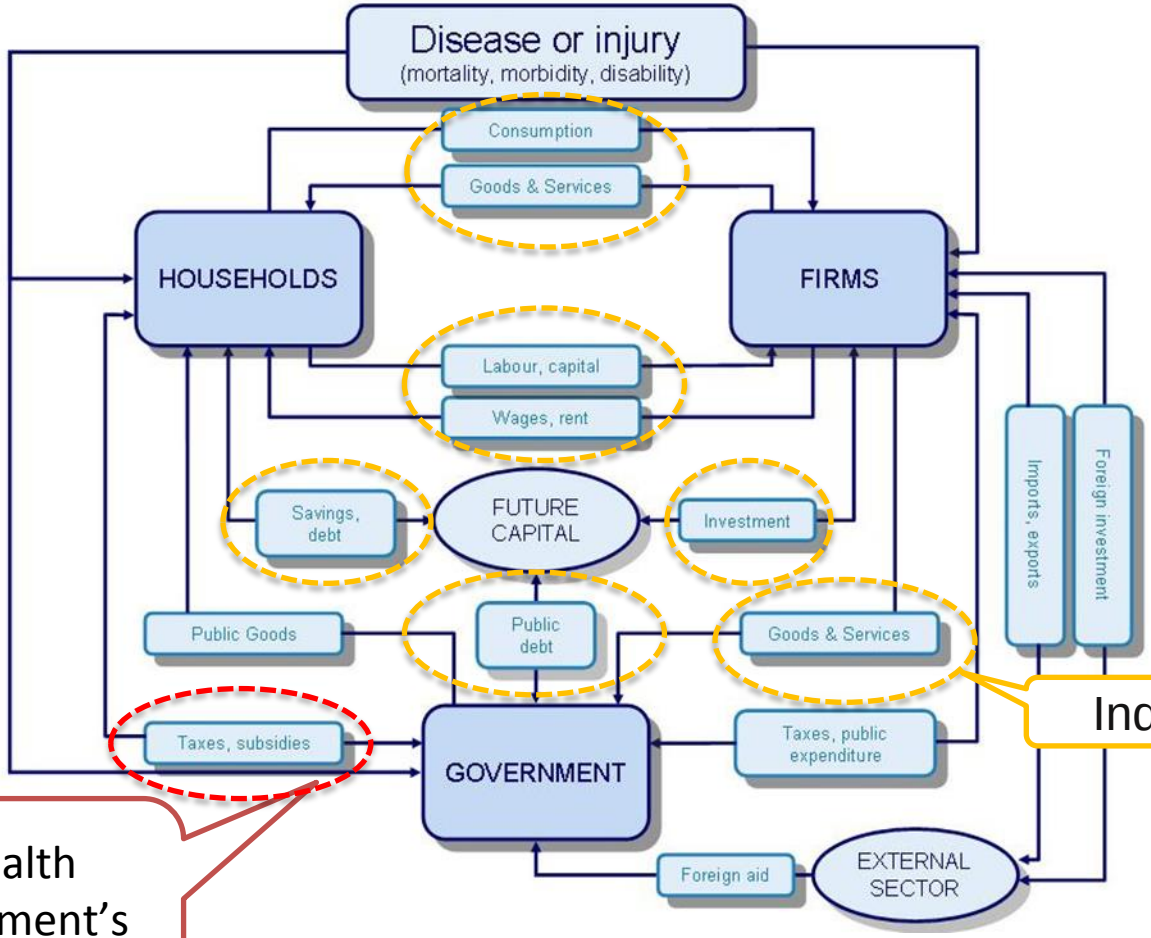


Benefit of Optimization Modeling?

- Reality situation: for many MoHs their starting point is often budget allocation by discipline/specialty
- Optimization process helps defining health goals to be reached: more appealing than to define a threshold value
- Finding combinations of different options allow flexible thinking and handling within budget assignment: helps planning
- Evaluation process is simpler to monitor and to improve
- Better dialogue with ‘non-health’ –economists: can integrate OM with fiscal modelling

FISCAL HEALTH MODELING

WHO Framework: Economic consequences of poor health



Indirect impact

How poor health impacts government's "fiscal health"

WHO guide to identifying the economic consequences of disease and injury (2009). ISBN 9789241598293

Healthcare Costs Represent Only a Fraction of the Total Governmental Economic costs in Relation to Poor Health

Government Perspective on Disease Burden in Working - Aged Adults in the UK

Impact on government accounts		Annual cost to government 2007 Billion £	Percentage government cost
Workless benefits	Government cost	29	43%
Healthcare	Government cost	5 – 11	**11%**
Foregone taxes	Revenue loss	28 – 36	46%
Total costs to government		£62 - 76	

Health has a cross-sectorial impact on government that is not considered within conventional CEA

Source: Dame Carol Black's Review of the health of Britain's working age population 17 March 2008, TSO London
https://www.gov.uk/government/publications/improving-health-and-work-changing-lives

Generational accounting framework for analyzing healthcare

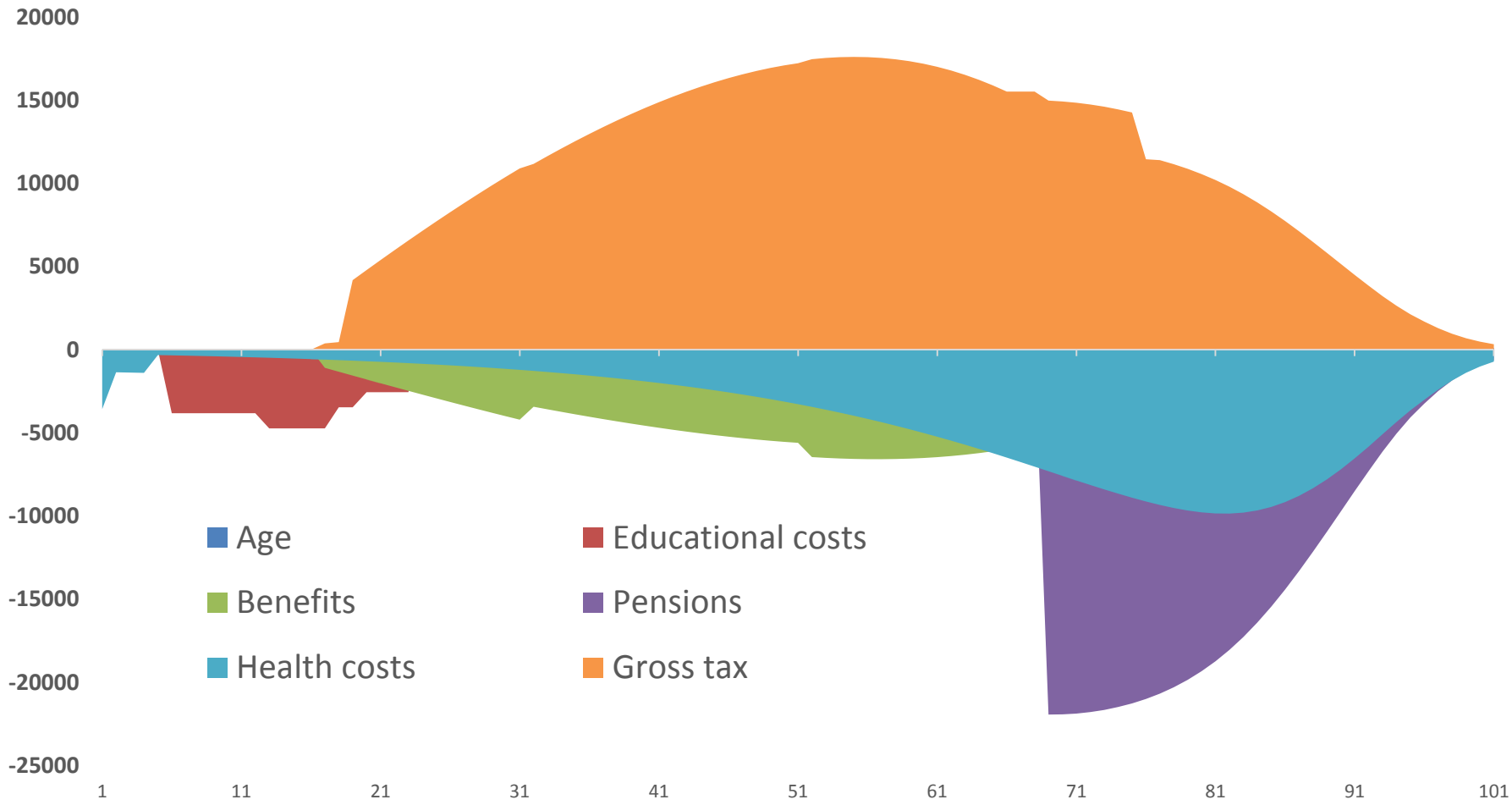
Costs and revenue by age

	Tax payments						Transfer receipts						
Age in 1995	Labour income	Capital taxes	Seignior-age	VAT	Excise	Social insurance	Social security	Health insurance	Unem-ployment insurance	General welfare	Youth and maternity	Education	Non-age-specific expenditure
0	43.9	12.3	0.8	43.6	16.5	73.1	19.6	30.7	5.4	5.3	19.9	48.3	96.2
5	52.4	14.7	1.0	44.1	19.6	87.0	23.5	30.6	6.3	4.6	18.7	51.7	94.9
10	62.3	17.0	1.2	45.2	23	103.2	28.0	33.0	7.5	4.0	14.8	40.6	93.2
15	72.9	19.8	1.5	45.9	26.8	121.5	33.0	35.7	9.5	3.7	9.6	26.6	91.1
20	83.2	19.3	1.4	46.3	29.9	137.4	38.0	38.1	11.6	3.5	4.1	14.6	88.7
25	87.5	19.1	1.4	45.5	29.4	140.5	45.4	40.0	10.7	3.4	2.4	4.7	86.0
30	83.3	19.5	1.4	43.8	27.6	133.9	54.3	41.7	9.8	3.2	1.1	0.0	82.7
35	75.7	18.8	1.3	42.6	25.1	121.4	64.6	43.4	8.3	3.0	0.4	0.0	79.0
40	64.0	18.0	1.3	41.0	22.1	103.7	76.1	45.2	7.1	2.8	0.0	0.0	74.6
45	50.2	16.2	1.1	38.6	18.9	81.9	89.4	46.9	6.4	2.8	0.0	0.0	69.7
50	32.3	13.2	0.9	34.8	15.8	56.6	106.2	48.1	5.5	2.8	0.0	0.0	64.1
55	15.5	11.1	0.8	30.4	12.7	31.0	125.8	49.1	3.8	2.9	0.0	0.0	58.0
60	4.6	9.2	0.7	25.8	9.8	9.5	147.7	49.9	1.6	3.1	0.0	0.0	51.4
65	0.6	7.8	0.6	21.1	7.3	1.2	146.7	50.0	0.0	3.0	0.0	0.0	44.5
70	0.0	6.8	0.5	16.7	5.2	0.1	121.9	48.6	0.0	3.2	0.0	0.0	37.8
75	0.0	5.5	0.4	12.3	3.6	0.0	97.1	44.7	0.0	2.7	0.0	0.0	30.4
80	0.0	4.2	0.3	9.1	2.6	0.0	72.0	39.3	0.0	2.2	0.0	0.0	23.6
85	0.0	3.2	0.2	6.4	1.8	0.0	51.8	33	0.0	1.7	0.0	0.0	17.9
90	0.0	2.6	0.2	4.6	1.3	0.0	37.1	25.6	0.0	1.3	0.0	0.0	13.4
95	0.0	2.0	0.1	3.3	0.9	0.0	25.9	17.8	0.0	1.0	0.0	0.0	9.6
100	0.0	0.7	0.1	1.2	0.3	0.0	10.4	4.9	0.0	0.3	0.0	0.0	3.5

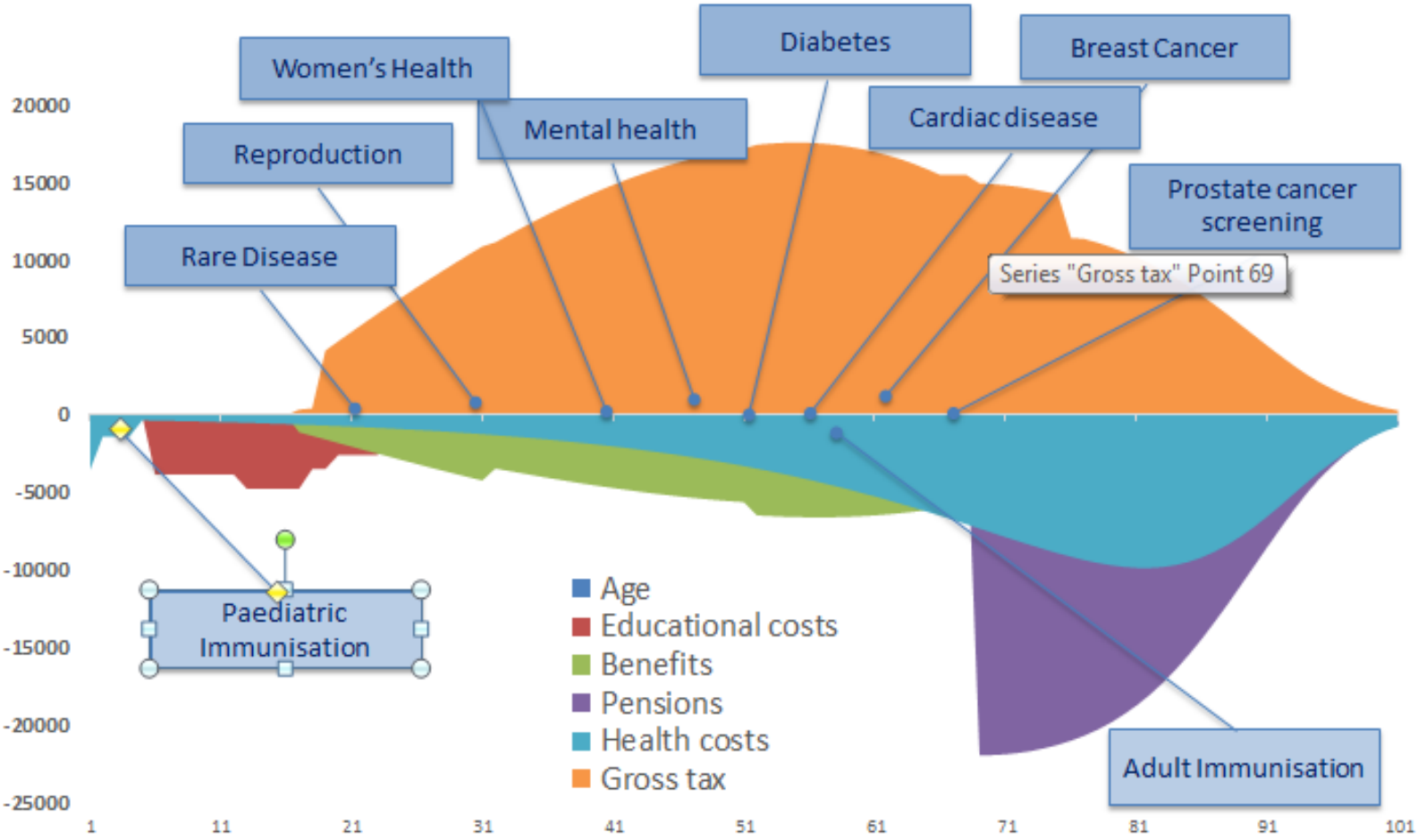
(*) 1995 value; baseline (r = 0.05, g = 0.015).

European Commission. (2000) European Economy: Generational accounting in Europe. Directorate-General for Economic and Financial Affairs.

The fiscal life course: Tax transfers and benefits between citizen and state



All health conditions and changes in health status have a fiscal consequence



If Treasury were allocating healthcare resources would treatments be prioritized differently?

Application of fiscal health modelling in healthcare

- Fiscal cost-benefit analysis (F-CBA) treats healthcare as an investment
  - Clinical benefits are translated into taxes and transfer costs to government
- Broader range of stakeholders are recognized using the fiscal health modelling approach and the cross sectorial government impact of health and investments in health
  - Particularly relevant in vaccine procurement as Ministry of Finance (MoF) often involved in process
- Defines how government benefits from investments in healthcare

Different perspectives – different costs

Perspective	Costs	Accounting for economic benefits
Health service	▪ Health service costs	No
Societal	▪ Health service costs ▪ Patient costs ▪ Indirect costs	▪ Lost wages ▪ Who really benefits: individuals, corporations, government ?
Government i.e. fiscal	▪ Health service costs ▪ Non-disease related health costs ▪ Family allowances ▪ Education costs ▪ Disability ▪ Pension costs	Lost tax revenue for government: i. Income taxes ii. Consumption taxes iii. Corporate taxes iv. Excise taxes

Health service and societal perspectives are often divorced from fiscal reality of government finance

Fiscal model evidence requirements

Category	Variables
Demographic	Life tables; age-pyramid of the current male and female population
Epidemiological	Age-specific incidence, morbidity and mortality of each HPV-related disease
Clinical	Vaccine efficacy in reducing the incidence of HPV-related disease and disease attributable mortality
Health economic	Direct medical costs of disease; cost of immunization
Fiscal	Direct and indirect tax and National Insurance contributions; government transfers (allowances, benefits, social protection)
Microeconomic	Age-specific earnings; discounting rate; cost inflation; wage growth

Interpretation of fiscal health modelling

- Fiscal health models are based on generational accounting framework used to measure intertemporal fiscal impact of government policies
- Fiscal health modelling can be thought of as a cost-benefit analysis conducted from the perspective of government

Costs to government	Benefits to government
• Lost tax revenue for government due to changes in morbidity / mortality	• Increases in tax revenue to government attributed to changes in morbidity / mortality or events avoided
Increased transfer costs attributed to changes in morbidity / mortality	• Decreased government transfer costs

Analytic outputs

- Gross taxes
- Net taxes
- Transfer costs (aggregated and disaggregated)
- Benefit cost ratio
- Net present value of investment

Application of fiscal modeling in resource allocation

- Broader range of stakeholders involved with funding decisions for vaccines
- Illustrates sustainability associated with investment decisions
- In context of development economics the method highlights the relevance of domestic revenue generation i.e. taxes

Relevance of fiscal messages to stakeholders

Governments (Treasuries and/or MoF)	• Interested in the sustainability of public finances in the short and long run • Public debts/deficit key in their political agenda • Cross-sectorial allocators of scarce resources • Payers of the "payers" • Involved in vaccination decisions
Payers/ budget holders	• Mainly interested in achieving technically efficient allocations within a health care budget as well as ensuring affordability and reasonable budget impact • Fiscal messages may be complementary to current CEA/BI messages
Physicians	• Simple and concise messages for supporting vaccination • Fiscal methodologies originate from financial analyses that citizens daily do
Patients/ advocacies	• Political messages to advocate the value of prevention and the need for additional investment as a means of sustaining long-term economic growth

HTA as typically applied and fiscal reality

Analytic input	Economic evaluation	Analytic weakness
Transfers	Ignore transfers	• Transfers represent actual fiscal costs incurred by government • Opportunity cost of transfers • Transfers paid for by current and future generations which can impair economic growth • Transfer of intergenerational debt transfer to future generations could be inequitable.
Taxes	Ignore taxes	• Changes in population health status influences economic growth which in turn influences tax revenue earned by governments

Health service and societal perspectives are divorced from fiscal reality of government finances

- Sign up as Review Group Member
- Join ISPOR Special Interest Groups
- Need ISPOR membership number
- Business card to Theresa or email
- ttesoro@ispor.org