Innovation in funding models for biologicals – A patient-centred approach

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2013

Disclaimer

This presentation reflects my personal opinion and does not reflect the views of the government or any other organization or committee that I am affiliated with.

Just to be sure!

Presentation is about

RE-IMBURSEMENT

And NOT about

PRICING

Some thoughts for discussion

- Patient access / assistance programme
- Re-imbursement linked to benefits (affordable benchmarks)
- Outcomes-based re-imbursement
- Personalised medicine
- Protocols driven by treatment intent
- Re-imbursement based on budget impact
- Pharmacoeconomic evaluation
- Carved out benefit for biologicals
- Vial sharing

Setting the scene

- Continual launch of new expensive medicines.
- Health gain of new drugs is just 0.97 QALYs.
- What classifies new drugs as innovative?

Legislation

Medicines and Related Substances Act, 1965 (Act No 101 of 1965).

18A Bonusing

No person shall supply any medicine according to a bonus system, rebate system or any other incentive scheme.

18B Sampling of medicines

1. No person shall sample any medicine

2. For the purposes of this section 'sample' means the free supply of medicines by a manufacturer or wholesaler or its agent to a pharmacist, medical practitioner, dentist, veterinarian, practitioner, nurse or other person registered under the Health Professions Act, 1974, but does not include the free supply of medicines for the purposes of clinical trials, donations of medicines to the State, tendering to the State and quality control by inspectors.

3. The use of medicines or scheduled substances for exhibition purposes shall be as prescribed.

Legislation

Regulations relating to a transparent pricing system for medicines and scheduled substances. 2004

6. A manufacturer, importer, distributor or wholesaler may not charge any fee or amount other than the single exit price in respect of the sale of a medicine or scheduled substance to a person other than the State.

International experience

Price volume arrangements

Patient access schemes (free drugs, price caps)

Risk sharing

Can we compare to SA?

Patient access programmes

Would you like to obtain free medicines now and in the future in the public and private sector?

Patient access programmes

Would you like to obtain free medicines under the current system in the private sector?

Patient access programme

Price caps:

- costs covered by pharma if exceed an accumulated dose.
- Pharma pay cost if more that a certain number of cycles are used.
- Reach of price cap of rands then payer receives additional supplies at no costs or large discount.

Patient access programmes

Formation of charitable programmes or trusts.

- Cover co-pays
- Free drugs

Re-imbursement linked to benefits

Develop affordable benchmark

For selected diseases determine actual costs per year:

Lab tests	Facility	Doctor
Medicines	Hospital	
Nursing		

Determine total costs as a reasonable cost for the treatment of a specific disease

Determine medicine cost as a percentage of total cost as cost per year

Proportion medicine cost to benefit

This forms a benchmark for medicines cost per year for the benefit.

Risk sharing models

- Financial based
  - price-volume arrangements / budget impact scheme
  - Based on payback mechanism

- outcomes-based /performance-based

Risk sharing

- Value-based pricing
- Conditional coverage
- Conditional re-imbursement
- Coverage with evidence
- No cure no pay
- Health impact guarantee
- Outcomes guarantee

Value-based pricing agreements

Outcomes-based re-imbursement

Payment is based on outcomes achieved in practice.

Payers and pharma companies agree to link payment for a medicine to value achieved, rather than volume. Agreement dictate the price relative to actual performance.

Definition

Agreements concluded by payers and pharmaceutical companies to diminish the impact on the payers' budget of new and existing medicines brought about by either uncertainty of the value of medicine and /or the need to work within finite budgets.

Adamski, J et al. Risk sharing arrangements for pharmaceuticals: potential considerations and recommendations for European payers. BMC Health Services Research 2010, **10**:153

Definition

Agreements between a payer and a pharmaceutical company where the price level and /or revenue received is related to the future performance of the product in either a research or real-world environment.

Towse A, and Garrison L. Pharmacoeconomics . 2010, **28**:93-102.

Pros: outcomes-based model

- Improve access to new, innovative drugs.
- Outcomes based approach (value metric)
- Guide product development
- Localised cost-effective targets
- Opportunities for partnership
- Encourage companies to develop biomarkers or other methods that help target patient populations where health gain and hence value is the greatest.
- Build clinical experience with medicines

Pros: outcomes-based model

- Enhancing-health gain within available resources
- Safety of new products in practice

Barriers: outcomes-based model

- SEP at launch could be set higher to compensate for risk
- Need approval from DOH for introduction on a medicine by medicine basis
- Early access to new technologies with as yet unproven efficacy and safety.
- Burdensome administration
- rules and conditions to participating providers
- Ethics and confidentiality issues

Barriers: outcomes-based model

- Implement an audit process
- Specific objective outcomes for clinical measures not always in place.
- May give some medicines ‘a foot in the door’
- Physicians may treat with medicines more freely they perceive to be free.
- Should not be a substitute for good clinical trials.
- New drug launched too early with considerable uncertainty with regards to safety.

Barriers: outcomes-based model

- High administration costs
- Funders may be funding an appreciable proportion of new drug's development costs.
- Payers need to consider the opportunity cost of risk sharing schemes if available resources are not used wisely.
- Validated measurement tools

Medicines for outcomes-based model

Candidates:

- Simple measure to measure outcome
- Clearly defined outcomes
- Products with high budget impact

Definition: Health Outcomes

A **scientific** discipline that evaluates the effect of **health care interventions** on patient-related, if not **patient specific**, economic, clinical and humanistic outcomes

ISPOR BOOK OF TERMS

Health Outcomes Assessment

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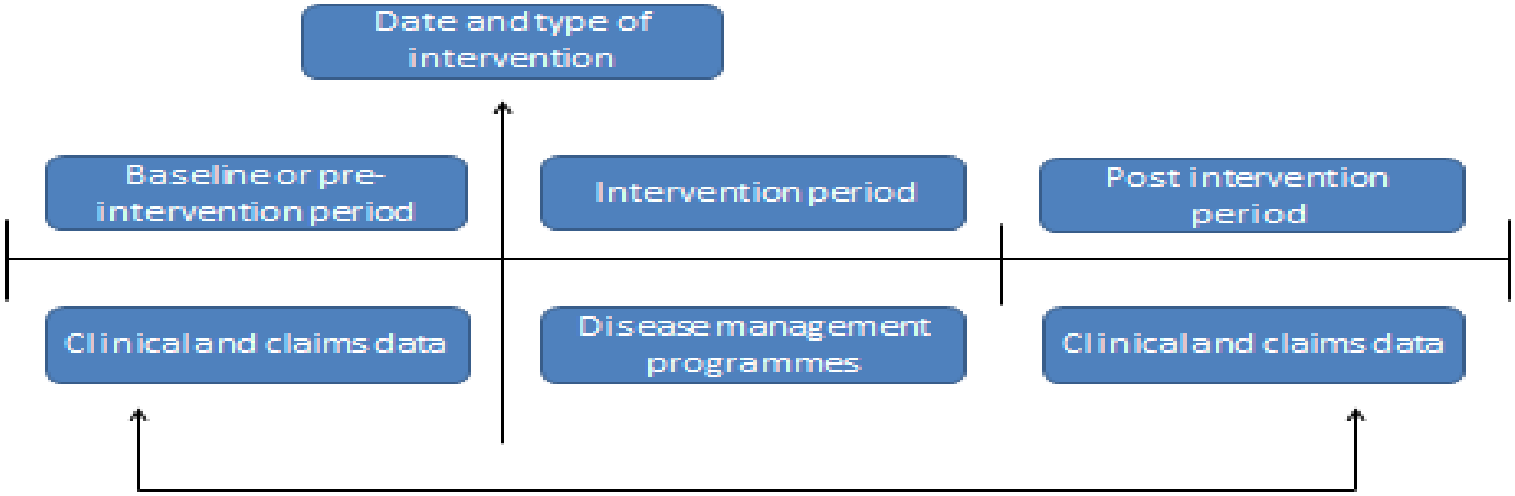
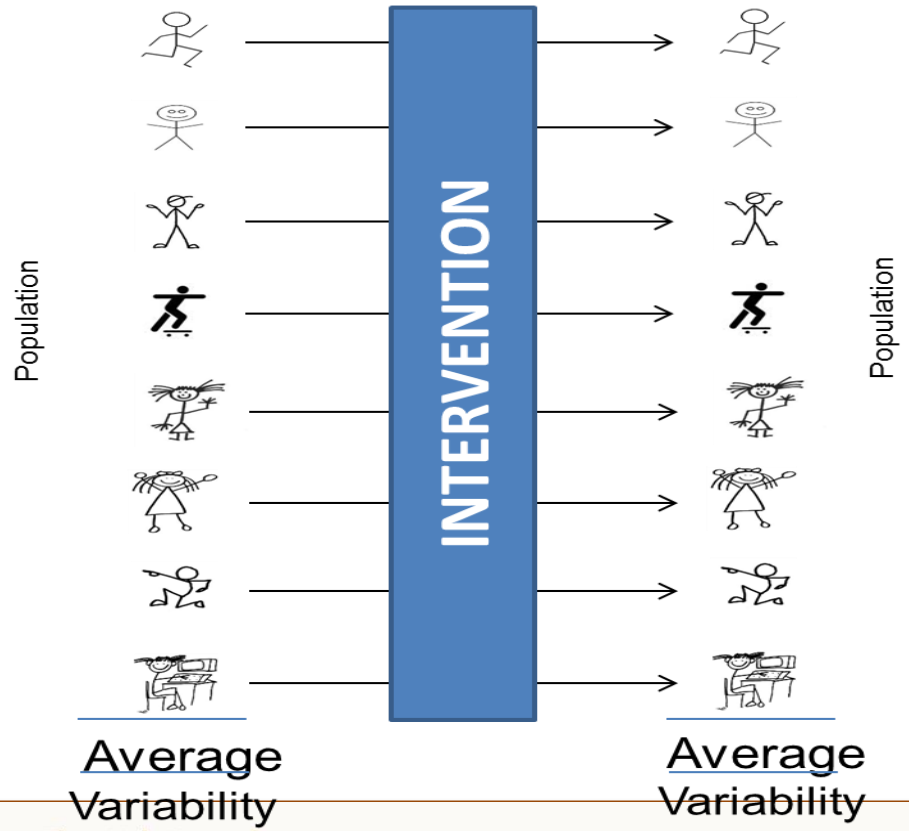


Difference = Outcome

Value of managed health care

Population vs Individual Health Outcomes Assessment



Measure Change

A

B

C

D

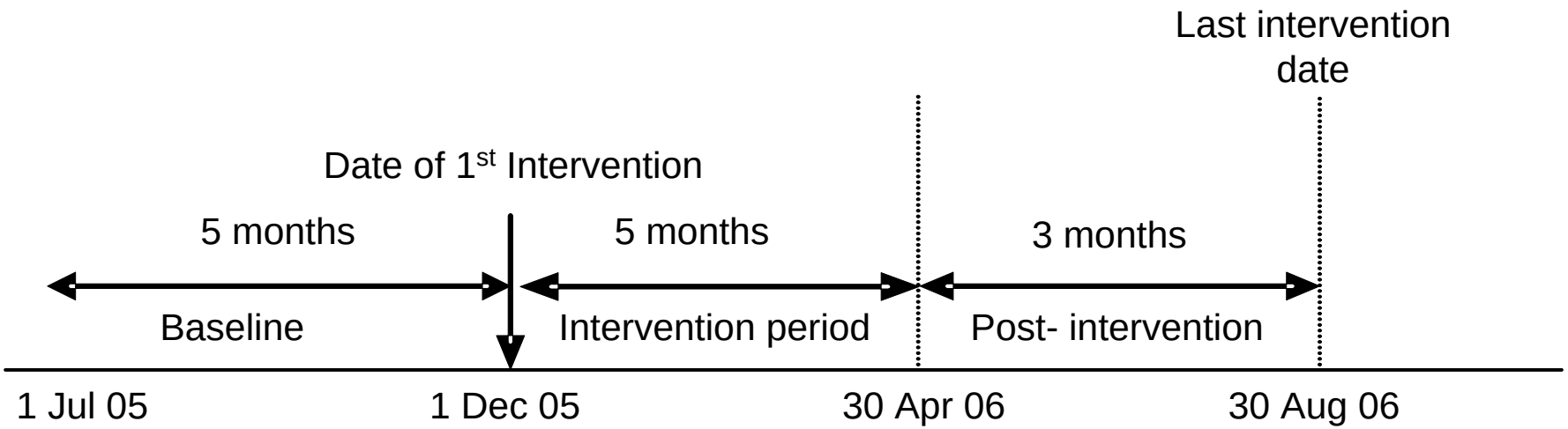
E

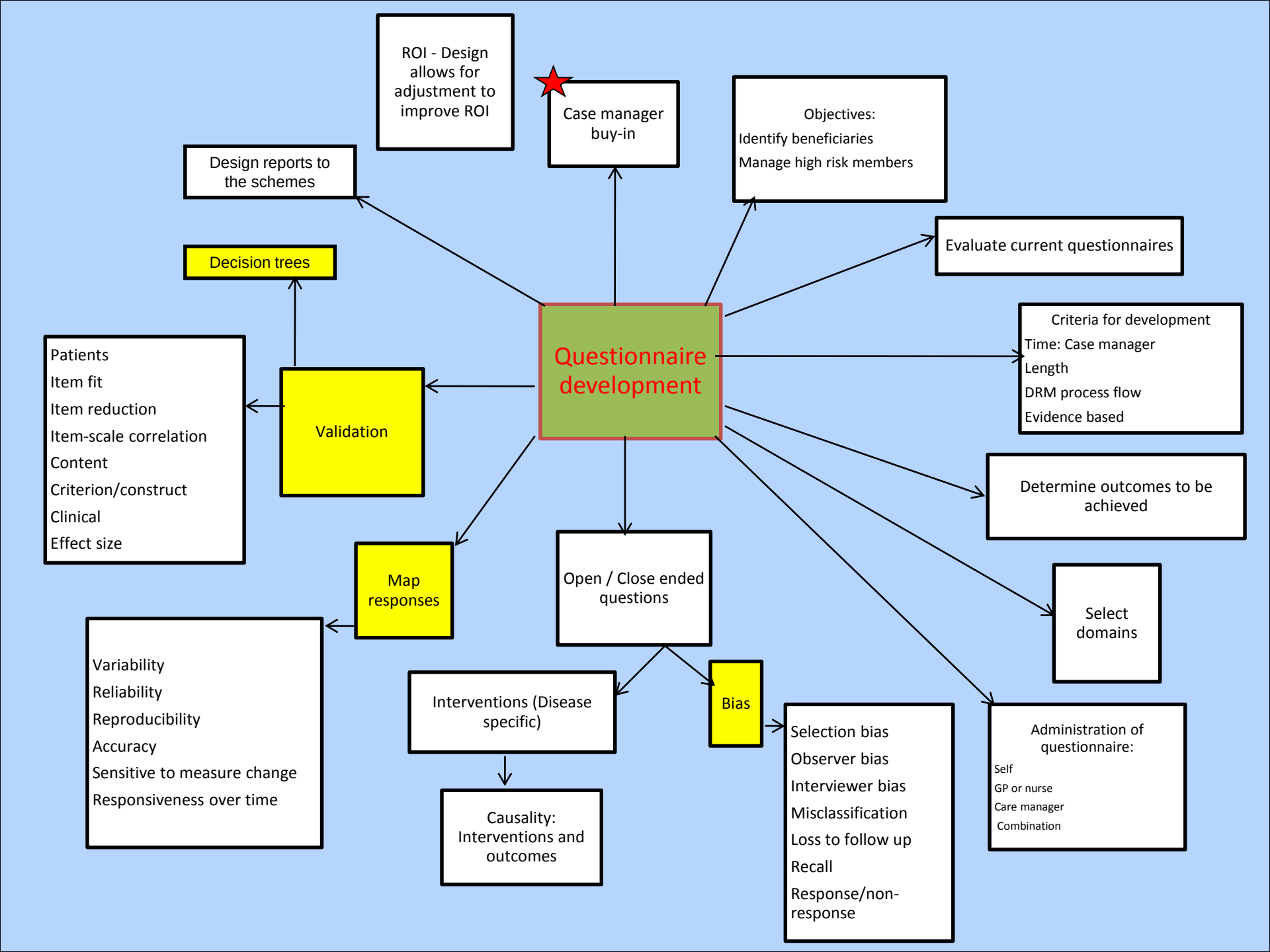
F

G

H

Pre- and post intervention




Questionnaire development
ROI - Design allows for adjustment to improve ROI
Case manager buy-in
Objectives:
Identify beneficiaries
Manage high risk members
Design reports to the schemes
Evaluate current questionnaires
Decision trees
Criteria for development
Time: Case manager
Length
DRM process flow
Evidence based
Patients
Item fit
Item reduction
Item-scale correlation
Content
Criterion/construct
Clinical
Effect size
Validation
Determine outcomes to be achieved
Map responses
Open / Close ended questions
Select domains
Variability
Reliability
Reproducibility
Accuracy
Sensitive to measure change
Responsiveness over time
Interventions (Disease specific)
Bias
Causality: Interventions and outcomes
Selection bias
Observer bias
Interviewer bias
Misclassification
Loss to follow up
Recall
Response/non-response
Administration of questionnaire:
Self
GP or nurse
Care manager
Combination

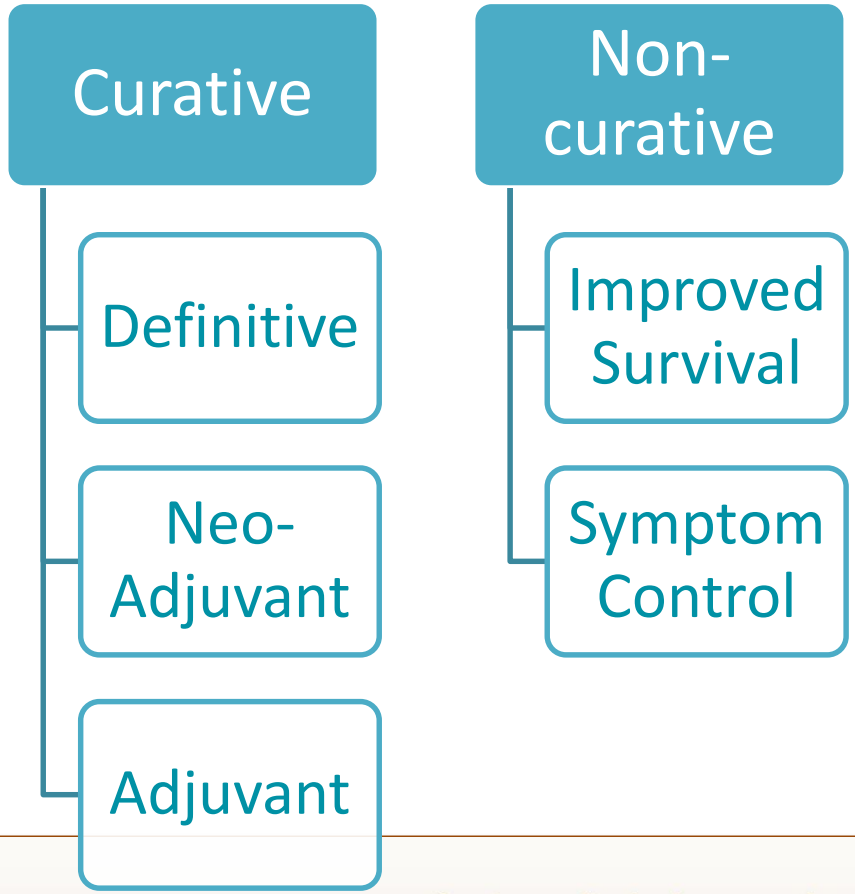
Challenges with measuring health outcomes

- Definition of health outcomes
- Careful planning of data collection
- Availability of good baseline information
- Missing data points
- Clinical and statistical differences
- A priori specification of confounding variables
- Integration with systems
- Disease specific clinical measurement

Personalised medicines

- the re-imbursement will be dependent in genetic and molecular profiling.
- genomic testing in oncology—where science and reimbursement meet
- drugs can be tailored to specific cancers depending on molecular aberations.

Protocols driven by treatment intent



Other funding considerations

- Re-imbursement based on budget impact
- Pharmacoeconomic evaluation
- Carved out benefit for biologicals
- Vial sharing

Key trends

- Move towards value-based pricing
- Impact of health economic data on efficiency of health care
- Comparative effectiveness evaluations is widely recognised
- Real-world evidence will become increasing important in value evidence.
- Personalised medicines

United Biosource Corporporation July 2012

Perception of value

Payers consider that less than half of recent drug launches represent sufficient value for money, indicating a gap between industry and payers on perception of value. Industry needs to work on more closely with payers to understand the drivers of value and address the payer perspectives earlier in product development.

United Biosource Corporation July 2012

Concluding remarks

Currently most funding models workable in the public sector

Transparency in pricing – prevent manipulation in private sector.

Rational use of medicines

- Evidence-based medicine
- Multi-disciplinary teams
- Clinical pathways

Treatment plans / discharge plans

Reduce wastage