

Pharmacoeconomics

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...or what's it worth?

Learning objectives

- Understand different perspectives on the value of a Biopharmaceutical
- Be able to make a structured, rational argument for funding or otherwise a Biopharmaceutical
- Refer to Chapter 23 of core text

Fundamentals of biopharmaceuticals

- Globalisations
 - Technically exciting, can't readily make these molecules with a chemistry kit!
 - Purification an issue and arguably only 12 years experience of biopharmaceuticals so RISK
 - Costly drugs treating rare conditions. Not a good starting point ☹️
 - You never get side-effects with a new drug!

Value



Job

- What is value?
- From the researcher's perspective?
- From the manufacturer's perspective?
- From the patient's perspective?
- From the funding organisation's perspective?



Process



Money



Money



Death



Time



Happiness



Time



Money

There is only ONE perspective

- The market place
- What is the competition?
- Is there a niche market?
- Can it cover costs (800 million € to phase 3)

..... Maybe now two perspectives

- Risk, Risk, Risk (TGN1412)
- Who determines value?
- Initially with the company, then the funding body, then prescribers and ultimately patients

What the market wants

- Lower costs
- Controllable costs
- Predictable costs
- Improved outcomes

\$

Money

£

Money

Oh and it must work, and be better than
the current options ... **IN SOME WAY**

€

Money

Oh and new drugs are a hassle, especially me2

Personal gripe

.... how *do* you get your vocal cords around these things?

Adalimumab

Try saying this 100 times, I did!



NICE
2002

Me2 Anti-TNF

	On the market	Cost, Adult 70kg cost/week
Infliximab	1998 Licence 1999 (UK)	IV 600€
Etanercept	1998 after Infliximab	SC 250€
<i>Adalimumab</i>	2007!	SC 500€

Process

- Compare with GOLD therapy in rheumatoid arthritis
- Do they work? YES
- 3 x more patient benefit/utility
- ... but QALY > ceiling therefore NO!

IN CANADA!

Examples

- Filgrastim (Recombinant Human granulocyte-colony stimulating factor [G-CSF]) priced to give a net reduction in cost/cancer patient/course ie obvious gain!

How is it done?

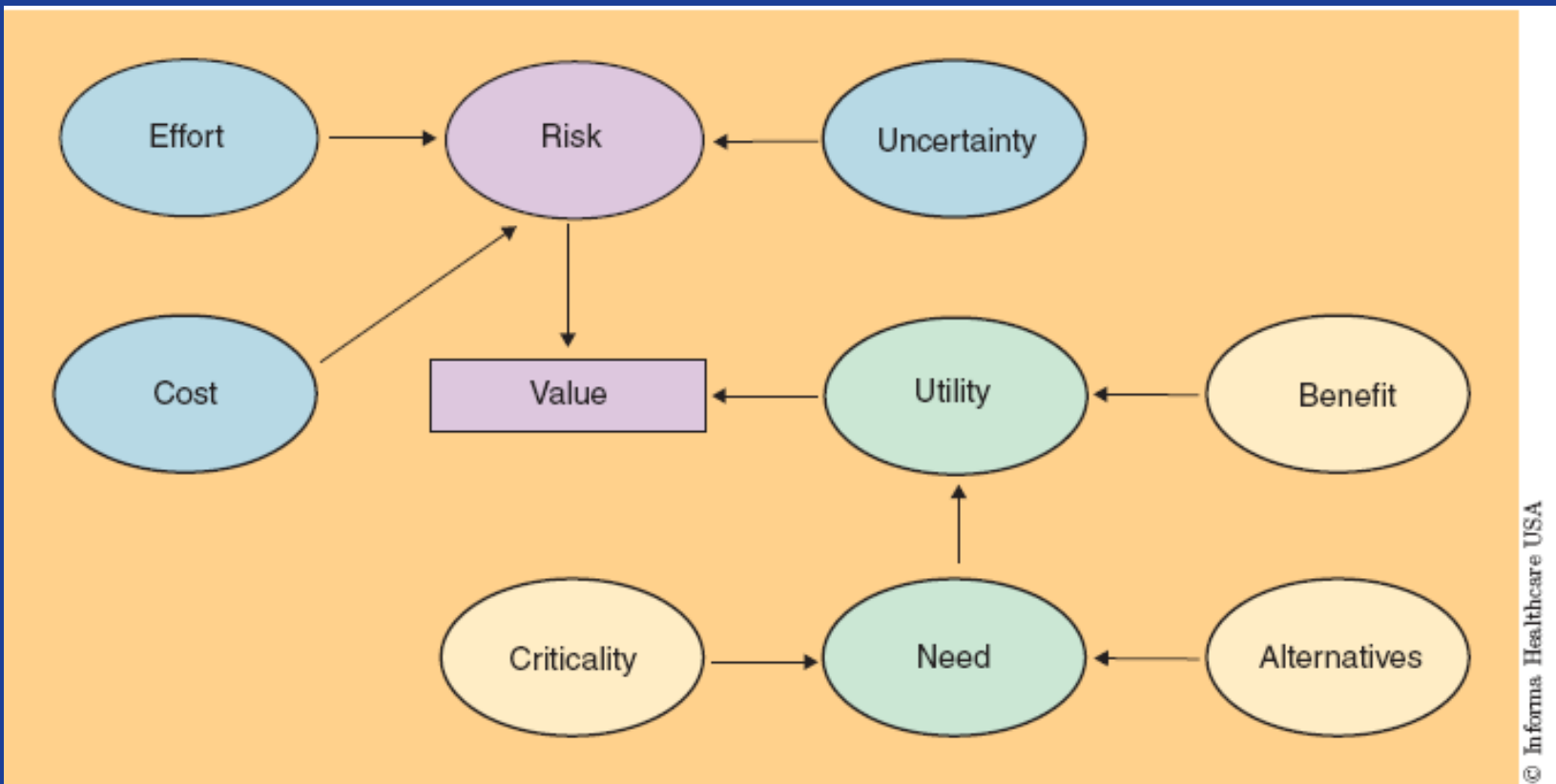
- Basic economic model of current treatment
- Pharmacoeconomics
CMA < CBA/CEA < CUT = (QALY)

Cost Minimisation Analysis (Money only)
(add how effective) = Cost Benefit Analysis or Cost-Effectiveness Analysis (add patient factors) = Cost Utility Analysis (CUA)

- Standardise CUA and you get QALY

(very big in the 1980s and 1990s, you couldn't get a hip without one!)

Global relationships



Complexity

- Product can provide significant economic benefit in one indication but not in another
- Ceiling for funding are emerging NICE (UK)/ Canada – and postcode healthcare
- “The fact that a new agent can treat a disease does not address the societal question of whether or not it should be used.”

Summary

- Know how to approach pharmacoeconomics
- You have the BUZZ terms
- ...but is it you?

HANDS UP who has been involved in a pharmacoeconomic analysis of a biopharmaceutical?

Biopharmaceuticals

1. Recombinant human growth hormone (somatropin) Plus 'biosimilars' Omnitrope and Valtropin
2. Human insulin, plus newer analogues (lispro/aspart and detemir/glargine)
3. Vaccines – hepatitis B; new influenza vaccines?
4. Recombinant human G-CSF (Filgrastim, Lenograstim)
5. Erythropoetin, plus analogue darbepoetin
6. Thrombolytic agents - Tissue type plasminogen activator (rt-PA) plus newer analogues reteplase and tenecteplase
7. Interferon alpha beta
8. Recombinant interleukin-2 (aldesleukin)

9. Monoclonal antibody drugs

Abciximab – antiplatelet

Adalimumab – autoimmune rheumatic disorders

Etanercept

Infliximab

Rituximab – lysis of B lymphocytes

Alemtuzumab

Basiliximab – prevent T lymphocyte proliferation

Daclizumab

Imatinib – tyrosine kinase inhibitors

Trastuzumab