Valuing innovation: HTA practice and the impact for future medicines

Mendel Grobler

Innovation: definable?

1. Definition
   - Different views: new vs.. better; improved vs. measured … driven by perspective
   - Systems view: a process integral to progress.
   - Requires effort and resource from someone
   - Therefore relies on incentive
2. How innovation is *valued* – interface between purchaser and producer
   - Market values ↔ government value
   - Each is an important economic signal and impacts innovation

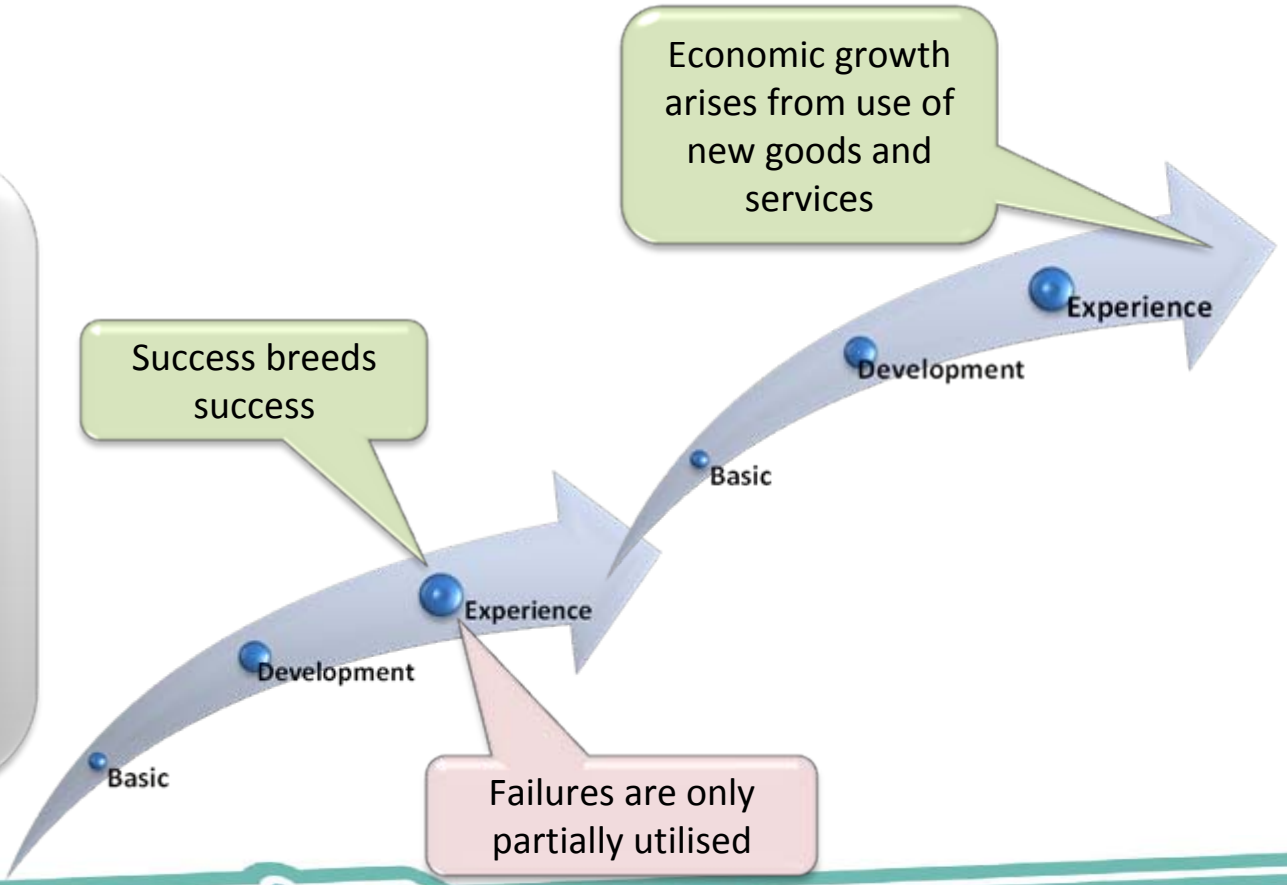
Do we need innovation?

- General: economic growth is dependent on innovation ✓
- Health : accept (?) human progress in health needed
  - while there is suffering and early death caused by disease ✓
  - progress requires innovation ✓
    - e.g. look back to 1991 PBS and see how we would manage HIV, many cancers, RA, schizophrenia
- Specific diseases: - it depends. ?
  - Able to technically solve need for innovation in some areas e.g. hypertension (contentious), gastric ulcer, etc

How much innovation and what is the trade-off?

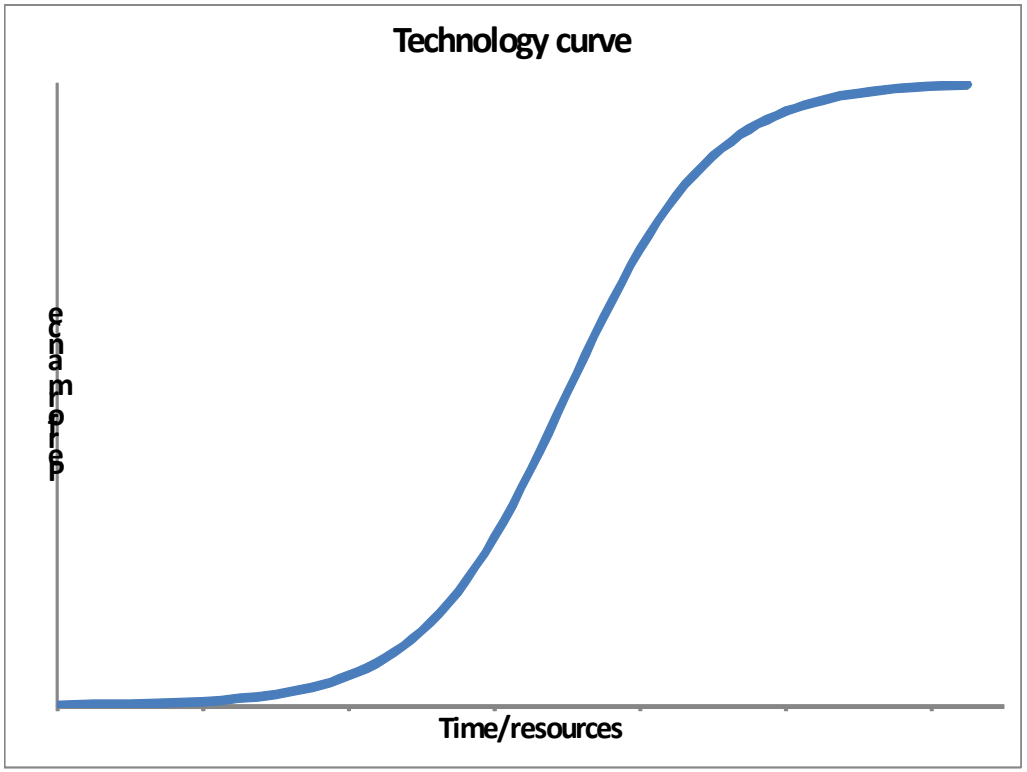
Medical innovation over time

→ Basic research builds a foundation of knowledge
→ From this potential treatments are developed
→ Experience informs next level basic research
❖ **The cost curve is correlated**



The innovation curve

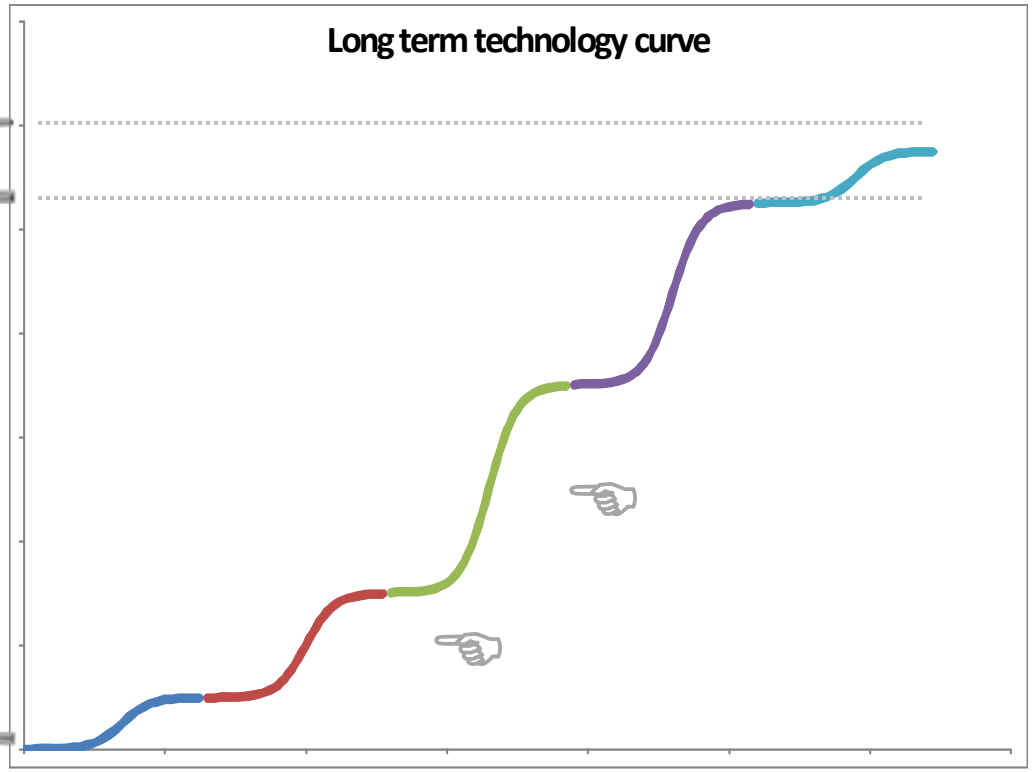
Initial slow start then steep rise and then tapering of benefit as we reach the limit of the technology



The long run: how much investment is needed?

Efficient point to disinvest in innovation
Upper limit of technology: end of disease

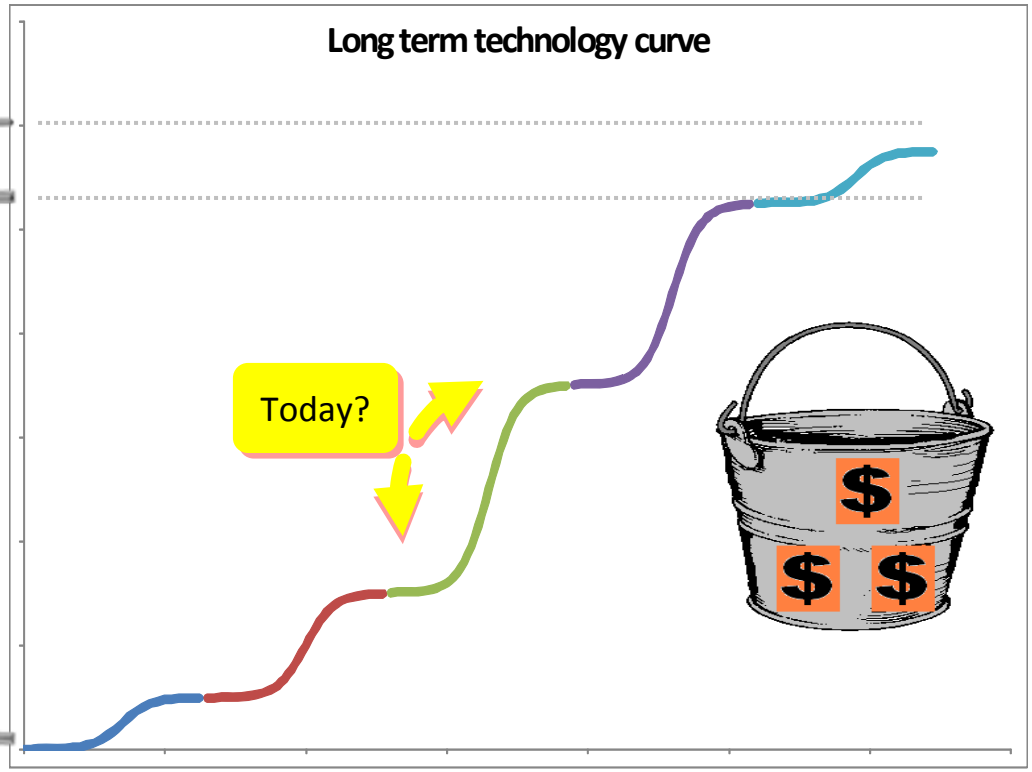
Inefficient point to disinvest in innovation
Gap = technical as well as social i.e. foregone health and welfare



The long run: how much investment is needed?

Efficient point to disinvest in innovation
Upper limit of technology: end of disease

Inefficient point to disinvest in innovation
Gap = technical as well as social i.e. foregone health and welfare



A glimpse into supply: venture capital

- Capital Asset Pricing Model[#]
  - Investing funds driven by financial rules
  - Financial rules exist to attract capital
    - Shareholders and banks
- All “projects” adopted must meet or exceed expected rate of return
  - Risk has a capital cost
  - Expected performance ≥ historic i.e. expect progress
  - Compete for capital: limited resources

Fama, EF; French, KR. The Capital Asset Pricing Model: Theory and Evidence. The Journal of Economic Perspectives, Vol. 18, No. 3. (Summer, 2004), pp. 25-46

Global R&D investment by therapeutic area

- Investment decisions *generally* follow expected population needs
- E.g. Investment in a therapeutic area influenced by
  - Unmet clinical need
  - Existing expertise (increases success rate, ↓ cost)
  - Serendipity, etc
  - CAPM i.e. Investing capital in area of equal or greater return

R&D investment: key challenges

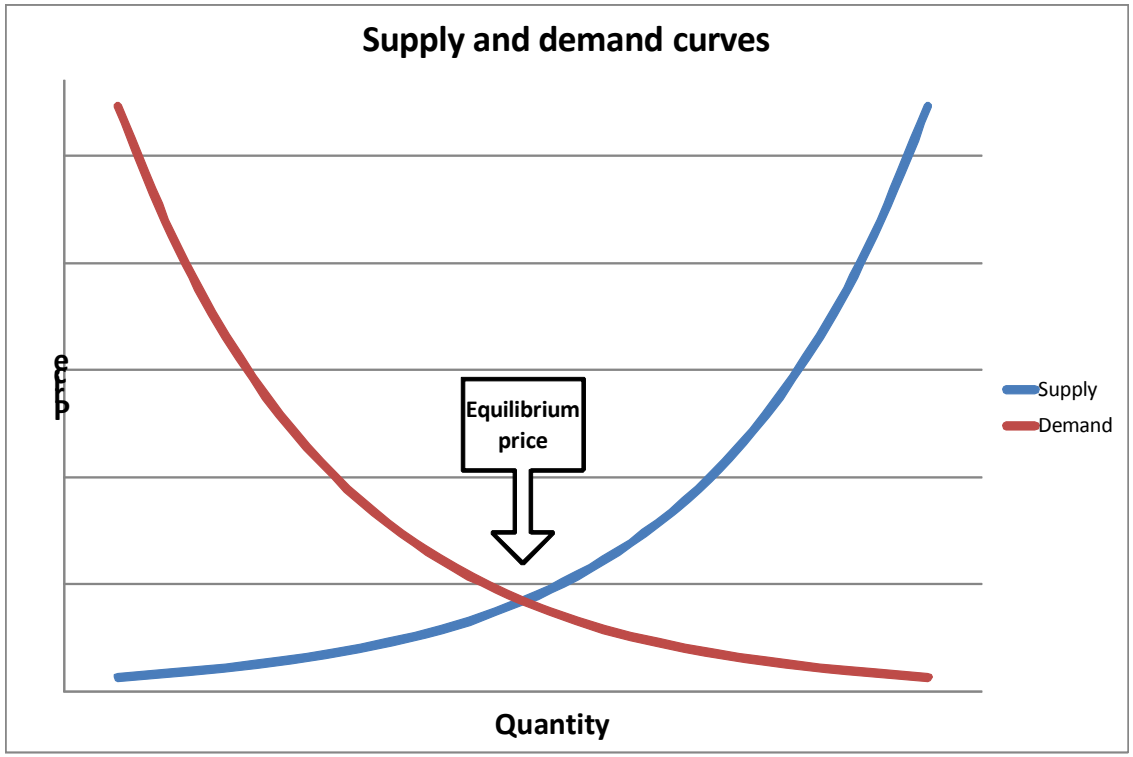
- Diminishing returns in major therapeutic areas
  - Incremental efficacy gains getting smaller in some areas
    - Top of curve in some, gap in science in others (see below)
- More targeted complex molecules
    - Treat a smaller fraction of the population
    - Same development costs and increased cost of manufacture
- Global shift to centralised technology assessment and cost reduction
  - Price is calculated and fixed - see following slides
  - Major patent expiries driving down existing prices
  - Linkages force flow on effect on pipeline innovation

Bringing the two sides together: price signals

- The PBS sets prices: ~ 80% QALY, 20% fine tuning
- Spillover: the PBS is leading influence in the global HTA network
  - Not a global uniform standard but converging trend
- Disclaimer: impact on supply not 100%: diluted but growing
  - Unseen to outsiders: internal company processes
  - Seen: media, public announcements on R&D, etc
  - Parallel issues: antibiotics, malaria, "3rd world"

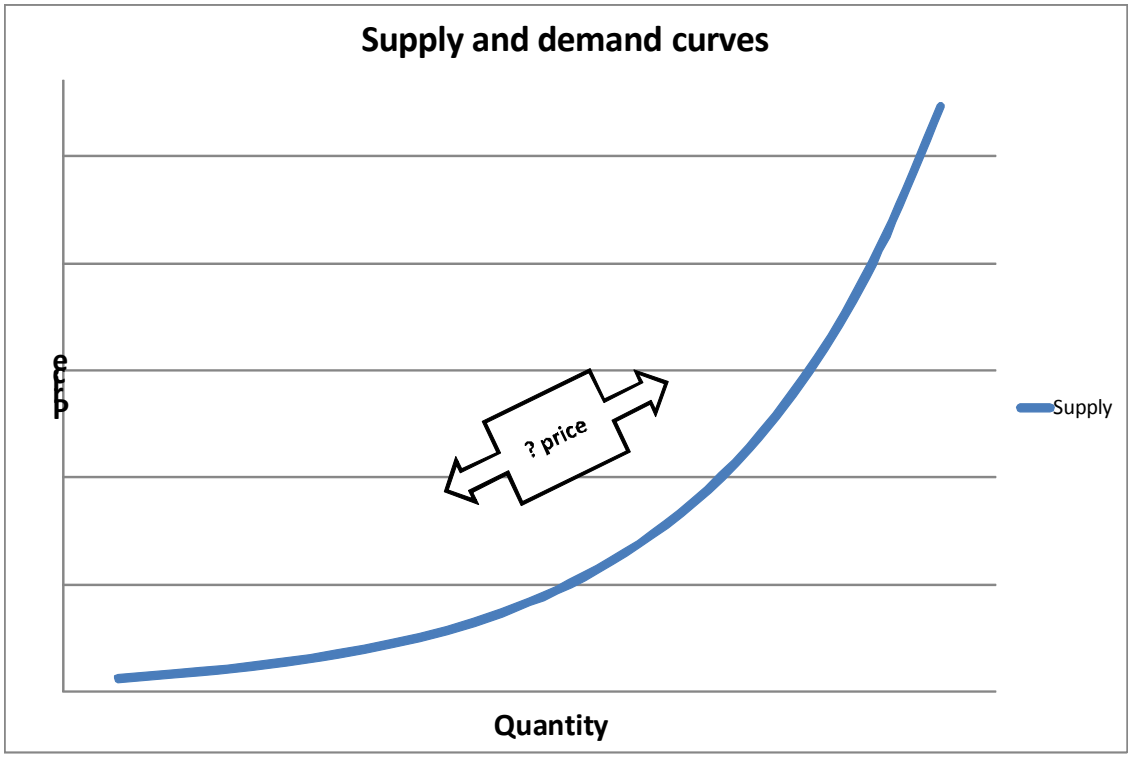
Markets, prices and innovation

- Perfect markets balance supply and demand and set the ideal price (efficient price).
- Perfect markets, through reacting to change, price innovation
- Imperfect markets invite government intervention
- An HTA market is a market – but the demand curve that informs price is replaced



Markets, prices and innovation

- The supply curve still exists
- Setting the price at a point has a consequence on supply including future supply
- The QALY thresholds used determine the price



Price follows threshold

"There is no known piece of work which tells you what the threshold should be."#

Sir Michael Rawlins, Chairman of NICE

Quoted from The Stockholm Network. http://www.stockholm-network.org/downloads/events/Kristian.pdf

Possible solutions

- Acceptance of need for a solution and engagement
- Quantitative solutions possible:
  - "QALY *plus*" e.g. include variables that indicate societal need; e.g. MCDA
  - "QALY adjust" i.e. correct for proven market failure[#] e.g. generic price comparison
- Qualitative solutions to explore:
  - Define innovation needs
  - Send consistent signals to supply
  - Revisit methodology and evolve

#Grobler, MP. Health technology assessment: longitudinal impact of fixed cost-effectiveness thresholds and comparator prices changes on the market. ECHE 2010: 8th European Conference on Health Economics; 2010 Jul 7-10; Helsinki, Finland