From price to value in breast cancer

Achieving fair, equitable and affordable care

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First question

Do we have a problem, and if so where?
For solid cancers value (economic definition) has been declining in clinical trials

*Higher prices, decreasing impact on outcomes*

1. Of *277 RCT* in last five years for **solid** cancers,

   17-20% of medicines met clinically meaningful thresholds (based on ESMO scale)

   (*All of these were described as ‘management changing’!)

2. Even in patient access schemes **only 1 in 5** cancer drugs met same evidentary thresholds for providing clinically meaningful benefit

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What about value of medicines in the real world?

How does one judge whether this is 'good' value?

David Howard @ Emory. Health Affairs 2016: 35: 1581-1587
Price and costs have been going up, and, overall, clinically meaningful impact has been declining.

Does not mean that there have not been some excellent individual technologies

Also the focus has been on medicines.

We know there are major issues with non-medical technologies but little good empirical work.
So, are cancer care systems as a whole delivering value?
What matters is total health care expenditure and governance
Some systems delivering very good value, many are not

The reasons for this are NOT just price & costs of cancer medicines (only a part, and in many cases a small part)

Governance, clinical pathway and economic failures have a dramatic impact on value

Overall from either a technology or systems perspective we do have a major problem
Second question

So what are the root causes?
The ‘market’ – technologies are ‘just’ commodities

Profits have NO relationship to investment in R&D

Systems have become used to these sorts of financial returns

Private sector is ‘just’ behaving according to normal rules of capitalism
Escalating prices are driven by market power, power to negotiate and perverse incentives, e.g.\textsuperscript{1}

a. Product hopping, evergreening, and pay for delay
b. Repurchasing own shares

\textsuperscript{1} American Society of Clinical Oncology Position Statement On Addressing the Affordability of Cancer Drugs
Our regulatory system and research community are also accepting lower and lower evidential thresholds.

68 indications give marketing authorisation by EMA only 35% demonstrated survival benefit, and 10% improvements in QoL.

Of 44 indications that showed no OS/QoL at MA in post marketing period only 3 showed survival benefit and 4 improvements in QoL.

All survival gains were limited on average 2.7 mths.
In whose interest is the faster to market paradigm?

Is this really in the public good?¹

Huge uncertainty which makes extrapolation of uncertain trial data to real world even more hazardous for cost effectiveness estimates and patients²

¹ Adaptive pathways to drug authorisation: adapting to industry. BMJ, 2016 354: 1-4
Beyond health economics value is a subjective battleground

Who’s value? (Austin Frankt. JAMA 2016, 316(10): 1033-34)

Finally problem is the nature of healthcare in rapidly ageing populations.
Solutions for delivering real value
Manage hype and hyperbole

Prasad et al found use of word *unprecedented* for 48 specific cancer drugs, of which only 19 were tested in proper trial and had not failed phase III, and even of these only 8 were given an FDA marketing authorization!

Use of word “unprecedented” in the media coverage of cancer drugs: Do “unprecedented” drugs live up to the hype? *J Cancer Policy* 2017: 14: 16-20
Hard to control media, and equally hard to control press releases (no standards for being balanced!)

Beyond traditional media social media is even more ‘feral’.

What percentage of ‘talking heads’ about cancer treatments on TV and radio over last five years met basic truthfulness and accuracy thresholds?

14%
Develop new pricing models with health technology assessment

- **Discount**
  - Agreeing to a reduced price

- **Price/Volume**
  - Payment level is set based on a certain volume of cases

- **Biomarker or Surrogate-based**
  - Reimbursement contingent upon items like biomarker status or tumor response rates

- **Patient Outcomes “Warranty”**
  - Manufacturer absorbs cost where the product fails to work based on a particular metric (e.g., fracture occurrence)

- **Short-term Performance-based**
  - Similar to outcomes warranty, but focused on short-term outcomes (e.g., HbA1C levels and compliance)

- **Population-based Performance**
  - Manufacturer guarantees longer-term, population outcomes
  - Can involve additional evidence development (e.g., CED)

- **Emerging**
  - Milestone payments and amortization for curative therapies
Great on paper BUT...legal, data, billing, socio-cultural barriers are substantial and very different from country to country\(^1\)

None of these models have been shown to improve value. Hope that indication-based pricing may do this....

How about changing the business model?

We have created and accepted legal monopoly(s) (patents) & systems such as maximizing shareholder value

Market power determines prices, national economic policies determine costs, and development determines affordability,

But changing this is going to require revolution not evolution. Unknown consequences.
Something more realistic then?

- Lets change the ‘choice architecture’ so that patients drive this. Great idea, not a shred of evidence that it can work. **Current activism is not for rational, staged access.**

- OK, mandate clinical trials that aim for significant clinically meaningful benefit **and** have socio-economic components as integral part. **Research funders need to do this, and so far they’ve not.**

- What about raising the regulatory threshold? **Good luck…!!**

- OK, limited, controlled release. **Specific centres over defined time-period.** Does this violate equality?
Market is not self correcting.

Need much greater value from all cancer technologies & systems\(^1\)

This requires buy-in from professional community, patient organisations and research funders.

\(^1\)Chalkidou et al. Evidenced informed frameworks for cost effective cancer care Lancet Oncology, 2014, 15:119-131
Value to one is not value to all
Change through collective action or train crash?