

Does Transparency Help or Hinder Emerging HTA Systems?

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Introduction

Background to Health Technology Assessment (HTA)

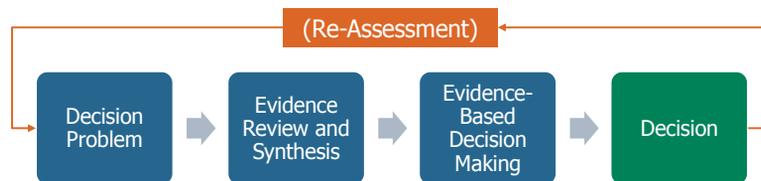
What?

HTA is the systematic evaluation of the properties, effects, and other impacts of health technologies

Why?

To inform health care policy and decision making, in the face of scarce resources

Typical Process



Areas of Transparency in HTA

Methods	What will be included for evaluation and how will the technology be evaluated?
Process/timing	What are the stages of assessment? When is a decision expected?
Consultation	Can submissions be made and by whom?
Meetings and minutes	Who can attend meetings and access minutes?
Assessment reports and decision	How is a decision explained?

Generally, the more that is publicly accessible, the more transparent the HTA system is

- Within assessment reports, certain items will need to remain confidential to protect the commercial or academic interests of a company (e.g. price discounts)

HTA Systems in Asia – Emerging and Established



Discussion

Could transparency be problematic for an emerging HTA system?

Which stakeholders will benefit from greater transparency?
How?

What can be learnt from the evolution of transparency of more established HTA systems?

The Panel



Societal Perspective

- **Dr Thomas Butt**, Research Fellow at Peking University and University College London



HTA Agency Perspective

- **Fiona Pearce**, Deputy Director/Senior Lead Specialist (Drug Evaluation) at Agency for Care Effectiveness, Ministry of Health, Singapore



Pharmaceutical Company Perspective

- **Brenda Pote**, Associate Director Market Access, Roche Australia



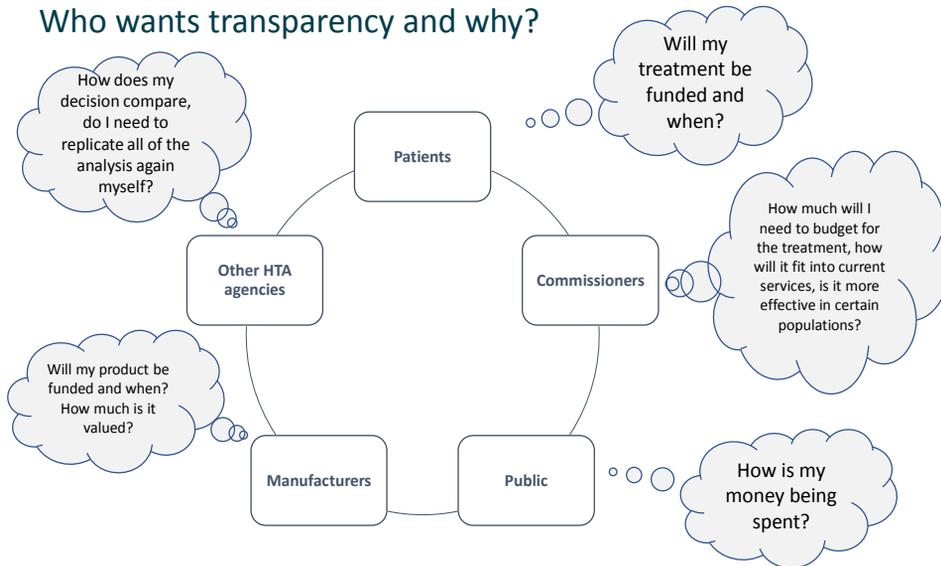
Does Transparency Help or Hinder Emerging HTA Systems? - Societal Perspective

Dr Thomas Butt

Research Fellow, Peking University

Principal Research Associate, University College London

Who wants transparency and why?



How does society benefit from transparency?

Information

- HTA is a systematic evaluation of the effects of a health technology
- Without transparency and consultation, HTA is likely to miss key information that could be provided by stakeholders: industry, patients, healthcare professionals, etc.

Perspective

- It is difficult for a decision-maker to assume the perspective of the end-user (public or patient)
- Without transparency, it is unclear that the decision-maker is making choices consistent with the preferences of the society it serves

Some areas for transparency

“Black-box” HTA



“This product is hereby recommended for use in health care system X”



Versus transparent HTA		Ideal
Methods	What will be included and how will it be evaluated?	Yes
Process/ timing	What are the stages of assessment? When is a decision expected?	Yes
Consultation	Can submissions be made and by whom?	Yes
Meetings and minutes	Who can attend meetings and access minutes?	Yes
Assessment reports and decision	How is a decision explained?	Yes

Not only about transparency? Other areas that can give stakeholders confidence in the HTA process



Stakeholder engagement: Maximizing opportunities for participation and input

- Clinical, patients, lay members, manufacturers, commissioners...

Transparency



Independence: Avoiding conflicts of interest

- Separation of evaluators, commissioners and decision makers



Re-assessment: New evidence

- Can decisions be appeals or reviewed?

Any downsides to this highly transparent HTA process?



Time

Engagement, re-assessments and arguably transparency all take time that may delay decision-making



Expertise

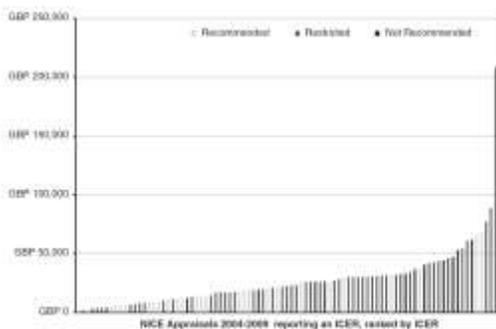
HTA methods can be difficult to understand for lay people, therefore benefits of transparency may be limited



Lobbying/ outside influence

Probably most of a risk for systems with medium levels of transparency (no transparency = no chance to influence vs. high transparency = easy to spot lobbying)

High transparency doesn't mean high predictability: What factors explain NICE decisions?



Significant associations between NICE recommendation and four variables:

- statistical superiority of the primary endpoint in clinical trials
- the incremental cost-effectiveness ratio (ICER)
- the number of pharmaceuticals appraised within the same appraisal
- the appraisal year

What should emerging HTA systems aspire to?

Methods	What will be included and how will it be evaluated?	Yes
Process/ timing	What are the stages of assessment? When is a decision expected?	Yes
Consultation	Can submissions be made and by whom?	May be limited at first
Meetings and minutes	Who can attend meetings and access minutes?	May be limited at first
Assessment reports and decision	How is a decision explained?	Yes

What should emerging HTA systems aspire to?

Minimising the downsides:

Time

- HTA hub approach – addresses resource challenges and gives some independence to HTA report

Expertise

- Train stakeholders to interact with the HTA system - role for societies such as ISPOR in public/ patient engagement, in order to build expertise and minimise lobbying risks?



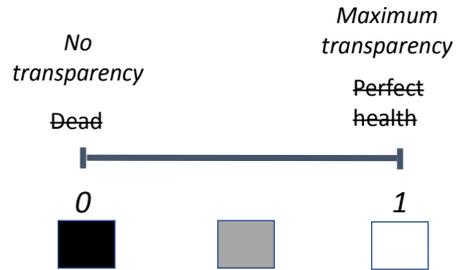
How much transparency is desirable?

International Journal of Technology Assessment in Health Care, 19:1 (2003), 1-3.
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TOWARD TRANSPARENCY IN HEALTH TECHNOLOGY ASSESSMENT

A Checklist for HTA Reports

David Hailey
Alberta Heritage Foundation for Medical Research



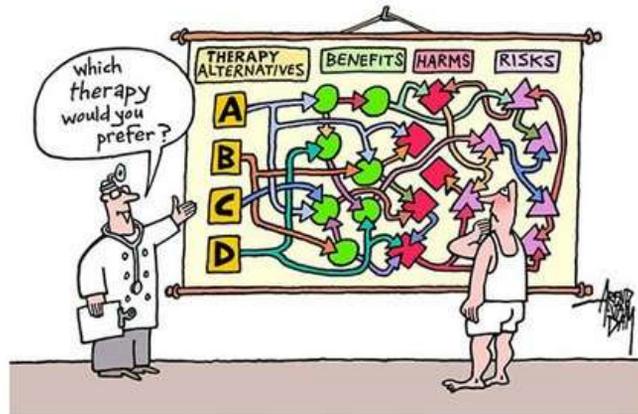
Checklist and a continuum?

Conclusions

- High levels of transparency in HTA will benefit:
 - Individual stakeholders e.g. patients who want to know why their treatment is restricted to a subgroup
 - Society through facilitating informed decision making in-line with social preferences
- Activities such as training stakeholders to engage effectively and spreading work via HTA hubs can minimize some of the challenges of high transparency

I suggest an extremely light grey box

Transparency: too much of a good thing?



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HTA Agency Perspective

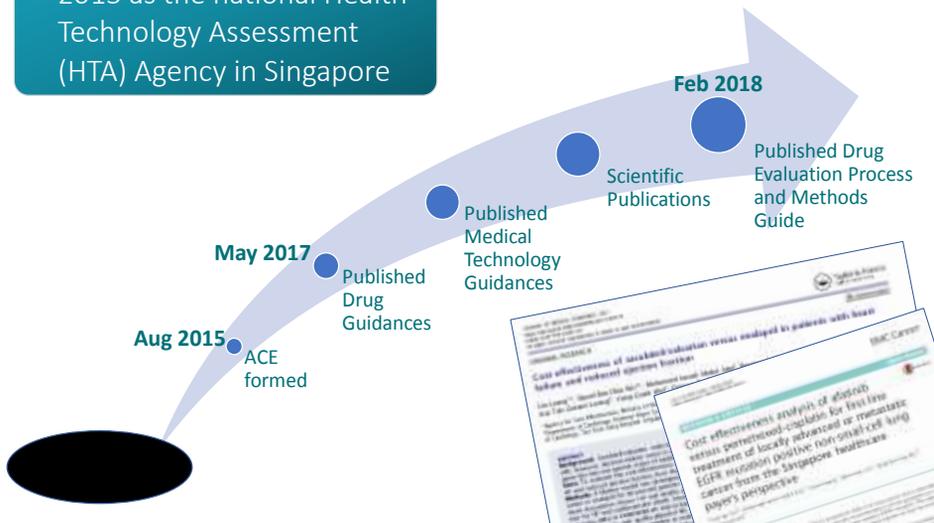
11th September 2018

Fiona Pearce

Deputy Director / Senior Lead Specialist (Drug Evaluation), ACE Singapore

Agency for Care Effectiveness (ACE)

- ACE was formed in August 2015 as the national Health Technology Assessment (HTA) Agency in Singapore



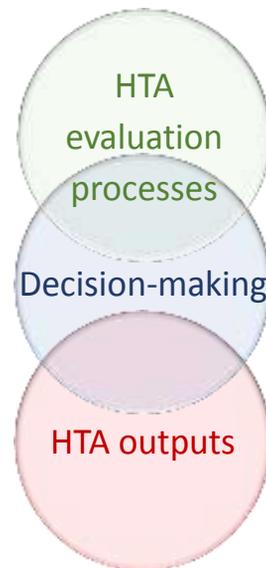
Transparency – the state of being transparent

- Openness
- Accountability
- Clear communication

Lack of transparency leads to:

- Sense of secrecy
- Lack of confidence in recommendations

- Transparency legitimises the work of the agency
- Reduces misconceptions and promotes trust
- Strengthens support from stakeholders



Transparent HTA processes



Transparent HTA processes:

- **Improve predictability** of evaluation timelines and time to decision
- Clearly **articulate evidence requirements** and HTA methodology (reference case) to **improve the quality** of submissions from stakeholders and ensure each topic is evaluated in a **consistent and robust** manner
- Provide **sufficient opportunities for stakeholders** to comment on the evaluation and decision (including feedback loops)



Increased stakeholder engagement

Patients

Clinicians

Industry

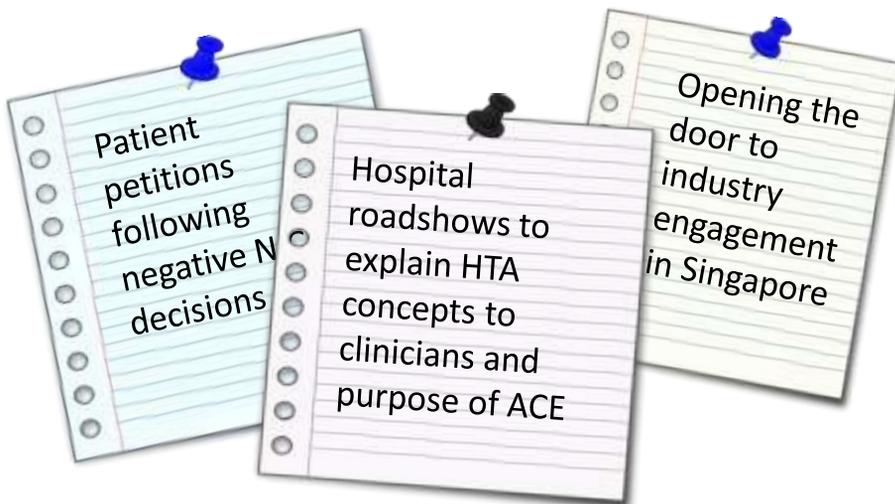
- Can enable stakeholders to shape/revise existing HTA processes
- Allows companies to provide evidence to inform assessment, including unpublished data (provides more certainty around estimates)
- Can help capture and improve the real world value and applicability of HTAs
- May help identify mistakes (if stakeholders can review or challenge assessments)
- Can enable companies to discuss innovative pricing arrangements with agency to secure market access for high cost treatments (risk-sharing/PVAs etc)
- Reimbursement decision is well informed by different viewpoints

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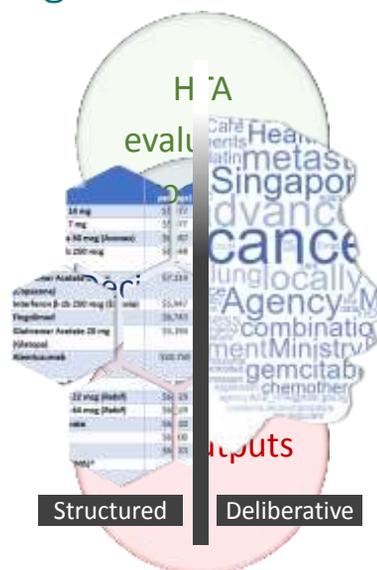
- Considerable time and resources required to facilitate meaningful stakeholder contributions
- Stakeholder involvement needs to be transparent and well managed to ensure objectivity of assessments is not influenced
- Effort needed to build up local understanding of HTA to ensure stakeholders understand methodology and processes
- Conflicting viewpoints can delay time to reach consensus/decision
- Potential lobbying/backlash if final decision differs from stakeholders' position

Considerable time and resources required to facilitate meaningful stakeholder contributions



Transparent decision-making

- The link between HTA findings and decision-making processes needs to be **transparent and clearly defined**
- Level of transparency will be influenced by:
 - ✓ **Structured vs deliberative** decision-making
 - ✓ **Implicit/explicit WTP** thresholds
 - ✓ Open vs closed door committee discussions (**cultural considerations**)



Reference: Drummond et al (2008), International Journal of Technology Assessment in Health Care 24:3; 244-258

ICER thresholds



NICE explicit threshold (£30K/QALY) vs PBAC implicit threshold (AU\$50K/QALY)

- ICERs in NICE submissions were statistically significantly higher than in matched submissions to PBAC
- Majority of submissions were equal to or lower than explicit/implicit threshold value in both countries

- ICER is not a magic solution to decision-making
- Value for money is only one element in decision-making process
- Increasing transparency of criteria and explicitness about the relative importance of each criterion should be the major goal

Decision-making factors in Singapore

Core Criteria	Factors considered
Clinical need of patients and nature of the condition	<ul style="list-style-type: none"> • Disease morbidity and patient clinical disability with current standard of care • Impact of the disease on patients' quality of life • Extent and nature of current treatment options
Impact of the new technology	<ul style="list-style-type: none"> • Comparative clinical effectiveness & safety of technology • Overall magnitude of health benefits to patients • Heterogeneity of health benefits within the population • Relevance of new technology to current clinical practice • Robustness of the current evidence and the contribution the guidance might make to strengthen it
Value for money (Cost effectiveness)	<ul style="list-style-type: none"> • The incremental benefit of the new technology compared to current treatment
Cost of the technology and the estimated number of patients likely to benefit	<ul style="list-style-type: none"> • Projected annual cost to healthcare payer – i.e. Singapore government and patients

Transparent HTA outputs

Opaque

- HTA and resulting decision should be made public (**know your audience**)
- Documents should be clearly written and understandable by all stakeholders
 - Provides proof that HTA has been conducted with rigorous well-documented methodology and all decision-making factors considered
- Recommendations more likely to be adopted and have an impact on behavioural change
- Commercially sensitive information (e.g. prices) typically not published which reduces transparency

ACE

PBAC

Summary table	- contains guidance recommendations and key considerations only
Short guidance	- contains guidance recommendations, concise summary of clinical and economic evidence base, and the Committee's key considerations that informed their subsidy deliberations
Long guidance	- contains guidance recommendations, overview of the clinical need for the treatment and current local practice, detailed overview of clinical and economic evidence base, and the Committee's key considerations that informed their subsidy deliberations.

Very transparent HTA evaluation

Decision-making processes

HTA outputs

Concluding remarks

- Transparency is important however the degree of transparency will need to differ across countries to align with cultural considerations
- Easiest approach for emerging HTA systems is to start with low level transparency while they build up capabilities and core processes and methods
 - Gradually share more information with stakeholders when resources allow
- Greater transparency will enable agencies to learn from each other and share experiences

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Pharmaceutical company perspective

Brenda Pote

Associate Director Market Access, Roche Australia

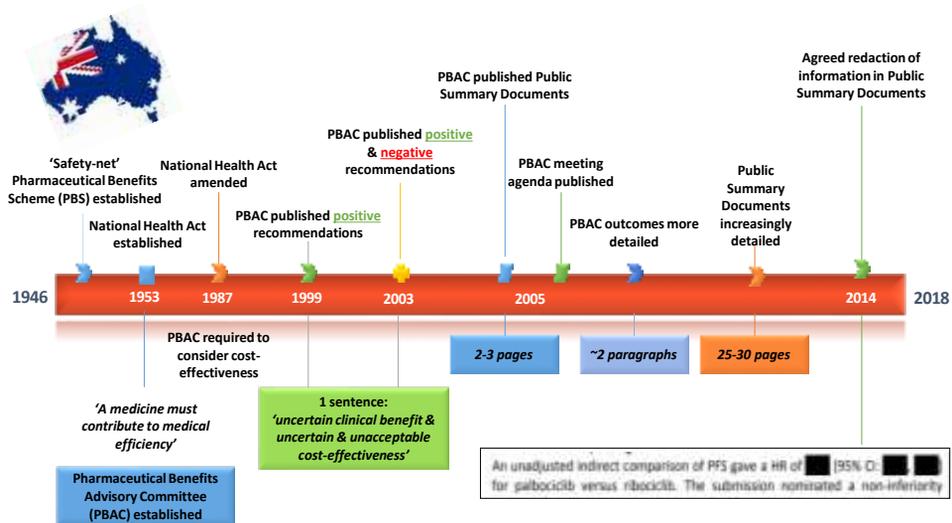
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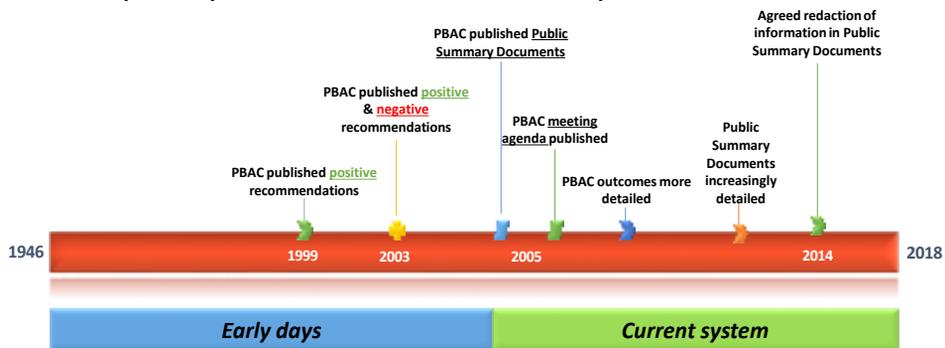
Agenda

- Evolution of transparency in Australian HTA system
- Early days versus current system
- Early days – low transparency
 - Problems
 - Benefits
- Current system – high transparency
 - Problems
 - Benefits
- Key learnings
- Conclusion

Evolution of transparency in Australian HTA system



Early days versus current system



Recommended the listing as requested.



Early days – low transparency



- Pre 1999 - ~50 years of ZERO transparency
- 1999 only positive recommendations made public – no ability to engage external stakeholder support for rejections
- 2003 negative recommendations made public – great fear of international payer referencing

Early days – low transparency

Benefits

- Very limited competitor intelligence publically available
- No risk of confidential information being released
- Possible competitive advantage if first to market

Current system – high transparency



- Risk of disclosure of commercially sensitive information
 - E.g., Unpublished data, intellectual property, innovative pricing proposals, price & volume discounts & net prices
- Resource intensive - checking & redacting information
- Stifles innovation – reluctance to (re-)present innovative proposal(s) where others have failed



Current system – high transparency



- Reduced competitive advantage
 - Insight into competition's negotiation culture & price flexibility
 - Fast follower advantage
- Complex documents - unintelligible to General Public??

 The Kaplan-Meier estimates of Time to Off-Treatment (TTOT) from the first-interim analysis (14 January 2012) were used up until the pooled median follow-up times from EMILIA (12.65 months or 54.8 weeks), after which TTOT was extrapolated using the fitted model for PFS.

Current system – high transparency



Benefits

- Revealed decision making informs:
 - Payer decision making criteria, willingness to pay, ICER thresholds, financial & economic modelling parameters, etc, etc
- Increased predictability of reimbursement timelines through review of precedents

Current system – high transparency



Benefits

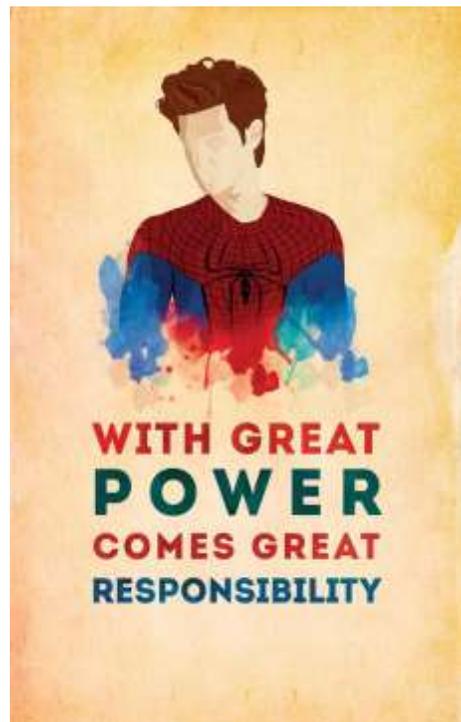
- Stakeholder engagement
 - Opportunity for stakeholders to input into payer decisions that effect their day-to-day life
 - Public Summary Documents can be useful to explain outcome to stakeholders & seek their input

Key learnings



Conclusion

- Greater transparency in HTA systems is clearly beneficial for pharma companies
- However, it comes with an increased risk of divulging commercially sensitive information
- A lower risk & less transparent approach may be preferred as emerging HTA systems develop



Discussion Session

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Acknowledgements

Thank you for your attention

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