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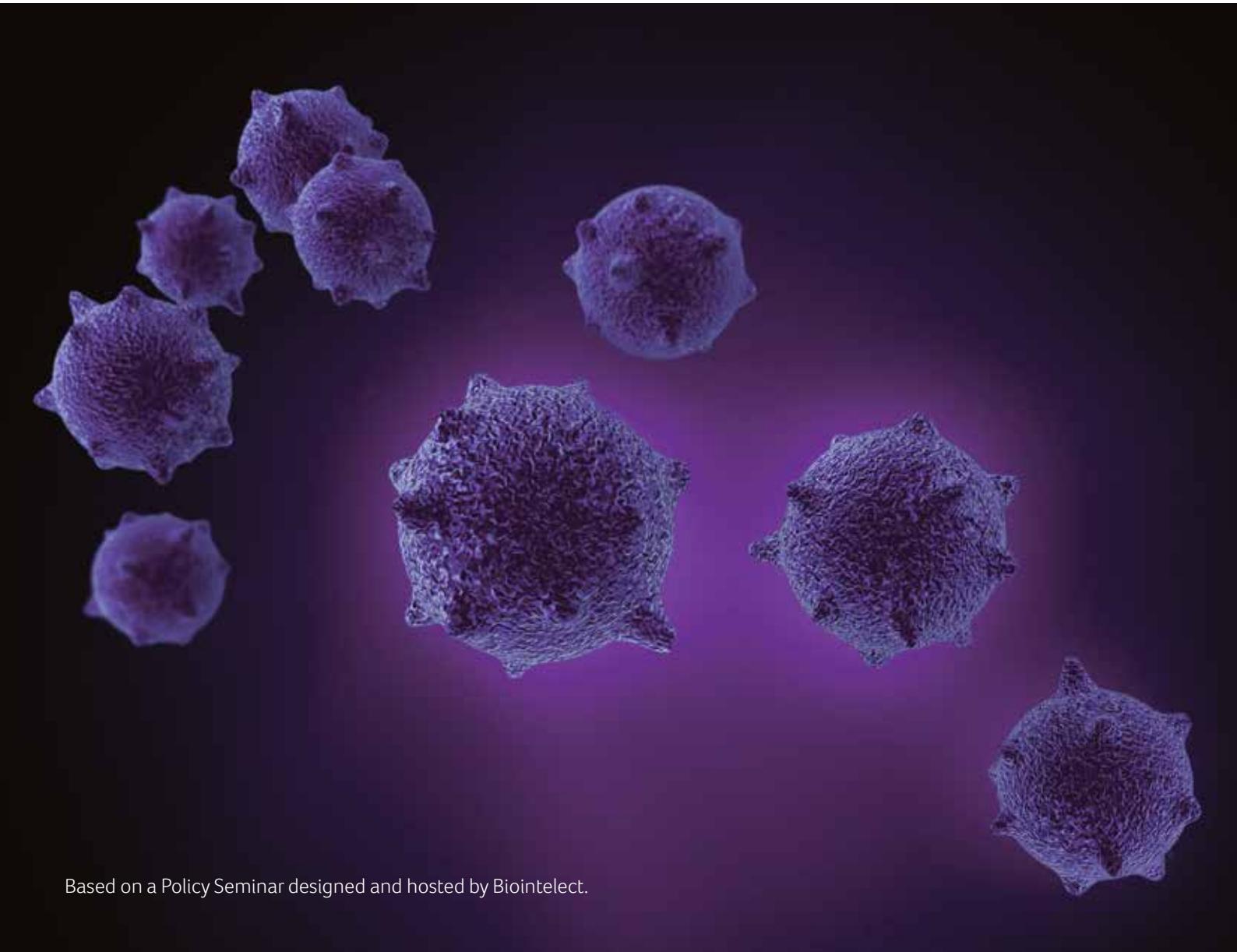
Biointelect Health Policy Symposium Report

Contemporary Issues in Valuing New Oncology Medicines

Do we need a new model?



Based on a Policy Seminar designed and hosted by Biointelect.

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On Monday May 6th 2019 Biointelect hosted its second annual medicines policy symposium. This brief report summarises the main points of the presentations and discussion. For a more in depth discussion of the topics presented and what they might mean for you, or if you would like to host a wider discussion with your internal teams, please contact Biointelect for a personal presentation.

Biointelect Health Policy Symposium Report

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BACKGROUND

In the lead up to the federal election, both major parties expressed commitments to increased access to cancer treatment. In the case of new medicines for cancer, this has been expressed as 'a commitment to fund whatever is recommended by experts', referring to the Pharmaceutical Benefits Advisory Committee. While all stakeholders welcome this commitment, the hurdle for a positive PBAC recommendation remains high. At the same time, new cancer medicines are changing the outcomes of treatment for many patients, in terms of both increased survival and quality of life/activities of daily living.

How well are the current health technology assessment processes able to evaluate these changed and evolving outcomes and experiences?

Do we need changes in approaches to better understand and value these new cancer treatments?

INTRODUCTION

David Grainger, Global Head of Health Outcomes and Policy at Biointelect, introduced the event by referring to some of the more dramatic and disruptive advances now being seen in oncology. These include the reimbursement in Australia of tisagenlecleucel (Kymriah ®) CAR-T therapy for patients with subtypes of acute lymphoblastic leukemia, advances in immunotherapy for more difficult to treat cancers, and combining cellular therapy and immunotherapy for advanced metastatic breast cancer.

These types of advances raise the question as to how the experiences of patients are being measured and considered as part of the health technology assessment process (HTA). While HTA approaches traditionally use health state utility measures (such as those derived using assessments like the EQ-5D), there is increasing concern that these measures are 'missing' aspects of value experienced by patients. Recent Public Summary Documents from the Pharmaceutical Benefits Advisory Committee indicate concern that the utility values being applied in economic models may be overestimated.

A second challenge being seen more frequently is the question of determining the local context for use of the new oncology treatment once reimbursed. This relates to the complex question of translation of evidence from clinical trials (often internationally conducted) to the local context of current standard of care and likely use in Australia.

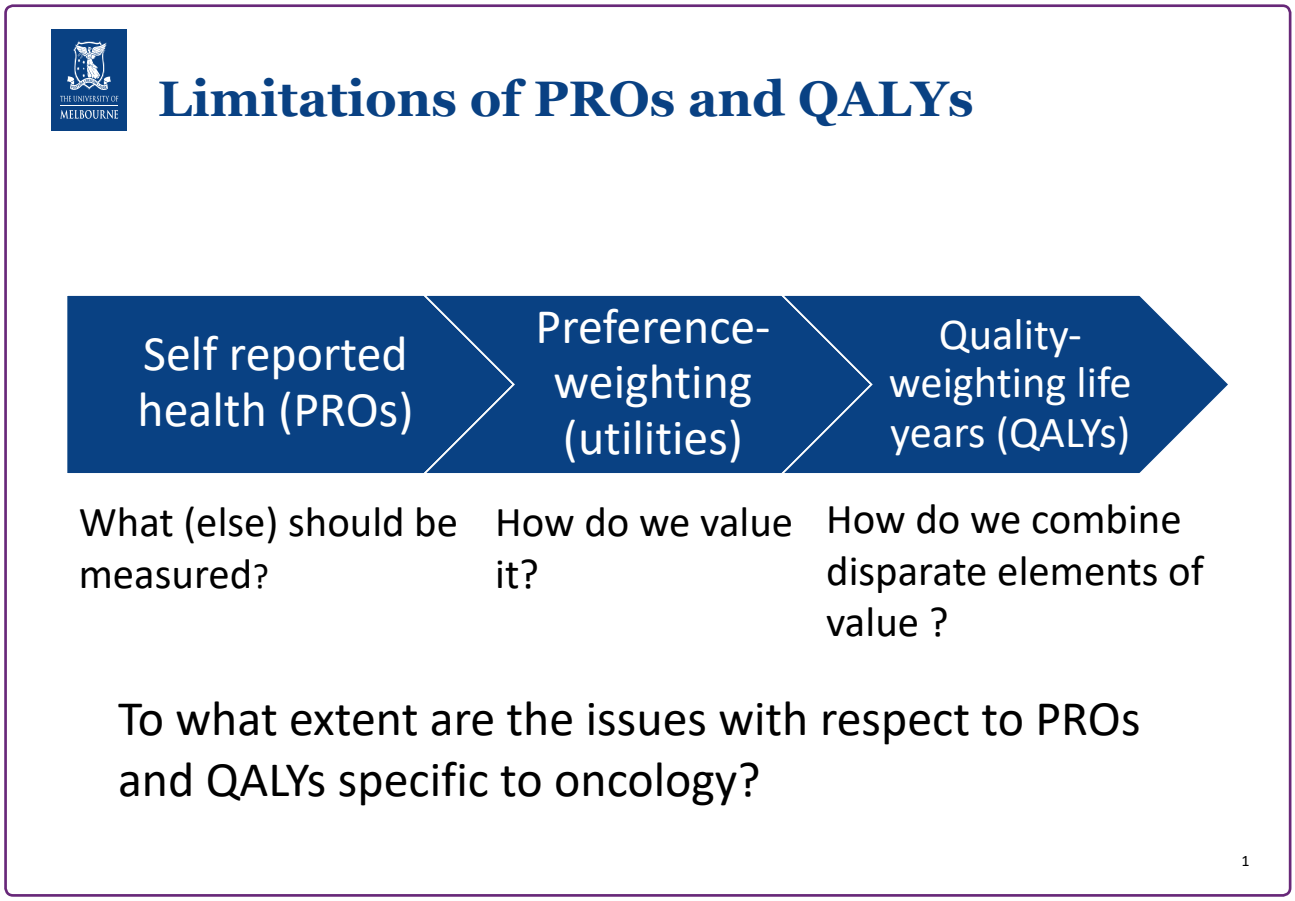
All of this raises the question: Do we need a new model? A recent article in the Australian Financial Review challenged economists to think more broadly, expand the scope of their analysis and to consider human interactions as well as insights from other disciplines. While not focused on health economics or medicines reimbursement, there may be aspects of this call for a new approach that are highly relevant to decisions on medicines access in Australia. Based on this context, Biointelect brought together four highly experienced experts from diverse backgrounds to discuss these issues. See the back of this report for their brief bios.

CHALLENGES IN VALUATION OF NEW ONCOLOGY MEDICINES

Professor Nancy Devlin

Director of the Centre for Health Policy, University of Melbourne

Professor Devlin began by discussing the limitations of Patient Reported Outcomes (PROs). While generic, preference-based PROs such as the EQ-5D are widely used and accepted, they do have limitations, with elements of value important to patients not always being adequately reflected in the dimensions and scoring. A wide range of cultural and other factors may limit comparability of PRO data collected across different countries and regions (Devlin, Lorgelly, Herdman 2019). There are a wide range of cultural or linguistic factors that that influence how a patient perceives their own health and how they complete the PRO instrument. This is an under-researched area, yet could limit the relevance of PRO data collected from multi-country studies to local decision making contexts.



Another PRO issue which has arisen in oncology (but may not be specific to oncology) is the existence of apparently healthy patients in clinical trials – that is, patients whose self-reported health on PROs indicates few or no problems, and where the average utility scores for patients is higher than that of the age/sex matched 'well' general public. Possible explanations include that patients meeting inclusion criteria for clinical trials may be relatively healthy (e.g. few co-morbidities) and well managed. But this issue does raise a challenge if a goal of treatment is to improve quality of life.

There are other limitations to utility analysis, becoming especially apparent in oncology HTA:

- If we take want to take patient preferences or other factors into account, the Quality Adjusted Life Year is not an optimal way to express value

- Including other elements of benefit to patients and society is possible via the methods of multiple criteria decision analysis – and cost per benefit score may be a better representation than cost per QALY
- Measurement of patients' subjective wellbeing provides yet another perspective and measurement approach.

2. Limitations of utility

- By convention, stated preferences of the general public
- Systematic differences between patients' and public's values
- Growing interest in the relevance of patients' preferences and 'experienced utility' eg 2nd Washington Panel; Veersteegh and Brouwer (Soc Sci Med 2016); TLV
  - Individualised patient 'value sets' possible eg. 1000Minds (Sullivan et al 2019)
- Ongoing challenge in PRO utilities: different methods & competing theories; yielding dissimilar results. Lack of consensus. Inability to validate values against revealed preferences (as in other fields, where preferences can be inferred from 'real' choices)
- The focus is still restricted to utilities for health/quality of life as defined by the PRO – not wider sources of utility (eg relating to process of care)

T Sullivan, P Hansen, F Ombler, S Derrett & N Devlin (2019) "A new tool for creating personal and social EQ-5D-5L value sets, including valuing 'dead'", *Economics Discussion Paper* No 1903, University of Otago

[2]

Some of these limitations are being examined in an important project currently underway, termed the Expanded QALY ('E-QALY'). This project is aiming to address these issues and develop a broader measure of QoL, moving beyond narrowly defined health related quality of life, that can be used to measure outcomes in both health and social care, and in both patients and caregivers. Staff from the England HTA agency NICE are directly involved in this project, and it is regarded as an important research area.

3. Extending what is captured in the QALY: the e-QALY project

- A collaboration between the University of Sheffield, NICE, and others
- Including international validity testing across multiple countries
- **The aim is to develop a new, broad measure of QoL for use in economic evaluation across health and social care**
- Based on aspects of life that patients, social care users and carers think are important to them and are impacted by their health or caring role and the care or treatment they receive
  - Reflects the extended remit of NICE and the English DH to health *and* social care
  - Creates a need for an outcome measure that can provide a commensurate measure of outcomes (and handle trade-offs between dimensions of outcomes) across both.
- Project website: https://scharr.dept.shef.ac.uk/e-qaly/about-the-project/

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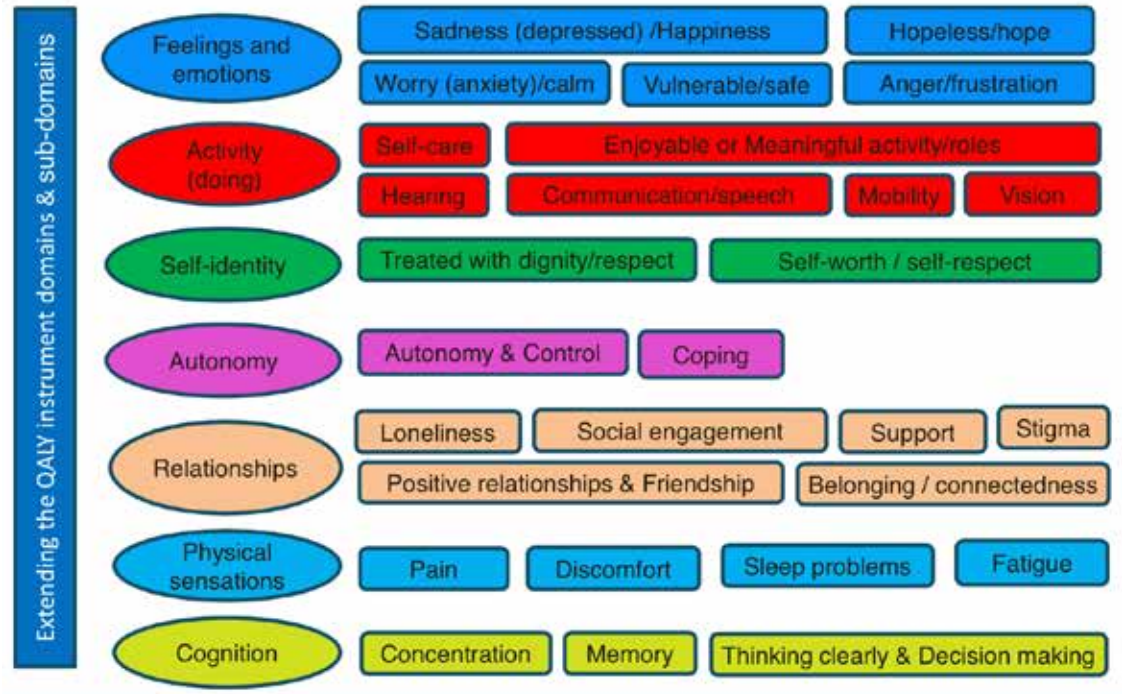
EQ-5D



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Source: Reproduced courtesy of the e-QALY project team. Note these are preliminary findings only

In addition, interesting work is ongoing to look at a broader description of 'health outcomes', where subjective wellbeing is considered to be the overarching concept, with health status being important but not all that matters in determining overall happiness.

Global Happiness and Wellbeing Policy Report 2019

Recommendations:

Health care appraisal (HCA) should

1. Guide decision-making in all countries.
2. Explicitly consider alternative uses of resources (opportunity costs).
3. Benefits should be measured in terms of happiness, broadly defined (health is an important part of people's lives but not all that matters).
4. The benefits of all those affected by the decision should be accounted for (patients matter, of course, but so do the carers and families of those affected by a condition).

Looking at HCA through the lens of happiness would lead to at least two major shifts in focus:

1. Greater priority to mental health.
2. Improved end-of-life care, with more emphasis on palliative care and pain relief.

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There are also oncology-specific instruments available for use in clinical trials, including the EORTC QLQ-30, FACT-8D (utilities for Australia only) and others.

More recently, we have seen the development in the US of a range of 'value frameworks' in part because stakeholders other than formal HTA agencies desire a means to gauge the relative value of new treatments and to take a wider (beyond QALYs) approach to assessing benefit to aid decision making. However, these value frameworks, while providing a useful way of thinking about different aspects of value, are still quite rudimentary when it comes to how the different aspects of value are to be aggregated.

Finally, the definition, measurement and valuation of some of these wider aspects of value present some challenges. For example, there has been discussion about the special value of a cure - but this depends on how one defines 'cure', and whether it confers extra value over and above health improvement as currently measured via QALYs. Similar measurement and valuation challenges arise with other extended aspects of value such as the value of hope, changes in productivity, scientific spillovers and so on.

In conclusion, a radical change to the overall HTA process is unlikely; however, it is apparent that wider aspects of treatment benefit and patient experience need to be valued. A change from the current cost per QALY gained method is inevitable. Exactly what shape that takes and how any change would be incorporated into decision-making is yet unclear and getting to that new place in HTA is likely to be slow.

ARE ONCOLOGY SUBMISSIONS OPTIMAL FOR ASSESSMENT OF VALUE? OBSERVATIONS FROM THE DECISION-MAKER PERSPECTIVE.

Michelle Burke

Member of the Pharmaceutical Benefits Advisory Committee

Michelle began with addressing the question of 'Are Oncology submissions optimal for assessment of value?' In order to address this we need to dig deeper into the context and consider some additional questions.

- Is this about oncology?
- Is this about "optimal"?
- Is this about the assessment?
- Is this about defining value?

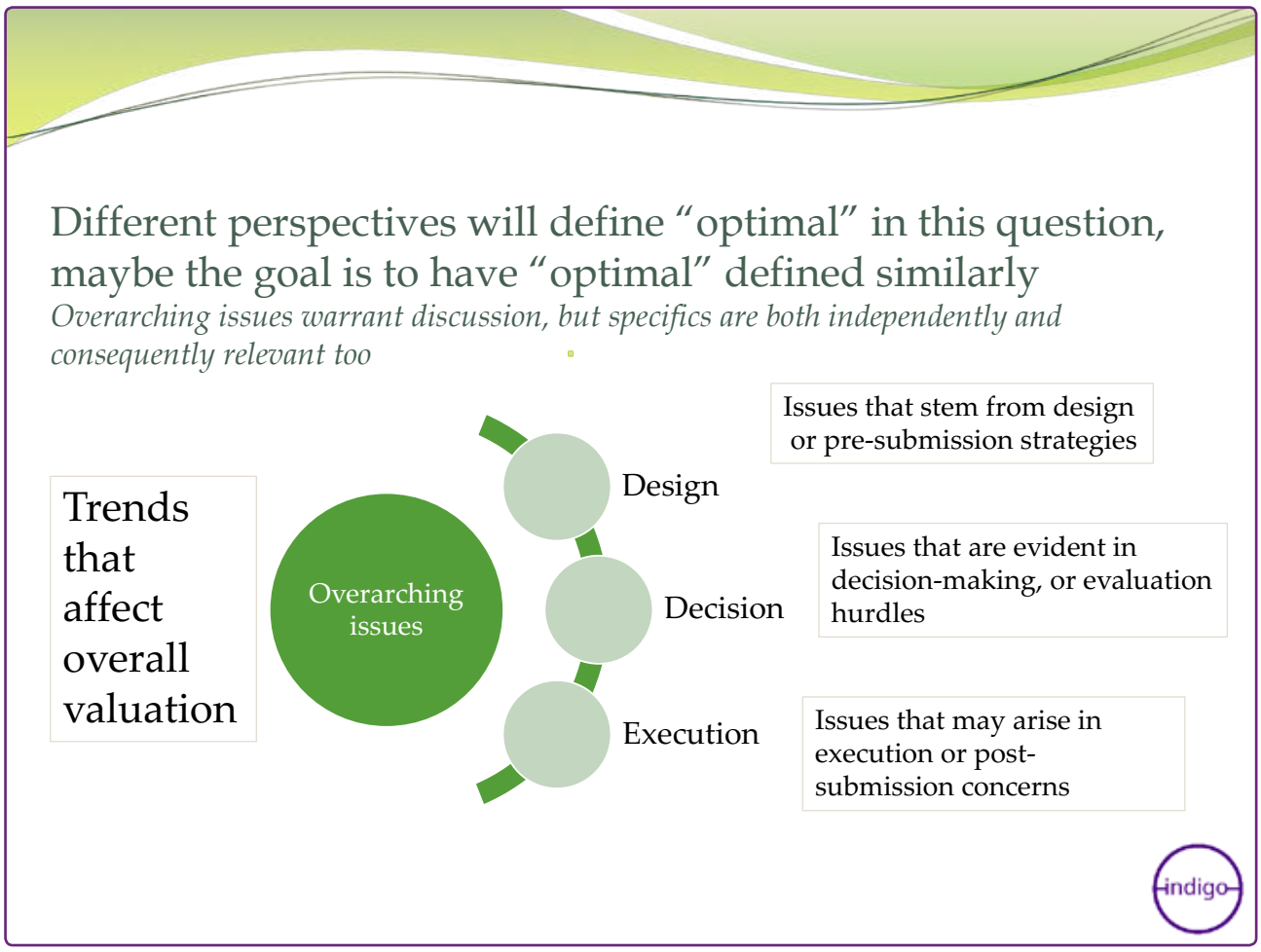
There is high motivation in the system for complexity, because these allow for the adjacent need to apply flexibility. Sponsor companies need to be clear about the flexibility in assessment that they consider relevant to their submission and support why it is justified.

There is also a strong need to overcome uncertainty. Sometime this is a 'best possible guess' in which predictions are made 'up front' and sometimes uncertainty needs to be embraced – if benefits outweigh risks. PBAC has multiple perspectives within the committee, but the job is the same. There are differing perspectives on the definition of 'optimal'. Will defining these in the same way solve the issue?

There are also many important decisions made by sponsors before lodging a PBAC submission.

Major trends that affect overall valuation:

- Design – issues from design or pre-submission strategies
- Decision – issues in decision-making, or evaluation hurdles
- Execution – issues in execution or post-submission concerns

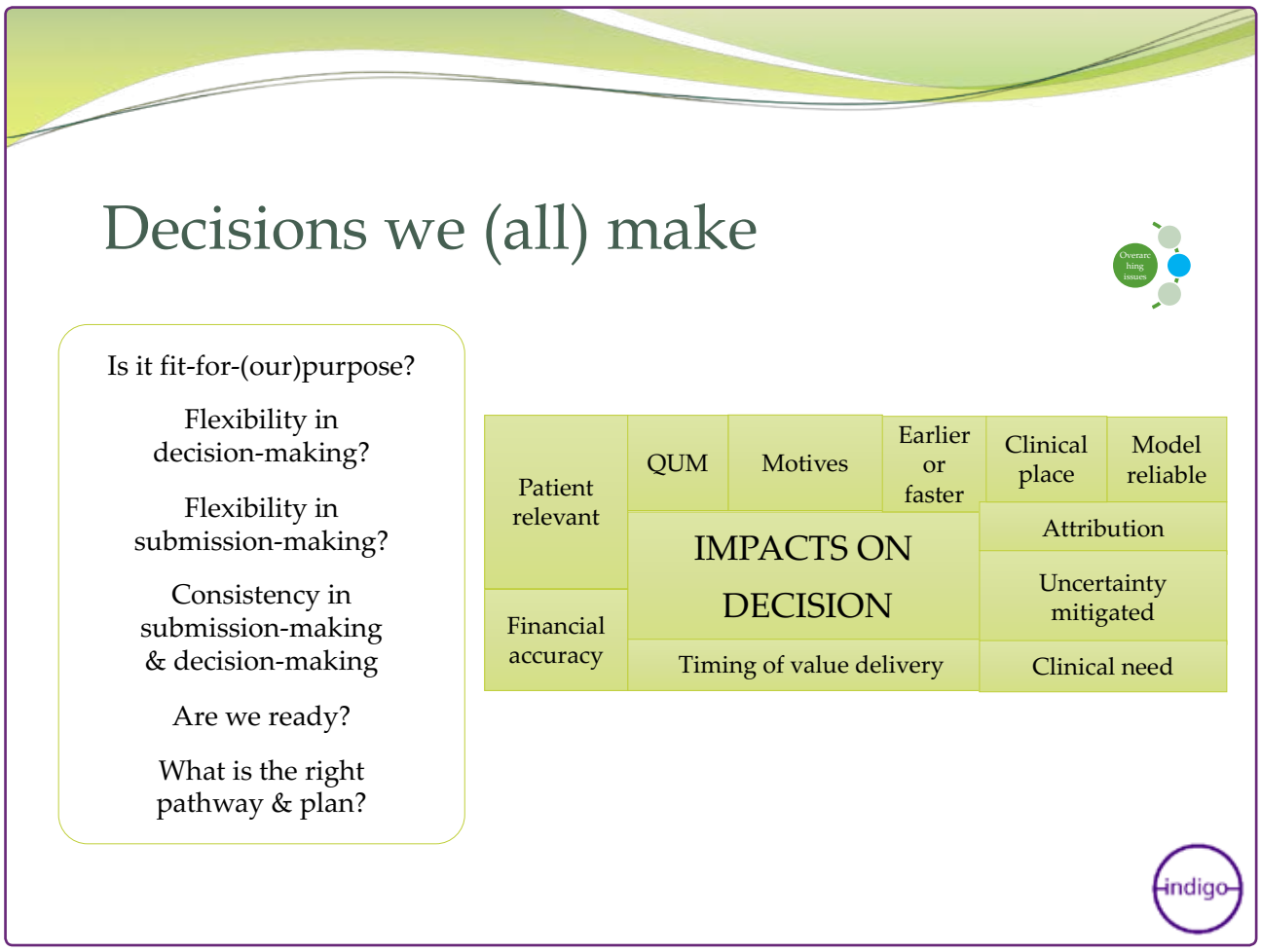


Key drivers of a case for change:

Michelle noted that if advocating for change, it is important to be clear about what change is being sought.

- HTA: Health *Technology* Assessment – definition problem for 'technology'. It is a complicated field which is moving extremely quickly (apps, digital health, gene Tx, mutation-based indications, cell Tx etc…)
- Attribution, valuation, contribution: In the face of this increasing complexity it is critical to be clear about evidence that the technology results in the claimed health outcome (attribution) and the extent to which the outcome is due to the technology or to other extraneous factors (especially important with devices).
- Pace of change

Michelle noted that given the rapidity of technological development, it is unlikely that value of a specific technology will ever be properly realised in the way originally envisaged. This articulates the challenging nature of implementing optimal value assessments.



Michelle identified four factors that impact on designing for 'optimal' value assessment:

1. complicated clinical place
2. feasibility of data collection
3. trial design not fit-for-purpose
4. disease management

Focusing in on oncology assessments, Michelle raised a series of questions for consideration:

- Is this difference relevant to patients, even if no Overall Survival benefit?
- Claims for improved quality of life questions are often not well supported. Is the evidence robust?
- While there is always a desire to submit earlier and achieve reimbursement faster, sponsor companies need to consider if the data is ready. PBAC might question how data is going to change further along the curve.

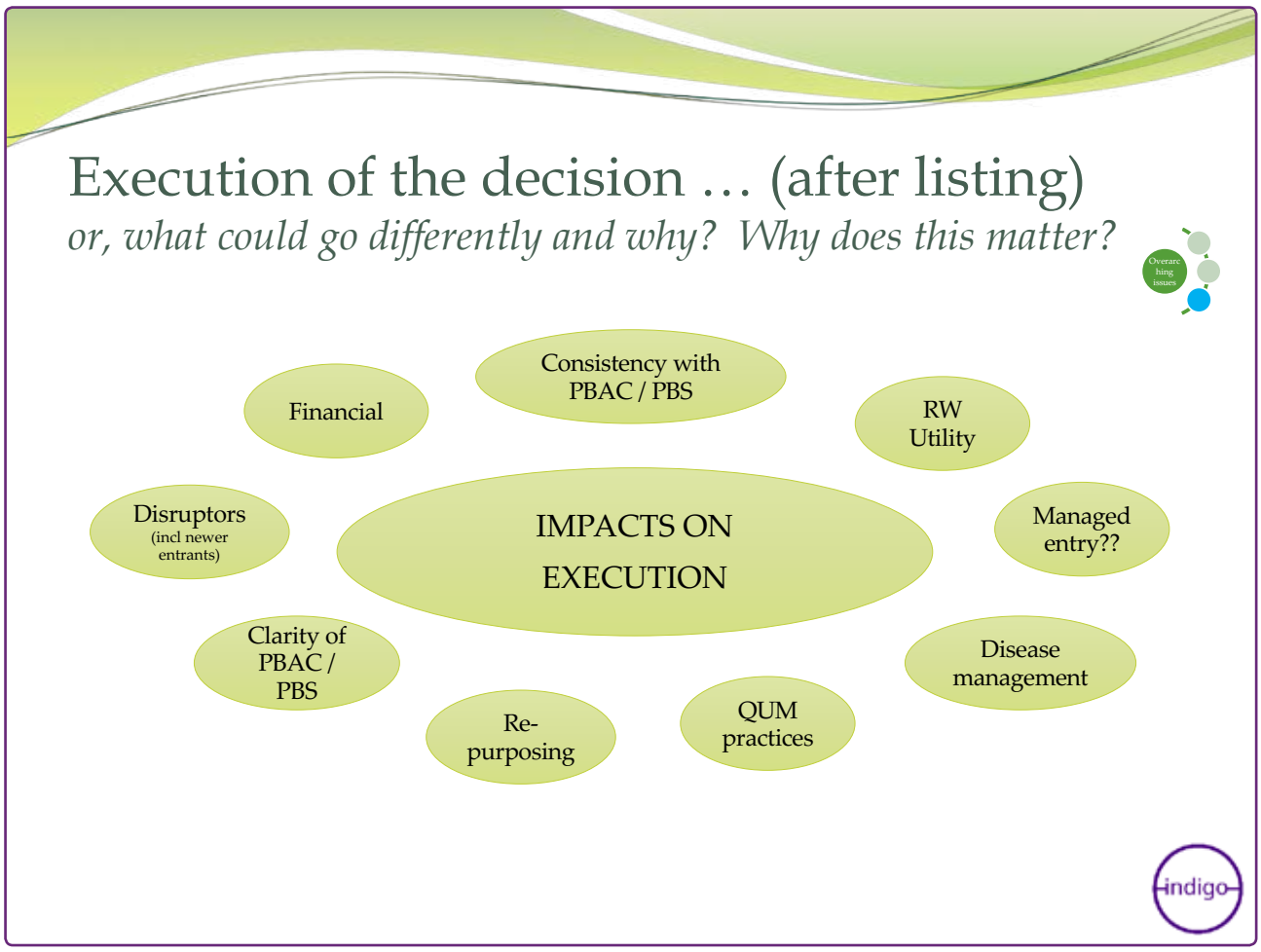
Importantly, all the above factors need to line up and tell a cohesive story. Michelle acknowledged this is a difficult undertaking and leads to the need for flexibility in some circumstances. It was suggested that sponsors need to be clear about what gaps in the data exist, where they are seeking flexibility in the evaluation and why.

Regarding **economic models**, Michelle emphasised that any extrapolation needs to be realistic. Do the curves eventually converge, or is it 'forced convergence'? Is the majority of benefit 'well beyond' the presented data? The time horizon needs to be relevant to expected nature of the overall survival.

Regarding input from consumers, physicians or others, Michelle noted the importance of these inputs while acknowledging that the sponsors have the most opportunities to comment, as well as best 'access' to the data and issues to be considered. There is a trend towards greater interaction, even at the expense of time invested. Michelle acknowledged that the system could do better at receiving consumer feedback and in understanding what is 'useful information'.

Michelle posed some questions for the panel and audience to consider:

- *How can we truly assess adaptive trials & model correctly?*
- *What is industry role in medicine supply / compassionate access when used in a trial (or as single use) for which drug efficacy and safety assessment is NOT primary purpose – can we collect that data in HTA and how to use it?*
- *How can we realistically measure the effect of a single intervention at a time? How do we assess a drug/device, drug/app, drug/service*
- *How do we realistically get OS when the PFS is already high, or when there is good sequencing potential?*
- *Can process improvements help or are they a distraction?*



In conclusion, Michelle encouraged the audience to think outside the box and in her view:

- Focus on the decision that is required, articulate the flexibility that is appropriate while making every attempt to be consistent.
- Collectively, recognise when fundamentals require change
  - Dissatisfaction with the outcome does not equal "not fit-for-purpose"
  - There are some interventions that will challenge the system, but they are still a minority
  - We have an opportunity to ask some questions about what needs fundamental change
- There is a need for this style of open conversation to continue

WHAT CAN WE LEARN FROM THE INTERNATIONAL DISCUSSION ON VALUATION: ISPOR TASK FORCES AND THE SECOND PANEL ON COST-EFFECTIVENESS

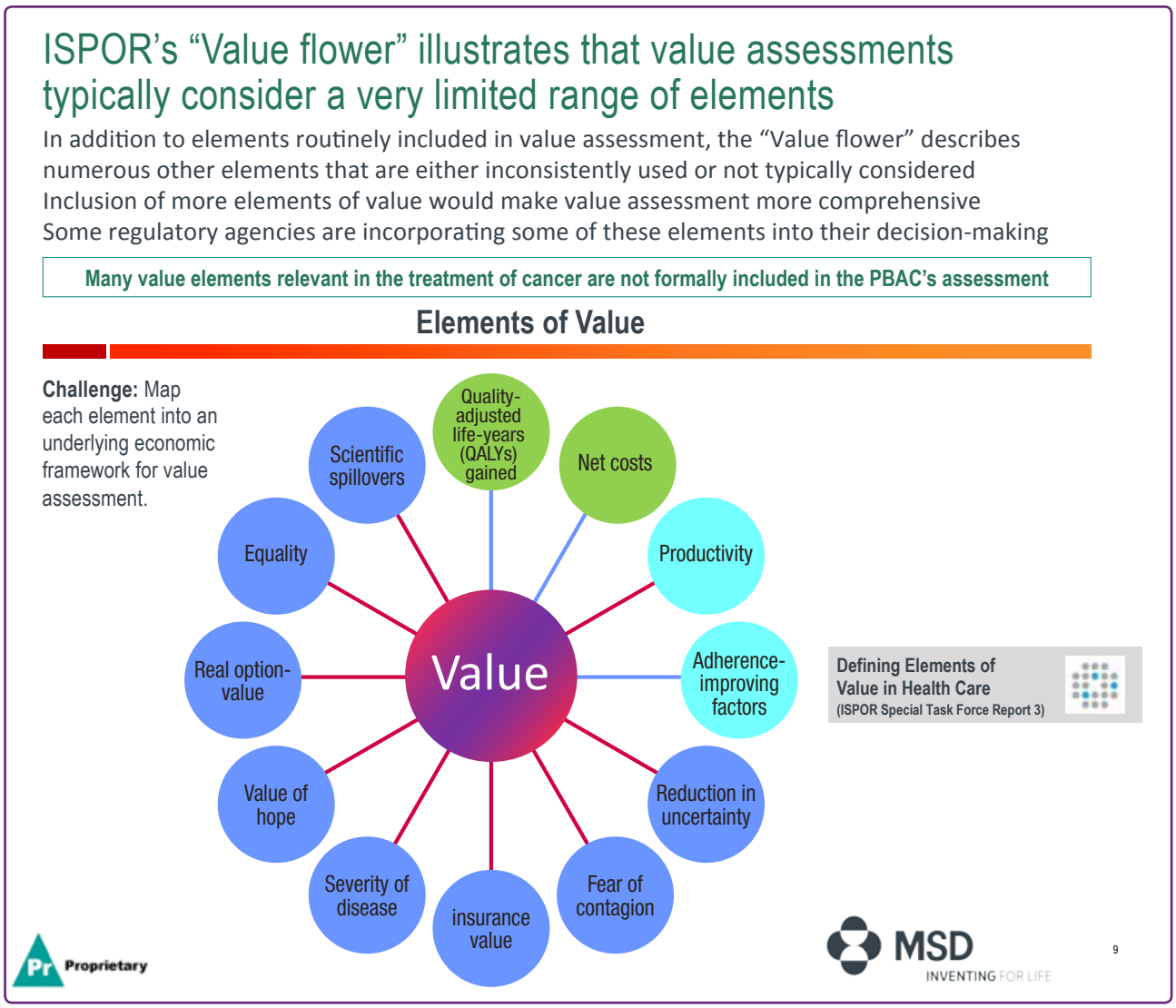
Julie Van Bavel

Centre for Observational and Real World Evidence (CORE)
Regional Team, Asia Pacific, MSD

Julie discussed what we can we learn from the international discussion on valuation, beginning with the observation that perspective matters when assessing value as one size does not fit all. Different jurisdictions have different perspectives even though they have similar approaches. As a result, decisions yield different outcomes in different jurisdictions.

Much international discussion is occurring around the concept of the Quality Adjusted Life Year (QALY). Although widely used because it consolidates health outcomes and can be used to compare across therapeutic areas, it is increasingly recognised it does not capture everything that matters.

Recent work by ISPOR and others has articulated a broader view of value:



For example, the value of hope in oncology is becoming recognised as important to patients and care givers. Other challenges in assessing value in oncology include:

- Mean survival is not a good basis for assessing value - Most patients value a “hopeful gamble” rather than a “safer” option which may be well documented but associated with a shorter life
- The incremental change may be the same magnitude in different settings but value is increased when the health condition changes from poor health to good health vs. from good health to better health
- Only some jurisdictions are incorporating these different value elements into their decision-making and some value elements relevant in the treatment of cancer are not routinely included in the assessment of PBAC

Individuals tend to prefer equal utility increments from initially more severe health states compared to a better baseline health state

QALY approach is indirect- it values health states rather than changes in health states which is what patients actually experience

Table 2 – Comparisons used in the VAS_{P+S},

	VAS			
	Gain X		Gain Y	
States	A	B	C	D
$Q1_{0.25}$	0.75	1.0	0.5	0.75
$Q2_{0.25}$	0.75	1.0	0.25	0.50
$Q3_{0.25}$	0.75	1.0	0	0.25
$Q4_{0.50}$	0.5	1.0	0.25	0.75
$Q5_{0.50}$	0.5	1.0	0	0.5
$Q6_{0.75}$	0.25	1.0	0	0.75

Table 3 – VAS_{S+P}; Stage 1 data and test results.

	Prefer Gain Y	Prefer Gain X	Indifferent
VAS_S Sample I, n = 35			
$Q1_{0.25}$	30 (86 %)	1 (3 %)	4 (1%)
$Q2_{0.25}$	34 (97 %)	0 (0 %)	1 (0.3%)
$Q3_{0.25}$	34 (97 %)	1 (3 %)	0 (0%)
$Q4_{0.50}$	34 (97 %)	0 (0 %)	1 (0.3%)
$Q5_{0.50}$	35 (100%)	0 (0 %)	0 (0%)
$Q6_{0.75}$	35 (100%)	0 (0%)	0 (0%)

Oncology value assessments could measure individual preferences for utility changes directly or set a higher threshold for an acceptable ICER in severe health states

[1] Taylor et al. Comparing Increments in Utility of Health: An Individual-based Approach. Value in Health (20) 2017 224-229

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Another problem raised by Julie is that budget impact can influence value assessments

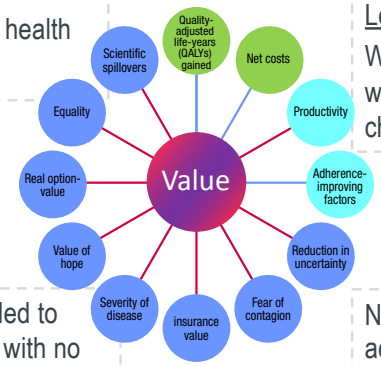
- High value treatments tend to be more likely to be restricted or delayed
- Budget focused assessments may not capture all elements of value
- Opportunity cost should be taken into account, and should include consideration of the impact of displacing less effective therapies
- Variation in individual’s Willingness to Pay should also be considered

In theory, the Healthcare budget, Individuals Willingness To Pay and services reimbursed are simultaneously determined and adjusted over time

Efficient healthcare system
Firm budget constraint fixed in the short term

Threshold = the opportunity cost of displacing existing covered technologies
So that the total health deliver in the budget period remains constant

Threshold, budget and measure of health gain cannot be set independently



Longer term

Willingness to pay is relevant to inform whether budgets and thresholds should be changed over time

If novel elements of value are added to the QALY measure of health gain with no change in the budget then the threshold would need to be reduced

New value-creating technologies can be accommodated by displacement of older, inferior technologies OR growth of health budget

Assessing budget impact should not be an integral part of value assessment. Rather it should be used to estimate and plan for future costs

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Julie also referenced the Second Panel on Cost-Effectiveness. This recommended a reference case based on a health system perspective accompanied by a true societal perspective. For assessments to truly incorporate a societal perspective, the Panel also recommended an impact inventory. This template approach would ensure a wider range of societal impacts were routinely included in decision-making.

The Panel Recommends reporting multiple reference cases, using QALY's and valuing a wide range of effects

KEY RECOMMENDATIONS

Report a reference case based on a healthcare perspective and another based on a societal perspective to evaluate the broader effects of interventions

Measure health effects in terms of QALYs and summarize the results of the healthcare sector reference as in incremental cost-effectiveness ration (ICER)

For the societal reference an Impact inventory listing, quantifying and valuing the health and non-health effects of an intervention should be included. This ensures consideration of all consequences is conducted in a transparent and explicit manner .

Figure 1. Impact Inventory Template

Sector	Type of Impact (list category within each sector with unit of measure if relevant)[a]	Included in This Reference Case Analysis From...Perspective?		Notes on Sources of Evidence
		Health Care Sector	Societal	
Formal Health Care Sector				
Health	Health outcomes (effects)			
	Longevity effects	☐	☐	
	Health-related quality-of-life effects	☐	☐	
	Other health effects (eg, adverse events and secondary transmissions of infections)	☐	☐	
	Medical costs			
	Paid for by third-party payers	☐	☐	
	Paid for by patients out-of-pocket	☐	☐	
	Future related medical costs (payers and patients)	☐	☐	
	Future unrelated medical costs (payers and patients)	☐	☐	
Informal Health Care Sector				
Health	Patient time costs	NA	☐	
	Unpaid caregiver time costs	NA	☐	
	Transportation costs	NA	☐	
Non-Health Care Sectors (with examples of possible items)				
Productivity	Labor market earnings lost	NA	☐	
	Cost of unpaid lost productivity due to illness	NA	☐	
	Cost of uncompensated household production[b]	NA	☐	
Consumption	Future consumption unrelated to health	NA	☐	
Social Services	Cost of social services as part of intervention	NA	☐	
Legal or Criminal Justice	Number of crimes related to intervention	NA	☐	
	Cost of crimes related to intervention	NA	☐	
Education	Impact of intervention on educational achievement of population	NA	☐	
Housing	Cost of intervention on home improvements (eg, removing lead paint)	NA	☐	
Environment	Production of toxic waste pollution by intervention	NA	☐	
Other (specify)	Other impacts	NA	☐	

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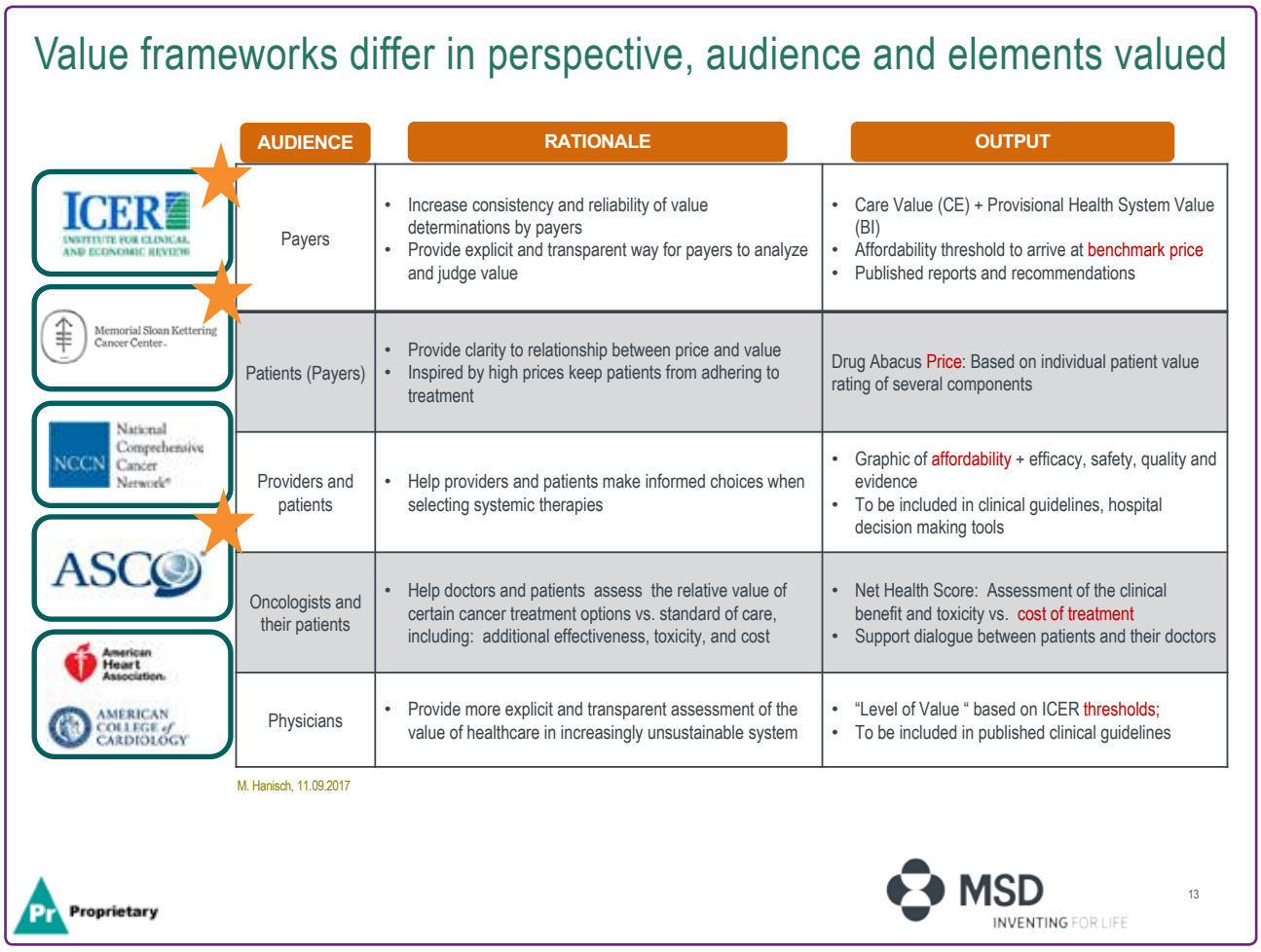
Julie suggested that in an ideal world, these wider elements of value would be combined with consideration of societal Willingness to Pay, in a dynamic fashion that allowed for adjustment over time (for example, adjustment in the Incremental Cost-Effectiveness Ratio threshold (or range), especially in regard to areas of high unmet need.

Finally, Julie described some of the novel 'value frameworks' that have emerged in recent years. These reflect the efforts of multiple stakeholders to better understand value, especially (but not only) in the oncology area. These include frameworks developed by the American Society for Clinical Oncology, the Institute for Clinical and Economic Research and the Memorial Sloan Kettering Cancer Centre.



ASCO's framework provides two perspectives, one for advanced disease and one for curative interventions. It includes a relatively narrow range of value elements.

ASCO has two different frameworks, one for advanced disease and one for curative disease

ASCO	Oncologists and their patients	Help doctors and patients assess the relative value of certain cancer treatment options vs. standard of care, including: additional effectiveness, toxicity, and cost

Frameworks:	1. Advanced disease	2. Curative disease
Maximum points	130	100
Clinical benefit	/80	/80
Toxicity	-20 to +20	-20 to +20
Palliation bonus points	+10	⊗
Treatment-free interval	/20	⊗

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ICER's framework uses a range of cost-effectiveness thresholds and considers societal perspective (family, school, work, etc) as well as clinical outcomes. It has been characterised by a continuous improvement approach with constructive engagement with all stakeholders, acknowledging this is an evolving field.

ICER Uses clinical And Cost Effectiveness Assessments to Evaluate Long-Term Value and considers some additional value elements

Physicians	• Provide more explicit and transparent assessment of the value of healthcare in increasingly unsustainable system

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Julie concluded that there is much to learn from these evolving initiatives and perspectives.

- Not all diseases/interventions should be held to the same decision-making rules
- Inclusion of additional elements of value is informative for decision-making
- Value assessment can and should include patient input
- Willingness to pay is important to consider and can impact conclusions
- Transparency is necessary
- Ethical challenges of value assessment should not be forgotten
- Methods and processes should be updated over time

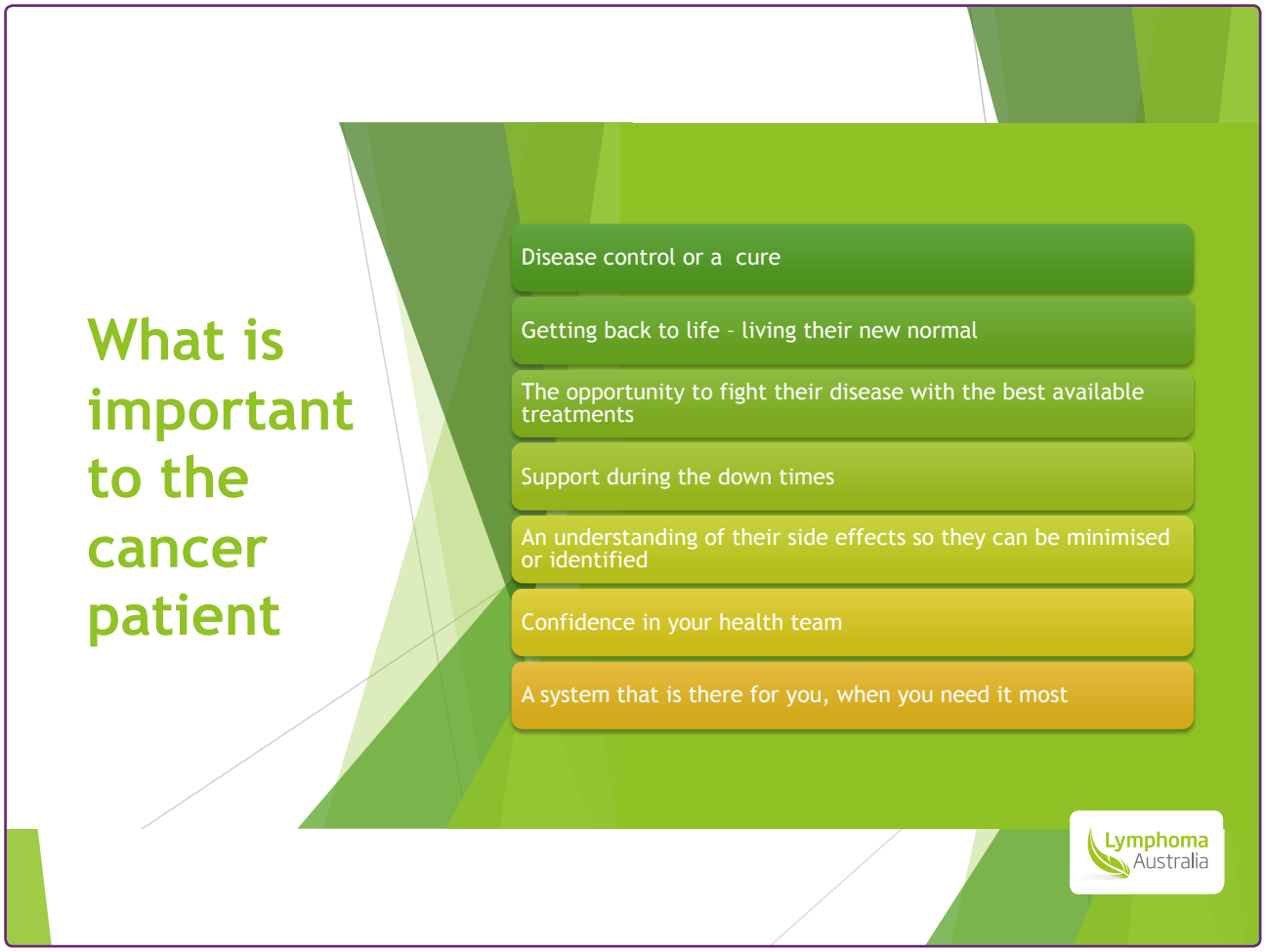
There is much that can be done and all stakeholders should engage in constructive dialogue to advocate for sound principles in health technology assessment, expand the elements of value being considered, separation of value and budget impact considerations, increased patient voice and reflect on how evolving societal willingness to pay can be incorporated.

PERSPECTIVES FROM THE ULTIMATE STAKEHOLDER – THE PATIENT.

Sharon Winton

CEO, Lymphoma Australia

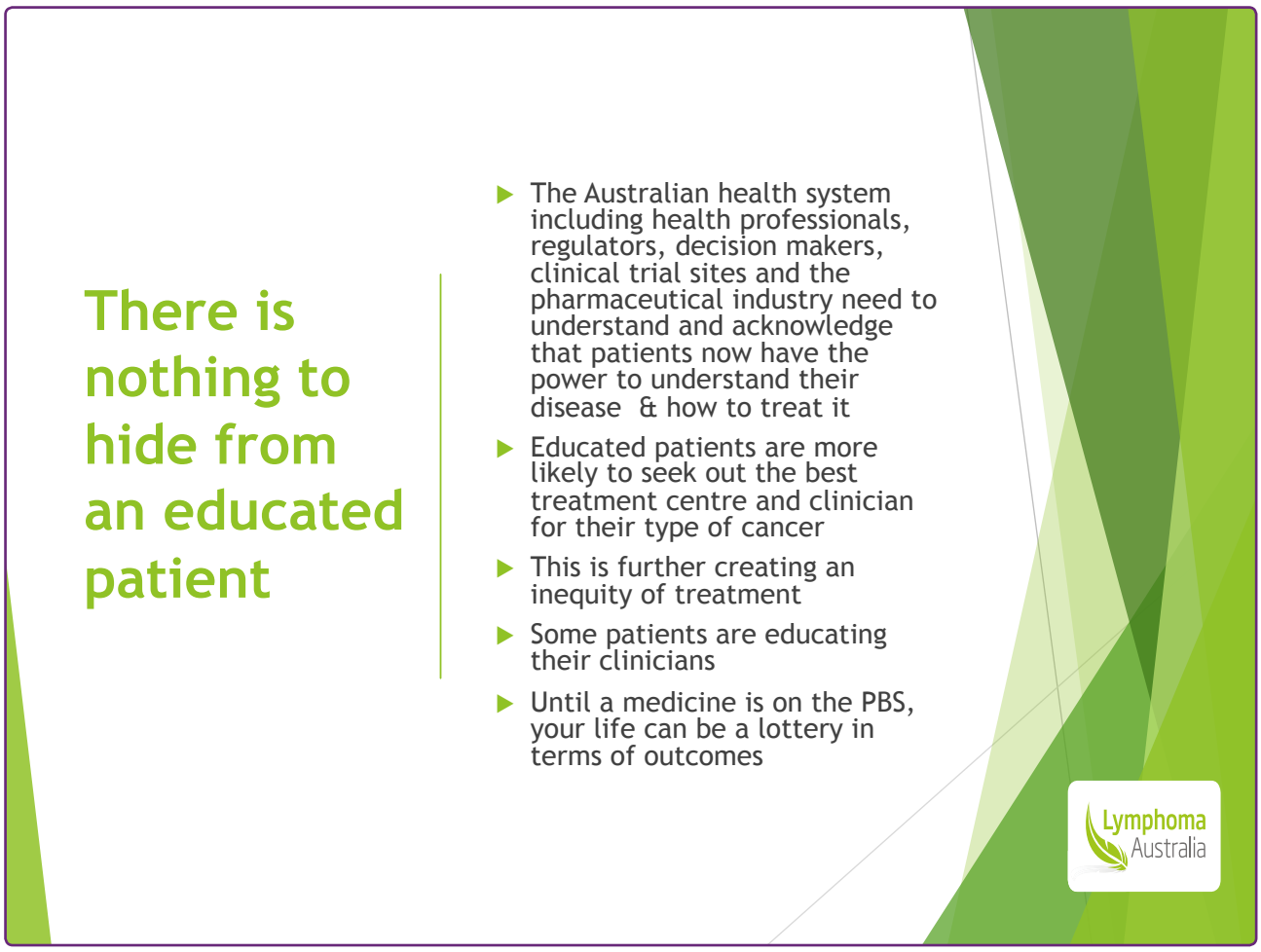
As the concluding speaker, Sharon remined the audience of what really matters to patients. Using some very moving and impactful patient stories, Sharon pointed out that while there is much to discuss about valuation and methodology, what matters to patients is being able to access (in any way, from compassionate use or clinical trials through to reimbursement on the Pharmaceutical Benefits Scheme) the right product for them at the right time. She also made the point that for oncology patients, there is usually little time to waste.



Sharon described how, once a diagnosis of cancer is received, the inequity begins:

- as disease progression or relapse occur, the geographical location can be a major barrier to getting onto clinical trials
- some patients will access new therapies in their hospitals, others are offered nothing
- community fundraising will work for well-connected people, for others it won't make any difference
- treatment experiences and outcomes can vary from public to private settings

Sharon also pointed out that with the advances in communication and access to information, patients are likely to be well informed regarding their condition and their treatment options. There is nothing to hide from an educated patient.



Using a real patient story, Sharon recounted how she had met the patient via a global Facebook page. Via connections with other patients, this young woman was able to identify a trial suitable for her condition. However, once a site was identified in her city, the trial had closed recruitment. This is a common occurrence and highlights the time it can take for patients to become aware of trial options, only to find they are unable to participate, either due to being too late for recruitment or in the wrong city (or rural) location.

'Patients teaching patients' is a common situation. However, the time spent educating themselves on treatment options (and how to access them), is time lost with loved ones. While options exist like Clinicaltrial.gov, the site is confusing to patients. Even if they can identify trials, it's often hard for patients to physically reach them. There are many different Tx pathways for patients; inevitably, the best educated patients will always find the best outcomes.

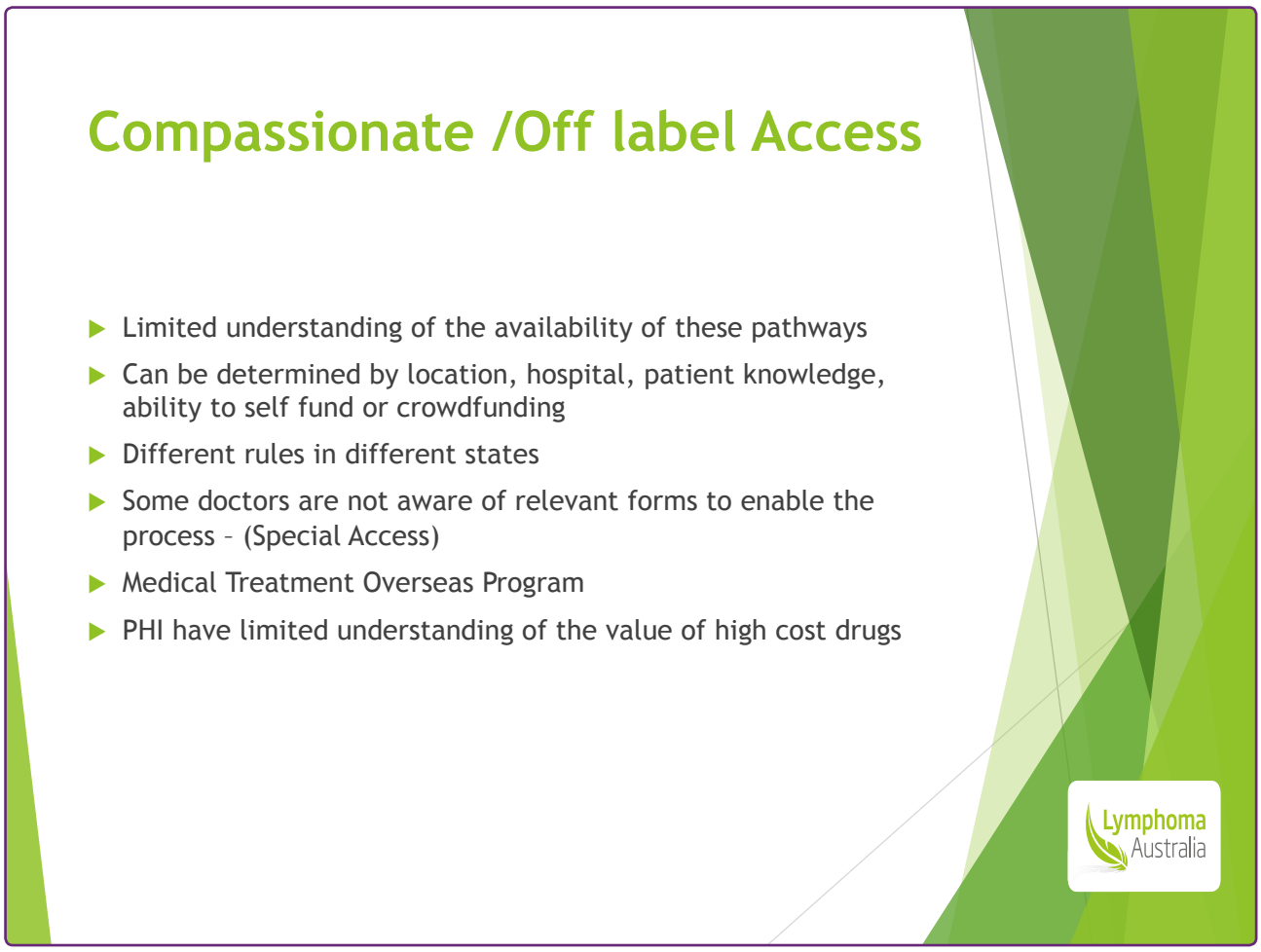
Sharon described the progress that has been made in reimbursement of new therapies for lymphoma, with 13 new medicines added to PBS over the last 30 months. However, as lymphoma has approximately 80 different subtypes, more options continue to be needed.

Regarding consumers engagement with the PBAC process, they are in the position of needing to guess what's in the submission – the Public Summary Documents released following the PBAC review are not consumer-friendly (although work is being done to address this).

There are two levels of feedback for submissions:

1. Patients as individuals
2. Patient groups – still unclear as to where inputs and data from patient groups fits in. There is a concern that this may negatively impact a submission if side effects are a large part of the patient experience. There is an added challenge for patient groups to evaluate data based on individual concerns and provided to them by individual patients.

Sharon also raised off-label access as an important concern for patients and advocates. The community doesn't understand the whole process and it appears there are different rules for different states. This can be compounded by media coverage of research results which may give false hope to patients and care givers.



More education is needed regarding these types of programs. For example, if many patients die while on a compassionate access programme this information needs to be shared with patients. It is apparent that some doctors are not aware of relevant forms to enable entry to or reporting on Special Access schemes.

Sharon offered suggestions as to what can be done by individuals:

- Advocate for a national clinical trial framework that meets minimum standards
- Demand equitable access for off label medicines – shouldn't be state-based/hospital dependent
- Use global data & approvals to enable faster access to medicines in Australia
- Include patient reported outcomes
- Validate concerns and have solutions with meaningful & accurate communication.

The question needs to continue to be asked: Why do some patients get free access, whilst others pay out of pocket?

Sharon concluded with her vision for what we should be aiming for:

- A health system that ensures patients are centric to all decisions
- The disease determines the treatment and not the hospital
- A system that identifies cost savings and delivers back to health
- A collaboration of key stakeholders that don't fear retribution due to transparency concerns
- Fair and responsible patient and community education by all stakeholders.

SPEAKER BIOS

DAVID GRAINGER

Head, Global Health Outcomes and Policy, Biointelect.

David Grainger has forty years of experience in the pharmaceutical industry, spanning Australia, New Zealand, the United States and short assignments in Brussels and London.

He completed his life sciences studies at the University of Auckland with majors in haematology and transfusion science, management studies with the New Zealand Institute of Management and health economics at Monash University in Melbourne.

David is the co-author of numerous publications on health economics and health outcomes research.

David's industry experience includes a range of roles in sales, marketing, health outcomes research and corporate affairs. This includes ten years as the director of corporate affairs and market access in Eli Lilly's Australian affiliate, responsible for all health outcomes research, reimbursement dossier development & pricing functions as well as the corporate affairs functions of government relations, advocacy & communications.

More recently, David held a senior role in Lilly's international public policy group, responsible for developing and supporting the company's external health care policy positions related to Health Technology Assessment (HTA). David also engaged extensively with governments and thought leaders in a range of markets on policy issues related to universal health coverage, formulary management, HTA, pricing and regulatory affairs.

David has had significant involvement with industry association policy efforts and for six years chaired the HTA Task Force for PhRMA International. For five years he was a member of the Board of Directors of Health Technology Assessment International, a professional society dedicated to HTA. David is also a member of the Policy Research Advisory Committee for the Office of Health Economics in London and a casual lecturer in the Masters of Pharmaceutical Medicine program at the University of New South Wales in Sydney.

MICHELLE BURKE

PBAC

Michelle Burke has been an industry nominee to the Pharmaceutical Benefits Advisory Committee since July 2017. She has a long history of working with multinational pharmaceutical companies and participating in high profile policy issues through Medicines Australia, including those related to PBS reform and industry development. Michelle joined the board of AusBiotech in 2012 and has worked with AusBiotech on issues including biologics medicines policies and opposition to the Private Members' (gene patent) Bill in 2011.

Michelle's previous role at Bristol-Myers Squibb (BMS) ensures an extensive knowledge of the policy environment, at a strategic and practical level, with responsibility for: Early asset commercialisation; market access; government affairs and policy analysis; and public affairs and communications. She has worked with the biotechnology sector and more specifically in pharmaceutical organisations for the majority of her career, after achieving a science degree (pharmacology and biochemistry majors).

NANCY DEVLIN

Director, Centre for Health Policy, University of Melbourne

Nancy Devlin is Professor of Health Economics and Director of the Centre of Health Policy, University of Melbourne. Her principal areas of research expertise are the measurement and valuation of patient reported health outcomes (PROs); the cost effectiveness thresholds used in making judgments about value for money in health care; priority setting in health care; production, performance and efficiency of hospitals; and the use of multi-criteria decision analysis in health care decision making.

Nancy has published over 100 original peer reviewed journal articles and reports on a wide range of empirical and theoretical topics in health economics, and is co-author of Economic Analysis in Health Care, a leading textbook on health economics widely used in the UK and elsewhere and now in its second edition. Her research, submitted as a case study to the UK's 2014 UK REF exercise, was judged by the sub-panel as 'demonstrating very considerable impact in terms of reach and significance'. Her work was highlighted in the UK's NIHR 10-year anniversary report, which noted 'The impact of her research is worldwide and highly significant in improving health and health care decision making'.

Nancy was recently elected as President of ISPOR, the US-based international professional society for health economists and outcomes research, which has 20,000 members worldwide. Nancy is past President of the EuroQol Group, the European-based international network of researchers that developed the EQ-5D, the world's leading measure of patient reported outcomes.

Prior to joining the University of Melbourne in 2019, Nancy was the Director of Research at the Office of Health Economics in London for ten years. Prior to that she was Professor of Economics at City University of London, where she held positions as Head of the Economics Department and Acting Dean of Social Sciences. She has over 30 years of experience as a researcher and as an advisor to health care organisations, both in the public and private sectors, in the UK and internationally.

Highly regarded as a presenter and educator in microeconomics and health economics, Nancy is a recipient of the UK Higher Education Academy prize for outstanding economics lecturer and was the founder of Health Economics Education (HEe) website, now run by the international Health Economics Association (iHEA). Nancy has a PhD in Economics from the University of Otago, New Zealand.

JULIE VAN BAVEL

Executive Director, CORE Asia Pacific, MSD

Julie Van Bavel has more than twenty years of experience in the pharmaceutical Industry in the United States and Australia.

Julie joined MSD-Australia in 1997 where after several years in Sales and Marketing, she transitioned to the health outcomes team in 2001, moving through positions of increasing responsibility in team management, HTA and Pricing & Reimbursement negotiations representing MSD with government agencies, taking the lead across all therapeutic areas by 2012, including responsibility for New Product Planning. In these roles, Julie gained valuable experience to design and execute health outcome and health economic research, building and aligning access strategies in support for the MSD-Australia product portfolio. In 2015, she joined the Centre for Observational and Real World Evidence (CORE) at Merck's Headquarters in the USA. In this role, Julie has continued to capitalize on her understanding of the HTA and payer environment at the country level. In particular, she was responsible for across-product policy research programs that broaden the focus of value evidence generation to address concerns of policy makers as well HTA agencies and payers.

Julie has been an active member of various Industry groups: The Health Economic Working Group, the Health Technology Assessment working group and the Educational subgroup of ARCs.

She is passionate about strategy development and execution, analysis and problem solving, negotiation, developing processes that increase efficiency and improve outcomes whilst still enabling creative thinking and innovation.

SHARON WINTON

CEO, Lymphoma Australia

Sharon Winton has been CEO of Lymphoma Australia for the last 7 years after becoming involved with the organisation after her mother Shirley Winton OAM was elected the founding president of Lymphoma Australia after her diagnosis with CLL and then Non-Hodgkin Follicular lymphoma. Prior to this appointment Sharon was part of the management team with a private health insurance company. In this role her focus was on product development and building relationships with key stakeholders within this industry. Sharon's current role encompasses an understanding of all aspects of the cancer journey for patients and carers including the regulatory process in Australia. Over the last 30 months the PBAC has recommended 13 medicines for PBS for lymphoma in Australia. Lymphoma Australia has made independent submissions to both PBAC and MSAC and has encouraged patients and carers to also make individual submissions to PBAC when it is appropriate to do so. Lymphoma Australia is on a number of national and international committees that are looking at ways to drive change to improve equitable access to medicines for all patients.

JENNIFER HERZ

Managing Director, Biointelect

Jennifer Herz founded Biointelect in 2011 to provide strategic commercialisation services to the biopharmaceutical industry. Jennifer has over twenty years commercial, business development and scientific affairs experience in the biopharmaceutical industry and has held a variety of roles with responsibility for Australia, New Zealand and European markets. She was the first Managing Director of Sanofi Pasteur in Australia which was a start-up company and grew significantly over the 6 years of her tenure to be an established major provider of vaccines to the public and private market in Australia, New Zealand and the Pacific Region.

She has previously served on the Board of Medicines Australia where she led industry discussions with government related to the new funding arrangements for vaccines on the PBAC. She was also active in a variety of European and International Industry Association working groups responsible for liaison with health authorities including European Institutions and the WHO.

She is a member of the Accelerate Commercialisation Expert Network, on the Steering Committee of the NHMRC funded Centre of Research Excellence: Policy relevant infectious disease simulation and mathematical modelling (PRISM) and is a member of the Expert Reference Group of the Australian Partnership for Preparedness Research on Infectious Disease Emergencies (APPRISE).

Jennifer is a member of the National Health & Medical Research Council Health Innovation Advisory Committee.

Jennifer has an extensive international & local network of industry, policy, scientific and clinical experts across many therapeutic areas and healthcare sectors along with global experience in multiple new product launches and start-ups at all stages of development.

For all further enquiries, please contact David Grainger

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