develop value propositions, inform HTA assessments, gauge market need and demonstrate where a new technology sits within an established clinical pathway. Although the HTA agencies present at the APF stated that RWD is available in the Asia region, this was not reflected by industry members who had limited awareness and access. Key concerns raised included whether this RWD is available for public use (and what caveats will be placed around its release), the quality of the data, whether it is longitudinal, and if it includes costs.

CONCLUSIONS:

There is a clear difference in the perspective of RWD between industry and HTA agencies in the Asia region. It is possible that this difference is driven by the apparent lack of publicly available data in the region and industry members comparing the use of RWD in Asia with the use in higher-income countries. This can be improved with clearer definitions, increased dialogue and multi-stakeholder collaboration in the region.

OP15 Actions Arising From The 2017 Health Technology Assessment International Asia Policy Forum

AUTHORS:

Brendon Kearney, Rebecca Trowman (rtrowman@htai.org)

INTRODUCTION:

Universal health care (UHC) leads to better health, educational outcomes and productivity. However, Asian healthcare systems are experiencing huge pressures and are striving to achieve UHC. With this in mind, the Health Technology Assessment International (HTAi) Asia Policy Forum (APF) tackled, 'Universal Health Care in the Asia Region: Overcoming the Barriers using HTA and Real World Data (RWD)'.

METHODS:

The HTAi APF convened forty-four senior representatives from HTA agencies and industry from Asia. Through a mixture of keynote presentations and guided group discussions, APF members spent two days grappling with the topic.

RESULTS:

There were a number of key messages from the APF, plus actions that were identified by APF members. The actions included: (i) A standardized HTA methodology for the prioritization of technologies in the Asia region should be developed to support health care systems; (ii) HTAi need to define what real-world data means in the HTA glossary; (iii) Members of the APF should develop a catalogue of what public and private data is available across countries in the region; (iv) A policy statement that agencies can use with a common approach to the release of data needs to be developed.

CONCLUSIONS:

HTA and access to RWD were identified as essential tools to be used in achieving the goal of UHC; this goal should indeed be pursued in the Asia region. However, issues such as transparency and accountability of HTA, and trust and collaboration between the public and private sectors are important concerns which need to be addressed in order to progress this goal. The recommendations for actions resulting from this successful APF update on progress towards these identified actions will be presented.

OP16 Decision Criteria That Influence Managed Entry Agreements

AUTHORS:

Maxine Freeman-Robinson (maxinerobinson@mac.com), Cathrine Mihalopoulos, Tracy Merlin, Elizabeth Roughead

INTRODUCTION:

Managed Entry Agreements (MEAs) enable payers to subsidize access to new medicines while addressing uncertainties. Uncertainties may relate to the criteria for decision-making articulated in decision-making frameworks. The study's aim was to determine if there was any association between the type of MEA and criteria considered during decision-making.

METHODS:

All medicines with MEAs listed on the Australian national subsidy scheme between 2012-2016 were identified. Data were extracted on the types of MEA and

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information related to the criteria considered in decision-making for each medicine and its associated indication (i.e. a medicine-indication pair [MIP]). The criteria considered in decision-making included the comparator (therapy to which it was compared), type of economic analysis, accepted value, budget impact, financial cost of supply, cost of therapy per patient, access control (such as restrictions or prior authorization), and clinical need. Associations between types of MEA and the criteria were assessed using Chi Squared test.

RESULTS:

There were 87 MIPs, of which 56 had only financial MEAs and 31 had performance-based MEAs. Coverage with evidence development MEAs had very high incremental cost-effectiveness ratio (ICER)/quality adjusted life year (QALY) (74 percent > AUD 50,000 [USD 37,822]). Financial MEAs where performance measures were linked to reimbursement had lower ICER/QALY (13 percent > AUD 50,000 [USD 37,822]) but greater budget impact (33% > AUD 80million [USD 60.5million]) compared to simple financial MEAs. A statistically significant association (Cramer's $V = 0.5$, $p < 0.001$) was only found between performance-based MEAs and the cost of unsubsidized therapy per patient.

CONCLUSIONS:

The main influence on the choice of performance based MEA was the provision of access to clinically important medicines with a high treatment cost for patients.

OP18 A Patient And Caregiver-Designed Framework For Managed Access Programs

AUTHORS:

Andrea Young, Devidas Menon, Jackie Street, Walla Al-Hertani, Tania Stafinski (aldunn@ualberta.ca)

INTRODUCTION:

Reimbursement decisions on orphan drugs carry significant uncertainty, and as the amount increases, so does the risk of making a wrong decision, where harms outweigh benefits. Consequently, patients often face limited access to orphan drugs. Managed access programs (MAPs) are a mechanism for managing risk while enabling access to potentially beneficial drugs. Patients and their caregivers have expressed support for these programs and see patient input as critical to successful implementation. However, they have yet to be systematically involved in their design. The objective of this study was to explore what a framework for MAPs might look like when designed by patients and caregivers.

METHODS:

Building upon established relationships with the Canadian Organization for Rare Disorders, the project team collaborated with patients and caregivers using the principles of participatory action research. Data were collected at two workshops and analyzed using a thematic network approach.

RESULTS:

Patients and caregivers identified six aspects of an ideal MAP relating to accountability (program goals), governance (program-specific committee oversight; patient input; international collaboration), and evidence collection (outcome measures and stopping criteria; ongoing monitoring and registries). Additionally, patients and caregivers recognized that health care resources are finite and considered disease or drug eligibility criteria for deciding when to use a MAP (e.g. drugs treating diseases for which there are no other legitimate alternatives).

CONCLUSIONS:

A patient and caregiver-designed framework was created, which emphasized patient involvement and transparency. Further research is needed to examine the feasibility of this framework and roles for other stakeholders.

OP19 Are Compassionate Use Programmes Good Predictors of Clinical Benefit?

AUTHORS:

Mackenzie Mills (M.J.Mills@lse.ac.uk)

INTRODUCTION:

In cases of high unmet clinical need, patients can access drugs prior to marketing authorization (MA) and Health Technology Assessment (HTA) through compassionate

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