

ASSESSING VALUE, BUDGET IMPACT, AND AFFORDABILITY IN ASIA

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Objectives: The aim of this study was to explore definitions of value and the use of budget impact and affordability considerations in health technology assessment (HTA) in the Asia region, particularly in relation to high cost technologies.

Methods: Issues were debated by senior representatives from HTA and payer systems in Asian countries, delegates from industry, and invited experts at the 2016 meeting of the HTAi Asia Policy Forum (HAPF). A premeeting survey was used to gather data on how value is assessed and budget impact calculations are used within current processes, as well as current approaches to managing affordability.

Results: All systems consider health benefit to be the key component of value. There is little consensus around “wider” elements of value that should be included. All systems use budget impact in decision making, although meeting attendees noted the challenges in making accurate estimates. The most common strategies used to address affordability concerns to date have been: restricting coverage, for example, to patients who are likely to get the highest value; discounts; and revenue caps. It was noted that these “solutions” may have unintended consequences of creating inequitable access to therapies and failing to provide adequate rewards for innovation.

Conclusions: Decision makers, HTA agencies, and industry need to continue to work together to find mutually agreeable solutions to ensure that patients continue to get equitable access to effective therapies at costs that can be afforded throughout the Asia region.

Keywords: Health technology assessment, Value-based purchasing, Costs and cost analysis

INTRODUCTION

Health technology assessment (HTA) processes are often used by decision makers to measure and assess the value of health technologies. HTA processes vary around the world, focusing on different elements of value according to local definitions and preferences. Definitions of value generally include elements such as health gain and change in direct costs. They may also include wider elements such as changes in social care costs and benefits to the wider economy. Views differ as to whether the concept of “value” should include opportunity cost, or whether this should be considered as a separate “value for money” assessment. Given limited resources, decision makers need to consider the overall budget impact and affordability of a technology, but these are not normally viewed as elements of value and instead are factored into decisions alongside assessments of value and value for money. HTA bodies may or may not be asked to estimate budget impact, depending on their remit. Affordability is generally left to decision makers to assess.

Recent “breakthrough” treatments (such as sofosbuvir for hepatitis C virus [HCV]) have been shown to offer good value for money by most standard approaches to assessment, but have

led to major challenges for affordability at the prices initially being sought by the manufacturers (1;2). This shows that value and affordability may not always align, and a technology may be considered to offer value for money but not be affordable within current budgets. Discussions at the HTAi Global Policy Forum in 2016 indicated that approaches to valuing innovation need to be revisited, and that questions remain as to the most appropriate role for HTA bodies (3).

Given the importance of these issues for the Asia region, it was agreed that the 2016 meeting of the HTAi Asia Policy Forum (HAPF) should discuss Assessing Value, Budget Impact and Affordability to Inform Decisions on Access and Reimbursement: Principles and Practice, with Special Reference to High Cost Technologies.

METHODS

The topic of the HAPF 2016 meeting was chosen in discussion with the HAPF Organizing Committee and members. It was agreed that the meeting should focus on: Defining and assessing value, and factoring those assessments into decisions; Defining, assessing, and making decisions on budget impact and affordability; Principles and approaches for technologies with very high budget impact.

The 2016 HAPF meeting was held from 17 to 18 November in Kuala Lumpur, Malaysia. Forty-six people participated. The

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meeting was convened by Health Technology Assessment International (HTAi) and organized by HTAi, the Office of Health Economics (OHE) that provided the Scientific Secretariat, and the Chair of the HAPF.

Attendance at the meeting was by invitation. Attendees included: 20 delegates from HTA and payer systems in Asian countries; 18 delegates from industry with interest and expertise in Asia; several invited experts; and the organizers (for a full list of attendees please see the Supplementary Materials). Representatives from each health/HTA system attending (China, Japan, Malaysia, Philippines, Singapore, Taiwan, and Thailand) completed a survey before the meeting on value assessment and budget impact/affordability considerations in their system. Delegates were asked to collaborate to produce one response per country or region.

A background paper was developed and circulated in advance of the meeting (4). Advice on the background paper was provided by the Organizing Committee.

The meeting was designed to promote in-depth, open, and constructive exchange, based around plenary sessions and some work in break out groups. The meeting was conducted under the Chatham House Rule (5), meaning participants are free to share information obtained at the meeting, but not the identity or affiliation of the person providing the information.

This study provides a summary of the results from the pre-meeting survey, and the authors' views on the key thoughts and suggestions emerging from the discussion at the meeting. It should not be interpreted as a consensus statement from the meeting, nor should it be taken to represent the views of any of the people attending (or organizations represented at) the meeting.

FINDINGS AND DISCUSSION

Defining and Measuring Value

There are various value 'elements' that can be included in value assessments of health technologies, depending on the decision-makers' definition of value. The core benefit is the health improvement for the patient (i.e., enhanced prognosis/survival and/or quality of life). Although decisions are typically a function of a range of benefits, cost, opportunity costs, and uncertainty, health gain is usually the single most important element (6). For this reason, all HTA bodies include, and often focus on, health effect in their assessments of value. Wider elements of value include nonhealth benefits for the patient (e.g., reduced out-of-pocket costs, or return to work), benefits for the carer/family (e.g., reduced burden of care), benefits for health and social care systems (improved health system efficiency, improvements in public health), and further benefits for society (such as support for disadvantaged groups or improved productivity). Different elements of value and different perspectives were discussed at the HTAi Global Policy Forum in 2013 (7).

A review by OHE and the European Personalized Medicine Association (EPEMED) (8) identified gains in life years, quality of life, and health system cost savings as elements of value that are usually included in assessments. Productivity is another important dimension that is sometimes included, albeit less routinely. However, there are many other elements that could be important, that are not widely included in HTAs, for example: scientific spillovers, insurance value, real option value, the value of hope, a reduction in uncertainty for patients, and cost savings outside the health system (see Figure 1, for a discussion of these concepts see Garrison et al.) (9).

In a premeeting questionnaire, delegates from the countries/regions represented ($N = 7$) were asked which elements of value are included within value assessments in their countries. Figure 2 shows the number of health benefits and non-health benefits that were reported to be included in HTAs. The term "Availability of Alternatives" refers to unmet need.

In addition to the elements included in the figure above, all survey respondents reported including elements that relate to benefits for health and social care systems (for example improved efficiency) and public health benefit (i.e., where the benefit from a treatment is greater than the sum of the individual patients treated). Five of the seven survey respondents also reported including some form of benefit to society and four reported including benefit to the caregiver/family, such as reduced burden of care and return to work.

Following discussions at the HAPF meeting, it appeared that, in some cases, the results of the survey may not accurately reflect current practice, and may have been influenced by the aspirations of respondents for the practice they would like to follow. Some HTA representatives said that they would like to extend their assessments to include the wider elements of value, but recognize difficulties in gathering evidence, particularly on those wider elements that are more qualitative.

Once a system has decided on the value elements to include, the next step is to consider how to measure these elements, and then how best the evidence can be considered by the decision maker. Measurement of some elements of value is relatively straightforward, for example, health benefits can be measured through standardized outcome measures in established clinical study designs. However, meeting attendees stressed that, although these methods are well defined, there are still discussions to be had around the most appropriate outcome measures and about study design (e.g., RCTs and/or the use of real world evidence in the form of observational designs or pragmatic clinical trials). Furthermore, it was noted that data in Asia can be limited for assessing even the more established (core) elements of value such as health gain and quality of life, and work often, therefore, focuses on overcoming this challenge rather than trying to measure wider benefits.

The measurement of wider elements, such as productivity, is less standardized. For example, Knies et al. (10) note that, despite many national guidelines recommending that wider



Figure 1. Elements of value of medical technologies. Light gray circles, traditional elements of value considered in HTA; dark gray circles, elements not traditionally measured; green lines, value from health system perspective; red lines, value also included in societal perspective. Source: OHE and EPEMED (8).

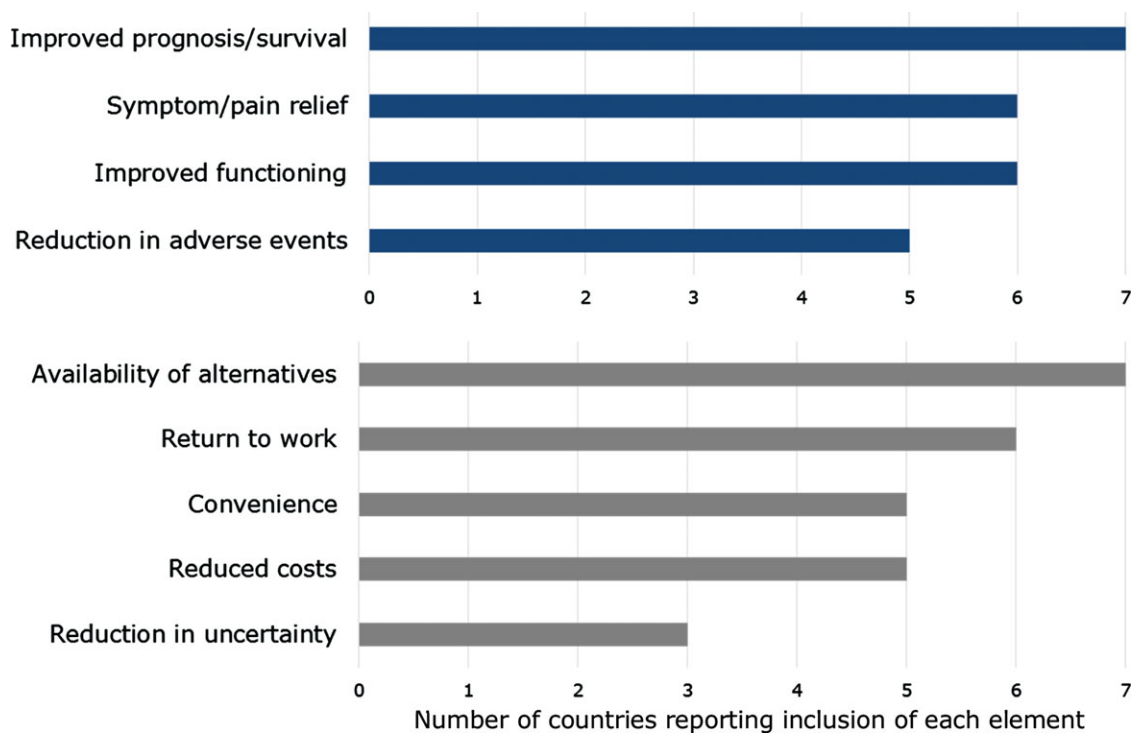


Figure 2. Health and non-health benefits for patients that are included in HTA (N = 7). Source: Authors analysis of questionnaire responses.

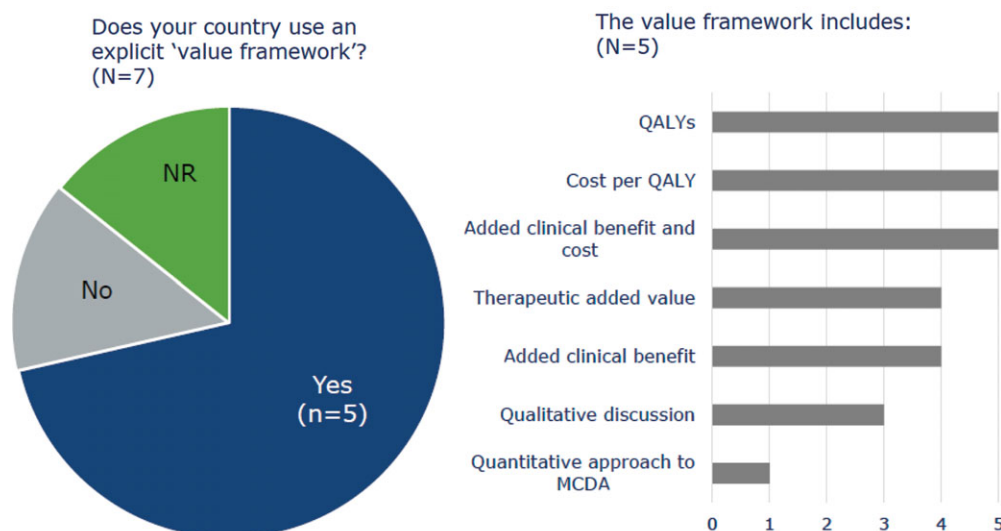


Figure 3. Reported use of value frameworks ($N = 7$). Source: Author's analysis of questionnaire responses.

benefits are included, only South Korea and France provide detail on, for example, how to measure lost productivity. Benchmarking and valuation of wider benefits is also challenging (e.g., even if evidence can be collected, how much extra for a treatment should we pay for an extra day back at work?). Attendees at the 2016 AHPF meeting noted that decision makers are likely to focus on the evidence that is available to them, and it is, therefore, difficult for decision-making bodies to take into account elements of value that are not measured. Industry representatives expressed uncertainty around how much time and resources they should invest in developing evidence for wider elements of value, when the extent to which they will be taken into account is not clear.

Combining Elements of Value in Decisions

Once value elements have been agreed upon and measured, the information needs to be combined in some way to help decision makers take appropriate account of it in the decision-making process. Value frameworks can help in identifying the elements of benefit to include, and can set out how to measure them and how to combine them for decision making. Five different value frameworks that have emerged recently from the United States were discussed. Reviews of these frameworks (11;12) have highlighted that health gains (clinical effects and safety) are included in all five, but that other elements of value differ between the frameworks and there is little consensus around which should be included.

Participants were asked about the use of value frameworks in the premeeting questionnaire. Five of the seven survey respondents reported that they use an explicit value framework. All five reported that cost-per-QALY is considered, as is added clinical benefit and cost (see Figure 3). Three of these five survey respondents reported that they use a different value framework and/or elements for drugs and medical devices.

Several important points emerged in the discussion. Not all countries represented at the Forum use a formal value framework, and not all elements of value are measured or considered within the value frameworks that are used. A comprehensive value framework that includes the patient experience and wider societal benefits, in addition to health gains, is an aspiration for decision makers in several Asian countries. But in practice, most healthcare resource allocation decisions in the Asia region appear to be based primarily on cost, health effects, cost effectiveness, budget impact and/or political considerations. There is little consensus around a specific wider set of value elements or a specific approach to measurement that could be adopted. Data are limited and cultural considerations are likely to be very relevant in any decision to include specific additional elements. Finally, and importantly, there may be a trade-off between the depth of value assessment and the time taken, with longer assessment possibly delaying patient access to therapies.

Budget Impact

The budget impact of a technology is the total expected cost impact over a defined time horizon (typically a few years). A recent ISPOR task force report (13) stated that “*Budget impact analyses (BIAs) are an essential part of a comprehensive economic assessment of a health care intervention.*” However, while being used by many decision makers around the world, there is debate over its place in decision making about the adoption of a technology, because budget impact is a function of treatment costs and population size, not of overall health gain or the ratio of benefit to cost.

All AHPF 2016 survey respondents reported that their system calculates the budget impact of new treatments, and that this is typically done from the perspective of the healthcare payer. Figure 4 shows the survey respondents reporting on the

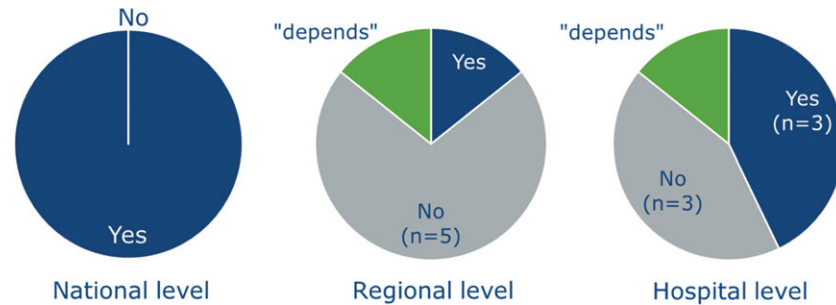


Figure 4. At which levels of the healthcare system is BIA a criterion for decision making? ($N = 7$). Source: Author's analysis of questionnaire responses.

extent to which budget impact is used as an explicit criteria within decision making at different levels of the healthcare system. Further data collected from the survey indicated that, in the majority of cases ($n = 6$), BIAs are conducted from the perspective of the health service (i.e., all costs that accrue to the health service are included; costs incurred elsewhere are not included).

Discussion identified that BIAs are typically built on questionable assumptions because of a lack of data on disease prevalence, epidemiology, and service usage, as well as uncertainty about the prescribing behavior of clinicians. In addition, they often use short time horizons, which means they will not capture savings that may accrue in the longer term. All this can give rise to serious doubts around the robustness of BIAs and the validity of their use for decisions on coverage and access.

Yet, despite these limitations, many at the AHPF emphasized that affordability is a key issue in countries facing major limitations on the available resources. BIAs are a key element informing discussions of affordability and decisions on access. When budget impact is expected to be high, the system may use these estimates in discussions with industry around discounts and alternative financing arrangements.

Affordability

Participants were asked to consider various scenarios which could give rise to affordability concerns: (i) A technology with a substantial budget impact exposes the decision-maker's doubt about the appropriateness of the existing criteria used to assess value relative to cost (for example by the use of a cost-effectiveness threshold). (ii) A technology has a nonmarginal impact on the health system, therefore, it requires that changes be made to the decision rules for adopting new treatments (for example by revising the cost-effectiveness threshold) to ensure optimal allocation of resources. (iii) Additional time is required to adjust to a different spending pattern—the system needs to disinvest, get efficiency improvements, or obtain higher budgets to fund the technology. (iv) The health system wishes to avoid paying “too much” for the technology. (v) High up-front costs lead to problems of “cash flow”, even when large savings and/or health benefits are expected down the line. This requires

annualization, that is, there is a need for a way of matching payments to the time during which benefits are realized. (vi) A technology is absolutely unaffordable as the cost exceeds all available current and realistic potential future resourcing.

The responses to the premeeting questionnaire indicated that in the majority of cases, scenarios 3 and 4 have been perceived to be the biggest challenges for the health/HTA systems represented. Concern was also expressed by five survey respondents, however, that some technologies, at least on the terms on which they are offered, are completely unaffordable to their system, as per scenario 6. Attendees at the meeting noted that for medical devices, the most relevant affordability challenge is likely to be the high volume at which some medical devices may be used (for example insulin pumps), rather than a very high unit cost for the technology.

Six of the seven survey respondents were able to provide examples of treatments that have been shown to be good value for money but have not been considered to be affordable. The majority of these mentioned as one example the recent curative therapies for HCV.

Current Approaches Around Technologies with High Budget Impact

Several mechanisms have been proposed in the literature to mitigate affordability challenges. These include: discounts and revenue caps, targeting the highest value patient groups, pay-for-performance risk sharing arrangements, managed entry agreements, annualization, and amortization/credit market solutions (14). Responses to the premeeting questionnaire indicated that the most common mechanisms that had been used by attendee countries were targeting the highest value patient groups, and discounts and revenue caps.

In the meeting, the case of sofosbuvir was discussed (the first to market of the new HCV treatments). Many of the countries represented at the meeting are not currently reimbursing sofosbuvir, due to the high expected budget impact. Taiwan, South Korea, and Japan are exceptions, but securing funding was said to be challenging in these countries and coverage depended on price negotiations.

The group agreed that the introduction of this technology has stimulated stakeholders to look for new approaches.

The following experiences were discussed which could inform approaches elsewhere: *Ignoring IP protection*: this has been considered in some jurisdictions but is not a sustainable approach globally. Infringing IP will adversely affect the incentives for innovation. *Robust price negotiations*: for example, in China, where a significant discount was apparently negotiated with the manufacturer at the national level. Even so, only around half of the provinces are reimbursing the treatment, so even significant discounting may not be a complete solution in developing economies. *Managed access agreements and other innovative approaches, often coupled with significant discounts*: for example, in Australia and Egypt, where payers and manufacturers have negotiated and come to an agreement that all parties are able to accept. Experiences with such methods have not been widely reported on in Asia if they have taken place. *Targeting the highest need/value patients*: five of the seven countries represented reported in the premeeting survey that this is a key mechanism for managing affordability concerns. *Availability of special funding*: this was seen as one of the most favorable solutions to explore further when the example of sofosbuvir was discussed during break out groups. Funds could be allocated specifically to treatments, or a special fund could be set up to pay for high cost drugs. *Competition*: the availability of an alternative product on the market was seen as a key factor in achieving access at an affordable cost.

In the case of medical devices, the view was that access to high cost technologies is likely to be managed through restricting their use to specialist centers, and/or controlling access through clinical guidelines, rather than a formal HTA process informing a decision by a national payer. Competition may also be a mitigating factor on budget access and affordability. It was noted, however, that very high cost equipment (such as the Da Vinci robot) can be seen as a sign of prestige and a means to retain staff, rather than a mechanism directly to improve clinical care.

For both drugs and medical devices, decision makers reported that reimbursement decisions may often reflect political considerations as much as, or more than, evidence on value, value for money and budget impact.

Reviewing General Principles and Approaches in the Light of Technologies with High Budget Impact

Several more general key themes or approaches emerged in the discussions on budget impact and affordability in the meeting: *Need for 'Intelligent' budget impact analysis*: BIA is not simply an accounting exercise and needs to include more sophisticated models over appropriate timescales with all relevant data (including costs such as training and transportation, and possible savings). *Budget silos*: budgets often have a tightly defined scope, which sometimes means that costs and savings that occur outside a decision-maker's remit are not considered. In some cases, a technology could become "affordable" if savings

across all areas were included in the budget impact calculations (and not only those accrued within the budget that pays for the technology). The challenge is for health systems and governments to adopt a wider perspective and ensure that relevant budgets are merged or coordinated. *Dynamic prices*: price is not fixed and changes over time. This should ideally be taken into account in estimates of value for money and budget impact analysis, but it is not clear how. *Need for informed and constructive negotiations*: negotiators on the payer (typically health system) side need to be commercially aware, and understand that companies need to make returns on investments; likewise, negotiators on the industry side need to be aware of each country's financial challenges. *Equity*: there is an important relationship between affordability and equity. Affordability issues kick in at a lower level when budgets are smaller (e.g. in less developed countries). The approach was discussed of 'just saying no' to high cost technologies in publically funded systems, but this leads to inequality if some members of population can then pay for the treatment themselves, and/or to financial hardship if the less well-off pay out of pocket. *Horizon scanning, HTA and decision making*: the time taken to assess new technologies and make coverage decisions in some systems can delay patient access to valuable treatments, and can appear to some as a deliberate way to delay introduction and manage affordability. Horizon scanning could be used to identify future budget challenges so that dialogue can be started earlier and decisions on access and uptake made more quickly.

It is important to note that the choice of approach may have an impact on manufacturers and future innovations. For example, simple discounts and budget caps may dis-incentivize investment in innovation and send signals that health systems do not value innovative technologies. If payers are not prepared to pay for innovation they are unlikely to get it. On the other hand, industry needs to be realistic about what is affordable in each country and not look for "innovation premiums" for products that are not genuinely innovative.

The point was also made that not all innovative drugs meet the thresholds set for cost effectiveness or value for money in some or all systems. Where these treatments do appear to offer good value, various approaches are available to manage affordability, but it would appear these have not yet been fully deployed in Asia. Many at the meeting emphasized the work that is being put into achieving universal coverage and equitable access to health care in Asian countries. It was believed to be important that approaches to pricing and managing affordability should not reduce access and equity.

There was agreement on the need for more engagement between HTA agencies, payers and manufacturers. In order for value assessment and budget impact assessment to be optimal, there is a need for all stakeholder groups to contribute to evidence generation and/or facilitate data sharing. Delegates from industry felt it would be helpful if HTA agencies and payers could provide guidance to industry around the types of

evidence that they should prioritize and the methods of financing that should be explored further.

CONCLUSIONS

The meeting and survey responses highlighted that, unsurprisingly, the value elements considered during decision making differ between countries in Asia according to different priorities and social contexts. Health gain is seen as the core of value in all systems represented at the meeting, but delegates reported challenges in finding robust data to demonstrate clinical efficacy and quality of life. Several countries at the meeting indicated that they consider elements of value beyond health gain, but that these can be even harder to assess; including wider elements of value is a lot easier in principle than in practice. Work is needed on the development of systems to collect and share epidemiological information and data on real world outcomes, and clarity is needed on the data that HTA bodies and decision makers wish to see and are able to take account of, so that industry resources can be focused on collecting this information.

Measuring budget impact is agreed to be important, but it is complex and needs to be approached as a science rather than purely as an accounting exercise. There is, however, also a lack of data available to inform robust models and calculations.

Affordability is a big concern in the Asia region, particularly with the expectation that more very high cost technologies will emerge in the coming years. Decision makers pointed out that high cost does not always indicate an innovative or curative therapy, or value for money; value considerations must still take center stage. A key concern for decision makers in Asia is that work to expand universal health coverage is not undermined by high expenditure on, and/or inequitable access to, high cost therapies.

For those high cost treatments that have demonstrated value, affordability appears to have been tackled in an ad hoc way to date in Asian countries, with discounts and patient eligibility restrictions as the main routes. There does not appear to be any clear movement, at least as yet, toward approaches such as managed entry and pay for performance. Special budgets and funding allocations have been used in the past for some technologies (such as human papilloma virus vaccines), and it is possible that this approach may be explored for new high value technologies that present major affordability challenges. There appears to be little interest at present in Asian countries in approaches such as amortization or annualization of payments.

Several policy implications can be identified. Further constructive and informed discussions are needed between decision makers, HTA agencies and industry to agree principles and to find mutually beneficial solutions for the rapid and equitable introduction of specific drugs and medical devices that offer high value but present significant challenges for affordability. Industry must recognize the severe financial restrictions faced by many Asian countries, and HTA bodies and decision mak-

ers must recognize that, if they wish their populations to benefit from innovation, it must be funded appropriately.

SUPPLEMENTARY MATERIAL

Supplementary Table 1:

<https://doi.org/10.1017/S0266462317000496>

CONFLICTS OF INTEREST

Mrs. Hampson reports grants from HTAi, during the conduct of the study; other from Various, outside the submitted work. Dr. Henshall reports personal fees from Health Technology Assessment International (HTAi), during the conduct of the study; personal fees from AstraZeneca, personal fees from Bayer, personal fees from Cornerstone, personal fees from Craig Rivers Associates International, personal fees from Eucomed, personal fees from Genzyme, personal fees from Medtronic, personal fees from Novartis, personal fees from Shire, personal fees from St Jude Medical, personal fees from Weber Sandwick, personal fees from Government of Alberta, personal fees from Centre for Medical Technology Policy, USA, personal fees from Health Technology Assessment International, personal fees from Institute of Health Economics, Edmonton, personal fees from Office of Health Economics, London, personal fees from RAND Europe, personal fees from Bellberry, Australia, outside the submitted work. Prof. Towse reports grants from HTAi, during the conduct of the study; other from Various, outside the submitted work.

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