TRANSCRIPTION:

VALUE-BASED PRICING: POTENTIAL & CONSIDERATIONS IN LMICs

Presented by Dan Ollendorf

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April 2022

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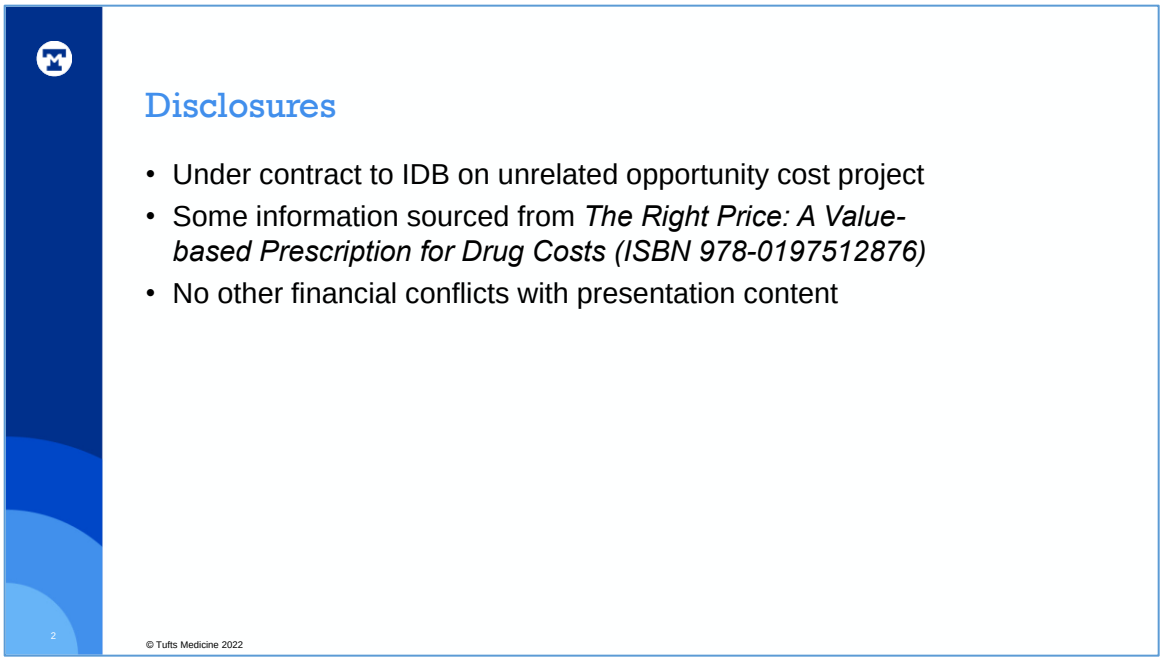
PRESENTATION

Introduction
Minute 00:06:10

I am very happy to be with you all again to speak about value-based pricing, both its potential as well as some considerations and challenges in applying value-based pricing in low- and middle- income countries. I think that the concepts I will be talking about are quite familiar to many of you, but the implementation of value-based pricing has many challenges in its own and I will get to some of those today.

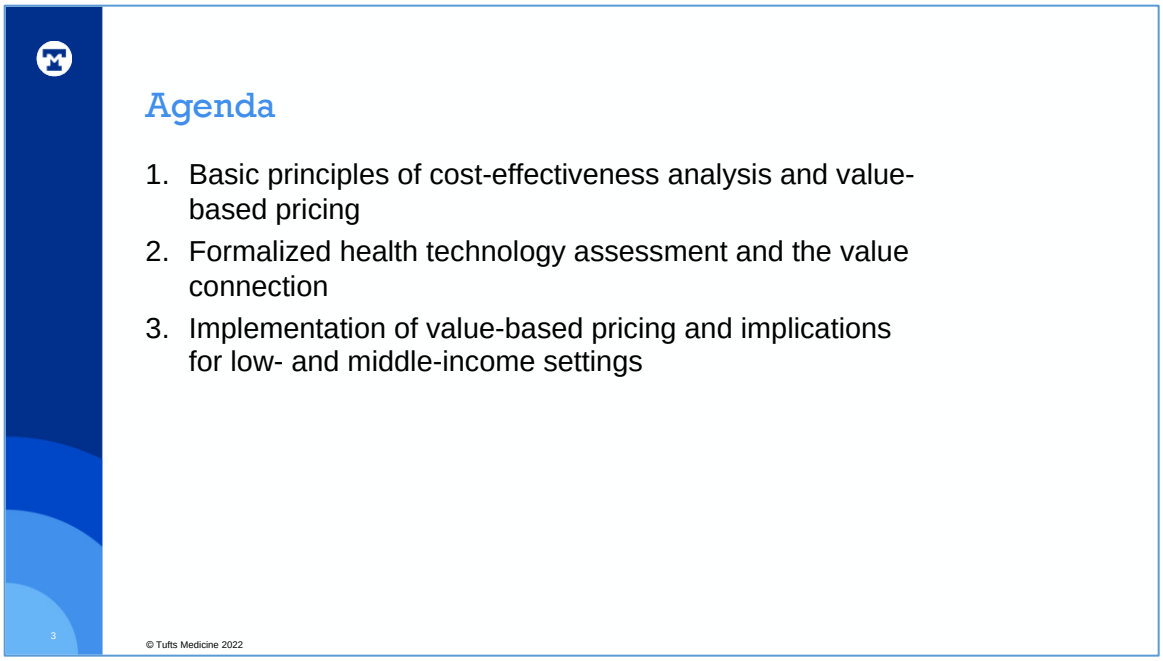


Disclosures
Minute 00:06:42

So just a few disclosures; I am, as Ursula mentioned, working with the IDB on an opportunity cost project, which is unrelated to the content of the presentation but of course share some of the same goals.

As Ursula mentioned I am the co-author of a new book and some of the information that I will be presenting to you today is sourced from that book. I believe it is available in a Spanish translation, but I can certainly try to confirm that for anyone who is interested.

I have no other conflicts with the content of this presentation.



Agenda
Minute 00:07:18

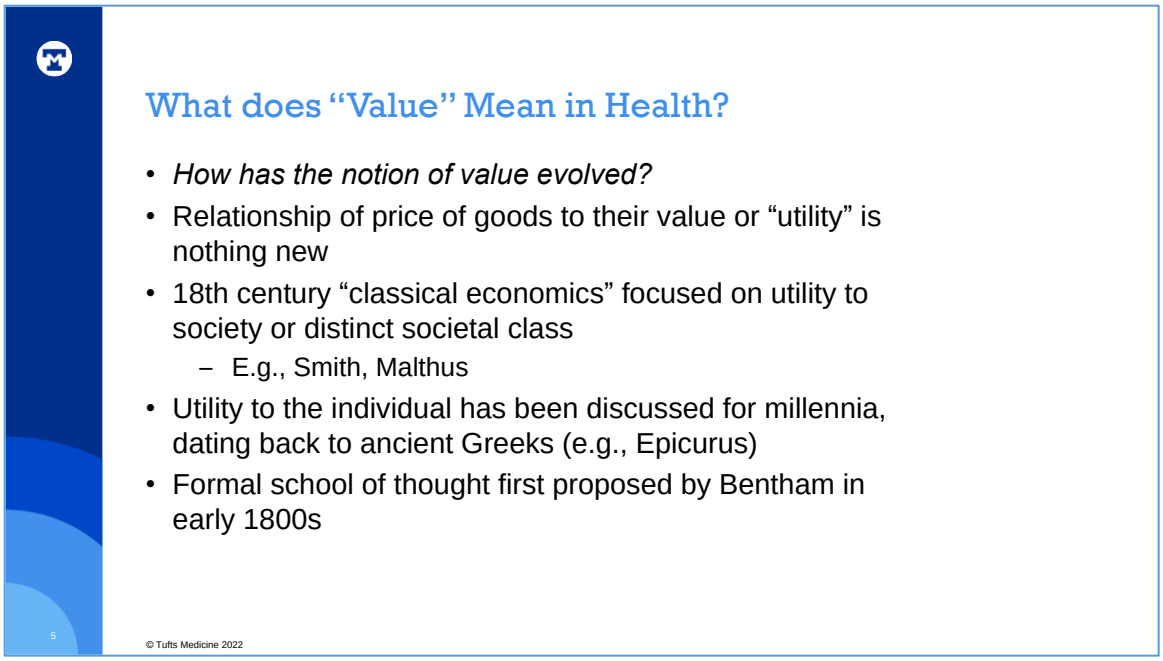
I am going to split my talk up into three major components. One is really to try to understand - going back to basics - the principles of cost-effectiveness analysis (CEA) and how that contributes to a strategy for value-based pricing of pharmaceuticals.

Then I will talk about the link between CEA and formalized health technology assessment, as well as that connection, again, to value.

And once we have gone through all of that background, we can talk about implementation of value-based pricing and potential implications for low-and middle- income settings.

Cost-effetiveness analysis and value-based pricing
Minute 00:08:00

Llet`s first go first back to basic principles for cost-effectiveness analysis and how we determine what we actually think off when we think of value-based pricing.

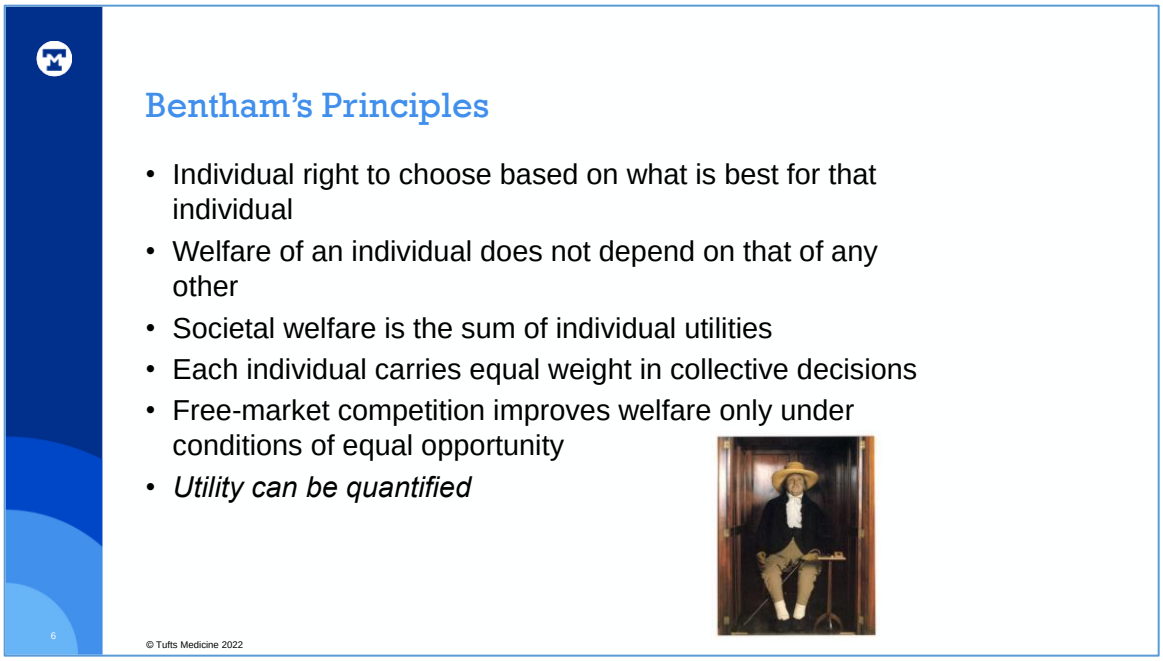


What does "value" mean in health?
Minute 00:08:13

How has the notion of "value" evolved in health? That is really a first principles kind of question. Really the relationship of the price of goods to their value or to their utility is nothing new. In 18th century classical economics there was a focus on utility or value to society broadly defined or to a distinct societal class, usually the upper class. So the economics of Smith and Malthus would be examples of this kind of view.

The utility to the individual person has also been discussed for a very long time, dating all the way back to the ancient Greeks.

But there was a formal school of thought around applying the utility to the individual that was first proposed by the philosopher Jeremy Bentham in the early 19th century.



Bentham's principles
Minute 00:09:10

What were Bentham's principles? When we look at these principles some of them are going to sound very familiar to you. And in fact, I would say that some of these principles are actually under threat in today's world.

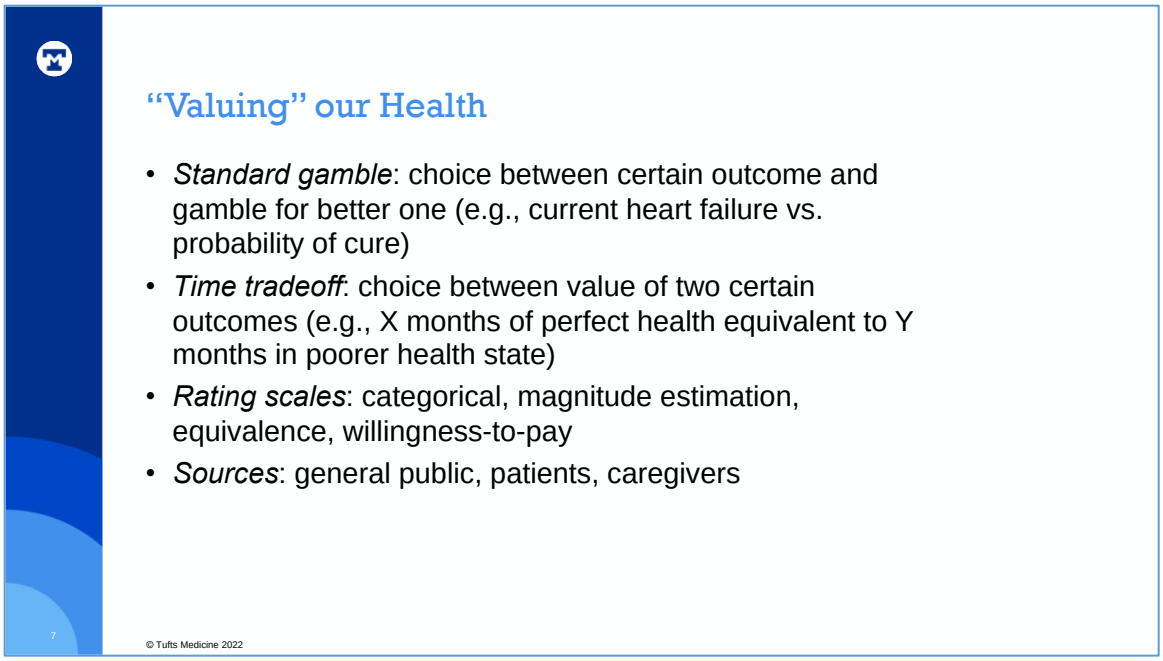
One is an individual right to choose based on what is best for that individual. Another is that the welfare of an individual does not depend on that of any other person. So, it really is an individual set of values; And that societal welfare is the sum of individual utilities. This really was a change in belief from societal welfare as dictated by the upper class to actually societal welfare as the sum of what each of us find valuable.

Each individual carries equal weight in collective decisions, so the views of one individual are not any more important than the views of another individual. This is a key consideration as well.
Free market competition, something that is often talked about in relation to drug prices here in the United States, improves welfare but only under conditions of equal opportunity. So that means, essentially, when we are thinking about interventions for health everyone really needs to have a fair chance of access to those interventions to really make competition work. And we know that that is a challenge in many settings.

But most importantly, for the purposes of this talk, utility can actually be quantified so these are not just philosophical thoughts or principles. They can turn into actual measures that can then be put in some sort of analysis, which I will talk through in a few minutes.

Now just a bit on the side on Jeremy Bentham; His contributions are very important of course. He was

also kind of an odd individual. In fact, if you go to London and you go to University College of London, you can actually see a caricature of his body on display. He put in his will that he wanted to be an icon after his death and he wanted to be wheeled out for dinner partied and be part of the conversations. So, Jeremy Bentham in some way lives on with us today.



"Valuing" our health
Minute 00:11:36

So how do we value our health? I am not going to go through the technical details of each of these but there are a number of ways in which individuals can assign utilities to states of health.

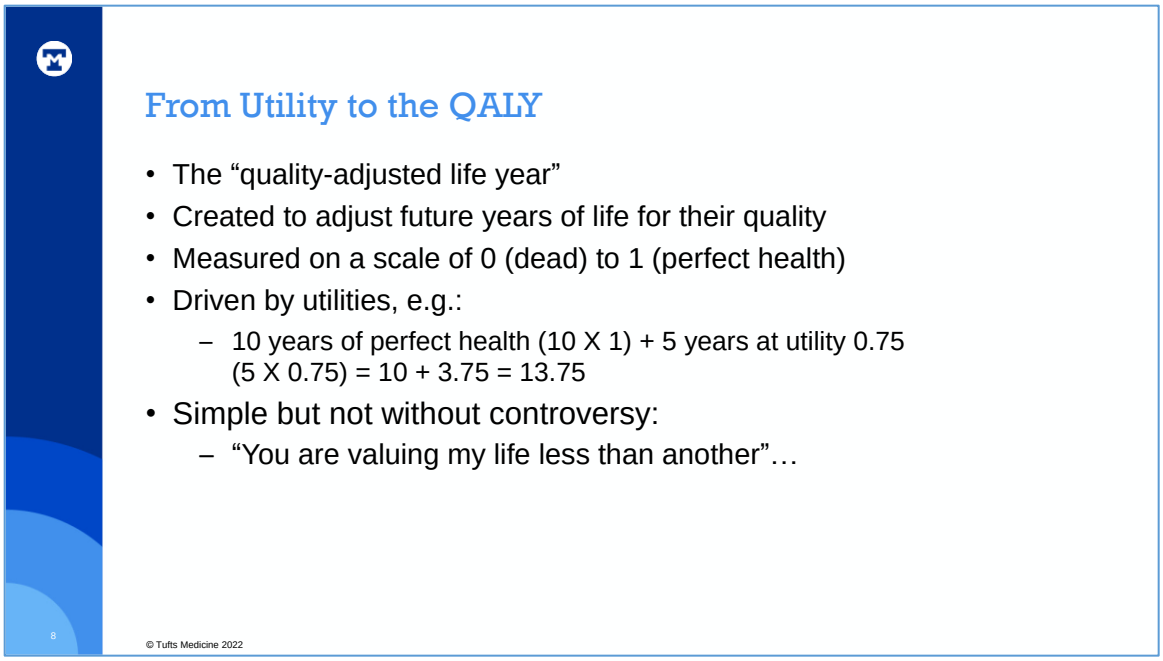
One is known as "standard gamble", which essentially represents the choice between a certain outcome and a gamble for what might be a better outcome. So, for example, existing in a current state of congestive heart failure in comparison to a small probability of a cure. What would you trade off in terms of your current health for the chance of getting better?
Also, there is also a time tradeoff, which is choice between the value of two certain outcomes, but it is the time spent in those states of health the individual is comparing. So, it is the number of months of perfect health that would be equivalent to a number of other months in a poorer health state. Where is the individual essentially trading off these two periods of time?

There are also rating scales, so categorical states or estimating the magnitude impact of a certain health condition when those health conditions are felt to be more or less equivalent or is the individual willing to pay a certain amount of money to move from one state of health to a better one, so onto different scales as well.

These instruments/surveys are applied to different populations. Sometimes the general public is surveyed, sometimes patients are surveyed about their own particular condition or caregivers acting as proxis for those patients. If, for example, a patient has a nerve degenerative condition they can't respond to the instrument or survey themselves, then a caregiver could be a participant as well.

Often times those who are interested in trying to look at measurement of value for societies purposes

will want the general public to be the source of this information because they can essentially balance the different characteristics of different conditions a bit better than those who are suffering from those conditions themselves. So that is the general preference but again a variety of sources are measured.



From utility to the QALY
Minute 00:14:05

Let’s go from the utility to the quality adjusted life here. The QALY was created to adjust future years of life for their quality. And this was developed essentially as a research tool initially in the 1960s to try to study the outcomes of hospitalized patients after they were discharged from hospital and it was really a collaborative effort to develop the quality of researchers in the UK, the US, Canada and elsewhere.

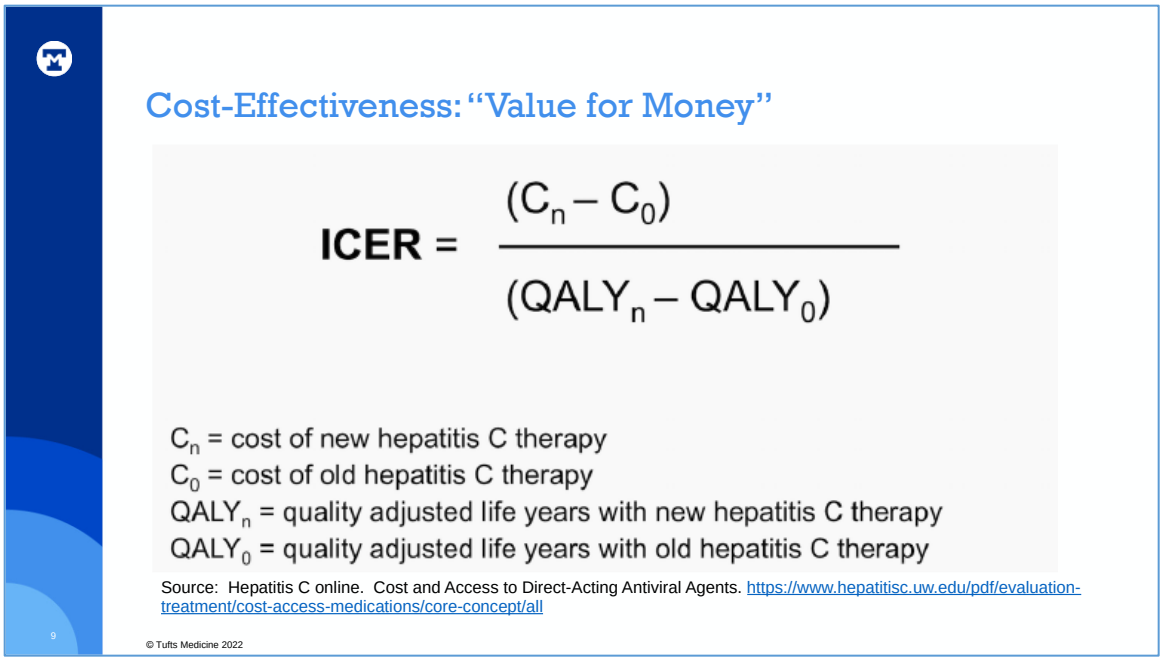
The QALY is measured on a scale from 0, which represents death, to 1, which represents perfect health. The measures of the impact of a disease or condition on health that falls somewhere in between 0 and 1 on that scale.

I should mention that I won’t be talking about it in detail today, but the disability adjusted life year, or DALY, is another measure that in some ways is comparable to the QALY. It operates also on a scale from 0 to 1 but in reversed direction. So, 0 is perfect health and 1 is complete disability or death, and so the DALY is also used. The results of QALY or DALY based cost-effectiveness analysis, while there are some differences in the domains and construct for each measure, are thought of generally as interchangeable.

Let’s return to the QALY for a second. It is really driven by that individual measure of what it is like to experience a particular condition or state of health. So, for example, in this simple calculation if an individual experienced ten years of perfect health at a rating of 1, that would be ten times one. If the individual then experiences five years of some kind of a decrement in health at a utility of 0.75, that represents 3.75 and so adding those ten years of perfect health and the five years of somewhat imperfect health you get a total number of QALYs of 13.75. So, it is really a straightforward measure

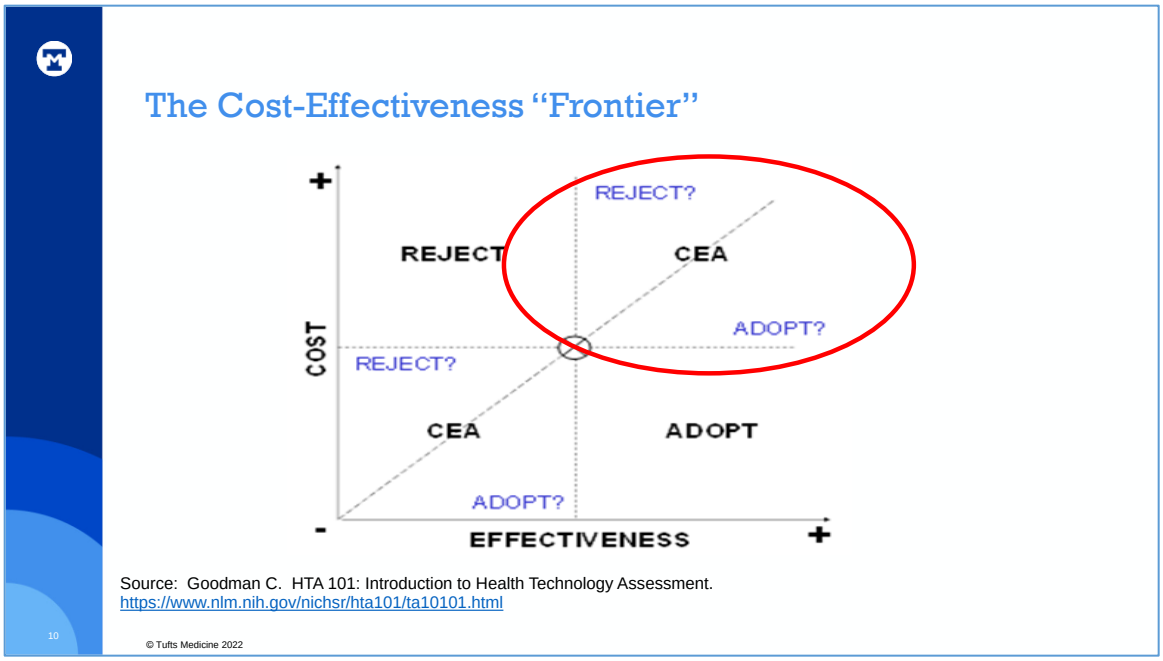
that is intended to try to reflect the impact of treatment on both length of life and quality of life.

I said it is simple, but it is not without controversy. In many settings, including my own country, there are many concerns from the patient community, for example about how QALYs are used to value individuals or you are valuing someone who is disabled or has severe disease at a value less than another individual. It is a bit of, what we might call in English "a red herring", that in fact the QALY as applied in cost-effectiveness analysis is typically used to value treatments, how treatments compare in terms of how they improve quality and length of life, not valuing individuals. And some might argue that the more serious the condition is the lower your utility, therefore the more headroom there is the more room there is to actually improve that with an effective treatment. So that is still a controversial conversation that is not likely to stop any time soon.



Cost-effectiveness: "Value for Money"
Minute 00:17:26

So again, the calculation itself is simple. Essentially for a new intervention, and in this example we are looking at a new therapy for Hepatitis C compared to an existing standard of care, you are looking at the incremental costs associated with that new treatment, which includes not only the price of the drug but the cost of monitoring, the management of side effects and other elements. You are subtracting the cost of treating the patient with the standard care therapy, soo you have incremental costs in the numerator. And then in the denominator it is the same calculation except of QALYs. So how many QALYs are generated by that new treatment, how many QALYs are generated by the existing standard of care and what is the difference. And the result is a ratio of incremental costs per QALY gained, so essentially how much do you need to spend to gain one QALY.



The Cost-effectiveness "Frontier" Minute 00:18:21

And then you can display these results on what we call the cost-effectiveness frontier. And what we are trying to do is look at that ratio in terms of its result and understand what you might do as a decision maker.

If you look at the lower right of this frontier you see the word "adopt". Essentially what that is saying to you, is that if a new therapy is both more effective and less expensive, if it actually saves money, then you would always adopt it because you are saving money and you are saving lives, essentially at the same time.

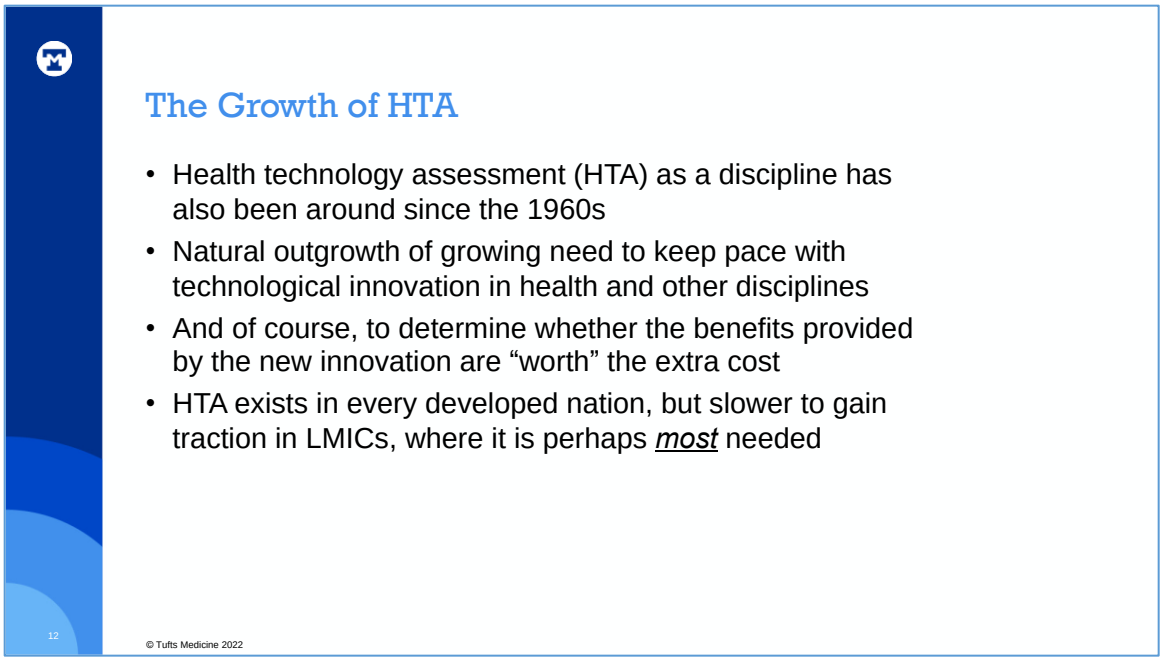
In contrast, if you look at the upper left of this frontier you would reject a therapy that costs more than the existing standard and is less effective because you don't want to bring in a new intervention that is effectively harming health at a greater cost.

On the lower left - we sometimes deal with this especially when we are thinking about generic medicines that might be replacing a branded product - something might be slightly less effective than the current therapy but could also be less expensive. I will talk about an example of this in a bit.

But most commonly, when you are thinking about adopting something new, you are looking at the possibility of bringing in a therapy that is both more expensive and more effective than the standard of care and so you then need to try to understand what exactly you can do as a decision maker, so what sort of parameters can be used to determine whether this investment is worthwhile.

Health technology assessment and value
Minute 00:20:00

Let´s move from there, once we have the calculation parameters in hand, to health technology assessment and its consideration of value.

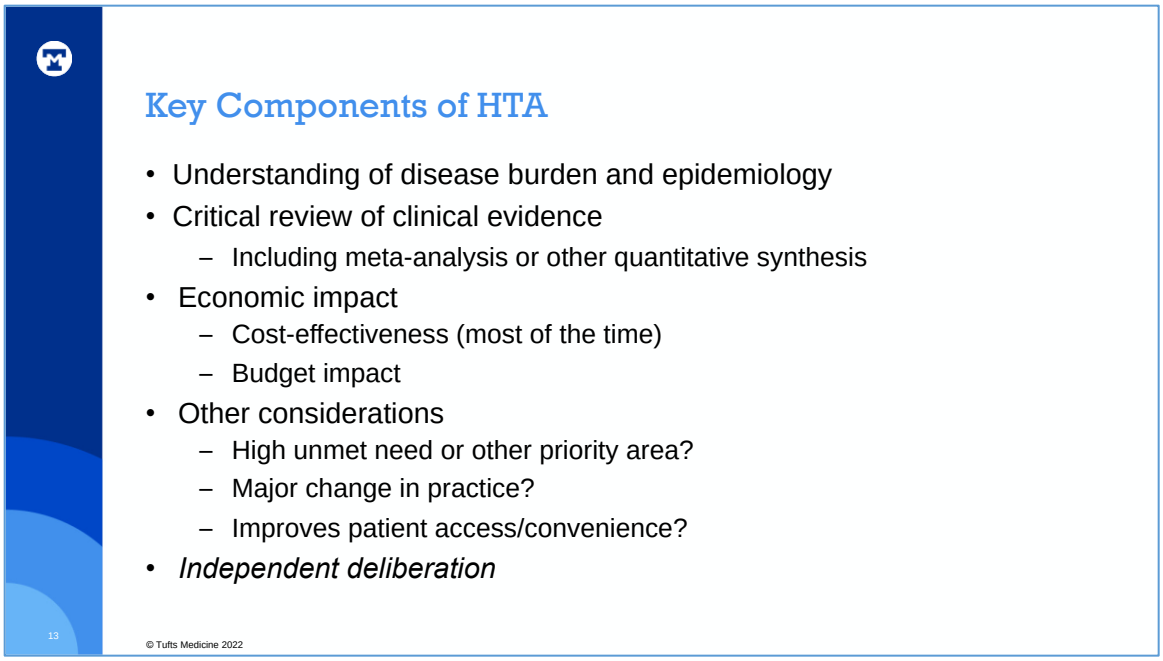


The growth of HTA
Minute 00:20:12

Health Technology Assessment has also, as a discipline, been around since the 1960s. And I would say technology assessment more broadly, not just in health, has been around since that time.
And really it was a natural outgrowth of a growing need to keep pace with technological innovation in health and other disciplines. And some of those other disciplines included a variety of industries such as defense, aerospace, environmental mitigation etc. And there is a growing need for the science to keep up with that growing pace of innovation.

And of course, turning back to health, or really any of these other disciplines, HTA´s purpose was also to determine whether the benefits provided by that new innovation are really worth the investment that the government or other decision makers might make.

HTA does exist in pretty much every developed nation but has been slower to gain traction in lower- and middle- income countries. And I might argue that this is where it is perhaps most needed where resources are most constraint and principle decisions need to happen. We will talk about that more as well.



Key components of HTA
Minute 00:21:27

What are the key components of HTA? And again, this is a very broad overview because we want to get through these comments and have time for both discussion as well as your questions. But it is important to understand that HTA is a societal and public good. It does not involve just economic analysis. And so really as a first principle there needs to be a good understanding of the burden of a given disease and the epidemiology of it to try to understand the context a new intervention or a drug is being considered.

There is a critical review of the clinical evidence, so to try to understand how the clinical effectiveness of this new technology compares to the existing standard of care. That may include some relatively advanced methods such as meta-analysis, the combination of multiple studies or other types of quantitative synthesis to really try to understand what benefit is being brought by this new intervention relative to the existing standard of care. And we do have economic impact. Cost effectiveness analysis is used widely within HTA but not all of the time. There are some jurisdictions - in terms of developed nations Germany is one example - where the incremental clinical benefit is really the most important factor that is considered at the point of HTA. Other economic considerations then follow on later during the period of negotiation and reimbursement.

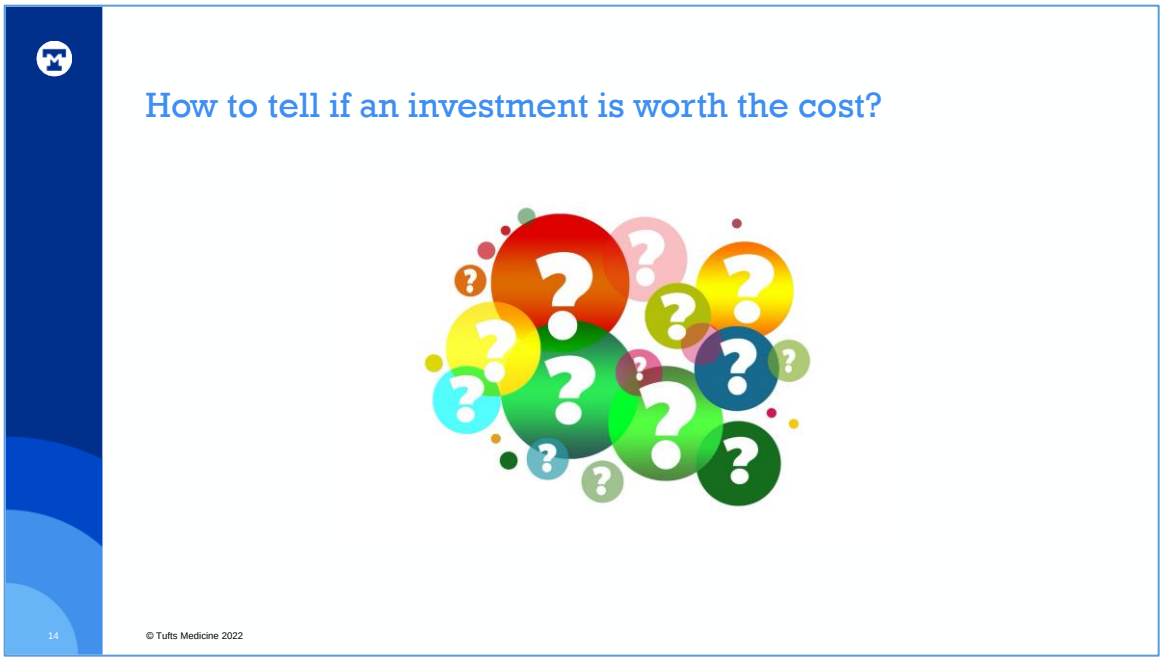
The budgetary impact is also critically important as well because looking back to that Hepatitis C example I provided, in many jurisdictions those new were very cost-effective at the level of the individual. They produced a lot of quality adjusted survival for an individual person and at a reasonable cost for that clinical benefit. But the population that was waiting for these therapies was so large that the budget impact often imposed many challenges for jurisdictions and health systems to be able to provide these drugs for everybody.

Other considerations fall outside of the quantitative analysis of the clinical data and the economic impact. So really even beyond that we are dealing with a situation where there is a really significant unmet need or other priority area. So you might have observed that with the development of COVID-19 therapeutics and vaccines, for example, the cost-effectiveness was really a secondary consideration if it was considered at all because getting control of the pandemic – which I know we are still struggling with – was thought to be such a priority that that was a secondary consideration.

Is there some sort of major change in practice that is being anticipated? So for example is a standard therapy that required a lot of monitoring potentially going to be replaced by a drug that does not require as much monitoring and so maybe frees up the health system to spend its resources elsewhere. Or conversely, is a new highly technological therapy being introduced that requires some shift in the health system in terms of being ready for it.

Does something improve patient access or convenience? Is the therapy able to be taken at home as opposed to going to the hospital or another facility? Is dosing less frequent than is required in standard therapy?

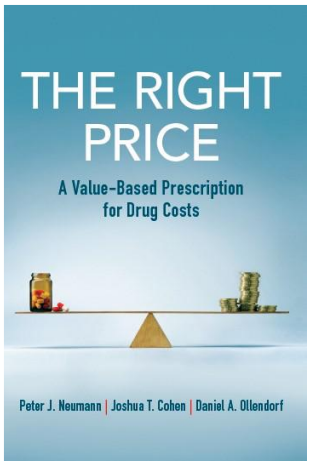
So those kinds of things don't easily fall into the quantitative analysis that HTA might do but they are certainly considerations that HTA has. And because of that most HTA bodies are agencies or other private organizations that produce their findings and results and share them with an independent committee of experts who represent different stakeholder groups, patients, clinicians, methodologists and others, who deliberate on this evidence themselves and then make a recommendation or decision independently of the HTA body. That is a very important step that really needs to make HTA work and be credible.



How to tell if an investment is worth the cost?
Minute 00:25:49

So again, even though all of these steps are taken, we have to return to that question: how to tell if an investment is worth the cost? As we have argued in our book the right price is a value-based price. What we mean really in our book is that aligning the price to the value of drug or treatment bring strikes an appropriate balance. It sends signals to manufacturers about the innovation that is really needed, and it also avoids paying so much that other valuable services are displaced. It really is that kind of sweet spot that sends the right signals for innovations but also represents a responsible investment for the health system.

The "right price" is the value-based price



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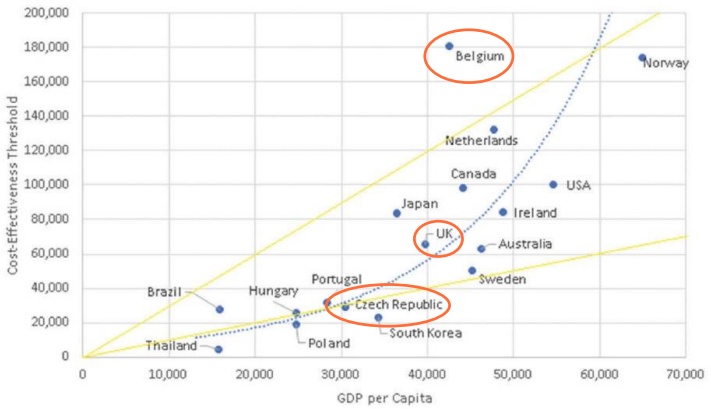
Decision-making thresholds



Source: Cameron D, et al. Global Health Action 2018
DOI: 10.1080/16549716.2018.1447828

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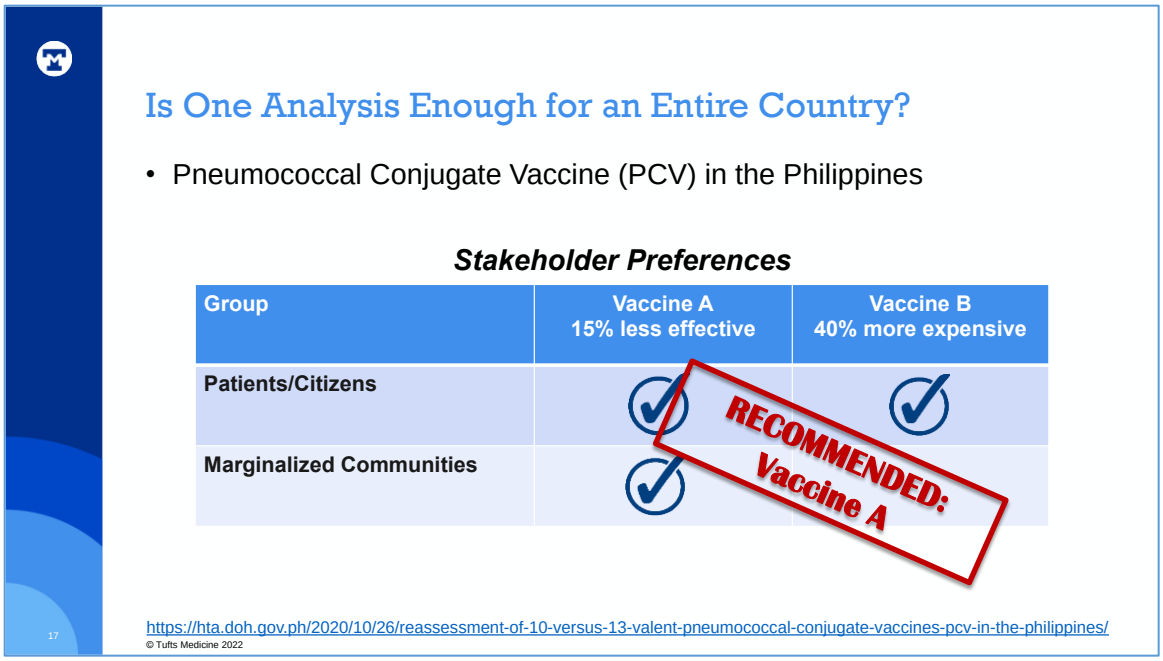
Decision making thresholds
Minute 00:26:43

The value-based threshold, so what threshold do we use to determine if something is of value, does differ by setting. For a long time it was thought that per-capita income, GDP per capita, was a good proxy for how much a given country was willing to pay, for example, for an extra unit of health, an extra QALY if you will. But as you can see here that's not always a great predictor.

We look at the UK, for example, these are purchasing power parity adjusted cost-effectiveness

thresholds in US dollars. You see that the UK is a little bit over 60,000 $ per QALY gained. GDP per capita in the UK is about 40,000$. But if you go to Belgium, which has a slightly higher GDP per capita, you see that the threshold for considering good value in Belgium is about three times as high as it is in the UK. And if you move down the scale, let´s say to the Check Republic, you see that the GDP for the Check Republic is maybe about 25% less than Belgium´s GDP but it´s threshold is six-fold lower.

You recall that I mentioned budget impact as an important step of HTA in terms of analysis. It is clearly more than GDP or income that is driving these numbers. And so it is really in many aspects how much each individual health system feels that it can afford that is an important parameter to consider alongside cost-effectiveness itself. And that is what that graph is really showing us.



Is one analysis enough for an entire country?
Minute 00:28:23

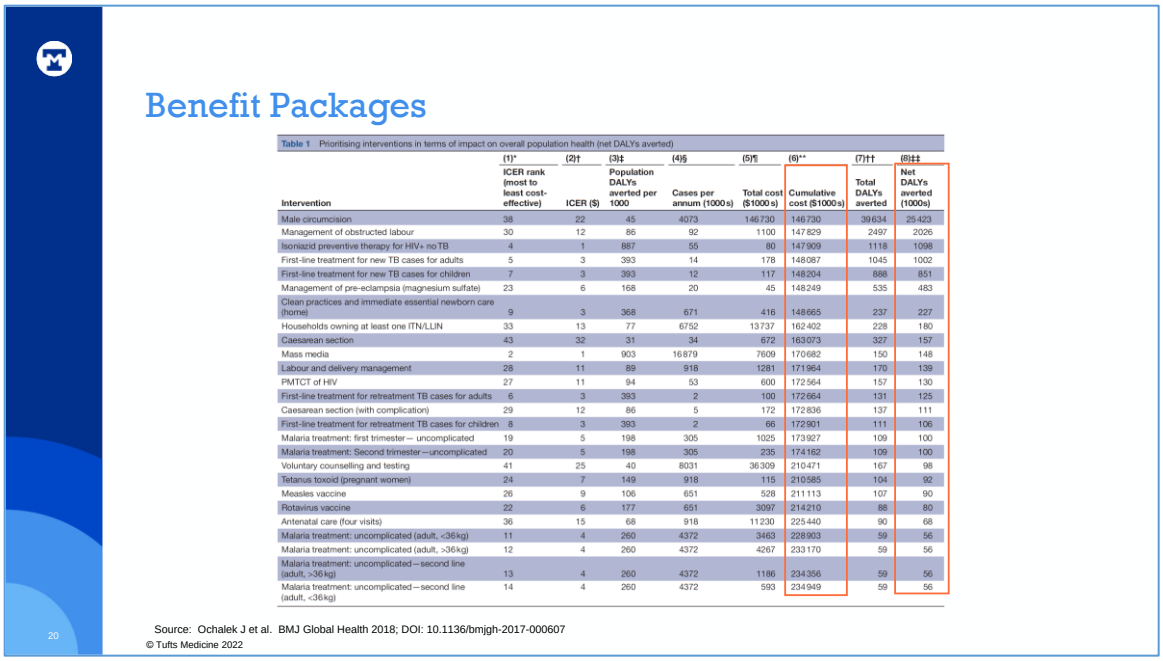
So a little bit of a departure here but I want to make sure that we think about not only economic impact, clinical evidence and some of those contextual considerations as important elements for decision making but we are also much concerned, across the world, with the potential equity of decisions that we make. Is really everybody able to access the gains in health we are talking about? The question is: is one analysis enough for an entire country and will all individuals be able to benefit from a new intervention at the same level? I am bringing in an example that explicitly deals with equity. And this comes from the Philippines. This is an assessment of the Pneumococcal Conjugate Vaccine in the Philippines. Pneumococcal disease is a big challenge worldwide but especially in LMICs because there is very serious pneumonia and meningitis in many cases. In this case the HTA body in the Philippines was considering two different versions of the vaccine. I am just calling these versions A and B for simplicity. Vaccine A was about 15% less effective than vaccine B but Vaccine B was 40% more expensive. And the Philippine HTA body did something very interesting in that they commissioned a survey of two important stakeholder groups, one representing patients and civil society, and the other representing leaders of historically marginalized communities, those who have had challenges with access in health care. When the patient citizen group was surveyed about which vaccine they prefer, initially they went with the more effective but more expensive vaccine. But then when they were told about the challenges with budget impact and that the budget would not be able to allow for everyone to receive this vaccine they changed to the less expensive and potentially more equitable choice. And similarly, leaders of marginalized communities overwhelmingly viewed vaccine A as the appropriate choice for the country because all individuals would be able to benefit. As a result, the HTA body actually ended up recommending the less effective but less expensive vaccine, so that lower left quadrant of the frontier that I was talking about.

Value-based pricing in LMICs: history and considerations Minute 00:30:57

Ok, we have done our historical tour. Now let´s talk about value-based pricing in LMICs, what is the history there and what sort of considerations should we think about in terms of implementing value-based pricing.

Value assessment in LMICs
Minute 00:31:15

Historically value-based assessment in LMICs has focused on two different needs. One is the design or redesign of an essential benefits package or medicines list in this case. And the other is the adoption of individual technologies, so what we might consider a single health technology assessment for a single decision.



Benefits packages
Minute 00:31:39

Let´s talk about benefits packages for a second and here is an example from Malawi, a lower income setting where there was determination about – as the country was moving from relying predominantly on donor aid to being able to fund some resources itself – the need to make decisions about what the highest priority interventions would be. The decision in this setting was based on the number of DALYs averted. As I mentioned, DALYs averted is essentially equivalent to QALYs gained because of the difference in scale. The more DALYs you avert the better the population health is. And on a population basis these interventions were ranked in terms of how many DALYs they would avert.

And then additionally they were assessed in terms of their cost to the system and that cost was accumulated over each intervention, so you see that the numbers go up as you go down the column. And the decision then is made to essentially fund those therapies and interventions that avert the most DALYs, essentially until the health system runs out of money. And then that is the line below which you can find no further intervention. It is a relatively straight forward process that determines what is essential to maximize population health based on the health gained by these interventions. We have other examples from countries, including Ethiopia, for example, which redesigned its essential health benefits package. In that case they used an incremental cost effectiveness ratio to rank order their therapies and interventions. And they also included considerations of equity and financial risk protection, so looking at what is the total amount of financial risk that a particular intervention or therapy is avoiding for a particular individual or household to be able to then essentially access the health they need. There are some other considerations included as well but it is a relatively similar effort.

Technology adoption
Minute 00:33:58

It is a bit more complicated when we get to technology adoption. The question is: Do LMICs really need to conduct value assessments of individual drugs or other technologies? Is that really important to them?

Here are some examples of pretty poor buys, kind of wasted money in LMIC settings that would have benefited from value assessment. One of the most common is the genexpert diagnostic test for TB and for multi-drug resistant TB and for HIV. These tests were widely marketed in LMIC settings. Much of the adoption that happened initially was done without any sense of cost-effectiveness or value in those given settings as well as with those health systems if they were paying for health care what they were able to afford. And in many situations those settings ended up being priced out of the ability to use these tests in populations that would benefit. And you then started to see calls for reduction in the price, calls to the manufacturer to reduce their price to really make that technology, which did have some value in LMIC settings, more accessible to those settings.

There are other examples as well and many of these have to do with important and potentially cost-effective interventions that were applied in the wrong populations. So preventive cardiology treatments, for example, in Tanzania, as opposed to being provided to medium- and high-risk individuals where these therapies would have been cost-effective, providing them to individuals at all risk levels.

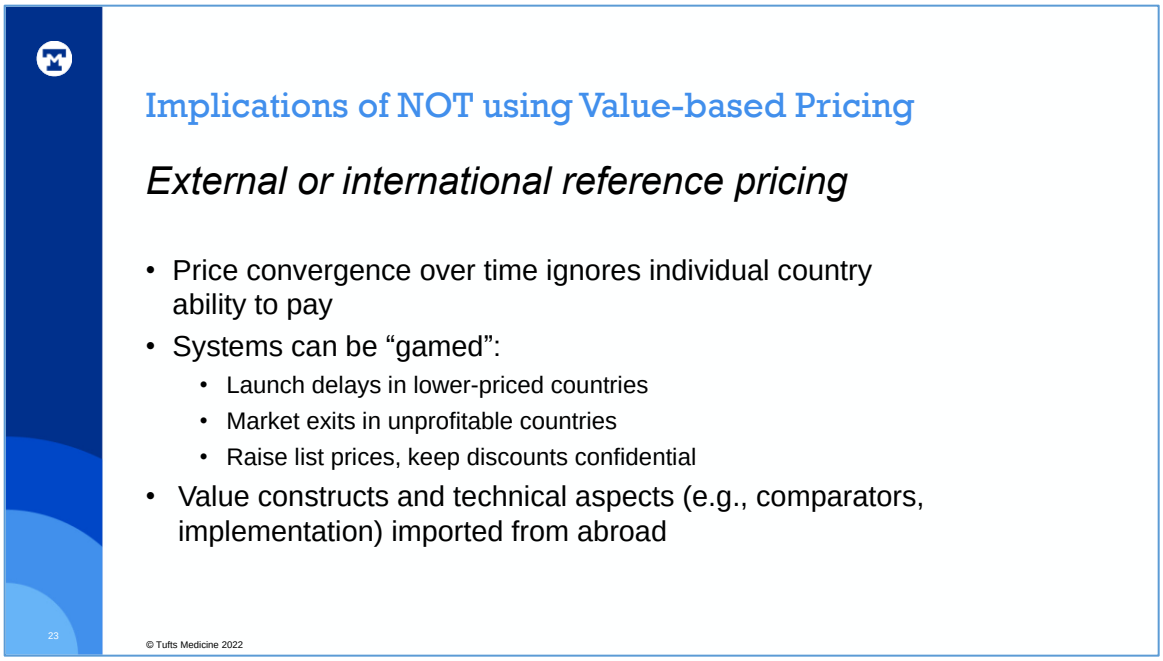
Diabetes screening in Thailand and Indonesia starting at age 15, which is really unnecessary until alter ages and so that is another challenge.

Pre-employment drug testing in Bhutan, that was done universally without regard to the potential risks associated with the given individual. So these are other examples where decisions were made to employ an intervention really in a broad population where a narrow use would have been a more cost-effective employment of resources.

Implications of NOT using value-based pricing
Minute 00:36:23

Ursula has actually published on other implications of not using value-based pricing besides the investment itself. Really the cost of overspending relative to the value that an intervention might bring cannot just be expressed in currency but in terms of lives lost. Health systems that overpay for high priced technologies, for example, and because of that cannot fund broad population-based interventions, are essentially sacrificing population health to make that purchase decision. That is a major challenge for these settings. It is something that hopefully we will be working on together moving forward in given settings, to really help governments and decision makers understand that they need to think about those essential benefits that are going to maximize population health first and then think about the adoption decision of something that might be a higher technology intervention.

And even when they are making those secondary considerations of those high-tech interventions to think about the value those interventions bring relative to price and be able to negotiate that price based on the value.



Implications of NOT using value-based pricing
Minute 00:37:39

Another implication of not using value-based pricing is that many LMICs use some form of price controls but there are major challenges associated with them. Let´s talk about external or international reference pricing, which is widely used in LMICs to try to control cost growth for pharmaceuticals. Often times these processes result in price convergence over time, so that´s ignoring an individual country´s ability to pay for health. And because the price converges essentially to one global price some settings are priced out of the ability to afford that drug.

The systems can also be gamed in multiple ways. There can be launch delays in lower price countries so the products may not be available so that the price can be kept higher in the reference pricing index for those higher income countries that can afford the drug.

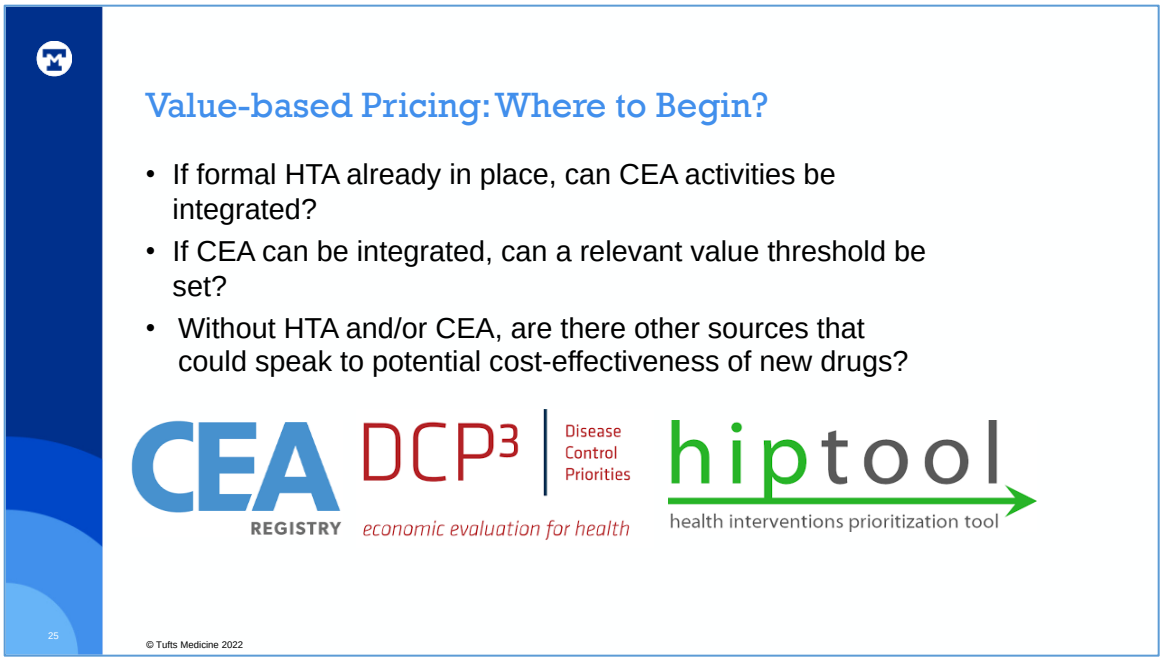
There could be market exits in countries that are felt to be unprofitable because the reference price is too low, again reducing access to patients.

In some cases, manufacturers might raise their list prices keeping the reference index high, apply discounts so that the individual health systems save money but keep those discounts confidential so that you cannot actually see those prices.

But most importantly the value constructs and the technical aspects of a reference pricing approach means that in some cases you are importing the societal value of notion from other countries into your own. So it is not really done with the ability to think what is of value to your own setting and what your health system can afford to spend.

Value-based pricing in LMICs: recommendations
Minute 00:39:26

So let´s conclude with some recommendations. We have seen the history and the challenges associated with value-based pricing in LMICs. Let´s think about how to move forward.



Value-based pricing: Where to begin?
Minute 00:39:39

A formal HTA is already in place in a fair number of LMICs but cost-effectiveness activities are not currently integrated. Can they be? And if cost-effectiveness activities can be integrated, can a relevant value threshold be set for a given country?

Let´s talk about how to do that in a minute. But even without formal HTA or CEA, are there other sources that could speak to the potential cost-effectiveness of new drugs?

And there are tools out there. Our center maintains a registry that now numbers over eleven thousand cost-effectiveness studies that have been published worldwide on drugs, devices, public health interventions and other types of health programs and so it is something that can be searched and relevant studies can be identified either within a given country or in a similar setting. Similarly, the DCP effort has created a library of economic evaluations for health and the ability to use those data to identify priorities for funding. Finally, the hiptool, which has been developed by University College London, with support from the World Bank, is helping countries prioritize interventions through the use of cost-effectiveness data and the data may be local or it may also be set as a default from resources like the CEA registry and DCP but also allows for the inclusion of other elements equity scores, financial risk protection and other approaches to try to optimize the health package for a given country. So there are tools out there that can help systems understand what the potential cost-effectiveness of a new therapy is even if they don’t have formal HTA or CEA in place.

Threshold-setting Guidance

- Based on relationship of local health spending to health outcomes, income elasticity of demand for health, and country income

Table 1

Example results for a range of countries and the World Bank income classification cutoffs (2013 GDP per capita)

Country/income classification	PPP-adjusted (2013 US $)		Actual values (2013 US $)		Threshold as % GDP per capita
	GDP per capita	Threshold range[2]	GDP per capita	Threshold range[2]	
Country					
Malawi	780	9–401	226	3–116	1–51
Indonesia	9,559	1,298–4,914	3,475	472–1,786	14–51
Chile	21,911	6,819–13,141	15,732	4,896–9,436	31–60
Kazakhstan	23,206	7,648–13,675	13,610	4,485–8,018	33–59
United Kingdom	36,197	18,609–18,609	41,787	20,223–20,223	48–48[1]
Canada	43,247	21,051–26,564	51,958	25,292–31,915	49–61
United States	53,143	24,283–40,112	53,042	24,283–40,112	46–75
Norway	65,461	28,057–60,862	100,819	43,211–93,736	43–93
Income classification					
Low/middle income[1]	1,045	16–537	NA	NA	1–51
Middle/high income[1]	12,746	2,307–9,028	NA	NA	18–71

Woods B et al. Value Health. 2016 Dec; 19(8): 929–935.

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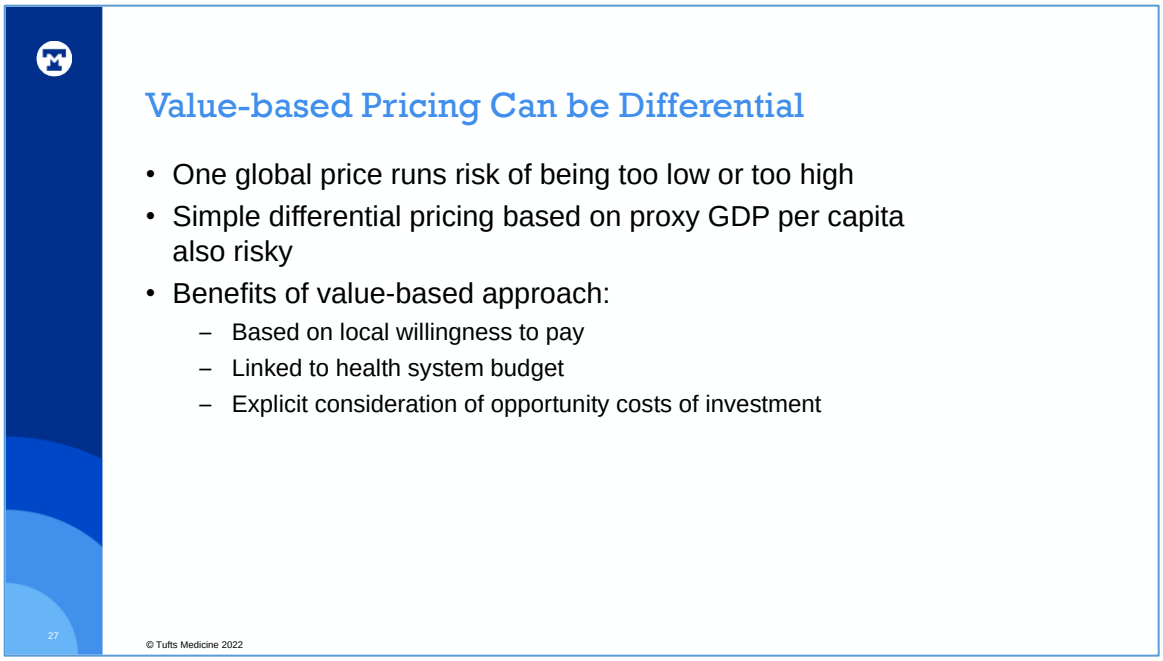
Threshold-setting guidance
Minute 00:41:37

So how to set this threshold regardless of the formality of your own approach? There has been work done by the University of York that looks at the relationship of local health spending – again that budget – to health outcomes, the measure of the demand for health benefits in the population and to a certain extent country income, but not in the same way that those GDP per capita proxis were used. Here is an example from one of the papers that has come out from this group. What speaks to that kind of inaccuracy of GDP per capita as a proxy is this measure. So the calculations that have been done using these factors outlined in the calculations that have been done using those factors outlined in the bullet above, really regardless of the income level of a given setting. Those thresholds are far below estimates of GDP per capita in all of these settings whether low-, middle- or high-income.

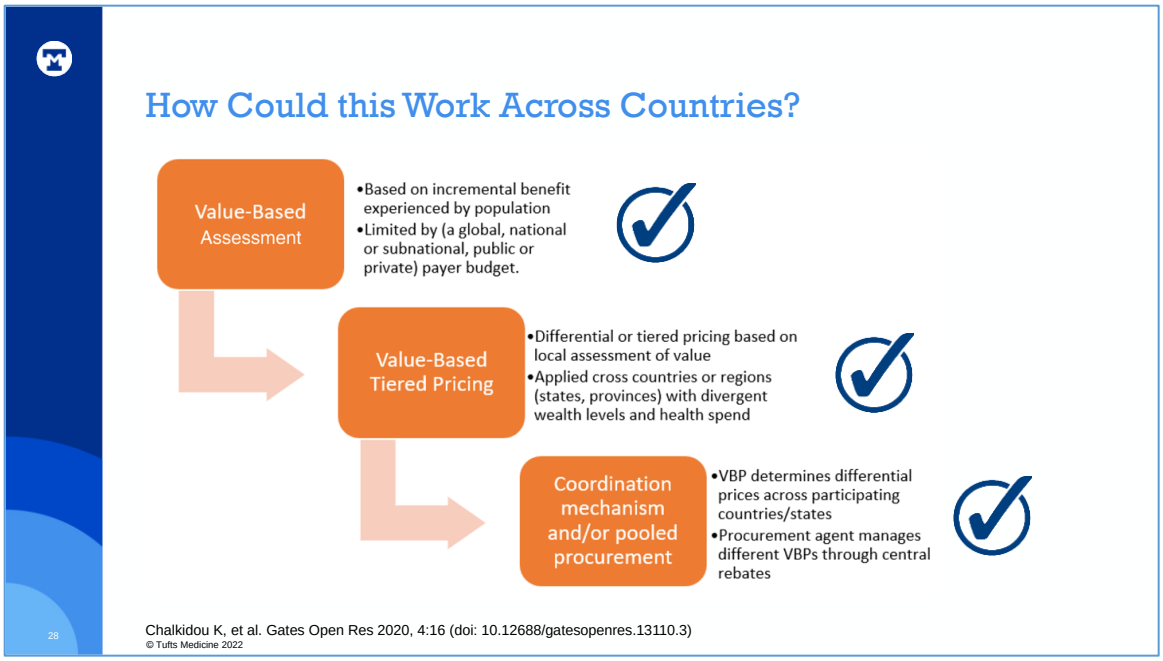


Value-based pricing can be differential
Minute 00:42:43

Value-based pricing can also be differential across countries. It is not as though we would as a community argue for a value-based price that could be shared across countries, for example.
As I mentioned, one global price, as sometimes we arrive at with reference pricing runs the risk of being too low or too high.

Simple differential pricing based on something like GDP per capita is also risky because it is not necessarily reflective of what those individual health systems can afford.

So the benefits of a value-based approach is that they are based on some estimate of the local willingness to pay and that they are linked to the health system budget either indirectly or directly, so that you are not outstripping your own resources. And there is an explicit consideration of the opportunity costs of the investment. So is a given country able to invest in a new product that will improve health as long as it doesn't do that to the detriment of overall population health.



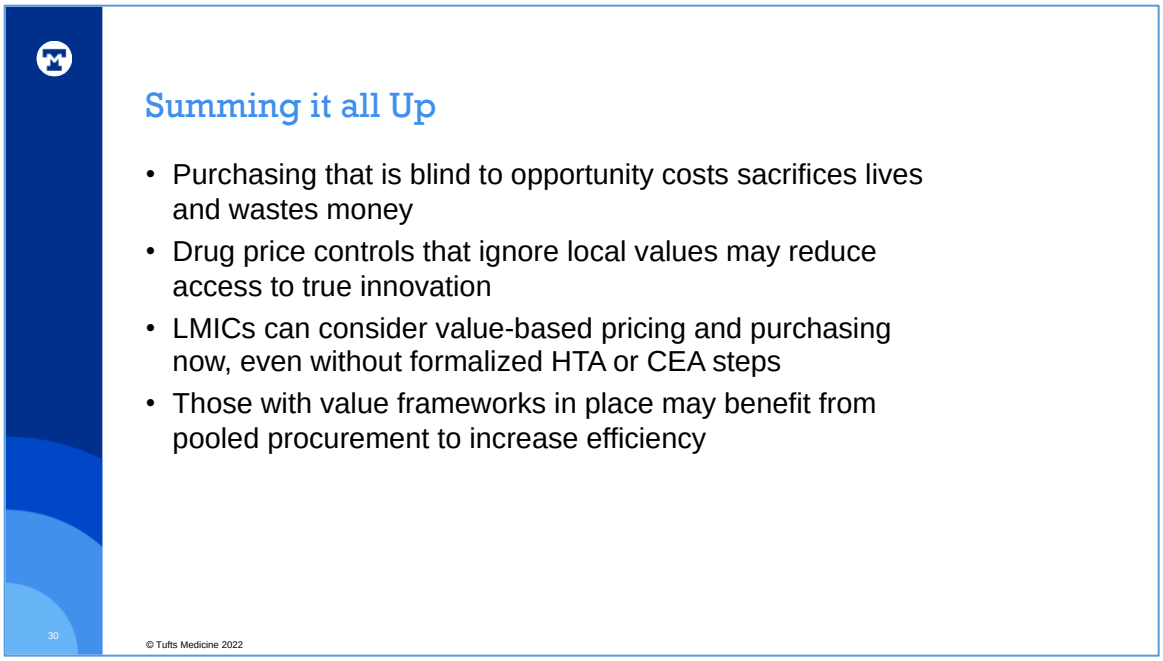
How could this work across countries? Minute 00:43:50

Could this work across countries? There is work done by Kalipso Chalkidou and colleagues that has been thinking about how to move from value-based assessment essentially to value-based procurement.

So we talk about assessment the way that we have talked about it technically in this conversation; Incremental benefit experienced by a given population that is limited in some way by the availability of the health system budget.

Then differential or tiered pricing based on local assessment of value; So different countries have different willingness to pay thresholds essentially based on those parameters and so they are applied across countries sometimes even regions within a country will differ or other jurisdictions. In my country it would be the individual payers that would differ in terms of their threshold for benefit.

Once all of those differential prices are set then there could be some international procurement exercise that would allow for those differential prices to be considered but then the procurement agent manages those different value-based prices through some sort of central rebating system. So it becomes an efficiency for the manufacturer to deal with one body rather than six or eight countries. There are examples of this already happening in high-income setting, the Beneluxa initiative, for example in Europe, is a purchasing corporative with a number of different countries involved all of whom have very different thresholds for what they consider value but this procurement is done in a coordinated way.



Summing it all up
Minute 00:45:35

Purchasing that is blind to opportunity cost, as we have discussed, sacrifices lives and wastes money. Drug price controls that ignore local value may actually reduce access to true innovation in some cases in those settings that need it most.

LMICs can consider value-based pricing now, even without formalized HTA or CEA steps in place. Our hope certainly is that all countries will be able to benefit from these steps but in settings where it is not feasible yet there are still things that can be done.

Those with value frameworks in place may benefit from a pooled procurement exercise, as I just mentioned, to increase efficiency.

Questions and answers

Minute 00:47:17 Katherine Del Salto: Many people are asking whether you have examples of how to set a different threshold, something you talked about a little bit towards the end of the presentation, and also if you have particular examples where countries have included other categories such as equity, severity of disease, spillovers or productivity. And I think also within this, the notion of the value of health as if it is a dichotomy towards the right to health when it isn't – personally I think it isn't – and we need to talk about value if we are serious about guaranteeing access to health.

Dan Ollendorf: So there is a lot to unpack in that question. So one thing that we also talk about in our book and that I also continue to talk about in a number of other settings, is that I view cost-effectiveness as a necessary input into a health technology assessment exercise. It is necessary, it is critical, but it is not sufficient on its own. So even if there is a defensible process used to set a reasonable threshold for decision making for a country, those other considerations have to play a role because if you rely strictly on cost-effectiveness findings you can make a decision that may not potentially harm overall population health but may harm other aspects like equity that can either directly or indirectly then contribute to challenges to population health. So the Philippine vaccine example is a perfect example of that. So there is a choice made to fund something that was less cost-effective in the abstract but much more equitable that all individuals have been able to access. So that's really why this has to be kind of a key input into a broader conversation that is hopefully done independently.

In terms of setting thresholds interestingly the York group has expanded their work from that initial publication I was describing to a proposed threshold for something like a hundred and twenty countries worldwide. So that is potentially a useful starting point for countries thinking about a threshold that considers not only the income of the country but the realities of a health system budget and the general demand for health benefit. It may be in a given setting that that may be a starting point but has to be adjusted based on the realities of the health system budget. In lower income setting there is the challenge that some care is funded by a country government or ministry and some care is still relying on donor aid. And so some of the exercises of essential benefits that I was describing in my talk, actually ended up changing the essential benefits list in some circumstances because there were donor aid priorities that were not on the list. And so they put those essentially back in the list. Therefore, the ability to make some of those decisions is an important consideration as well. But I think that starting with the York work is probably a good first effort for countries that are thinking about setting their own threshold.

Katherine Del Salto: Is there any experience of regional threshold setting? You talked about regional recruitment or pooling the demand or these processes, but does it even make sense to try to set regional thresholds or which parts of this process could be shared to make it more efficient?

Dan Ollendorf: That is an interesting thought. Maybe I have two answers. I think that setting a regional threshold has a lot of challenges associated with it, particularly if the resources and if the

health care that is provided is not shared itself. So if the budget is not shared then setting a regional threshold may not make the most sense. That is not to say that regional efforts to consider clinical evidence and potentially even to evaluate cost-effectiveness with a general model that could be customized for a given country, for example, are not feasible. We know – and it is again using high-income settings as an example – that in Europe the voluntary European Network for HTA or EUNETA has done clinical assessments through a number of years. That is now transitioning into a regulated effort, so the European Union is now regulating and mandating these joint clinical assessments across all of the EU member states while still allowing individual economic evaluation and population considerations to play a role as well. How that actually ends up shaping up we have to see how that plays out over the next few years but there are definitely examples of regional corporation in health technology assessment that could be applied in a situation like it is perfectly feasible to think about individual cost-effectiveness analysis in those participating countries as well as individual thresholds.

Katherine Del Salto: This idea of putting value into the decision is also a political decision. Marcus asks here: From your experience, which factors have hindered the development of value-based pricing and the adoption of HTA in LMICs and if you have seen a way to bring these topics onto the decision-making table?

Dan Ollendorf: It´s a very good question. I think there are so many factors associated with why the growth has not been more significant. At times this is, without question, a political exercise. HTA becomes a political animal because it is trying to serve so many stakeholders at the same time. It is not just the ministry of health or the health system, it is also the patient community, the manufacturer community, civil society and others. And oftentimes the interests of those communities differ with each other. And so that becomes a challenge. And there are examples of HTA getting political support and starting off the ground only to be discontinued because there was a change in government or political alliances shifted. So that has been a major challenge. Another, quite frankly, is that this is a relatively rarified community in terms of technical expertise. So there is a significant need for training, for capacity building to do this kind of work in these settings. You do see a lot of NGOs and academic institutions who are trying to help that happen but until there is really a collective on the ground in a given country who can do this work themselves, it is difficult to think about having HTA really get off the ground.

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