WEBINAR TRANCRIPTION:

HOW TO IDENTIFY THE MOST IMPORTANT INTERVENTIONS AND THE VALUE OF EXPANDING HEALTH PACKAGES?

Presented by Jessica Ochalek. July 19, 2018.

IDB

CRITERIA

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HOW TO IDENTIFY THE MOST IMPORTANT INTERVENTIONS AND THE VALUE OF EXPANDING HEALTH PACKAGES?

July, 2018

This transcription is based on the webinar presented by **Jessica Ochalek** to CRITERIA.

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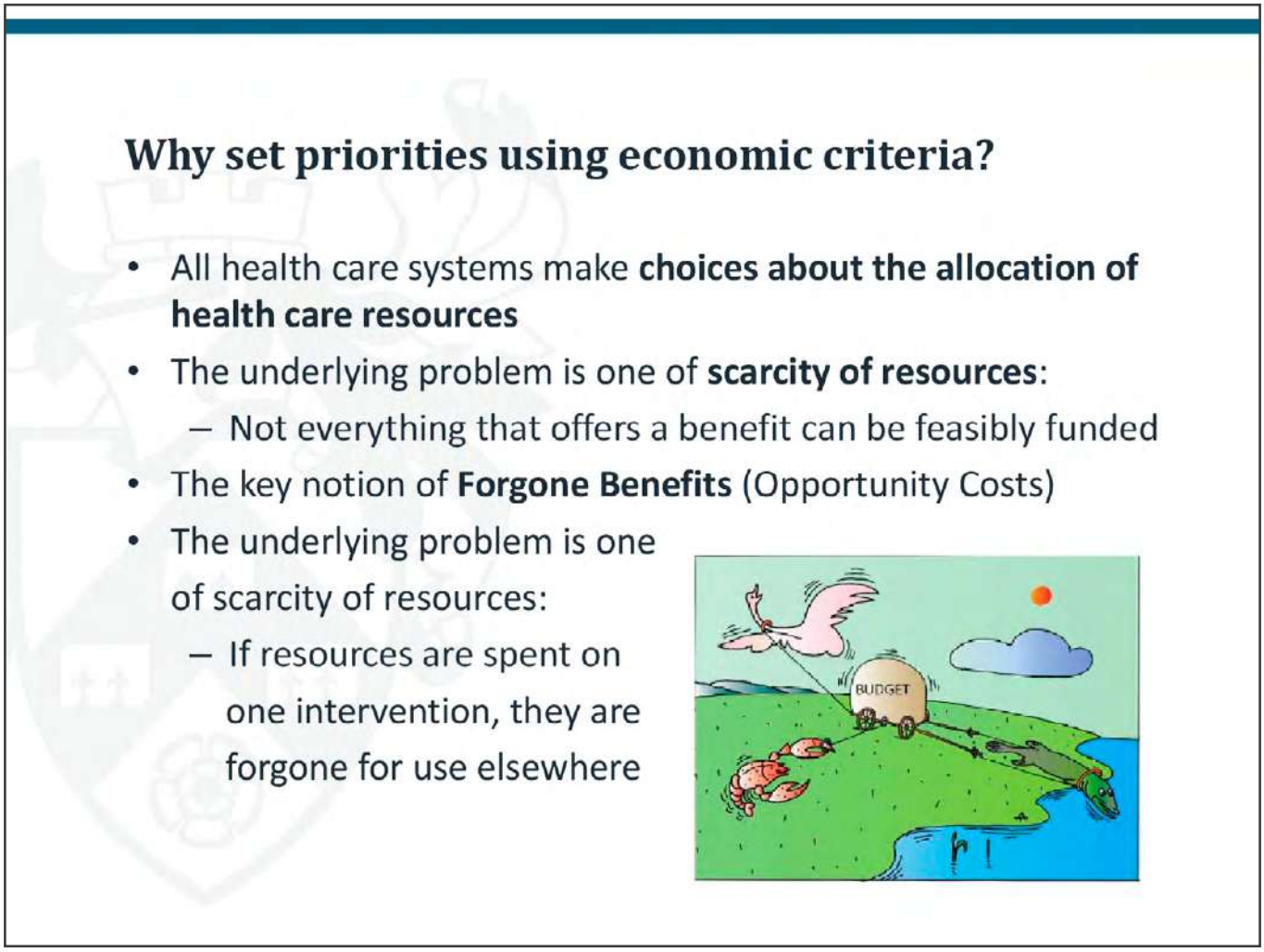
INTRODUCTION

(Min. 00:04:27)

As Pamela said, I am Jessica Ochalek. I am from the Center of Health Economics at the University of York, where my research focuses on methods for priority setting. I have been involved in work around health benefits package design and the estimation of cost-effectiveness thresholds representing health opportunity costs.

This talk is going to focus around the key inputs that we need to know for health benefits package design and how they can be used to inform key questions in package design around best buys for the healthcare system, or determining those things that legitimate the most overall popu-

lation health. We will also look at how to incorporate additional objectives, in addition to maximizing health and how to prioritize investments in scaling-up interventions that aren't provided fully and considering health system strengthening.

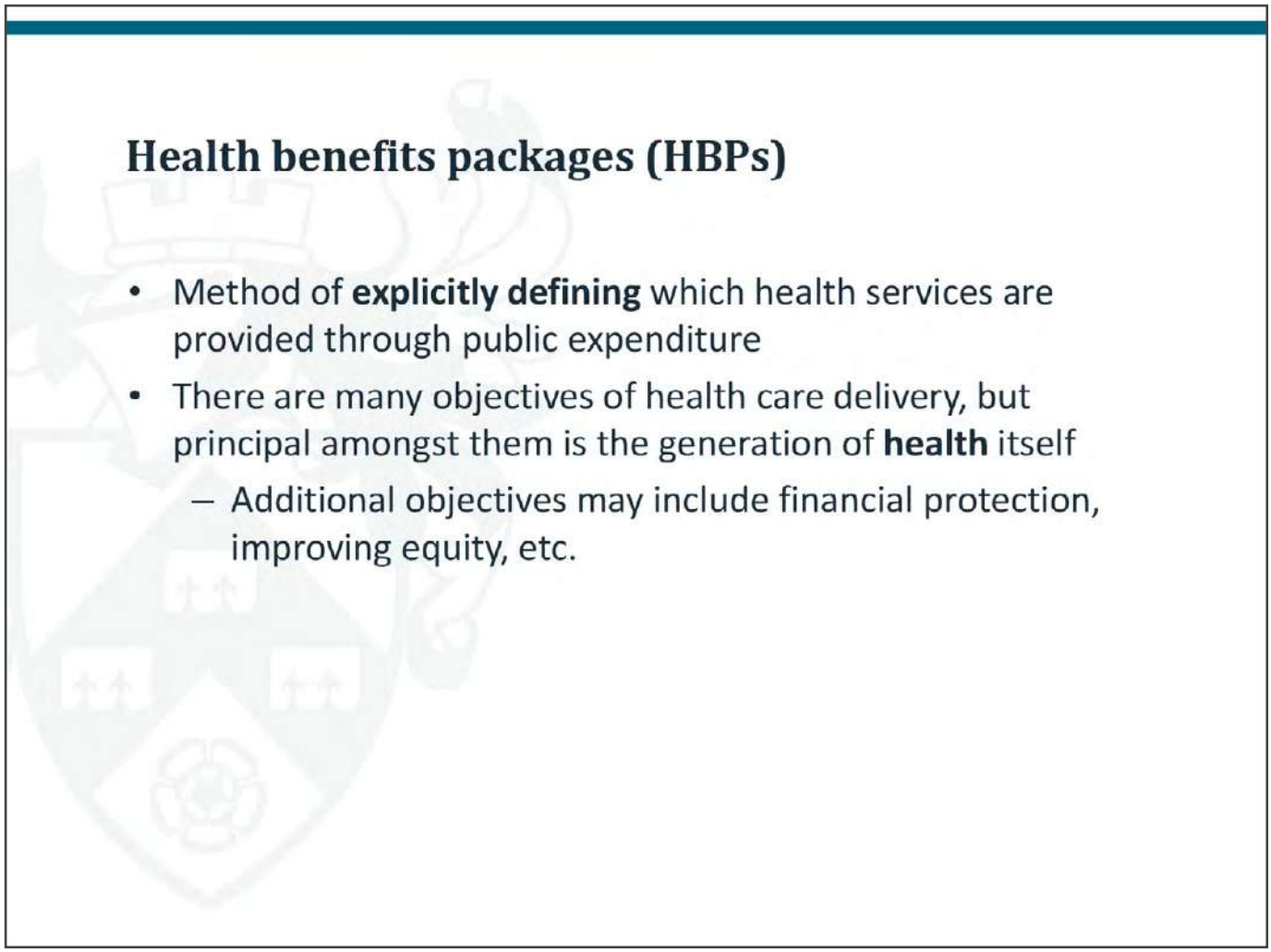


WHY SET PRIORITIES USING ECONOMIC CRITERIA?

(Min. 00:05:23)

So why bother setting priorities using economic criteria? All healthcare systems make choices about the allocation of healthcare resources. The underlying problem that we face is one of scarcity of resources. Not everything that offers a health benefit can feasibly be funded. So the key notion that we are working with is one of foregone benefits, or as we call them in health econom-

ics: opportunity costs. So if I book a trip home to visit my family that means that I cannot afford to pay for some of the repair works that I need to be doing on my house and there are potentially infinite things that I might want to spend my money on right now, but I have to choose between them because at any given time my budget is limited. The same applies in healthcare where there is potentially infinite demand for health, but we cannot provide everything. So if we don't decide how resources are allocated, allocation will be done implicitly. What is likely to happen is that people with more money and better access will get more care. So there is a role for economic criteria to ensure that resources are explicitly allocated in the most fair and efficient way possible, or in other words, in the way that generates the most health for as many people as possible.

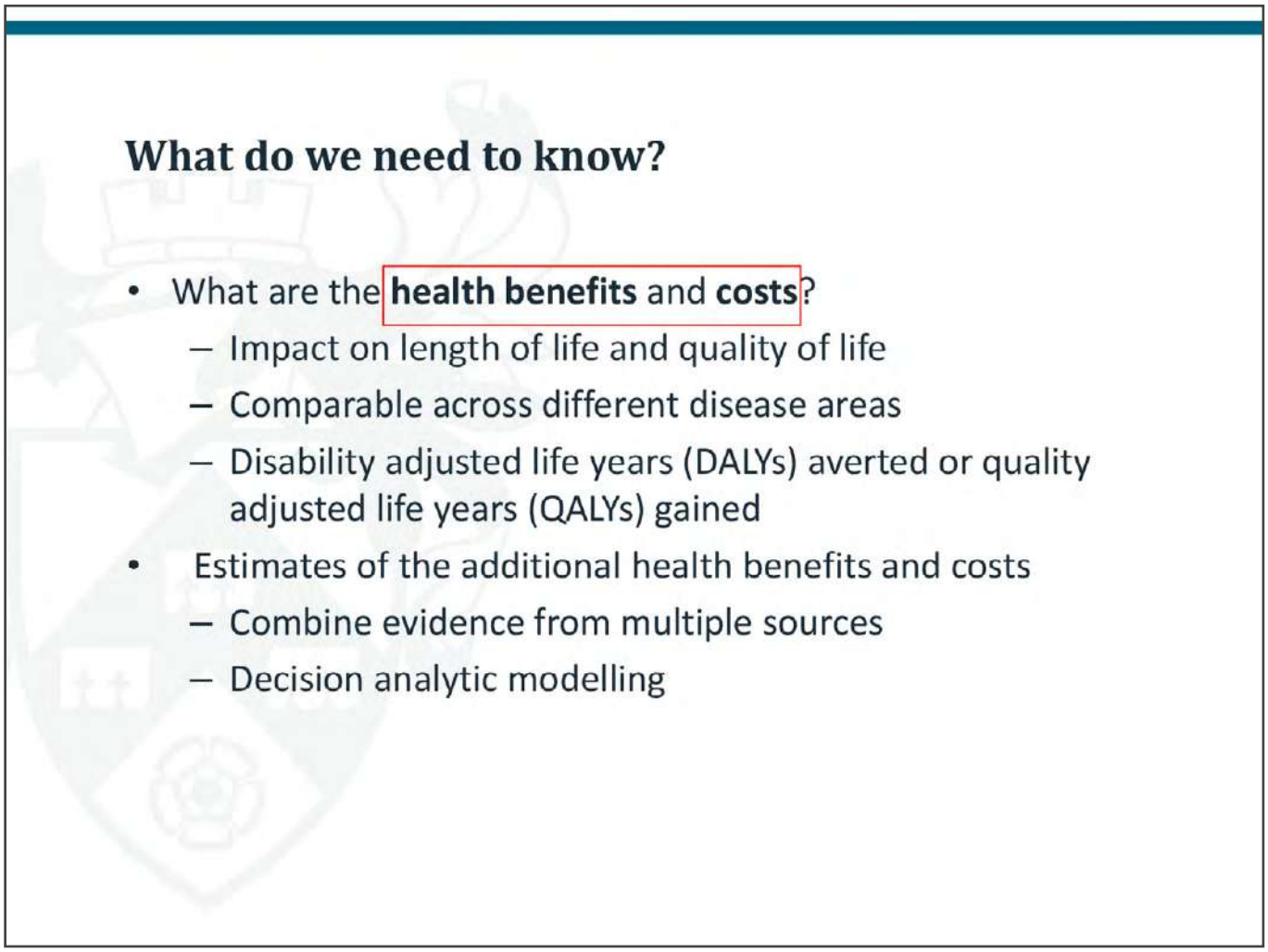


HEALTH BENEFITS PACKAGES

(Min. 00:06:34)

Health benefits packages are an increasingly common way of explicitly defining which health services are provided through public expenditure as we make progress towards the Universal Health Coverage. The World Health Organization has defined Universal Health Coverage as ensuring that all people have access to needed health services, including prevention, promotion, treatment, rehabilitation and palliation, of sufficient quality to be effective, while also ensuring that the use of these services does not expose the user to financial hardship. Although there are many objectives of healthcare delivery, generating health is core to these. Additional to this, we might also be entrusted in financial protection, for example, and in improving equity. We can use

methods to trade off the gains in health with gains in these other objectives, which I am going to address this a little bit later on when I start talking about package design in a bit more detail.



WHAT DO WE NEED TO KNOW?

(Min. 00:07:33)

I am going to start with what we need to know to define a health benefits package that maximizes health. And later on, when I get into package design in a bit more detail, I will talk about how to incorporate these other objectives and how to decide what interventions to scale up and where to make investments in healthcare system strengthening. To do any of this we need to know some basic key things. These are good to know whether interventions are good value for

money. We need to know something about the health benefits that they offer and their costs. For example, one intervention might avert infant death from neo-natal sepsis, another intervention could avert malaria cases and still another could improve the quality of life for people who are living with a chronic disease. So how can we compare the cost of averting a case of malaria against the cost of averting an infant death or against the cost of improving the quality of life of someone with a chronic disease? What we need is a measure that is comparable across disease areas, but it needs to account for the length and quality of life.

We have two commonly used measures that capture length and quality of life. These are: Disability adjusted life years averted and quality adjusted life years gained, or DALYs averted and QALYs gained. These have some differences in terms of how they are calculated but what is important is that they are the same in what matters most, which is that they are both generic measures that capture the length and quality of life.

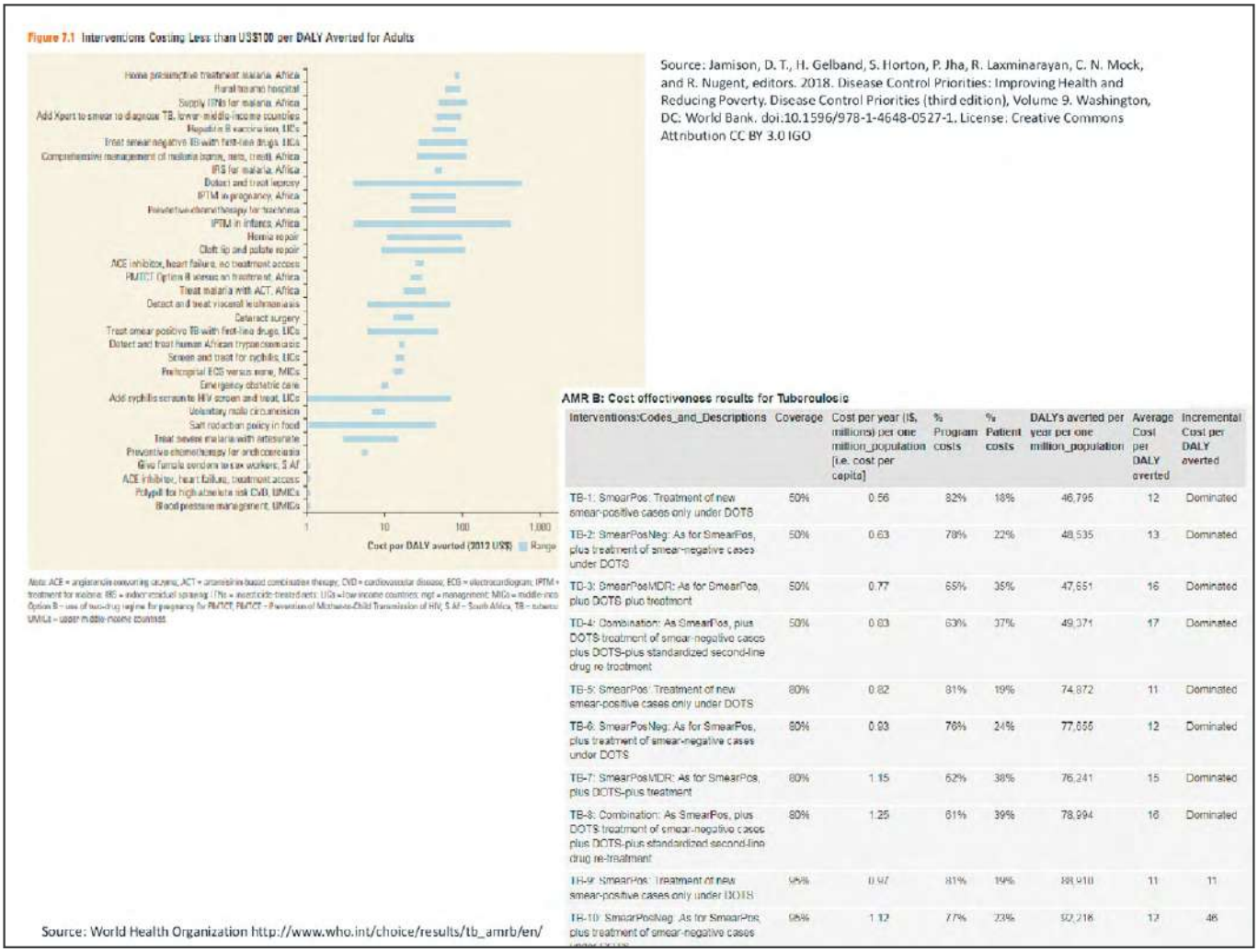
What do we need to know?

- What are the **health benefits** and **costs**?
  - Impact on length of life and quality of life
  - Comparable across different disease areas
  - Disability adjusted life years (DALYs) averted or quality adjusted life years (QALYs) gained
- Estimates of the additional health benefits and costs
  - Combine evidence from multiple sources
  - Decision analytic modelling
- Summary measure of cost-effectiveness
  - Incremental cost-effectiveness ratio (ICER)
    - Cost per disability adjusted life year (DALY) averted
    - Cost per quality adjusted life year (QALY) gained

WHAT DO WE NEED TO KNOW?

(Min. 00:09:25)

We also need estimates of the per-patient cost of providing the intervention. To get these estimates and the estimates of health effects we are often required to combine evidence from multiple sources. We tend to use Decision Analytic Modeling to do that. And the end result is often that there is an incremental cost-effectiveness ratio. So that is a cost per DALY averted or cost per QUALY gained ratio.



Source: Jamison, D. T., H. Gelband, S. Horton, P. Jha, R. Laxminarayan, C. N. Mock, and R. Nugent, editors. 2018. Disease Control Priorities: Improving Health and Reducing Poverty. Disease Control Priorities (third edition), Volume 9. Washington, DC: World Bank. doi:10.1596/978-1-4648-0527-1. License: Creative Commons Attribution CC BY 3.0 IGO

AMR B: Cost effectiveness results for Tuberculosis

Interventions:Codes_and_Descriptions	Coverage	Cost per year (I$, millions) per one million_population (i.e. cost per capita)	% Program costs	% Patient costs	DALYs averted per year per one million_population	Average Cost per DALY averted	Incremental Cost per DALY averted
TB-1: SmearPos: Treatment of new smear-positive cases only under DOTS	50%	0.56	82%	18%	46,795	12	Dominated
TB-2: SmearPosNeg: As for SmearPos, plus treatment of smear-negative cases under DOTS	50%	0.63	78%	22%	48,535	13	Dominated
TB-3: SmearPosMDR: As for SmearPos, plus DOTS-plus treatment	50%	0.77	65%	35%	47,651	16	Dominated
TB-4: Combination: As SmearPos, plus DOTS-treatment of smear-negative cases plus DOTS-plus standardized second-line drug re-treatment	50%	0.83	63%	37%	49,371	17	Dominated
TB-5: SmearPos: Treatment of new smear-positive cases only under DOTS	80%	0.82	81%	19%	74,872	11	Dominated
TB-6: SmearPosNeg: As for SmearPos, plus treatment of smear-negative cases under DOTS	80%	0.93	76%	24%	77,655	12	Dominated
TB-7: SmearPosMDR: As for SmearPos, plus DOTS-plus treatment	80%	1.15	62%	38%	76,241	15	Dominated
TB-8: Combination: As SmearPos, plus DOTS-treatment of smear-negative cases plus DOTS-plus standardized second-line drug re-treatment	80%	1.25	61%	39%	78,994	16	Dominated
TB-9: SmearPos: Treatment of new smear-positive cases only under DOTS	95%	0.97	81%	19%	88,910	11	11
TB-10: SmearPosNeg: As for SmearPos, plus treatment of smear-negative cases	95%	1.12	77%	23%	92,218	12	46

Source: World Health Organization http://www.who.int/choice/results/tb_amrb/en/

EXAMPLES ICERs

(Min. 00:09:54)

And we can find these ICER ratios or estimates for a number of different treatments, which is great. Here you can see estimates from disease control priority 3 on the top left, and WHO choice data on the bottom right. The DCP3 are providing estimates of ICERs from most cost-effective, in the bottom left, and moving up to less and less cost-effective as we go up towards the right. The WHO choice table is providing estimates of cost-effectiveness ratios moving from most to least cost-effective top to bottom. So what both of these are doing is just ranking based on increments of cost-effectiveness ratio and cost-effectiveness generally. This is what we typically do in practice and people tend to choose some threshold or cut-off value and say that if an intervention

is less than that value the intervention is cost-effective and if it costs more than that value it is not cost-effective. So things that are considered cost-effective then might be considered for inclusion in the benefits package, or if you are thinking about making decisions at the margin you might consider bringing this on board and displacing something else that is currently being provided. I am going to talk a bit later about what threshold or cut-off values are used in practice, what these represent and what they should represent. But first I want to have a closer look at ICERs. What do they actually tell us and what they don't tell us.

Incremental cost-effectiveness ratios (ICERs)

	Expected cost ($)	Expected DALYs averted
B	700	5
A	500	4

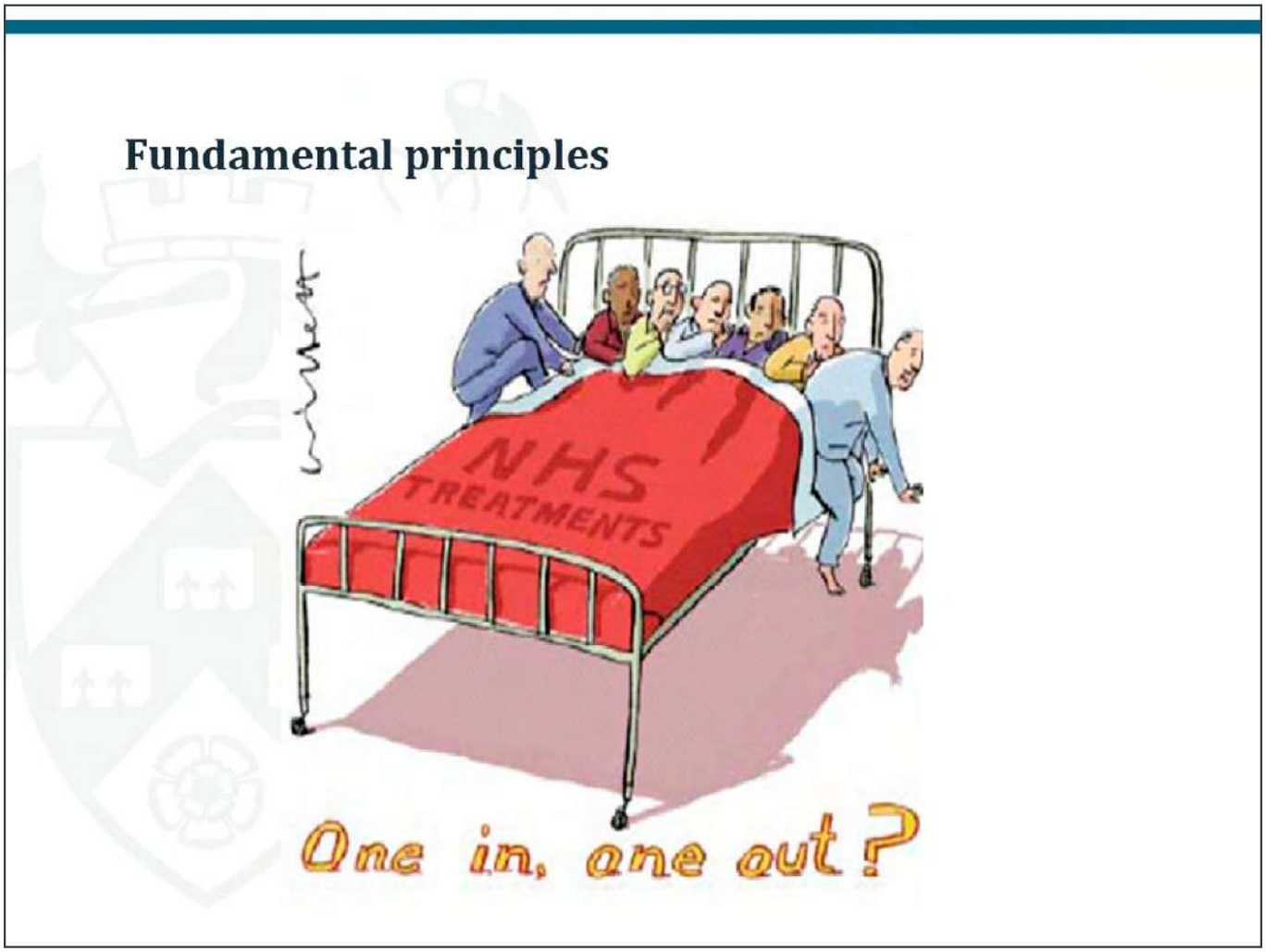
- Incremental cost of B compared to A = C_B-C_A= $200
- Incremental benefit of B = H_B-H_A=1
- ICER = (C_B-C_A)/(H_B-H_A) = $20,000/1 = $200/DALY averted
- Should we change to B or stick with A?

INCREMENTAL COST-EFFECTIVENESS RATIOS (ICERs)

(Min. 00:09:54)

Let us look at this example where we have two mutually exclusive treatments. So you can do one or the other, but you wouldn't do both. So, for example, let's think this could be anti-retroviral therapy and anti-retroviral therapy plus viral load monitoring. B generates more health, but it also costs more. So how can we make a decision about trading off the fact that this costs more but also generates more health? What the ICER is telling us is that the ratio is the ratio of the incremental cost of B, compared to A and compared to the incremental health benefit of B compared to A. So when we are looking at ICERs it is critical that we are comparing B to A and that A is indeed the next best thing to be. If we use the wrong comparator and there is actually

something better than A, but not as good as B, our ICER would be misleading. But assuming that we have all the right comparators then we can make categorical judgments by cost-effectiveness comparing the ICERs to some threshold value. However, the ICER ratios don't tell us anything about the scale of the benefit, meaning how much health will be generated by providing this intervention to all those patients who need it, and how much health would be foregone elsewhere in the healthcare system if we include this intervention. So that second question is one of opportunity cost, which is a fundamental principle that underpins health technology assessment and should be central in health benefits package design.



FUNDAMENTAL PRINCIPLES

(Min. 00:13:06)

So what does this concept of opportunity cost really mean? Imagine that this bed is the National Healthcare System. We can only afford to treat these seven guys. Maybe effective treatment exists for all seven of them but the healthcare system cannot financially support all seven. So funding a treatment for one patient means that another patient is going to forego treatment? At the national level funding a treatment for one group of patients means that another group of patients somewhere else in the healthcare system will forego treatment. Unlike in this illustration, in reality we cannot actually identify the individuals whose treatment will be displaced but we can identify how much health, in terms of length and quality of life, will be displaced. So we cannot identify and observe this but we can estimate it.

Fundamental principles

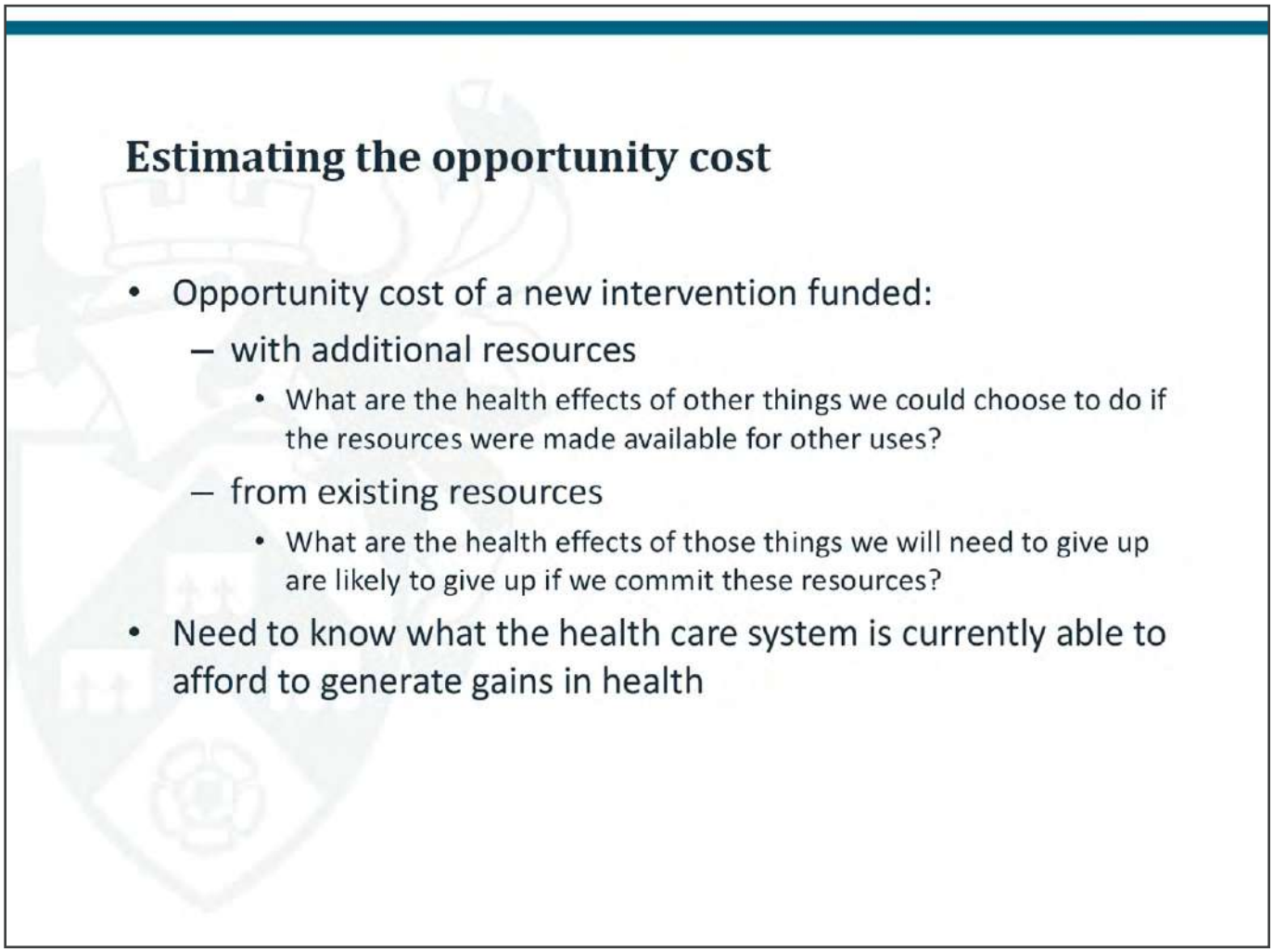
Guide to the methods of technology appraisal 2013 (PMG9)

1.4.2 In general, a technology can be considered clinically effective if, in normal clinical practice, it confers a health benefit, taking account of any harmful effects and opportunity costs. A technology can be considered to be cost effective if its health benefits are greater than the opportunity costs of programmes displaced to fund the new technology, in the context of a fixed NHS budget. In other words, the general consequences for the wider group of patients in the NHS are considered alongside the effects for those patients who may directly benefit from the technology.

FUNDAMENTAL PRINCIPLES

(Min. 00:13:56)

This principle of opportunity cost underpins everything that we do in the UK. It is enshrined in the NICE guides to the methods of technology appraisal. The guide says: “In general, a technology can be considered to be clinically effective if, in normal clinical practice, it confers a health benefit, taking account of any harmful effects and opportunity costs. A technology can be considered to be cost-effective if its health benefits are greater than the opportunity costs of programs displaced.”



ESTIMATING THE OPPORTUNITY COST

(Min. 00:14: 29)

So what do we need to know to get at this opportunity cost? Well, we need to know what the healthcare system is currently able to afford to generate gains in health. This is relevant regardless of whether we are talking about making incremental changes to an existing package, or deciding what the package should be if we are able to start from scratch. It does not matter if the intervention will be funded with additional resources or from existing resources. If it is something that is going to be funded with additional resources the question then becomes: what are the health effects of the other things that we could choose to do if the resources were made available for the other uses? If it is something that we are going to be funding using existing

resources, the question then becomes: what are the health effects of those things that we will need to give up, or are likely to give up, if we commit these resources?

So what we need is an estimate of what the healthcare system is currently able to afford to generate gains in health.

Estimating the opportunity cost

- What is the health care system currently able to afford to generate gains in health?
  - Recent estimates from higher income countries
    - UK £12,936 per QALY (Claxton et al 2015)
    - Australia AUS$28,033 per QALY (Edney et al 2018)
    - Spain €21,000 and €24,000 per QALY (Vallejo-Torres et al 2016)
    - Netherlands, Norway, South Africa
  - Potential implications for other HCS (Woods et al 2016)
  - Using published estimates of the mortality effect of health care expenditure from country level data (Ochalek et al 2015)

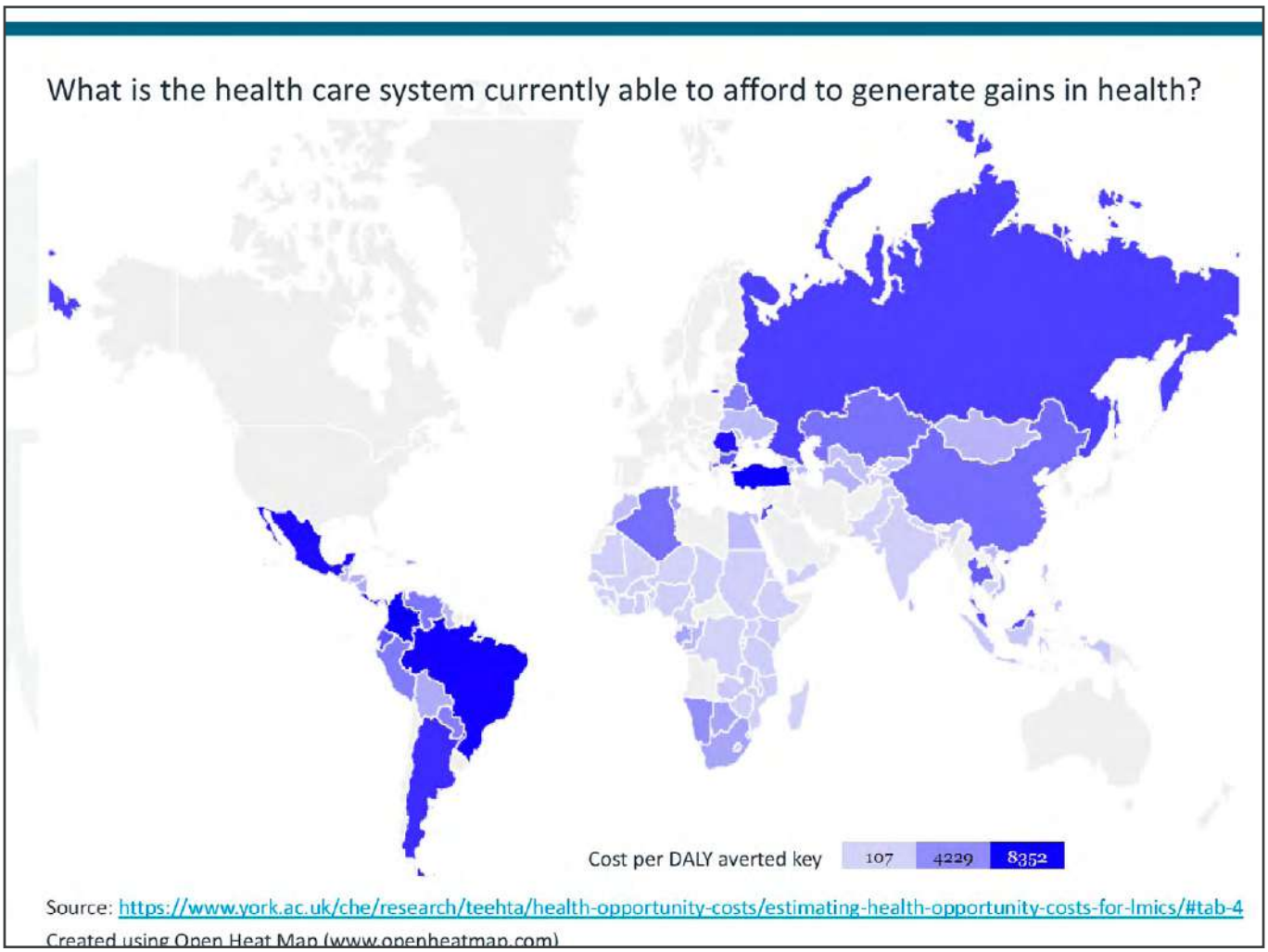
ESTIMATING THE OPPORTUNITY COST

(Min. 00:15:26)

This question of what the health system is currently able to afford to generate gains in health can be answered using econometric estimation of the effect of a change in health expenditure on health outcomes. Today very few countries have been able to estimate this using within country

data. But we do have estimates from a couple. We have an estimate from the United Kingdom that suggests that the UK can afford today about 13,000 pounds per QALY gained. An estimate from Australia suggests that they can afford to pay about 28,000 Australian dollars per QALY gained. An estimate from Spain is between 21,000 and 24,000 Euros per QALY. And there are also estimates currently being undertaken in the Netherlands, Norway, South Africa, as well as some other countries.

Unfortunately, this does not tell us anything about the countries that don't have these within-country estimates and don't have the data necessarily to do that. So what can we tell about those countries? There is a paper by my colleagues Woods *etal*, who have looked at the implications that the UK estimates might have for other countries. And what they do is to take the UK estimate and using information about the income elasticity of demand consider how this might translate for other countries. We can also use published estimates of the mortality effect of expenditure from country level data and apply that to what we know about health expenditure, demography and epidemiology in a particular country. So that is what I have done with colleagues here at the Center for Health Economics.



WHAT IS THE HEALTH CARE SYSTEM CURRENTLY ABLE TO AFFORD?

(Min. 00:19:39)

Just to recap a bit from the last slide: there are initiatives to estimate cost per QALY or the rate at which the healthcare system in different countries is able to produce health. In particular though that is primarily happening in high-income countries. A work that I have undertaken with colleagues here at the Center for Health Economics has looked at using cross-country data to estimate the effects of a change in health expenditure on health outcomes across countries, accounting for differences in donor-funding and levels of infrastructure between countries. And then we have applied demographic data and epidemiologic data on the back end so you get

what seems like a reasonable range of how much each country is able to afford to generate health gains. So this figure broadly shows what these ranges look like for different low- and middle-income countries. What we have is the countries with the lighter color. These have a lower cost per DALY averted. Countries in darker blue have a higher cost per DALY averted. What this tells us is a couple of things. First of all, that it shows us that it costs less to generate health in certain countries and actually I think that is sometimes interpreted as being a negative thing. But we can also think of it positively because what this is also telling us that if we were to extend the budget for healthcare in these countries, there is a lot of health to be gained at margin by that expansion. This can be useful in negotiations about budgets within a country and also with donors as well. At the moment, these are some of the estimates that are available. I think other estimates are being undertaken in Indonesia and possibly a few other countries in Africa. I am not sure about any in Latin America though.

(Min. 00:21:50)

Question:

Is this in US dollars?

Answer:

Yes, this is in 2015 US dollars.

Clarity about cost-effectiveness "thresholds"

- Health opportunity costs
  - "Supply side"
  - What the health care system is currently able to afford to generate gains in health
- Implied values or norms
  - WHO-CHOICE 1 and 3x GDP per capita
  - NICE (UK) £20,000 to £30,000 per QALY
- Society's monetary valuation of health gains
  - "Demand side"
  - Tend to be higher than "supply side" estimates

CLARITY ABOUT COST-EFFECTIVENESS THRESHOLDS

(Min. 00:21:55)

What these estimates in the UK, Australia, Spain and the estimates of the figure I showed in the last slide are showing, are estimates of what the healthcare system is currently able to afford to generate. And this reflects health opportunity costs. This is often called a supply side estimate of a threshold. There are other values out there that have been called thresholds and these have different conceptual foundations. We got implied values or norms. WHO choice for a long time recommended using thresholds of 1 and 3 times GDP per capita, where 1 times GDP per capita was considered to be very cost-effective and 3 times GDP per capita was considered to be cost-effective. But what we can see from the estimates that we have from high-income countries, using within country data, is that these are all about half of GDP per capita or less. And similarly,

the estimates that are using cross-country data also suggest quite a bit less than 1 times GDP per capita. Another threshold range, that is sort of an implied value or norm, is the range that is used by NICE in the United Kingdom. That is 20,00 to 30,000 pounds per QALY. On the slide before the last slide I showed that there was an empirical estimate for the UK of about 13,000 pounds. That reflects how much health the healthcare system is currently able to generate. This range is the one that is used in policy and in practice actually and it is quite a bit higher.

We also have thresholds that are based on society's monetary evaluation of health gain. These are often called demand side thresholds. They can reflect values such as willingness to pay estimates. And generally, what it is telling is how much individuals collectively are willing to pay for changes in health. But these estimates tend to be higher than supply side estimates. And there are issues with using estimates that don't reflect health opportunity costs and particularly when they are higher than estimates of health opportunity costs. That can cause problems.

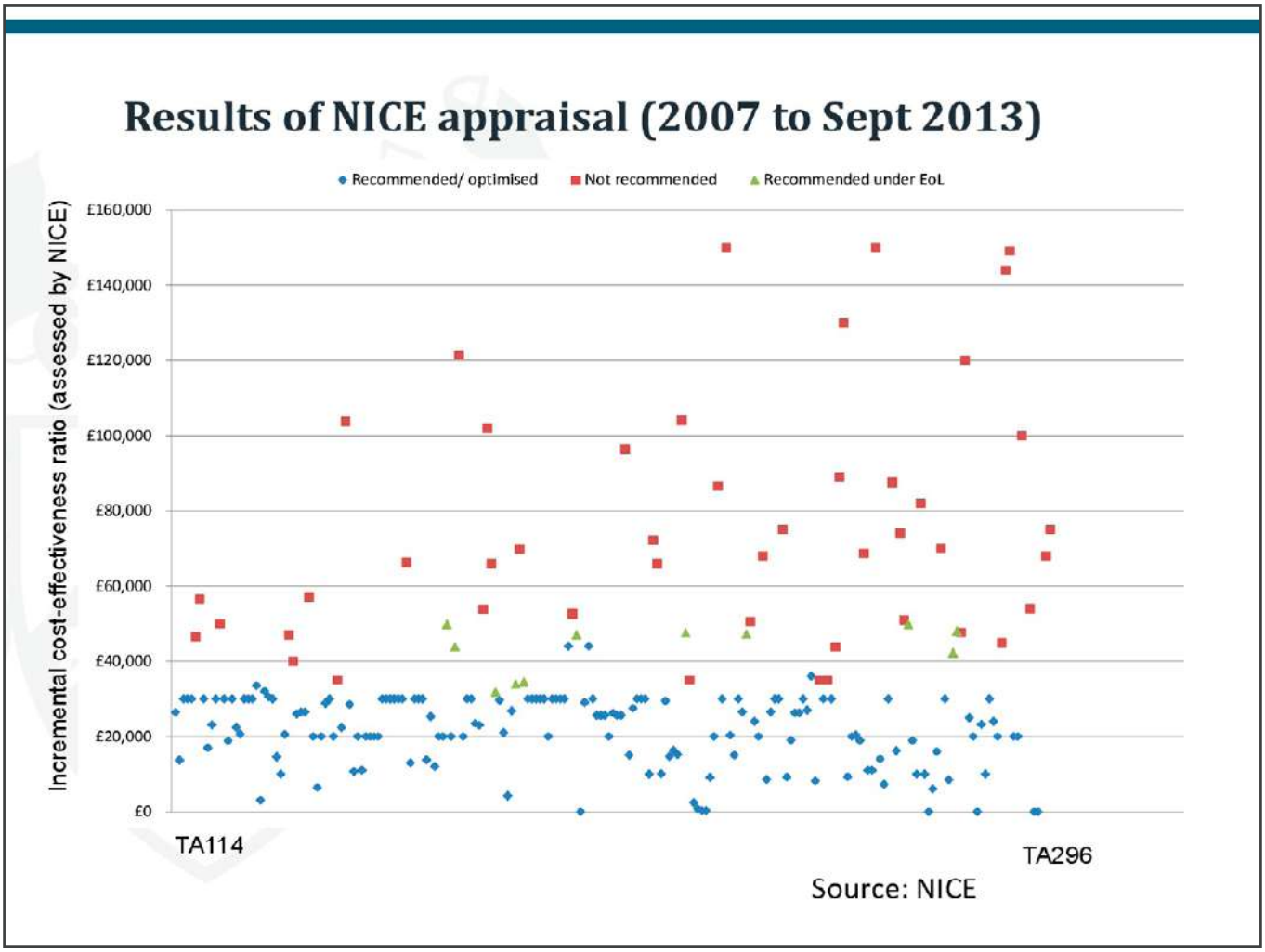
(Min. 00:24:23)

Question Elise Bautista:

For example, Mexico experiences higher costs per DALY averted, meaning it is more expensive than Africa?

Answer:

I think what it means is not that it is more expensive than Africa, but since it is reflecting the size of the budget for healthcare, as well as underlying mortality rates, and the age and gender distribution of the population. So where you have a smaller budget and a higher burden of disease, in terms of infectious disease and things like that, you are going to tend to have a lower cost per DALY averted threshold. So there are a number of different factors that play into it. It is not necessarily that you want to be comparing between countries but rather what this is telling you is what a given country is able to produce at the margin. So what decisions should be made at the margin in a given country.



RESULTS OF NICE APPRAISAL

(Min. 00:25:25)

I am going to use the example of the UK to talk through why using a threshold value that doesn't reflect how much the healthcare system is currently able to produce can cause some problems. The reason I am using the UK as an example is because we have an empirical estimate and we also have the range that is used in policy. And we have this evidence here on the slide that shows us what decisions have actually been taken. So this shows us decisions that were taken or recommendations that were made to the NHS between 2007 and September of 2013. All of the numbers in blue reflect the ICERs of interventions that were recommended by NICE to the NHS.

So you can see everything that is 30,000 pounds or less is recommended. Above that, we still have recommendations in green and these are under the end of life criteria. So we can see there are things being recommended as high as 50,000 pounds per QALY. And this has implications for the healthcare system.

What should the "threshold" be?
Example of the UK

- NICE threshold range (2004)
  - £20,000 to £30,000 per QALY (implied by past decisions)
  - NICE does not reject below £30,000 per QALY
  - Evidence that the effective threshold is £40,000 per QALY
  - In some circumstances £50,000 per QALY
  - £100,000 and £300,000 per QALY when appraising treatments for 'very rare diseases'
- Estimate of what the health care system is currently able to afford to generate gains in health
  - £12,936 per QALY (Claxton et al 2015)

WHAT SHOULD THE THRESHOLD BE?

(Min. 00:26:36)

The threshold range, the 20,000 to 30,000 pounds per QALY that are referenced, is implied by past decisions. So it was implied by decisions from 2004 and previous. And it will probably be even higher now if we were looking at decisions that were made up to 2010, 2015 or even up

to now. We can see from evidence that NICE does not reject any interventions below 30,000 pounds per QALY. There is evidence that the effective threshold is 40,000 pounds and it could even be higher. And in fact, recently NICE added some new guidance to say that it would use a new range of 100,000 to 300,000 per QALY when appraising treatments for very rare diseases. So these are a lot higher than the empirical estimate of what the healthcare system is able to produce, which is about 13,000.

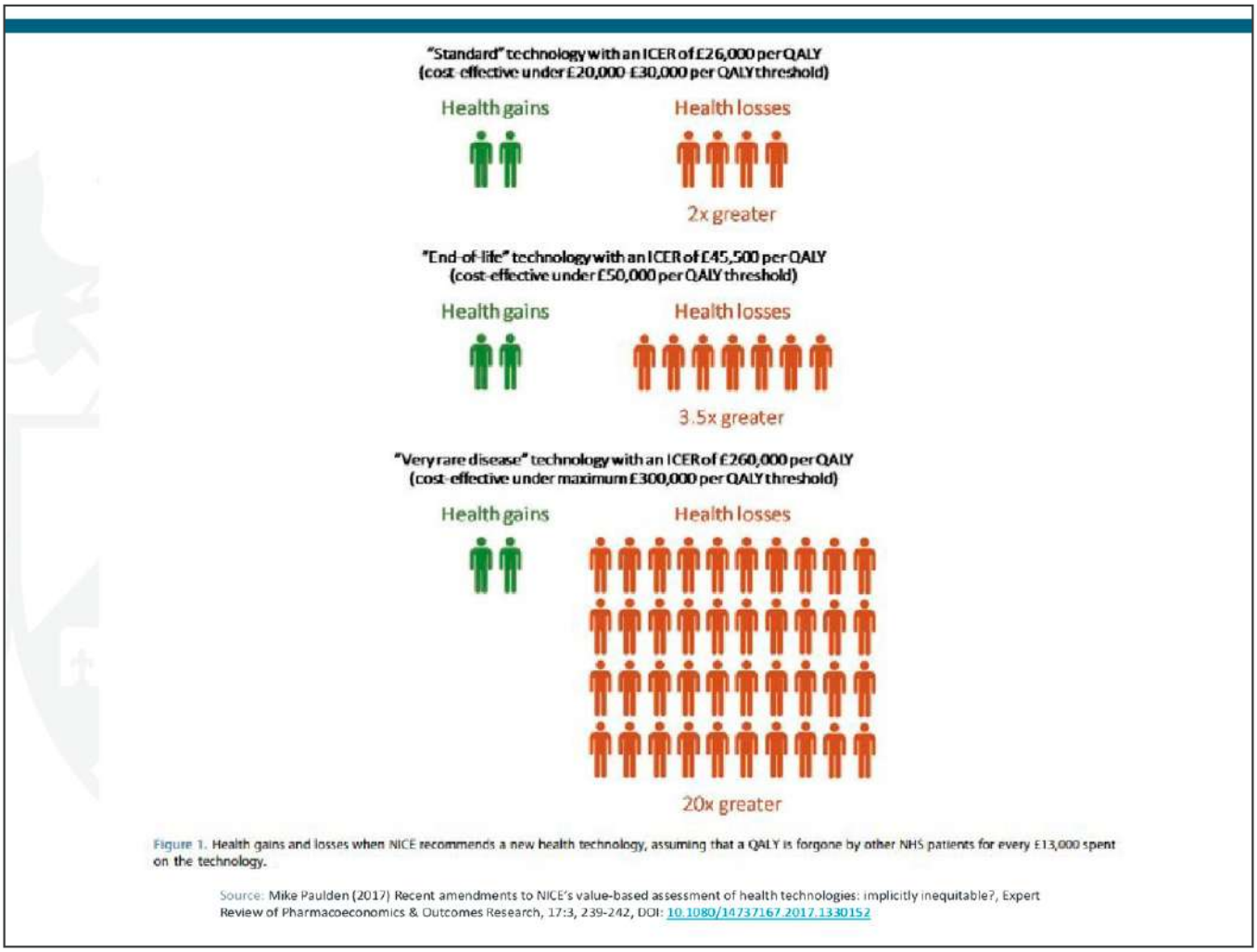


Figure 1. Health gains and losses when NICE recommends a new health technology, assuming that a QALY is forgone by other NHS patients for every £13,000 spent on the technology.

Source: Mike Paulden (2017) Recent amendments to NICE's value-based assessment of health technologies: implicitly inequitable?, Expert Review of Pharmacoeconomics & Outcomes Research, 17:3, 239-242, DOI: 10.1080/14737167.2017.1330152

CONSEQUENCES OF USING THRESHOLD THAT ARE TOO HIGH

(Min. 00:27:35)

This slide tries to illustrate what the consequences of using this threshold that are too high actually are. So based on what we know about how much the UK healthcare system is currently able to afford to achieve gains in health, an intervention with an ICER of 26,000 pounds per QUALY, which is within that 20,000 to 30,000 pound range, would generate two QALYs, but four QALYs would be foregone elsewhere in the healthcare system. So it is going to cause a net loss in health. For interventions which much higher ICERs the expected health opportunity costs would even be greater. An intervention that meets that end of life criteria, with an ICER of about 45,500

per QALY that would be expected to displace approximately 3.5 QALYs for every QALY gained. And you can see that the losses are greater and greater as the ICER increases.

The reverse of this is an intervention with an ICER that is less than our estimate of how much the UK healthcare system currently can afford to pay for improvements in health. And that would generate a net gain.

(Min. 00:29:02)

Question:

Are the WHO choice estimates for QALYs or DALYs?

Answer:

The WHO choice estimates are for DALYs. A lot of the research that has been undertaken in high-income countries is for QALYs and that is largely because there are value sets for using QALYs in these countries. But when we tend to do cross-country work we tend to use DALYs. They are different in how they are estimated and put together but they represent the same thing, in terms of both being generic measures of length and quality of life. I would not necessarily say you could use them interchangeably, but at the moment there is an absence of evidence to show which one would be higher or lower in which circumstance. So we use what is available really.

Consequences of using a "threshold" that is too high

- Does not reflect how much health the HCS currently delivers
  - Reduction in health outcomes
  - Underestimates the value of increased health expenditure
- For example: using "threshold" of £30,000 per QALY when the health care system is able to produce health at a rate of 1 QALY per £12,946
  - Intervention at £26,000 is implemented but reduces health outcomes overall
  - Additional £10 million would gain 773 not 273 QALYs

CONSEQUENCES OF USING A THRESHOLD THAT IS TOO HIGH

(Min. 00:29:47)

Ok, so getting back to talking about using a threshold that is too high, just to summarize this, what happens is that it doesn't reflect how much the healthcare system currently delivers. So the result is a reduction in overall health outcomes and that loss in health. It also underestimates the value of increased health expenditure. So, for example, if we use a threshold of 30,000 pounds per QALY, then the healthcare system is able to produce health at the rate of 1 QALY per 13,000 pounds and we are going to be losing health on that. It also underestimates the value of increases in the budgets. In the UK an additional 10 million pounds would gain 773 QALYs, but if

we were using 30,000 pounds as a threshold value would think that that would gain us only 271 QALYs.

What do we need to know to inform HBP design?

- Requirements
  - Per patient costs
  - Per patient benefits
  - Estimate of what the health care system is currently able to afford to generate gains in health (i.e., a measure of opportunity cost)
- Other commonly used inputs
  - ICERs
    - Enable categorical assessment of cost-effectiveness
  - Thresholds
    - Can have varying empirical and conceptual foundations
    - Should represent what the health care system can currently afford to generate gains in health

WHAT WE NEED TO KNOW TO INFORM HBP DESIGN

(Min. 00:30:50)

Up to this point I have talked about the key inputs that we want to know to inform health benefits package design. These are per patient costs, per patient benefits and, critically, an estimate of what the healthcare system is currently able to afford to generate gains in health. This is sometimes called the measure of health opportunity cost. Other commonly used inputs are ICERs. These are useful especially because they allow us to make categorical assessments of cost-

effectiveness by comparing the ICER to a threshold. But we have to be quite careful because thresholds can have varying empirical and conceptual foundations. What they should represent is what the healthcare system can currently afford to generate gains in health. And when they represent something else they tend to be a bit higher and then we end up in a position where we might be approving things that actually cause a net loss in health.

All of this is really important in terms of thinking about how to inform benefits package design. I am going to switch into talking about that from this point in the presentation.

Accounting for the scale of costs and benefits

- Need a measure of the scale of the potential health impact of including an intervention in the HBP net of associated health opportunity costs
  - Net health impact (net DALYs averted)
    - Difference between DALYs averted by an intervention and DALYs that could have been averted with any additional HCS resources required to implement it, or, if the intervention saves HCS costs, it is the DALYs averted by the intervention plus the DALYs that can also be averted with the cost savings offered
  - Financial value to the HCS
    - Amount of additional healthcare resources that would be required to deliver the equivalent net DALYs averted with other interventions

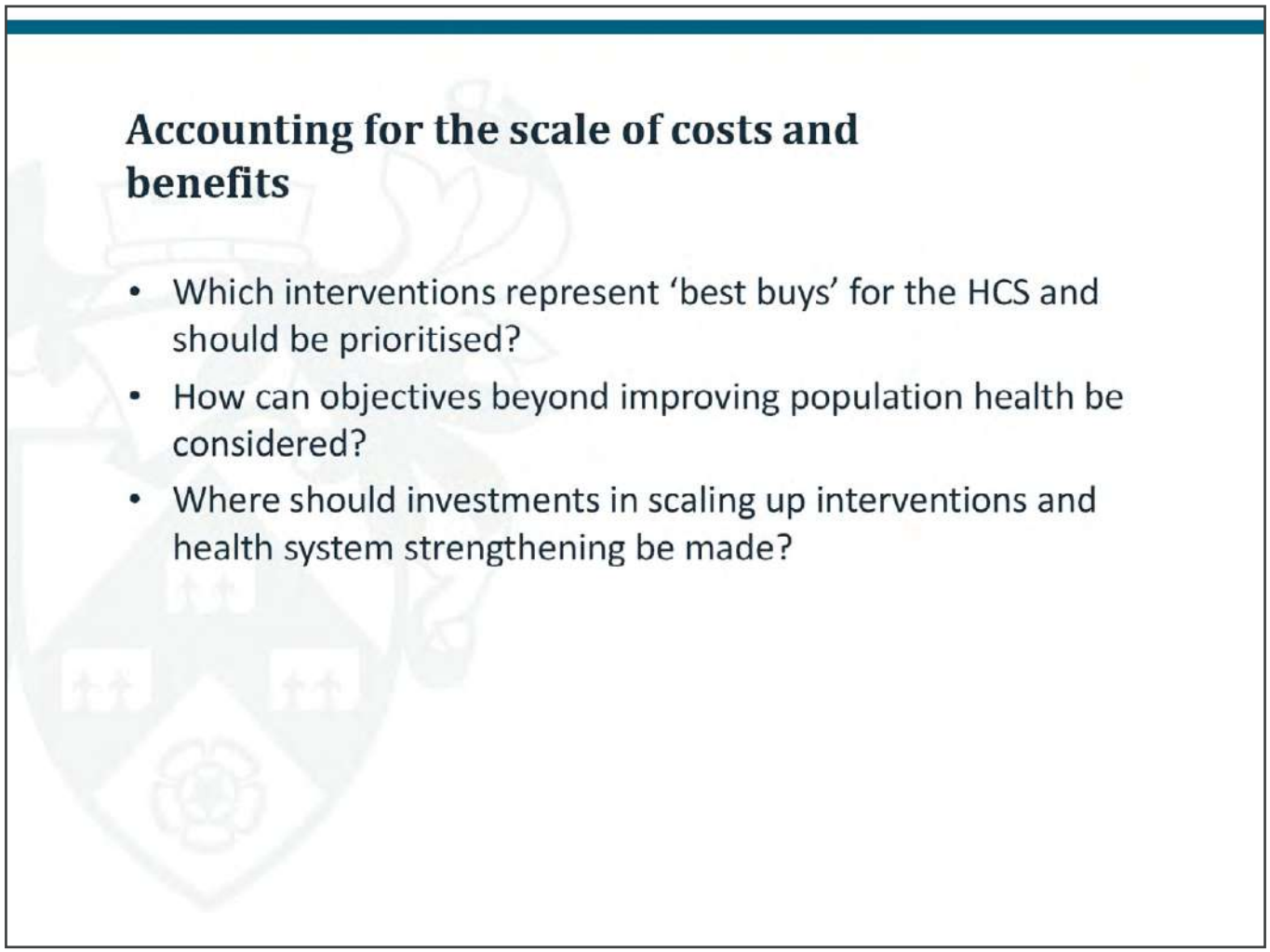
ACCOUNTING FOR THE SCALE OF COSTS AND BENEFITS

(Min. 00:31:56)

In terms of thinking about benefits package design, what do we need to know? Well, we need a measure of the scale of the potential health impact of including an intervention in the benefits package, net of the associated health opportunity costs. This enables us to go beyond this categorical “yes” or “no” assessments of cost-effectiveness. There are two ways we can think about this. One would be in terms of thinking about net health impact, so the net DALYs averted by an intervention. Or if we are using QALYs, the net QALYs gained. And this is the difference between the DALYs that are averted by an intervention and the DALYs that could have been averted with any additional healthcare system resources that are required to implement it. Or if

the intervention saves healthcare system costs it is the DALYs that are averted by the intervention plus the DALYs that can also be averted with the cost savings offered.

We can also think about this in monetary terms. So, that would be the financial value to the healthcare system. It is the amount of additional healthcare resources that would be required to deliver the equivalent net DALYs averted with other interventions.



ACCOUNTING FOR THE SCALE OF COSTS AND BENEFITS

(Min. 00:33:16)

And this allows us to answer some key questions in benefits package design. I am just going to talk through three but we can also think about conditions on donor funding, the scale of the benefits package and a number of other important questions. But, the three of them that I am going to talk about are: Which interventions represent "best buys" for the HCS and should be prioritised? How can objectives beyond improving population health be considered? Where should investments in scaling up interventions and health system strengthening be made?

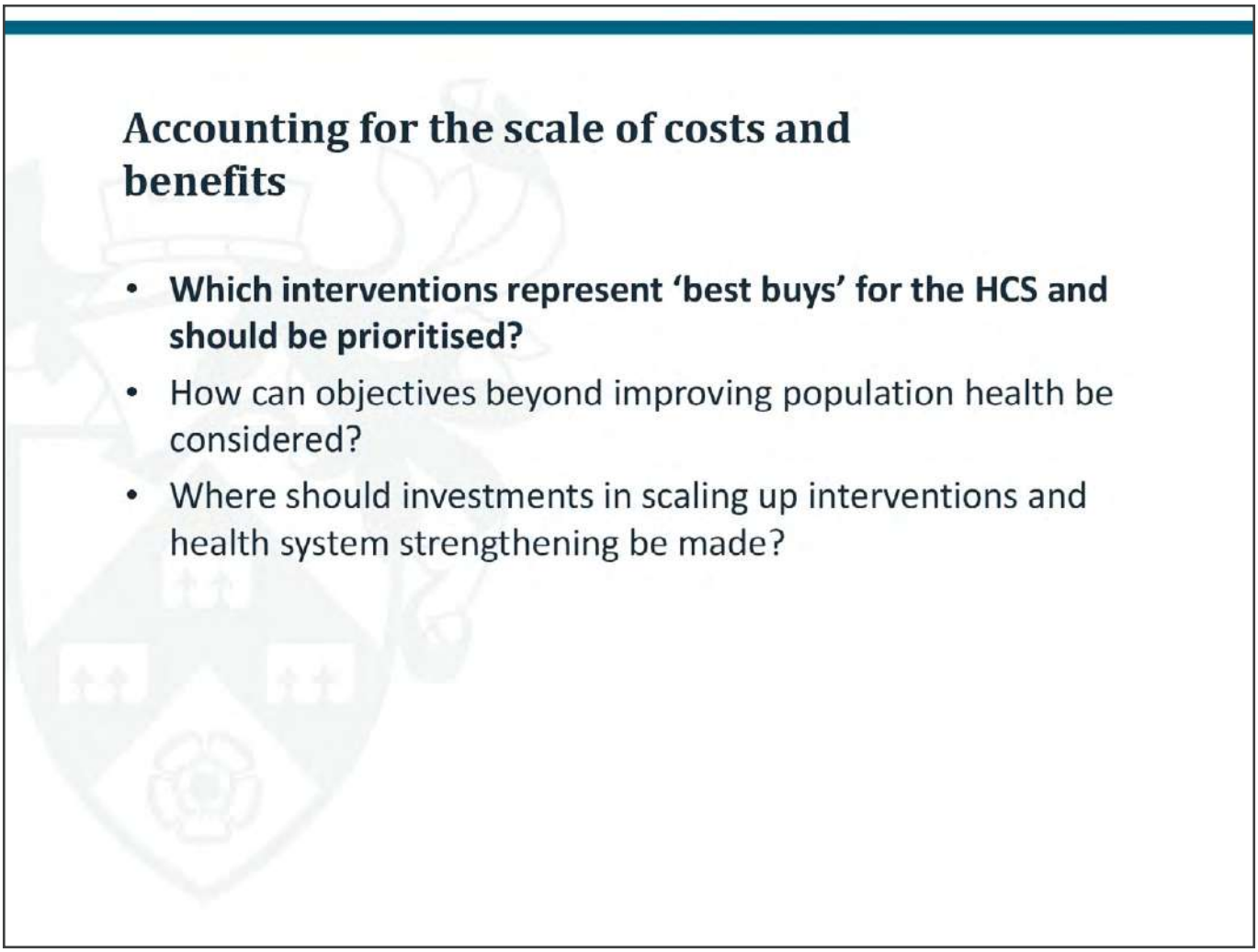
* Ochalek, J, Revill, P, Manthalu, G, McGuire, F, Nkhoma, D, Rollinger, A, Sculpher, M & Claxton, K 2018, 'Supporting the development of a health benefits package in Malawi' BMJ Global Health, vol 3, no. 2,

** Government of the Republic of Malawi, Health Sector Strategic Plan II 2017-2022: Towards Universal Health Coverage, 2017.

EXAMPLE MALAWI

(Min. 00:33:55)

I am going to illustrate this using data from Malawi, where this framework supported the development of an essential health package and fed into the latest health sector strategic plan. This is collaborative work that was undertaken between individuals in the Ministry of Health in Malawi and researchers of the Center for Health Economics. And I think that one of the colleagues from the Ministry of Health in Malawi, Dr. Gerald Manthalu is with us today, so he will hopefully be available for any questions specific to this as well during Q&A. So this is just a picture of our paper in BMJ Global Health, which fed into the essential health package, which is part of the latest health sector strategic plan.



ACCOUNTING FOR THE SCALE OF COSTS AND BENEFITS

(Min. 00:34:45)

So starting by thinking about which interventions represent "best buys" for the HCS and should be prioritised? I am going to start with a really straightforward hypothetical example. Current research has suggested that the rate at which the Malawian healthcare system is currently able to afford to generate gains in health is 61 dollars per DALY averted. In Malawi for using an ICER decision, we are saying anything that costs more than 61 dollars per DALY averted is not cost-effective and anything that costs less than 61 dollars is cost-effective. What we are going to do is that we are going to include interventions A through D. But because we are looking at the ICERs,

the information that we want to know about per patient cost and the per patient benefit of each intervention is obscured here. So we can't really say a lot about the scale of the benefits from any of these interventions. All we can do is really to make a categorical decision whether it is cost-effective or not. And so we can say: yes, A through D are cost-effective.

What interventions to prioritise?

- A and B same cost effectiveness ratio
- A averts fewer net DALYs than B or C per patient

Intervention	Cost per patient	DALYs averted per patient	patient population	Cost-effectiveness ratio	Net DALYs averted at 100% implementation
A	**100**	**5**	**1**	**20**	**3**
B	**400**	**20**	**1**	**20**	**13**
C	**600**	**15**	**1**	**40**	**5**
D	**900**	**15**	**1**	**60**	**0**
E	800	10	1	80	-3

WHAT INTERVENTIONS TO PRIORITISE?

(Min. 00:35:52)

But if we expand this table to include costs and benefits, using our measure of the rate at which the Malawian healthcare system is able to produce health, then we can now go on to calculate net DALYs averted. And this is going to then reflect the scale of the benefit. Even though A and

B have the same ICER, the scale of the benefits offered by A and B are not the same. B has a larger net effect on population health than A. In fact, even C offers more health than A does. And E, as you would expect, is negative and this reflects the fact that health benefits offered by E are lower than the health that is produced by the healthcare system now with the same money. So if we did implement E we would generate a net health loss. However, at this stage we still have not incorporated any information about the size of the patient population for each intervention. We are just looking at the per patient health effects.

What interventions to prioritise?

- Varying the size of the patient population

Intervention	Cost per patient	DALYs averted per patient	patient population	Cost-effectiveness ratio	Net DALYs averted at 100% implementation
A	100	5	1,000	20	3,361
B	400	20	500	20	6,721
C	600	15	10,000	40	51,639
D	900	15	1,000	60	246
E	800	10	10,000	80	-31,148

WHAT INTERVENTIONS TO PRIORITISE?

(Min. 00:36:51)

On this slide I have gone ahead to change the size of the patient population. And now we can see that for every dollar we spend on A we get more health, but the ceiling that we are looking at would be hit more quickly. So the net health gains, in total, will be much bigger from C. And when we take the patient population for each intervention into consideration, the rankings then change again. And now it is clear that actually C offers the greatest gains in population health. Just how detrimental E would be to implement, also becomes clear.

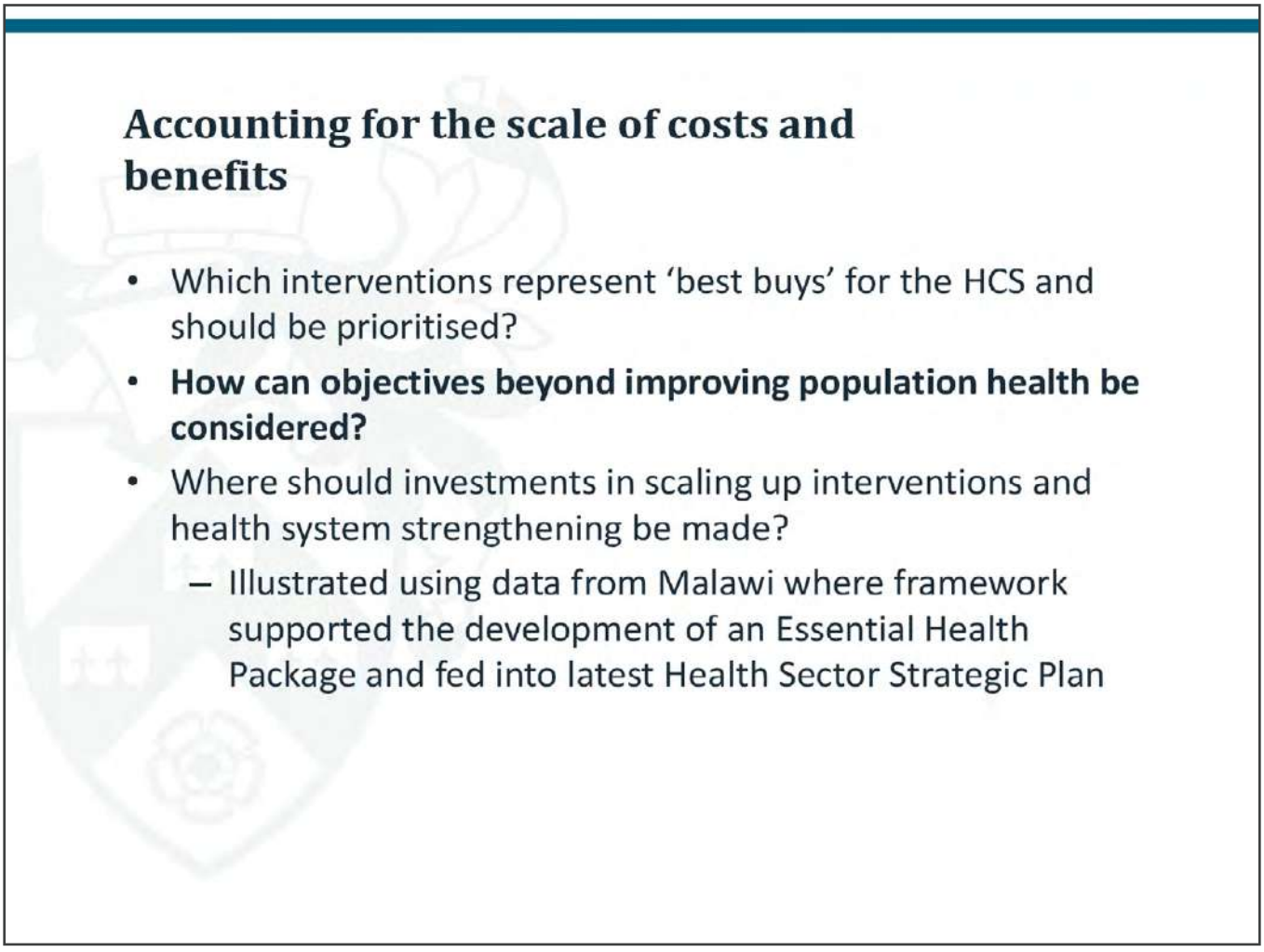
Prioritising interventions in terms of impact on overall population health (net DALYs averted)

#	Intervention	ICER	Population DALYs averted per 1,000	Cases per annum	Implementation level	Total cost	Cumulative cost	Total DALYs averted	Net DALYs averted (full imp.)
38	Male circumcision	$ 22	45	4,073,420	100%	$ 146,729,553	$ 146,729,553	39,634,464	25,423,008
30	Management of obstructed labor	$ 12	86	91,844	100%	$ 1,099,805	$ 147,829,358	2,497,118	2,025,734
4	Isoniazid Preventive Therapy for HIV+ no TB	$ 1	887	55,132	100%	$ 79,518	$ 147,908,876	1,118,463	1,097,909
5	First line treatment for new TB Cases for adults	$ 3	393	14,465	100%	$ 178,018	$ 148,086,894	1,045,196	1,001,800
7	First line treatment for new TB Cases for children	$ 3	393	12,265	100%	$ 116,948	$ 148,203,842	887,697	850,840
23	Management of pre-eclampsia (Magnesium sulphate)	$ 6	168	20,022	100%	$ 45,439	$ 148,249,281	534,719	482,789
9	Clean practices and immediate essential newborn care (home)	$ 3	368	671,464	100%	$ 415,687	$ 148,664,968	237,261	226,760
33	Households owning at least one ITN/LLIN	$ 13	77	6,751,018	100%	$ 13,736,789	$ 162,401,757	228,063	179,981
43	Cesearian section	$ 32	31	33,992	100%	$ 671,704	$ 163,073,461	327,465	156,536
2	Mass media	$ 1	903	16,879,044	100%	$ 7,608,778	$ 170,682,239	150,390	147,674
28	Labor and delivery management	$ 11	80	918,437	100%	$ 1,281,436	$ 171,963,675	170,442	139,385
27	PMTCT	$ 11	94	52,791	100%	$ 600,432	$ 172,564,107	167,074	129,751
6	First line treatment for retreatment TB Cases for adults	$ 3	393	1,808	100%	$ 99,632	$ 172,663,740	130,651	125,227
29	Cesearian section (with complication)	$ 12	86	5,051	100%	$ 171,925	$ 172,835,665	137,341	111,415
8	First line treatment for retreatment TB Cases for children	$ 3	393	1,536	100%	$ 65,831	$ 172,901,496	110,963	106,356
...		...	...	...	...	...	...	...	...
1	Cotrimoxazole for children	cost saving		127,265	100%	$ 219,803	$ 248,642,789	318	22,564
15	Malaria treatment: Uncomplicated (children, <15 kg)	$ 4	260	1,042,154	100%	$ 4,576,454	$ 253,219,243	14,115	13,231
16	Malaria treatment: Uncomplicated (children, >15 kg)	$ 4	260	1,042,154	100%	$ 4,768,246	$ 257,987,489	14,115	13,231
17	Malaria treatment: Uncomplicated - 2nd line (children, <15 kg)	$ 4	260	1,042,154	100%	$ 35,322	$ 258,022,811	14,115	13,231
18	Malaria treatment: Uncomplicated - 2nd line (children, >15 kg)	$ 4	260	1,042,154	100%	$ 70,685	$ 258,093,496	14,115	13,231
35	Under five children who slept under ITN/LLIN	$ 13	77	494,267	100%	$ 1,005,632	$ 259,099,129	16,696	13,176
42	Schistosomiasis Mass drug administration	$ 29	35	388,695	100%	$ 76,527	$ 259,175,656	23,754	12,562
45	Antibiotics for pPROM	$ 40	25	64,291	100%	$ 38,796	$ 259,214,452	29,509	10,473
37	Blood safety	$ 15	66	39,554	100%	$ 1,625,986	$ 260,840,439	11,866	8,914
32	Vaginal Delivery, with complication	$ 12	83	137,766	100%	$ 803,890	$ 261,644,329	10,026	8,056
44	Maternal Sepsis case management	$ 39	26	64,291	100%	$ 2,730,718	$ 264,375,047	20,052	7,324
21	Malaria treatment: Pregnant Women - complicated	$ 5	198	15,613	100%	$ 139,592	$ 264,514,639	5,574	5,116
10	Case management of MDR TB cases	$ 3	297	70	100%	$ 12,249	$ 264,526,889	5,162	4,896
63	GIT, Intestine cancer	$ 604	1	156	100%	$ 2,711	$ 264,529,599	0	0
65	Cervical cancer (first line)	$ 1,087	1	2,477	100%	$ 161,625	$ 264,691,224	1	-15
61	Ischemic heart disease	$ 453	2	128,130	100%	$ 4,193	$ 264,695,417	7	-45
52	IPT (pregnant women)	$ 110	9	734,760	100%	$ 34,712	$ 264,730,129	99	-79
57	Diabetes, type I	$ 296	3	23,063	100%	$ 4,303,914	$ 269,034,043	26	-96
49	High Cholesterol	$ 68	15	222,947	100%	$ 6,702,709	$ 275,736,752	921	-98
50	Basic psychosocial support, advice, and follow-up, plus anti-epileptic medication	$ 82	12	508,371	100%	$ 1,265,925	$ 277,002,677	689	-237
56	Treatment of depression	$ 265	4	168,790	100%	$ 331,621	$ 277,334,298	115	-382
58	Diabetes, Type II	$ 296	3	138,381	100%	$ 4,210,622	$ 281,544,920	149	-568
66	Treatment of acute psychotic disorders	$ 1,646	1	168,790	100%	$ 958,081	$ 282,503,000	27	-693
62	Treatment of bipolar disorder	$ 557	2	523,250	100%	$ 10,361,996	$ 292,864,996	182	-1,463
67	Treatment of schizophrenia	$ 1,646	1	2,363,066	100%	$ 13,413,129	$ 306,278,095	376	-9,704
55	Hypertension	$ 159	6	845,659	100%	$ 1,337,730	$ 307,615,825	44,495	-70,870

EXAMPLE MALAWI

(Min. 00:37:37)

This is just a table from our work in Malawi and I am not expecting anyone to actually read this. But I just want to point out one thing, which is on the right-hand side. We sorted things by net DALYs averted, assuming we can fully implement everything. What I have circled here are the ICERs. What we see is that the ICERs are not ranked the same as the net health benefit or the net DALYs averted. And that is what we would expect because the net DALYs averted are reflecting the net opportunity cost and the scale of the benefit, so it is incorporating something about the size of the patient population that is not in the ICER calculation.



ACCOUNTING FOR SCALE OF COSTS AND BENEFITS

(Min. 00:38:25)

I am going to talk through about how we can think about objectives beyond improving population health because I know that we don't just care about whether something is cost-effective or not. We also want to think about whether it improves equity or financial protection, for example.

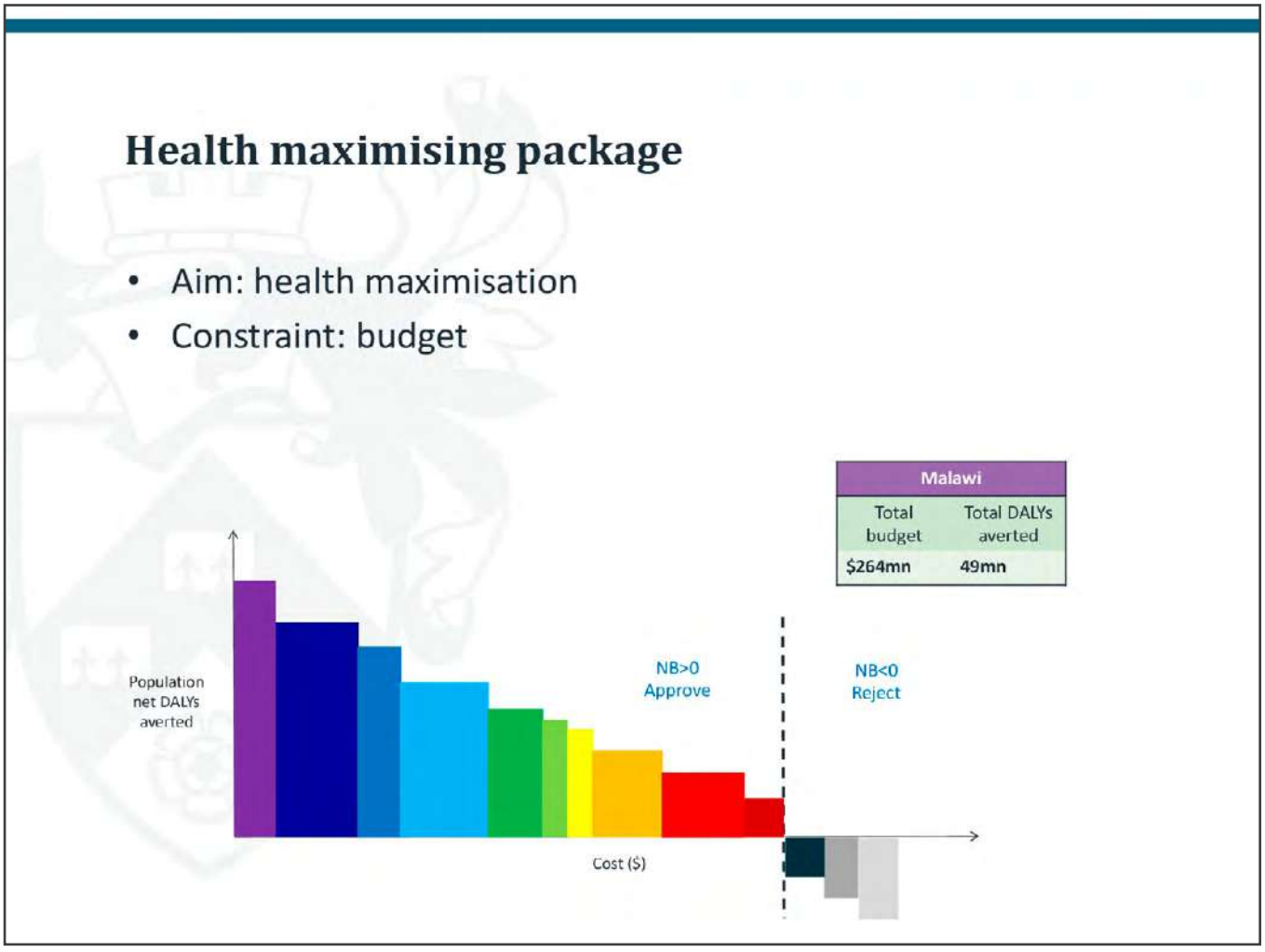
How can objectives beyond improving population health be considered?

6.2.21 The concept that underlies the Committee decision-making is that of the opportunity cost of programmes that could be displaced by the introduction of new technologies. This way, NICE seeks to maximise the health benefit gained from a fixed NHS budget. This principle is correct if the sole purpose of the health service is to improve health. While this may be the primary purpose of the NHS, it is acknowledged that care delivered by the NHS could have other benefits that are considered socially valuable but are not directly related to health and are not easily captured in a cost per QALY analysis. Techniques exist to consider the trade-off between health benefits and non-health benefits quantitatively. These techniques require that all relevant criteria are identified in advance, quantified and then weighted to reflect aspects of social value in a way that can be regarded as legitimate by all stakeholders. At present the introduction of such techniques into the Committee's decision-making is considered unsuitable. Therefore the Committee will take non-health objectives of the NHS into account by considering the extent to which society may be prepared to forego health gain in order to achieve other benefits that are not health related.

OBJECTIVES BEYOND IMPROVING PATIENT HEALTH

(Min. 00:38:40)

This is something that is enshrined again in the NICE technology appraisal guidance.



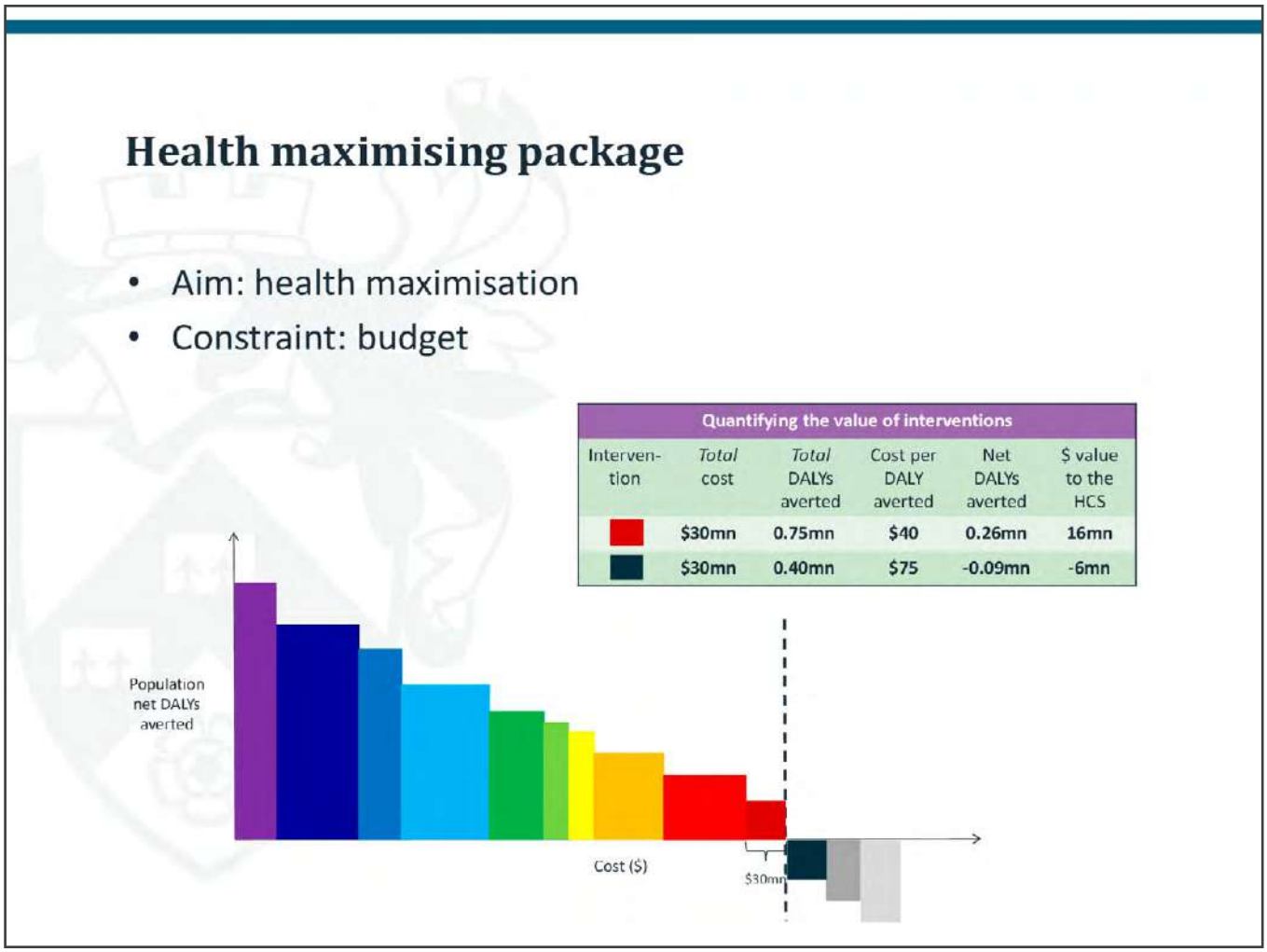
HEALTH MAXIMISING PACKAGE

(Min. 00:38:52)

So let's start by looking at a situation where we are aiming to maximise health and that is our only aim. And our constraint is the budget and that is our only constraint. This is never the case in reality but what this does give us is a hypothetical against which we can trade off those additional objectives like equity. So how we do this is we start by turning that table into a figure. So we are going to be ranking things by population net DALYs averted. On the Y axis, we have the population net DALYs averted, so that is the individual net DALYs averted by the intervention times the size of the patient population. And on the X axis we have the cost, which is just the per patient cost times the number of patient. We add each intervention in accordingly and we ranked these. We also have some interventions in grey. These are the interventions that cost more than

61 dollars per DALY averted. Those are the ones that therefore generate a negative net health benefit.

We can also use this to get to the size of the budgets. The dotted line here can be thought of as representing our net benefit decision. So if we have a positive net benefit we are going to approve and if we have a negative net benefit we are going to reject. And that is relevant whether we are thinking about incremental changes at the margin to a package that is already existing or thinking about building a package up. It is also worth pointing out that there are some benefits to using a net benefit over and above using ICERs, in terms of certain technical aspects, but in the interest of time I will skip over those as well. So what we can see from this is that we have got a total budget and in Malawi in the initial work that was determined to be 264 million and the package would have averted 49 million DALYs.



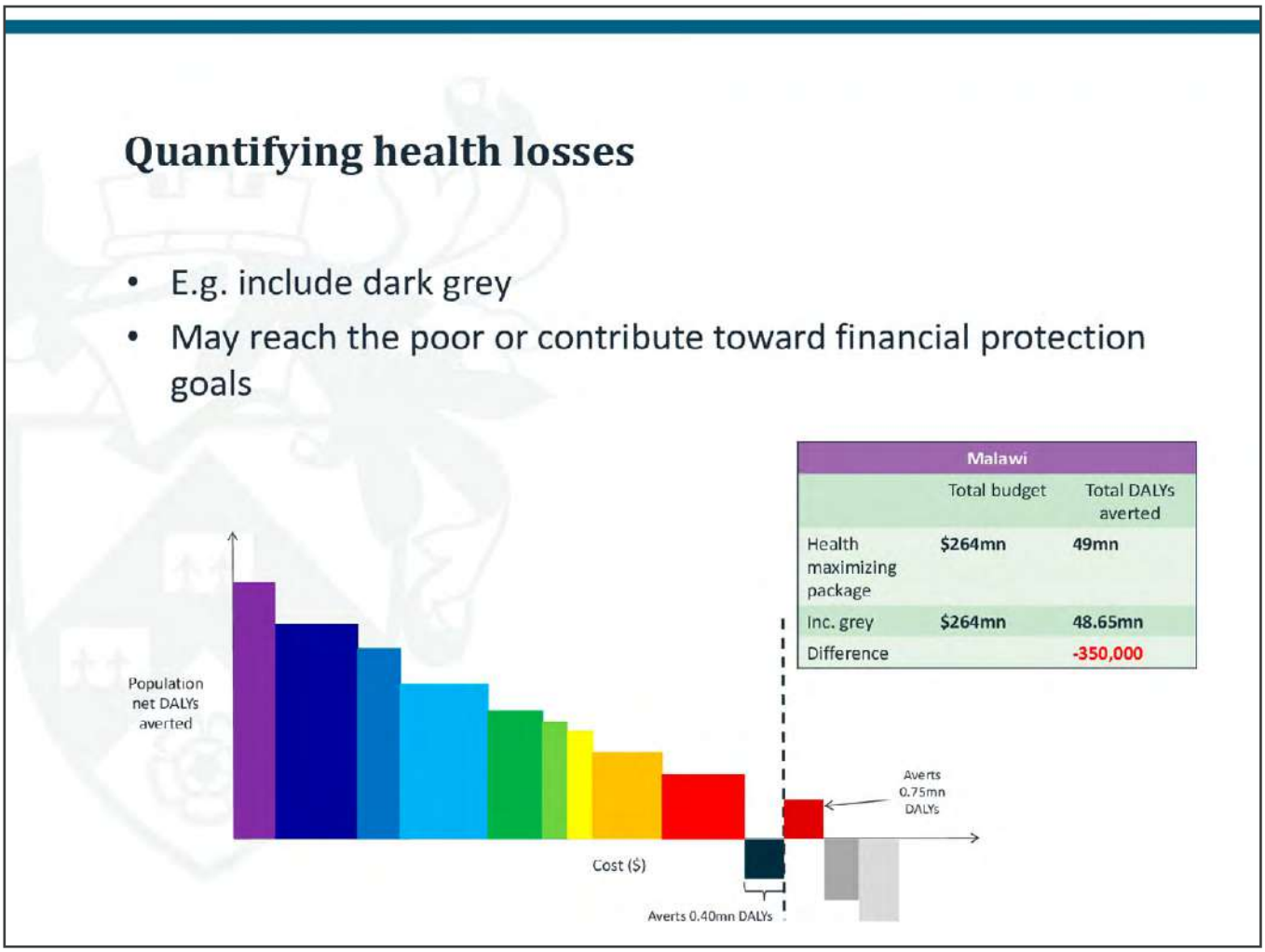
HEALTH MAXIMISING PACKAGE

(Min. 00:40:54)

I think to make this clear it helps to look at the two interventions at the margin. Conveniently these two both 30 million dollars, but the dark red intervention averts 750,000 DALYs, while the dark grey one averts 400,000. So we have got two different ICERs. The cost per DALY averted for dark red is 40 dollars and the cost per DALY averted for the dark grey is 75 dollars. So one is above our 61 dollars per DALY averted cut-off, and one is below. And as we would expect then the one that is cost-effective therefore has positive net DALYs averted and the one that is not cost-effective has a negative net DALYs averted.

It may however be the case that we don't just care about health and that we also want to consider something else. Let's say the dark grey intervention reaches the poor or contributes towards

financial protection goals. Maybe there are some really very legitimate reasons for wanting to include that intervention instead of the dark red one. So what we can do is we can quantify the health loss that would result from including that intervention and make a decision about whether or not it is worth it then.

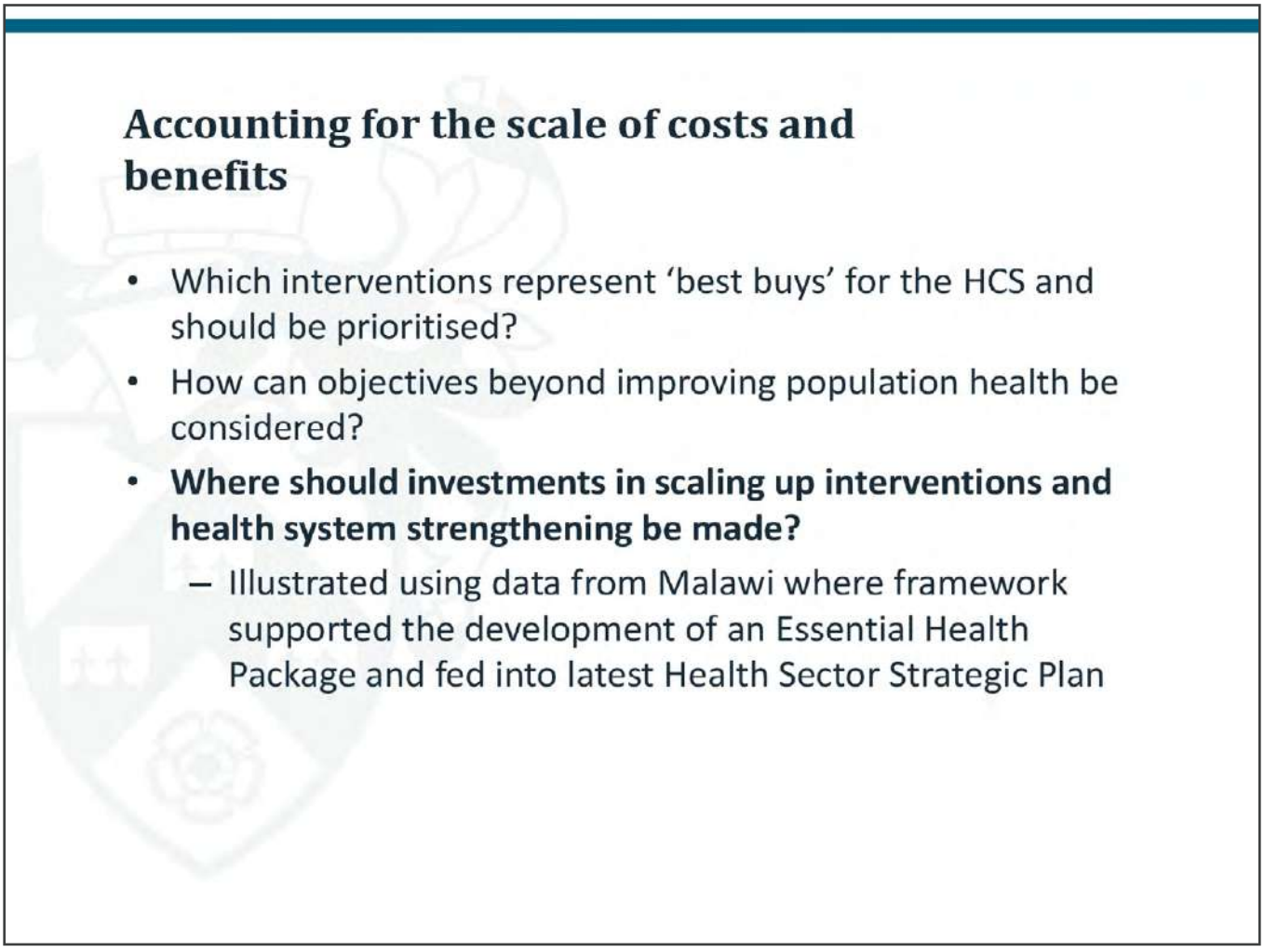


Malawi		
	Total budget	Total DALYs averted
Health maximizing package	$264mn	49mn
Inc. grey	$264mn	48.65mn
Difference		-350,000

QUANTIFYING HEALTH LOSSES

(Min. 00:42:05)

If we swap these two out then what we can see is that the difference of the DALYs averted is 350,000. The package with the darker intervention averts 350,000 fewer DALYs, and that may well be worth it so that could be a good decision.



ACCOUNTING FOR THE SCALE OF COSTS AND BENEFITS

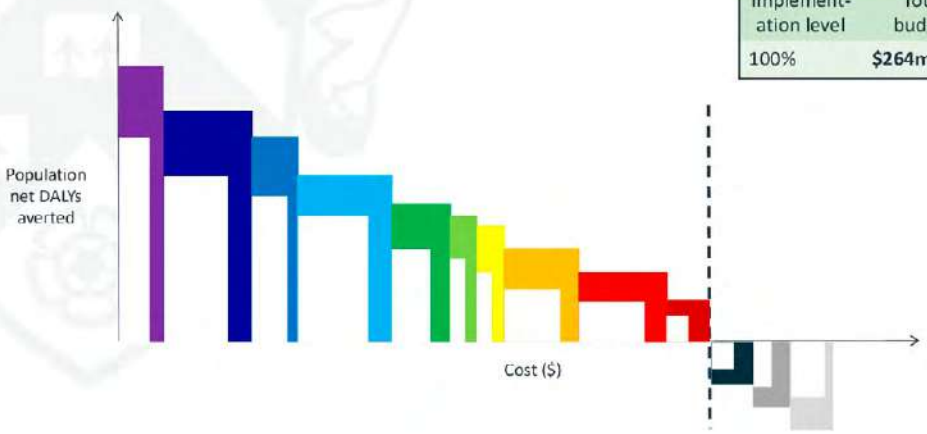
(Min. 00:42:50)

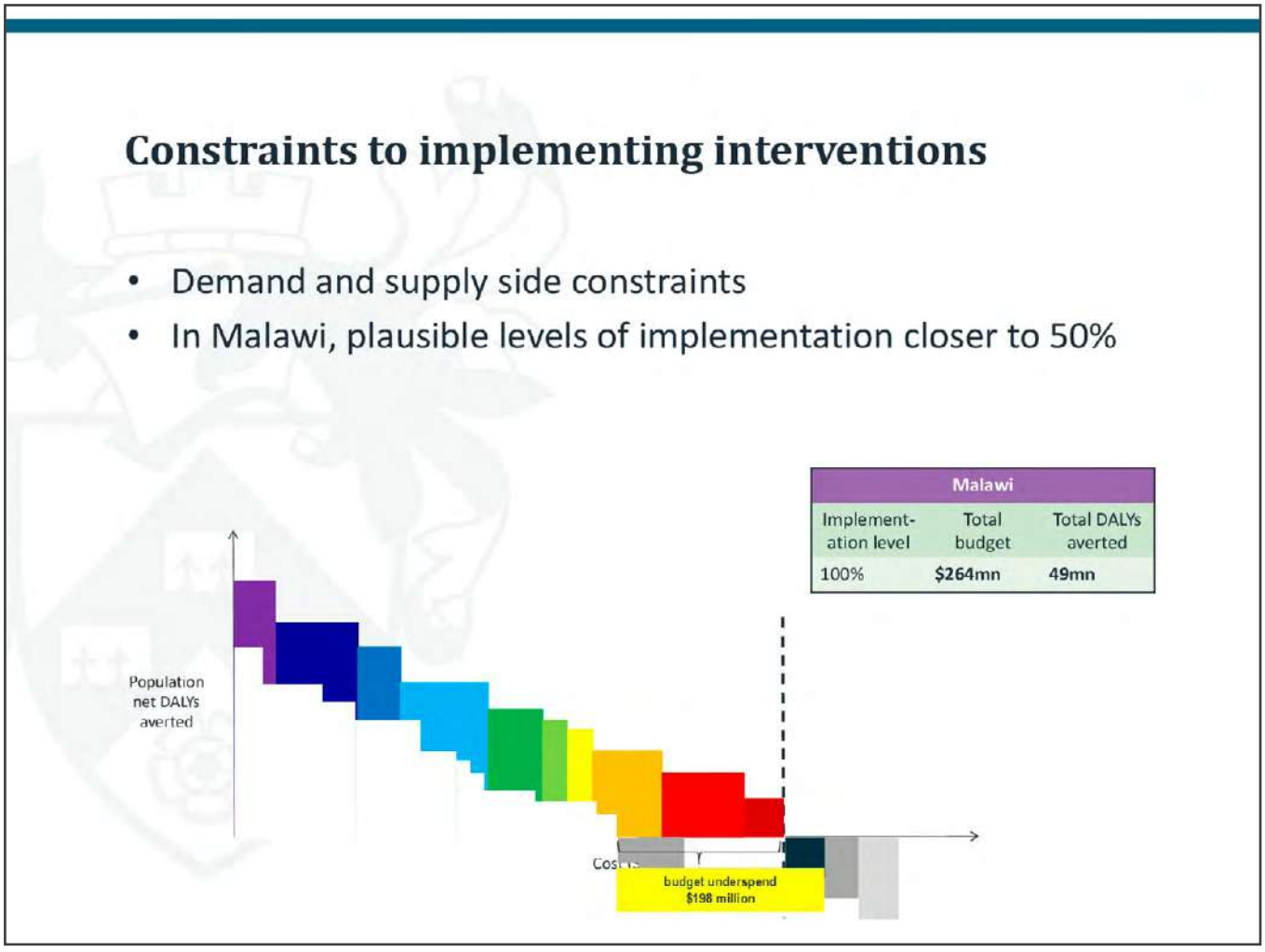
The last section is just thinking about scaling up interventions and ways to think about health system strengthening. So far this figure assumes that we are able to implement everything at a 100%. In reality, obviously that is not the case. It might be difficult to reach populations that live in rural areas or we might have a limited supply of drugs there, so there are a number of reasons why we can't implement everything fully.

Constraints to implementing interventions

- Demand and supply side constraints
- In Malawi, plausible levels of implementation closer to 50%

Malawi		
Implement-ation level	Total budget	Total DALYs averted
100%	$264mn	49mn

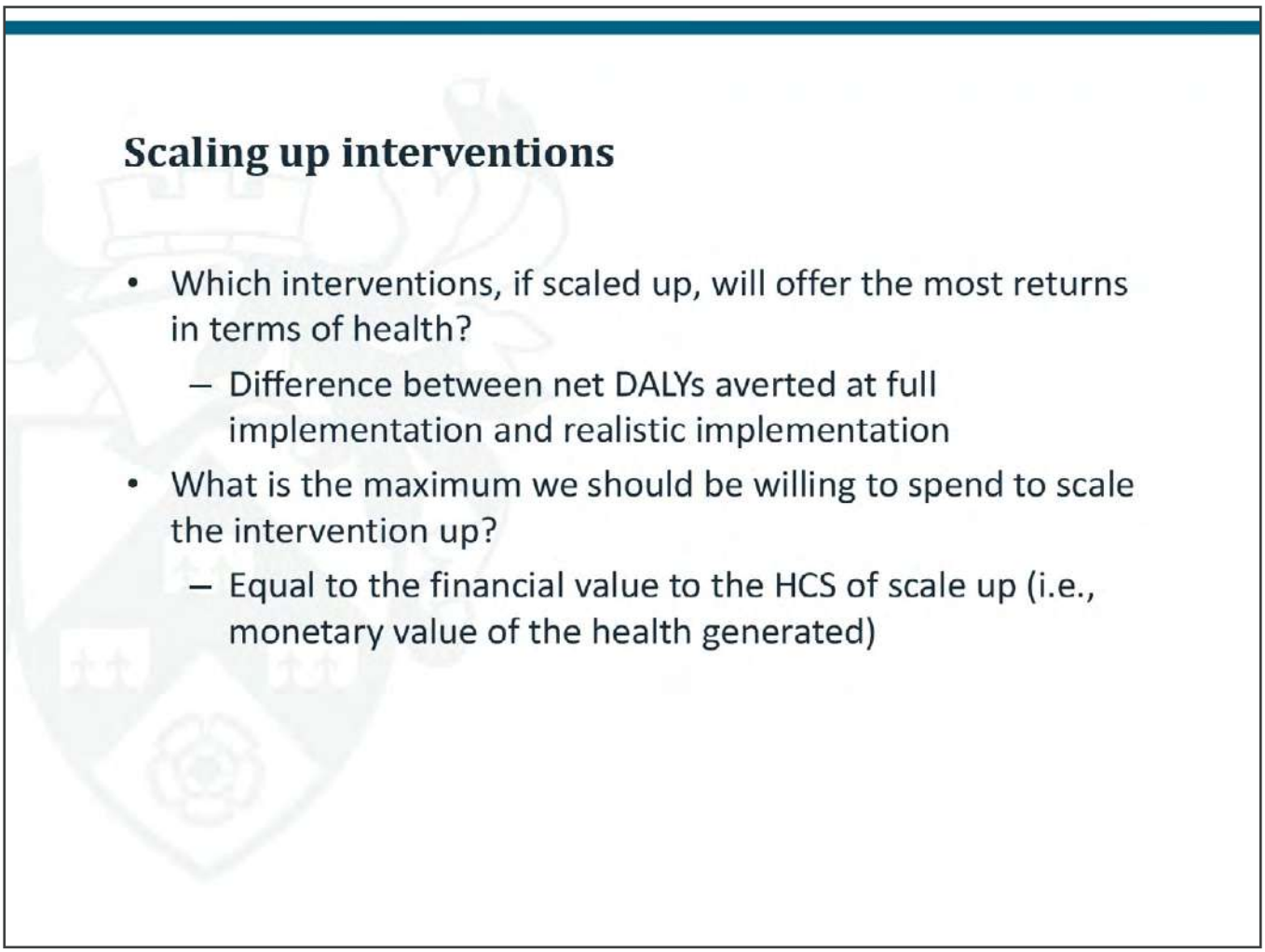




CONSTRAINTS TO IMPLEMENTING INTERVENTIONS

(Min. 00:43:17)

These lighter color bars represent how much we are actually able to implement something hypothetically. So if we squish all of these over to the left, what we can see is that not only are we not generating as much health for each intervention as we would have if it was fully implemented, we are also not spending the money that we would otherwise spend on the intervention if we are only supplying 50% we are only spending 50%. The question then becomes: what do we do with that remaining money? Should we spend it scaling up interventions? Should we spend it on health system strengthening? Or should we be spending that on adding in new interventions that are not currently included.



SCALING UP INTERVENTIONS

(Min. 00:43:59)

In order to answer these questions we need to know which interventions, if scaled up, would offer the most returns in terms of health. And that is the difference between net DALYs averted at full implementation and realistic implementation. We can also look at the maximum we should be willing to spend to scale the intervention up. So that it is equal to the financial value of the healthcare system of scale up. And that gives us an upper limit on how much we would want to spend on that. So if we would know, for example, that it would take a mass media campaign to increase demand to the level that we would be able to reach all the patients who need something, we could see how much is the maximum that we could spend on that. And then we

can also think about this in terms of the health care system as a whole where we just aggregate all these values across all interventions. That gives us an idea of how much we can spend on things like improving hospital infrastructure and human resources.

Summary

- Cost effectiveness thresholds should reflect evidence of the likely health opportunity costs in the settings and HCS in which it will be used.
- Heath opportunity costs are the amount of health that a HCS currently delivers with more or less resources.
- Many of the cost-effectiveness "thresholds" that have been recommended, or have become widely cited, are not founded on an assessment of the likely health opportunity costs, their use is likely to reduce rather than improve health outcomes overall.

SUMMARY

(Min. 00:44:57)

Just to close in summary, I covered quite a lot, the main key things to take home from this are that the cost-effectiveness thresholds that we use should reflect evidence of likely health opportunity costs. So what we want to be thinking about are how much the health care system is currently able to produce in terms of health and using that value. A lot of the thresholds that are currently

recommended are not funded on that assessment. So we have to be quite careful in using those. And, although there is not a bullet on that slide, the key thing is really that we want to be using measures that reflect the scale of the benefit to the population. So moving beyond of just making these categorical "yes" or "no" decisions about ICERs and really thinking about how much we can get in terms of population health benefit from each intervention and using that information to make trade-offs about including things that maybe aren't cost-effective but improve equity and thinking about health system scale up.

QUESTIONS & ANSWERS

(Min. 00:46:55)

Gerald:

Just to start by saying that we are grateful to the Center of Health Economics team at the University of York for really supporting Malawi to revise its essential health package using this new approach. There are few points that I want to mention. The most helpful part for us was, I think, the estimation of a threshold that is based on local data from Malawi. It was estimated at 61 US dollars per DALY averted, which is actually much lower than the one we were using before. The WHO choice recommended 3 times GDP per capita. What we learned from that process is that actually the previous benefit package was achieving less health that we could have reached. So I think that was a very important step in this process. And also the team that was tasked to revise the benefit package, what we did initially was to use the interventions that were cost-effective, using the health maximization criteria. And then, because the team had also agreed on other criteria to use to determine the package, it was really interesting to understand what the impact of using the other criteria would be. For example, including equity and including other donor-funded interventions, which were not cost-effective according to our threshold, and other criteria to see what sort of health we are foregoing by introducing those criteria. It was really very useful to use that framework in that sense. Lastly, I think the issue that we had an idea at the Ministry of Health of which interventions we wanted to prioritise and scale up within the essential health package because of the financial value that was estimated as part of this. At least now we know that if we get an additional amount of resources, about 2.65 million, which was estimated for the previous financial year and is also roughly the same for this financial year, then these would be the sort of interventions we would target first. And, of course, it was not without its limitations. In our context I think the biggest limitation was that we didn't have data for all interventions that are currently being implemented in Malawi. There was also quite a significant use of expert opinion because the agreement was that as long

as we should engage in the process of collecting data for other interventions we should have enough data to continue the process of revising the essential package as new data is generated. I think these are the key points I would highlight about the process.

(Min. 00:51:01)

Question from Paul from Colombia:

Is there any initiative to generate QALY estimates valid for Latin America?

Answer Jessica:

I am not aware. I last heard that Brazil had enshrined in its constitution, I think, something about using cost-effectiveness and needing a threshold estimate. So I think there is an interest in Brazil to estimate something like this but I can't say anything for other countries. But if there was interest I would certainly be more than happy to chat offline about that. So if anyone knows of anything definitely please feel free to get in touch with me.

Question:

When estimating the appropriate scale of the health benefit package, you basically assume that each intervention is being fully implemented, right? Do you think it is always possible to fully implement each intervention? Maybe can we think about the possibility of targeting the most disadvantaged population groups in the case of certain interventions to allow other interventions to be included in the health benefit package?

Answer Jessica:

Yes, I think this is a good question for me and for Gerald as well, actually. So from my perspective I think it is useful to know how much health will be gained by being able to implement the intervention fully and also how much health would be gained at current implementation level. So the gap, or the difference, between those two tells us the potential net health gains we would have if we were able to scale things up. If we could incorporate that, then with additional information about which population groups would be benefiting from each intervention, I think we would definitely want to target that. So the way that I think we have been thinking about it up to this point is assuming that net health gains are health gains across the population, not thinking about to whom exactly, in terms of whether someone is more well off or less well off, and just thinking about maximising the potential benefit of that. Gerald did you have anything to add on that?

Gerald:
Not really. No thanks.

(Min. 00:53:44)

Question:
Considering that commonly used cost-effectiveness thresholds do not provide correct information, what would be the alternative to these thresholds?

Answer Jessica:
That is a good question. I would probably recommend using the best available evidence that you have that reflects what the healthcare system is currently able to do in terms of producing health given the budget, the current infrastructure and things like that. I think that the only estimates available at the moment are the cross-country estimates that have been produced here with colleagues. I think I would recommend those. I forgot to mention, but there is a tool on our website where you can look at the exact range by country. This is also being reviewed at the moment so hopefully it should be published soon. But those estimates are definitely better than using estimates that reflect things to pay or a demand side type of value. That would be something you could use in the interim before you have a country specific estimate that has been estimated using within-country data.

Question from Rafael:
It seems to me that for this work to be carried out one of the biggest challenges might have been the massive need of data on outcomes, costs and effects. How was this overcome in Malawi and how could it be overcome in low- and middle-income countries?

Answer Jessica:
That was definitely one of the biggest challenges that was faced. For data on costs and effects we had hoped to be able to use data from WHO choice and DCP 3, because these both have done systematic reviews of the literature looking at what data is currently available, but both are using only ICERs and we needed more than ICERs. We needed the per patient benefits and costs. So we used those databases to start identifying what interventions we might be interested in, based on what looked cost-effective. But then we used the 'TUFTS Global Health Cost-Effectiveness Analysis Registry' for the majority of the literature review. That database provides sort of a library of papers that have been published on cost-effectiveness in low- and

middle-income countries on various different interventions. And so we took those and had to make decisions about whether they were generalizable to the context of Malawi. Of course, there is very limited evidence for all countries, unfortunately, so it was a matter of finding the best available evidence and then complementing that information with expert judgment within country. We were not able to get cost-effectiveness and cost and benefit information for every intervention. So, some of those judgments had to be made just based on what people in Malawi actually thought. So if there were interventions that were not included but should have been included, those would then be included on the basis of expert judgment. We also needed information on the size of the patient populations. That came from Malawian data sources, as well as the levels to which things were currently being implemented. And that again came from Malawian data sources.

(Min. 00:58:03)

Question:

Could you recommend literature about the methodology to calculate these health opportunity costs?

Answer Jessica:

That is another really good question. To my knowledge, there isn't currently any one single source that explains particularly well how to do this, because it depends on the countries data sources that are available, for example, if you got panel data or cross-sectional data. I think the best thing that you could do at the moment, would be to look at the countries that have done it and how they have done it, so looking at the Australia paper, the UK paper and the Spanish paper. I think the key things that need to be done are first getting an estimate of the health effects of changes in expenditures. So we need elasticity on that. And once you have that you can apply demographic data from within the country on the back end, so taking the elasticity and applying it to the current mortality rates, or current information on the DALY averted, or QALYs for example. That's the best way to do it. Unfortunately, there is not a go-to source for that, but I would be happy to share a list of papers that I think are relevant, which you can send around then.

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