

Value Insider Season I Episode I: The Importance of Payers and HTA: How Did We End Up Here? (Introduction to Value) [Podcast]

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Abstract: The importance of payers and HTA: How did we end up here? In this episode of the Value Insider podcast, host Mike Chambers speaks with Prof. Mike Drummond about Health Technology Assessment (HTA) and how value is defined. Prof. Drummond is professor of Health Economics of York University, former president of the International Society of Pharmacoeconomics and Outcomes Research (ISPOR), and author of two major textbooks in the field, as well as over 700 publications, and has acted as consultant to the WHO as well as European Union with regards to value assessment. Starting from the very beginning, Prof. Drummond explains in a simple yet engaging way why demonstrating value of new interventions has become so important.

Keywords: market access, healthcare reimbursement, health technology assessment, HTA, value demonstration, health economics and outcomes research, payer

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Host: Mr Mike Chambers (MC), Independent expert.

Guest: Prof. Mike Drummond (MD), Independent expert.

Chapter I: General Introduction [00.00]

MC: Welcome to the Value Insider podcast series. In this series, with the help of experts in the field, we will be exploring the fundamentals of assessing value in healthcare, especially when looking at the value of new healthcare interventions.

My name is Mike Chambers, I am founder and director of MC Healthcare Evaluation, and I have spent the last twenty-five years working in health economics and health technology assessment for the pharmaceutical and medical diagnostics industries, and more recently as an independent advisor. I am also a member of the Technology Appraisal Committee at NICE: the National Institute for Health and Care Excellence in the UK. It is my great pleasure to be your moderating host for this season of the Value Insider podcast series.

Chapter 2: Episode Introduction and Welcome [00.58]

MC: Today we will be introducing Health Technology Assessment, and how value is defined, with our first guest speaker: Professor Mike Drummond. Mike is professor of Health Economics of York University, former president of the International Society of Pharmacoeconomics and Outcomes Research, and author of two major textbooks in the field as well as over 700 publications. Mike is currently Editor-in-Chief of the journal *Value in Health*. Welcome, Mike.

MD: Thanks for that introduction, Mike. It is a great pleasure to be involved it is very interesting.

Chapter 3: Value and Stakeholders [01.31]

MC: So let us start with the question: Why has demonstration of value of new interventions in healthcare become so important?

MD: I think the main reason is the increased pressure on healthcare budgets, even in the richer countries.¹ Also, I think this is driven by the extent of innovation we have at the moment. We have lots of new drugs coming through, and these offer great potential for patients, but obviously come at a very high price.² And I think the third reason is that we are now dealing with a much more informed patient population. And they are demanding the latest treatments, and they have read about things on the internet before they go and see their physician.³

MC: Right and so, how should we think of value?

MD: Well, value really is the benefit or satisfaction you get from consuming a product or a service. So in the case of healthcare, the main elements of value would be the benefits in terms of improved survival, possibly reduced symptomology, increasing your mental and physical functioning from receiving healthcare. And more generally, improvements in health-related quality of life.

But the other element here, of course, is that if you have a fixed budget, when you introduce a new therapy, something else has to be displaced and therefore, we have to think of almost the net value, the value that we get from using the new therapy, less the value that we are giving up from an existing one.⁴

MC: Does value differ between different types of decision makers or stakeholders in the healthcare environment?

MD: I suppose the main difference is between the perception of the patient, and the perception of the payer or decision-maker. There is no reason to suppose that everybody perceives value in the same way. And I think the decision-makers tend to focus on value in terms of increased population health, whereas the patient might think about things like the added convenience of a given therapy. And the payer may not value that in the same way. So I think there are these undeniable conflicts in terms of thinking about value.⁵

Chapter 4: Value Frameworks [03.56]

MC: In recent years, we heard a lot of talk about so-called value frameworks. These perhaps capture the different perceptions of the different stakeholders in the healthcare system. Could you describe some of these frameworks for us?

MD: Yeah, I think there's three that are worth talking about. The more general one, is the one that tends to be used by decision makers, which is focusing very much on length of life, and quality of life, as the two major benefits from giving people healthcare. There's another one that has been proposed recently by a taskforce of ISPOR,⁶ and the leader of that was Lou Garrison, his framework, which he calls the Value Flower, basically tries to extend beyond that narrow one, focusing on length of life and quality of life. The central concept of the Value Flower is trying to look more broadly than what many would regard as the core elements of value, which is the fact that healthcare extends your life, and improves your health-related quality of life.

MC: One of the best-known frameworks, particularly to clinicians, is the value framework put forward by Michael Porter.

MD: Yeah, Porter's framework is basically outcome divided by cost.⁷ So I think the reason clinicians can identify with it, is that in every clinical field, there is some key outcomes that you are trying to achieve. And so the clinicians can select which is the most important outcome, and then we have to recognize that we also have to consider the cost. So I think, economists would call that "value for money".

Chapter 5: Payers and Payer Mechanisms [05.49]

MC: Now turning to healthcare payers, and how they think of value. I think, payers is a difficult word. Who are healthcare payers? And what drives their decision-making?

MD: Well, of course it depends on which healthcare system you are talking about. So, a national health service, like we have in the UK,⁸ the payer would essentially be the government. Many countries in Europe have a national or social insurance system, which is somewhat independent of government, and that will be the main payer. So for example in Germany, you have the statutory health insurance, would be the main payer.⁹ In some other countries, predominantly the US, you have a large public system, Medicare/Medicaid, but you also have a lot of private

insurers, so you have got a multitude of payers in the US system.¹⁰ And we should not forget actually, that in some countries the patient is a substantial payer.¹¹

MC: Are there different sorts of mechanisms or ways in which they assess value to support their decision-making?

MD: Well, I mean, the clear way they assess the value is from the initial clinical evidence. And in some countries, that is the main assessment that is made. You know, for example in France and Germany. In some countries the payers may try to develop a generic measure of health gain. So the most famous one is the Quality Adjusted Life Year,¹² which is a kind of a composite measure of the improvement that the therapy delivers in survival, plus the improvement it gives us in quality of life. And of course the issue there is how would one measure quality of life? Countries like Germany that focus on the clinical evidence, are probably a little bit wary about some of those extra manipulations you might have to make to the data to get the Quality Adjusted Life Years gained. But, you know, other countries, predominantly northern and western Europe, tend to favor the QALY measure.

Chapter 6: Health Technology Assessment (HTA) [08.05]

MC: One of the most prominent mechanisms or processes for assessing value that has emerged in the last twenty to thirty years, is called Health Technology Assessment, or HTA for short. Just looking at a definition from the International Network of Agencies for HTA, INAHTA.¹³ It defines HTA as “a multi-disciplinary process that uses explicit methods to determine the value of a healthcare technology at different points in its lifecycle”. Do you have any thoughts about this definition?

MD: Yeah, I think it's good some good elements to it. It stresses, first of all, that health technology assessment is a multi-disciplinary process. I think in some countries people believe the economists have taken it over, but it does involve an interaction of clinical assessments, economic assessments, broader social assessments, and sometimes an examination of the legal and ethical aspects of introducing a technology.

What we should also stress here, though, is, what is a technology? We tend to think of technology as CT scanners and MRI machines, and so on. But a technology is a drug, it can be a medical device, it could be a prevention measure, it could be a system of organizing healthcare.

MC: We hear a lot about HTA in the support of new medicines. So bringing in new technologies, these being medicines or devices, that sort of thing. We hear less about the use of HTA for disinvestment decisions. Do you have any thoughts about that?

MD: The way in which the disinvestment agenda is operationalized, in some healthcare systems, is through evidence-based clinical practice guidelines. I think you are absolutely right that health technology assessment has tended to focus on new things coming into the system, rather than disinvestments.

Chapter 7: The Wider Stakeholder Environment [10.06]

MC: So in a lot of countries there have been efforts to align their health technology assessment process with the regulatory or marketing authorization process for new medicines, to try and reduce that time to a minimum. I think on the other hand, there may be more interest in the future in looking at medicines or new technologies not just on the basis of clinical trials, but when they have been used in the real world to make further assessments later in the life cycle.

MD: The regulators, their concern is to look at the new drug, let us say, and consider whether it's effective, safe, and good quality of manufacture.^{14,15} It's not really comparing that new drug with other drugs that we already have in the system, because the license is granted just on what that drug does, not on how much better or worse it is than other drugs. Whereas of course with health technology assessment, it's more of a comparative process. That you want to see whether the new technology is giving you better value for money, or is superior in many ways, to what you are currently doing.

I think there's three dimensions in which there's a difference. One is: how much comparison is there with other therapies? And HTA is by definition comparative,¹⁶ whereas the licensing tends to focus on that individual product. The second dimension of difference is the outcomes that are considered. And I think the regulatory bodies will accept surrogate outcomes,^{17,18} not necessarily final outcomes for patients. Also, they tend not to focus very much on quality of life measures, although that's increasing. And then I think the other dimension is the length of the time span over which you would make the assessments. So HTA tends to look longer term. And that's why there's a growing interest, certainly in HTA, in looking at real world evidence. You know, what

happens when that drug or device is actually used in regular clinical practice. Particularly with some technologies, the role of how it's used, is quite important.

Ideally, you'd want a kind of seamless process of assessment at the appropriate stages in the development of that technology. What we are finding, is that there's a tension now because, the regulators have these new accelerated approval processes, which bring the technologies to the market quicker, but then the HTA bodies are saying, well, hold on we do not have all the evidence we need to make our decision. So, as you suggested, what has been proposed, is for the regulators and the HTA bodies to get together more often and talk about what they'd like to see in terms of evidence, so that the manufacturer has a clearer idea of what they should be producing, at what time in the development of that technology. And they call it "parallel advice", or "early engagement".

MC: Coming back to something you said earlier: I think it's important to realize that within the decision-making groups that work with HTA, it's very multidisciplinary. There's a lot of input from clinicians, although one may hear that it's all very technical and statisticians, health economists, doing all the work, but that's not the case in terms of decision-making. And a large amount of input from patients and patient organizations to understand the condition, and how the new intervention may impact on that condition.

MD: People often talk about the difference in that process between assessment, and appraisal. And what they mean is by assessment, that's really essentially the science-bit of it. Looking at the data and, statistically, from an economic viewpoint, and so on. But the appraisal is this whole deliberative decision-making process that accompanies that assessment of the data. And that process could involve evidence being given to the committee from clinical experts in the field. Occasionally patients or their carers may have the opportunity to make some input to that process. This varies a lot by country, of course. But I think one should make the point that a good HTA process is a lot more than just looking at the data. I think it does involve all these other elements of stakeholder involvement and engagement.

MC: Yes, and I think it is communication, and we spoke about accountability and patients wanting to be involved, the general public, in decision-making, understanding what happens.

MD: I found it is been very helpful to have a patient representative to give the committee a bit of a reality check on what this means for patients. They came up with some really interesting perspectives on the whole matter.

Chapter 8: Evidence Challenges in HTA [15.33]

MC: What do you think are the main challenges for developing evidence for HTA purposes?

MD: I think the main challenge remains the clinical evidence, particularly with the need for accelerated approval. So drugs originally, in the old days so to speak, there would be two well-conducted large clinical trials in what the pharma industry calls Phase III of clinical development. But now, we are making the judgment on relatively immature clinical data. Costing is not as easy as it looks. Then quality of life, a quality of life measurement is a real challenge.

MC: So I think it is valuable to think of the word "perspective" in this context: that the regulators have a certain perspective, as to what is the scope of health outcomes they are looking at, and whose health outcomes. The HTA may have a slightly broader perspective in who is relevant? Whose outcomes, whose costs are relevant to decision-making.

MD: I think that is a fair comment. It does depend on the country: if you look at the HTA process in Germany, it is probably a lot similar to what the regulators would look at, than say, the HTA process in Sweden, which has a broad societal perspective, looks at things like impact on productivity.¹⁹

MC: Are there initiatives to strengthen this link or interaction between regulatory and HTA agencies?

MD: The early dialogue^{5,20} and the joint discussions are very useful. In Europe, there has been some discussions recently about regulations of HTA within the European Union, which would involve two things. One is joint clinical consultations between the regulators and the different HTA bodies, to try and get on the same page as to what they want to see in terms of data. And then there will be a single joint clinical assessment, which would be available for every HTA body in the European Union. Some of the poorer countries in Europe, or those with lack of resources for HTA may not be able to do the assessments.

Chapter 9: Centralized HTA [17.56]

MC: Why is not there just a single centralized system for HTA in Europe? Or in the US, for that matter.

MD:

Although it introduces an inequality we do not like to see, I think it is somewhat unavoidable that different payers may have different budgets, and different ability to pay for different technologies. So that's why we have struggled to have a single HTA decision across Europe.

The US situation is that the healthcare system is divided into two: fifty percent of it, roughly, is a public healthcare system, limited by legal provision. Then, the private system is 2000 different payers, with different budgets. So it is difficult for them to reach common decisions. Central bodies have emerged: There is one that is called ICER,²¹ Institute for Clinical and Economic Review, which is providing HTA assessments, which the private payers can either use, or disregard, depending on their own preferences.

MC: I think what you said about the US is quite interesting. Ironically, a lot of the foundations for HTA came out of the US, in the 70s and 80s. And I think in the US there is quite a lot of what could be called elements of HTA, happening in various parts of the healthcare system.

MD: I think that is a fair point. The Europeans kind of took it over quite quickly. You know, the Swedes, and the Dutch, in particular.³

Chapter 10: The Success of HTA [19.33]

MC: So, to conclude, the question remains: has HTA been successful?

MD: Yeah, I wish I knew the answer to that question. I think there is a couple of points you could make. I mean, the first thing is, let us take an individual body, like NICE in the UK.⁸ Now, we can assess what NICE has done, but we do not know the counterfactual. We do not know how things would have developed, if there'd never have been a NICE. If you'd ask me what is been the main benefit of HTA, I think first of all it is made everybody consider evidence more thoroughly. The fact that HTA bodies are doing these assessments, has had some spillover within the healthcare system. You know, there is a strong evidence-based medicine movement in certain countries. And I think also it is not the refusal of a technology, it is more the targeting of these technologies to the patients who would benefit the most. If you think of governments that adopt HTA, very few abandon it. Whereas there's lots of other policies that come and go on a regular basis.

I remember the quote from Yogi Berra, the baseball player, who said: do not predict anything, especially the future. Which I think is a good adage for HTA.

Chapter 11: Conclusion [21.02]

MC: So I think in summary, what you are saying is, you think HTA is here to stay, at least for the time being. And in a world with finite resources and the needs that outstrip budgets, there needs to be some method of allocating resources to these new technologies, and technologies with perceived value, as opposed to those without value.

So I think we have come to the end of our time, and Mike, Professor Drummond, I'd like to thank you very much for joining us today on this podcast. I'd like to thank you for an engaging conversation, and for giving us such a comprehensive overview of HTA and more broadly how value is defined.

I hope that all you listeners can join us for the second podcast in this series with Professor Nancy Devlin, at the University of Melbourne, where we will focus on assessing value from the perspective of the patient, by measuring and valuing quality of life.

If you have enjoyed this podcast, please do subscribe to the series, and thank you for listening.

Acknowledgment

The authors thank Rachel Emerson-Stadler (Boehringer Ingelheim International GmbH, Germany) for her early contributions in the design of the podcast series and most particularly Dr. Lindsay Nicholson (Maverex Ltd, UK) for her expert assistance at all stages in the development of this episode, including diligent background research and curation of content under direction of the authors.

Disclosure

Those involved have been compensated for their time by Boehringer Ingelheim. Speakers on this podcast speak on personal behalf, independently of Boehringer Ingelheim. E.S. Hartgers-Gubbels is an employee of Boehringer Ingelheim International GmbH. M Chambers is the founder of MC Healthcare Evaluation and a former employee of GSK and GE Healthcare. The authors report no other conflicts of interest in this work.

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