

# Value Insider Season I Episode 6: How Will Market Access and Value Demonstration Evolve? (Future Outlook) [Podcast]

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**Abstract:** How will market access and value demonstration evolve? In this episode of the Value Insider podcast, host Mike Chambers speaks with Ass. Prof. Panos Kanavos about the future of value assessments in healthcare. Dr Kanavos is Associate Professor of the International Health Policy in the Department of Health Policy at London School of Economics and Political Science as well as Deputy Director at LSE Health and Program Director of the Medical Technology Research Group (MTRG), and advisor to prominent organizations including the European Commission, the European Parliament, the World Bank, the WHO and OECD. Discussing key changes, Dr Kanavos outlines which opportunities and challenges will alter the way we value healthcare interventions.

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

Host: Mr Michael Chambers, Independent expert (MC)

Guest: Dr Panos Kanavos, Independent expert PK

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## 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: Thank you for joining us today, be sure to subscribe to the Value Insider podcast series to ensure that you do not miss any of the informative podcasts in this series.

In this Value Insider series, we have been on a journey to uncover how elements of value are used to support decision-making in healthcare. We began with Professor Mike Drummond discussing the importance of value assessments in healthcare. In Episode 2, Professor Nancy Devlin helped us to understand how quality of life of patients is measured and valued. Professor Sean Sullivan and Professor Maureen Rutten-van Mólken in Episodes

3 and 4, explained how healthcare payers assess the affordability and cost-effectiveness of new technologies. Finally, in Episode 5, Professor Lou Garrison explained the value flower and how we could measure value in a much broader sense.

Which leads us today to our crystal ball episode. What will the future bring for value assessments in healthcare? And we will be discussing this with our guest speaker Panos Kanavos. Panos is Associate Professor of International Health Policy in the Department of Health Policy at the London School of Economics and Political Science, where he is Deputy Director at LSE Health and Program Director of the Medical Technology Research Group. Panos has acted as an advisor to several international governmental and non-governmental organizations, including the European Commission, the European Parliament, the World Bank, the World Health Organization and the Organization for Economic Co-operation and Development. Welcome, Panos.

PK: Thank you, for the warm welcome, Mike. Delighted to be with you.

## Chapter 3: Changes Driven by Challenges [02.47]

MC: So previous episodes have discussed the current situation, but maybe you can help us understand what to expect for the future. How might demand for value assessments change as healthcare systems develop over the next few years, to address the newly rising challenges? And then, what does this mean for the supply of value assessments?

PK: I think healthcare systems do face a lot of challenges, and I think it is important to reflect on these before we start, before we start to talk about value assessments.

I think the first challenge is that of different expectations by different groups of citizens. The twenty-year-olds have got different expectations compared to the thirty-year-olds, the forty-year-olds, and so on, and so forth.

The second challenge is the rising prevalence of chronic disease.<sup>1</sup> Because that, unavoidably, will have an impact on resources, resources dedicated to healthcare are not going to increase substantially over the next five, ten, fifteen or twenty years.

The third one is that of technological change, which is actually breathtaking. I think for healthcare systems to keep up pace with technological developments, will be very, very difficult.

And finally, the issue of multi-morbidities. That also poses a lot of challenges in terms of care coordination, care integration, and pathways.<sup>2</sup> About five to ten percent of patients in any OECD country account for approximately sixty to seventy percent of total healthcare expenditure.<sup>3</sup> The big question for decision-makers going forward, will be whether we can actually identify these five, ten percent of patients, so we can actually target healthcare interventions appropriately, to them, in terms of improving health outcomes, but also in terms of rationalizing on healthcare resource utilization.

So I think these are some of the big challenges that I see going forward. And they all relate to resource use, effectiveness, efficiency, but also population expectations.

## Chapter 4: Decisions-Makers of the Future [04.48]

MC: In our first episode, we learned that decision makers have different perceptions of value, but their overall aim is to increase population health. Who are the decision makers of the future? And how might their perceptions of value change?

PK: The decision makers of the future are not likely to change substantially compared to what we have today. The decision makers of the present, current decision makers, and the future, are always going to be those who fund health services. So we are looking at benefit designers, whether you are in a tax-funded system or a social insurance funded system or even a privately funded system. These may operate at the central level, so Ministry of Health, Department of Health or health authorities, or strategic health authorities. Or at the regional level, as we have in countries like Sweden, or even Spain.

So these people are actually making the decisions. The health technology assessment agencies are tasked as intermediaries, to make funding recommendations. And I think it is important to draw that distinction between those who pay for services, and those who actually make their recommendations for the payers to enable these decisions to be taken.

So we have seen phenomena whereby procurement agencies employed by benefit designers, in other words the healthcare system, are actually making decisions about coverage, in other words reimbursement, based on recommendations, or improving the recommendations made by HTA agencies. An HTA organization may have

recommended a technology for funding, but the procurement agency may want to improve on the terms of that recommendation.

So I think the environment is becoming a bit more adversarial and to a certain extent a bit more complex, going forward. In order to improve on affordability, but also improve on elements of cost-effectiveness whenever cost-effectiveness is a criterion for decision making.

I would not want to disregard the role of patients, and the role of healthcare professionals, in that context, because everyone, from their perspective, have important things to say, about benefits, about value, it is important to reflect on their value concerns as well.

MC: Thank you for that. What you have told us about the difference between HTA and procurement, and payers or purchasers, is actually very important, to bear in mind.

## Chapter 5: Changing Processes for Value Decision-Making [07.17]

MC: How do you see the processes for decision making changing, based on value assessments?

PK: I think from a European perspective, is what we have experienced over the past few years, is an attempt to centralize decision making at one level, the assessment level. And I think going back a little bit on...on what health technology assessment organizations do, they work on assessment, they work on appraisal, they work on funding recommendations, and they work on clinical guidance.<sup>4,5</sup>

What has happened at EU level, is the creation, of a European mechanism, that will conduct assessments of new technologies in Europe post 2024. I am hoping that we can have a more sort of harmonized way of reaching decisions, based on assessment. Of course, the localization of these decisions takes place through what we call “appraisal”. In other words, whether new techniques or new technologies are useful for a particular or in a particular setting. Looking at the next five or ten years, we will probably witness a lot more of that. And I think we have started to see some of that in other jurisdictions as well, in Latin America,<sup>6</sup> or in South-East Asia,<sup>7</sup> but these are very preliminary.

There are two more elements which I would like to draw our attention to, here. One is the cross-border collaboration. We will probably witness a lot more cross-border collaboration in the future. One of the institutions we have seen, is BeNeLuxA,<sup>8</sup> which promotes HTA collaboration between the countries that are participating. And that goes into a number of different stages, so, the horizon scanning process, the HTA collaboration. So countries participating in these efforts have to have faith in each others’ processes. So some degree of discussion and collaboration has to go into a harmonization process.

But it is also an issue relating to joint negotiation. One party can negotiate on behalf of others. And finally, the joint procurement where there may be opportunities to put money on the table and procure technologies based on what is negotiated on behalf of the participating countries.

So I see that as a potential model for particularly personalized medicine and technologies which are very, very streamlined and relevant for few patients. So the ultra-orphan conditions, maybe some of the orphan conditions as well.<sup>9</sup> In order not only to safeguard affordability, potentially also cost-effectiveness and creating efficiencies in the system, but also in terms of safeguarding equity.

## Chapter 6: Harmonization of HTA [10.13]

MC: So, I am hearing quite a lot about harmonization, about increasing efficiencies, and new models for decision making, which may go across countries. For those who do not know, BeNeLux is Belgium, Netherlands and Luxembourg, which I think other countries will reflect on.

Now thinking about the elements of value that these decision makers are drawing on, in our fifth episode, Lou Garrison discussed the broader societal perspective, and the potential to incorporate novel elements of value alongside conventional elements of value. Are any of these novel elements of societal value influential now, and do you see them becoming more prominent in the future?

PK: I think they are prominent in some healthcare systems. In countries like the UK, we have elements along the lines of end-of-life criteria, or rarity.<sup>10</sup> In Sweden, we have the unmet medical need. So there are some, “social value judgments”<sup>11</sup> which are important, and are already being taken into consideration.

But by looking at HTAs, the assessment reports, we know that a whole bunch of other societal considerations are taken into account for a very specific reason: because we need to safeguard equity. Cost-effectiveness in its own right, in principle, violates the principle of equity. And therefore we have to re-introduce other elements of

benefit, in order to safeguard equity,<sup>12</sup> and I think that is going to be strengthened in the future, impact on family, impact on caring, the ability to return to work. The problem that I see is that they are taken into account on an ad-hoc basis, and therefore we need to introduce some method or some way that explicitly value these considerations. It may be worthwhile looking at alternative methods of value assessment. For example along the lines of Multi Criteria Decision Analysis,<sup>13-15</sup> which allows us through scoring, and weighing processes, to value exactly what the impact or the likely impact could be of all dimensions of benefit, both clinical and non-clinical. In other words, so-called social value judgments.<sup>11</sup>

## Chapter 7: The Role of the Quality-Adjusted Life Year (QALY) in Future HTA [12.26]

MC: In our second episode, Nancy Devlin explained about the quality adjusted life year, the QALY, being a cornerstone of value assessments in many countries in HTA. Thinking to the future, do you think the QALY will retain such a central position in value assessments? Will MCDA become an alternative? Or will the two be brought together?

PK: I think we probably look at some fusion of techniques going forward. I do not know how this is going to take place. I think there is a lot of work, a lot of research taking place in different jurisdictions. But two things are important in this context.

First, that we have to take into consideration the value concerns of different stakeholders going forward. They include patients, but also HTA agencies in the healthcare systems among others. I think we need to reflect on that one, so through a process of MCDA we can actually do that.<sup>13-15</sup>

And the other thing is that we need to account for different techniques or different dimensions of benefit. Now, in some systems, we have done that already, through the QALY, or the ICER.<sup>16</sup> The QALY has different acceptability in different settings. It is not necessarily the best metric, maybe countries like Germany, for example, would like to think about life-years gained.

The other thing which is interesting, and I think is important to reflect on, is, whose values are we thinking of? Average values of citizens? Or are we thinking about values of patients. Bottomline is the QALY is something that we are probably continuing to use until something better, something more robust comes to the fore. We recognize it is something incomplete, and therefore it needs to be supplemented.

## Chapter 8: Real-World Data [14.13]

MC: So, I think we can expect changes in the healthcare decision making environment, are likely to impact on how we assess the value of new interventions in the future.

Over the next few years, what will happen to our ability to identify, measure and communicate elements of value, to supply the information that go into these assessments?

PK: I think that takes us into the domain of real-world data. An increasing number of new technologies are approved with incomplete or early-phase evidence, and that obviously creates a lot of uncertainty. Uncertainty about benefits, the clinical value. One way to bridge those uncertainties, and make decision makers cover these new technologies, is to generate data in real-world settings.<sup>17,18</sup>

I think this is a good compromise, and I think this will intensify in the future. In fact, this is probably the only way forward. And therefore, real-world data and real-world evidence becomes a one-way street. For the generation of information, for the creation of contracts, value contracts, and perhaps arrangements along the lines of coverage with evidence, with evidence development.

The big question, of course, for industry, is, what kind of prices are we talking about, and how contracts are going to be constructed, that are fruitful and reasonable from both the supply side, which is the industry side, but also the demand side, which is the healthcare system.

MC: Do the regulators and the HTA organizations, do they trust real-world data?

PK: I think there is a scepticism in the past, but I think there are ways of selecting or conducting studies which are robust, methodologically, in order to enable those value concerns to be reflected in our decision making processes.

So good selections need to take place. HTA is not a one thing happening at a point in time. We will have a process whereby technologies are evaluated and re-evaluated. I would not say continuously, but as soon as new pieces of evidence come about.

MC: So real-world data, with all its faults, is going to become more important in decision making, and it is not necessarily going to replace the need for randomized controlled trials.

PK: You are absolutely right there, and I think some of the initiatives that we have seen also at European level, like DARWIN for example, from the European Medicines Agency.<sup>19</sup> I think they go hand in hand with other developments which link the regulatory side with the health technology assessment side. Not necessarily to satisfy micro-political perspectives, in other words, do a real-world evidence study in country A, so that you can obtain coverage. But, what evidence generation needs to take place as part of a common market, in order to satisfy general evidentiary requirements.

So HTAs need to change the way they do things. In the quantity and the quality of the data they want to see. In the collaboration they have with regulators, but also in the extent to which they involve other stakeholders. Particularly, specifically, patients.

MK: So, I think that in recent years, and I'd see that moving forward, that's going to be a lot of work, improving those aspects of real-world data, so that the analyses based on the real-world data are trustworthy and more helpful for decision making.

PK: Definitely. I think one of the issues that we need to reflect on is how we reduce uncertainties. Uncertainties in evidence, in clinical evidence. Those relate primarily to study design, trial concerns, comparator concerns, and of course, there are similar issues when we are talking about economic uncertainties for those countries that do implement cost-effectiveness.

If there are meaningful ways of reducing uncertainty through real-world data, with improved methodologies and collaborative frameworks, then I think this is viable and a very useful way forward.

## Chapter 9: Big Data [18.40]

MC: So, Panos, everybody knows the buzzwords “big data”, along with artificial intelligence, machine learning. What is meant by big data, and how can big data be valuable to healthcare decision makers?

PK: A very sensitive topic. Big data, really a large amount of information, of data, that we are able to link together, to make informed decisions about policy interventions, about coverage, and so on. The data interlinkages that we have in many healthcare systems, are reasonable, at the moment, although they can be improved quite, quite significantly.<sup>20</sup>

The problem that I see is our ability to leverage all of that information at system level and design the interventions that are needed.<sup>21</sup> I am less impressed by the discussion on big data, artificial intelligence, and whatever else. But I would be a lot more impressed if we were in a position to design interventions, using the data that we have available to ourselves, right now. Then we can move on to leveraging big data, linking data sources from different perspectives.

And, of course, there are additional qualitative elements that artificial intelligence is not able to capture at this point.

That does not mean to say that I completely reject the idea of artificial intelligence in healthcare, on the contrary. But I think we have to have a measure of success. And my measure of success at this point in time is going to be to leverage the information that we have available to us.

And the key issue is where do we start from? And yes, we do need to have the infrastructure, yes, we do need to be able to design interventions, but how we improve equity, or how do we improve access to the service, or how do we improve a specific outcome.

For example, we collect painstakingly, prescribing data and information. Probably we can link it to laboratory data, we can design interventions at sub-indication level. The whole idea of population health is to be able to offer integrated care services. The extent to which we are doing that, is probably problematic in many, if not most healthcare systems.

MC: As this new world of data comes about, I am struggling a bit with seeing how this will all take place even jumping five years ahead. How do you think this is going to work out?

PK: I do not see value as one size fits all. So, I think we need to reflect on – how – reflect these technologies, and probably this is where additional evidence, real-world evidence would be extremely important.

And we have technologies which are much more amenable to population health improvement. So improvements in, in efficiency, but also improvements in healthcare outcomes. We still need to have better care

coordination, and integrated care pathways.<sup>22</sup> So these may be considered as ground-breaking, but they do require significant changes in the way the healthcare system reacts to the adoption of those technologies.

We will have technologies that are amenable to interventions in very small populations. And we will have technologies that are amenable and implementable in, let us say, cardiovascular disease. Different things may be necessary. So, these two things will coexist. Unavoidably, the healthcare system will need to adapt itself to both types of technology. And so does HTA.

## Chapter 10: The Future of HTA [22.32]

MC: At the start of this podcast series, we asked the question “has health technology assessment been successful?” How do you see HTA evolving to remain relevant to the decision makers of the future?

PK: HTA has been extremely useful, from my perspective. It has provided the rationale for decision making. The explicit consideration of evidence, and considered a way of looking at evidence and linking it to the decision making.<sup>23</sup> But health technology assessment is part of a continuum. And that continuum says that funding decisions and the conditions for coverage cannot be taken solely based on a Phase II or a Phase III clinical trial.

We need to consider the evidence, the quantity and the quality of that evidence, we need to interpret that evidence, and make it relevant to our setting, and our priorities. These priorities may differ in different healthcare systems, and therefore the so-called social value judgments may differ in individual healthcare systems.

Health technology assessment may change in shape or form, because we have important challenges ahead of us. For example: what value metrics to use for different indications? How do we deal with HTA of combination pricing? How do you assess value for a cure, from a healthcare system and a societal perspective? How do you assess value of digital technologies?

So, these concerns are quite different to the kinds of problems we had twenty years ago, when we were still considering issues around costing, and issues around direct costs, medical cost vs non-medical cost.

So I think it's an evolving, it's an evolving process. But I think an essential one, for decision making purposes.

## Chapter 11: Conclusion [24.26]

MC: Well thank you very much, Panos. I think you have helped us today to understand aspects of evidence to support robust and reliable social value judgments, and to make sure that the organizations responsible for doing that within countries, have common understanding, of the information that they are basing their decision making on. And also that they make different value judgments, based on differences in the healthcare systems.

And with that, I think we have come to the end of our time, today. Panos, I'd like to thank you very much for joining us today on this podcast, and for an intriguing conversation about the future of value assessments.

PK: Thank you, Mike.

MC: And thank you listeners for joining us for this final episode of the Value Insider series. I hope that you have found this episode and the whole series informative and enjoyable, and – indeed – of value!

Be sure to listen to earlier episodes if you have not yet done so, and look out for Value Insider season 2.

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