

# Value Insider Season I Episode 3: How Does Budget Impact and Affordability in Healthcare Work? (BI and Affordability) [Podcast]

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**Abstract:** How does budget impact and affordability in healthcare work? In this episode of the Value Insider podcast, host Mike Chambers speaks with Prof. Sean Sullivan about affordability and budget impact for the “payers” of healthcare interventions. Prof. Sullivan is Dean of the University of Washington School of Pharmacy. He is past president of the International Society for Pharmacoeconomics and Outcomes Research (ISPOR) and served as chair of the health technology assessment (HTA) committee of US Health Insurer Premera Blue Cross, was part of the US Governmental Medicare coverage evidence committee and led the ISPOR Task Force on Methods for Conducting and Reporting Budget Impact Assessments. Prof. Sullivan explains how budget impact and affordability are intertwined and how this plays a role in decisions in the US, but also the rest of the world.

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

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Host: Mr M Chambers (MC), Independent expert

Guest: Prof. SD Sullivan (SS), 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: 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 the series.

Today, we will be talking about affordability to payers, and budget impact with our guest speaker, Professor Sean Sullivan. Sean is Professor and Dean of the University of Washington School of Pharmacy. He is past president of the International Society for Pharmacoeconomics and Outcomes Research (ISPOR). He served as

chair of the Health Technology Assessment committee of Premera Blue Cross for fifteen years, and on the Medicare coverage and evidence committee for ten years. Importantly, Sean led the ISPOR Task Force on Methods for Conducting and Reporting Budget Impact Assessments. Welcome Sean.

SS: Thank you, Mike, it's a pleasure to be with you here, today.

### Chapter 3: Payers and Value [01.49]

MC: The term “payer” is used frequently as decision-makers in healthcare and key stakeholders for those developing new interventions. Who are payers?

SS: Well, a healthcare payer is a body or an agency or organization that holds, and then allocates, a healthcare budget. That is, they finance, or they reimburse the cost of medicines or health services. They are very different from healthcare providers, like hospitals, physicians, pharmacists, who actually deliver healthcare services, and they, in turn, are reimbursed by the healthcare payers. In the US we have some integrated healthcare systems that serve both roles. They are payers, and providers. With respect to payers in the US, we have sort of three different kinds. There's government entities, there are private sector employers, and then individuals actually are payers in the US, in that they for a fair amount of their own healthcare out of pocket. And the public entities, the government entities, are organizations like Medicare, and Medicaid. The private sector insurers are very large, multi-state organizations that insure and then pay for healthcare services on behalf of employers. Just as a reminder, Mike, there is no single national system of health insurance in the US.<sup>1</sup>

MC: And what elements of value are of most importance to healthcare payers, especially in the US?

SS: I think the list can be very long. And I would also say that it depends on the payer. The elements of value for a government payer may be very different than for private sector, private insurer. But the things that are important to payers certainly include the elements of patient benefits and improvements in health outcomes that go along with all of the healthcare services that payers pay for. They are quite interested in paying for things that have a positive impact on, for example, quality of life, life expectancy, disease progression, etcetera. And of course, attended risks that go along with those interventions that they pay for.

They are also though, very interested in from a value perspective,<sup>2</sup> the service level that their contracted providers provide to patients. And I think of course all of that taken together, they are very interested in the costs of providing all of those services. In part because payers have limited budgets. And they need to, then, make decisions about what technologies they would fund, and which they would not.

### Chapter 4: Time Horizon [05.04]

MC: When we are thinking of costs, over what sort of time period are payers thinking about?

SS: Well, this is a great question. It depends, particularly in the US, about what payer we are talking about. Government payers like Medicare<sup>3</sup> insure healthcare services for folks in the US once they reach the age of 65. And then those patients are with the Medicare system for the balance of their life. And so for Medicare, their perspective on costs and benefits of treatments is quite extensive. With respect to the private sector, the health insurers, again linked to the provision of healthcare payments by employers, their perspective is necessarily shorter, because they are insuring employees of organizations that buy health insurance, and oftentimes those employees are not with an employer for an extended period of time.

MC: So it always seems to me a bit of an issue from the US healthcare system that these longer term, we sometimes call them ‘downstream cost savings’, the cost that you might prevent by treating people better now, or preventing progression of disease, may not be recognized so strongly by the payer who has a short-term perspective.

SS: Well, for sure Mike, they may not internalize the cost-savings that come from preventive therapies that require up-front costs, and the benefits from improved. for a while. But if you look at the services that they do reimburse, the private sector, even though they have this dis-incentive, if you will, to invest in preventive therapies, they in fact do. And the future savings, if you will, happen downstream. They do make those kinds of investments, because clinically they need to. They do not want to be found to be out of line reimbursing for therapies that are not consistent with, let us say, clinical guidelines and clinical recommendations.

## Chapter 5: Budget Impact Analysis (BIA) versus Cost-Effectiveness Analysis (CEA) [07.28]

MC: So a vehicle for calculating the budget impact is often called a “budget impact model”. Could you tell us a little bit about what a budget impact model is?

SS: I can! A budget impact model is a calculator, if you will, that compares scenarios for the population that is covered by the payer. And those scenarios would be, in the simplest sense, one scenario with and one without the adoption of the new technology. And the aim here, of the calculator and this model, is to estimate the financial consequences of introducing the new technology for that specific payer, over the timeframe of the model.<sup>4</sup>

The result of that exercise, that sort of calculation produces an estimate of the sort of additional costs to the payer’s budget during the time frame of that assessment. The payer would then make a judgement about whether or not that additional expense is affordable (or not) given other possible uses of the resources. This judgment that they make, is an expression of affordability for that specific payer. Each payer has their own threshold for the magnitude of budget expense that would appear to them to be affordable, or not.

And the model uses estimates, at the population level, of various things, like adoption of the new technology. How will that occur, and over what timeframe? It will also use estimates of whether or not that new technology might supplant existing technologies. And that could result in savings of costs, for example.

And this model, Mike, can be free-standing, or it could be considered as part of a comprehensive economic assessment, alongside for example a cost-effective analysis that would be conducted. The consideration of both the economic evaluation, along with the budget impact evaluation would comprise part of a submission, for example to a payer in the United States, or of course this happens in other countries too. Like the UK, for example, Australia, Canada, where there are mandatory requirements for budget impact as part of a submission to a Health Technology Assessment agency.<sup>5-7</sup> I will point out in the US that we have an organization, third-party organization here, that’s not a government entity, nor is it formally aligned with private sector payers. It sits as a third-party organization called ICER.<sup>2,8</sup> That’s the name of the organization. And ICER has similar requirements as part of its own assessments, relative to budget impact evaluation and cost-effectiveness evaluation.<sup>9</sup>

MC: Just to add to that, I think many countries, even those who do not have requirements all the time for cost-effectiveness analyses, do have mandatory requirements for budget impact analyses. For example France and Germany, where cost-effectiveness analyses are less frequently used. And we will hear more about cost-effectiveness analyses in our next episode, so please join us for the next episode.

### What are the Main Components of Budget Impact Models?

SS: First and foremost the estimated size of the patient population that’s eligible for the treatment. The more individuals that are eligible for treatment, and that ultimately receive the treatment, the larger the potential budget impact. Second element, is to identify what the current interventions are. Those that represent the standard of care, for example, and then, juxtaposing all the current interventions, what would be the estimated uptake of the new intervention? How might that occur? Over what period of time? You might ask, Mike, what. How we estimate adoption, because it is rather art-form, if you will. And there are really several ways, but the two that are most widely used: first is to ask the manufacturer what their market forecasts are; the second is to look for a like-example, in a prior time period, of a technology in a therapeutic area similar in nature, and then to use data to estimate the uptake of this new technology, a product.

The final two elements, components of the budget impact model are the prices, so you need prices of all the technologies that are being used, including the new intervention. And then finally any impact that the new technology might have on healthcare resources, and healthcare costs downstream.<sup>4</sup>

MC: Thank you, Sean, that was really clear. I think it’s really important to clearly understand the difference between affordability and budget impact, and cost-effectiveness.

SS: The point to make here is that budget impact is an evaluation of incremental expense. And the payer can use that estimate to make a judgment on affordability. Cost-effectiveness analysis gives an estimate of value for money. That is, is the additional benefit worth the additional cost? That also requires the payer to make a judgment on value for money. And there are for some jurisdictions and some HTA bodies there are well-accepted thresholds for value for money. Whereas there are not well-accepted or conventional thresholds for affordability.

Imagine a one-time gene therapy treatment for an ultra-orphan disease for which there is only one patient eligible. And that that therapy would cost two million euros. So, if that therapy is approved by the regulators, the uptake would be for one patient, and that two million dollars, I will use dollars, is now spread across the entire

healthcare system. It could very well be that that very expensive gene therapy, two million dollars for one the patient, is actually quite affordable. Now contrast that with, let us say, a treatment, that might be used to treat cardiovascular disease, over the lifetime of an individual. Here now you have a highly prevalent set of conditions. The treatments are given not just once, but many times, for the remaining period of their life. Of course, unless those treatments are then supplanted by new treatments in the future. So making the budget impact assessment here is a little more complicated. And so now you might have a budget impact that is much larger, [laughs] and may be judged as not affordable. Even though the cost of the therapy per patient is a whole lot less, than the two million dollar gene therapy.

MC: So we can have cost-effective interventions, that are not considered to be affordable.

SS: So true. And here I will give you another example, here, this is a real example that played out in the US about ten years ago. We were, like all the world, were experiencing a revolution in drug development related to Hepatitis C. Prior to these new anti-virals, we had therapies that were not very effective, and in fact had serious side effects associated with them. The introduction of the first hepatitis C anti-viral in the US that would be used as model therapy, were found to be incredibly effective. Ninety-plus per cent cure rates. Not managing the disease, but actually curing them. And when those treatments were assessed for their cost-effectiveness, they were viewed to represent very good value-for-money. But when this entire sort of mix of hepatitis C patients were modeled in terms of budget impact, that was very scary for healthcare payers in the US. And as a consequence, payers decided to restrict the use of these treatments. At least early-on, because they were very worried about the affordability.<sup>10</sup> Hepatitis C treatments were cost-effective, but they were viewed skeptically as being a therapy that would be unaffordable. Or what, the phrase that was used in the US, was that these treatments would break the budget.

MC: And I know certainly outside the US, in the European context, sometimes the commitment to fund new therapies, a mandatory commitment to fund new therapies that are considered to be cost-effective. This caused a serious problem, in many countries.

## Chapter 6: Health Technology Assessment (HTA) [18.03]

MC: So thinking of health technology assessment. How should budget impact assessment be used alongside cost-effectiveness assessments? These different, but somewhat interrelated analyses.

SS: Most of the budget holders in the US, particularly the private payers, are quite interested in estimates of budget impact. And in fact, they utilize budget impact models.<sup>2,4</sup> The estimates of budget impact actually feed their internal decision-making processes. In the US, cost-effectiveness evaluation is not used as widely as it is in countries outside of the US, like the UK for example. And frequently the private sector health plans, with a couple of rare exceptions, actually do not even allow for cost-effectiveness arguments to be part of their decision-making processes. We do have, as I mentioned earlier, a third-party organization in the US called ICER, and they recently released their 2020 to 2023 assessment framework,<sup>8</sup> where they propose not only new thresholds for cost-effectiveness evaluation, but also an affordability threshold. Having said that, there really is no agreed decision threshold for budget impact in the United States. And so you might then ask, [laughs] so how do payers decide whether a new technology is affordable or not, and I would say that in the US these are highly individualized assessments of affordability. And they are not explicit. So you cannot look, for example, on an insurer's website and it will tell you criteria for what is affordable or not. But that it factors into this multi-criteria decision assessment that a health plan might make, about whether or not to cover, and reimburse, a new technology.

MC: So these are private, confidential discussions that happen within the organization, based on a wealth of previous experience on considering affordability of previous technologies.

SS: Yes. Correct.

MC: Right. Thanks, Sean.

## Chapter 7: Risk-Sharing [20.37]

MC: And in recent years, we have heard the use of the term “risk-sharing”. How can budget impact analyses help share financial risks?

SS: Well, let me come back to the hepatitis C example, and use that to highlight how budget impact forecasts might result in some information that the manufacturer and the payer might use to then wrap around an innovative contract.<sup>11</sup> I want to differentiate this, though, Mike, from outcomes-based agreements, because there are no

health benefits that are necessarily being linked to a financial agreement in this example. These are purely around budget forecasts, and reducing the risk of, on the part of the payer for example, of exceeding their budget.

I live in the state of Washington. And in our state, we have a government payer, called Medicaid, where the budgets are derived from taxpayer moneys. Washington state also pays for individuals who are incarcerated. There are a number of people in the Medicaid program who have hepatitis C. And so the state of Washington was concerned about how much it might have to pay for these new hepatitis treatments. And when they did the budget impact evaluation, the financial risk to the state was huge. And then the payer, Washington state, and the manufacturers, agreed to a cap on the budget. And they did that by agreeing to all the elements that comprise the budget impact assessment, including the size of the patient population, that would be eligible for treatment. And then, once that agreement was finished, the payer, Washington state, allowed those technologies to be used without any restrictions on uptake. So if the uptakes of the product exceeded the estimates of the budget impact model, Washington state was absolved from any increase in costs.<sup>12</sup>

MC: So there has been a growth in these innovative methods of contracting to manage financial risks, as the risks are increasing, would you say?

SS: I think there has been. A couple of things to highlight, though, is that this agreement that I am telling you about is not, it's a public agreement, but you cannot find much written or published about it, just because it's a management policy that is used by the state. And sometimes, these agreements, when they are done in the private sector, are hidden behind walls of confidentiality. So you cannot really learn about them, unless you are having a coffee with someone and they are telling you about this.

And I think the second thing to say, is that, while these agreements might mitigate expense increases in the short term, ultimately what really has to happen is an allowance for even new technologies to come in during or after the treatment that may change the budget forecasts for the next period after that. And that's where I think there is a lot work going on right now, in terms of how to account for that, and how to make sure that these agreements are conducive to both the payer as well as the manufacturer.

MC: There may need to be a broader change to these decision-making criteria, to address that challenge of affordability in the future.

SS: Indeed, yes, I agree.

## Chapter 8: Conclusion [24.33]

MC: Well, thank you very much, Sean, for joining us today on this podcast. I would like to thank you, Professor Sean Sullivan, for an engaging conversation and for giving us a comprehensive overview of affordability to payers in healthcare, especially in the United States.

SS: Thank you Mike.

I hope you can join us for the fourth podcast in this series where we will discuss cost-effectiveness analysis with Professor Maureen Rutten-van Mólken, Professor of Economic Evaluation of Innovations for Health at the Erasmus School of Health Policy & Management, in Rotterdam, the Netherlands.

If you have enjoyed this podcast, please subscribe to our 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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