

# Value Insider Season I Episode 5: What Other Aspects of Value May Be Relevant? (Societal Impact) [Podcast]

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**Abstract:** What other aspects of value may be relevant? In this episode of the Value Insider podcast, host Mike Chambers speaks with Prof. Lou Garrison about the societal perspective on value of healthcare interventions. Prof. Garrison is Professor Emeritus in The Comparative Health Outcomes, Policy, and Economics institute (CHOICE) in the School of Pharmacy at the University of Washington. Lou is past president of the International Society for Pharmacoeconomics and Outcomes Research (ISPOR) and he is currently co-chair of its Policy Outlook Committee. Going beyond the “conventional” elements of value assessment, Prof. Garrison highlights which additional impacts may be at play. He shares his concept of the “Value Flower”, explaining elements such as insurance value and scientific spill-over.

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

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Host: Mr Michael Chambers, Independent expert (MC)

Guest: Professor Louis P Garrison, Independent expert (LPG).

## Chapter 1: 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 heard about the different elements of value, especially those included in health technology assessments by agencies such as NICE in England, and ICER in the US, in deciding whether new technologies should be provided by the local healthcare system. These include demonstration of unmet need

for the new interventions, clinical effectiveness based on patient-relevant endpoints, affordability as measured by budget impact, and for many healthcare systems, cost-effectiveness often based on Quality Adjusted Life-Years, QALYs. These may be considered to be the “conventional” elements in value assessment.

Today, we will be talking about the value of societal impact, with our guest speaker, Professor Louis Garrison. Lou is Professor Emeritus in The Comparative Health Outcomes, Policy, and Economics Institute, that’s called CHOICE, in the School of Pharmacy at the University of Washington. Lou is also past president of the International Society for Pharmacoeconomics and Outcomes Research, ISPOR, and he is currently serving as co-chair of the policy outlook committee for ISPOR’s Health Science Policy council. Importantly, Lou was instrumental in defining elements of value in healthcare, termed the “value flower”, as part of the ISPOR Special Task Force, which will be discussed in further detail in this podcast. Welcome, Lou.

LPG: Thanks very much, Mike, it’s a pleasure to get to talk with you.

## Chapter 3: Perspective and Decision Context [02.41]

MC: Lou, when undertaking assessments of value in healthcare, the perspective of the decision maker is important. What do we mean by “perspective”?

LPG: Thanks Mike, it’s actually a more interesting question than people might think. Perspective, it really derives from the idea that there are various stakeholders.<sup>1</sup> There are patients, there are payers, there are providers. So each of the new technologies can be viewed from the perspective of each of those stakeholders. The field of economics and health economics has developed the idea that there is the perspective that could be called the “societal perspective”,<sup>2</sup> which is trying to identify the effects of the technology, the benefits and costs, without regard to who is paying them. As if we had a benevolent dictator who is looking at it, and that’s the societal perspective.

We would argue that, well actually, we do not have a benevolent dictator, so who takes the societal perspective? And actually what we have is the individuals operating from the viewpoint of their own perspective, and their own incentives, and then we can step back and say, well what if we would look at it from societal perspective, are we aligned? Are we functioning well, as a market place or as a society. And that’s really the societal perspective, and it takes that very broad point of view.

MC: And another term that’s used frequently, is “decision context”. The context for decision, which is linked to perspective. Can you tell us a little bit about the decision context when we are doing value assessments?

LPG: It is a structured process for decision-making that involves multiple stakeholders over the life cycle of the product. These stakeholders interact in different decision context. So the first one you might think of, is the regulatory sphere, where we are trying to decide the benefits and risks. And then, once they have decided the benefits outweigh the risks, the product is put on the market, and then the question is: who will include it in their health benefit package for the society or the private health plan, and at what price? What will be the reimbursement?

And I would say, for health economists, when they think about HTA, they are generally thinking about that decision. But it’s obvious: once you brought it into the health plan, there are a whole kind of cascade or value chain of subsequent decisions or decision context. The first being: OK, we have it in the health plan, are we going to let everyone have access? Are we going to have co-pays? Are we going to tell the providers they need to get approval before they use it?

And then there’s another level, that’s: OK, we have written guidelines, we have specified pathways, and now the patient is sitting with the physician, and they have to decide what is optimal for that patient. And we call that the shared clinical decision-making context.

But most of the time, for the health economists, when we are thinking about this first level decision, of “do we include it in the health benefit package and at what price or what value”? And that’s where value assessment comes up in that process.

## Chapter 4: Perspectives in Health Technology Assessment (HTA) [05.36]

MC: A lot of people in the healthcare system who do HTA, but they may be doing HTA and doing value assessment, but in different decision contexts, to answer different questions and problems, different decision-making. And sometimes that can be the cause of some confusion, when discussing what HTA is all about.

LPG: Yes, you are exactly right. People were propagating what we are now calling value frameworks, but they were thinking about different decision contexts. So the oncologists were thinking about interacting with the patients, whereas the Institute for Clinical and Economic Review, ICER in the US,<sup>3</sup> NICE in the UK,<sup>2</sup> you know, is also looking at the same decision, but they were looking at that approval of decision. That’s not to say they do not

subsequently look at the downstream things like guidelines and pathways. NICE is well-known for having a guidelines process.<sup>4</sup>

MC: So some commentators think that the perspective of Health Technology Assessment, HTA, organizations, is quite narrow, and fails to include some important elements of value that are relevant to a broader societal perspective. Would you agree with this?

LPG: You know, I would say that “quite narrow” is too strong, because I think that most of the HTA processes that are developed in places like US, UK, Canada, Australia, but also Germany, have a stakeholder engagement process. And once you bring interest groups into the discussion, then it automatically broadens to a societal perspective. The formal methodology that we refer to, is conventional cost-effectiveness analysis,<sup>5</sup> or I would say technically cost-utility analysis, the cost per quality-adjusted life year, is narrow. It starts out as starts out at kind of the core and central concept, and it has some merit in that regard, but there are a whole lot of other effects, societal effects that we can talk about, that are not covered in that perspective. So it’s a little narrow, but I would argue that most systems filled in processes that try to deal with broadening it out.<sup>11</sup>

## Chapter 5: Quality-Adjusted Life Year (QALY) as Central Feature of HTA [07.38]

MC: In particular, we have heard about QALYs as a central feature of uh. representing the benefits of new technologies, in earlier episodes. Are there limitations in using it as central feature of value assessment?

LPG: Well, let me make a couple of points there. Yes, I think the QALY is a great starting point. We had a special Task Force a few years ago at ISPOR that basically said: at least for health technology assessment for purposes of health benefit plan inclusion and pricing,<sup>6</sup> the QALY is a great starting point but we need to recognize some of the limitations.

One of the limitations is that, why do we need the QALY at all? And the answer is really, “what makes healthcare different, is uncertainty”. Uncertainty is everywhere. It’s prevalent, it’s pervasive. And in fact, what do we have? So that’s why we have health insurance.

So hence, we need a kind of work-around, to say “well how valuable is this diabetes drug vs an oncology drug?” And I think what our field says, you know, when you think about healthcare, there are really two core things are: do you improve my length-of-life and my quality-of-life? And that’s what we roll into the QALY, we say whether there’s length of life, that’s mortality improvement, obviously that’s important to people. And quality of life is important to people, no one would deny that. And I say our field calls that “health gain”. But we also say, well there’s another dimension, are you saving me money? Are you helping me avoid an expensive therapy? So those become the essence of the conventional cost-effectiveness analysis.

People should know that in the US, to some extent our government decision-maker has outlawed the use of the QALY and said it cannot be used for public decision making, which puts us in a bind, right? Now that does not stop our field. I would say people find this idea straightforward and useful, despite its imperfections. And it’s a pragmatic work-around for the fact that we cannot rely on markets through direct purchases, to judge value.

## Chapter 6: Beyond the QALY: ISPOR Task Force [09.33]

MC: So the QALY is a good starting point, but it is not the end. We need to think beyond the QALY. Maybe we can talk a bit about the panel, this initiative that you have been involved in, to consider other elements of value that could be included.

LPG: We observed a plethora of value frameworks that were emerging, and it was really confusing people. So the cardiologists had a value framework, the oncologists, we had the Institute for Clinical and Economic Review in the US,<sup>7</sup> we had something called Drug Abacus.<sup>8</sup> I would say that the motivation for all of those was the perception that drug prices were rising too fast, and that price that people paid was not related to value. That was part of it, OK. And just on the side I would say that is another failure of our system, economists would argue “we shouldn’t have high co-payments when people don’t have a choice”. When there’s no moral hazard, as we call it, people need this care, we would like for them to get it.

So we formed a Task Force at ISPOR to try to sort this out. And I think that we ended up – and this was health economists from the US and the UK, and then we ran it through several stakeholder meetings, invited commentaries and so on, but the panel sort of came to the view that the cost, the conventional CEA or cost utility

analysis is a good starting point, with a cost per QALY. But we identified a number of other elements that would go into a broader societal perspective that need to be considered.<sup>9-12,19</sup>

One of the things that the ISPOR Task Force brought out, was that there are actually a couple of different approaches to valuation. And one of them is what's called "multi-criteria decision analysis". And that's much more of a decision-maker process, where the elements of value are weighted, based on a grouped process for weighting those elements. So it is not necessarily relying on conventional cost utility analysis. I think our panel was agnostic with regard to whether we should use conventional cost utility analysis, or multi-criteria decision analysis. But both of those could bring in the broader set of elements of value.

## Chapter 7: The Value Flower [11.39]

MC: When thinking about these value elements that you identified, and elaborated in your work in this panel, you summarized these value elements in using a concept called the "Value Flower". Perhaps you could tell us a bit more about some of the key petals that you have for the Value Flower.

LPG: Yes Mike, happy to take a shot at it, though it is hard to describe the figure. The hub is the word value. And then the spokes go out to different elements. At the top, at twelve o'clock and one o'clock, we have the cost offsets, or net costs, and the QALY. We are calling them petals, we are calling it a flower. And then we go around with ten other petals that represent other elements of value, that came out of the Task Force deliberations.<sup>9-13</sup>

Perhaps the misleading part of the Value Flower, since all the petals are the same size, you might say "well the QALY should be a much larger petal". And I think you could argue that.

And for me, the key one is what we called "insurance value". From your point, from the subscribers' point of view, the members of a health plan, it's obviously very important when a new technology is covered in the health plan. Because now I am protected, financially. So just bringing it into the NHS or into your health plan gives you financial risk protection, which raises your well-being, your utility.

Now the other one that's more interesting, I think, is what we call a "health risk protection". So if we all think back to two years ago, the idea that COVID-19 was out there, made all of use worse-off, in terms of the utility sense. Once we had a proof of concept that vaccines worked, and to our surprise at over ninety percent efficacy, we were all better off. Even if I had not had access to it yet, because I knew there was a solution. So it raises the value of an innovation, because now you know that you are protected.<sup>14</sup>

There are also other ones related to uncertainty. One has to do with personalized medicine, knowing that we can tailor the treatment to your needs, another was "real option value", which is the idea that in areas where there's a lot of innovation, we might be willing to spend more there because we know that if we save you, you'll benefit downstream for the next round of innovation. One of them was called "fear of contagion", which is really goes back to COVID-19 and risk protection. We also had severity of disease, which interacts with this uncertainty.

There are two other petals added that are more cross-cutting from a societal point of view. One was scientific spillovers, which have to do with knowledge externalities that the scientific enterprise in R&D is a collective ecosystem, so people learn from what other people are doing. And then, there's what we called equity, or health equity. And that's become a big issue, because we are looking at differential access to medicines and other technologies.<sup>15,16</sup>

You can think about the value flower as having those placeholders for further discussion. Now again, I just say it with caution, we did not think that we had reached consensus on the final petals on the Value Flower. That is work in progress.

MC: So all this work that we have seen recently in mRNA vaccines to address COVID, can have a spillover in terms of research for vaccines for other disease areas in the future.

LPG: Now that's a great example, Mike, thanks for bringing that up. We get these kind of cross-cutting advances,<sup>17</sup> that work in a variety of disease areas, everyone can leverage that knowledge, and we are seeing a number of emerging gene therapies, because now we understand how that works, better. And that's a good example of broad scientific progress.

## Chapter 8: Societal Elements in HTA [15.07]

MC: So Lou, are any of these societal elements you have mentioned, currently considered in HTA assessments?

LPG: Yes, going back to the earlier point, um, most systems, I would say, these days have a stakeholder engagement process, in addition to the core analytic process. And so, that gives an opportunity for people to provide input from a broader perspective than just that narrow kind of calculation perspective. So you can submit comments to

them, saying, the conventional C, cost-utility analysis is too narrow, you should consider health equity, you should consider uncertainty, and you should consider particular care-giver burden.

Think of Alzheimer's disease, where caregiver burden becomes a big issue, and costs on caregivers becomes a big issue. You can sort of do an add-on to the methodology, the mathematical methodology, but I would say we have not worked out yet how that affects the decisions directly, as well as we would like to.

MC: I know in certain countries such as Sweden or the Netherlands, there's a lot of interest in productivity cost, and people being able to work, and the impact of the healthcare system on people remaining or returning to economic activity. These are sometimes called indirect costs in economic evaluations.

LPG: You are exactly right, I am glad you raised that. That is something that we recognize for, I would say, twenty-five years. So, productivity and time-cost have routinely been part of what we call the societal perspective, in our field. It's just that now we are thinking more broadly than that.

MC: And I think that references to the US, where the employer has a more significant role, in terms of purchasing insurance on behalf of employees.

LPG: Yeah, you are exactly right, that's a great point. As the purchaser of insurance on behalf of the employees. But also the employer, they want people to be at work, and be, not be absent, and be functioning well at work. So they may look at a new product, a migraine medicine, differently than somebody else would, as just looking at it from the patient's point of view.

## Chapter 9: Barriers for Incorporating Societal Elements in HTA [17.10]

MC: What are the barriers to incorporating these elements of value into health care decision-making, especially within health technology assessment?

LPG: The barriers have to do with the way we have had to structure health insurance. We have people operating in their own silos, right, what we sometimes call budget silos. So, we have, you know, we have health insurance companies, but we also have providers who have incentives, that we may have to counter. And patients would like everything, right? How do we deal with our allocation of limited resources? Which is what health economics is all about.

The patient would say, well, I want my medicine now. But the regulators say, well, I have to represent the society in trying to balance those benefits and risks. So, you know, we are dealing with a complex set of systems. We get incentives and counter incentives, and so we are trying to manage that. So all those things, become potential barriers and may slow things down, but they are probably inevitable, because we are making hard choices.

MC: So you are optimistic that, if there is enough of a push, work can be done to generate the right metrics to include these other societal elements. It's work that needs yet to be done.

LPG: Yeah, no, even since the Task Force ended, I think about three years ago, we have seen work developing the societal perspective, that's broader than just the productivity. And actually thinking of, realizing that these interventions from a societal point of view can affect many sectors, you know. Education, criminal justice, environment. This broader societal perspective, going beyond productivity impacts, was developed nicely in a report issued in 2017, by a group of distinguished health services researchers, called the "Second US panel on cost-effectiveness in health and medicine". They were finishing up as our ISPOR Task Force was getting started, to support a broader application of the societal perspective, they developed a checklist called an "impact inventory" that included these other sectors that I mentioned.

Education is a good example. And I think we all recognize that, again, in the COVID context, we are worried that the staying at home from school that we had to undertake for our children, is going to adversely affect their education. Then the value of the intervention that gets them back into school, is going to create value. And it's beyond the QALY. We are talking about their lifetime earnings, and their happiness, and so on. So, it's clear that these interventions spill over to other aspects of society, to other family members, and so on.

## Chapter 10: Assessing Innovation Value [19.34]

MC: And I do not think we can leave this topic without mentioning the word innovation. Many developers of new therapies claim their therapy to be innovative. How do HTA systems see innovation?

LPG: Mike, that's really a great question, and I would say that there's no uniform approach around the world for that. As I have argued over the years, at a first pass, we can start out with the idea that there's unmet medical need. We would like to address that unmet medical need. And so you could say, anything that addresses unmet medical need is innovative, regardless of how sexy or what level of novelty there is of the idea.



Like you say, the mRNA vaccines are quite exciting, from a scientific point of view, that we understand how these things work. But as a payer and as a citizen, what I really care about, is: does it improve my length of life, my quality of life, and give me greater certainty about benefit, OK. So I would say our systems by taking into account of the QALY, capture a good part of the value of the innovation.

So, I would say, a lot of what we are trying to do in the valuation, is to reward innovation and encourage innovation.<sup>18</sup> And we do, to some extent. But it does not pick up everything. So, we have, that's why we fund government bodies, and why we might need to add on, put more money into the pot. Just because it will promote innovation through the collective ecosystem of research and development.

MC: So innovation may not be mentioned explicitly, but it lies behind quite a lot of these elements of societal value.

LPG: Yeah, you are exactly right!

## Chapter 11: The Future of Value Assessment [21.10]

MC: Wrapping up a bit now. Looking forward, which of these value elements that you have articulated so nicely today, do you think are most likely to see a wider use in healthcare decision-making over the next few years?

LPG: Well, as I mentioned, since the Task Force was over, there's already been, I think, substantial progress in trying to measure, define insurance value, severity of disease, that interaction. One of the things that it does, is it argues for a more variable threshold. Two of our Task Force members, Darius Lakdawalla and Chuck Phelps, have gone on to delineate and refine several elements of the value flower, including adjustments for severity of disease, and certainty risk aversion, and the value of hope, related to cures.<sup>19</sup> I think this is really path-breaking work.

And as you know, NICE in the UK has long made other adjustments for severity of disease, and end-of-life situation.<sup>20</sup> What we see in the UK is consistent with the idea that citizens value treatments for rare health-catastrophic conditions, and would argue for a higher threshold.

And so, I think we have worked out more of the math on that, we have made progress on measuring real option value, I think people are working on measuring value of hope. So I think there's methodological work happening in all those areas, both in the kind of standard health economics, but also in the global health context. Peter Neumann, Dick Wilkey and I, who were the co-leaders of the Special Task Force, reviewed the progress over the past five years, and we emphasized the need for additional empirical work, to provide estimates of these elements of value, as well as work to integrate them into delivery processes of Health Technology Assessment. A recent paper, on the history and future of the ISPOR Value Flower, published in the journal *Value in Health*.<sup>10</sup>

Now, the thing I am most worried about, honestly, I should say, is, access to medicines globally. Because, we know that once we borne these substantial investments, it's very costly, and the cost of producing new molecular entities has generally been rising. And yet, we recognize that these can benefit all seven billion people on earth. And we would like them to get access, but not everybody can afford to contribute the same amount to R&D.

So that's why we have differential pricing, and that's why economists would argue we should have global differential pricing. People should pay different amounts, and contribute to R&D, and essentially pay different prices, based on their budget constraint.

So, I think that's the other salient issue we need to worry about. We are making some wonderful innovation, it's very costly, we're only able to produce maybe 50 new medicines a year, but we would really like everyone in the world to have access to those as soon as possible. Working towards a more workable system of differential pricing.

MC: Thanks very much for that thought, Lou.

## Chapter 12: Conclusion [24.03]

MC: I think it's important to note in conclusion, that including all these novel elements of value, will not solve all the issues that we are facing relating to value measurement and decision-making in healthcare. But I think they can help us to lay out more clearly and comprehensively, what trade-offs individuals in society are willing to make in their decision-making.

LPG: Thanks very much, Mike.

MC: Thank you for joining us today on this podcast. I would especially like to thank Professor Lou Garrison for an engaging conversation, and for giving us a comprehensive overview of the different elements of value, that make up the value flower. I hope you can join us for the sixth and final podcast in this series, where we will discuss the future outlook and the potential ways in which value demonstration may evolve with Doctor Panos Kanavos, Associate Professor of International Health at London School of Economics. If you have enjoyed this podcast, please subscribe to our series, and thank you for listening.

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