



ISPOR Member Comments Requested - ISPOR Task Force on Good Research Practices—Use of Drug Costs for Cost Effectiveness Analysis (DCTF)

Societal Subgroup Leader Lou Garrison PhD, Professor and Associate Director, Pharmaceutical Outcomes Research and Policy Program, Department of Pharmacy, University of Washington, Seattle, WA, USA

The following are comments received from the ISPOR Membership on the Task Force Report, *Good Research Practices for Measuring Drug Costs in Cost Effectiveness Analyses: A Societal Perspective: A Report of the ISPOR Drug Cost Task Force – Part II*

COMMENT 1

Insofar as it is not that easy as one might find to think of a concise definition of societal perspective, shouldn't the recommendations address this (by way of suggesting that efforts should be made to at least define one and perhaps even propose one?)

Section 6 - Shouldn't a societal perspective include all citizens rather than patients of interest?

Section 6 - Global perspective. Do you mean international perspective (i.e. Part VI)? Should there be some cross-referencing here?

Section 6 - I am not really sure whether the second and fourth paragraphs belong here.

Section 6 - Third paragraph: they would yield different recommendations in different countries. You have assumed that the decisions are/will be based solely or are/will be heavily driven by the results of an economic evaluation. This may not always be true / correct.

Global willingness to pay is a rather hard concept for me to grasp.

Section 7 - Whilst the document states that you have attempted to clarify the appropriate definition and use of the concept of the societal perspective, I wasn't left with a clear picture on what you think it means after reading the paper.

Section 7 - There are indeed substantial questions and issues about current practice. In some countries, analysts use (in some cases, are obliged to use) a (public) health care system perspective (this appears not to have been considered in the project) and I doubt if they will ever change to a truly societal perspective. A health care system perspective is not the same as a "restricted" or "limited" societal perspective.

COMMENT 2

I would like to see any assessment or value based on “population and community” in CEA method. “Societal benefit” is debatable for any definition. I would like to know any “operational” definition as an example if ISPOR will set the guideline.

COMMENT 3

The Part II: societal and other perspectives.

From a microeconomic perspective, capturing the CS+PS in the CEA may be appropriate.

The guidance on societal perspective seems to digress unduly from the issue at hand.

Should it concentrate on;

- A. The complexities of using current approaches to calculate drug prices in PE analysis
- B. Clarity on the rationale for the new approach and recommendations
- C. Anticipated impact on PE analysis

In countries where the value of the next best alternative is infinitesimal, the Cost/QALY threshold may be too low; which may exactly defeat the global perspective approach discussed in the report.

From the discussion on using “restricted” or “modified” societal perspective, it appears these definitions are not unambiguous. What is acceptably modified or restricted?

Key question: doesn't the AWP reflect transaction cost (information cost, negotiating costs, time, energy, etc.) required to secure the price actually paid by the PBM or MCO?

Implications: using a price < than the AWP might underestimate the true cost of the drug and bias the results. The use of the AWP may be ideal and this is confirmed by the piece from the industry perspective.

Additionally, if we assume that the only relevant costs are drug costs, and if the cost of the drug for the new strategy and the current practice both reflect AWP then I believe it shouldn't matter in terms of its impact on the CEA (i.e. reducing the AWP of both drug by 60 percent may not be impact). Maybe I am missing something!!!

Evidence also seems to suggest that, in general, drug costs are only a small portion of the overall cost of treating some diseases.

How does one distinguish between normative and positive aspects of CEA? The former seem to be a more applicable concept.

COMMENT 4

I am a pragmatic practitioner, not a theoretician, not a conservative, and not a liberal, but I am troubled by the second paper, “Societal Perspective,” which appears to turn everything upside down from what I ever learned in economics. On p. 8 (societal perspective) we learn that the patent system should be overturned, yet the first paper discusses with references (p. 4, Issues & Recommendations) all the wonderful gains due to patents, R&D, drugs, etc. Which is it? Not surprisingly, the societal paper concludes/recommends that we should use 40-60% of the price in societal studies. This is total, utter nonsense and relies on only one paper for this conclusion. The cost taskforce is going to have to decide whether it wishes to provide practical advice to practitioners or to try and revolutionize our notions about pharmaceuticals thru this societal paper. Surprise I urge that the societal paper be dropped from the sequence and/or totally re-developed along more practical lines.

I have no other comments on the other papers except to note that the “industry perspective” appears short, less-developed than some of the other papers. It would benefit from being longer, a more in-depth treatment.

Hope this helps a little bit,

COMMENT 5

Overall this report seems a bit different -not as applied -more educational at raising issues about what is societal etc. May want to add a line at the beginning to set up reader expectation for this type of report - which is different than the rest of the series.

COMMENT 6

Here are my comments to the different chapters. In general they read well, some of them especially the one dealing with the societal perspective have more aside information than some may like, at least for my taste. The recommendations are straightforward and easily presented, and are what I believe people would take from these documents.

Chapters 2 and 4 have a different font, and chapter 5 industry has a different way of separating the paragraphs.

Here are minor details I captured while reading the chapters.

Chapter II.

1. Page 2, paragraph 4, ... but may also greatly societal opportunity (needs a verb)
2. Page 3, The PCEHM discussion in relation to - (is it another paragraph? if so needs to be separated from the previous one).
3. Page 4, beginning of the quote, has too many periods before the closing “ (p.195) (I believe)
4. Page 4, 3. An Economic Perspective. In the first paragraph the reference is using a key rather than an opening bracket { instead of [.
5. Page 5, Reference to Luce, et al, pages do not match (pp.183-40) Was it 138?
6. What is the difference between normative and behavioral CEA.

COMMENT 7

The guidance on societal perspective seems to digress unduly from the issue at hand. We believe it should concentrate on:

- (1) The complexities of using current approaches to calculate drug prices in pharmacoeconomic analysis
- (2) Provide clarity on the rationale for the new approach and recommendations, especially the suggestion to use 40-60% net acquisition drug costs.
- (3) What is the anticipated impact of the recommendations on the pharmacoeconomic analysis from stakeholders perspectives (all of the perspectives listed)

From the discussion on using “restricted” or “modified” societal perspective, it appears these new definitions are not unambiguous. What is restricted? What is modified? How is it restricted and modified?

Does the AWP reflect the transaction cost inherent in the negotiation to arrive at the average acquisition cost (AAC)? If so, the AWP may be the ideal drug cost parameter in a CE model. This view that the AWP is appropriate is confirmed by the report on the industry perspective

where they specifically say “While ASP and AWP are both still just averages they more accurately reflect actual costs after discounts and rebates.”

Assuming that the only relevant costs in a CE model are drug costs, then if drug A and drug B face the same/similar acquisition and dispensing environment, what would be benefit of reducing the AWP of both drugs by the same percentage (e.g., 20-60%)?

Which concept of value should be used: value over time, value in use or value in exchange?

In the fourth recommendation of the task force, the authors’ suggest that cost values should be used that more accurately reflect true society drug costs (e.g., 20% - 60% of average sales prices). It seems as though 20-60% is quite a large range and therefore could significantly impact the results of a cost-effectiveness model. Therefore, if the committee believes that true society drug cost values should be used, then more research needs to be done to quantify true society drug cost rather than suggesting such a wide 20-60% band that could significant impact the modeling results.

For the fifth recommendation, how does one distinguish between normative and positive CEA since CEA taps into both concepts because CEA is usually a normative analysis?

For recommendation number six, please recall, that CEA is but one of the tools used in the decision making process for adopting a new technology. Thus, a CEA submitted by the manufacturer to a payer that instructs the payer what to do with the CEA may unduly bias the use of the CEA for decision-making (somewhat marketing/sales approach).