



A Pragmatic Payer-Patient Engagement Framework (PPEF) to Support Ethical Formulary Decision Making Process in Rare Disease Arena in Commercial Payer Settings in the U.S.

Siva Narayanan, Ph.D

Avant Health LLC, 6701 Democracy Blvd, Ste 300, Bethesda, MD 20817, USA.

P: +1 301.799.8268 / E: SNarayanan@Avant-Health.com

Background

- Payer stakeholders occasionally utilize existing drug value assessment frameworks, and even less so, direct patient stakeholder input to inform their drug formulary decisions that impact the lives of patients (the customers).
- Patient perspectives on (drug’s) value may differ from that of physicians and payers, and even among patients, individual values and preferences may differ. (1,2)
- Patient input on drug’s value may assume importance in rare disease arena, where payers encounter incomplete evidence supporting orphan drug value and high prices, while patients suffer disproportionate morbidity/mortality, amidst high disease burden and limited treatment options. (3-5)
- Even if payers have the best of the intentions to help patients in need and make value judgement about drugs of interest to patients, the mere lack of direct involvement of patients to understand their value perceptions & preferences may fail to do justice to payer intentions.
- The disconnect between the payer and patient views of therapeutic value sometimes could lead to payers severely restricting or blocking access to medicines that patients are in dire need for.

Objective

- Develop a pragmatic PPEF that facilitates incorporation of patient input on drug’s value into payer drug coverage decision-making process in the U.S, in the context of rare disease (RD).

Methods

- Literature review encompassed value assessment frameworks (VAFs), ethical decision making (EDM) and corporate social performance (CSP) theories.
- Content analysis integrated literature with qualitative telephone interviews of 24 payer and RD patient stakeholders to contextualize the factors influencing the current payer decision-making process, lack of incorporation of patient input into that process and the ways to improve the process while considering patient input in drug formulary deliberations; PPEF was formulated as a result

Disclosure

- There are no conflicts of interest to declare.

Results

- Review of VAF literature revealed suboptimal use of patient preferences and input on drug’s value, and inadequate use of VAFs by payers to aid formulary decisions.
- Issue-contingent, neurocognitive, and sensemaking EDM models were identified to contextualize the influence of moral issue/intensity/intent/behavior on ethical decisions.
- Wood’s CSP model and issue-contingent model were identified to contextualize the importance of principles/processes/outcomes, in the context of external stakeholder perceptions/needs, to improve credibility/trust/loyalty and reputation.
- Payer/patient interviews highlighted these aspects and identified the utility of RD patient’s direct input and ways to solicit and use such input.
- Figures 1-2 were derived from the aforementioned content analyses, contributing to PPEF shown in Figure 3.

Figure 1: RD Drug Value Assessment and Stakeholder Communication

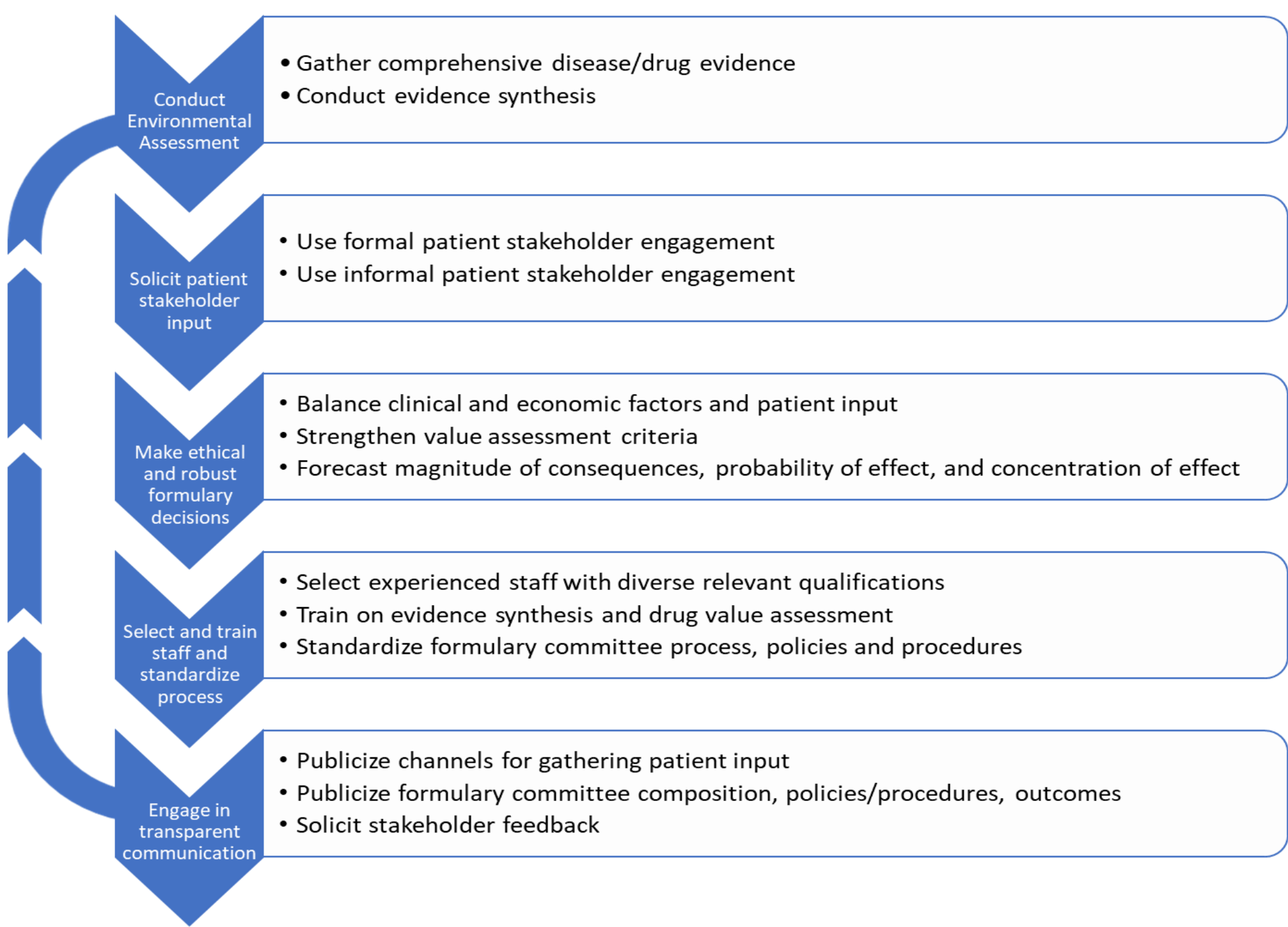
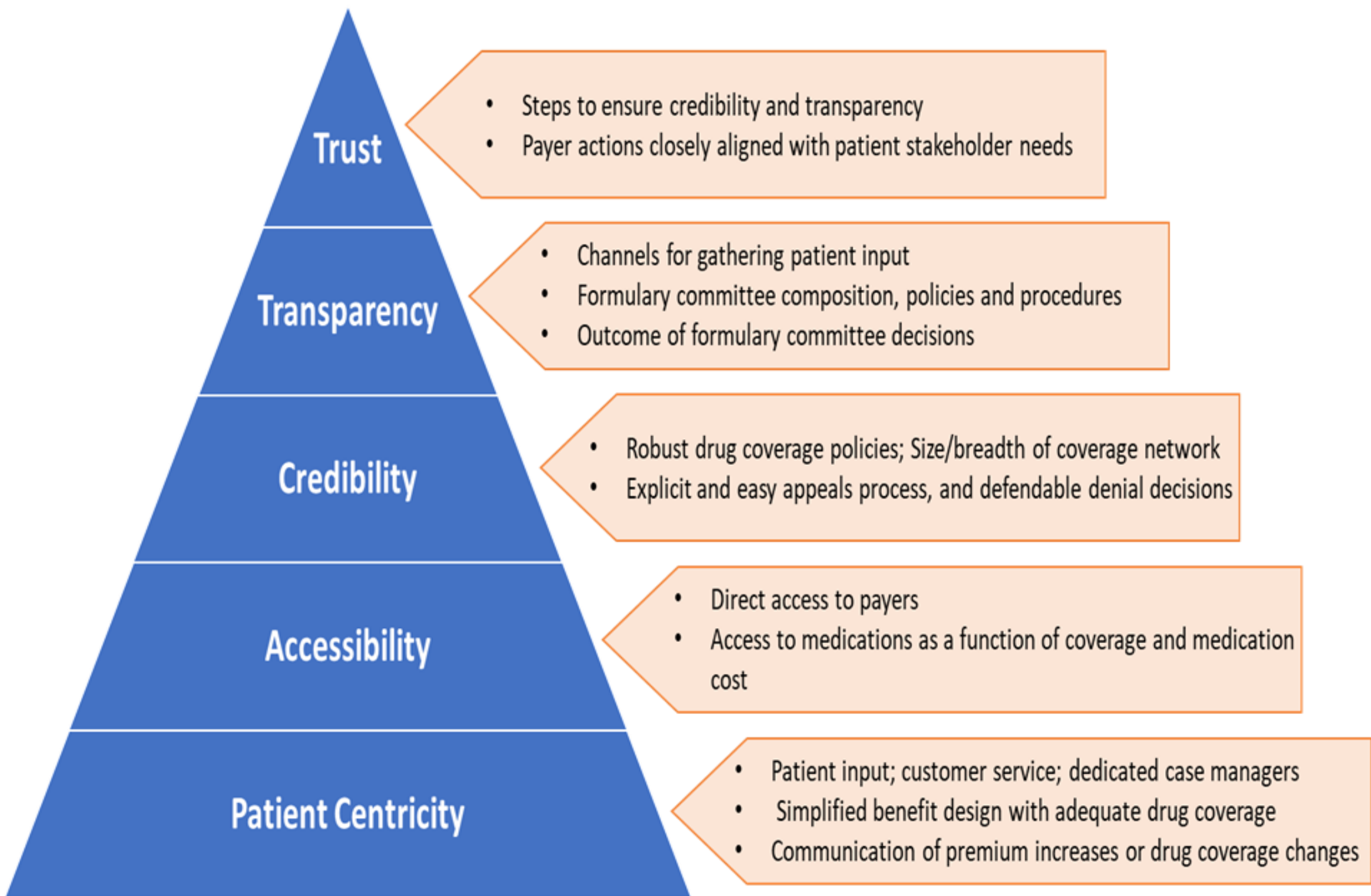


Figure 2: Factors Influencing Stakeholder View of CSP and Corporate Reputation



Conclusion

- PPEF may serve as a simple standardized framework by which commercial payers in the U.S could engage and communicate with patients, solicit their input/preferences (where relevant) and incorporate such input into formulary decision-making process.
- PPEF in RD arena could be an ideal way for payers to engage RD patients, solicit patient stakeholder perception of disease burden and orphan drug’s impact/value, augment their evidence-base, and make informed formulary decisions. Improved and timely access to orphan drugs may alleviate RD patient burden.
- Using PPEF, payers could improve their customer’s view of their patient-centricity, CSP and corporate reputation.

References

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Figure 3: Framework for Payer-Patient Engagement and Payer Incorporation of Patient Input in Formulary Decisions

