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EDITORIAL

Where Are We on "Risk-Sharing" Agreements?

The conceptual appeal of "pay-for-performance" or "risk-sharing" agreements is understandable. The agreements offer an innovative payment model under which payers reimburse manufacturers on the basis of health outcomes achieved rather than products provided [1–3]. In theory, the effects of these arrangements can be far-reaching, promising to improve population health and drive systemwide efficiencies [1,4].

The hype around risk-sharing agreements, however, has always seemed to outpace the accomplishments. Despite an abundance of articles, presentations, and discussions on the topic, actual experience has demonstrated that they are challenging to execute [5]. Barriers include high implementation costs, measurement issues, a lack of trust between payers and product manufacturers, and the absence of a suitable data infrastructure [5]. For many potential partners, negotiating price discounts has proven easier and less risky than entering into risk-sharing agreements.

Given the disconnect between expectations and reality, the new ISPOR Task Force Report on Performance-Based Risk-Sharing Arrangements (PBRSAs) is a welcome development [6]. The entire field will benefit from its clear-eyed analysis and guidance on good practices for the design, implementation, and evaluation of the arrangements. Experience has shown that ISPOR Task Force reports become well-cited and used reference documents. They reflect consensus efforts by multidisciplinary teams with input provided by the broader ISPOR membership. At their best, they provide a framework for organizing and critiquing key issues and questions, and they furnish a practical set of recommendations for the field. The PBRSA Task Force follows in this tradition, drawing in part on previous task force reports on modeling, retrospective database analysis, prospective observational studies, and real-world data [7–12].

The PBRSA Task Force Report is notable in several ways. First, it provides a useful taxonomy for PBRSAs. Part of the problem with risk-sharing agreements has been a lack of clear and consistent terminology and classification. As the Task Force report notes, PBRSAs can fall under a variety of names and categories, including outcomes-based schemes, risk-sharing agreements, coverage with evidence development, access with evidence development, patient access schemes, conditional licensing, and managed entry schemes. Many agreements advertised as "risk sharing" are actually price discounts (sometimes cleverly disguised), which do not tie payment explicitly to product performance [5,13]. The PBRSA Task Force Report usefully distinguishes payer-manufacturer arrangements that measure health outcomes in characterizing performance from those that do not. They further differentiate outcomes-based arrangements that attempt to directly manage utilization and guarantee cost-effectiveness (i.e., "utilization-based") versus those that include a strong research element (i.e., "research-based").

Second, the Task Force highlights the potential value of PBRSAs in reducing uncertainty through additional data collection. As the report notes, a PBRSA is perhaps best thought of as a "mechanism for reducing uncertainty through greater investment in evidence collection while a technology is in use within a health care system." The intention is to provide a different distribution of risk between the payer and the manufacturer compared with the historical relationship between the parties.

Furthermore, PBRSAs can reduce uncertainty through data collection related to product effectiveness in various ways. For example, they might address broader populations than those used in registration trials, or collect evidence on end points not considered in trials, such as adherence, hospitalization, or longer term clinical outcomes. As the report notes, which PBRSA research design is most suitable in any given situation will depend on the nature and type of the uncertainty that the evidence collection is trying to address.

Third, the Task Force highlights that PBRSAs have "public good" aspects, which should be considered from a policy perspective. In part that means that public authorities who negotiate and fund evidence-generating arrangements should make the results of that research public where possible. But the Task Force goes further, pointing out that *private* insurers, who seek valid scientific answers to the outcomes questions embedded in the arrangements, should also be encouraged to put findings in the public domain, as long as it does not deter them from negotiating agreement in the first place.

Importantly, the Task Force argues that the societal desirability of PBRSAs is fundamentally a value-of-information question, comparing the societal costs of additional data collection with the societal benefits of improved resource-allocation decisions. Moreover, the report adds that as an innovation in and of them, PBRSAs should also be evaluated from a long-run societal perspective in terms of their impact on dynamic efficiency (eliciting the optimal amount of innovation).

Finally, the Task Force highlights research and operational "good practices," emphasizing issues related to design, implementation, evaluation, and governance. It notes that outcome measures should be selected with care, that they should be clear, measurable, objective, realistically achievable, and relevant. Ideally, this means that parties should address a series of questions *before* entering into agreements: What is the specific research design? Is the time horizon realistic? Is the funding arrangement clear? Who is responsible for data collection and analysis? What is the process for reviewing and analyzing the evidence in order to make a revised decision on price, revenue, or coverage? Will discounts or rebates be paid on the basis of provisional results? The Task Force adds that to the extent possible, certain matters should be prespecified, including arrangements about access to data, opportunities for stakeholder input, rules about reporting of results, and so forth.

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Where PBRSAs are on their adoption curve is unclear. The Task Force's discussion of experience with the agreements in different countries indicates a great deal of interest and ongoing experimentation, suggesting that the model may be in a protracted but early stage of evolution. Whether they truly take off or muddle along in the years ahead remains to be seen. Whatever the outcomes, the work of the PBRSA Task Force will sharpen the debate and solidify the foundation.

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