THE PAST
Risk-sharing agreements are innovative contracting arrangements where payers and manufacturers agree to “link payment for drugs to health outcomes achieved, rather than the volume of products used” [1]. These agreements have been used for many years to enable drugs to gain access to markets, with payment conditional upon the drug delivering on pre-defined clinical or economic results. Financial risk-sharing models often employ budget caps to limit overall expenditure for a given product, regardless of volume used. Manufacturers of high priced pharmaceutical products have publicly embraced both outcomes based and budget-cap risk-sharing agreements as a way to negotiate for market access with payers and health systems.

Risk sharing has been an option of choice when:

- Demonstrating cost-effectiveness to payers is difficult without price concessions;
- The body of efficacy data is not enough to justify coverage and access; or
- Significant concerns exist related to over-utilization.

Risk-sharing agreements are always time-bound and require a period of look-back to assess if the product achieved clinical and economic performance goals.

The mechanics of risk-sharing agreements rely on payers and pharmaceutical companies agreeing on a set of measurement criteria a priori, having the mechanism to measure outcomes and the patient volume to make those results meaningful, and then evaluating performance against goals after a predetermined period of time. Though many deals have been put in place over the last 10 years, the arrangements have been difficult to implement on a large scale due to high implementation costs, measurement issues, and data infrastructure challenges within payer organizations or health systems [1]. Nonetheless, certain agreements have worked well for some high-cost or novel pharmaceuticals, enabling market access where it would not have otherwise been granted.

Up until recently, risk-sharing agreements have not been considered viable for medical devices for many reasons. First, medical devices are most frequently purchased by the hospital, and hospitals receive a DRG-based (global) payment for the procedure, agnostic to any device that may be involved. Hospitals have thus been incented to purchase the least expensive device available in order to maximize the margin against the DRG reimbursement. While hospitals have always had a clinical or moral incentive to provide good quality care, prior to health care reform, they had little financial incentive to consider quality of care outside its impact on facility reputation or complication rates. Issues that required readmissions or surgical revisions created new revenue streams in most cases.

In this environment, medical device manufacturers in many saturated therapeutic areas (i.e. joint replacement, stents, or catheters) were forced to compete predominately on price with little room to differentiate their products based on clinical value. In situations where a medical device could offer some meaningful value to hospitals above low cost, for example, in reducing lengths of stay, hospitals often lacked the infrastructure to quantify that impact due to disparate and outdated information systems.

THE PRESENT
But the hospital landscape in the United States is undergoing a period of great change brought about by market conditions, the Affordable Care Act, and advances in information technology. Firstly, consolidation in the hospital market has led to larger systems managing a greater number of technical and human resources, many of which are aligned to provide a more integrated continuum of care to patients. These new hospital systems have greater market power, deeper financial reserves, and represent more lives, making them attractive potential partners for medical device companies.

Recognizing that hospital spending was the largest single segment of overall health care spending, Washington, DC has taken steps to shift some of the financial risk for spending on in-patient care to hospitals themselves. Value-based purchasing, which took effect in fiscal year 2013, requires hospitals to report on certain quality measures, including adherence to clinical guidelines, reduction in 30-day mortality, and reduction in 30-day readmissions for certain diagnoses. One to two percent of a hospital’s reimbursement is at risk if the hospital fails to achieve against these benchmarks relative to its peers or past performance. This can amount to several million dollars for some hospitals. As a result, hospitals have a financial incentive to focus on quality in addition to throughput. Lacking the internal know-how to manage this risk, many hospitals are looking for partners who can support their efforts towards improving quality.

Lastly, while hospitals have embraced advanced technologies like Da Vinci robots and hybrid ORs in the clinical realm, they have historically been slow to adopt technology in the administrative world. That has changed in recent years as hospitals have moved on to electronic medical record (EMR) and electronic health record (EHR) systems, a move that was accelerated by incentive payments from Medicare. While EMRs and EHRs have some short comings that limit their usefulness in managing to quality benchmarks, they do enhance information exchange and adherence to practice guidelines. The massive amounts of patient data that are accumulating within them will have a much bigger impact on hospital contracting in the future, as administrators will have a more detailed view on practice and outcomes allowing them to intervene to improve quality and manage costs.

Given the changes in the hospital landscape, it’s not surprising that a pilot risk-sharing arrangement at the hospital level was announced by Johnson & Johnson earlier this year. Johnson & Johnson has some experience with these arrangements at the payer level through its pharmaceutical line of business and has applied those learnings to an agreement tied to positive readmission trends at the hospital. The agreement focuses on the orthopedics space and takes advantage of Johnson & Johnson’s range of products from prosthetic devices to instrumentation. It will be some time before the success of the arrangement can be assessed, but it is a clear indication that manufacturers see the shift from volume to value as an opportunity. They also see the need to change business-as-usual contracting strategies. It remains to be seen if this form of innovative contracting that has been pioneered by Big Pharma in markets around the world will become prevalent within American hospitals.

Given many of the changing market dynamics and evolving hospital information systems today, risk-sharing arrangements may be ideally suited to many medical devices and health systems that purchase them. Accountable Care Organizations (ACO) and Integrated Delivery Networks (IDN), for example, are device purchasers uniquely positioned to achieve financial benefit from using high quality medical devices, especially if outcome assessment is supported by existing EMRs or simple registries. These types of health systems hold financial risk for patient outcomes rather than being incented by procedure based reimbursement alone.
THE FUTURE

Looking forward, significant challenges exist for the widespread roll-out of risk-sharing agreements between device manufacturers and hospitals. There still remain capacity issues within hospitals to review, manage, and measure multiple concurrent deals. While they may have incentives to participate, certain hospitals may lack the human resources necessary to pursue these deals. As such, and as with the previous Johnson and Johnson deal, there remain questions as to whether future progress in this space will be focused on portfolio rather than product specific risk sharing. Portfolio based deals benefit larger device companies who have the ability to conduct portfolio pricing or negotiation strategies with hospitals. Portfolios based risk-sharing agreements, however, are also likely to be more complex and could create measurement challenges which confound outcomes. As a result, not all product portfolios are aligned with this type of strategy.

On the other side, single products (and the companies who develop them) may also provide an opportunity for risk sharing. Where a manufacturer has a great degree of confidence in the comparative performance of its product against the current product being used by the hospital, risk sharing can be a good option to displace that product and educate the hospital about the value of the new entrant. This paradigm works well, when the comparative value can be measured with simple objective analytics, the benefits accrue to the hospital, and the impact occurs in a short time frame – for example, 30-day readmission or mortality.

Moving forward there may also be an opportunity for companies to collaborate, bringing together a suite of offerings that together provide a significant benefit over the standard of care. While legal and operational challenges may impact the viability of such an approach, collaboration by manufacturers may better meet the needs of resource constrained hospitals by creating agreements that more closely mirror actual practice. This type of multi-provider risk-sharing agreement also has the potential to be managed by a third party, like a purchasing organization, though questions remain related to desire for such an approach, legal viability, and internal expertise to manage the program.

For risk sharing to become a reality for hospitals and device manufacturers, increased clarity is needed as to which products are most appropriate, what type of infrastructure and personnel are needed to support programs, and how best to implement multiple concurrent programs. As details of more deals become available, interested parties will have a better idea of whether they increase the pace of adoption of novel products and help hospitals to provide higher quality and more efficient care. In the meantime, expect to see more of these deals in the coming year as hospitals feel the pressure of value-based purchasing and device manufacturers see a new opportunity to position their products in terms of value.

REFERENCES