

# The Need for Value-Based Outcomes in Future Dialysis Access Device Trials

Defining clinically and economically meaningful outcomes in the new environment of value-based health care.

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**T**he value of medical devices is becoming increasingly important in the practice of interventional medicine. This is especially evident in patient care related to end-stage renal disease (ESRD), where the emergence of the ESCO (ESRD Seamless Care Organization)—an effort to control costs and improve outcomes for the 1.3% of the Medicare patient population that consumes 7.5% of Medicare spending<sup>1</sup>—could rapidly and radically change how physicians deliver care. Indeed, many physicians are increasingly being asked to justify device use to decision makers in their institutions, which fundamentally requires an understanding of the value of a given device. Yet, have device manufacturers armed physicians with the data they need to justify device use when talking to a diverse set of stakeholders, which often includes nonclinical procurement staff? In this author's opinion, physicians and medical device manufacturers must work together to better define, collect, and communicate device value. This will ultimately result in clinical study endpoints that are more clinically and economically meaningful to the provider, payer, physician, and, most importantly, the patient.

## HOW VALUE IS DETERMINED

At its core, value means that the physician's selection and use of a device balances the outcomes they expect to achieve against costs of care—both upfront and ongoing costs—over a period of time. Historically, value has been defined by the equation:

$$\text{Value} = \text{Outcome}/\text{Cost}$$

Accountable care organizations/accountable care entities are altering this equation by tying payments to specific quality initiatives. Therefore, quality will figure into the value proposition by becoming a part of the outcome

measure; outcomes will include a quality component. The new paradigm for value will then change the equation to:

$$\text{Value} = (\text{Outcome} \times \text{Quality})/\text{Cost}$$

Are interventionists armed with the correct information to make value arguments, specifically information focused on outcomes and quality? What data are needed, and how do these data differ from those produced in the past? How can device manufacturers provide the data needed to promote interventional techniques?

## OUTCOME MEASURES AND THE DIALYSIS ACCESS POPULATION

The outcome for any medical diagnostic modality or treatment is variably defined—survival, quality-adjusted life-years, and time to progression are some common measures. In the future, outcome measures will increasingly have to consider cost and value. The following are this author's views on how outcome measures will be affected by value-based health care, with specific examples focused on the dialysis access population.

### Clinical Trials Comparing Single Outcomes Will No Longer Be Adequate

Traditionally, clinical trials, including randomized controlled trials, have had one primary endpoint. In the dialysis access population, this endpoint has traditionally been 6-month primary patency of the anatomic region intervened upon or patency of the circuit. This endpoint will continue to be important, but other measures will likely take precedence. This shift to new outcome measures will be driven by the need for interventional devices to drive down the total cost of care—estimated by the US Renal Data System to be approximately \$85,000 per hemodialysis patient per year<sup>2</sup>—and not just the primary patency of the first intervention.

### Endpoints Focusing on Repeat Interventions Will Be Most Important

Not only are repeat interventions costly and resource intensive (and raise questions about the quality of the first intervention), but they also lead to patient dissatisfaction that subsequently can lead to migration of patients from one ESCO to another. In the ESCO model, these combined factors will lead both to significantly increased expenses and decreased revenues for a health care organization. For example, consider a device that could alert a physician to a condition that requires an intervention and thus avoid hospitalization for care. This could significantly reduce the total cost of care for that patient, even though in both instances, the procedure would be reported clinically in terms of a single intervention.

### A Cost Component Must Be Included in Future Clinical Studies

Costs of procedures have historically been ignored in clinical trials, particularly with regard to imaging and endovascular intervention publications. As value will be tied into costs and quality, these variables must be quantified and reported in future clinical trials. As for the dialysis access population and the use of stent-grafts, it is likely that the increased upfront cost of the device will be negated when the patient undergoes fewer future reinterventions compared to angioplasty alone. This argument is particularly important to health system administrators, who will not only be interested in charges to third-party payers, which have been focused on in the past, but also in overall costs of performing these procedures to the health care system. This includes direct costs as well as indirect costs, the former of which significantly increases with reinterventions.

### Evolving Payment Structures Will Likely Affect the Provider Decision-Making Process

With physician payments and technical fees all coming from the same limited funds within the accountable care organization/accountable care entity structure, the incentive to perform one procedure instead of two will

become greater by an order of magnitude. The financial incentive to perform multiple procedures will disappear as the interventional suite converts from one of the largest revenue producers in a health care system to one of the largest cost centers; this will not go unnoticed by health care administrators. Future clinical trials must take into account not just the costs of such repeat procedures, but the quality measures that should be tied into the outcomes. Outcomes related to the health care system, outcomes based on provider specialty, and outcomes based on specific devices will become increasingly important in future clinical trials.

### SUMMARY

The changes in health care delivery are intimidating to those in the medical field. However, such changes are overdue and already occurring, and practitioners and device manufacturers need to adjust accordingly. By remaining patient focused, with an eye to outcomes, cost, and quality, clinical trials will be the key to producing value-based medical care for all patients. Medical device manufacturers and physicians have the opportunity to work together to define clinically and economically relevant outcomes for medical devices. Examining the value of a device over a relevant period will enable physicians to justify their selection and use to decision makers. ■

1. Centers for Medicare & Medicaid Services. Comprehensive ESRD care model fact sheet. Available at: <https://www.cms.gov/Newsroom/MediaReleaseDatabase/Fact-sheets/2014-Fact-sheets-items/2014-04-15.html>. Accessed April 5, 2016.

2. US Renal Data System (USRDS). USRDS 2015 annual data report: atlas of chronic kidney disease and end-stage renal disease in the United States. Bethesda, MD: National Institutes of Health, National Institute of Diabetes and Digestive and Kidney Diseases; 2015. Available at: [http://www.usrds.org/2015/download/vol2\\_11\\_MedicareExpenditures\\_15.pdf](http://www.usrds.org/2015/download/vol2_11_MedicareExpenditures_15.pdf). Accessed April 5, 2016.

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