Demonstrate Value Efficacy Studies Offer Evidence

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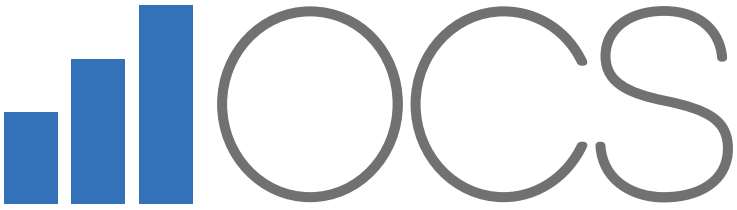

ELEVATING HEALTHCARE INTELLIGENCE

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Home Care Market Fosters Evidence-Based Purchasing

Vendors and consultants within the home care market face an increasingly competitive marketplace. In this environment that includes a multitude of options for products and services ranging from medical information software to wound care supply vendors, home care providers face a dizzying array of choices. Add to this the recent changes to the Medicare beneficiary payment system and the expanding implementation of pay-for-performance systems by multiple payors, and it's clear that the purchasing decisions of providers, more than ever, can be influenced by credible evidence that a product or service can help them achieve high quality outcomes and positive financial results. Smart businesses in the home care environment have the opportunity to use efficacy studies to differentiate themselves from their competitors while helping to assure providers that they are spending their limited resources in a strategic manner.

Efficacy Studies Generate Evidence

Efficacy refers to the power and capacity to produce a desired effect or outcome. Within the health care market, providers are particularly interested in products and services that have the power and capacity to improve the quality outcomes of their patients. Although there are different approaches to demonstrating whether a product or service is related to a desired outcome, all can be referred to as efficacy studies.

When investigating the association between a product or service and a desired outcome, it is important to choose an appropriate method for investigation. Key considerations for choosing the approach include the funding available, the urgency with which results are needed, and the potential audience with whom the results will be shared. Common methodological approaches include:

- Randomized control trial (RCT)
- Cohort study
- Case-control study

Borrowed from the field of Epidemiology where they were developed to study disease causation, these three approaches can be adapted to investigate the association between a product or service and patient outcomes, just as they have been adapted and heavily used by the pharmaceutical industry to study drug efficacy.

Randomized Control Trial (RCT)

Typically considered the gold standard of efficacy studies, compares the outcomes of subjects exposed to an intervention to subjects that were not after controlling for difference between the groups that might influence achieving or detecting the outcome. Control is exerted by randomly assigning a homogenous set of subjects into control and intervention groups and blinding the subjects and the researchers to this assignment. A primary advantage of RCTs is that they can provide strong, widely accepted evidence of whether a causal relationship exists between an intervention and an outcome. This advantage, however, is often offset by the extreme cost, time, and labor associated with designing and implementing such a study.

Cohort Study

Similar to an RCT, this study involves comparing the outcomes of two subject groups (cohorts) – one that receives the intervention of interest, and one that does not. In an observational cohort study, subjects are selected into groups, rather than the random distribution employed in an RCT. Cohort studies can be done prospectively where compare groups are defined prior to collecting data or retrospectively where subjects are grouped after the data has been collected. Strict inclusion criteria and other methodological choices are typically employed to reduce differences between the two cohorts and produce an "apples to apples" comparison.

Although cohort studies do not provide evidence of causation, they do provide strong evidence of whether an association exists between an intervention and an outcome as well as clear evidence of the temporal sequence of intervention and outcome. They also allow for the study of multiple outcomes related to a specific intervention. Similar to RCTs, the disadvantages of cohort studies typically include cost, time and labor to implement. These disadvantages can be offset by conducting retrospective studies on data that has already been collected.

Case-Control Study

This study involves identifying patients who have an outcome of interest (cases), identifying similar patients that did not have the outcome (controls), and looking back to see if there are characteristics or intervention (product or service use) that differentiate the two groups. Typically data is gathered through interview or through secondary analysis of records.

Unlike the cohort study, a case-control study is well-suited to the study of rare outcomes and those with a long latency period between intervention and outcome. They also can be less expensive as they can be launched and conducted over relatively short periods of time, especially when employing secondary data sources. While a case-control study permits the study of multiple interventions, it is limited to investigating only one outcome. Furthermore, choosing an appropriate control group can be challenging.

Cohort studies, cost-effective method within home care. Given the interest in multiple patient outcomes and the unique availability of standardized patient data within home care, the retrospective cohort study stands out as a cost-effective method well-suited for conducting efficacy studies of products and services in the home care industry, assuming patient-level data regarding product or service use is available.

Multiple Patient Outcomes

Home health providers track and monitor a whole host of patient outcome measures. All are important, whether included in the public release quality measures made available through the Centers for Medicare and Medicaid Services (CMS) on their Home Health Compare web site, in adverse event measures that draw scrutiny from accreditation organizations, in specific measures that are part of pay-for-performance reporting requirements, or in internally identified measures used to evaluate quality improvement goals. Through the use of cohort studies, smart businesses can offer providers compelling

evidence whether the return on investment associated with their product or service is likely to be felt across multiple outcomes, such as improvement in pain, improvement in getting in and out of bed, reduced rates of hospital admission, and increased rates of staying at home when discharged from home care.

Standardized Patient Data

As a condition of participation in Medicare, nearly all home health providers collect the standardized Outcome Assessment and Information Set (OASIS) on a large volume of their patients. OASIS data is collected at specific time points over the course of a patient's case of home health care starting with admission and continuing through discharge, and includes information ranging from demographics to living situations to clinical and functional patient outcomes.

Expert Access

The largest repository of such data, as one might expect, is housed by Medicare. The second largest repository, with more than 18 million patient assessments, is in the OCS Inc. (OCS) data warehouse. This data warehouse includes not only OASIS data, but also patient-level visit and resource utilization data and agency-level financial and operational data. Add patient-level information about the use of a specific product or service to this rich OCS data warehouse and the time and labor typically associated with doing a cohort study is dramatically reduced.

OCS Healthcare Analytics has helped a variety of business partners employ cohort studies to produce compelling evidence of efficacy. The key to success for many of these projects has been OCS Healthcare Analytics expertise in home health data, experience with operationalizing research questions with existing data, and synergistic relationships with thoughtful and forward-thinking business partners.

Kinetic Concept Incorporated (KCI)

KCI has been among those thoughtful businesses with which OCS has partnered. The vignette below summarizes key facets of the efficacy study conducted on behalf of KCI and highlights the impact the results had on their marketing campaign.

KCI Vignette	
Methodology:	Retrospective cohort study
Research Question:	Do home health patients with stage III and stage IV pressure ulcers using KCI Vacuum Assisted Closure (V.A.C.), the first Negative Pressure Wound Therapy (NPWT) recognized by CMS, have lower rates of acute care hospitalization and emergent care than similar patients using other wound care therapy?
Findings:	V.A.C. was significantly associated with reduced hospitalizations and emergent care (Table 1 and 2 provide detail)
Marketing Impact:	Findings published in peer-review journal, Ostomy/Wound Management Presented the study at numerous conferences for physicians, wound care specialists, home health providers, and WOCN (wound, ostomy, continence nurses) Included the results in advertisements and sales materials

Table 1. Acute Care Hospitalization Rates by Treatment Groups

	NPWT (n=60)	Comparison Group (n=2,288)
Instances of hospitalization (n, %)		
Stage III pressure ulcers	24% (7)	44%* (756)
Stage IV pressure ulcers	45% (14)	59% (337)
Total	**35% (21)**	**48% (1,093)**
Instances of hospitalization for wound problem (n, %)		
Stage III pressure ulcers	3% (1)	11%* (194)
Stage IV pressure ulcers	7% (2)	20%* (116)
Total	**5% (3)**	**14%** (310)**

** P < .05 for differences between groups (t-test)*

*** P < .01 for differences between groups (t-test)*

Table 2. Emergent Care Rates by Treatment Groups

	NPWT (n=60)	Comparison Group (n=2,288)
Instances of emergent care (n, %)		
Stage III pressure ulcers	21% (6)	32% (551)
Stage IV pressure ulcers	26% (8)	38% (220)
Total	**23% (14)**	**34% (771)**
Instances of emergent care for wound problem (n, %)		
Stage III pressure ulcers	0% (0)	7% (126)*
Stage IV pressure ulcers	0% (0)	11% (63)*
Total	**0% (0)**	**8% (189)***

** P < .05 for differences between groups (t-test)*

By leveraging available data through OCS and choosing to report on multiple outcomes that resonate with home health providers, KCI, with one cohort study, generated compelling evidence with which to drive multiple marketing efforts and to present to the academic community.

Conclusion

Smart businesses use smart methods. Home health providers are increasingly making

evidence-based clinical and business decisions in their efforts to demonstrate achieving a myriad of high quality outcomes while also looking to contain costs. Simultaneously, they are becoming increasingly savvy about what constitutes compelling and sound evidence. Smart businesses will take advantage of this growing focus on evidence within the industry and the ease with which they can conduct rigorous efficacy studies with smart methods to meet this demand for evidence head-on. With evidence that their product or service has the power to impact one or more outcomes, these businesses will differentiate themselves from their competitors while helping assure providers that they spend their limited resources in a strategic manner.

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