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Challenges and Benefits in Using Productivity Data from Clinical Trials for VBP Decisions

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Making value based purchasing decisions in healthcare requires balancing data from several sources. Information on *effectiveness* of interventions often comes from clinical trials, with less reliance on observational studies. Historically, the opposite has been true of information on the *cost* of interventions. More recently, providers of healthcare interventions such as drugs, devices, and disease management programs have begun to understand and appreciate the importance of costs in healthcare decision making. Because of this, the clinical trials used to demonstrate effectiveness have begun to gather data on costs. This article describes some benefits and detriments of collecting cost data as a component of clinical trials, focusing specifically on the data related to productivity.

Studies evaluating the cost of an intervention can look at a variety of different types of costs depending on the perspective of the study. For an organization whose sole function is to pay for healthcare (e.g., Pharmacy Benefits Managers), the direct costs (e.g., the price of a pharmaceutical) are the only ones with importance. For employers, it is essential to consider the indirect costs and, in particular, productivity.

Productivity can be measured in a variety of ways, but it is usually reported as an amount of *productivity lost* due to a certain disease, or the amount of *productivity loss avoided* by using a specific type of intervention. Productivity loss due to medical conditions can present itself in 2 ways. The first is *absenteeism*, often measured by means of reviewing employee records of sick days or disability leave.

The second type of productivity loss - *presenteeism* - is more difficult to measure. Presenteeism is defined as an employee being present at the work place but unable to perform at his or her usual level of productivity. This type of productivity loss is often measured by surveying employees with certain conditions. The employees are asked to report the percent of time they have lost from work as a result of their condition.

The value of lost productivity can be calculated through either the friction cost approach, or the human capital approach. The *human capital approach* yields estimates of wages lost for the time that an employee was not working. The *friction cost approach* adds to that the cost of recruiting and training additional labor to replace that which was lost. Depending on the condition and the

characteristics of the work environment, either of these approaches may be appropriate.

Using clinical trials to measure changes in productivity due to a medical intervention has a number of benefits. These trials are viewed as the gold standard for understanding the impact of medical interventions on health because they control for a lot of potentially confounding issues. In these trials, patients are carefully controlled on one or more specific interventions, and the outcomes are measured prospectively. This allows researchers to arrive at strong conclusions about the causes and effects observed in the trial.

There are also some limitations when using clinical trials to measure productivity changes due to medical interventions. First, one must recognize that health is only one of many factors that contribute to work productivity. Changes observed during a clinical trial may not be due entirely to the intervention being tested. In addition, some individuals choose their jobs, at least in part, in order to mitigate the limitations of that condition. For example, a retail worker with back pain may choose to look for a job at a pharmacy rather than a home improvement store in order to lessen the likelihood of heavy lifting as a job requirement. This type of decision lessens the perceived impact of a medical intervention on productivity from a clinical trial point of view.

Interpreting studies that evaluate the impact of medical interventions on productivity can be difficult, but it is an essential step in understanding the effect of purchasing decisions on employees. For instance, it is important to understand how the conditions in which the study was conducted differ from those at the company purchasing the medical intervention. The type of work being done as well as the demographic characteristics of the workers may influence the estimation of wages for those workers.

Although it has been demonstrated that productivity loss is one of the largest disease-associated costs for employers, we are still in the early stages of measuring productivity gains due to specific interventions. As this important information becomes more available, employers should recognize its value in making purchasing decisions. It is equally important that the consumers of this information understand the benefits and detriments of these study designs.

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