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Follow These Basic Tenets to Ensure Valid Comparisons

New Guidance on DM Program Evaluation Published

Two researchers have offered the disease management (DM) community new guidance on how to evaluate their DM programs objectively and prove to purchasers the extent to which they are getting financial and clinical returns on their investment (ROI) in DM.

The guidance comes in the form of a set of "principles of good program evaluation" that the researchers urge people to consider when conducting a credible evaluation of DM programs and when assessing the integrity of DM program evaluation done by others. If adhered to, these principles will ensure that objective financial, clinical and other outcomes information will result no matter what kind of outcomes measurement methodology is used to evaluate a DM program, the researchers believe.

The primary means of evaluating DM programs today are based on study designs that sit at either end of the spectrum of scientific rigor, explains Thomas Wilson, an epidemiologist and principal with Loveland, Ohio-based Wilson Research and the lead researcher on the project. At one end are highly rigorous -- and expensive -- randomized clinical trials (RCTs), which many people in the DM community view as the "gold standard" of DM program evaluation and the only method that can produce statistically valid and reliable information on ROI, he tells *DM News*. At the other end are the less rigorous -- and less expensive -- "pre-post" studies that compare performance before and after a DM program is launched. Proponents of pre-post studies advocate them as practical yet acceptable methods of DM program evaluation.

Wilson and co-researcher Martin MacDowell, an associate professor at the University of Illinois School of Medicine in Rockford, Ill., say there's a workable way to conduct DM program evaluation that lies between those two polar extremes, one that balances the importance of business practicality with scientific validity. It centers on adhering to three basic principles no matter what program evaluation methodology you use:

• **Using a reference population or benchmark in any study involving DM.** The identification of a reference group, whether historical or concurrent, is essential, Wilson says. In a pre-post study, for example, the "pre-" period serves as the reference.

• **Ensuring that the DM population and the reference population are "equivalent" to each other.** The reference group should have an "equivalent risk" to the intervention group, according to Wilson. "In other words, the outcome, were it not for the intervention, would be identical in both groups," he explains. "If equivalence does not exist, adjustments and/or more robust study designs are necessary."

• **Ensuring that the metrics methods used in the DM population and the reference population are comparable.** When evaluating ROI, metrics that are measured in a comparable way must be used in both the reference and the intervention groups, Wilson says.

Methodologically sophisticated studies that follow these so-called "principles of causality" will greatly enhance the reputation of the important and growing efforts in DM outcomes measurement, Wilson says. "By incorporating these three principles, even a basic pre-post study may be not only practical but may also provide a credible estimate of ROI and clinical impact," he says. "Or it may not. The validity of this approach -- or any other approach -- depends on the degree to which the study achieved equivalence and comparability. Those who provide DM services and those who purchase DM services need to be cognizant of these extremely important principles."

This middle-ground approach to DM program evaluation is based on the recognition that the double-blind RCT is considered the gold standard for one primary reason, Wilson tells *DM News*. "The two randomized groups are assumed to be 'equivalent' to each other on all important factors besides the intervention. Thus, the trends of the reference group are considered valid expectations of the trends to be expected in the intervention group had that intervention group not experienced the extra intervention. Therefore, the difference between the two groups can be effectively attributed to the intervention itself. The results are, therefore, a credible and valid estimate of value."

However, since RCTs will likely never become a day-to-day standard for evaluating DM programs because they are impractical for financial and other reasons, other program evaluation designs

must be used, Wilson adds. In these other designs, "equivalence" can still be approached, if not achieved, as long as they follow and involve the three basic principles.

In formulating his so-called "principles of causality" that should guide DM program evaluation, Wilson says he took his cue from architecture. "Metrics are comparable to a plumb line and a level and equivalence is comparable to load-bearing walls and nonload-bearing walls," he explains. "There are many ways to build buildings, but, no matter how you do it, you have to abide by some basic principles. What's different from DM and architecture is that we can look at a building to see if it stands or not. But when you measure abstract things like population health, you can't look at it to see if it stands up or not. The only way you know if it stands is to ask the questions about the principles."

An accepted set of evaluation principles has been sorely lacking in DM because the industry has been focusing so much on metrics, Wilson says. "The entire industry has been so focused on metrics," he says. "But you have to be more precise in how you measure things. Metrics is a necessary part, but it is not sufficient to evaluate DM programs."

The industry also has been overemphasizing the need to identify a single outcomes measurement methodology, Wilson adds. He and MacDowell consciously steered clear of that pitfall, he says. "We did not recommend metrics or any study designs," he explains. "We said there are many ways to do this, but no matter how you do it you have to follow basic principles."

Recommending a specific DM evaluation design "is like saying the best way to enclose space is an A-frame," Wilson adds. "That's all right because you can sleep in an A-frame and seek shelter from rain, but you might also want to build a gothic cathedral. They both provide comfort, but they're very different. What we strive for is heterogeneity. There are many ways to build a building and do a valid study. But I would never come out and say one method is better than another one."

Because it is unlikely that RCTs can become a dominant design in assessing the value of DM program, the solution offered by Wilson and MacDowell give the DM community another valid approach to assessing DM program performance, says Jeffery Gruen, M.D., senior medical director of New York-based UnitedHealthcare. "Rather than fall into the trap of recommending a specific study design, the authors advocate that key principles of causality be followed regardless of study design," he tells *DM News*. "Their work deserves serious consideration. It reminds me of the famous sign on [Albert] Einstein's Princeton office: 'Not everything that can be counted counts, and not everything that counts can be counted.' This paper could lead to the establishment of new standards for determining which of the disease management effects we believe we are counting truly count."

Others in the DM community have reacted equally favorably to Wilson's and McDowell's concepts. "This paper is right on target," says Richard Vance, M.D., president and chief executive officer of Rosemont, Ill.-based CorSolutions Medical Inc. "I applaud the heterogeneous approach to measuring ROI and clinical impact. The authors do not recommend a specific method to do ROI studies. Rather, they discuss important principles one should consider when choosing methodologies. This is a significant contribution to the literature on disease management measurement and assessment."

Jaan Sidorov, M.D., medical director of care coordination for Danville, Pa.-based Geisinger Health Plan, says the researchers' ideas serve as "an excellent primer" on outcomes assessment for anyone interested in DM. Like Wilson, Sidorov believes the DM industry has focused too much on metrics and methodology at the expense of rationale. Wilson and MacDowell "provide the horse we need to put before the cart," says Sidorov, who also chairs the Quality and Research Committee of the Disease Management Association of America. "They present a no-nonsense, practical, easy-to-read and rigorous review on assessing the true impact of disease management programs. This is a 'must-read' for public policy makers, purchasers, managed care leaders, clinicians and vendors."

David Krause, senior economic analyst with Greensboro, N.C.-based Accordant Health Services, believes the DM program evaluation principles will hold DM executives to a higher standard. "The author's have clearly stated what we all need to think about when evaluating ROI of disease management," he tells *DM News*. "To their credit, their approach doesn't dwell on the technical issues related to methodology. Rather, they stress principles of causality -- principles that are well-known to the world of academic research, but often ignored in the practical world of ROI assessment. I predict that these principles will become the basis for lots of excellent questions asked by CEOs and others to the purveyors of DM programs. It will force them to better justify their claims regarding program effectiveness. This paper is a practical treatise with clear implications: DM outcome studies must be conducted and evaluated in a more scientific manner."

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