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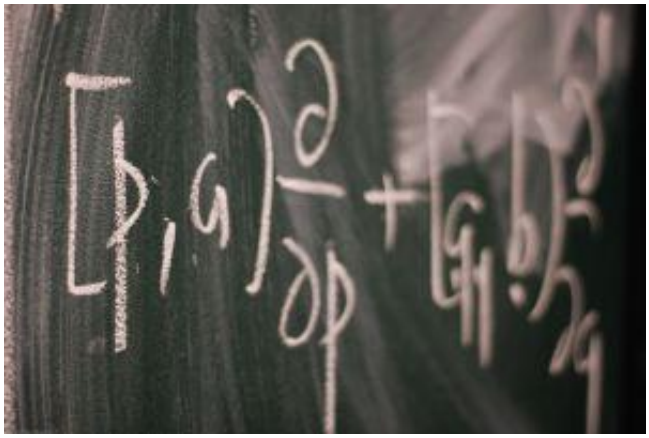
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by Tom Serena MD, FACS, FACHM, FAPWCA

"Price is what you pay. Value is what you get"
-Warren Buffet[1]

Lawrence Mills introduced the concept of Value Analysis to the manufacturing industry a half century ago. The basic idea entails analyzing the function and importance of the various parts of a product as they relate to cost. He derived the following equation[2]:

$$Value = \frac{Function}{Cost}$$ [10]

I admire my colleagues in economics and industry, although I admit that in my younger years, I dismissed all but the biological sciences as the impractical folly of academicians. What possible use would I have for economics, of all fields, in the practice of medicine? My misguided arrogance as a surgeon has since afforded me a fine taste for crow. There is a seriously pressing need for value analysis in medicine, most especially in selecting from the dazzling array of Cellular and/or Tissue-based Products [11] (CTPs).

Determining Which Cellular and/or Tissue-base Product to Use

CTPs for the treatment of chronic wounds have undoubtedly improved patient outcomes; however, the Cambrian-like proliferation of these products has led to considerable confusion

as to which to choose for a particular patient or wound type. I reckon from my last count that there are more than 70 CTPs approved for use through a variety circuitous FDA pathways. Daily, I face the question from my fellow woundologists: which product should I use? Of greater concern is that many of us are victims of our last success. CTP "X" worked recently on a difficult patient; therefore, I am prone to using it on the next 10 patients, often times forgetting my own admonition to practice evidence-based, fiscally responsible medicine. I believe this conundrum can be resolved through a value analysis process uniquely adapted for our discipline.

I have humbly defined "value" (in deference to my economic colleagues with far greater skill) in the wound care marketplace as the strength of the clinical evidence multiplied by a constant plus a factor to account for the number of grafts required plus product reimbursement.

$$CTP\,Value = (E * S) + R + (2 - A)$$ [12]

First of all, products with randomized, controlled trials (RCT) will be highly favored in this formula. This narrows the field substantially from 70 products to 8 that have RCT evidence. Clinical evidence (CE) is evaluated using a scale ranging from -2 to +3,

Calculating Clinical Evidence Score (E):
-2: Mechanism-based reasoning
-1: Case-series, case-control studies, or historically controlled studies
0: Non-randomized controlled cohort/follow-up study
+1: Randomized trial single
+2: Randomized trial(s) and comparative effectiveness trial
+3: Systematic review of randomized trials

The CE score is then multiplied by a constant in order to give greater weight to clinical evidence over reimbursement. I have called this the "Serena Constant" (**S**). It is completely arbitrary; therefore, if anyone is to take the blame for determining its value it is me. Reimbursement is the cost of the product minus its average blended net payment. Medicare's introduction of the high and low bundles has made this process much simpler. A score is given to the reimbursement and it is inserted into the equation. We have proposed the following scale for reimbursement,

Calculating Reimbursement Score (R):
The facility profits from the product: +1
The product is budget neutral: 0
The facility does not profit from the product: -1

Finally the number of graft applications required (**A**) to achieve closure will also be taken into consideration in this formula.

The calculation of CTP Value can be performed per wound type. Potentially it could be performed for each individual facility and clinician as well.

For example, CTP "Y" has an RCT demonstrating efficacy in the treatment of diabetic foot ulcers. It has a single RCT giving it a CE score of +1. This is then multiplied by the S constant of 3. CTP "Y" is in the high bundle and the cost of a 1.5 x 1.5 sheet is $800. The reimbursement is $1407 netting a profit to the center of $607. The reimbursement score

would be +1. Finally, CTP "Y" requires an average of 2.5 applications to achieve complete closure.

$$CTP\,Value = (1 * 3) + (1) + (2 - 2.5) = 3.5$$ [13]

A total score of +3.5 would suggest that CTP "Y" should result in a good evidenced-based clinical outcome in a fiscally responsible manner. In addition, CTP "Y" could now be compared to all of the other CTPs allowing physicians to choose the best product for his or her patient.

A Call for Wound Care Community Input

The final step is to publish the results annually for all of the CTPs. This formula is a first draft. I would invite my fellow clinicians or industry partners interested in this venture to join me. Please e-mail me at serena@serenagroups.com [14].

References:

1. Warren Buffet. 1930. American Investment Entrepreneur
2. Adapted by Kenneth Crow DRM Associates. Value analysis and function analysis system technique. Accessed at http://www.npd-solutions.com/va.htm [15] 10/15/2015.

About The Author

Dr. Thomas Serena has published more than 75 peer-reviewed papers and has made in excess of 200 presentations worldwide. He has been elected to the Board of Directors of both The Wound Healing Society and the American College of Hyperbaric Medicine (ACHM), the leading academic society in the field of Hyperbaric Medicine. In 2014 Dr. Serena was elected president of the American Professional Wound Care Association (APWCA). Dr. Serena has opened and operates Wound Care and hyperbaric oxygen treatment clinics across the United States.

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