THE VALIDATION INSTITUTE BOOSTS CREDIBILITY OF HEALTH OFFERINGS

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Health industry claims of efficacy are not always accurate

At $1.7 trillion and 784,000 companies, the healthcare industry and its adjacent and ever-multiplying suppliers, consultants, new products, old products, services, is rich with claims about impact and evidence.[1] A day doesn't pass without an announcement of a new 'study' presenting 'facts' about products, treatments, therapies, and programs, not to mention the many new apps focused on wellness and coaching. Human resource executives face widespread assertions about the positive impact of wellness programs. Study result headlines can be big; claims of efficacy can be bigger -- but studies may be small and correlations must be inferred.[2]

Are the promises really to be believed?

Can a wellness program reduce employee healthcare costs by 20%? Are wellness programs effective? What is to be believed? Corporate wellness programs lure employers with promises to reduce healthcare costs and to help retain employees and these programs are now a $6 billion industry. More than half (52 percent) of all employers that offered wellness programs in 2012 believed that they were effective in reducing the firm's health care costs, according to a survey by the Kaiser Family Foundation and the Health Research and Educational Trust (HRET), 2012.[3] But are they really?

Some studies supporting wellness programs are designed by the product vendor itself.[4] For example, one vendor claimed savings of $20,000 per person who reduced his/her health risk factors (such as being overweight). This made for significant savings, but failed to take into account that the average annual cost per person began at $6,000 and that higher health risk

factors do not necessarily correlate to higher medical costs. Nevertheless, the study was persuasive to the employer.[5]

According to this skeptical NY Times article: "More rigorous studies tend to find that wellness programs don't save money and, with few exceptions, do not appreciably improve health."[6] One reason many wellness programs do not save money is that they promote health screenings that encourage overuse of care, pushing spending higher without improving health. Biometric tests popular with wellness programs include blood pressure, blood cholesterol, and cancer screening. When these tests are used properly with the patients most likely to benefit, they can be beneficial. But wellness programs tend to promote all participants getting all tests, ignoring the medical guidelines. Thus, the program has the expense of unnecessary and inappropriate tests, plus follow-up tests and care.

When an employer's health costs do go down, it may or may not be a credit to the wellness program. "Any population will have a good year, a bad year. A wellness program can arrive at any point and take credit for having an impact, but chances are that if the program was looked at over time, what it demonstrates is regression to the mean -- that is, the improvement would have happened anyway as part of a cycle" says Linda Riddell, a population health scientist and measurement expert. Calculating true savings is a complex undertaking, even for large sophisticated government programs that have the expertise.

CBO study: hindsight shines a skeptical light on 'cost savings'

Long ago (2006) Medicare Part D was introduced and was expected to lower Medicare's costs.[7] The Congressional Budget Office estimated "that medical spending decreases by 0.2

percent for each 1 percent increase in drug prescriptions filled." This conclusion was based upon sub-groups of Medicare members. However, it turned out that selected subgroups did not represent the experiences of Medicare subscribers at large, many of whom already had some type of drug coverage prior to Part D.[8]

About the new study from the School of Pharmacy at Northeastern University, Becky Briesacher, a health services researcher at the school observes: "You have to be realistic about the fact that giving people access to medication is important, but it's not going to substantially save money in other parts of the health care system or keep a significant number of people out of the hospital."[9]

Behind claims of accomplishment – how big was that study?

Studies can be skewed by self-defining population selection rules or tiny samples that can be viewed with skepticism by doctors.[10] Consider the now-famous example of the study linking vaccines to autism:

Published by the Lancet in 1998, Dr. Andrew Wakefield's study suffered not only method flaws, but also lacked approval from the ethics committee. Far from a random sampling of children, the study enrolled children whose parents were attracted to Wakefield's stated goal of linking the measles-mumps-rubella vaccine to autism. The study was not retracted until 2010.[11] In the meantime, the study captured the imagination of the world despite many other valid studies finding no causal link between vaccines and autism.

Both the CBO and Wakefield autism studies underscore the issues resulting from drawing confident conclusions from studies that may have selection or sample limitations. An

employer's wellness program has inherent selection and sample problems, as do many other types of health products and programs.

A Specific Example: Cancer Screening in Wellness Programs

Consider the following wellness program claim. Is it accurate and science-based?

"The program will cut medical costs by screening employees for cancer"

Conventional wisdom and many wellness program promoters say that diagnosing cancer in its early stages means that treatment will cost less, and the patient's health will be better. This is partly true, in that an early stage cancer patient spends less on care than a late stage cancer patient. However, cancer screenings ultimately lead to higher costs, do not improve health and do not save lives. Why?

- The screening tests detect small cancers that may have never progressed to produce a symptom or a problem.
- Experts agree that we are over-treating cancers; that is, removing tumors that could be left alone.
- Cancers detected by screening tests are, by definition, not aggressive cancers.
- Treatment outcome for screening-detected patients is already favorable, and not improved by early treatment.

"Saying that 'screening catches cancer early' ignores the number of over-diagnoses and actual mortality statistics. These can be gamed – more patients are labeled as cancer survivors, but the actual mortality rate hasn't changed." Linda Riddell, MS, quality measures expert and independent validator for the Institute.

While incidence of new breast cancer cases is on the rise (more people are diagnosed), the 10-year mortality rate from the cancer has not changed. In short, finding more early stage cancers is not reducing the number of people showing up with and dying from late stage cancers. Instead, it is putting a lot more people through cancer treatments and follow-up; this only adds to total expenses, without improving anyone's health.

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Health-related industries need a "CarFax"

Prior to 2014, no organization existed to certify a vendor's claims – the achievement of cost savings, for example, versus the *appearance* of cost savings. The health and wellness industry also has no widely-accepted method of determining its results. Buying a health or wellness program has a parallel with buying a used car without consulting CarFax: confidence and trust in the salesperson may be all you have. CarFax came up with four universal measures and a system to publish them. It is so successful that 90% of all car manufacturers that offer certified pre-owned vehicles require their dealers to have a CarFax report.[12]

According to its founders, this is the role that the Validation Institute seeks to fill – to provide buyers and investors with independent, science-based valid measures for health and wellness programs' true results. Instead of relying upon each company's "customized" measures and oft-exaggerated marketing claims, buyers and investors can use the Institute's review to validate and substantiate the value of the program or product: Notes Karissa Price, Executive Director for the Validation Institute: "It couldn't come at a more opportune time for investors. The 'Wild West Gold Rush' raised $4.1 billion for Digital Health startups in 2014 alone.[13] This is a continuation of the frenzied wave of investor enthusiasm about tools, apps, and initiatives to improve healthcare outcomes and lower costs."

Measurements matter – their proper design and clear communication matters more. Whether it is an existing company, a new health tech startup, an established process, or a program effectiveness study – the industry ecosystem benefits from establishing measurement standards. Some industry leaders have joined together to boost the claims' credibility to a standard that is well-communicated and well-understood. Intel-GE Care Innovations provides a

process for establishing a commonly understood level of credibility through a process they call **Validation** as part of their new Care Innovations Validation Institute™ -- which was officially launched at the middle of 2014.[14] Its first advisory board meeting, led by its Chair, Dr. David B. Nash was held in March, 2015, during the Population Health Colloquium held in Philadelphia.[15] The Validation criteria and process strive to address the issues described and boost credibility in outcomes for the health care ecosystem – enabling participants to compete on the 'basis of integrity and proven performance." Members of the Validation Institute's esteemed Advisory Board are drawn from across the Population Health and Healthcare ecosystem and are listed in **Appendix I.**

What is the motivator for validation?

According to Karissa Price: "Validation is sought by any healthcare industry stakeholder that wants to both confirm and proclaim the validity of the claims that they make about population health outcomes. This includes insurance companies, hospitals, employers and vendors of healthcare products and services**."**

Companies that have their outcomes and contracts validated show their customers the true impact of their product, and show their integrity in having an independent, scientific review of their measures. Customers will also be able to hold validated companies accountable for results achieved. Over time, customers should come to expect independent validation from all of its health-related vendors.

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What are the principles underpinning the study designs review in validation?

Study designs must be in accordance with best practices, adhering to three basic principles which apply to all types of studies.

- Willingness to participate must be held constant, to adjust for the 'volunteer effect'
- There must be an adjustment for *what would have happened anyway*
- The process has to be consistent with the outcomes

These are the types of validations performed by the Institute:

1. **Stated savings or outcomes measurement.** Enterprise programs like wellness or productivity include measurements of proposed savings or intended outcomes.
2. **Financial spreadsheets.** When an organization wants to validate claims made via an interactive spreadsheet or model, the spreadsheet must exhibit the following characteristics:

✓ The figures all add up — with no mistakes in the formulas themselves
✓ Inputs and other assumptions are clearly sourced and linked
✓ Assumptions that are just assumptions — assumptions with no specific inputs — need to be labeled as such
✓ The user may change any assumption that is not clearly sourced.

3. **Contractual language states product or service actual capabilities.** Valid metrics have been used to design contractual clauses, and if something is guaranteed, the contractual metrics must support the statement made. Inputs must be clearly measured and the methodology of measurement and sources of data are agreed to in advance.

For validation, program goals must be both beneficial and explicit.

The program must be linked to what the vendor or program is doing. For example, if the program is focused on reducing heart disease, its results or measurements must be linked to heart disease rates. Any cost savings must be driven by utilization changes, not unit-cost changes. Cost changes are a negotiated or contracted item, while utilization changes are due to population health.

What types of organizations go through the validation process?

Companies from all facets in the healthcare industry are candidates for validation by the Validation Institute and many have gone through the process in the past year. For example, Healthsense, a well-respected firm offering smart sensor software, was one of the early organizations that went through the process to validate its Outcomes Measurement Contract Language. Whereas most vendors want to compare motivated participants to non-participants, and/or measure the difference between the high-cost baseline and the study year, in order to benefit from regression to the mean, Healthsense will offer to compare to a validly measured control group, including a study design that controls for motivation, using a "dummy year analysis."

Validated companies receive confirmation through a certificate as shown and are listed in the Trusted Community section of the Validation Institute's website, www.validationinstitute.com.

For a list of validated companies, see **Appendix II**.

In Closing

Intel-GE Care Innovations has a bold vision for future health and wellness product consumers:

- A market in which vendors have clear and validated measures of health improvement and cost savings;
- A straightforward method to compare the value and impact of one program to another; and,
- Vendors that compete on the basis of true effectiveness of their products, winning market share by providing superior value.

Through its review services and publicity of member companies, the Validation Institute will play an important part in bringing this vision to reality.

Appendix I – Members of the Validation Institute Advisory Board

Chaired by **David B. Nash, MD, MBA**, founding dean of the Jefferson College of Population Health (JCPH) and the Raymond C and Doris N. Grandon Professor of Health Policy at Thomas Jefferson University in Philadelphia. Joining Dr. Nash in the Advisory Board will be nine respected leaders in the population health space, including:

Jan Berger: Jan is the CEO of Health Intelligence Network and a member of the Breakaway Policy Strategies Medical Advisory Board. She is also an author of several books and is the Editor-in-Chief of the *American Journal of Pharmacy Benefit*.

Steve Chick: Steve is vice president at Humana and the leader of Comprehensive Health Insights, a wholly-owned subsidiary of Humana. He is currently a member of the International Society for Pharmacoeconomics and Outcomes Research.

Ian Duncan: Ian is adjunct professor of Actuarial Statistics at the University of California, Santa Barbara and served as vice president of clinical outcomes, analytics and reporting at the Walgreens Company from 2010 to 2014.

Dee Edington, Ph.D.: Dr. Edington is the founder and chairman of Edington Associates, LLC. He is the founder and professor of the University of Michigan Health Management Research Center and was the director of the Center until June 2011.

Walter S. Elias, PhD: Dr. Elias has consulted extensively on health & productivity, drawing on extensive population health management expertise.

Frank Frigo: Frank is the co-founder of Edj Analytics, LLC and is a past winner of the Backgammon World Championship in Monte Carlo.

Fred Goldstein: Fred is the president and founder of Accountable Health, LLC. He has over 25 years of senior management experience in the health care industry.

Matthew Holt: Matthew is the founder and Co-Chair of Health 2.0, the founder and occasional author of The Health Care Blog.

Don McDaniel: As President and Chief Executive Officer for Sage Growth Partners, Mr. McDaniel is responsible for executing SGP's go-to-market strategy. Mr. McDaniel is also a member of the professional faculty at the Carey Business School, The Johns Hopkins University.

Tricia Parks: She is the founder, chairman, and CEO of Parks Associates, a market analyst and research company dedicated to providing meaningful information and counsel to companies offering technology-based products aimed at improving people's lives. She presents worldwide on consumer trends, market requirements, and industry structure.

Karissa Price-Rico, Ph.D.: Dr. Price is the executive director at the CI Validation Institute and the chief marketing officer at Intel-GE Care Innovations™.

Sean Slovenski: Sean is the CEO at Intel-GE Care Innovations™ and is a proven innovator and entrepreneur with an established track record in defining and building businesses from concept to viability.

Jason Wainstein: Jason is a principal in Deloitte Consulting LLP's health plan practices and serves as the national leader for Deloitte Consulting LLP's health plan technology strategy and information management/analytics practices and as an industry innovation champion.

Appendix II – List of Validated Organizations

Accordant
Blue Cross Blue Shield of Louisiana
EdisonHealth Network
Harvard-Pilgrim Health Care
Healthentic
Healthsense
Healthways
iDiet
Kinesis Health Technologies
The Leapfrog Group
MCCI Medical Group
NY44 Health Benefits Plan Trust
PSC Healthcare
Presbyterian Healthcare Services
Procter & Gamble
Providence Health Plan
Quantum Health
Quizzify
stickK
US Preventive Medicine (USPM)

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