

Wellness Program Alert

How to Avoid Getting Sued Like Yale

Free Webinar

September 4, 2019

Wednesday | 2PM ET



Webinar Handouts



ValidationInstitute



Q & A Follow Up

Good Afternoon - would you consider promoting "disease management" not a "wellness initiative" that helps save money and quality of employee life?

Validation Institute (VI) doesn't really "promote" entire industries but we would be happy to look at a company that wants to be validated, that has outcomes. As a general rule, disease management is completely voluntary so there is no issue of implied coercion. By the way, the presenter and VI co-founder/advisor, Al Lewis, is sometimes credited with inventing disease management. (Try googling on "invented disease management" in quotes and see what pops up.)

Hi Al, when offering a discount to employee premium cost sharing to attest to being tobacco free, does granting the discount when an employee completes a cessation program sensible

Asking people about smoking/nicotine is NOT considered a clinical inquiry. So you are OK.

I understand how an annual exam might be overkill and may not help. But, how exactly can seeing my doctor and having a few tests each year cause me harm?

Glad you asked. See this discussion of false positives. There are both clinical and arithmetic reasons why the overwhelming majority of lab tests done on seemingly healthy people are false, and can lead to all sorts of follow-up issues. This is not intuitively obvious. One would expect that if a test were 90% accurate, only 10% of the positives would be false. And yet scroll down on this <https://dismgmt.wordpress.com/2018/10/30/false-positives-for-dummies-and-smarties/>





Q & A Follow Up

If the incentive is a raffle, does this affect the liability related to size of the reward?

It's the expected value (raffle times probability of winning), and it would be hard to imagine a raffle with such a high payout that you could get dinged for it, so you are likely perfectly OK. Also, we are told that for legal reasons you should call it a drawing, rather than a raffle.

Our wellness program is through our medical provider. If they do not participate they are assessed a 15% increase to their premium. It resets every year. Can the 15% increase be an issue?

Absolutely. It would depend on what the actual dollar figure is. And is it 15% of the total premium paid by both the employer and you combined (likely an issue) or just a 15% increase in the amount you would pay otherwise (likely within the realm of OK)?

Please give us an example of a well-rounded, wholistic employee wellness program

That is a great question, but one that probably deserves its own webinar. It would combine voluntary age-appropriate screening with employee health literacy, an activity program, perhaps a farmer's market, and maybe an on-site or near-site clinic.





Q & A Follow Up

RCT are, by nature, not going to show good results because they are doing wellness TO people. If you're randomized then it's not going to be your choice, by definition. So I would argue this isn't the gold standard for this type of research

You are saying something very much like “let’s compare participants to non-participants, because that’s the only way we’re going to get a good result.” However, you need to either include both participants and non-participants in both the study and control groups, or just ask for participants and don’t offer the program to half of them. The BJ’s study was the first. The U of Illinois study was the second. Both showed no outcomes at all, to speak of.

Otherwise, you will always show an impact, because participants will always outperform nonparticipants...even (as was shown) if there isn’t a program to participate in.

Thank you for the information.

Thank you for your appreciation of it.

Thank you!!!

See above response. 😊



Q & A Follow Up

This presentation title was very deceiving and has just been a bashing session on all the different wellness vendors. I think that if we wanted to learn why wellness doesn't produce ROI then we would have signed up for a webinar with that title. ROI is not something that is even discussed in the wellness space much anymore, you put wellness programs in place to give employees tools and resources to empower them in their health and wellness journey.

Not sure how Yale's program "empowered" the employees. I might recommend reading the entire Complaint. Hard to see how a program that employees dislike so much that they sue their employers helps the "health and wellness journey." And here is the link to yesterday's article, [The Scourge of Workplace Wellness Programs](#).

It would have been great to present something more balanced, and it was noted in the presentation that there is a distinction between wellness done to employees and wellness done for employees, the latter of which is great and perhaps that is what you are referring too.

However, presenting something "balanced" on wellness done to employees would be like presenting something "balanced" on climate change – impossible to do without ignoring the facts. In the case of forced wellness programs, a presentation would either be "balanced" or accurate. It can't be both.





Q & A Follow Up

What about a goal of keeping employees from entering a higher risk vs trying to make them lower risk. If people don't increase in risk, the costs will be less over time (by not increasing).

I would encourage you to use the objective measurement tool that accompanies these answers. You'll see that indeed the Health Enhancement Research Organization is correct in asserting that the savings from attempting to reduce or maintain risk is trivial as compared with the cost. Since only a very small percentage of hospitalizations and ER visits are wellness-sensitive medical events, not increasing risk factors would make only the most trivial reduction in eventual costs. [See this proof of how wellness has failed to reduce costs over a 14-year period.](#)

If indeed that were an economically and clinical sound outcome, someone would have used it to [claim the \\$3 million reward](#) by now.

Is he going to make suggestions on how to improve the health of our workforce? This is disheartening, and while interesting, it's not helpful.

That was not the agenda. As noted on the above comment, we were already pushing the boundaries of the agenda. Perhaps another conference. HOWEVER, you can try different programs and use the BEST tool that is attached to measure their cost-effective engagement.





Q & A Follow Up

Normal BG and cholesterol is not a deterioration.

If you have glucose in a good range already and it goes down quite a bit (as it did in the Wellsteps data), you are likely to become a bit lethargic, with some people becoming actually hypoglycemic. Not a good thing. Our suspicion is that Wellsteps just did the analysis incorrectly, because the odds are remote that a large group of employees with normal glucose would see a significant decrease in a program which failed in so many other ways.

Employees whose cholesterol was originally normal did not show a decrease in the Wellsteps program. See the chart.

With the Chronic disease events, how accurate is it with employee turnover?

You are paying for all employees regardless of tenure, so it is totally accurate. You will show less of an impact from your wellness or disease management program if turnover is high, but as noted in the answer to your first question, there is virtually no impact on chronic disease events anyway. Indeed, Ron Goetzel, who is the unofficial leader of the wellness promotion crowd, [published an article](#) finding zero impact on costs of wellness programs. If he can't find an impact, there is no impact to be found, even with "investigator bias."





Q & A Follow Up

If employees act on their health checks, what is the impact?

If everyone goes to the doctor every year and follows up every recommendation for tests or drugs, the data from the Journal of the American Medical Association shows they will get more tests and drugs, but no reduction in morbidity or mortality.

What are the most common adjustments made to commercial insurance coverage to encompass growing focus on Wellness and more companies implementing wellness programs?

That is a good question and it's tough to know the answer. The average incentive/penalty in large companies (prior to the EEOC Safe Harbor being vacated) was about \$800. This can take many forms. Examples are:

- *Access to a “better” health benefit*
- *Switching to a high-deductible plan and letting employees earn back some of the deductible*
- *A change to the monthly contribution, which was Yale’s choice.*

Smaller companies tend to have smaller incentives, and offer gift cards or drawings. The larger numbers are the ones at risk for EEOC litigation.





Q & A Follow Up

Why do you call out specific vendors in your presentation? e.g. Wellsteps and Interactive Health? Do you have recommendations and/or encourage other solutions for wellness?

They weren't "called out." Their publicly available information was used to make valid points (this is, after all, the Validation Institute) about fallacies in measurement. Both companies knew they were snookering employers (and still are), and have been asked to stop, but haven't. They have also had the opportunity to sue the presenter, [who very considerably has published his address and his attorney's address](#) to make himself easier to sue. They have passed on this opportunity, for the simple reason that every single material statement that Al Lewis has made about these two vendors is true, according to the vendors' own data.

Those vendors also haven't agreed to abide by the [Employee Health and Wellness Code of Conduct](#). Wellsteps has specifically rejected it. We would encourage you to look at it and ask why a vendor would find agreeing to standards of do-no-harm and don't-lie-about-outcomes to be objectionable.

"Other solutions" for wellness – those that are validated – are on the [Validation Institute website](#). The only traditional wellness program which has been able to "move the needle" on risk factors (excluding Wellsteps, which "moved the needle" backwards) is US Preventive Medicine. They are listed on the site with additional information.





Q & A Follow Up

What is your opinion of the likely outcome of this lawsuit?

Just an opinion, but we can't see how Yale could prevail. AARP will likely not agree to a settlement that doesn't include an apology/admission, because they are trying to establish a precedent.

Yale appears to be doing exactly what Judge Bates said couldn't be done, which is calling a program with very large penalties voluntary.

They could immediately mitigate the damages by offering an alternative of a non-clinical program, and/or getting indemnification from their vendor, but according to their website, they are proceeding with the program as described in the webinar. They could also sue their consultant, who should have known their program was very high risk but perhaps didn't tell them. If their consultant did indeed advise them not to do the program and they did it anyway.

How does the NCQA accreditation for wellness vendors mesh with the Validation Institute's standards?

There is no relationship. We are not privy to their decision process, but no company with NCQA accreditation has been able to achieve validation, and one such company (Interactive Health) was cited yesterday as an example of invalid outcomes measurement. We do know that their process does not involve independent analysis of outcomes or savings, however.





Q & A Follow Up

What is the best argument in favor of annual screenings?

There is no clinical basis for screening employees of every age every year for every blood value. The US Preventive Services Task Force recommends frequencies like the ones in the Yale program, listed in your slides.

Vendors are aware of this disparity between annual frequencies and appropriate frequencies, but disclosing this disparity to employers might cause employers to demand a large reduction in fees, as appropriate screening costs much less than annual screening.

Additionally, if you are requiring annual checkups plus annual screenings, that is much too much medical care, according to all experts. One or the other is too much. Both combined would be even greater overkill.

Thanks AI Great presentation! Tom C.

From AI Lewis: "And thanks for being a worthy competitor of [Quizzify](#) with a fine product that makes the whole healthcare literacy Q&A industry (meaning your company and mine) look good, and definitely deserved my shout-out. P.S.: Try using the BEST tool. I bet you get the same great results Quizzify gets."





Q & A Follow Up

Are all major vendors aware of the existence of the Validation Institute?

Yes. Many were on the call yesterday. You should ask yours to get validation. Excellent advice comes from Comcast's Shawn Leavitt:

"If an employee benefit vendor comes to us promising an outcome or result, we would ask if that outcome is validated by the Validation Institute, or if not, why not? We will be interested in hearing their responses."

A good question for an RFP would be: "Do you have validation from the Validation Institute? If so, for which of the four levels? If not, why not?" A similar question could be asked about endorsing the [Employee Health and Wellness Program Ethical Code of Conduct](#).

Women have always had physicals yearly...what do you recommend?

It is very flattering that you ask for our recommendation, but the VI is a repository of valid information. We don't make recommendations. We do, however, make factual observations. The observation we would make about the annual GYN physical is that [the pelvic exam part may have zero value, according to experts who have studied it](#).





Q & A Follow Up

Would you advise against a policy that requires employees to get an annual physical from their PCP in exchange for a lower premium cost? The results of the physical are not shared with the employer and kept completely confidential.

We don't really advise, at the VI, but would make two observations. First, yours should not be a compliance issue, as you've stated it. We can't guarantee that because it hasn't been determined in court, but the current and likely programs to be litigated are vastly more intrusive than what you are describing. So, compliance-wise, you should be fine.

The question that clinical experts would ask is, why require employees to get an annual physical when there is zero value to them? The presenter (whose company, Quizzify, works with Harvard Medical School doctors to come up with recommendations) suggested two alternatives:

- *2 in your 20s, 3 in your 30s, 4 in your 40s, 5 in your 50s, and annually after that*
- *Asking employees to have their doctors advise when they should get their next physical, and crediting them with the lower premium for the years in between physicals recommended by their doctors.*





Insist on Indemnification for the ENTIRE program from your vendor

- Why should you take the liability (and professional!) risk when vendors are willing to?
- Use a clause like this one to transfer risk to vendors:



EEOC Indemnification Guarantee

Offering Quizzify as an alternative makes screenings/HRAs truly voluntary, and removes your program from EEOC jurisdiction. We indemnify you (or if you are a vendor, your customers) for any adverse judgments on cases brought by employees claiming that your wellness program includes "involuntary medical exams or inquiries" as defined under ADA or GINA.

This indemnification covers 80% of any award, up to ten times the total value of your Quizzify contract.

- Other vendors are offering similar indemnification...AND screening compliant with guidelines!





A template for all you need to indemnify

Choice of screening
vs.
non-clinical option


*Doesn't cost a nickel more
than you're spending now.*

HOW TO EARN YOUR 2019 INCENTIVE THIS FALL


Choose between our **traditional screening/weigh-in** at our annual health fair, or play an **online health education game**. The choice is yours.

Select the **SCREENING/WEIGH-IN** if:

- You haven't seen your doctor in the last 24 months, nor intend to in the next 6 months.
- You are over 35 (male) or 45 (female) and have been told you have significant risk factors.
- You believe you may have undiagnosed chronic disease (for example, one parent died of chronic disease before age 60).
- You are very concerned about your weight.
- You want to "know your numbers."



Play the **GAME** if:


 You feel you might learn something from short, multiple-choice quizzes about health and healthcare. You will need to complete 4 quizzes to receive credit.

Topics include:

Diabetes How much do you know about the #1 chronic disease of all time?	Everyday Health Hazards Is it OK to dip a chip after someone has double-dipped?
Surprising Hazards of the Medical System What common surgery do 99% of surgeons admit they themselves would never undergo?	Fats, Salt, Sugar, Eggs What are the biggest nutritional no-no's...and what can you indulge in guilt-free?
Opioids How many painkiller pills can you take before they start becoming addictive?	Health Insights for Ages 50+ Can shingles be avoided?
Women's Health Are pelvic exams useful?	Your Health Benefit What's the difference between a co-pay and co-insurance?

Unsure of which one to choose?

You can start by playing the game, but can switch to the screening if you feel you are not learning anything.



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All Quizify content is reviewed by physicians at Harvard Medical School.





Tools to trend your wellness-sensitive medical events (WSMEs)

(1) Collect the ICD10s for 2016-2018 for WSMEs

Chronic Condition	ICD10 Codes (includes all subcategories)
Asthma	J45
Chronic Obstructive Pulmonary Disease	J40, J41, J42, J43, J44, J47, J68.4
Coronary Artery Disease (and related heart-health issues)	i20, i21, i22, i23, i24, i25.1, i25.5, i25.6, i25.7
Diabetes --including likely non-cardiac complications	E10, E11.0-E11.9, E16.1, E16.2, E08.42, E09.42, E10.42, E11.42, E13.42, E08.36, E09.36, E10.36, E11.311, E11.319, E11.329, E11.339, E11.349, E11.359, E11.36, E13.36, L03.119, L03.129, i96, E08.621, E08.622, E09.621, E09.622, E10.621, E10.622, E11.621, E11.622, E13.621, E13.622, L97
Hypertension, Heart Failure and related diseases	i50, i10, i11, i12, i13



Tools to trend your wellness-sensitive medical events (WSMEs)

(2) Tally them using this tool

	ER Events	+	Inpatient Events	=	Calculated
<u>2016</u>					
ASTHMA					
CAD					
CHF					
COPD					
DIABETES					
<u>2017</u>					
ASTHMA					
CAD					
CHF					
COPD					
DIABETES					
<u>2018</u>					
ASTHMA					
CAD					
CHF					
COPD					
DIABETES					

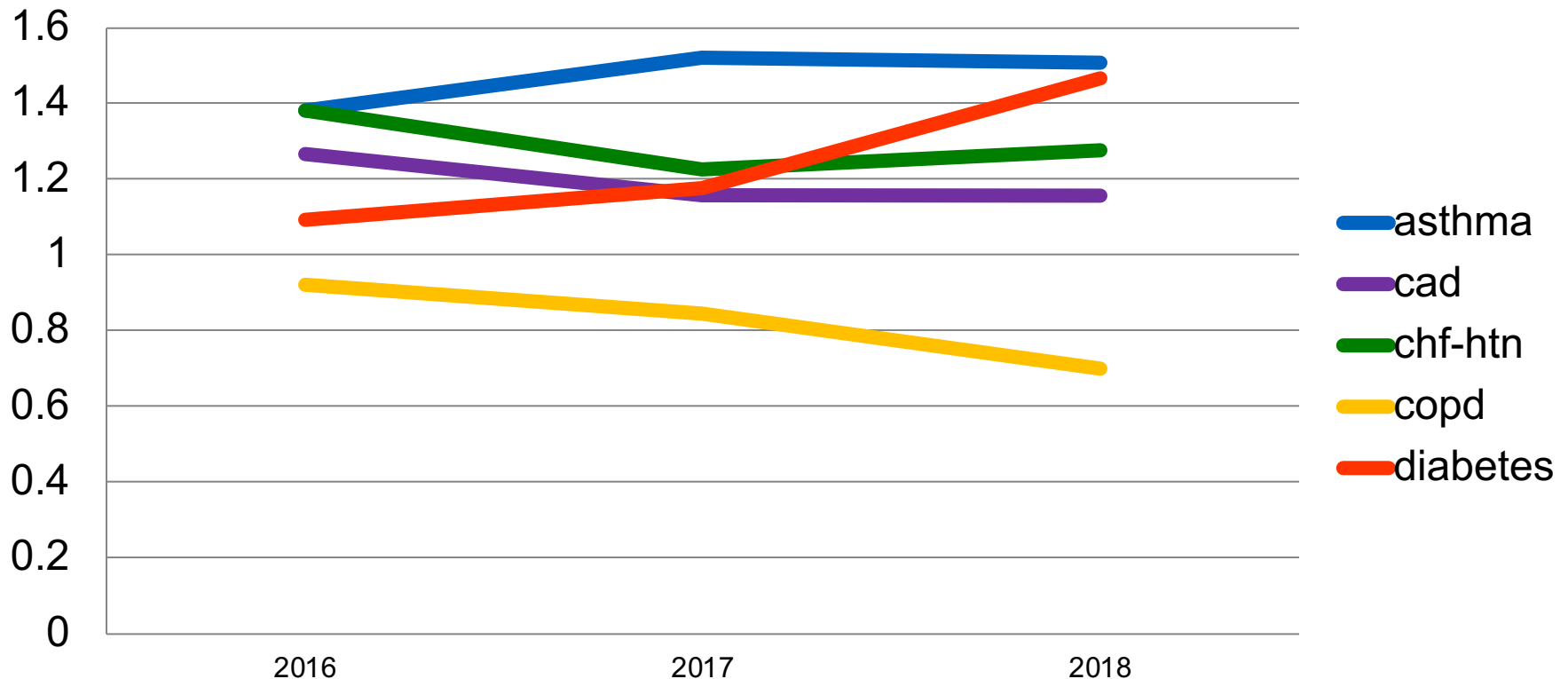




Look at trends to see how your program did.

3) Graph events as shown in this example. (This company did a COPD program and a diabetes program.)

Chronic Disease Events per 1000 members
(short view for all algorithms – all ICD 10s)





B.E.S.T. Tool

Benefits Engagement Survey Tool

Estimate your PEPY cost/1000 or total cost for each of your tools

- In this case, it was a small group so we did total cost
- Measures Quizzify, screening, HRA, portal, and EAP*





Determine which tools offer cost-effective engagement

Engagement vs. Cost





Ask your employees:

1. **“How many times if at all did you use it?”** *Measures participation*
2. **“Was it useful?”** *Measures perceived value*
3. **“Do you feel this benefit enhances/reflects a positive corporate culture?”** *Measures what Lee Lewis calls “nice programs” that only a few people use, like fertility benefits*



- Number of uses **X** usefulness = **total workforce engagement**
- #3 will be the size of the bubble, representing **impact on culture, independent of use**



Engagement survey for up to five tools

(1) Did you use it? (2) How useful was it? Multiply participation times usefulness to get total engagement

Did you use Resources for Living in the past 12 months? *

☐ No

☐ Yes, one time

☐ Yes, two times

☐ Yes, four times

☐ Yes, five times

☐ Yes, more than five times

Section 6 Continue to next section

Section 7 of 12

Resources for Living Feedback detail

Description (optional)

How useful was the Resources for Living? *

☐ Very useful

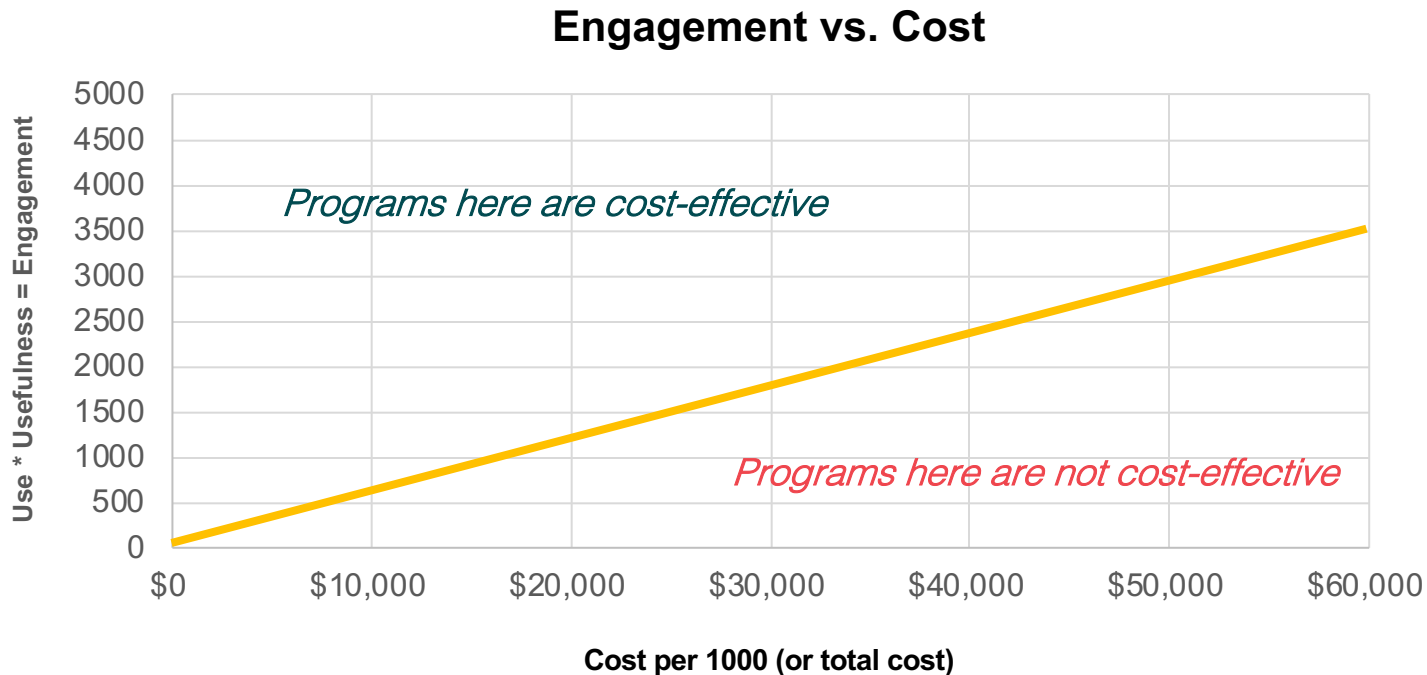
☐ Somewhat useful

☐ Not very useful

☐ Not useful at all



Determine which tools offer cost-effective engagement





Recommended Articles and Downloads

[It's time to believe the research: Wellness isn't working](#)

The highly-publicized, randomized control trial of the wellness program at BJ's Wholesale Club published recently in the *Journal of the American Medical Association* found virtually no value in the program. While most pundits applauded the study, wellness vendors — whose livelihoods, of course, depend on believing the opposite — attacked it.

[The Outcomes, Economics and Ethics of the Workplace Wellness Industry](#)

On its surface, who can argue with the concept of workplace wellness? How could there be anything wrong with corporations helping their employees reduce their risk of disease while saving money in the process?





Bibliography of Wellness/Screening Programs

The following is a cross-section of nationally known publications' coverage of screening-intensive workplace wellness programs, that your consultant or broker may not have brought to your attention. The bibliography excludes articles published by workplace wellness vendors/consultants due to "investigator bias". A summary of all articles through 2017 can be found in the Case Western Reserve law-medicine journal's article: [The Outcomes, Economics and Ethics of the Workplace Wellness Industry](#).

- New York Times: [Workplace wellness programs don't work well.](#)
- New York Times: [Employee wellness programs yield little benefit, study shows](#)
- Inc.: [Randomized controlled studies show wellness programs don't work](#)
- Modern Healthcare: [Workplace wellness programs don't improve employee health](#)
- Employee Benefit News: [Time to believe the research: wellness isn't working](#)
- Slate: [Workplace wellness programs are a sham](#)
- Los Angeles Times: [Why workplace wellness programs cost employers and scam employees](#)
- Harvard Business Review: [Corporate wellness programs lose money](#)
- Harvard Medical School: [Do employee wellness programs actually work?](#)
- Health Affairs: [The risks of using workplace wellness programs to foster a culture of health](#)
- New England Journal of Medicine: [Physician as double-agent in workplace wellness programs](#)
- New York Times' economics blog: [Workplace wellness programs don't save money](#)
- Reuters: [Wellness programs and waists spread together](#)
- Fortune: [Corporate wellness programs: Hokey or healthy?](#)
- NPR: [Why employer incentives to lose weight fall flat with workers](#)
- STATNews: [Top wellness award goes to program where health got worse](#)
- SHRM: [Time to set limits on workplace screening?](#)
- The New Republic: [The Scourge of Workplace Wellness Programs](#)
- Wall Street Journal: [Here Comes Obamacare's Workplace Wellness Program](#)



Certified Outcomes Report Analysis (CORA)

Learn to distinguish between high-value and low-value healthcare programs/services by analyzing outcome and performance claims:

- Four self-paced modules (30 minutes total) give you the tools to make more informed, value-based purchasing decisions
- Discover key terms and concepts critical to program design and results measurement
- Printable checklist used alongside real-life application examples
- Designed for easy and immediate implementation
- **SHRM-approved** for professional development



ValidationInstitute



Certified Health Value Professional (CHVP)

Highly specialized training to help employers move the needle with health care benefits:

- Self-paced, online training
- 14 modules covering topics critical to maximizing value and health outcomes, such as:
 - ✓ Identifying high-performance niches
 - ✓ Effective plan design
 - ✓ Reference-based and bundled pricing
 - ✓ Maximizing claims reviews
 - ✓ CORA
- Content designed and taught by industry-leading experts and in-field practitioners
- **SHRM-approved** for professional development



ValidationInstitute



Validate. Educate. Connect.



Validate.

Independently verified results.



Educate.

Empowered health benefits
purchasing.



Connect.

Bringing healthcare purchasers
and solution providers together.



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