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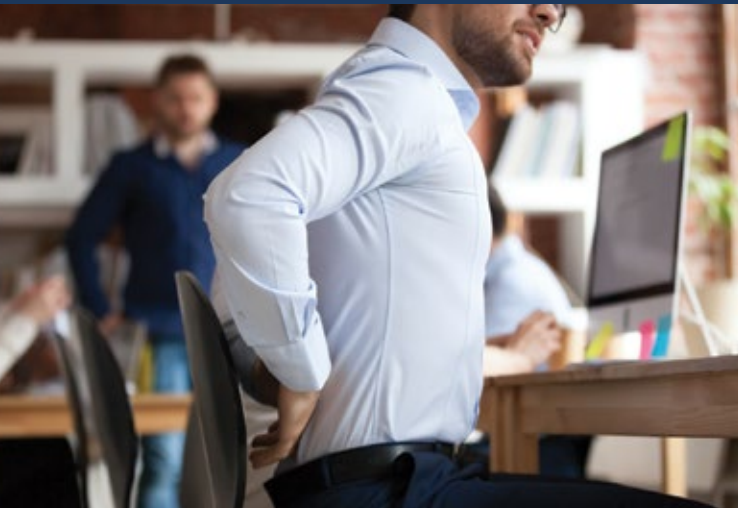
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# NO PAIN = GAIN!

## HOW TO INCREASE PRODUCTIVITY AT WORK BY PROMOTING SELF-CARE FOR MILD PAIN



Consequences of pain for an individual are self-explanatory. What are the consequences and costs for employers?<sup>1</sup>

1. Employees take **more time away from work**
2. Their **productivity** at work **decreases**

Low back pain is a frequent cause of time away from work. Most pain sufferers report only mild pain, yet they **cost** their employers **10% of total productive time**—the equivalent of two lost workdays every month.

Data from Germany for low back pain alone reveal a cost of lost productivity from work absence that is three times greater than the direct cost of medical treatment.<sup>2</sup>

### How common is low back pain among workers?

- About 1 in 10 people worldwide suffer from low back pain<sup>3</sup>
- Chronic low back pain is more common among those in their 50s and 60s<sup>4</sup>
- Thus, it mostly affects experienced employees at the peak of their professional productivity<sup>1</sup>

The World Health Organization defines self-care as *“the ability of individuals, families and communities to promote health, prevent disease, maintain health, and to cope with illness and disability with or without the support of a healthcare provider”*<sup>5</sup>

### What is the recommended approach for mild pain?

- Over-the-counter (OTC) medication and topical treatments can be effective for low back pain and are key in managing minor ailments through self-care<sup>6</sup>
- OTC medication provides quick symptomatic relief to improve wellness and quality of life<sup>1</sup>
- OTC medication is cost-effective<sup>1</sup>
- The World Health Organization recommends managing mild pain with OTC analgesics<sup>7</sup>

### Is there evidence that people with mild pain follow this approach?

- Unfortunately, the evidence shows that the uptake of OTC medication as self-care for minor ailments varies across the world and across Europe<sup>8</sup>
- One of the possible causes for lower uptake is the lack of knowledge about the appropriate use of these medicines<sup>1</sup>
- Education on the appropriate use of OTC medicines is essential<sup>1</sup>

Employers have an **opportunity to promote self-care among employees and increase productivity at work.**

Fostering self-care by employees is one of the quickest and surest ways for employers to realize economic gains from improved work force productivity. Health value studies suggest that increased awareness of OTC analgesics and their role in treatment of musculoskeletal pain could help reduce pain-related absences and increase productivity at work.

Employees should be given reliable information and appropriate health management tools enabling them to practice responsible **self-care**.

This research was sponsored and funded by Sanofi.

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MAT-GLB-2101907

**SANOFI** CONSUMER  
HEALTHCARE



## HONORING A REMARKABLE LEADER

## In Tribute and Memoriam to Dr. William B. Bunn III, MD, JD, MPH

**T**his latest edition of IHPM's *International Journal of Health & Productivity (IJHP)* pays tribute to its Founder (in 2006) and Editor-in-Chief, Dr. William B. Bunn III, MD, JD, MPH – as we deliver the sad news of his unexpected passing on January 18 of this year.

Our world without “Dr. Bill” seems unimaginable. He was a seminal figure in the field of Health and Productivity Management, and a key member of IHPM's original “brain trust” from its founding 24 years ago.

Upon retirement from his globally unique role as Navistar International's Vice President for Health, Safety, Productivity & Security (1995 – 2012), Dr. Bill also became IHPM's Consulting Global Medical Director, he maintained his own international consulting practice and found time to teach at the Medical University of South Carolina.

It is difficult to overstate the contributions Dr. Bill made to the fields of occupational health and occupational medicine, as well as to the emerging new field of health and productivity that he helped establish. The list of health issues on which he could truly be deemed an expert is longer than this page can accommodate. His medical mind was encyclopedic, and his record of published research studies – based on actual workplace health program outcomes – is without peer.

The outpouring of appreciation – and celebration – of all that Dr. Bill meant to so many people has been extraordinary. His work educated and motivated countless others worldwide, while his life touched and encouraged so many other lives. He is one of those few “irreplaceables” who comes along in each generation; words like “icon,” “legend,” and “visionary” are overused today, but – appearing in many of the testimonials from Dr. Bill's colleagues – when applied to him, they fit.

Brilliance and congeniality rarely are found together in the same person, but they existed together in Dr. Bill – whom we already miss more than merely words can express. To honor this remarkable leader, mentor colleague and good friend to so many, starting this year of 2021 IHPM's Annual President's Award will become the Dr. William B. Bunn III Award for Global Leadership in Health and Productivity Management – in recognition of someone whose entire career was worthy of such an award.



William B. Bunn III, MD, JD, MPH  
Editor-In-Chief

We honor this remarkable  
leader, mentor and good  
colleague and friend to  
so many

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## INTERNATIONAL JOURNAL OF HEALTH & PRODUCTIVITY

### Volume 13, Number 1 – May 2021

**THE INTERNATIONAL JOURNAL OF HEALTH & PRODUCTIVITY** (ISSN 2164-4373) is published by the Institute for Health and Productivity Management (IHPM), with corporate offices located at 17470 N Pacesetter Way, Scottsdale, AZ 85255 USA. Periodical postage paid at Richmond, VA, and at additional mailing offices.

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Richmond, VA 23255-1895

Tel. 804.387.7580 Fax. 703.997.5842

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## FROM THE PRESIDENT'S DESK

Sean Sullivan, JD

This edition of the *IJHP* has a powerful lineup of articles addressing two of the most important health issues related to the pandemic – sleep and mental health. These are supplemented by a trio of IHPM White Papers all based on published peer-reviewed research, addressing major domains of health and functionality:

- persistent cardiovascular risk heretofore unaddressed.
- the global burden of musculoskeletal pain.
- self-care of low back pain with non-prescription medications.

***Online Cognitive Behavioral Therapy Improves Productivity and Sleep Health in the Workplace*** – authored by Dominic Munafo, MD, Debra Lerner, MSc, PhD; Derek Loewy, PhD, Gary Kavy, MBA, Bretton Beine, RPSGT, Karen Reuben MS, Andrew Molesworth, AS, evaluates the effect of improving employee sleep health on workplace productivity. Sleep has come into its own in recent years as a recognized leading influence on all aspects of health and well-being, and this article – based on actual field research with a major employer – shows its substantial impact on productivity, as well, as measured by the leading measurement instrument of functional impairment, or presenteeism – the biggest reason for health-related lost productivity.

***Innovative Approaches Can Help Employers Play a Critical Role to Reduce Healthcare Costs and Support Employee Productivity*** authored by Brian Sullivan, PsyD; Melissa Milanak, PhD; and Delaney M. Wallace, BS is based on original research assessing mental – or, more precisely, emotional – health as measured by eight “affective determinants” of peoples’ feelings about their own health and well-being. The measurement is done using a unique set of “Morphiis” that assess these feelings more exactly and continuously than previous methods, and they engage individuals more readily in responding to the psychometrically developed survey instrument used. “Employers are in a unique position to help reduce the impact of the megatrends, more effectively support their employees’ emotional, behavioral, and physical health, and improve their business’ viability in an economy that has been wracked by the novel coronavirus that causes COVID-19.”

**IHPM’s own secondary research in published peer-reviewed sources, produces the first comprehensive look at:**

- ***Reducing Persistent Cardiovascular Risk:  
Meeting Unmet Needs in Treating Cardiovascular Disease***
- ***Global Burden of Chronic Musculoskeletal Pain in the Workplace***
- ***Self-Treating Low Back Pain with Over-the-Counter Medications:  
Economic Value Proposition for Employers and Health Systems***

All these articles focus on subjects within the scope of IHPM’s Workplace Centers that address priority areas of health and productivity for employers – in these instances the Centers for Sleep Health, Behavioral Health, Metabolic Health, and Pain Management.

Sleep and mental health are two of the most important health issues related to the pandemic



## FURTHER NEWS FROM IJHP

There is good news to share for the editorial future of the IJHP. We are honored to introduce its new Co-Editors who are longtime associates of the Institute – Wayne Burton, MD, and Samantha Horseman-Kozak, DBL, MBA.



Dr. Wayne Burton

**Wayne N. Burton, M.D., FACP, FACOEM**

Dr. Wayne Burton is a strategic advisor and healthcare consultant. Previously he was the Corporate Medical Director for American Express from 2009 to 2017 and the Corporate Medical Director for JPMorgan Chase and its legacy banks from 1982 to 2009.

He has been the recipient of several awards including the Inaugural Corporate Health and Productivity Award from IHPM, Global Leadership in Corporate Health Award, American College of Occupational and Environmental Medicine/ National Business Group on Health, Mark Dundon Research Award, Health Enhancement Research Organization (HERO), Adolph G. Kammer Merit in Authorship Award, ACOEM, Health Achievement Award from the American College of Occupational and Environmental Medicine (ACOEM), the Jonas Salk Health Leadership Award from the March of Dimes, the Innovation Award from Mental Health America and the Innovation in Health and Productivity Award from National Business Group on Health (NBGH).

Dr. Burton is Board Certified in Internal Medicine and is Associate Professor of Clinical Medicine, at the Feinberg School of Medicine, Northwestern University and Adjunct Professor of Environmental and Occupational Sciences at the University of Illinois in Chicago, IL. He is a Fellow of the American College of Physicians and a Fellow of the American College of Occupational and Environmental Medicine.

Dr. Burton was previously Chairman of the Board of the Midwest Business Group on Health and was a member of the Board of Directors of the National Business Group on Health.



Dr. Samantha Horseman-Kozak

**Samantha Horseman-Kozak, DBL, MBA**

Dr. Samantha Horseman-Kozak is President of the Innovation Ecosystem Society (IES) and Lead at Saudi Aramco Entrepreneurship Center (Wa'ed).

Samantha is a well-known innovator and entrepreneur spanning an impressive two-decade career at Aramco. She is recognized as a highly motivated thought leader because of her human-machine interface (HMI) portfolio of 60 granted patents, 15 prototypes, 22 publications, and a total of 25 local, regional, and global awards. This recognition resulted in being one of the first recipients of the Aramco CEO Excellence Award in 2014. She continues this pioneering work through leading the Innovation Ecosystem Vertical for Saudi Aramco Entrepreneurship Center, Wa'ed.

Samantha is President of the Innovation Ecosystem Society (IES) and Director for the 'google for startups' Dhahran Chapter. Additionally, following her work with the World Economic Forum Global Study "Workplace Wellness Alliance" she has continued to accelerate this work in her role as President of the MENA Chapter for Health & Productivity Management (IHPM).

*Specialties:* Presenter, Leader, and Author in the fields of Innovation, Health and Productivity Management, Maximizing Performance through Healthy Human Capital Investment, Data Science, Predictive Analytics, Entrepreneurship, Commercialization, Human Machine Interface (HMI) innovations and inventions.

# Online Cognitive Behavioral Therapy Improves Productivity and Sleep Health in the Workplace

Dominic A. Munafo, MD; Derek H. Loewy, PhD; Gary Kavy, MBA; Debra Lerner, PhD; Bretton Beine, RPSGT; Karen Reuben MS; Andrew Molesworth, AS

## ABSTRACT

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**OBJECTIVE:** To evaluate the effect of improving employee sleep health on workplace productivity.

**METHODS:** Retrospective analysis of pre-post data from employees who completed an online personalized cognitive behavioral therapy (CBT) program (ProjectZ) aimed at improving their sleep health. Pre-CBT and post-CBT measures included the Work Limitations Questionnaire (WLQ), the Abbreviated Insomnia Measurement Scale (AIMS), and the Epworth Sleepiness Scale (ESS).

**RESULTS:** Overall, 9,380 employees were eligible for the program. A total of 2,126 completed the initial screener and 335 completed ProjectZ and the post-CBT assessment. Mean WLQ at-work productivity loss declined by 43.0 percent. The percentage of individuals meeting the criteria for insomnia or daytime sleepiness declined by 89.7 percent and 77.2 percent, respectively.

**CONCLUSIONS:** Employees completing the program had outcomes suggesting economically and clinically meaningful improvements in productivity and sleep health.

## KEY WORDS:

Insomnia, workplace productivity, work limitations questionnaire, cognitive behavioral therapy, obstructive sleep apnea, sleep health, web-based

## INTRODUCTION

---

Sleep disorders are prevalent among the adult populations of developed nations.<sup>1</sup> Disorders such as insomnia, insufficient sleep syndrome, sleep apnea and circadian rhythm disorders can lead to sleep deprivation and fatigue. Sleep deprivation has been found to have a negative impact on mood, cognitive performance and motor function.<sup>2</sup> Specific neurocognitive domains such as executive attention, working memory and divergent thinking are especially vulnerable to insufficient sleep.<sup>3,4</sup> Insomnia and sleep deprivation have been associated with anxiety and depression.<sup>5,6</sup> Forty percent of adults in the United States (U.S.) get less than the recommended 7 to 9 hours of nightly

sleep.<sup>7</sup> Sleep deprivation is also prevalent among American workers. In a 2007 survey of workers in the U.S., 37.9 percent reported daytime fatigue and this was associated with a threefold increase in lost productivity hours.<sup>8</sup>

Insomnia, the most experienced sleep disorder is defined as difficulty falling asleep, staying asleep, awakening too early in the morning, or feeling generally unrefreshed the next day. Insomnia occurring at least three days a week for at least three months is chronic. Surveys of the general U.S. population suggest that as many as 20 percent of adults experience chronic insomnia annually.<sup>1</sup> Insomnia prevalence increases with age across both sexes.<sup>5</sup>

Obstructive sleep apnea (OSA) is the most common form of sleep-disordered breathing and is caused by repetitive complete or partial collapse of the upper airway during sleep. Population-based estimates suggest that at least 13 percent of men and 6 percent of women have OSA and that in the past two decades, prevalence rates have grown substantially.<sup>9,10</sup> Numerous comorbidities including hypertension, congestive heart failure, stroke, diabetes mellitus and an increased risk of motor vehicle accidents are found in patients with OSA.<sup>11-17</sup> Yet, the majority of individuals in the general population with moderate to severe OSA remain undiagnosed.<sup>18</sup>

The economic costs of sleep disorders to society and businesses are enormous. Insomnia's direct costs, including medical services, sleep medications and hospitalizations have been estimated to be \$13.9 billion annually.<sup>19</sup> When indirect costs, such as presenteeism, secondary depression and substance abuse are factored in, the amount skyrockets to about \$100 billion.<sup>20</sup> A study in Canada found that the average annual per-person economic burden (direct and indirect costs combined) was \$5,010 for individuals with insomnia syndrome and only \$421 for those without sleep complaints.<sup>21</sup> OSA also places an additional financial burden on the healthcare system, with the cost of untreated OSA in the U.S. estimated to be \$67 billion to \$165 billion.<sup>22</sup>

ProjectZ is a web-based comprehensive sleep health program that identifies and helps to reduce the consequences of prevalent sleep disorders. ProjectZ's algorithms offer each participant an individualized, self-paced, structured, online program of strategy modules for identified sleep issues. Participants screening positive for insomnia symptoms are offered cognitive behavioral therapy for insomnia (CBTi). CBTi is a multi-component, non-pharmacological approach to insomnia. The effectiveness of CBTi for relieving insomnia has been demonstrated in randomized, controlled studies.<sup>23-25</sup> Moreover, CBTi has better long-term effectiveness than prescription sleep medication.<sup>26</sup> The American College of Physicians has endorsed CBTi as first-line treatment for chronic insomnia.<sup>27</sup> Recently, CBTi has been made available online and

studies have found it to be as effective as in-person treatment.<sup>28-30</sup> Online CBTi has also been shown to improve sleep among workers with a concomitant reduction in performance impairment in the workplace.<sup>31</sup>

Our *a priori* hypothesis was that providing ProjectZ to an employee population would reduce their work limitations as defined using the Work Limitations Questionnaire (WLQ) by improving symptoms of insomnia and excessive sleepiness. The primary endpoint was the change from baseline of the WLQ at-work productivity loss score and secondary endpoints were scale scores from the Abbreviated Insomnia Measurement Scale (AIMS) and the Epworth Sleepiness Scale (ESS).

## METHODS

This was a retrospective analysis of an uncontrolled, non-blinded intervention study with a pre/post design occurring from October 2015 through April 2017. The protocol was reviewed and approved on September 18, 2015 by the Chesapeake Institutional Review Board. Protocol # - Pro00012248. Subjects were not consented as this study was a retrospective analysis of de-identified data.

## STUDY POPULATION

Employees participated through pilot programs offered by MetLife, Inc (as an employer), Hyatt Hotels Inc., Omaha Public Power District, Manatee YourChoice Health Plan, and Morrison Healthcare. Employees had to be at least 18 years of age and could be working full-time or part-time. This convenience sample offered a range of different industries, occupations, earnings levels, and geographic locations.

The data were collected initially by anonymous online screening offered through the worksites. Employees could complete the screening from any computer or mobile device. The dynamic screening questionnaire consisted of approximately 35 to 45 questions. Screener questions assessed the frequency of an employee's work limitations related to health problems, as well as the frequency and/or severity of significant sleep issues such as elevated OSA risk, insomnia symptoms, excessive daytime sleepiness, disrupted circadian rhythm (jet-lag, shift



work, advanced and delayed sleep phases), restless legs symptoms, stress disrupting sleep and chronic hypnotic use. Self-reported health conditions such as anxiety, depression, chronic pain, hypertension, and diabetes were also assessed.

Each screened employee received a message with their screening results and was offered the program. To encourage participation, employees were offered modest incentives by their respective employers in the form of gift cards or prize raffles. The median amount spent per eligible employee was \$1.42 with a range of \$0.24 to \$12.30. ProjectZ game points were awarded for completing various milestones along the way. Achieving streaks and trophies were all part of the gamification of the program. Gamification has been shown to improve engagement by users of online programs.<sup>32</sup>

## DATA COLLECTION

In addition to the screening questionnaire, which served as the pre-intervention baseline, ProjectZ participants were invited to complete a post-intervention online questionnaire administered upon program completion. Because the program was self-paced, the time from pre-intervention baseline assessment to post-intervention assessment varied from individual to individual. Only after completing all the assigned content was a post-intervention assessment offered. These post-intervention assessments were conducted for workplace limitations (WLQ), insomnia symptom severity (AIMS), excessive daytime sleepiness (ESS) and satisfaction with ProjectZ.

## PROJECTZ INTERVENTION PROCEDURE

For employees who elected to participate in ProjectZ, the screening not only served as the pre-intervention baseline measure but also determined their initial program content. ProjectZ offered CBT and educational content to all employees who completed the screening. Personalization was based on a set of algorithms that were initially informed by this screening data. This content was further adapted during the intervention based on ongoing sleep diary data from employee self-report or the use of a synchronized wearable device. ProjectZ issued automatic reminders

to employees to enter daily sleep diary information. Sleep diary data were used by ProjectZ's algorithms to make ongoing modifications to the sleep compression algorithm. All diary data were anonymous. The therapeutic content was presented as a personalized series of sleep improvement strategy modules. Each strategy module offered techniques in the form of a series of challenge cards. The challenge cards were assigned a point value which was determined based on the employee's answers to the screener questions. This yielded an individualized CBT program specifically tailored to each employee's needs. Program completion was defined as finishing all the modules/challenge cards that had been assigned, while allowing the person to progress through the program at his or her own pace.

In the subgroup of employees assessed as having significant insomnia symptoms, the core elements of CBTi were provided, which included stimulus control, sleep compression, relaxation, cognitive therapy and sleep hygiene.<sup>33,34</sup> ProjectZ differentially weighted and then allocated the core elements of CBTi based on an individual's responses to the screening questionnaire.

Those with sleep disorders other than insomnia were provided with CBT content relevant to their sleep issues as well as content utilizing the broader CBT principles of behavior change. Employees for whom no significant sleep issues were identified were presented with sleep education and sleep hygiene modules. An extensive sleep education library was offered to enhance the learning experience.

In addition, every employee's OSA history was obtained and their OSA risk level classified using a modified version of the STOP-Bang Questionnaire.<sup>35</sup> OSA risk was stratified as low, moderate, or high. Employees who indicated they had a current diagnosis of OSA were asked if they were adherent (at least 5 days a week) to their OSA treatment. Questions concerning snoring, feeling tired or fatigued and witnessed apnea were used to determine if those adherent to treatment were experiencing ongoing symptoms. Employees at increased risk for OSA received a message in which they were encouraged to schedule a consultation with their physician to discuss

their symptoms and diagnostic options. Those employees who were using hypnotics regularly or experiencing significant restless legs symptoms were also referred to their physician.

## OUTCOME MEASURES

### Work Limitations Questionnaire

The WLQ is a validated instrument developed by Lerner et al. (2001) for assessing the frequency of health-related work limitations during the prior two weeks. The WLQ's primary outcome is a summary score estimating at-work productivity loss.<sup>36</sup> The short-form version of the WLQ consists of eight questions with two questions for each of its original four dimensions of work limitations. Scores are generated for health-related limitations for four types of work tasks: Time Management, Physical Tasks, Mental-Interpersonal Tasks and Output Tasks. The scale scores are expressed as a percentage of time with limitations. A global summary score estimating productivity loss due to work limitations is based on a validated algorithm. The score reflects the estimated percentage loss in productivity relative to a healthy benchmark population. Productivity loss scores can be monetized and annualized by multiplying the score by annual employee salary obtained from the sample or an external source (e.g., national median job earnings). As a hypothetical example, if one assumes an annual salary

plus benefits cost of \$75,000 per employee, a company of 1,000 such employees that demonstrates a 1 percent decrease in global productivity loss, stands to save \$750,000, or the equivalent of 10 full-time employees. The WLQ has been used elsewhere to demonstrate that sleep disorders may be associated with work productivity loss.<sup>37-39</sup> As with prior studies, the WLQ assesses the total health burden, not only sleep.

## SECONDARY OUTCOME MEASURES

### Insomnia Frequency

The Abbreviated Insomnia Measurement Scale (AIMS) was developed prior to deploying ProjectZ and was used to assess symptoms of insomnia. The AIMS consists of five questions which evaluate the employee's frequency of insomnia symptoms (Table 1). For each question, respondents are asked to rate their answers on a 4-point scale, (0) Never or Rarely, (1) Sometimes, (2) Often, (3) Always. Each item is equally weighted and the AIMS score is the sum of the five question scores and ranges from 0 to 15. A score of 0 to 3 is interpreted as no insomnia, 4 to 7 is subclinical insomnia, 8 to 11 is moderate and 12 or greater is rated as severe insomnia. The validity of the AIMS in assessing insomnia symptomatology was evaluated in a pilot study in which the AIMS was correlated with scores on the Insomnia Severity Index (ISI). The ISI, developed

**Table 1: Abbreviated Insomnia Measurement Scale (AIMS)**

Please rate how often the following occur for you:

Response Options:	Never	Rarely	Sometimes	Often	Always
Points Allocated:	0	0	1	2	3
1. I have difficulty falling asleep at night.					
2. I have difficulty staying asleep at night.					
3. I wake up in the morning earlier than I prefer.					
4. I feel tired, fatigued or sleepy during the daytime.					
5. My sleep is having a negative effect on my ability to function during the day.					

Severity Scale: No Insomnia (0 to 3); Subclinical (4 to 7); Moderate (8 to 11); Severe (12 to 15)

by Morin and colleagues, is a validated instrument for assessing insomnia symptom severity in clinical and research contexts.<sup>40</sup> The correlational study was conducted online with 143 community-dwelling adults. The overall AIMS score highly correlated with the ISI with  $r = 0.86$  (95% confidence interval of 0.82 to 0.90).

### Excessive Daytime Sleepiness

The Epworth Sleepiness Scale (ESS) is a validated, self-administered rating scale for assessing symptoms of excessive daytime sleepiness.<sup>41</sup> The ESS is comprised of eight questions and respondents are asked to rate, on a 4-point scale (0-3), their likelihood of dozing off or falling asleep in eight different situations. The ESS score is the sum of the eight question scores and ranges from 0 to 24. ESS scores  $> 10$  were deemed to reflect significant daytime sleepiness.

### Satisfaction Measures

The final assessment included five binary questions to gauge employee satisfaction with ProjectZ. These subjective evaluation questions asked if the employee had learned more about sleep, knew how to apply the knowledge to their circumstances, felt the program was personalized, had experienced improved sleep and felt overall health or well-being had improved.

## STATISTICAL METHODS

### Endpoint Comparisons

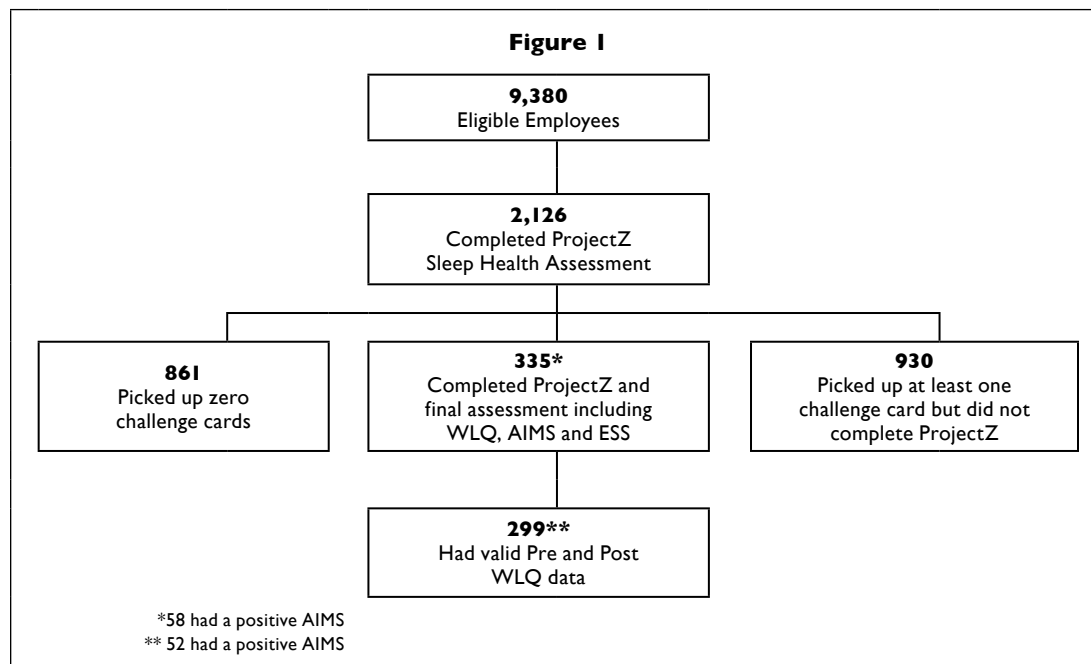
For the endpoint analyses, WLQ scores were calculated using the algorithms of Lerner et al.<sup>36</sup> This yielded a global productivity loss change score and frequency of limitations scores for each of the four WLQ scales. To assess the magnitude of change in insomnia symptom severity, z-scores were calculated for the pre-CBT baseline and post-CBT end assessment AIMS scores. The number of employees who had either moderate or severe insomnia symptoms at pre-CBT baseline was compared to the number at post-CBT assessment and the change was expressed as a percentage. Similarly, the number of employees in the subclinical group at pre-CBT baseline was compared to the number at post-CBT assessment. To assess excessive daytime sleepiness, the number of employees who had a positive ESS at the pre-CBT baseline was compared to the number at post-CBT assessment and the change was expressed as a percentage. Finally, responses of employees to the satisfaction measurement questions were tabulated.

## RESULTS

### Screening Data

#### Employee Characteristics

A total of 9,380 employees were eligible to participate in ProjectZ (Figure 1). Of



those, 2,126 (22.7%) finished the initial screening and of these, a total of 335 (15.8%) completed their ProjectZ program and the post-assessment (completers). Median time to complete ProjectZ was 50.0 days (7.1 weeks). Another 930 employees participated in some but not all their assigned modules and 861 employees did not participate past the initial screening. Together the latter two groups constituted the non-completers and totaled 1,791 employees. When comparing completers to non-completers there were some statistically significant differences (Table 2). Namely, completers had a larger percentage of females (70.2% versus 58.3% respectively,  $z = 4.0506$ ,  $p < 0.05$ ), younger age (41.6 versus 43.8,  $z = 3.142$ ,  $p < 0.05$ ), milder insomnia (AIMS 4.9 versus 5.4,  $z$

$= 2.723$ ,  $p < 0.05$ ), less sleepiness (ESS 6.9 versus 7.5,  $z = 2.426$ ,  $p < 0.05$ ) and less at-work productivity loss (WLQ 3.5 versus 4.2,  $z = 2.781$ ,  $p < 0.05$ ).

In the full-screened sample, the self-reported pre-existing health conditions with the highest prevalence were anxiety (15.1%), hypertension (14.5%) and depression (10.3%). The remaining self-reported pre-existing health conditions included diabetes (6.7%), OSA (6.5%), chronic pain (5.4%) and insomnia (4.3%). A total of 39.6 percent of the screened employees were found to be at elevated risk for OSA, with men twice as likely to be at elevated risk 57.1 percent versus 28.0 percent, respectively. Of all the self-reported pre-existing health conditions, completers had a lower prevalence of

**Table 2: Employee Characteristics**

	Screened (n = 2,126)		Non-Completers (n = 1,791)		Completers (n = 335)	
Sex	Numbers	Percentage	Numbers	Percentage	Numbers	Percentage
Males	846	39.8	746	41.7 <sup>2</sup>	100	29.8 <sup>2</sup>
Females	1,280	60.2	1,045	58.3 <sup>2</sup>	235	70.2 <sup>2</sup>
Age	Mean ± S.D.	Median	Mean ± S.D.	Median	Mean ± S.D.	Median
Total	43.5 ± 11.8	44.0	43.8 ± 11.7 <sup>2</sup>	44	41.6 ± 12.1 <sup>2</sup>	41.0
BMI						
Total	29.9 ± 7.3	28.7	29.8 ± 7.2 <sup>1</sup>	28.5	30.5 ± 7.9 <sup>1</sup>	29.6
AIMS						
Total	5.3 ± 3.1	5.0	5.4 ± 3.1 <sup>2</sup>	5.0	4.9 ± 3.0 <sup>2</sup>	5.0
ESS						
Total	7.4 ± 4.2	7.0	7.5 ± 4.2 <sup>2</sup>	7.0	6.9 ± 3.9 <sup>2</sup>	7.0
WLQ	(n = 2,013)*		(n = 1,696)*		(n = 317)*	
Total	4.1 ± 4.1	3.0	4.2 ± 4.2 <sup>2</sup>	3.1	3.5 ± 3.7 <sup>2</sup>	2.7

<sup>1</sup> Comparing non-completers to completers – N.S.  $p > 0.05$

<sup>2</sup> Comparing non-completers to completers –  $p < 0.05$

\* Numbers are adjusted to only include those employees who had a valid pre-CBT and post-CBT WLQ score.

hypertension than non-completers. The percentage of all screened employees with at least one significant sleep issue was 75.6 percent. The percentage with two or more or three or more significant sleep issues was 50.5 percent and 29.7 percent, respectively. No significant sleep issues were identified for 24.4 percent of the screened sample.

In the full-screened sample, the mean WLQ at-work productivity loss score was 4.1 percent  $\pm$  4.1. The mean WLQ score was higher for women (4.3%  $\pm$  4.2 compared to men 3.8%  $\pm$  4.0,  $p = 0.015$ ) (Table 3). The mean AIMS score was within the subclinical range (AIMS 4 to 7) at 5.3  $\pm$  3.1. When examined by level, the severity of insomnia symptoms were 30.6 percent no insomnia, 46.5 percent subclinical, 19.6 percent

moderate and 3.3 percent severe (Table 4). The mean ESS score for the population was 7.4  $\pm$  4.2. A positive ESS score ( $> 10$ ) was observed for 21.6 percent of the employees (Table 5).

### Pre-Post ProjectZ CBT

#### Work Limitations Questionnaire

The mean pre-CBT baseline WLQ score for all completers (who also had a valid post-CBT WLQ score  $n = 299$ ) was 3.5 percent  $\pm$  3.7 percent which declined to 2.0 percent  $\pm$  3.0 percent post-intervention ( $z = -8.4$ ;  $p < 0.0001$ ) (Table 3). This represented an overall reduction in productivity loss of 43.0 percent.

Among those completers who screened positive for insomnia (AIMS  $> 7$ ) and had

**Table 3: WLQ Scores\***

<b>WLQ Global Score (mean percentage <math>\pm</math> S.D.)</b>						
	<b>Screened (n = 2,126)</b>	<b>Pre-CBT (n = 299)</b>	<b>Post-CBT (n = 299)**</b>	<b>Pre-Post Percentage Change</b>	<b>Pre-Post z-score</b>	<b>Pre-Post p value</b>
Male	3.8 $\pm$ 4.0 <sup>1</sup>	3.1 <sup>2</sup>	2.3	-27.9 <sup>3</sup>	-2.7	$p = 0.004$
Female	4.3 $\pm$ 4.2 <sup>1</sup>	3.7 <sup>2</sup>	1.9	-48.8 <sup>3</sup>	-8.4	$p < 0.0001$
Total	4.1 $\pm$ 4.1	3.5 $\pm$ 3.7	2.0 $\pm$ 3.0	-43.0	-8.4	$p < 0.0001$
<b>WLQ Individual Domains</b>						
	<b>Screened (n = 2,126)</b>	<b>Pre-CBT (n = 299)</b>	<b>Post-CBT (n = 299)**</b>	<b>Percentage Change</b>		
Time Management	19.4	17.3	9.0	-47.9%		
Physical Demands	15.3	14.5	10.5	-27.2%		
Mental-Interpersonal Demands	16.0	14.6	7.9	-45.7%		
Output Demands	11.7	8.7	4.8	-44.4%		

\*Scores indicate the average percentage of productivity lost in the past two weeks due to health problems.

\*\* A total of 335 employees completed ProjectZ, however, 299 had valid Pre/Post WLQ data.

<sup>1</sup> Screened Male versus Female  $p = 0.015$

<sup>2</sup> Pre-CBT Male versus Female N.S.  $z = 1.35$ ;  $p = 0.18$

<sup>3</sup> Pre-Post percentage change Male versus Female  $p < 0.0001$



**Table 4: AIMS Insomnia Scores and Tiers**

<b>AIMS Scores by Sex at Screening, Pre-CBT and Post-CBT</b>						
	<b>Screened (n = 2,126)</b>		<b>Pre-CBT (n = 335)</b>		<b>Post-CBT (n = 335)</b>	
	Mean ± S.D.	Median	Mean ± S.D.	Median	Mean ± S.D.	Median
Males	4.9 ± 3.0	5.0	3.9 ± 2.7	3.0	2.0 ± 2.2	1.0
Females	5.6 ± 3.1	5.0	5.3 ± 3.1	5.0	2.3 ± 2.0	2.0
Total	5.3 ± 3.1	5.0	4.9 <sup>1</sup> ± 3.0	5.0	2.2 <sup>1</sup> ± 2.1	2.0

<b>AIMS Insomnia Tiers* at Screening, Pre-CBT, and Post-CBT</b>			
	<b>Screened (n = 2,126)</b>	<b>Pre-CBT (n = 335)</b>	<b>Post-CBT (n = 335)</b>
No Insomnia	30.6%	36.7%	77.6%
Subclinical	46.5%	46.0%	20.6%
Moderate	19.6%	14.6%	1.5%
Severe	3.3%	2.7%	0.3%

<sup>1</sup> Pre-CBT versus Post-CBT  $z = 13.2$ ;  $p < 0.0001$

\* AIMS Severity Scale: No Insomnia (0-3); Subclinical (4-7); Moderate (8-11); Severe (12-15)

a valid pre-CBT and post-CBT WLQ score ( $n = 52$  of 335) the pre-CBT baseline WLQ score was 6.2 percent  $\pm$  4.8 percent and the WLQ score declined to 3.4 percent  $\pm$  4.1 percent. This represented an overall reduction in productivity loss of 45.2 percent ( $z = 4.3$ ;  $p < 0.0001$ ) (Table 6).

Among those completers who screened negative for insomnia (AIMS  $< 8$ ) and had a valid pre-CBT and post-CBT WLQ score ( $n = 247$  of 335) the pre-CBT baseline WLQ score was 3.0 percent  $\pm$  3.2 percent and the WLQ score declined to 1.7 percent  $\pm$  2.7 percent ( $z = 7.5$ ;  $p < 0.0001$ ). This represented an overall reduction in productivity loss of 41.9 percent.

At the pre-CBT baseline, women showed a trend toward a higher degree of lost productivity than men (3.7% versus 3.1%), however, this difference was not statistically significant ( $z = 1.35$ ;  $p = 0.18$ ). Women did show a greater magnitude of improvement by the end of the program that was

statistically significant (48.8% versus 27.9%;  $p < 0.0001$ ). When the four domains of the WLQ were assessed individually, the degrees of improvement from pre-CBT to post-CBT were as follows: Time Management (17.3% to 9.0%), Physical Demands (14.5% to 10.5%), Mental-Interpersonal Demands (14.6% to 7.9%) and Output Demands (8.7% to 4.8%) (Table 3).

### Abbreviated Insomnia Measurement Score

The mean pre-CBT baseline AIMS score was  $4.9 \pm 3.0$  and decreased to  $2.2 \pm 2.1$  at post-CBT assessment ( $z = 13.2$ ,  $p < 0.0001$ ) (Table 4). The net number of employees with moderate or severe AIMS scores (AIMS  $> 7$ ) was reduced from 58 to 6, a reduction of 89.7 percent from pre-CBT to post-CBT ( $z = 7.7$ ;  $p < 0.0001$ ). Among employees who screened positive for insomnia ( $n = 58$ ), the mean AIMS score decreased from  $9.7 \pm 1.7$  to  $4.2 \pm 2.6$ , a 56.7 percent improvement ( $z$

**Table 5: ESS Scores**

<b>ESS Scores by Sex at Screening, Pre-CBT and Post-CBT</b>						
	<b>Screened (n = 2,126)</b>		<b>Pre-CBT (n = 335)</b>		<b>Post-CBT (n = 335)</b>	
	Mean ± S.D.	Median	Mean ± S.D.	Median	Mean ± S.D.	Median
Males	7.4 ± 4.2	7.0	6.1 ± 3.5	5.0	4.3 ± 2.9	4.0
Females	7.4 ± 4.2	7.0	7.3 ± 4.0	7.0	4.6 ± 3.0	4.0
Total	7.4 ± 4.2	7.0	6.9 <sup>1</sup> ± 3.9	7.0	4.5 <sup>1</sup> ± 2.9	4.0
<b>Number of Employees with Positive ESS at Screening, Pre-CBT, and Post-CBT</b>						
	<b>Screened (n = 2,126)</b>		<b>Pre-CBT (n = 335)</b>		<b>Post-CBT (n = 335)</b>	
	Numbers	Percentage	Numbers	Percentage	Numbers	Percentage
Males	176	20.8	13	13.0	2	2.0
Females	283	22.1	44	18.7	11	4.7
Total	459	21.6	57 <sup>2</sup>	17.0	13 <sup>2</sup>	3.9

<sup>1</sup> Pre-CBT versus Post-CBT  $z = 12.9$ ;  $p < 0.0001$

<sup>2</sup> Pre-CBT versus Post-CBT  $z = 34.2$ ;  $p < 0.0001$

**Table 6: AIMS, WLQ & ESS Data Among Insomniacs Who Completed ProjectZ**

	<b>Pre-CBT (n = 58)</b>		<b>Post-CBT (n = 58)</b>		
	Mean ± S.D.	Median	Mean ± S.D.	Median	Percentage Change
AIMS Score	9.7 ± 1.7	9.0	4.2 ± 2.6	4.0	-56.7% <sup>1</sup>
Number of AIMS Positive Employees	58		6		-89.7% <sup>2</sup>
	<b>Pre-CBT (n = 58)</b>		<b>Post-CBT (n = 58)</b>		Percentage Change
WLQ Global Score	6.2%		3.4%		-45.2% <sup>3</sup>
	<b>Pre-CBT (n = 52)</b>		<b>Post-CBT (n = 52)</b>		Percentage Change
ESS Score	9.3		5.0		-46.2% <sup>4</sup>

<sup>1</sup> Pre-CBT versus Post-CBT percentage change  $z = 16.4$ ;  $p < 0.0001$

<sup>2</sup> Pre-CBT versus Post-CBT percentage change  $z = 7.7$ ;  $p < 0.0001$

<sup>3</sup> Pre-CBT versus Post-CBT percentage change  $z = 4.3$ ;  $p < 0.0001$

<sup>4</sup> Pre-CBT versus Post-CBT percentage change  $z = 7.3$ ;  $p < 0.0001$

= 16.4;  $p < 0.0001$ ) (Table 6). A pre-CBT to a post-CBT breakdown of the AIMS data by severity (negative, subclinical, moderate, severe) showed the following: the percentage of employees with no insomnia at pre-CBT was 36.7 percent and increased to 77.6 percent post-CBT, subclinical insomnia pre-CBT was 46 percent and decreased to 20.6 percent post-CBT, moderate insomnia was 14.6 percent pre-CBT and decreased to 1.5 percent post-CBT and severe insomnia pre-CBT was 2.7 percent and decreased to 0.3 percent post-CBT (Table 4).

Among the employees who began ProjectZ in the “no insomnia” tier, none moved into either the “moderate” or “severe” tier. For those employees who began in the “subclinical” tier, 76.6 percent moved down to the “no insomnia” tier, whereas only 0.6 percent moved up into the “moderate” tier. None moved into the “severe” tier. Of those who began in the “moderate” tier, 49.0 percent improved to the “subclinical” tier and 44.9 percent improved to the “no insomnia” tier. None moved in the direction of worsening symptoms.

### Epworth Sleepiness Scale

The average ESS score for all completers at pre-CBT baseline was  $6.9 \pm 3.9$ . This was reduced to  $4.5 \pm 2.9$  at completion of the program ( $z = 12.9$ ;  $p < 0.0001$ ). In a binary comparison (ESS > 10 versus ESS < 11), the percent of completers with a positive ESS at pre-CBT baseline was 17.0 percent (57 of 335) and decreased to 3.9 percent (13 of 335) by completion ( $\chi^2 = 34.2$ ;  $p < 0.0001$ ) (Table 5). This constituted a 77.2 percent reduction in the number of employees with an ESS > 10. Among employees who screened positive for insomnia and completed ProjectZ ( $n = 58$ , 17.3%), their ESS score decreased from 9.3 to 5.0, a 46.2 percent improvement ( $z = 7.3$ ;  $p < 0.0001$ ) (Table 6). Among employees who screened positive for insomnia, had an ESS > 10 and completed ProjectZ ( $n = 22$ , 6.6%), their ESS decreased from 13.8 to 6.0, a 56.6 percent improvement ( $z = 7.9$ ;  $p < 0.0001$ ).

### Satisfaction Measures

The majority of employees stated that they learned more about sleep (98.2%),

knew how to apply the knowledge to their circumstance (97.6%), felt the program was personalized (94.3%), believed sleep was improved (85.1%) and believed that overall health or well-being had improved (81.2%).

### DISCUSSION

This study demonstrates the feasibility of using a personalized, self-paced online comprehensive sleep health program, ProjectZ, to achieve economically and clinically meaningful improvements in employee productivity and sleep health in a diverse working population.

To our knowledge, this is the first report using the WLQ to quantify improvements in work productivity following an online sleep health program. The degree of workplace limitations, as measured by the WLQ, showed statistically significant improvement among the 335 employees who completed ProjectZ across all four of the WLQ domains. The average global WLQ productivity loss score declined by 1.52, representing a 43.0 percent improvement. This means that the productivity of 1.52 full-time employees per 100 was recovered in those who completed the program. If one assumes a range of annual salary plus benefits cost of \$50,000 to \$100,000 per employee, a company of 1,000 employees with a similar sleep profile stands to save \$760,000 to \$1,520,000, or the equivalent of just over 15 full-time employees. Importantly, the summed demographic characteristics of these five companies are a good reflection of the U.S. workforce in terms of age, BMI<sup>42</sup>, the prevalence of insomnia<sup>43</sup> and undiagnosed apnea risk.<sup>10</sup>

Women showed a statistically significant greater magnitude of benefit by program end than men. We speculate that this finding may reflect the higher incidence of insomnia (20.9% versus 9.0%) and lower incidence of OSA (28.9% versus 50.0%) seen in the women who completed ProjectZ. These sex differences are also observed in the general U.S. population.<sup>43,10</sup> Because the process of progressing from OSA case-finding to successful therapy often takes longer than the median time (50.0 days) taken to reach the endpoint assessment, the full benefit of ProjectZ for an apnea patient may not be

captured at the time of final assessment.

The potential clinical benefit from ProjectZ comes not only from helping those who begin with significant symptoms of insomnia (AIMS > 7, moderate and severe tiers) but also by reducing the risk of symptom progression for those who begin in the subclinical tier (AIMS 4 to 7). While it is unknown how many of the subclinical individuals would have progressed to clinically significant insomnia had they not had an intervention, the improvement identified in this group was both clinically and statistically significant.

There was also a significant reduction in mean ESS scores for completers at final assessment. This was true for both insomnia and non-insomnia cohorts. High degrees of daytime sleepiness among workers may significantly increase the rates of absenteeism, presenteeism and the potential for workplace accidents. ProjectZ's program may significantly mitigate these risks.

There were some limitations to this study. First, this is a non-randomized, uncontrolled study in which data were analyzed retrospectively only for program completers, which limits both external and internal validity. While some of the improvements observed may have been the result of employees paying more attention to their sleep, naturally occurring improvements over time, the effects of other interventions and self-care, it is very unlikely that the robust outcomes obtained herein were due to placebo effect or regression to the mean. Kaldo et al., examined the effect of online CBTi versus an online active treatment control condition and found 51 percent of treatment responders in the CBTi group versus only 24 percent among controls.<sup>44</sup> Espie et al., reported 75 percent of insomniacs achieved a sleep efficiency of 80 percent or greater using online CBTi whereas only 20 percent did so in the 'treatment as usual' group.<sup>29</sup> Similar findings have been reported with in-person CBTi. Two landmark randomized, controlled studies reported control group response rates of only 12 percent and 22 percent as compared to active CBTi response rates of 54 percent and 56 percent, respectively.<sup>23,26</sup> A second limitation is that the AIMS has not yet

been fully validated. All the elements of the AIMS have considerable face validity and in a comparison with the validated ISI showed a very close correlation. The questions closely reflect those that would be asked in a clinical encounter; however, it remains to be fully validated as an independent measure of insomnia severity. Lastly, it could be argued that the use of incentives for participation by the employers may have contributed to positive outcomes either because employees may have wanted to "look good" for their employer or they may have believed that improvement increased their chances of winning an incentive. To dispel this bias, employees were informed at the outset that their individual data would remain anonymous and would not be shared with their employer. In addition, the incentives were tied to levels of participation, not outcomes.

This study had several strengths. First, it was able to demonstrate that program completion was associated with statistically significant improvement in well-validated metrics of work productivity (WLQ) and excessive sleepiness (ESS). Second, the study sample included a diverse group of employees from five different companies. The data suggest that ProjectZ can be applied across an entire workforce, in a variety of workplace environments. Third, ProjectZ was overwhelmingly well received by the employees. Lastly, it is a HIPAA-compliant, highly scalable sleep health program that can address the overall health, safety, and productivity of the workforce.

## CONCLUSION

As healthcare delivery in the U.S. continues to evolve, there is increasing pressure to focus on business efficiency and cost management. More streamlined approaches to providing health care such as ProjectZ will be necessary to maintain quality, increase access to care, all while reducing costs.

## ACKNOWLEDGEMENTS

The authors wish to thank Dave French, Tay Nguyen, Thomas Lee, William Hevener and Mike Floyd for their invaluable assistance in the design, building and deployment of ProjectZ.

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# Innovative Approaches Can Help Employers Play A Critical Role to Reduce Healthcare Costs and Support Employee Productivity

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## ABSTRACT

### KEY WORDS:

Chronic disease,  
adherence, mental health,  
affective science

Employers bear a significant portion of the \$3.5 trillion in annual United States (U.S.) healthcare spending. They now face impending increases in costs, as well as reduced workforce productivity, as the deleterious effects of chronic diseases, disease-management treatment plan non-adherence, increasing but unmet mental health demands, the novel coronavirus pandemic, and a backlog of deferred and neglected healthcare utilizations that constitute mega-trends that are combining into a tsunami-like swell. Employers and their associated EAP services are uniquely positioned to help mitigate the impact and severity of these factors, provided they have access to and adopt advanced tools, methods, and analytics to support their employees' health and wellness in new ways. A solution set centered on several key affective determinants of health augmented by a novel technology platform that captures these along with other emotions, moods, and a wide array of affective phenomena with greater fidelity than traditional methods, is described. The assessment and monitoring of these critical affective determinants of health can help to more rapidly direct employees to the support services and resources. Support resources directed toward the ADoH factors can thus be evaluated across time to help increase predictive capacities with respect to chronic diseases. This paradigm can help prevent mental health conditions, mitigate chronic health conditions, and diminish non-adherence to healthcare treatment plans, more effectively and efficiently.

## INTRODUCTION

It has been estimated that 90 percent of the \$3.5 trillion spent on healthcare in the U.S. annually is for people with chronic and mental healthcare conditions.<sup>1</sup> Now, amid a pandemic which has created and exacerbated issues within U.S. healthcare, our nation is faced with two large-scale trends:

1. High prevalence of stress and distress
2. The resultant mental health crisis

These trends as well as increasing prevalence of chronic disease and, treatment non-adherence, will soon to be compounded by the consequences of deferred care due to COVID-19. A recent study<sup>2</sup> indicated that because of COVID-19, an additional 35 million people could experience behavioral health issues. Given that employers bear direct and indirect costs of their employee's

mental health crises and chronic diseases,<sup>3</sup> these trends set the stage for dramatic increases in employee healthcare costs and productivity losses in coming years. Fortunately, employers, their associated EAP services, internet-based counseling support services, and traditional healthcare systems—particularly those who have adopted telehealth—are positioned to help mitigate the impact and severity of these factors, provided they have access to, and adopt, advanced tools, methods, and analytics to support their employees' health and wellness in new ways.

This report outlines two “megatrends” which include various sources of stress and their negative health, mental health, economic, and socio-cultural effects,

exacerbations by the COVID-19 pandemic, the ongoing issues of mental health treatment resource inadequacies, the epidemic of treatment plan non-adherence, and the deleterious effects of a new phenomenon prompted by the COVID-19 pandemic – deferred and neglected healthcare. The authors then describe and propose a solution set centered on the domain of several key affective determinants of health that can be leveraged by employers. The assessment and monitoring of these critical factors should become a national imperative. Employers that adopt the technologies that will support this initiative can help to more effectively direct employees to the support services and resources they need to address the ADoH factors. Such supports can help prevent mental health conditions, mitigate chronic health conditions, and diminish non-adherence to healthcare treatment plans, more effectively and efficiently.

## **Two Megatrends Could Swamp the U.S. Healthcare System and Drown Employers**

### ***Megatrend 1: Increasing Stress, Distress, and the Growing Mental Health Crisis***

Economic stressors such as unemployment,<sup>4</sup> underemployment,<sup>5,6</sup> wage stagnation,<sup>7</sup> increasing healthcare costs,<sup>8</sup> childcare costs,<sup>9</sup> tuition,<sup>10</sup> and mounting racial inequities in wages,<sup>11</sup> employment,<sup>12</sup> and healthcare<sup>13</sup> amidst a global pandemic are providing Americans with numerous potential stressors and an increasingly uncertain future. At the same time, there is a dangerous mismatch between our mental health needs and resources.

In October 2020,<sup>14</sup> against the backdrop of a highly contentious presidential election, the third wave of COVID-19 hit the U.S., but Americans were struggling even prior to the first wave that swept the country. With mental healthcare inaccessible to many Americans according to the National Alliance on Mental Illness<sup>15</sup> and a 35 percent increase in suicide rates from 1999 to 2018,<sup>16</sup> a mental health epidemic was already upon us. Now, with the additional stressors of COVID-19 and the exacerbation of pre-existing stressors, Americans are experiencing stress at an alarming intensity.<sup>17</sup>

According to a recent report,<sup>18</sup> the persistent stress caused by the COVID-19 pandemic

is hitting Americans hard, especially Generation Z, who are reporting elevated levels of stress and depression. Seventy-eight percent of adults report that the pandemic is a significant form of stress, and 67 percent report experiencing higher levels of stress over the course of the COVID-19 pandemic; 77 percent of adults say that America's future is a significant source of stress compared to 66 percent in 2019. Generation Z is disproportionately stressed by the pandemic, and they are reporting issues such as suicide rates (62%), news reports of extensive sexual assault/harassment (58%), and changes to abortion laws (50%) as being higher sources of stress compared to other adults.<sup>19</sup>

According to the U.S. Bureau of Labor Statistics (BLS),<sup>20</sup> unemployment reached historic highs in many states in February 2020. In September 2020, the BLS reported that the unemployment rate was at 7.9 percent – equal to 12.6 million unemployed persons.<sup>21</sup> These reports demonstrate that the U.S. unemployment rate has steadily declined since it spiked in March 2020, and September saw another overall decline of .5 percent.<sup>22</sup> That month, joblessness among adult men and women, White individuals, Asian and Asian American individuals saw decreases, while joblessness among Black/African American individuals, teenagers, and Hispanic individuals was unchanged.<sup>23</sup> At 12.1 percent, the unemployment rate of Black/African American workers was significantly greater than the 7 percent of unemployed White workers.<sup>24</sup>

While unemployment rates may have been at historic highs in February 2020, those statistics do not account for the underemployed. Researchers have created a broader measure to capture a rate of underemployment, which has revealed a rate of 8 to 11 percent of total underemployment in the U.S.<sup>25</sup> This measure reveals that underemployment affects those that have been historically marginalized the hardest – workers of color experience underemployment at twice the rate of White workers.<sup>26</sup>

While many people struggle to find jobs and many part-time workers fight to get more hours, today's average hourly wage (after accounting for inflation) has only approximately the same purchasing power

it did in 1978.<sup>27</sup> According to Camilo Maldonado, a Senior Contributor at Forbes, the largest proportion of non-housing debt in the U.S. is owed to student loans.<sup>28</sup> In 2016, the average cost across four-year institutions in the U.S. was \$104,480 over four years – which is double the average cost in 1989 (after adjusting for inflation); comparatively, real median wages barely increased from \$54,042 in 1989 to \$59,039 in 2016.<sup>29</sup>

From 2013 to 2019, a study by the childcare website Care.com reported that the cost of hiring a nanny rose more than 20 percent, after-school care cost rose 34 percent, and the cost of a week at a family care center rose 58 percent.<sup>30</sup> Now, more than 52 percent of parents anticipate an even higher cost of childcare than before the pandemic, which is alarming given that 72 percent of families now spend 10 percent or more of their household income on childcare, and 55 percent report spending at least \$10,000 per year on childcare.<sup>31</sup>

According to the U.S. Census Bureau's 2019 Personal Income Report, on average, women are paid 82 cents for every dollar made by men, and women of color in the U.S. experience an even more severe gender wage gap.<sup>32</sup> On average, Latina women are paid 55 cents, Native American women 60 cents, Black women 63 cents, White women 79 cents, and Asian American women 87 cents for every dollar paid to White, non-Hispanic men.<sup>33</sup> Additionally, the last thirty years have seen an expansion in the racial wealth divide.<sup>34</sup> The median Black family owns \$3,500 in wealth, and the median Latino family owns approximately \$6,500 in wealth, which account for 2 and 4 percent, respectively, of the wealth of the median White family (\$147,000).<sup>35</sup> Similarly, the proportion of Black or Latino families with zero or negative net worth is double that of white families.<sup>36</sup> While 72 percent of white families own their home, 44 percent of Black and 45 percent of Latino families own their homes.<sup>37</sup>

Racial inequalities against the backdrop of the pandemic extend to both wealth and health. COVID hospitalizations are significantly greater among people of color compared to White individuals.<sup>38</sup> Additionally, the mortality rates of Black and Indigenous people due to COVID-19

are significantly greater than those of other races; specifically, the mortality rate of Black individuals is more than double that of White Individuals.<sup>39</sup> According to a study conducted by researchers at the Commonwealth Fund, when COVID-19 hit, over 43 percent of adults aged 19 to 64 years reported having inadequate health insurance with 12.5 percent uninsured, 9.5 percent insured but with a gap in coverage, and 21.3 percent underinsured.<sup>40</sup> Twenty-five percent of those who were continuously insured and failed to meet the criteria for underinsurance still reported difficulty paying bills.<sup>41</sup> Over 33 percent of Latino adults, small business workers, and low-income adults spent some time uninsured over the last year, and Black/African American individuals reported significantly more issues paying medical bills compared to White individuals.<sup>42</sup>

Families at or below 133 percent of poverty report uninsured and underinsured rates two to three times higher than individuals with income at least 400 percent above the poverty level (\$51,040 per individual or \$104,800 per family of four).<sup>43</sup> Research has documented racial disparities in physical aggressiveness/invasiveness of encounters with police.<sup>44</sup> Police use of force is one of the leading causes of death among young men of color, and researchers have estimated that Black men have a 1 in 1,000 chance of being killed by police in their lifetime.<sup>45</sup> A 2014 study determined that young men who encountered more police contact also experienced more trauma and anxiety.<sup>46</sup>

Loneliness is a stressor in and of itself that many Americans were experiencing at an alarming intensity prior to coronavirus social distancing and stay-at-home initiatives enacted in many areas of our nation.<sup>47</sup> Cigna's 2018 study on loneliness determined that most Americans are lonely, and loneliness is worse with each subsequent generation.<sup>48</sup> From March to June 2019, among adults aged 50 to 80 years, 41 percent reported a lack of companionship, 56 percent felt socially isolated, and 46 percent had infrequent social contact and, whilst these numbers may seem unsurprising in the current climate, they indicate a significant increase since 2018.<sup>49</sup> While loneliness has increased across the board, it has affected some groups disproportionately. Sixty-one

percent of women reported feelings of isolation compared to 50 percent of men. Seventy-two percent of individuals with fair or poor mental health, compared to 55 percent of individuals with excellent, very good, or good mental health, reported feeling isolated.<sup>50</sup> Eighty-nine percent of individuals who more reported symptoms of depression compared to 52 percent with fewer depressive symptoms reported feelings of isolation.<sup>51</sup> A UK study on the effects on loneliness of the lockdown due to the COVID pandemic determined that people that live alone, possess less education or income, women, ethnic minorities, and urban residents had a higher risk of loneliness before and during the pandemic.<sup>52</sup>

As of late June 2020, 40 percent of adults reported a mental health or substance use issue.<sup>53</sup> From April to June 2020, anxiety and depression symptoms increased compared to the same two-month period in 2019.<sup>54</sup> In that same time period, 10.7 percent of respondents reported suicidal ideation in the month prior, with 25.5 percent of 18 to 24-year-olds experiencing suicidal ideation, 18.6 percent of Hispanic respondents, and 15.1 percent of Black respondents.<sup>55</sup> Of the 5,470 respondents, 40.9 percent reported one or more mental or behavioral health conditions, with 74.9 percent of 18 to 24-year-olds, 51.9 percent of 25 to 44-year-olds, 52.1 percent of Hispanic respondents, and 66.2 percent of individuals who had received less than a high school diploma had reported one or more mental/behavioral health conditions.<sup>56</sup>

The suicide rate increased 35 percent from 1999 to 2018.<sup>57</sup> In 2019, a reported 12 million adults seriously considered suicide, 3.5 million made plans to kill themselves, and 1.4 million adults made suicide attempts.<sup>58</sup> For those seeking help mental health and substance abuse support, accessibility and affordability raise issues for many. Insufficient community mental health services funding has itself been cited as a cause of the nation's mental health crisis.<sup>59</sup>

***Megatrend 2: Increasing chronic diseases, persistent treatment non-adherence, and the impending cost of deferred care***

The Center for Disease Control (CDC) reports the leading causes of death and disability in the U.S. are heart disease,

cancer, and diabetes – three of the seven most common chronic conditions, the other four being: stroke, chronic lung disease, kidney disease, and Alzheimer's disease.<sup>60,61</sup> Cardiovascular diseases, heart disease, and stroke contribute to one-third of all deaths in the U.S. each year.<sup>62</sup>

Today, there are 34.2 million Americans with diabetes, of which 25 percent are undiagnosed, 88 million have prediabetes, of which 90 percent of which are undiagnosed, 42 percent of adults and 19 percent of children are obese.<sup>63</sup> About 25 percent of Americans (54.4 million) have arthritis, which is the leading cause of work disability and one of the most common sources of chronic pain.<sup>64</sup> Every year, 1.6 million are diagnosed with cancer and over 600,000 die from it.<sup>65</sup>

According to the American Public Health Association chronic disease may be the leading cause of death but is also considered among the most preventable.<sup>66</sup> While chronic diseases are linked to several major risk factors such as, tobacco use, lack of physical exercise, poor nutrition, and excessive alcohol use, there are a myriad of factors that can contribute to and exacerbate these chronic conditions (as cited by the CDC)<sup>67</sup>. Specifically, there are socioeconomic and affective factors that contribute to adherence to treatment.

The National Center for Chronic Disease Prevention and Health Promotion reports that 90 percent of annual healthcare costs in the U.S. (\$3.5 trillion) are due to chronic and mental health conditions.<sup>68</sup> Heart disease and stroke cost the U.S. healthcare system \$214 billion per year and \$138 billion in productivity loss.<sup>69</sup> The cost of diabetes is a combined \$327 billion in direct medical costs and productivity loss.<sup>70</sup> Arthritis (and related conditions) cost \$140 billion in direct and \$164 billion in indirect costs,<sup>71</sup> while Alzheimer's disease is predicted at \$370 billion to \$500 billion,<sup>72</sup> the cost of cancer treatment and care was expected to be around \$174 billion in 2020,<sup>73</sup> and dental disease costs over \$45 billion in productivity loss.<sup>74,75</sup>

One key aspect of effective medical treatment is patients' treatment plan adherence. Conversely, non-adherence is defined by a patient's failure to follow instructions or recommendations prescribed



by a healthcare provider.<sup>76</sup> As adherence to treatment can be essential to a patients' treatment and survival, non-adherence to treatment poses a serious threat to the patient's health outcomes. In 2020, against the backdrop of COVID-19 and the prevalence of chronic diseases and mental health issues reaching epidemic-proportions, the argument can be made that recognizing and reducing risk factors of non-adherence is of paramount importance.

The rate of non-adherence is approximately 50 percent, and researchers and clinicians are still grappling for answers.<sup>77</sup> As cited in a CDC Report, 3.8 billion prescriptions are written in the U.S. each year<sup>78</sup> and about 20 percent of new prescriptions are never filled.<sup>79</sup> Of those that are filled, only half are taken correctly.<sup>80</sup> Researchers Osterberg and Blaschke reported that non-adherence contributes to 125,000 avoidable deaths annually,<sup>81</sup> and, while the rate of non-adherence may be unchanged, the associated costs have exploded to between \$100 billion<sup>82</sup> and \$300 billion<sup>83</sup> annually.

It is well-established that non-adherence to treatment contributes to negative patient outcomes, recurrent re-hospitalizations, and increasing healthcare costs.<sup>84,85</sup> Unstable living conditions, limited healthcare access, medication costs, lack of financial resources, and busy work schedules contribute to medication non-adherence.<sup>86</sup> Younger patients, minorities, and those of low SES are less likely to adhere to treatment.<sup>87</sup> The higher the involvedness of treatment, the less likely patients are to adhere.<sup>88</sup> Availability of transportation to and from appointments, co-pays, length of appointments and provider availability for follow-up are just some of the other contributors to treatment adherence.<sup>89</sup> Of the disease-related factors, depression and other mental health issues increase the probability of non-adherence<sup>90</sup> – a point that will be expanded upon significantly later in this work.

With non-adherence an already critical concern, providers are now faced with evidence that 48 percent of Americans have delayed or skipped medical care due to COVID-19.<sup>91</sup> In a study conducted by Wilson Towers Watson, 44 percent of the 5,000 employees surveyed reported that they deferred treatment during the pandemic.<sup>92</sup>

Of the 44 percent, 29 percent reported that their health suffered because of it, while another 40 percent anticipated negative health effects as a result of the deferred care.<sup>93</sup> Medical groups have observed significant decreases in emergency room patients across the U.S., which has some organizations, such as the American Heart Association, speaking out and urging the public to seek necessary care.<sup>94</sup> Now, 70 percent of those that deferred their care originally expect to seek care in the next few months<sup>95</sup> implying that providers could be seeing an unprecedented wave of patients.

Two studies highlighted another daunting impact of COVID-19, being the number of delayed breast cancer and prostate cancer screenings, such as mammograms, ultrasounds, and MRIs due to the pandemic.<sup>96</sup> According to one study 31.7 percent of those diagnosed with breast cancer reported a postponement in care, 22 percent with delayed screenings and 9.3 percent with delays in treatment.<sup>97</sup> Of those who had never been diagnosed with breast cancer, 31.5 percent delayed screening and 1.6 percent delayed treatment.<sup>98</sup> In 2019, the number of 2D mammograms in March was 13.6 per 1,000 women, however, in April of 2020, only 0.25 2D mammograms were performed per 1,000 women.<sup>99</sup> In April of 2019, an average of 34.7 3D mammograms per 1,000 women were performed, and in stark contrast, an average of 1.4 3D mammograms per 1,000 women were performed on average in April of 2020.<sup>100</sup>

As COVID continues to test our healthcare system and the consequences of delayed or missed appointments loom, understanding the ubiquity of chronic disease in the U.S., their disparate spread across ethnicities and racial groups, and those factors impacting adherence to treatment are necessary in determining how our healthcare system can manage such challenges. In doing so, understanding how chronic disease and treatment adherence intersect with mental health are necessary in facing such a challenge.

### ***The Intersection of Mental Health, Chronic Disease, and Treatment Non-Adherence: Affective Determinants of Health***

Stress, distress, and suffering can manifest in many ways including negative emotions,

disruptive/destructive behaviors, and poor health management and lifestyle – including poor treatment adherence.<sup>101</sup> In turn, these experiences and behaviors can themselves contribute to and exacerbate feelings of stress and distress and disrupt a variety of physiological systems, increasing risk for development and exacerbation of some of the costliest and disabling chronic diseases, as will be outlined below. These risks, therefore, can be conceptualized as operating through both psychobehavioral and psychophysiological channels. With reference to those channels, the subjective experiences of stress, anxiety, loneliness, irritability, depression, pain, fatigue, and illness (i.e., the antithesis of a sense of wellness and vigor) warrant special attention. As such, they are among the most important of what authors define as the affective determinants of health.

Researchers define “affective” broadly to include phenomena such as transient and persistent emotions and moods, complex or mixed emotions, meta-emotions, and affective cognitions (among other and overlapping terms in the fields of psychology and affective science), but also bodily sensations such as pain, fatigue and energy levels, hunger, and ill health to name a few, that have emotional tone and/or about which we have feelings of an emotional nature. Defined as such, affects may include such phenomena as opinions and preferences as residing under the phrase affective phenomena, or alternatively conceptualize them as overlapping with those phenomena more traditionally referred to as cognitions. More extensive elaboration is beyond the scope of this work, but readers are referred to further reading.<sup>102–105</sup> Thus, the various affective determinants of health to which the authors refer in this paper are a subset of a larger collection of phenomena that may productively be called affective in nature. Moreover, for the purpose of defining affective determinants of health for both research and applications, the authors agree with theorist-reviewers such as Roseman et al.<sup>106</sup> that emotions and other affective phenomena are best appreciated as they pertain to motivated action and biasing of choice-making, both conscious and unconscious, but the authors also include those that have been demonstrated by

research to correlate with, and potentially contribute to, various chronic diseases and other maladies, as will be explicated.

Firstly, chronic stress can disrupt immune, digestive, cardiovascular, sleep, and reproductive systems<sup>107</sup> and has been identified as a risk factor for cardiovascular disease,<sup>108</sup> hypertension,<sup>109</sup> diabetes,<sup>110</sup> obesity,<sup>111</sup> and diminished memory and cognitive capacities.<sup>112</sup> It is a major contributor to alcohol and drug abuse, poor diet, physical inactivity<sup>113</sup> and can contribute to instances of interpersonal violence. It has also been implicated in poor medication treatment adherence.<sup>114</sup>

Anxiety has been implicated in several chronic illnesses, including heart disease,<sup>115</sup> chronic respiratory disorders,<sup>116</sup> and gastrointestinal conditions.<sup>117</sup> Like stress, chronic anxiety and worry is a contributing factor in alcohol and drug abuse,<sup>118</sup> smoking,<sup>119</sup> overeating,<sup>120</sup> and has been implicated in poor medication treatment adherence.<sup>121</sup> A 2016 study indicated that anxiety and depression disorders cost the global economy \$1 trillion annually, but that every \$1 spent in increased treatment for these disorders returns more than \$4 in health improvements, diminished risks and work productivity improvements.<sup>122</sup>

Loneliness is both a stressor unto itself and a common risk factor for depression.<sup>123</sup> It has been linked to alcoholism<sup>124</sup> and drug abuse, antisocial behaviors, cardiovascular disease<sup>125</sup> mortality,<sup>126</sup> hypertension,<sup>127</sup> obesity,<sup>128</sup> inflammatory disease,<sup>129</sup> stroke,<sup>130</sup> suicide,<sup>131</sup> sleep disturbance,<sup>132</sup> and diminished memory and cognitive capacities.<sup>133</sup> It has also been identified as a potential risk factor for Dementia of the Alzheimer’s Type (DAT).<sup>134</sup> In a 2017 study, the cost of social isolation and loneliness in the U.S. was estimated at \$6.7 billion annually.<sup>135</sup>

Irritability has been linked with greater cardiovascular reactivity to stress,<sup>136</sup> reduced quality of life,<sup>137</sup> greater risk and persistence of depression,<sup>138</sup> heightened risk of suicide,<sup>139</sup> and lower educational achievement.<sup>140</sup> Irritability can itself be a cause of stressful interpersonal events and may point to bipolar mood disorder presence or development, particularly if seen with elevated energy.<sup>141</sup> It can mask depression,<sup>142</sup> may occur alongside depressive symptoms, or may exist entirely separately from depression,<sup>143</sup> Research

suggests 40 to 50 percent of depressed adults experience irritability.<sup>144</sup> It has been estimated that anger underlies half of all violent crimes committed in the U.S.<sup>145</sup>

Depression can contribute to and exacerbate pain and pain-related conditions<sup>146</sup> and has been identified as an independent risk factor for cardiovascular disease, heart failure, coronary artery disease<sup>147</sup> and gastrointestinal problems.<sup>148</sup> It has been linked to inflammatory conditions [96]<sup>149</sup> and autoimmune disorders,<sup>150</sup> including Type 2 diabetes,<sup>151</sup> Insomnia, a form of sleep dysfunction frequently associated with depression, can contribute to hypertension,<sup>152</sup> Depression is a leading contributor to alcohol and drug abuse, as well as suicide.<sup>153</sup> It's also a leading cause of physical inactivity and has been implicated in poor medication treatment adherence.<sup>154</sup> A 2015 study suggested depression cost the U.S. \$210 billion annually, and for every \$1 spent on depression treatment, an additional \$6.60 was spent on direct and indirect costs of related illnesses, suicide-related costs, and workplace costs.<sup>155</sup>

Health economists have estimated that pain and pain-related disorders cost the U.S. as much as \$635 billion per year – more than cancer, heart disease, and diabetes.<sup>156</sup> Individuals with moderate pain experienced annual healthcare costs twice the annual average for U.S. adults, and those with severe pain cost 32 percent more than those with moderate pain.<sup>157</sup> Total incremental healthcare costs were in the range of \$261 to \$300 billion, with lost productivity costs totaling an additional \$261 to \$300 billion.<sup>158</sup> Pain is a major risk factor for prescription and non-prescription opioid abuse<sup>159</sup> and has been implicated in poor medication treatment adherence.<sup>160</sup> Pain that interferes with daily life has been implicated as a significant risk factor for premature death.<sup>161</sup> A connection between pain and depression is well-established, with each serving potentially to exacerbate the other.<sup>162</sup> This has been shown also for the three-way relationship between pain, depression, and anxiety.<sup>163</sup>

According to physicians, many are experiencing sleep disturbances as a result of the coronavirus pandemic, the surge has been so dramatic that sleep neurologists have termed it COVID-somnia.”<sup>164</sup> Fatigue

and chronic low energy states have been implicated in low behavioral activation, impediments to sustained attention and effort on tasks, and poor motivation,<sup>165</sup> including reduced activity and exercise.<sup>166</sup> This has implications for treatment non-adherence<sup>167</sup> and increased risk for work-related injuries.<sup>168</sup> It is a major indicator in the development of a host of medical disorders including diabetes,<sup>169</sup> hypertension,<sup>170</sup> cardiovascular diseases,<sup>171</sup> obesity,<sup>172</sup> and adverse reproductive outcomes.<sup>173</sup> It is a commonly-reported symptom correlated with depression and anxiety.<sup>174</sup> In 2015, the estimated annual U.S. cost of insufficient sleep alone was over \$410 billion.<sup>175</sup>

Self-ratings of health are among the most assessed factors in epidemiological research.<sup>176</sup> Somatic symptoms can reflect cardiopulmonary, gastrointestinal, musculoskeletal, pain, more diffuse, and general systemic functions. One's subjective sense of health/sickness serves as an indicator for the severity and course of medical diseases as well as monitoring of treatment progress.<sup>177</sup> Self-appraised general health is a powerful predictor of future morbidity and mortality, even after controlling for a variety of physical, socio-demographic, and mental health factors.<sup>178</sup> Ironically, a high sense of wellness (low somatic symptom burden) can negatively impact treatment adherence due to a low subjective sense for the importance of disease management and prevention activities, such as may occur with hypertension<sup>179</sup> and bipolar mood disorder.<sup>180</sup>

### ***These Megatrends Demand Innovative Approaches to Risk and Cost Reductions***

Chronic diseases and mental health concerns interact and contribute to employee absenteeism, presenteeism, reduced productivity, and increased healthcare costs. As it should now be clear, the capacity to capture, measure, and analyze data related to the affects of stress, anxiety, loneliness, irritability, depression, pain, wellness/illness, and energy/fatigue is of paramount concern in the interest of detecting, addressing, and preventing the detrimental effects of excessive and/or persistent degrees of these feelings. This is particularly true at this point in history. What were enormous needs for innovation and effective implementations

against these phenomena before the COVID-19 pandemic have now become truly larger and more urgent. This urgency reflects the increased stress the pandemic and economic recession have caused and the destructive effects of deferring or otherwise failing to seek preventative and palliative healthcare.

Fortunately, innovations and changes in the healthcare system are occurring and are being adopted. These include telehealth, which has increased from an 11 percent adoption rate in April of 2019 to a 46 percent adoption rate by May of 2020, and an even higher proportion (76%) reported an interest in utilizing telehealth in the future.<sup>181</sup> Also, online-only platforms for the delivery of mental health services and basic supports (i.e., Talkspace,<sup>182</sup> Betterhelp,<sup>183</sup> etc.) have emerged in recent years.

One area that has yet to enjoy such innovation, however, is the assessment and monitoring of the broad range of affective phenomena outlined above. While there exist published, standardized scales for each of those constructs, some of which have been popularly adopted and used (e.g., the PHQ<sup>184,185</sup> and the GAD7<sup>186</sup>) many of those constructs, such as irritability, are rarely assessed in a formal, standardized manner. Others, such as self-reported health, are generally not assessed other than informally. The results of such assessments are not quantified and therefore are not available for analysis.

Because of their critical role in the overlapping domains of mental health risk, chronic disease risk, and treatment non-compliance risk, researchers assert that these eight critical affective determinants of health should be assessed commonly and frequently. This would provide for more widespread and accurate risk analyses, results of which can be used for risk reduction strategy development. Furthermore, as the needs for care reflected in such assessments are illuminated, resources directed to addressing them should be made immediately evident, available, and affordable to individuals and to populations thus identified. Employers are in a key position to help provide those assessments, facilitate access to support resources, and reduce those risks, particularly as so many people are not visiting their doctors as they

otherwise might during the pandemic.

A logical start is with improved assessments of affective determinants of health and encouraging widespread adoptions of such measures on a national scale. Such an effort would require that assessments be implemented in several delivery channels – national epidemiological studies, healthcare systems (particularly in primary care settings), and in conjunction with both COVID-19 testing and COVID-19 vaccine administrations. At the same time, employers can function as key operators in this initiative, because many people who are not reached in epidemiological studies, who do not visit healthcare centers, and who do not participate in COVID-19 testing or vaccination nevertheless are employed.

For employers to participate optimally in this proposed initiative, the “Affective Determinants of Health Assessment” (the instrument) should meet several criteria to aid adoption and distribution, return high participation rates, coordinate with healthcare systems, and provide insights useful to those employers:

1. To require minimal time commitment from employees the instrument should be brief.
2. To support high participation rates and encourage accuracy of self-report the instrument should be crafted in such a manner as to encourage engagement.
3. Language proficiency demands should be minimal, to reduce the cognitive burden on respondents and to accommodate persons for whom English is not their primary language.
4. The instrument should be well-standardized.
5. Delivery should be made in an electronic format within a secure environment, to ease distribution, scoring, analysis, and reporting of results, alone or in combination with other data.
6. The data should be exportable to other systems, such as Electronic Healthcare Records (EHR) systems, to support interoperability with healthcare environments so that the data can be used in healthcare delivery and planning. This exportability also should support delivery to third parties who conduct epidemiological studies, such that results

from employees of one business entity can be meaningfully compared to those of other business entities and aggregated to create larger population analyses.

7. The instrument should be viable for repeated measurements, so that status on each factor can be monitored across time both as a means of risk assessment and as a means of progress monitoring to help determine the effectiveness of interventions, such as those that might be provided by Employee Assistance Programs (EAPs), healthcare workers, professional online support services, peer support networks, and even non-personnel support agents, such as healthcare chatbots.

Additionally, it is imperative that such instruments not be mere assessment tools, but also vehicles for connecting people with resources that can provide supports (i.e., interventions) to reduce the number and/or severity of those factors operant within everyone reporting them. In practical terms, two criteria could be added to what would constitute an optimized, innovative approach to risk/needs assessment.

1. The instrument itself should be a vehicle to provide the respondent with immediate, evident opportunities to self-initiate connection to support services that may help to reduce the number and severity of the feelings of stress, anxiety, loneliness, irritability, depression, pain, fatigue, and ill-health that the respondent reports.
2. The instrument should exist within a platform that allows those tasked with tracking the effectiveness of interventions against workplace health and productivity risks (as well as those hoping to understand and improve the effectiveness of interventions) to analyze which interventions and sources of support produce which types and degrees of effectiveness, with which persons and types of persons, across time.

This is an extensive criteria list that includes elements commonly associated with new and emerging assessment instruments and outreach efforts, as well as elements not commonly seen. To meet these criteria, both new assessment methodology and a

dedicated platform for assessment instrument distribution, scoring, and reporting is needed. Furthermore, with respect to adoption and use by employers, separately and in combination with adoption by healthcare providers and epidemiological researchers, one final criterion is in order: They should be compatible with other employment-centered assessments, such as work performance rating scales and workplace productivity risk assessments.

### ***Emotii<sup>®</sup>, the ADoH8, and the Platform for Assessment and Intervention Research (PAIR)<sup>™</sup>***

It is with these considerations that a new assessment methodology has been developed, along with a new scale, and a software-as-a-service platform. The combination of these elements constitutes an enterprise-level solution designed for ease of implementation and use, with high usability, utility, and value.

### ***Emotii Digital Affect Mirror Experience Measurement Technology***

The lead author (Sullivan) is co-inventor of a novel, patented apparatus for capturing and measuring emotions, moods, other affective phenomena, including attitudes and preferences.<sup>187</sup> This technology captures and measures the affective determinants of health and productivity constructs reviewed above, as well as other constructs including such “core” emotions as anger, sadness, fear, and surprise<sup>188</sup> and related affects such as delight, satisfaction, indifference, and frustration. The technology represents a novel variation on traditional visual analogue scales, since the user’s input is translated into objective quantification, rather than requiring respondents to use numbers to try to estimate the intensities of their subjective experiences, as occurs with Likert scales. Dynamic, user-adjustable digital graphic images allow people to “dial in” the type and intensities of their emotions, moods, feelings, attitudes, and other affective phenomena, via a slider mechanism or other input method. As such, in contrast with Likert-style reporting, they do not require people to try to quantify their feelings’ intensities. Instead, the technology provides the user the opportunity to modify the graphic’s appearance until such point as



the user sees a depiction that most closely approximates and represents his or her subjective experience. This offers a more direct (i.e., less analogue) opportunity for communication of otherwise difficult-to-quantify internal states and experiences. The technology returns nominal data to reflect the type of affect being reported (e.g., 1 = depression, 2 = anxiety, 3 = loneliness) and ratio data reflecting the intensity of the experience, scored on a 0 to 100 scale with specificity up to four decimal places. As a digital system, data are available in near-real-time for reporting and analyses.

### ***ADoH8 Assessment Scale***

The ADoH8 system uses eight distinct Emotii corresponding to the affective determinants of health described above. Each function is a stand-alone single item scale that may be used in various combinations. User testing indicates that all eight can be completed validly in 60 seconds or less, as each generally takes less than 10 seconds to complete particularly when a user has become familiar with the process of adjusting the graphic to best match the intensity of their subjective experience of the construct being assessed. These eight Emotii measures have been combined with a single self-report item of dysfunction to comprise an assessment scale, the ADoH8.

Four major investigations of these Emotii measures have been executed thus far. What follows in this section are some highlights from those works, which are artifacts of research and development efforts by the authors in their respective roles in a commercial venture, ADoH *Scientific*.

The studies have varied in number of participants, U.S. population representativeness, the number of and combinations of Emotii measures included, and the depth of the analyses undertaken. In all studies, participants were anonymous, and solicited via the Prolific Academic platform and paid nominally (generally less than \$1.00) for their participation in each study.

### ***Reliability***

The ADoH8 assessment achieved a Cronbach's alpha coefficient of .862. The Cronbach's alpha was not calculated in the first three studies, as only the fourth study

contained the full ADoH8 assessment Emotii available at that time.

### ***Concurrent/Divergent Validity***

The authors have compared the Emotii measures to a variety of traditional scales recognized for their widespread use and/or strong psychometric properties, to examine the extent to which the Emotii measures correlate well with target measures and less well with other measures.

Most of these measures were normed using a recent two-week time frame for self-reporting. Instructions were modified for the remaining traditional scales to conform to the two-week reporting period, except for the Brief Aggression Questionnaire<sup>189</sup>, which is designed as a trait (versus state) measure. Instructions for Emotii measures also used the two-week reporting period.

The Stress Emotii has been compared to the PSS4<sup>190</sup> in four studies, and Pearson correlation coefficients have ranged from .617 to .666, with sample sizes ranging from N = 599 to N = 1,156 subjects. In each case the correlation was significant  $p < .00$  (2-tailed).

The Anxiety Emotii has been compared to the GAD-7<sup>191</sup> in all four studies, and Pearson correlation coefficients have ranged from .731 to .815, with sample sizes ranging from 599 to 1,156 subjects. In each case the correlation was significant  $p < .00$  (2-tailed).

The Loneliness Emotii has been compared to the UCLA Loneliness Scale (3-item abbreviated version)<sup>136</sup><sup>192</sup> in four studies, and Pearson correlation coefficients have ranged from .702 to .770, with sample sizes ranging from 599 to 1,156 subjects. In each case the correlation was significant  $p < .00$  (2-tailed). In our fourth study, the Loneliness Emotii was also compared to the full, 20-item version of the UCLA Loneliness Scale,<sup>193</sup> and a Pearson correlation coefficient of .638, also significant at  $p < .00$  (2-tailed) was determined.

The Irritability Emotii has been compared to the BITE<sup>194</sup> in our two most recent studies, and Pearson correlation coefficients have ranged from .755 to .787, with sample sizes ranging from 929 to 985 subjects. In each case the correlation was significant  $p < .00$  (2-tailed). As expected, it correlated much less strongly with a measure of trait anger/

aggression (the BAQ)<sup>195</sup>, at .388, though this was nevertheless significant  $p < .00$  (2-tailed).

The Depression Emotii has been compared to the PHQ2<sup>196</sup> in four studies, and Pearson correlation coefficients have ranged from .753 to .784, with sample sizes ranging from 599 to 1,156 subjects. In each case the correlation was significant  $p < .000$  (2-tailed). In our fourth study, the Depression Emotii was also compared to the longer PHQ8<sup>197</sup>, and a Pearson correlation of .716, also significant  $p < .00$  (2-tailed), was determined.

The Pain Emotii has been compared to the P-4 Pain<sup>198</sup> scale in three of our four studies, and Pearson correlation coefficients have ranged from .756 to .770, with sample sizes ranging from 599 to 1,156 subjects. In each case the correlation was significant  $p < .00$  (2-tailed).

The Wellness Emotii has been compared to a variety of measures in four studies. Pearson correlation coefficients have ranged from -.519 with the SF-36 Vitality Subscale<sup>144</sup><sup>199</sup> to .182 with the Epworth Sleepiness Scale,<sup>143</sup><sup>200</sup> with sample sizes ranging from 599 to 1,156 subjects. In each case the correlation was significant  $p < .000$  (2-tailed). This indicates that the Wellness Emotii is not much contaminated by somnolence, but does correlate moderately with subjective energy/vitality, as hypothesized. The Wellness Emotii itself was then subjected to several revisions and studied with smaller samples, in which it was compared to the SRH-5<sup>201</sup> and SRH-7<sup>202</sup> (Eriksson et al., 2001) single-item objective self-report ratings of health appraisals. In those comparisons, Pearson correlation coefficients of .809 and .805, respectively, were significant at  $p < .000$  (2-tailed) against those two measures, which were modified for study purposes to restrict respondents to reports on the recent two weeks (in contrast to their original design which offers no guidance on period for responding).

Our investigations with this Emotii have produced tantalizing evidence that this format captures unique information pertaining to the qualitative experience of an affect that is distinct from the more cognitively mediated appraisal of one's status or state that results from more traditional Q & A formats with Likert-style, true-false, or

other response capture methods.

The Energy Emotii has been compared to a variety of measures in just one study to date ( $N = 985$ ), our most recent and comprehensive one, which was designed partially to investigate this newest construct. Pearson correlation coefficients have ranged from -.730 with the SF 36 Vitality Subscale<sup>203</sup> to .165 with the Epworth Sleepiness Scale.<sup>204</sup> In each case the correlation was significant  $p < .000$  (2-tailed). This indicates that Energy Emotii is not much contaminated by somnolence, but correlates strongly with subjective energy/vitality, as hypothesized.

### ***Relationships with Self-Reported Dysfunction***

Validation Studies #3 and #4 were U.S. census-matched samples of  $N = 929$  and  $N = 985$  persons, respectively, ages 18 to 80, and included a question assessing levels of dysfunction respondents would attribute to the affective determinants of health that were measured. After they submitted answers for the Emotii questions, participants were asked, "If you endorsed any intensity of any of these experiences, how difficult have they made it for you to manage your health, get your work done, take care of things at home, or manage your relationships with other people?" Participants were given the following Likert scale options: Not At All (0), A Little Bit (1), Somewhat (2), Quite A Bit (3), Extremely (4). This question was modeled after similar questions in measures such as the PHQ<sup>205</sup>, modifying it to expand the array of functional domains typically assessed to include health management.

Pearson correlations between dysfunction and each of the eight Emotiis were significant at the  $p < .00$  level, ranging from a low of .42 (Loneliness) to a high of .61 (Depression). None were negative in direction, and this finding was in line with expectations as there was no reason to believe intensity of any of the Emotii measures would correlate negatively or non-significantly with dysfunction.

An experimental composite score comprised of the eight Emotii constructs has been found via Pearson correlation coefficient to correlate significantly with self-reported dysfunction levels,  $r(985) .712$ ,  $p < .00$  (2-tailed), and via linear regression

to account for 50.7 percent of the variance in self-reported levels of dysfunction ( $R^2 = .51$ ), which was gathered in Validation Studies #3 and #4 but not in Studies #1 or #2.

#### ***Age, Ethnicity, Sex and Other Cohort Effects***

Age and student/non-student status have emerged as significant demographic variables. Gender, ethnicity, and employment status has not been found to exert significant effects.

#### ***Emotii versus Likert-style Response Type Preference Ratings***

Each study required respondents to complete both Emotii items and several multi-item traditional tests of various constructs in each study. Respondents were subsequently asked which type of response format they preferred – Emotiis (described as “adjustable graphical images” and not by the trade name Emotii), the traditional Q & A format with Likert-type response options and/or radio buttons, or neither style of response option. A consistent trend reflecting an overall preference for the Emotii items emerges. For example, in Validation Study #4 respondents who expressed a preference (55.2%) chose the Emotii type at a 2.5 to 1 ratio. A clear age trend was observed, with those 55 years of age and younger showing a much stronger preference for the Emotii type. Older respondents tended primarily to have no preference. The preference ratio has been found to be as high as six to one among the youngest age cohorts in our studies.

More extensive analyses of the results from these studies have been conducted, including exploratory and confirmatory factor analyses as well as receiver operating characteristic analyses for several Emotii measures vis-a-vis the scales against which they have been compared. Results of these and other analyses will be published separately and are available for review via correspondence with the authors.

#### ***Platform for Assessment and Intervention Research (PAIR)***

The novel measurement technology outlined above is designed to be implemented by means of self-report scales in a digital format for electronic presentation, distribution,

scoring, reporting, and analysis. To provide for the configuration of scales that may range from single items to multiple items, along with electronic display (e.g. on a tablet computer, mobile phone, desktop computer, or other such devices), electronic media distribution (e.g. via email or SMS), automated scoring, automated reporting and on-demand reporting (e.g. via comma-separated values, or CSV), combinatorial database mergers, and in support of machine learning and advanced analytics capacities, the authors and their collaborators have developed the Platform for Assessment and Intervention Research, or PAIR. This platform has many attributes, which are described more extensively in ADoH Scientific documentation. What follows is a brief overview of many of its features, as pertains to the criteria outlined above for innovative assessment and monitoring services.

PAIR is a software-as-a-service platform allowing administrative-level users to distribute surveys and scales composed of various combinations of the Emotii-type affective determinants of health construct measurement tools. The platform also allows for more traditional question-and-answer formats for items that might not be suitable for Emotii-type responses, such as when simple radio buttons for true-versus-false responses without concern for the intensity of such responses, or Likert-style responses. Moreover, the platform can be configured such that upon completion of a scale for affective determinants of health, respondents may be presented with immediate feedback as to their relative standing (e.g., in percentile scores) vis-a-vis any of one or more normative samples with respect to composite scores and/or individual construct scores. In our studies, participants generally complete the eight Emotii items in about a minute, and one feature of the platform is its capacity to measure respondents' time-on-task in scale completion.

Of critical importance, the platform may be configured so as to provide respondents with one or more one-click options to connect with available resources and supports, such as making an appointment with a business's Employee Assistance Program, with an online provider of SMS-based counseling supports

(which may be paid for or fee-supplemented by an employer), with a free local or national telephone hotline (e.g. Crisistextline.org), and/or with scheduling connectivity with healthcare providers in the respondent's geographical area. Those options for action might also include information and guidance resources, such as literature pertaining to the importance of self-care, the nature of clinical mood and anxiety disorders, self-directed meditation instruction videos, peer support message boards, and others.

Configured thusly, the platform can allow researchers within a business or outside (e.g., healthcare payers) to conduct queries against its databases to help identify which types of supports are and are not initiated via the system by respondents, and whether and to what degree the respondent's subsequent scores – as in temporal monitoring of progress – reflect impact of those interventions. The system's analytics further provide for risk stratification of respondents within a given sample or across aggregated samples. This feature is augmented by the near-real-time

reporting capabilities of the platform. These data may be combined with those emerging from more traditional, established workplace environments, workplace culture, and employee functional assessments, to provide more comprehensive assays from which employers can devise, deliver, and refine the effectiveness of various forms of employee wellness and productivity support protocols. In the interest of brevity and to minimize time and cognitive demands placed upon employees, brief or abbreviated measures, such as the Workplace Outcome Suite (WOS) would be preferred.<sup>206</sup>

## CONCLUSION

The two “megatrends” that have been discussed include such factors as stress, emotional distress, physical functional impairments, chronic disease development and exacerbation, mental healthcare and substance abuse treatment demand increases, the persistent challenges that healthcare treatment non-adherence, and the deleterious and even dangerous consequences of

**Table 1:**

*Pearson's Correlations for ADoH-8 and Dysfunction*

Item	WLNS	STRS	LONE	ANX	IRRT	DPRS	PAIN	ENGR	DYSF
<b>WLNS</b>	1.00								
<b>STRS</b>	.33*	1.00							
<b>LONE</b>	.26*	.44*	1.00						
<b>ANX</b>	.34*	.80*	.46*	1.00					
<b>IRRT</b>	.32*	.62*	.41*	.62*	1.00				
<b>DPRS</b>	.39*	.66*	.58*	.67*	.62*	1.00			
<b>PAIN</b>	.45*	.30*	.16*	.28*	.33*	.32*	1.00		
<b>ENRG</b>	.49*	.41*	.34*	.40*	.36*	.45*	.33*	1.00	
<b>DYSF</b>	.52*	.54*	.42*	.53*	.50*	.61*	.45*	.51*	1.00

Note. \*  $p < .00$

deferred or avoided healthcare access. These factors individually and combinatorically portend higher healthcare costs, diminished productivity, and higher presenteeism among employed U.S. persons. These are risks to employers that could be toxic, if not deadly, to their profitability and viability.

Given these megatrends, 10 criteria for novel, innovative methods to more effectively assess and monitor what have been labeled as eight critical affective determinants of health have been described. In light of the critical importance of identifying which populations experience varying levels of risk based on these factors, screening for mental health concerns, helping people to connect with needed services (e.g. EAP services), and monitoring the effectiveness of such interventions, researchers have

presented a novel technology for capturing and measuring affects, moods, emotions, and other subjective experiences (Emotii), presented data indicating that constructs measured with the Emotii technology enjoy favorable psychometric properties, and described a new software-as-a-service platform (PAIR) suitable for adoption by our nation's employers. These technology innovations have been configured to capture and measure eight key affective determinants of health for several reasons, not the least of which being the relevance of those constructs to mental health, chronic disease development and management, and healthcare treatment plan adherence. When all eight Emotii measures of those constructs are assessed, the completion time is quite minimal, while providing a comprehensive

**Table 2:**

*Convergent Validity for ADoH-8 (Pearson's Correlations)*

Scale	WLNS	STRS	LONE	ANX	IRRT	DPRS	PAIN	ENRG	WHO5	PSS4	UCLA3	GAD7	PHQ2	BITe	PAIN4	SF36
<b>WLNS</b>	1.00															
<b>STRS</b>	.33*	1.00														
<b>LONE</b>	.26*	.44*	1.00													
<b>ANX</b>	.34*	.80*	.46*	1.00												
<b>IRRT</b>	.32*	.62*	.41*	.62*	1.00											
<b>DPRS</b>	.39*	.66*	.58*	.67*	.62*	1.00										
<b>PAIN4</b>	.45*	.30*	.16*	.28*	.33*	.32*	1.00									
<b>ENRG</b>	.49*	.41*	.34*	.40*	.36*	.45*	.33*	1.00								
<b>WHO5</b>	-.46*	-.54*	.44*	-.53*	-.52*	-.60*	-.31*	-.58*	1.00							
<b>PSS4</b>	.46*	.65*	.51*	.63*	.59*	.67*	.30*	.47*	-.65*	1.00						
<b>UCLA3</b>	.29*	.40*	.70*	.39*	.37*	.53*	.22*	.35*	-.49*	.56*	1.00					
<b>GAD7</b>	.38*	.67*	.46*	.73*	.63*	.67*	.29*	.41*	-.60*	.71*	.50*	1.00				
<b>PHQ2</b>	.42*	.54*	.53*	.57*	.52*	.76*	.30*	.47*	-.61*	.71*	.57*	.72*	1.00			
<b>BITe</b>	.37*	.60*	.44*	.59*	.76*	.62*	.32*	.40*	-.57*	.67*	.51*	.78*	.67*	1.00		
<b>PAIN4</b>	.45*	.29*	.18*	.26*	.29*	.31*	.76*	.33*	-.34*	.36*	.27*	.39*	.38*	.39*	1.00	
<b>SF36</b>	-.52*	-.54*	-.41*	-.54*	-.50*	-.60*	-.41*	-.73*	-.76*	-.65*	-.46*	-.60*	-.62*	-.58*	-.43*	1.00

Note. \*\*  $p < .00$

essay. Furthermore, this methodology is popular with respondents, who report a consistent overall preference for it over traditional, lengthier scales that rely on Likert-style responding.

Within workplace environments, when combined with other important affects such as the feeling one has about their relationship with their supervisor and their sense of psychological safety in the workplace, this conceptualization may be extended to what may be called the *affective determinants of wellbeing*. These descriptions should suggest to the reader that the first nine proposed criteria are met by the combination of these technologies. This combination is suitable for deployment alongside more traditional measures of workplace health and productivity, and the authors are currently investigating opportunities for collaborative research as to the insights such

co-deployment may provide, to help satisfy the 10th criterion.

Employers are in a unique position to help reduce the impact of the megatrends, more effectively support their employees' emotional, behavioral, and physical health, and improve their business' viability in an economy that has been wracked by the novel coronavirus that causes COVID-19, particularly as the provision of these assessment and supports-connection services can help to compensate for a national trend of people deferring or simply avoiding visits with healthcare professionals during the pandemic. With innovative approaches, their position may be leveraged to great effect to their own fiscal benefits and contribute to what the authors assert should become a national imperative to leverage the affective determinants of health approach.

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# Reducing Persistent Cardiovascular Risk: Meeting Unmet Needs in Treating Cardiovascular Disease

Co-authors: William B. Bunn III, MD, JD, MPH; Sean Sullivan, JD

*This research was commissioned and funded by Amarin Pharma, Inc.*

**CARDIOVASCULAR DISEASE:** A type of disease that affects the heart or blood vessels. The risk of certain cardiovascular diseases may be increased by smoking, high blood pressure, high cholesterol, unhealthy diet, lack of exercise, and obesity. The most common cardiovascular disease is coronary artery disease (narrow or blocked coronary arteries), which can lead to chest pain, heart attacks, or stroke. Other disorders of the heart and blood vessels include hypertension (high blood pressure), coronary heart disease, cerebrovascular disease, and peripheral vascular disease.

**AMERICAN HEART ASSOCIATION & WORLD HEALTH ORGANIZATION:**  
[www.heart.org/en/health-topics/consumer-healthcare/what-is-cardiovascular-disease](http://www.heart.org/en/health-topics/consumer-healthcare/what-is-cardiovascular-disease)  
[www.who.int/cardiovascular\\_diseases/about\\_cvd/en/](http://www.who.int/cardiovascular_diseases/about_cvd/en/)

## ABSTRACT

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**OBJECTIVE:** Assess the impact of persistent cardiovascular risk in the work force.

**CONCLUSIONS:** Strategies beyond cholesterol management are necessary to significantly reduce persistent cardiovascular risk (P-CVR) and need to be made a part of employer programs for cardiovascular risk reduction.

**KEY WORDS:**

Work Productivity,  
Prescription Medications,  
Cardiovascular Disease

## INTRODUCTION

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The Institute for Health and Productivity Management (IHPM) has worked extensively in the domain of Cardio-Metabolic Health with employers for years. IHPM conducted worksite programs that significantly reduced chronic health risk factors of the Metabolic Syndrome (*a cluster of conditions that includes too much fat around the waist, high blood pressure, high triglycerides, high blood sugar and abnormal cholesterol levels*)—preventing many future cases of cardiovascular disease and diabetes, as well as reducing work impairment (presenteeism) to improve productivity.

The published outcomes from those programs have educated employers and

other health care stakeholders globally about the critical “risk cluster” of this Syndrome. This has led many companies to focus more intently on the expanding population of workers who are pre-diabetic and obese, to slow the disturbing rise in Type 2 Diabetes.

While diabetes is getting more of the employers’ attention, missing from the disease management story is the “*unfinished business*” of reducing significant, persistent cardiovascular risks. These risks have contributed to reversing the longtime favorable trend of declining deaths from heart disease and led to a continuing rise in mortality; the number of deaths



annually fell from 700,000 in 2000 to a low of just under 600,000 in 2012, but then rose to more than 650,000 again in 2019.<sup>1</sup>

**Cardiovascular Disease (CVD)** remains the leading cause of death for both men and women in the United States, and the prevalence is expected to increase – making it a top ongoing public health crisis, largely because of unaddressed persistent cardiovascular risk.

### Impacts of Persistent Cardiovascular Risk in the Work Force

A substantial majority of large, self-insured employers have disease management programs to reduce the risk factors for CVD. The usual targets are elevated blood pressure and dyslipidemia, which can be a combination of high levels of LDL or “unhealthy” cholesterol, low levels of HDL or “healthy” cholesterol, and high levels of total cholesterol. Until very recently, there has been little awareness of or attention to an additional risk factor for CVD – **triglycerides**.

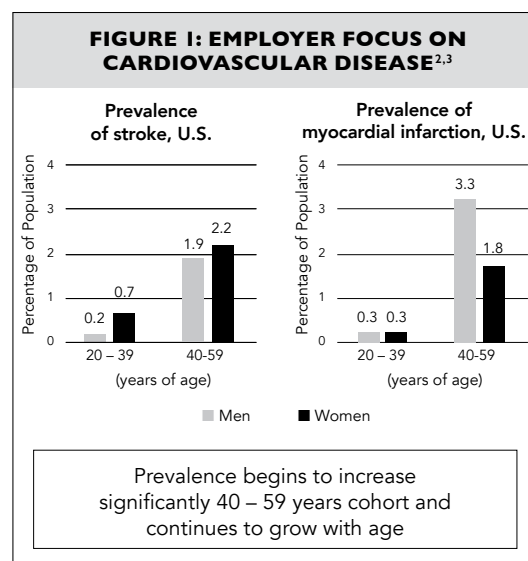
**tri·glyc·er·ide:** Triglycerides are the main constituents of natural fats and oils. High concentrations in the blood indicate an elevated risk of stroke and additional cardiovascular events and are an important measure of heart health. Extremely high triglycerides may put you at risk for acute inflammation of the pancreas.

These employer CVD programs first emphasize healthy lifestyle behavior change – healthier diets and more physical activity to help maintain these measurable risk factors below recommended clinical guideline levels. For those whose risk levels are above clinical guidelines, pharmacotherapy often is required to reduce these levels – making **medication management a key to good outcomes**.

Like cholesterol, triglycerides are naturally occurring fats in the blood, which, although similar, are not the same. Elevated triglycerides are a **cardiovascular risk factor**. Elevated and high triglycerides also may be a flag for other cardiovascular risk factors and so far have largely been overlooked by employers’ programs.

It is natural for employers to focus on CVD – along with diabetes – in their choices of workplace disease management programs:

the **prevalence begins to increase significantly in the cohort of workers 40 and older** – who are the most experienced and generally most productive. The charts below illustrate the need for such programs to prevent serious adverse events for older workers:



**Cardiovascular events have significant, direct medical costs to employers** as the numbers below show:<sup>4</sup>

Event/Procedure	2018 USD
• Fatal CVD	\$96,000
• Fatal MI	\$81,000
• Nonfatal MI	\$55,000
• Fatal stroke	\$95,000
• Nonfatal stroke	\$66,000
• Coronary revascularization	\$48,000 to \$102,000
• Post MI follow-up	\$28,000
• Post stroke follow-up	\$20,000

ASCVD = atherosclerotic cardiovascular disease;

CVD = cardiovascular disease;

MI = myocardial infarction;

PCI = percutaneous coronary intervention;

PVD = peripheral vascular disease;

SD = standard deviation

**Treatment of CVD is a lifelong process**, as those with a prior event remain at greater risk for subsequent events – making assessment of subsequent events necessary to determine the total CVD burden.<sup>5-7</sup>

- Thirty to 50 percent experienced recurrence of a cardiovascular event or undergo coronary revascularization



within **one-year post-MI**

- Up to 75% experience a recurrent CV event within **three years post-MI**

**Impact of CVD on Productivity** – an employee with CVD costs the employer nearly 60 hours and over \$1,100 more in lost productivity annually than an employee without CVD. In 2010, nearly \$42 billion in potential productivity was lost from CVD-related employee morbidity, and more than \$137 billion was lost because of CVD-related premature deaths.<sup>8,9</sup>

**Prescription medications for lowering cholesterol** are widely used in populations that have CVD and diabetes. The numbers below show the use of prescription cholesterol-lowering medications in adults aged 40, who had the following diseases (in 2011-2012).<sup>10</sup>

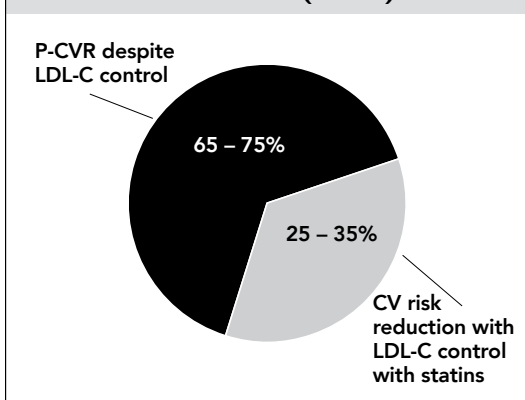
CV Disease	71%
Diabetes	63%
Hypercholesterolemia	54%

Overall, **one-quarter (24%) of adults aged 40 to 64 years (working age)** who had health insurance coverage **used a prescription cholesterol-lowering medication**.<sup>11,12</sup>

Nevertheless, as shown below, **Significant Persistent Cardiovascular Risk (P-CVR) remains despite the benefit of LDL Cholesterol-Lowering Medications:**

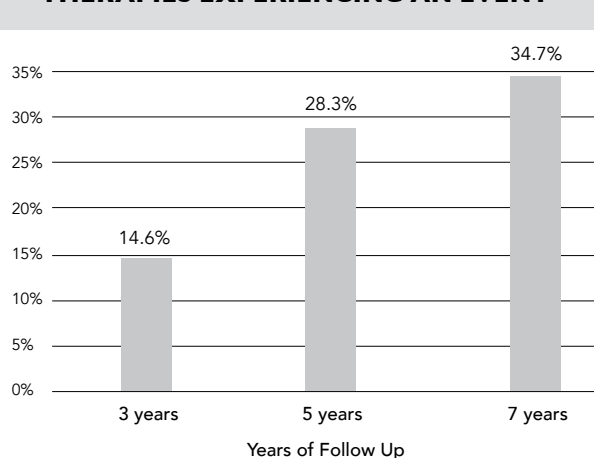
- Sixty-five to 75 percent of P-CVR is beyond the current standard of care
- P-CVR remains high even with controlled LDL-C
- Increased control of LDL-C does not eliminate CV risk

**FIGURE 2: DESPITE BENEFIT OF LDL-C LOWERING, SIGNIFICANT PERSISTENT CARDIOVASCULAR RISK (P-CVR) REMAINS<sup>13</sup>**



**Even in patients treated with historical standard-of-care, persistent cardiovascular risk remains high – and increases over time.** The chart below shows the *Percentage of Patients on Statin-Based Standard of Care (SOC) and other standards of therapy who, even with well-controlled LDL-C levels, still experience a Major Adverse Cardiovascular Event (MACE) after:*

**FIGURE 3: PERCENTAGE OF PATIENTS ON SOC THERAPIES EXPERIENCING AN EVENT<sup>14-16</sup>**



Cross-trial comparisons are subject to differences in populations, primary outcomes, and other trials' design aspects

One hundred percent of patients were on a statin, and > 70 percent were taking an antiplatelet and/or an anticoagulant, ACEi/ARBs, and a beta-blocker. FOURIER: Patients had clinically evident ASCVD; REDUCE-IT: Patients had established CVD or had diabetes mellitus and at least one additional risk factor. IMPROVE-IT: Patients had been hospitalized within the preceding 10 days for an ACS.

ACEi = angiotensin converting enzyme inhibitor;

ARB = angiotensin II receptor blocker;

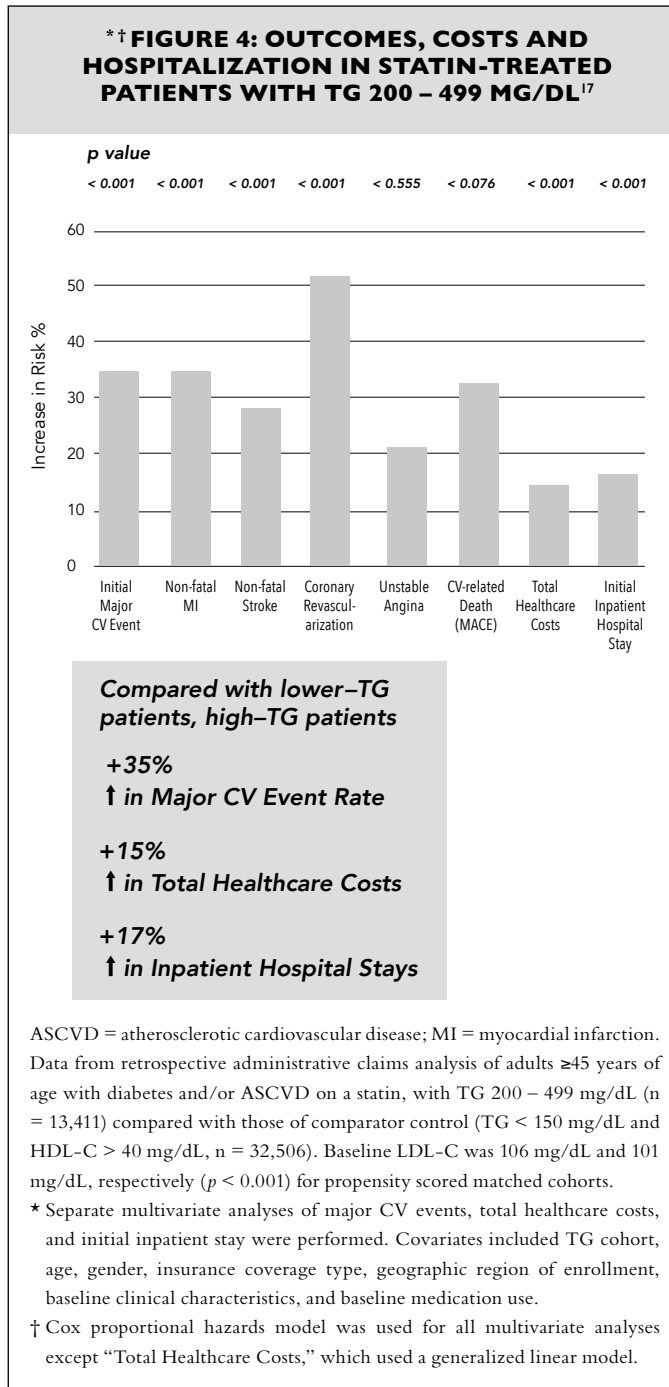
CVOT = cardiovascular outcome trial;

MACE = major adverse cardiovascular event;

MI = myocardial infarction.

## Managing Persistent Cardiovascular Risks in the Work Force

*Patients with high triglycerides (TG) have higher risk and higher costs as shown in the bar chart that follows:*



In conclusion: strategies beyond cholesterol management are necessary to significantly reduce persistent CV risk (P-CVR) and need to be made a part of employer programs for cardiovascular risk reduction.

Amarin Corporation plc is a rapidly growing, innovative pharmaceutical company focused on developing and commercializing therapeutics to cost-effectively improve cardiovascular health. Amarin's lead product, is available by prescription in the United States and an increasing number of other countries. Amarin is headquartered in Dublin, Ireland. Amarin's U.S. office is in Bridgewater, New Jersey. Amarin is listed in the U.S. on NASDAQ (symbol: “AMRN”).

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# Global Burden of Chronic Musculoskeletal Pain in the Workplace

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*This research was commissioned and funded by Pfizer*

**“THE LEADING REPORTED REASON WORLDWIDE FOR NOT BEING ABLE TO WORK EFFECTIVELY IS CHRONIC PAIN.”<sup>19</sup>**

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## ABSTRACT

### KEY WORDS:

Work Productivity,  
Prescription Medications,  
Chronic Musculoskeletal  
Pain, Painkillers

**OBJECTIVE:** Assess the impact of chronic musculoskeletal pain in the global workplace.

**CONCLUSIONS:** Findings suggest that musculoskeletal pain has a huge impact on the functional capacity to work, and better management of chronic musculoskeletal pain presents an equally huge opportunity to improve the health and productivity of the global workforce.

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## INTRODUCTION

It results in being less productive on the job because of functional impairment, or exit from the workforce entirely because of disability. The great majority of chronic pain is musculoskeletal – especially low back pain (LBP) and osteoarthritis (OA) – although the precise proportion of either is rarely specified in studies.

### Prevalence of Chronic Musculoskeletal Pain

The average global prevalence of LBP at any point in time – the “point prevalence” – is reported between 9.4 and 11.9 percent,<sup>1,2</sup> while 23.2 percent of people worldwide experience such pain during any given month – the “period prevalence.”<sup>3</sup>

Among workers in the United States, the prevalence of LBP in any two-week period has been reported at 15 percent – with more than 40 percent of them experiencing

exacerbations that increase the workplace impact and cost burden to employers – i.e., 50 percent more LBP-related lost productive time.<sup>4</sup> Strikingly, after an initial episode of LBP, 50 to 75 percent of people suffer at least one relapse.<sup>5</sup>

Chronic LBP increases linearly from age 30 to age 60, reaching peak prevalence between ages 50 and 60.<sup>6</sup> Based on Institute for Health and Productivity Management’s (IHPM) field work with employers, these are the most experienced, often most dedicated and productive employees in any organization – whom no employer wants to lose after investing many years in their training and development.

In Europe, the incidence of the first episode of LBP has been reported to range from 6.3 to 15.5 percent over a one-year period, with many patients having recurrent episodes. About one-third of workers who

have been injured have a recurrence of LBP within a year.<sup>7</sup>

Elsewhere around the globe, estimates of the “point prevalence” of LBP vary widely:

- 6.3 to 11.1 percent in the United Kingdom<sup>8</sup>
- Chronic pain affects 10 to 20 percent of Japanese, with back pain the most prevalent at 72 percent<sup>9</sup>
- 10.5 percent on average for all of Latin America<sup>10</sup> (studies in Brazil alone, reported in *Cadernos de Saude Publica*, ranged from 4.2 to 14.7<sup>11</sup> percent “with a high risk of bias”)
- A higher range was reported in a study of people age 50 and up, in “six less fully developed nations” – 22 percent in China, 36 percent in Mexico, 39 percent in India and South Africa, 41 percent in Ghana, and 56 percent in Russia – with three-quarters or more of sufferers in all the countries reporting “*moderate intensity*” of pain.<sup>12</sup>

The prevalence of LBP increased in every region of the world over the years 1990–2010,<sup>2</sup> but especially in North America and Western Europe – where increasingly sedentary lifestyles have led to rising levels of obesity. Not surprisingly, Disability-Adjusted Life Years (DALYs) related to chronic musculoskeletal pain jumped from 58 to 83 million over the same 20 year period.<sup>2</sup>

### Impact of Chronic Musculoskeletal Pain on Countries

In Europe, the presence of **moderate-to-severe** daily pain reduced the probability of working full-time by 10 to 20 percentage points – much greater than the impact of any other health status measure on labor force participation.<sup>13</sup> The impact of pain on absenteeism and presenteeism also exceeds that of other health measures.<sup>13</sup> In the United States, OA and LBP together have been found by the Centers for Disease Control (CDC) to account for one third of all work disability, in nearly equal shares of 17.5 percent and 16.5 percent, respectively.<sup>14</sup>

Musculoskeletal Pain in general accounts for 21.3 percent of total **Years Lost to Disability (YLD)** globally, second only to

Mental and Behavioral Health conditions at 23.2 percent.<sup>15</sup>

*“Low back pain by itself has become the single leading reason for YLD in every region of the world ...*

*... after significant increases in prevalence in most regions over the two decades from 1990 to 2010.”<sup>15</sup>*

### Economic Costs Associated with Chronic Pain

Reliable estimates of the overall economic costs of chronic pain in studies published to date are mostly available for the U.S. and the EU, and these vary considerably. The *Institute of Medicine*<sup>16</sup> puts the total annual cost of chronic pain in medical care and lost productivity for all Americans at between \$560 and \$635 billion, with lost productivity accounting for \$297 to \$336 billion (2011). The cost of lost wages for employees was \$226 billion, while the actual cost to employers in lost work time from absenteeism (*not at work*) and ‘presenteeism’ (*functional impairment while at work*) was \$109 billion.

A study in *Journal of the American Medical Association*,<sup>17</sup> that focused on LBP alone, estimated the cost for 26 million working-age Americans (20 – 64 years of age) to be \$86 billion. Another study in the *American Journal of Public Health*<sup>18</sup> noted that LBP is the leading cause of workers’ compensation claims, adding additional employer costs. A third study in the *Journal of Occupational and Environmental Medicine*<sup>19</sup> showed that arthritis and associated joint disorders resulted in higher health care, absence, prescription drug, disability and workers compensation costs totaling \$1,800 per employee – as well as a 4 percent reduction in productivity, equaling a 4 times greater revenue loss of \$7,454 per employee.

An associated cost of the rising prevalence of chronic pain – somewhat unique to the United States – is the widely reported “epidemic” of overuse and abuse of opioid painkillers. This often starts appropriately enough with a prescription intended for relatively short-term use, that can extend to longer-term inappropriate use of Rx drugs, and finally can cross the line into use of illegal

synthetic drugs. Improved management of chronic pain – with appropriate use of opioids – would reduce the alarming human cost of abuse seen in daily headlines about deaths from overdose of these drugs, now estimated by the Centers for Disease Control (CDC) at more than 50,000 annually in the U.S. alone.<sup>20</sup> This issue has now received the attention of the nation's political leaders.

In Europe, the estimated direct health care and indirect productivity loss costs of chronic pain disorders in EU member states has been estimated as high as €441 billion,<sup>21</sup> or between 3 and 10 percent of GDP across the EU.<sup>22</sup>

A few notable data points from other research conducted in the EU region:

- Musculoskeletal pain generally accounted for nearly half of all absences of three days or more, and 60 percent of reported work incapacity.<sup>21</sup>
- Direct health care costs for LBP were €7,000 per affected patient in Germany, but 75 percent of total costs resulted from work absenteeism.<sup>8</sup>
- Indirect costs of OA from lost productivity greatly exceed direct medical care spending, ranging from 60 percent of total costs in Italy and Belgium to more than 80 percent in the Netherlands.<sup>23</sup>

Data for Japan are not as abundant, but are the most complete and reliable numbers obtainable for Asia:

- LBP accounts for 62 percent of work-related disease that results in four days or more of “temporary retirement” from the work force;<sup>24</sup>
- Differences in absence and presenteeism were large between employees reporting chronic pain and those without pain – 4.74 percent versus 2.74 percent reporting absence because of pain, and 30.19 percent compared with 15.19 percent reporting presenteeism because of pain – twice as many in both cases;<sup>25</sup>
- Indirect costs of lost productivity for workers reporting moderate pain were the equivalent of US\$17,000 annually versus US\$9,500 for those without pain.<sup>25</sup>

## Impact of Chronic Musculoskeletal Pain on Employers

**Figures 1 & 2** present the findings from an early IHPM Survey of 34 large multinational companies with a total of 1.2 million employees,<sup>26</sup> showing the leading health-related reasons reported for absence and presenteeism – with musculoskeletal (MSK) conditions leading the way:

**FIGURE 1: Leading Reported Health Reasons for Absence from Work**



**FIGURE 2: Leading Reported Health Reasons for Presenteeism**

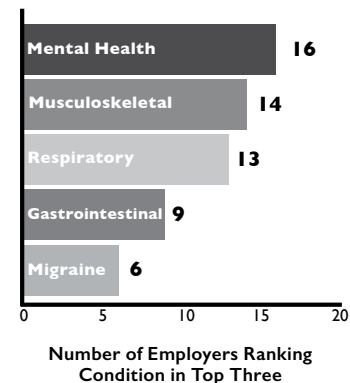


Figure 2 – Health & Productivity Management: Vol 1 No 3, of Health & Productivity Management, pages 4-6<sup>26</sup>

- Musculoskeletal was the number one reported reason for absence from work, ahead of mental health and pregnancy
- Musculoskeletal was the number-two reported reason for presenteeism after mental health.

This study (see *Figure 3*) found that about 80 percent of the \$10,000 per capita total cost burden of back and neck pain was



accounted for by combined absenteeism and presenteeism (called in the study “work impairment”) – mostly the latter.

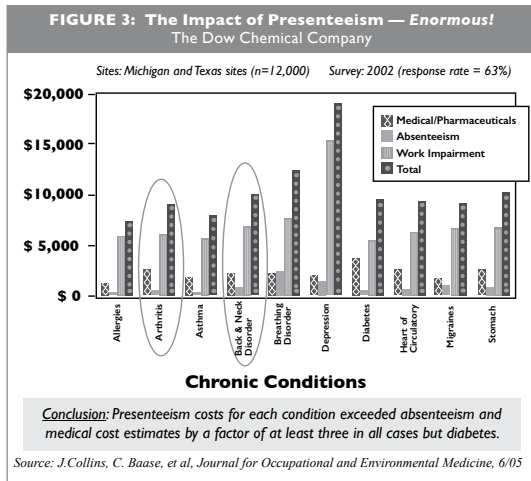


Figure 3 – published in the *Journal of Occupational & Environmental Medicine*<sup>27</sup> – depicts a landmark study carried out at the Dow Chemical Company.

- These economic costs of lost productivity for back and neck pain were about 4 times the direct financial cost of medical care and pharmaceuticals.
- Figure 3 also shows a similar situation concerning arthritis – with about 75 percent of the \$9,000 per capita total cost burden accounted for by absenteeism and presenteeism together – again, with the latter mostly responsible.

**A survey on the impact of chronic pain on both absenteeism and presenteeism was conducted in the Big 5 European economies of Germany, the United**

**Kingdom, France, Italy and Spain**, with results published in the *Journal of Medical Economics*<sup>28</sup> that included the following key findings:

- Twice as many workers experiencing chronic pain reported absence from work, compared with those not reporting any pain – 18 percent versus 8 percent.
- A full two-thirds (68 percent) of workers experiencing chronic pain reported reduced productivity while at work – presenteeism – compared with fewer than half of workers (44 percent) not reporting any pain.
- Presenteeism had a 3-times greater impact than absenteeism on reduced productivity for workers reporting chronic pain.

These European findings on the significantly larger impact of presenteeism than of absenteeism on the productivity of chronic pain sufferers reinforce the results in Figure 3 above from the Dow Chemical study in the U.S.

A 2016 study of estimated absenteeism and presenteeism costs in the U.S. workforce by chronic condition, done by the *Center for Work Force Health and Performance at the Integrated Benefits Institute (IBI)*, August 2016<sup>29</sup>, found that chronic back and neck pain resulted in the most lost work days – from absenteeism and presenteeism combined – and the highest lost productivity costs of any condition (roughly equal to arthritis and other chronic pain combined):

FIGURE 4: Center for Workforce Health and Performance at the Integrated Benefits Institute

	Percent of Workforce	Lost Work Days (millions)	Lost Productivity Cost (billions of \$)
Chronic back/neck pain	14.3	128.1	42.4
Other chronic pain	5.6	60.6	20.0
Arthritis	13.5	57.4	19.7

These three categories of chronic pain together accounted for 246 million lost-work-days from absence and presenteeism, and cost \$82 billion in lost productivity – 75 percent due to musculoskeletal pain.

## Chronic Lower Back Pain & Arthritis: The Lockheed Martin Study

The Lockheed Martin Aeronautics Employee Survey:

Condition	Prevalence	Average Productivity Loss	Aggregate Annual Loss
Migraine	12.0%	4.9%	\$434,385
Arthritis	19.7%	5.9%	\$865,530
Chronic lower-back pain (w/o leg pain)	21.3%	5.5%	\$858,825
Allergies or sinus trouble	59.8%	4.1%	\$1,809,945
Asthma	6.8%	5.2%	\$259,740
GERD (acid reflux disease)	15.2%	5.2%	\$582,660
Dermatitis or other skin condition	16.1%	5.2%	\$610,740
Flu in the past two weeks	17.5%	4.7%	\$607,005
Depression	13.9%	7.6%	\$786,600

IHPM

Source: Hempt P. Presenteeism: at work – but out of it.  
Harv Bus Rev. 2004; 10:49-58. Debra Lerner, William H. Rogers, and Hong Chang, at Tufts-New England Medical Center

Figure 5: Harvard Business Review

This table taken from the *Harvard Business Review*<sup>30</sup> shows the survey findings for prevalence of nine chronic conditions at Lockheed Martin Aeronautics, along with the average productivity loss and aggregate annual financial cost of presenteeism alone for each – and highlights the findings for Arthritis and Chronic Lower Back Pain (LBP).

- LBP and Arthritis are 2nd and 3rd, respectively, in prevalence after Allergies or Sinus trouble.
- They also are 2nd and 3rd in average productivity loss after Depression, and 2nd and 3rd as well in aggregate annual financial cost of lost productivity.

**Figures 6.1-6.3** – Published in *Health & Productivity Management*, Vol. 4 No. 3 as an *IHPM Academy Brief* taken from the *Journal of Occupational and Environmental Medicine*. 2005; 47(7):658-670.<sup>31</sup> These figures show the burden of chronic pain on productivity at Pitney Bowes Company, as measured by both absence from work and presenteeism, and also by the severity of the pain.

Employees suffering chronic pain lost the equivalent of four full days of work over the previous four weeks from absenteeism (.85) and presenteeism (3.11) combined – compared with one-third of a day for employees without pain.

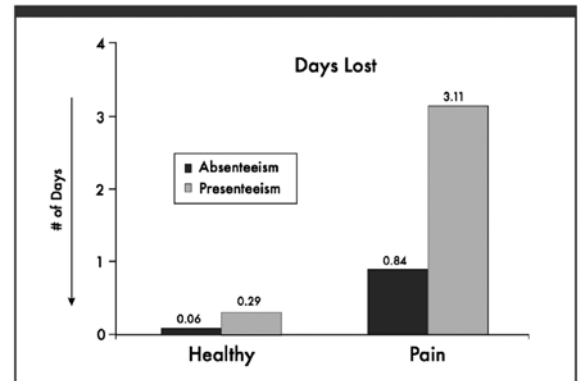


Figure 6.1: Pain and Workdays Lost to Health Problems: Last 4 Weeks

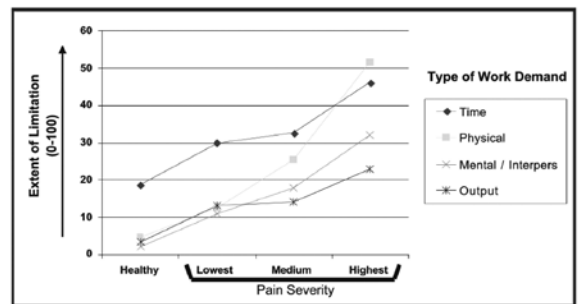


Figure 6.2: Burden of Pain on Performance at Work: Difficulty in Meeting Job Demands

The burden of chronic pain on performance at work increases dramatically with the severity of that pain, along all measurement scales of work limitation.

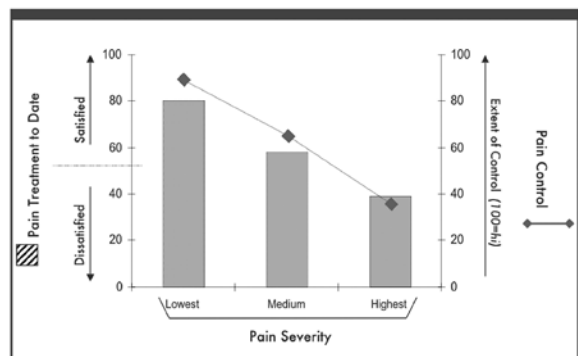


Figure 6.3: Management of Pain: Outcomes

Employees with the most severe chronic pain are least satisfied with their treatment to manage that pain – and will remain the most limited in their ability to perform the demands of their work.

## CONCLUSION

Musculoskeletal pain has a huge impact on the functional capacity to work – responsible globally for more than one-fifth of the total Years Lost to Disability (YLD),<sup>15</sup> with Low Back Pain the single leading reason for YLD in every region of the world.<sup>15</sup>

*In the United States, LBP and Osteoarthritis together account for one-third of all work disability.<sup>14</sup> Chronic pain ranks at the very top in Europe,<sup>13</sup> as well as the U.S., in its total impact on day-to-day productivity – absence from work and presenteeism*

*while at work – with suggestive evidence of similar impact in Japan.<sup>25</sup>*

Better management of moderate-to-severe chronic musculoskeletal pain presents an equally huge opportunity to improve the health and productivity of the workforce in all industrialized countries, as well as prevent the loss of prime-age skilled workers to early disability. It should be a public policy as well as a business health priority for the global workforce.

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# Self-Treating Low Back Pain with Over-the-Counter Medications

## Economic Value Proposition for Employers and Health Systems

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*This research was sponsored and funded by Sanofi*

**“...A HEALTHY WORKFORCE IS VITAL TO A COUNTRY’S COMPETITIVENESS AND PRODUCTIVITY.”** — KLAUS SCHWAB, CEO, WORLD ECONOMIC FORUM

### ABSTRACT

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#### KEY WORDS:

Self-care, Over-the-Counter Medications, Low Back Pain, Economic Impact

**OBJECTIVE:** Examine the fostering of self-care by employees as one of the quickest and surest ways for employers to realize economic gains from improved work force productivity.

**CONCLUSIONS:** Self-care must become an essential part of health care delivery because it improves wellness and quality of life for millions of workers. Self-care is cost-effective for all parties at a time when health care costs are rising worldwide because of aging and more chronically ill populations.

### INTRODUCTION

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The Economic Value Proposition for Employers and Health Systems as reported by the *World Economic Forum’s* 2016 – 2017 ***The Global Competitiveness Report*** states that “a healthy workforce is vital to a country’s competitiveness and productivity.” Workers with health issues cannot perform to their full potential, costing their companies lost productivity from being (1) more often absent from the workplace, and (2) less effective when they are at work because functionally impaired – known as presenteeism (at work, but not fully functional).

Fostering self-care by employees is one of the quickest and surest ways for employers to realize economic gains from improved work force productivity. Self-care is defined by the *World Health Organization (WHO)* as “personal health maintenance to improve or restore health or treat or prevent disease – with or without the support of a healthcare provider.”

Over-the-counter (OTC), medications are a vital part of managing minor ailments

through self-care. *Institute for Health and Productivity Management (IHPM)* interviews on this subject with American and European employers in 2017 produced the following recommendations:<sup>1</sup>

- Self-care by employees – to include appropriate use of OTC medications – should be made an integral part of employers’ workplace health and wellness programs.
- OTC medication options should be expanded to help prevent or alleviate chronic health conditions that impact work performance and productivity.
- Employees should be given reliable information and appropriate health management tools enabling them to practice responsible self-care.

### Low Back Pain: Starting Place for Expanding Self-Care

Low Back Pain (LBP) continues to be the leading reason for *Years Lost to Disability*

(YLTD) in every region of the world according most recently to the 2017 Global Burden of Disease Study.<sup>2A,2B</sup> IHPM's seminal 2004 survey of 34 United States (U.S.)-based multinational employers, published in *Health and Productivity Management* journal, found musculoskeletal pain – LBP and osteoarthritis – the (1) leading reason for absence from work, and (2) second-leading reason for presenteeism.<sup>3</sup>

In Europe, the financial expense of medical care for chronic pain in general – combined with the economic cost of lost productivity – has been estimated at between 3 and 10 per cent of GDP (Gross Domestic Product) for the member countries of the European Union (EU).<sup>4</sup> Data from Germany for LBP alone reveal a cost of lost productivity from work absence that is three times greater than the direct cost of medical treatment;<sup>5</sup> this three-to-one ratio of lost productivity to medical costs is similar to multiple study findings from the U.S.<sup>6</sup>

At the workplace level, IHPM's field research with a multinational company suggests a big opportunity for self-care and greater use of OTC medications to (1) bring pain relief to employees, a clear majority of whom are not satisfied with their treatment, and (2) produce economic gains for employers from increased productivity.<sup>7</sup>

Most pain sufferers report only mild pain, yet they cost their employers the equivalent of two lost workdays every month – 10 percent of total productive time.<sup>8</sup> They are ideal candidates for self-medication with OTC products. The WHO has lent its authority by advising the millions suffering mild pain to treat it with non-prescription NSAIDs (non-steroidal anti-inflammatory drugs), or with acetaminophen;<sup>9</sup> these are easily available in the U.S. and, to a lesser extent, in Europe. Published research also suggests that topical treatments can be effective for LBP, with fewer side effects for some individuals than systemic medication.<sup>10</sup>

### Prevalence and Incidence of LBP

At any one time, about 1 in 10 people worldwide is suffering from low back pain – the “point prevalence”<sup>11</sup> – while nearly one-quarter of them experience such pain during any given month – the “period prevalence.”<sup>12</sup>

The prevalence of low back pain among workers in the U.S. has been reported at 15 percent in any two-week period. More than 40 percent of these workers experience exacerbations that increase the impact of pain on their functionality at work, as well as the total cost burden on their employers – resulting in 50 percent more lost productive time.<sup>13</sup>

In Europe, the incidence of the first episode of LBP reportedly ranges from 6 to 15 percent of workers over a one-year period – many suffering recurrent episodes of such pain. And, in addition, about one-third of European workers who have been injured on the job experienced a recurrence of LBP within a year.<sup>14</sup>

The prevalence of chronic low back pain increases in linear fashion from age 30 to age 60, peaking between ages 50 and 60.<sup>15</sup> These are the most experienced and often most dedicated and productive employees in any company, whom no employer wants to lose after investing many years in their training and development (recall that LBP is the leading reason worldwide for Years Lost To Disability).

The prevalence of LBP has increased around the world over the past few decades, especially in North America and Western Europe – where more sedentary lifestyles also have contributed to higher levels of obesity, which is a co-morbid condition with low back pain. Disability-Adjusted Life Years (DALYS) related to chronic musculoskeletal pain rose from 58 to 83 million over the same period.<sup>16</sup>

### Economic Impact of LBP

Reliable estimates of the overall economic cost of chronic pain are available mostly for the U.S. and Europe. One U.S. study focused on LBP alone estimated a total cost of \$86 billion for 26 million working-age Americans (20 to 64 years).<sup>17</sup> Another study found LBP to be the leading reason for workers compensation claims from injuries on the job.<sup>18</sup> Field studies with a Fortune 50 global company showed that 80 percent of the total annual cost of LBP was from lost productivity.<sup>19</sup>

In Europe, musculoskeletal pain in general accounted for nearly half of all work absences of three days or more, as well as



60 percent of reported work incapacity or functional impairment.<sup>20</sup> A survey on the impact of chronic pain on both work absence and presenteeism in the Big 5 European economies (Germany, UK, France, Italy, Spain) found that presenteeism had a three-times greater impact than absence on reduced productivity.<sup>21</sup>

In Germany, the world's fourth-biggest economy, direct health care costs for LBP alone were €7,000 per patient – but three times that amount for the economic costs of lost production resulting from work absence.<sup>22</sup> A significant portion of both these medical and absence costs would be recoverable through expanded access to, and greater use of, OTC medications (and these figures do not include the certainly larger lost productivity costs of presenteeism).

As a point of comparison with the world's third-biggest economy, data from Japan show LBP accounting for 60 percent of work-related chronic health issues that result in four days or more of “temporary retirement” from the work force (equivalent to short-term-disability in the West).<sup>23</sup>

### Policy Implications for Employers and Governments

For both employers and governments, it is useful to consider the policy implications of these findings on Low Back Pain with respect to Self-Care and use of Over-the-Counter medicines. Here are the percentages of common ailments treated with OTC products in the U.S., compared with leading countries in Europe:<sup>24</sup>

United States	33%
Germany	28%
UK & Spain	24%
Italy	20%

The “gap” between the U.S. and leading European countries with respect to consumers' use of OTC medicines ranges from 5 percent for Germany to 13 percent for Italy – with the UK and Spain in between at 9 percent. There are several possible reasons for this gap in consumer behavior:

1. Ease of access to these OTC medicines
2. Knowledge about their appropriate use
3. Satisfaction with results from their use

Consumer satisfaction is not the explanation, because 9 of 10 European

consumers report that self-care with OTC medicines is vital to managing symptoms that cause functional impairment (presenteeism) and reduce their productivity at work.<sup>25</sup> Self-care also engages them more actively in managing their own health – leading to better outcomes at lower cost.

If only a small percentage of employees who self-treat mild lower back pain with OTC medicines – as recommended by the WHO – took time off work to visit a doctor, it would lead to:

- Additional office visits, with their attendant financial costs – including prescribing of costlier prescription medicines.
- More time away from work, with resulting hours of lost productivity.

### Consumer/Employee Education on Self-Care Should be a National Health and Economic Priority

Expanded self-diagnosis and self-treatment with at-hand analgesics and topicals will reduce the following, as demonstrated in countries like the UK, Australia, and the U.S.<sup>26A,B,C</sup>

- Unnecessary physician and prescription drug expense
- Unnecessary time away from work for physician office visits
- Presenteeism/work impairment that decreases productivity

Patient/consumer education on appropriate use of OTC medicines is essential to “validate” self-care.

- But only 1 in 5 physicians currently provides such education – despite recommendations by medical associations<sup>27</sup>
- Two-thirds of U.S. consumers think that pain research and management should be made a top medical priority<sup>28</sup>

### Collaboration is Needed with Health Care, Employer and Patient Groups to Establish Accepted Policies and Guidelines for LBP

Objective is to expand the domain of self-care and OTC medicines for treating mild to



moderate pain.

- Credibility with, and acceptance by, medical and government leaders in public and population health are required.
- Self-Care Guidelines for Employers – endorsed by appropriate professional bodies such as ICOH and GAMH – must be adopted and implemented globally, for use by employers in managing LBP in their work forces.

The goal is to translate evidence into practice and, thereby, ease access to OTC medicines by.

- Accelerating approval for the switch of more Rx drugs to OTC status for easier access and cost-effective use.

### **Self-Care Must Become an Essential Part of Health Care Delivery for Two Compelling Reasons**

1. It provides quick and safe symptomatic relief to improve wellness and quality of life for millions of workers.
  - Enabling them to be more productive at work, and helping their employers realize greater financial returns on investments in their health.
  - Reducing the pressure on overburdened medical providers and health care systems worldwide
2. It is cost-effective for all parties at a time when health care costs are rising worldwide because of aging and more chronically ill populations.
  - Increasing personal responsibility for individual health status, as well as for the cost of health care that is rising faster than the ability of governments or employers to pay for it.

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President & CEO, Institute for Health and Productivity Management  
Fortune Magazine, 12.12.05

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