



Technology Enabled Management of Sleep Loss as a Strategy to Mitigate the Underlying Cause of Fatigue in Transportation

Jeffrey Durmer, MD, PhD
Chief Medical Officer, FusionHealth



Sleep



Recover



Perform





Defining and Identifying Fatigue

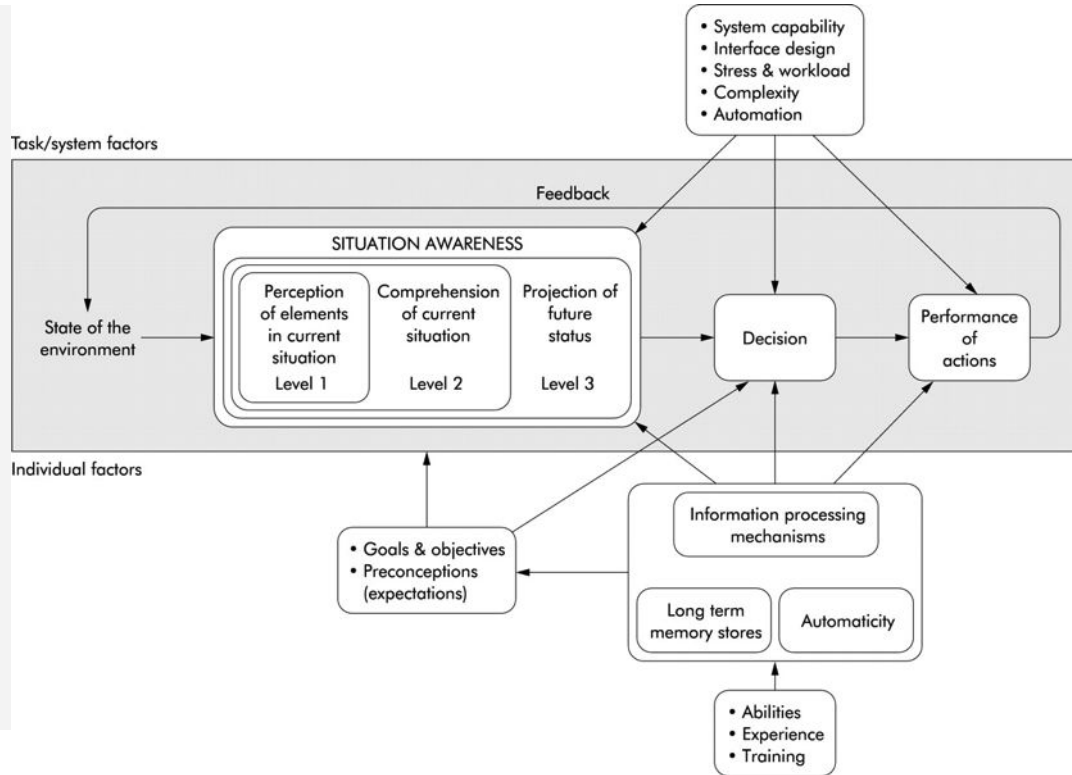
Fatigue is Defined By its Effects

<i>Cognitive subscale</i>	<i>Never</i>	<i>Rarely</i>	<i>Sometimes</i>	<i>Often</i>	<i>Almost always</i>
1. I have been less alert	0	1	2	3	4
2. I have had difficulty paying attention for long periods of time	0	1	2	3	4
3. I have been unable to think clearly	0	1	2	3	4
4. I have been forgetful	0	1	2	3	4
5. I have had difficulty paying attention for short periods of time	0	1	2	3	4
6. I have had difficulty making decisions	0	1	2	3	4
7. I have been less motivated to do anything that requires thinking	0	1	2	3	4
8. I have had trouble finishing tasks that require thinking	0	1	2	3	4
9. I have had difficulty organizing my thoughts when doing things	0	1	2	3	4
10. My thinking has been slowed down	0	1	2	3	4
11. I have had trouble concentrating	0	1	2	3	4
Cognitive subscale score _____					
<i>Physical subscale</i>	<i>Never</i>	<i>Rarely</i>	<i>Sometimes</i>	<i>Often</i>	<i>Almost always</i>
12. I have had to pace myself in my physical activities	0	1	2	3	4
13. I have been less motivated to do anything that requires physical effort	0	1	2	3	4
14. I have trouble maintaining physical effort for long periods	0	1	2	3	4
15. I have trouble maintaining physical effort for short periods	0	1	2	3	4
16. I have been physically uncomfortable	0	1	2	3	4
17. I have been less able to complete tasks that require physical effort	0	1	2	3	4
18. I have needed to rest more often or for longer periods	0	1	2	3	4
Physical subscale score _____					
<i>Psychosocial subscale</i>	<i>Never</i>	<i>Rarely</i>	<i>Sometimes</i>	<i>Often</i>	<i>Almost always</i>
19. I have avoided/eliminated certain tasks, activities and lifestyles	0	1	2	3	4
20. I have been less motivated to participate in social activities	0	1	2	3	4
21. I have been limited in my ability to do things	0	1	2	3	4
Psychosocial subscale score _____					
Total MFIS-SCI score = _____					



Modified Fatigue Impact Scale
(Fatigue Severity Scale)

Studying the Effect of Fatigue on Situational Awareness

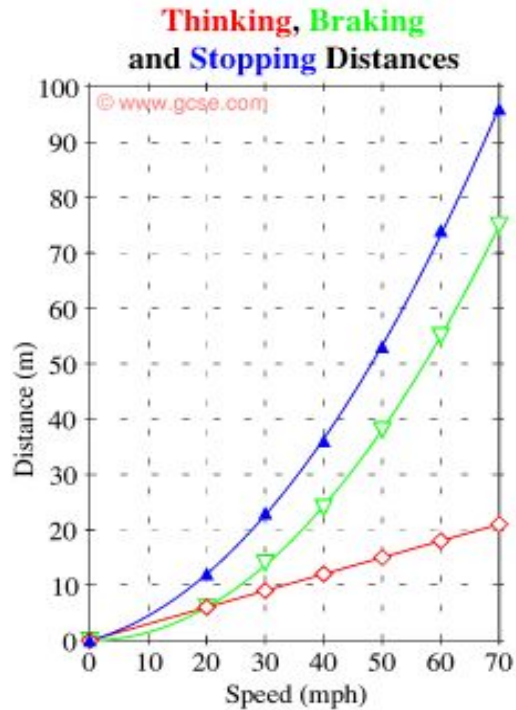


The Focus is on the Task

The Focus is During the Task

Model of Situational Awareness in Dynamic Decision Making (Endsley, 1995)

Tools that Focus on Individuals *During* a Task



New Focus on the Individual Before a Task

Biometrics Predict Risk for Situational Awareness Related Accidents

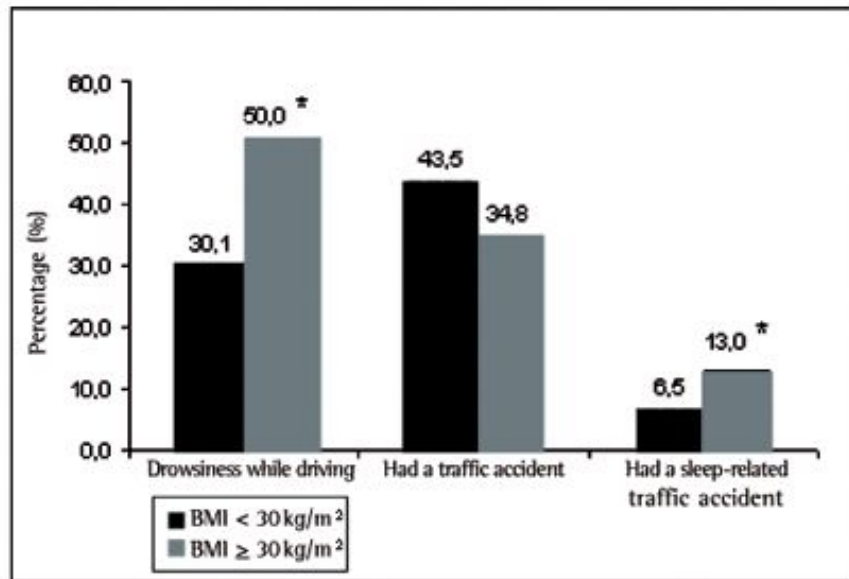


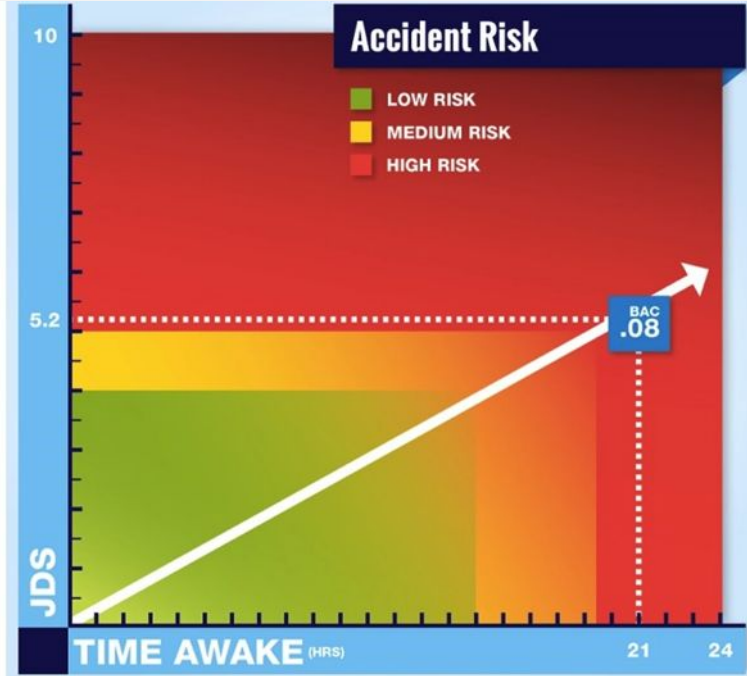
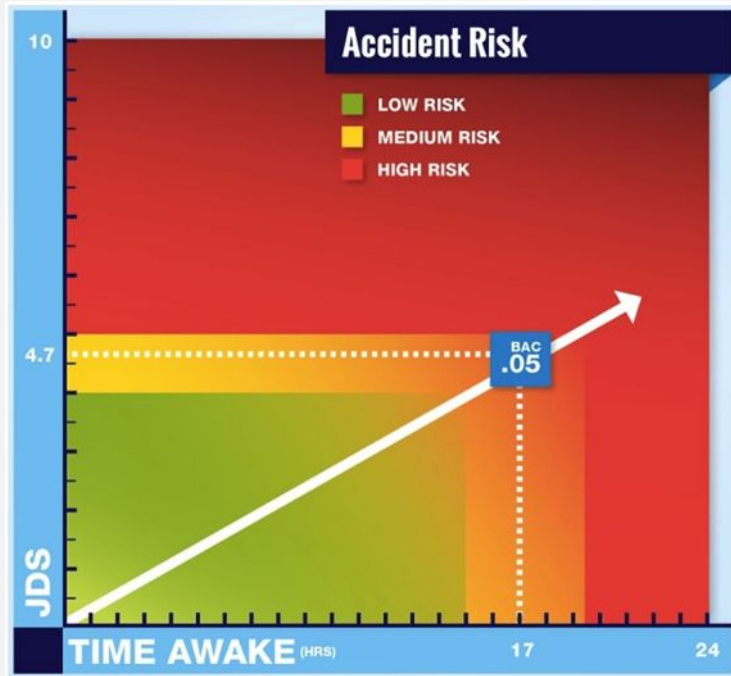
Figure 3 - Drivers divided according to sleepiness, number of accidents and BMI, in percentages $p < 0.05$; BMI: body mass index

Focus on the Person BEFORE the Task

Predict and Prevent Accidents

Research on the Individual Risk Factors

Sleepiness is Equivalent to Alcohol Intoxication when it comes to Accidents



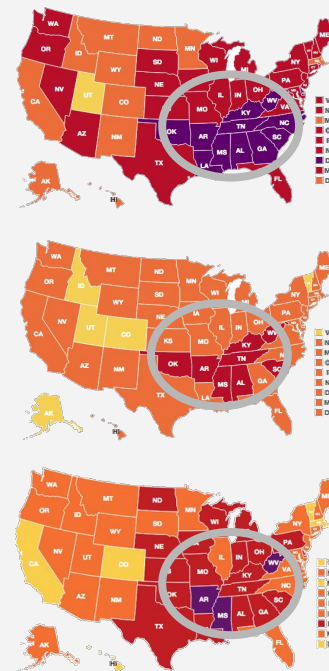
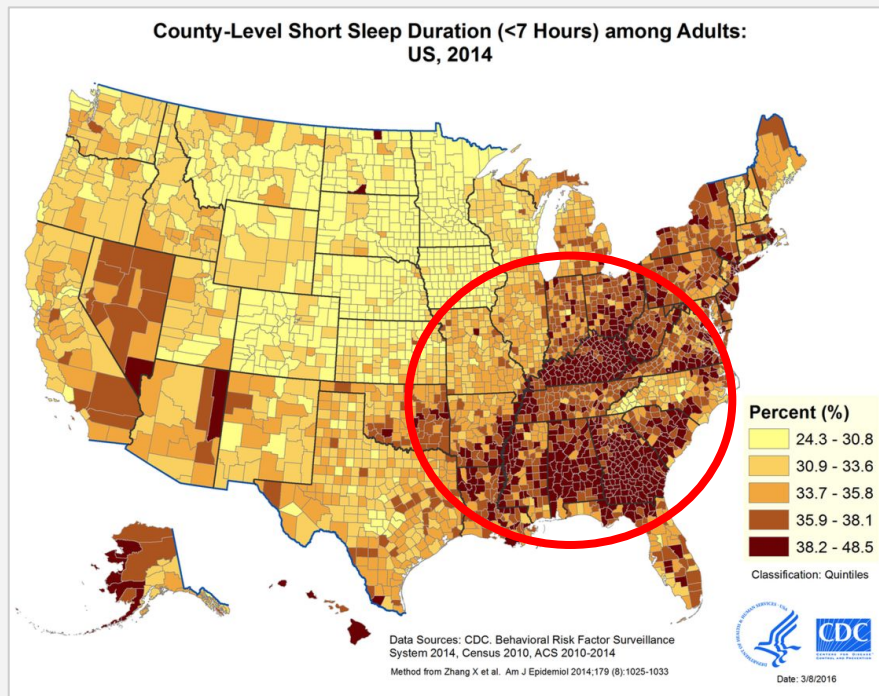
Williamson AM and Feyer AM. Moderate sleep deprivation produces impairments in cognition and motor performance equivalent to legally prescribed levels of alcohol intoxication. *Occup Environ Med* 2000;57:649-55

Research on People with Chronic Diseases

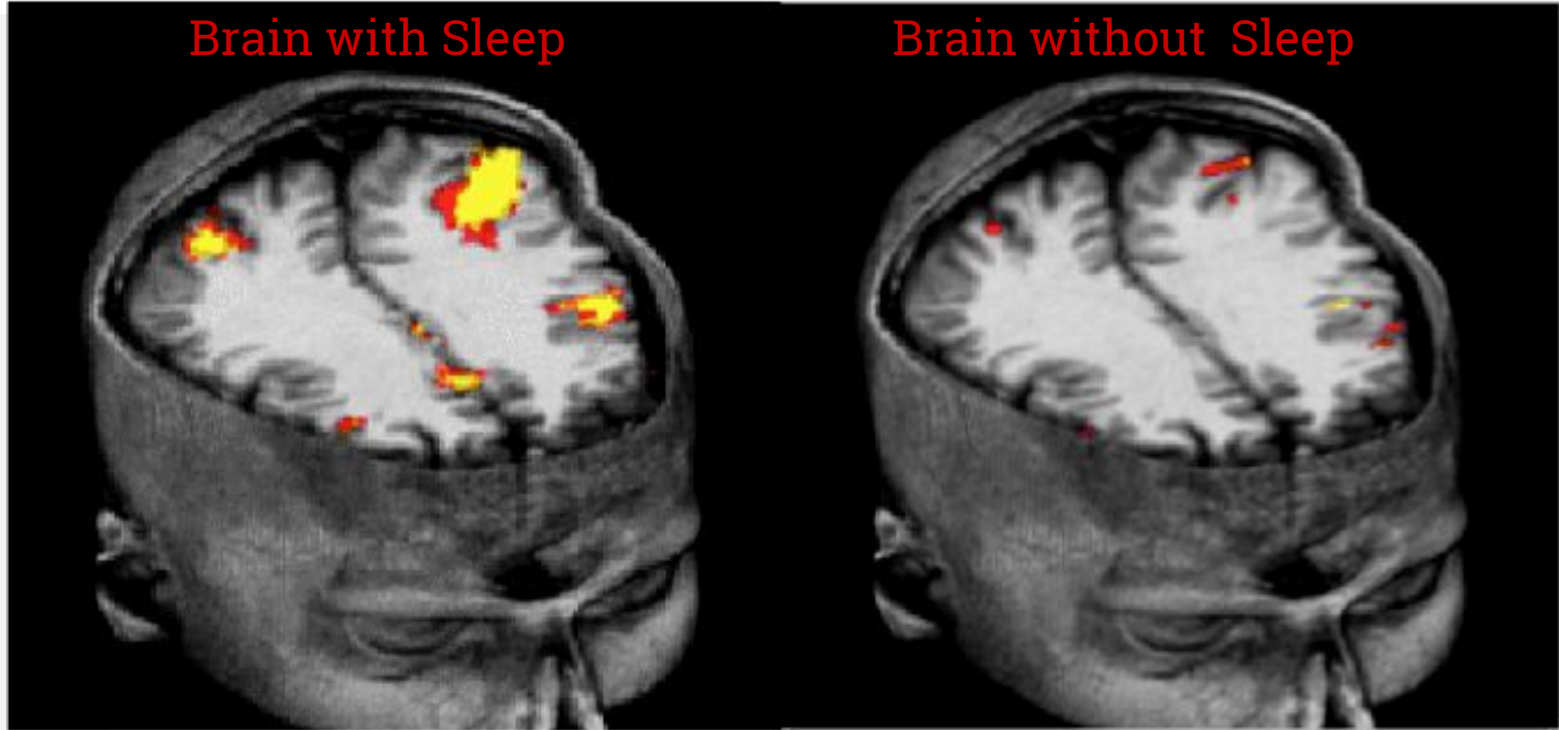
Data Demonstrates Poor Sleep May Drive Disease

Over 1/3 of US adults Do Not sleep 7 or more hours/night

Adults in the Southeast and Appalachian Mountains had the lowest average sleep times



Sleep Deprivation Affects All Cognitive Skills

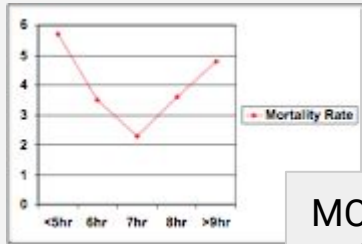
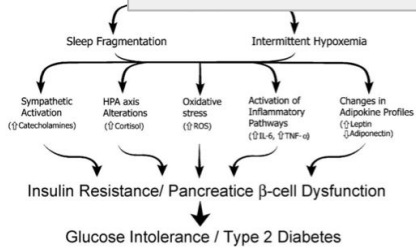


Sleep - Normal Activity & Preserved Performance

Sleep Deprivation - Loss of Activity & Loss of Performance

Body System Functions Depend on Sleep

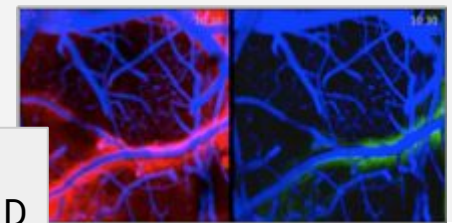
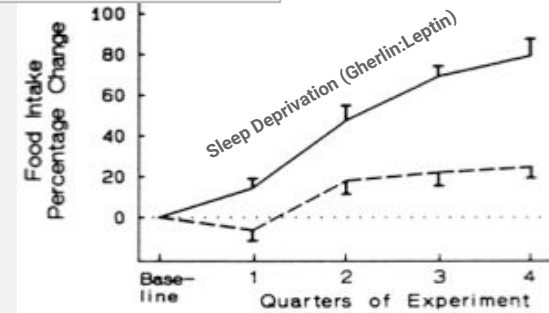
CHRONIC DISEASES ACCELERATE



MORTALITY RISK INCREASES 4 FOLD



LOSE HORMONAL APPETITE REGULATION

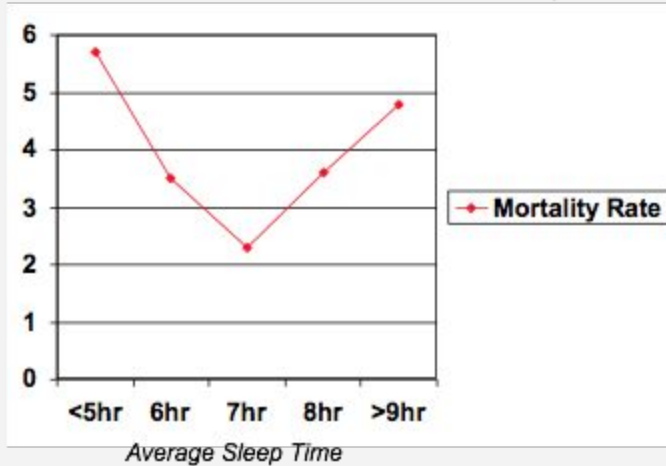


TOXIC WASTE PRODUCTS BUILD IN BRAIN

Adapted from: http://www.huffingtonpost.com/2014/01/08/sleep-deprivation_n_4557142.html

Sleep Duration is Correlated with Sickness Absence from Work

10,308 British civil servants followed 17 years



3,760 working men and women 7.2 years

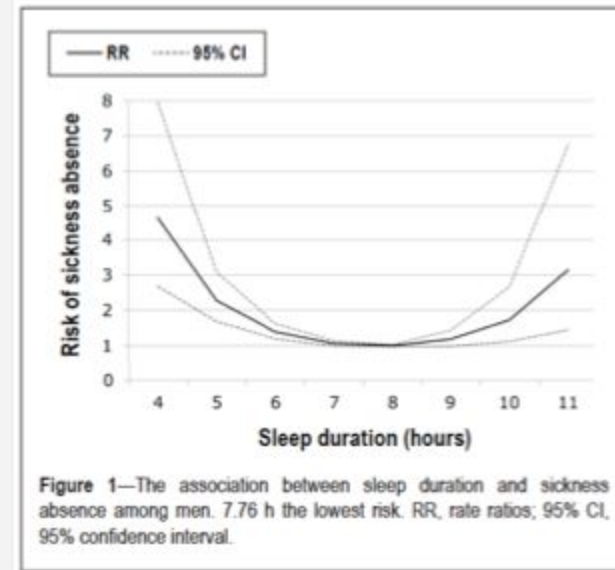


Figure 1—The association between sleep duration and sickness absence among men. 7.76 h the lowest risk. RR, rate ratios; 95% CI, 95% confidence interval.

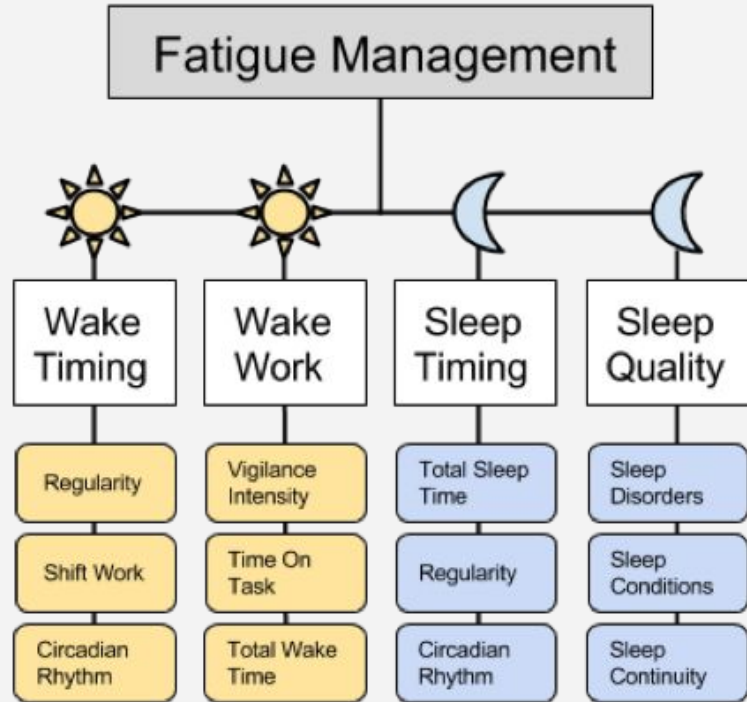
(Ferrie et al., Sleep 2007)

(Lallukka T et al., Sleep and sickness absence: a national representative register-based follow-up study SLEEP 2014;37(9):1413-25)

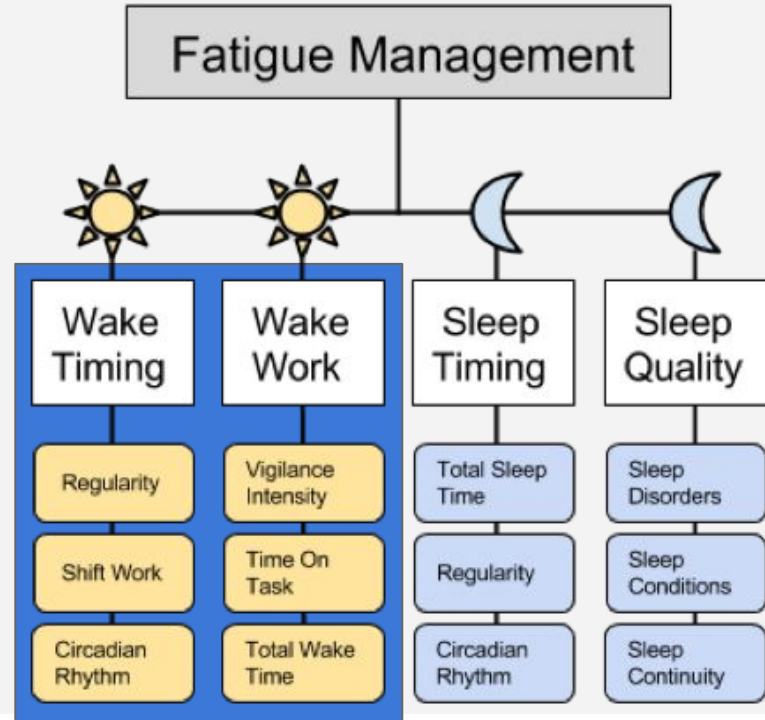


A New Model
of Fatigue
Management

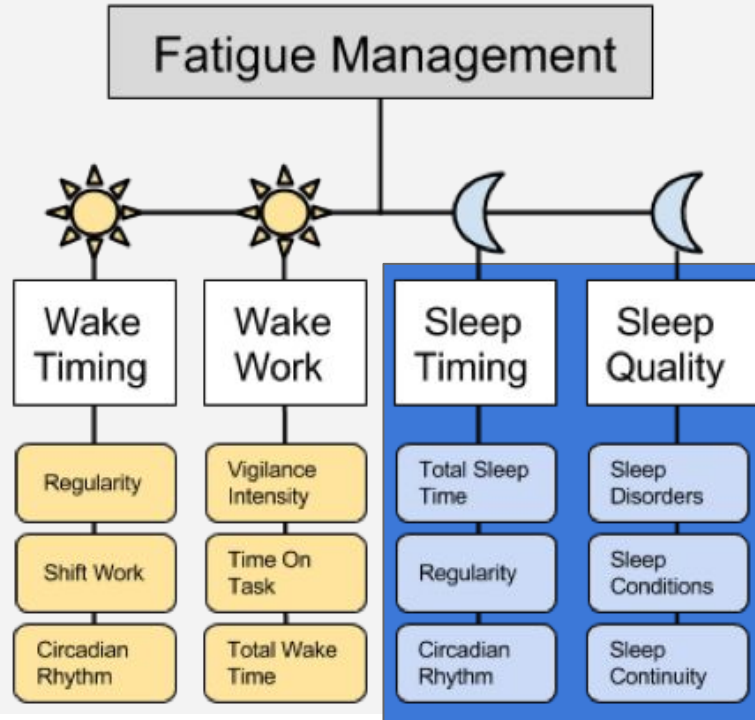
Workplace Fatigue Management



Many Safety Sensitive Workplaces Know...



Most Workplaces Do Not Know...



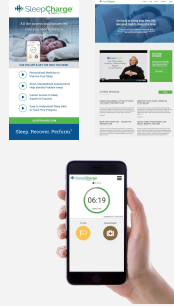
Engaging a Large Mobile Population

AWARENESS

Wellness Programs
DM Programs
HR Programs
Safety & Risk

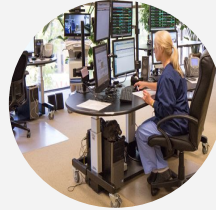
Connect™
Integration Points

ENGAGEMENT



SleepCharge™
Member Experience

GUIDANCE



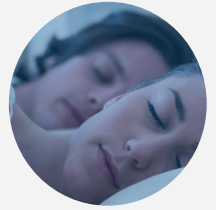
Newton™
Guidance Logic

INTERVENTIONS



Restful™
Pathway Solutions

MANAGEMENT

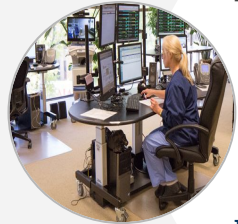


Restful™
Continuous Care

SUPPORT: Engagement Plan Design + Sleep Coaches + Sleep Therapists + Physicians

Integrated Pathways Create Complete Solutions

GUIDANCE



Resourceful™
Tech & Materials

Mindful™
Thoughts
& Behaviors

Powerful™
Physical Performance

Newton™
Guidance Logic

INTERVENTIONS



Breathing

Mind

Body

Rhythms

Connected

Restful™
Pathway Solutions

MANAGEMENT



Tracking



**Sleep
Coaching**

**Therapy
Support**

**Multi-Level
Telemedicine**

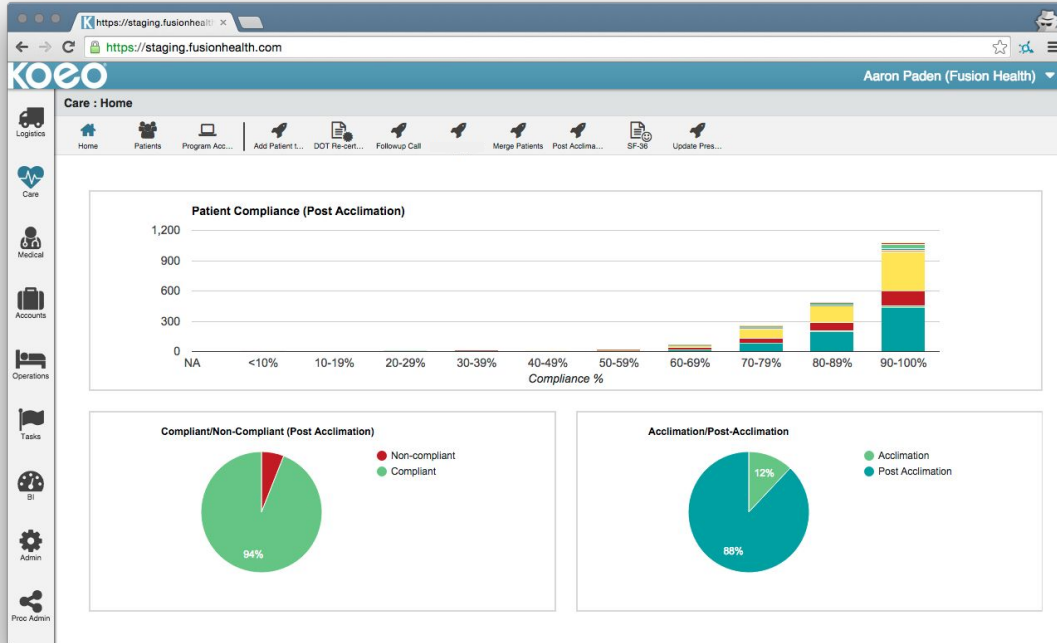
Connected

Restful™
Continuous Care



Fatigue Management:
A New KPI for
Business

Obstructive Sleep Apnea Outcomes



For All Participants (n=4,508)

Avg Age	49.8 yr
Male / Female	90% / 10%
Avg AHI reduced from	34 to 1.5
Avg. Daily Adherence	96%
Days Use/Wk	6.4 days
Hours Use/Day	6.1 hours
Avg. Program Retention	94% over 6 yr

Obstructive Sleep Apnea Outcomes

n = 2,844 Professional Drivers

Avg Hrs Succ Use	n	Avg Hrs Use/Day	Avg Days/Week	Test AHI	AHI 30d	Effort 30d	Compliance 30d
> 8	435	8.7	6.9	49.4	1.3	98	96.0
7.5-7.9	199	7.8	6.9	30.0	1.5	99	97.0
7.0-7.49	295	7.2	6.9	32.0	1.2	98	95.0
6.5-6.9	344	6.7	6.9	39.0	1.2	98	94.0
6.0-6.49	344	6.3	6.8	37.3	1.3	96	91.0
5.5-5.9	354	5.7	6.7	37.8	1.3	94	88.0
5.0-5.49	260	5.3	6.6	37.8	1.3	92	85.0
4.5-4.9	258	4.8	6.4	33.9	1.1	89	82.0
4.0-4.49	164	4.3	6.1	34.3	1.3	83	76.0
< 4.0	191	2.9	4.6	33.9	1.8	62	54.0

> 4 hrs

2653

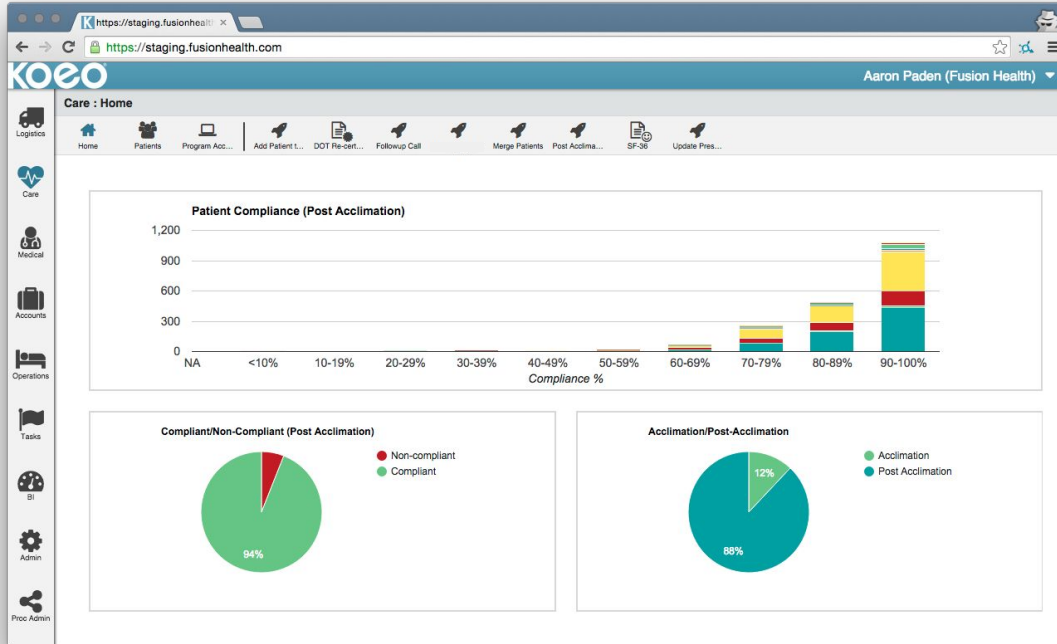
6.3 hrs/day

6.7 days/wk

94% Effort

90% Compliance

Obstructive Sleep Apnea Outcomes



For Professional Drivers (n=2,653)

Avg AHI reduced from 37 to 1.4

Use \geq 6hr/night 60%

Days Use/Wk 6.7 days

Hours Use/Day 6.3 hours

QoL changes at 90 days:

Mental Health +19%

Physical Health +14%

Vitality +25%

Health Change +38%

Two Year Matched Cohort Study



Measure	Subjects	Matched Cohort	12 Mo (n=96/96)	24 Mo (n=85/85)
Med/Pharm. Costs	22.4%	45.1%	-22.8% pts	-22.7% pts
ER Visits	11.5%	-5.4%	•-88.9% pts	16.9% pts
Hospital Admits	49.3%	84.4%	-60.0% pts	-35.1% pts
Hospital Days	70.0%	394.0%	-923.1% pts	-324.0% pts
Preventable Accidents	-44.9%	30.3%	❖-68.8% pts	★-75.2% pts
Incidents	8.2%	19.6%	10.6% pts	-11.3% pts

•p = 0.06
❖p = 0.02
★p = 0.04

Subjects

100 employees and 100 matched cohort recruited from existing employer population based on need for OSA evaluation

Matched Cohort

From claims over same time period – matched for age, gender, BMI, medical conditions, job, and cost quartile. No OSA diagnosis noted in claims data.

Fortune 500 Company



VITALITY, SOCIAL FUNCTIONING, HEALTH,
PRODUCTIVITY AND RETENTION

Employees are

50%
healthier

25%
more productive



SLEEPINESS, ACCIDENT INCIDENTS AND
HEALTHCARE COSTS

Reduced accident
rates by

55%
in 1 Year

SAVED
56%

in
healthcare
claims
costs

SleepCharge™ Program Outcomes by FusionHealth

Fortune “200” Company



EFFECTIVE DELIVERY OF CARE
SIGNIFICANT PHYSICAL & MENTAL BENEFITS

Health Care delivery
improved by

160%

Employees show

34%
more **Vitality**



MANUFACTURING ERROR RATES
HEALTH CARE SPEND WASTE

In 3 months,

40% +
less **Errors in**
Production

SAVED
\$250k

in Health Care System
Expense Waste



APPENDIX

2016 FMCSA MRB OSA Recommendations



CURRENT STATE OF FMCSA GUIDANCE
FOR OBSTRUCTIVE SLEEP APNEA

Jeffrey S. Durner, MD, PhD
Chief Medical Officer

2016 Federal Motor Carrier Safety Regulations, § 392.3

"No driver shall operate a commercial motor vehicle, and a motor carrier shall not require or permit a driver to operate a commercial motor vehicle, while the driver's ability or alertness is so impaired, or so likely to become impaired, through fatigue, illness, or any other cause, as to make it unsafe for him/her to begin or continue to operate the commercial motor vehicle."

All commercial drivers whose medical certificate expires on or after May 21, 2014, at expiration of that certificate must be examined by a medical professional listed on the National Registry of Certified Medical Examiners.

Medical Examiners must enroll, complete necessary training, pass a certification test in order to be listed on the National Registry, and are required to submit to retraining every 5 years and be recertified by examination every 10 years¹.

In order to drive with the diagnosis of Obstructive Sleep Apnea (OSA), a driver must demonstrate medically approved control of OSA for at least 70% of the time (i.e., using positive airway pressure (PAP) therapy) or must obtain medical certification that their OSA has been adequately controlled and does not represent a cause for disqualification to carry out the duties of a truck driver (i.e., annual sleep testing following surgery or other treatment for OSA).

Changes in 2016 Medical Review Board (MRB) Recommendations vs 2012

Sleep Testing required with BMI is now ≥ 40 vs. 2012 guidance ≥ 35

Sleep Testing required with BMI ≥ 33 with three or more of the contributing factors listed below vs 2012 suggestion of sleep testing based on the following:

	% of Truck Drivers
a. Small or recessed jaw	unknown
b. Small airway (Mallampati Scale score of Class 3 or 4)	unknown
c. Neck size ≥ 17 inches (male), 15.5 inches (female)	70 ²
d. Hypertension (treated or untreated)	45
e. Type 2 Diabetes (treated or untreated)	33
f. Hypothyroidism (untreated)	35
g. Age 42 and above	60
h. Family History	unknown
i. Male or postmenopausal female	95
j. Experienced a single-vehicle crash	unknown

Drivers must be referred to a board certified sleep physician vs 2012 recommendation, that drivers be referred to "a clinician with relevant experience".

¹ <https://nationalregistry.fmcsa.dot.gov/nRP-ubbCtU/MeDiX/AsstExam>

² 70% is an estimate based on the high rate of obesity in trucking (74% with a BMI ≥ 30)

Testing Criteria

Individuals with a **BMI of 40** or greater, and
Individuals with a **BMI 33 to 40** with at least three or more:

Hypertension (treated or untreated)
Type 2 Diabetes (treated or untreated)
History of stroke, coronary artery disease, or arrhythmias
Micrognathia or retrognathia (receding chin)
Loud Snoring or Witnessed apneas
Small airway (Mallampati Classification of Class 3 or 4)
Neck Size of > 17 inches (male), 15.5 inches (female)
Hypothyroidism (untreated)
Age 42 and above
Male or postmenopausal female

2016 FMCSA MRB OSA Recommendations



CURRENT STATE OF FMCSA GUIDANCE FOR OBSTRUCTIVE SLEEP APNEA

Jeffrey S. Durner, MD, PhD
Chief Medical Officer

2016 Federal Motor Carrier Safety Regulations, § 392.3

"No Driver shall operate a commercial motor vehicle, and a motor carrier shall not require or permit a driver to operate a commercial motor vehicle, while the driver's ability or alertness is so impaired, or so likely to become impaired, through fatigue, illness, or any other cause, as to make it unsafe for him/her to begin or continue to operate the commercial motor vehicle."

All commercial drivers whose medical certificate expires on or after May 21, 2014, at expiration of that certificate must be examined by a medical professional listed on the National Registry of Certified Medical Examiners.

Medical Examiners must enroll, complete necessary training, pass a certification test in order to be listed on the National Registry, and are required to submit to retraining every 5 years and be recertified by examination every 10 years¹.

In order to drive with the diagnosis of Obstructive Sleep Apnea (OSA), a driver must demonstrate medically approved control of OSA for at least 70% of the time (i.e., using positive airway pressure [PAP] therapy) or must obtain medical certification that their OSA has been adequately controlled and does not represent a cause for disqualification to carry out the duties of a truck driver (i.e., annual sleep testing following surgery or other treatment for OSA).

Changes in 2016 Medical Review Board (MRB) Recommendations vs 2012

Sleep Testing required with BMI is now ≥ 40 vs. 2012 guidance ≥ 35

Sleep Testing required with BMI ≥ 33 with three or more of the contributing factors listed below vs 2012 suggestion of sleep testing based on the following:

	% of Truck Drivers
a. Small or recessed jaw	unknown
b. Small airway (Mallampati Scale score of Class 3 or 4)	unknown
c. Neck size ≥ 17 inches (male); 15.5 inches (female)	70 ²
d. Hypertension (treated or untreated)	45
e. Type 2 Diabetes (treated or untreated)	33
f. Hypothyroidism (untreated)	35
g. Age ≥ 42 and above	60
h. Family History	unknown
i. Male or postmenopausal female	95
j. Experienced a single-vehicle crash	unknown

Drivers must be referred to a board certified sleep physician vs 2012 recommendation, that drivers be referred to "a clinician with relevant experience".

¹ <https://nationalregistry.fmcsa.dot.gov/NRP/ubbcl/med/0/Asst/Exam>

² 70% is an estimate based on the high rate of obesity in trucking (74% with a BMI ≥ 30)

Given the Known Prevalence of Drivers
with a **BMI ≥ 33** who are also:
Male
Over 42
>17" Neck

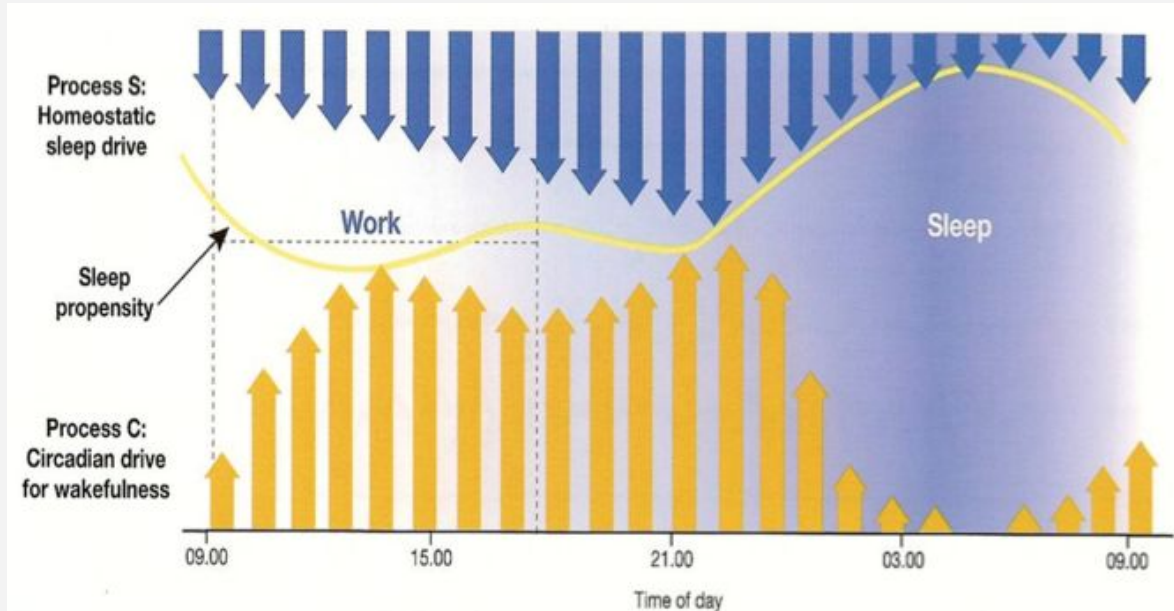
It is Expected that **56-64%** of All Current
Truck Drivers **May Require Sleep Testing**
&
As Many as **54%** May Require Treatment

Life on Earth Follows a Universal Rhythm

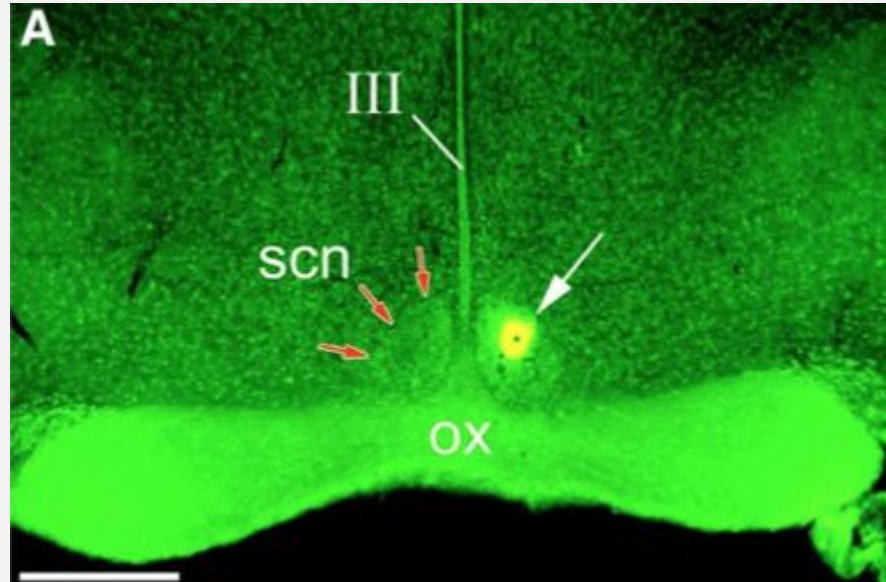


Circadian means “around the day”. All life on Earth has adapted to the regular 24 hour circadian pattern of our environment.

Light Activates Our Circadian Rhythm

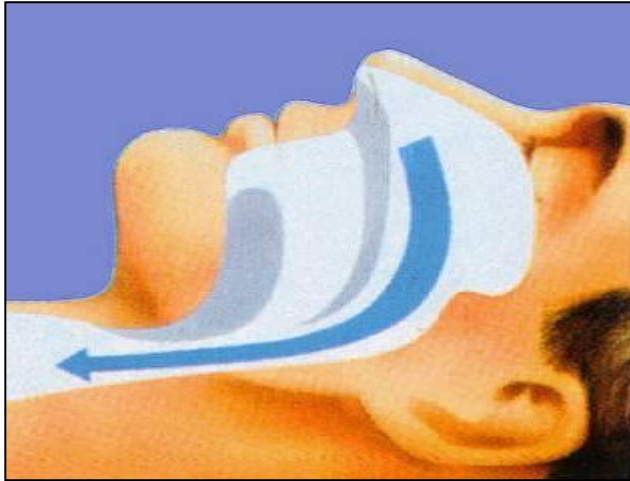


Our Brain Has Adapted to Create Sleep and Wake



In the human brain, 10,000 neurons fire together every 23.8 to 24.6 hours and drive us into wake and stop sleep. This intrinsic pattern is our Circadian Rhythm.

Obstructive Sleep Apnea (OSA)



OPEN

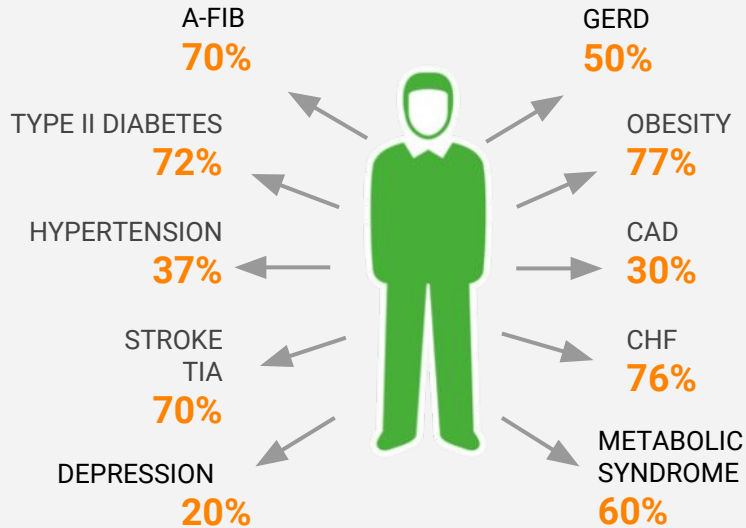


OBSTRUCTED

Apneas + Hypopneas / Hours of Sleep = **Apnea Hypopnea Index (AHI)**
(Normal ≤ 5 /hr) (Mild = 5.1-14.9/hr) (Moderate 15-29.9/hr) (Severe ≥ 30 /hr)

OSA is a SILENT KILLER

OSA PREVALENCE IN CHRONIC DISEASES



PREVALENCE OF CHRONIC DISEASES IN OSA POP

Prevalence of Sleep Disorder Related Conditions	Sleep Apnea Multiplier
Obesity	6.4x
Hypertension (HTN)	3.2x
Coronary artery disease (CAD)	4.1x
Peripheral vascular disease (PVD)	3.0x
Cardiac dysrhythmias	4.0x
Cerebrovascular disease, ischemic (eg., ischemic stroke)	4.1x
Cerebrovascular disease, hemorrhagic (eg., hemorrhagic stroke)	1.2x
Congestive Heart Failure (CHF)	6.3x
Diabetes mellitus (DM)	3.8x
Hyperlipidemia	2.8x
Pulmonary heart disease	6.0x
Gastroesophageal reflux disease	3.7x
Iron deficiency anemia	2.8x
Depression	1.6x
Headache, migraine/vascular type	2.0x
Headache, non-migraine type	2.8x

Einhorn et al. Endocrine Prac 2007; O'Keefe and Patterson Obes Surgery 2004; Tasali E et al., OSA and type 2 diabetes. Chest 2008;133:496-506; Sjostron et al. Thorax 2002, Bassetti et al. Sleep; 1999, Schafer et al. Cardiology 1999; Oldenburg et al. Eur J Heart Failure, 2007; Harvard Med School & McKinsey Co. The Price of Fatigue Report: the surprising economic costs of unmanaged sleep apnea, December, 2010; National Institute of Health, Centers for Disease Control and Prevention; Lee J. et al. Poor-quality sleep is associated with metabolic syndrome in Korean adults, Tohoku J Exp Med 2013;231:281-91; Tasali E et al., OSA and metabolic syndrome. Proc Am Thorac Soc 2008;5:207-17; Parish JM et al., Relationship of metabolic syndrome and OSA. J Clin Sleep Med 2007;3(5):467-72; Goyal SK and Sharma A, atrial fibrillation in OSA. World J of Cardiol 2013;5(6):157-63; Kanagala R et al., OSA and the recurrence of AFib. Circulation 2003;107:2589-94; Jung H et al., GERD and sleep disorders. J Neurogastroenterol Motil 2010;16(1):22-29; Basoglu OK et al., OSA and GERD-the importance of obesity and gender. Sleep Breath 2015;19(2):585-92; Sharafkhaneh A et al., Association of psychiatric disorders and OSA in large cohort. Sleep 2005;28(11):1405-11; Gupta MA et al., OSA and psychiatric disorders-a systematic review. JCSM 2015;11(2):165-75.

Integrated Pathways Create the Solution

GUIDANCE



Resourceful™
Tech & Materials

Mindful™
Thoughts
& Behaviors

Powerful™
Physical Performance

Newton™
Guidance Logic

INTERVENTIONS



Breathing

Mind

Body

Rhythms

Connected

Restful™
Pathway Solutions

MANAGEMENT



Tracking



Sleep
Coaching

Therapy
Support

Multi-Level
Telemedicine

Connected

Restful™
Continuous Care

Diagnosing OSA

HOME



MOBILE



LABORATORY



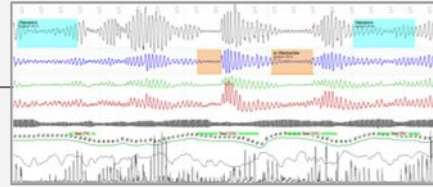
SUPPORT



TEST TYPE



INTERPRETATION



RESULTS

12% Inconclusive
&
66% Positive on
Mobile Retest

98% Conclusive

MEDICAL REPORTING

TREATMENT HISTORY REPORT

FusionHealth APEIA TEST INTERPRETATION REPORT

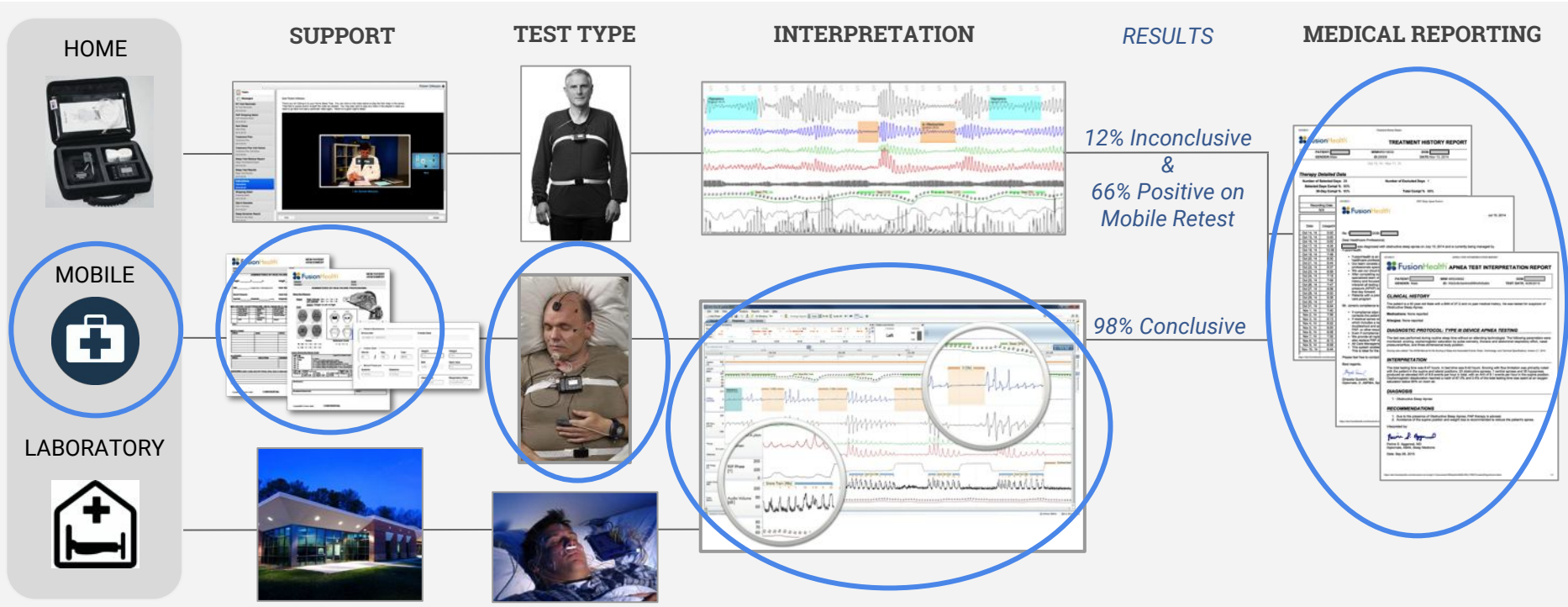
CLINICAL HISTORY

DIAGNOSTIC PROTOCOL, TYPE & DEVICE APEIA TESTING

INTERPRETATION

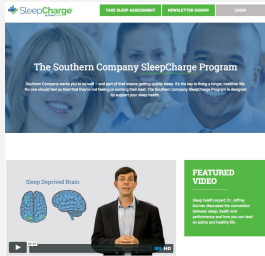
RECOMMENDATIONS

Diagnosing OSA for Professional Drivers

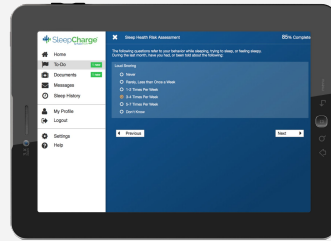


User-Centered Engagement

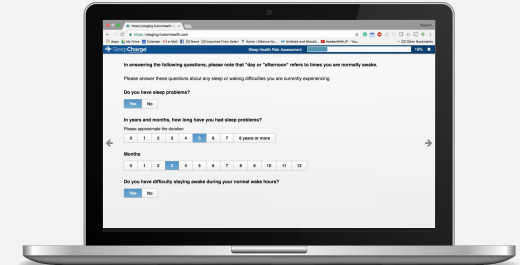
SleepCharge
Client Website



SleepCharge
Mobile Platform App



SleepCharge
Web App



= SEAMLESS EXPERIENCE + CONTINUOUS SUPPORT