Arkansas Trucking Association

Sleep Apnea: The Science

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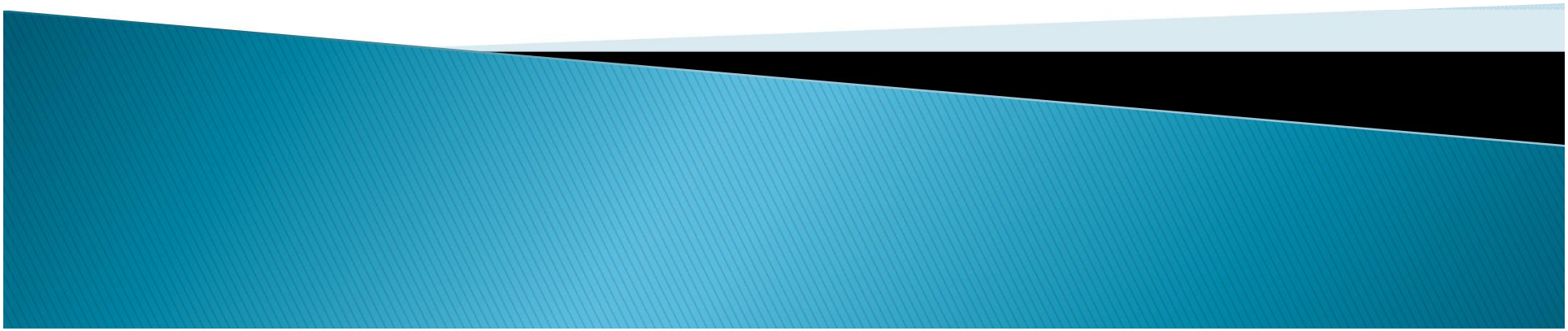
SleepSafe Drivers



DEFINITION OF OSA

Normal

Obstructed

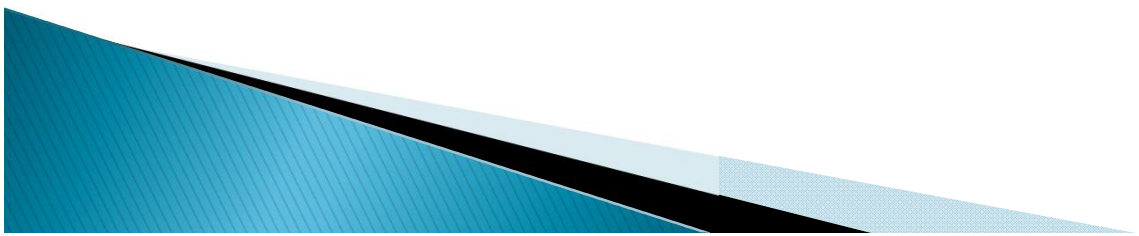
OSA (Obstructive Sleep Apnea) occurs when the upper airway repeatedly collapses during sleep, causing cessation of breathing (apnea) or inadequate breathing (hypopnea) and sleep fragmentation.

KEY SIGNS/SYMPTOMS OF OSA

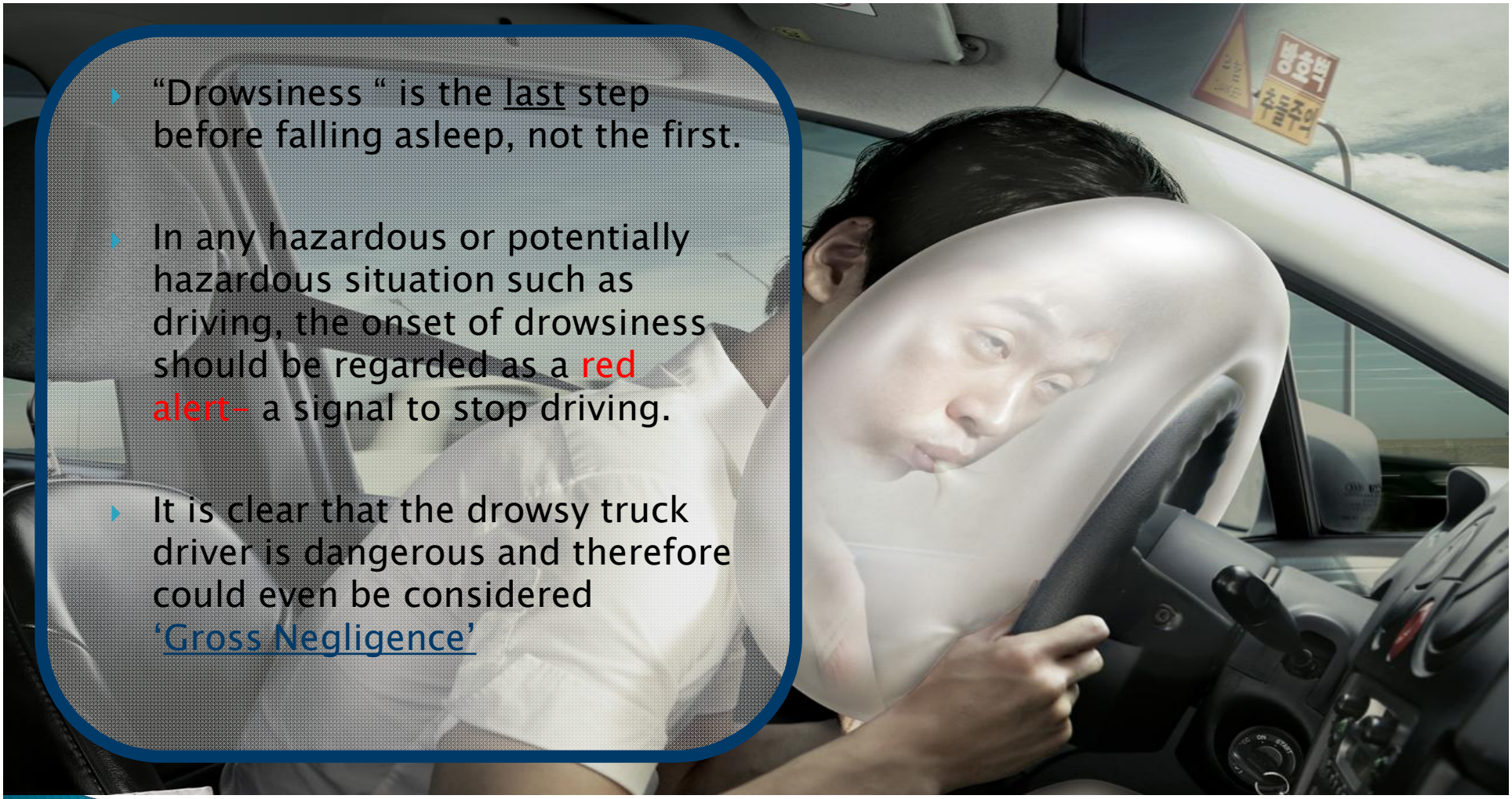
- Excessive daytime sleepiness
- Loud snoring
- Pauses in breathing at night
- Waking up gasping or choking
- Witnessed snoring or pauses in breathing
- High blood pressure

FYI……

- A word about MICROSLEEPS
  - People don't have to LOOK sleepy to make mistakes
  - The brain can take short "naps" even in the middle of performing a task
  - Safety procedures can be performed "automatically" without thought or recognition of warnings



What Legal Could State:



- "Drowsiness " is the last step before falling asleep, not the first.
- In any hazardous or potentially hazardous situation such as driving, the onset of drowsiness should be regarded as a red alert– a signal to stop driving.
- It is clear that the drowsy truck driver is dangerous and therefore could even be considered 'Gross Negligence'

FACTS

28% of Truckers are at Risk for OSA, at 4-7 times higher crash risk

- Fatigue is a contributing factor in up to 35% of motor vehicle crashes

Driving a vehicle is a complex task requiring the coordination and integration of many skills

- Cognitive
- Perceptual
- Motor-control (control of muscles)
- Decision-making

Excessive daytime sleepiness can influence these skills negatively

[1]Young et al, 1997; [2]Horstmann et al 2000; [3]Barbe et al, 1998; [4]Dingus et al, 2006

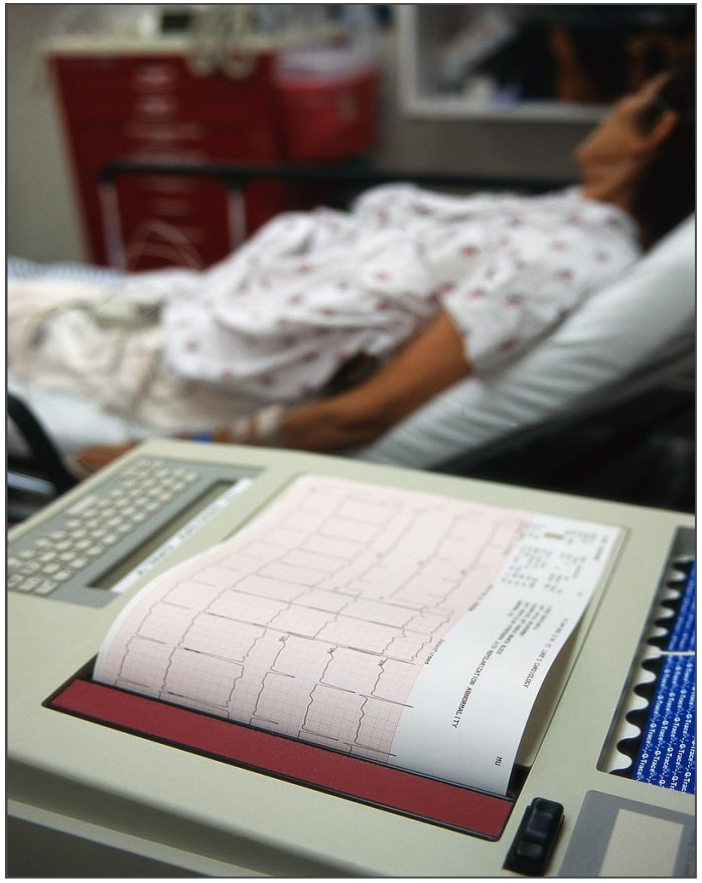
POTENTIAL HEALTH CONSEQUENCES IF UNTREATED

Short-Term

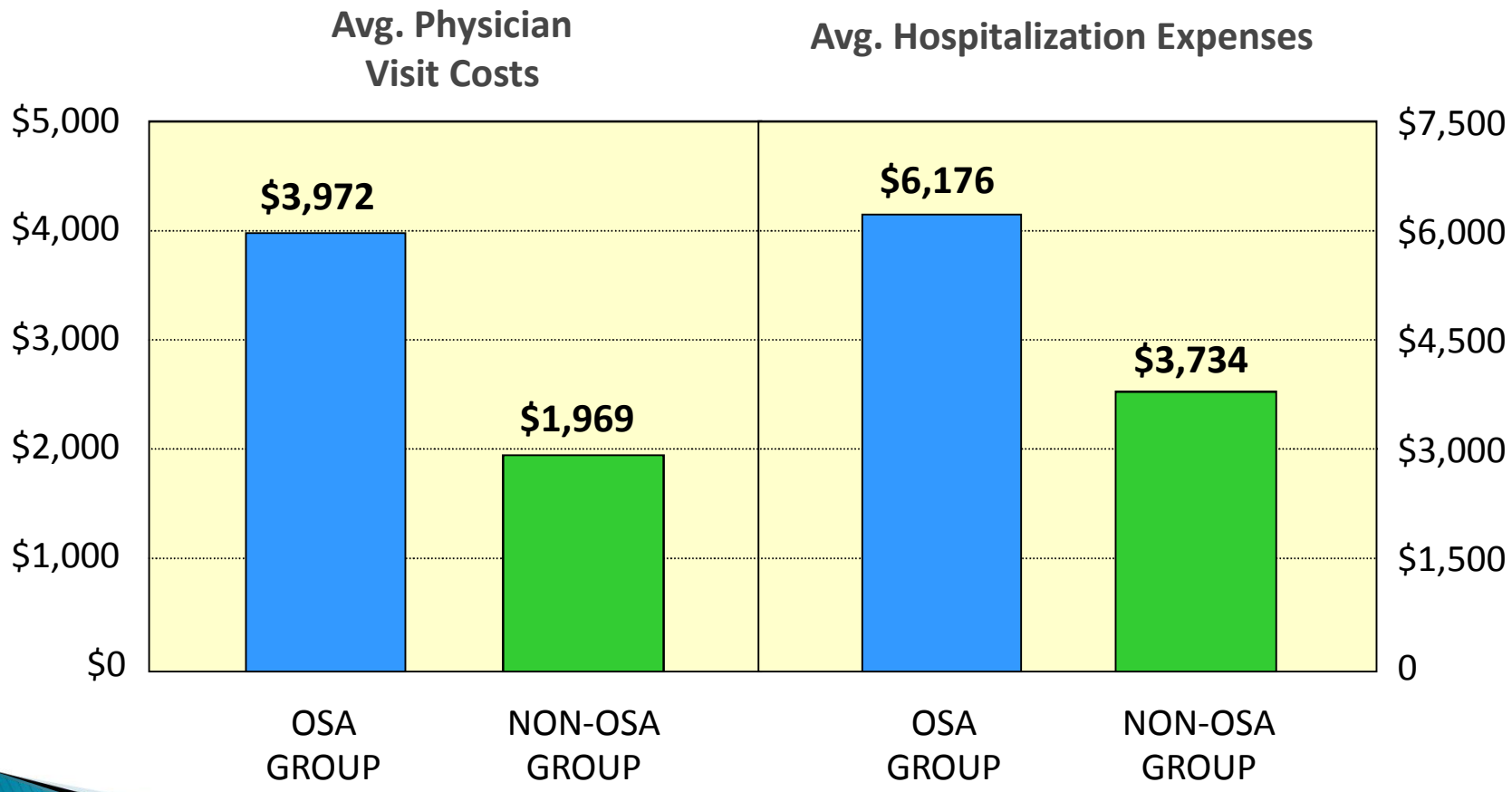
- Vehicular accidents
- Excessive sleepiness
- Decreased quality of life
- Neurocognitive and performance deficits

Long-Term

- Hypertension
- Heart disease
- Heart attack
- Arrhythmias
- Stroke
- Impaired glucose tolerance



THE IMPACT OF OSA ON UTILIZATION COSTS



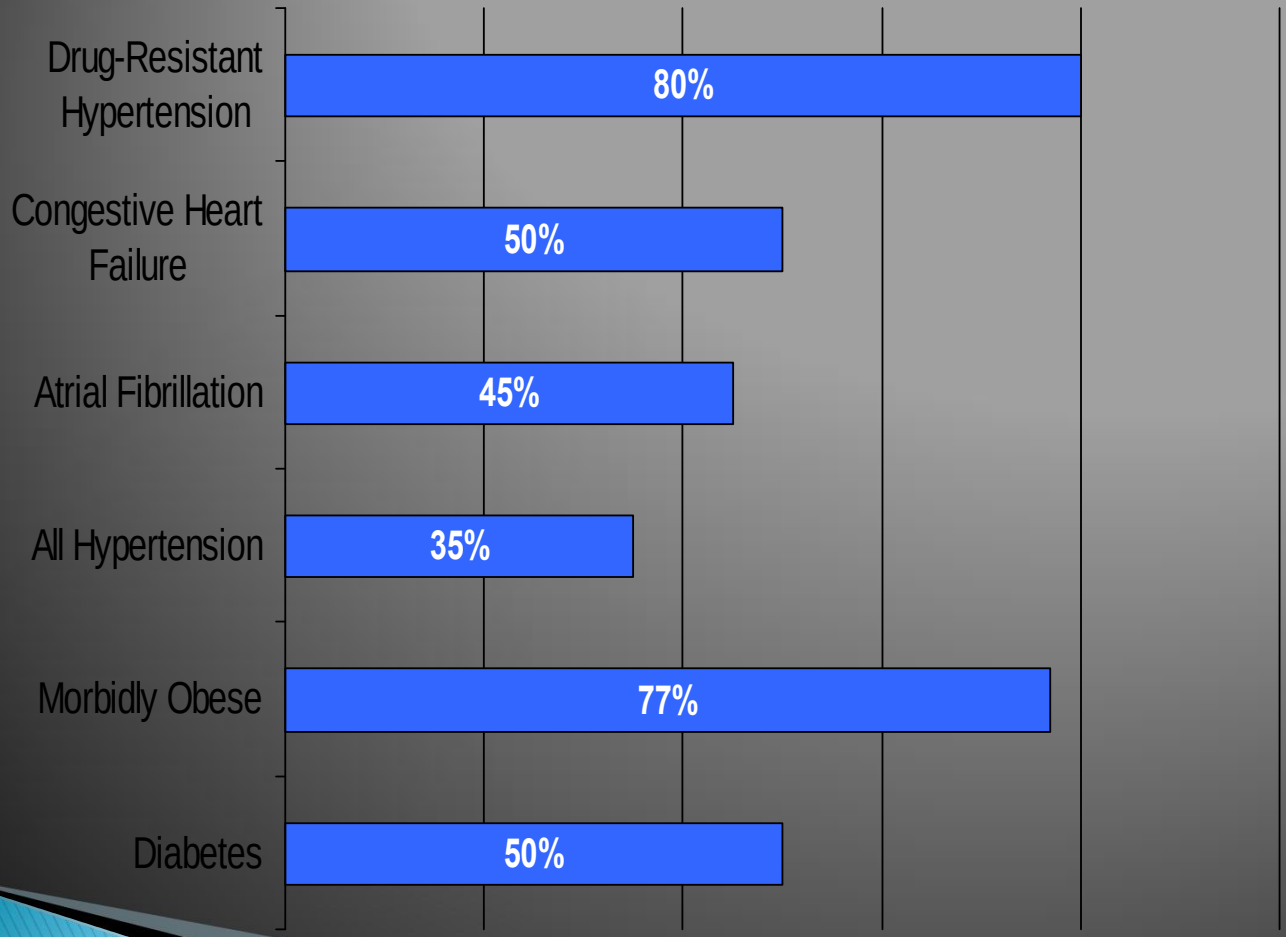
[1] Kryger, et al. OSA Patients Use More Health Care Resources Ten Years Prior to Diagnosis. Sleep Research Online 1998:1(1):71-74

Three of the Top Healthcare Expenditures within the Trucking Industry:

- Hypertension
- Diabetes
- Cardiovascular Disease

Sleep apnea helps cause and worsen them all

Prevalence of Sleep Apnea Co-morbidities



Logan et al.
J. Hypertension 2001

Javaheri et al.
Circulation 1999

Somers et al.
ATS Pres. 2004

Sjostrom et al.
Thorax 2002

O'Keefe, Patterson.
Obes Sugery 2004

Einhorn et al.
Amer Diab 2005

THE LINK BETWEEN OSA AND HYPERTENSION

- > 40% of patients presenting with OSA have daytime hypertension (HTN)[1]
- 30 to 50% of patients with HTN have OSA[2]
- Even mild OSA is a risk factor for HTN[3, 6]
- Patients with untreated OSA may be resistant to their anti-hypertensive medications[4]
- Even small decreases in blood pressure may help to decrease the risk of heart attack and stroke[5]

[1]Silverberg, et al., Curr Hypertens R 2001
2 Kraicze, et al., AJRCCM 2000
3 Bixler, et al., Arch Intern Med 2000
4 Logan, et al., J Hypertens 2001
5 Heinrich, et al., Circulation 2002
6 Neito, et al., Jama 2000

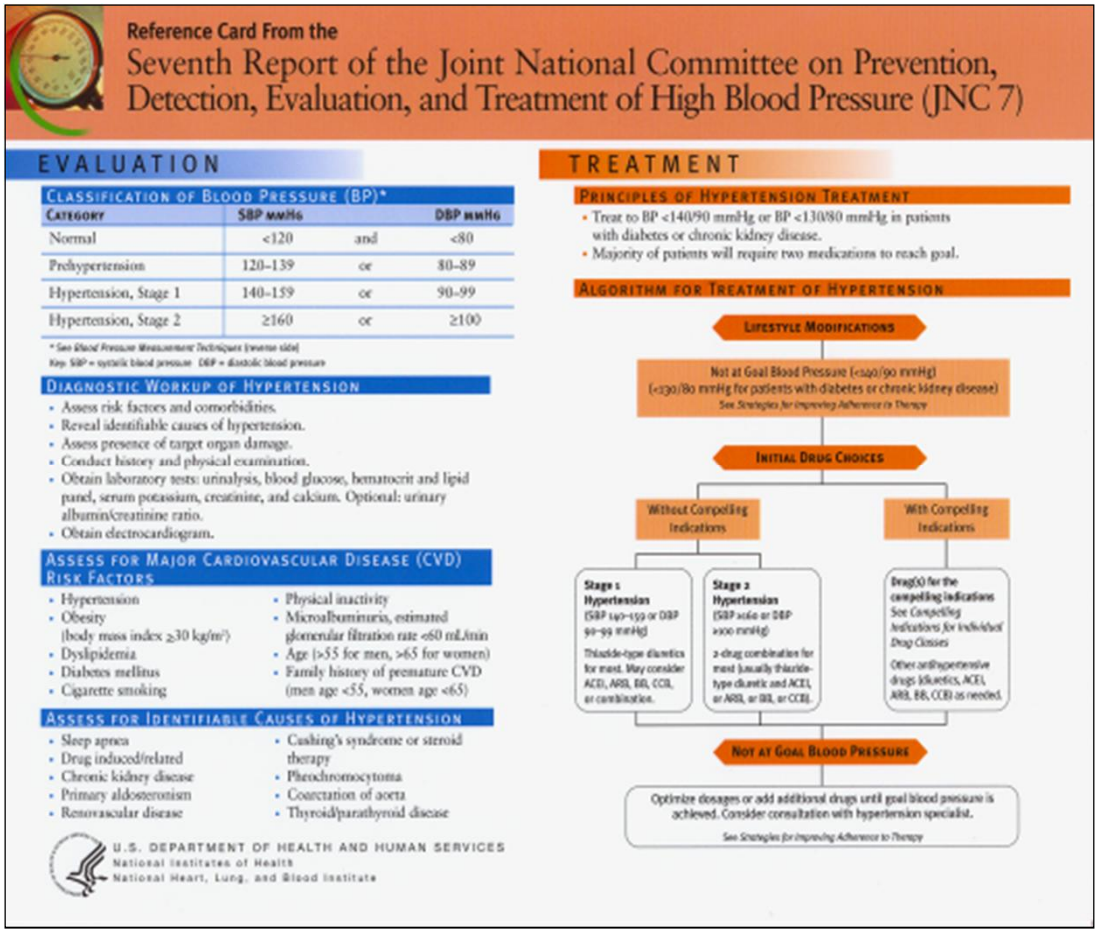
RECOMMENDATIONS FOR HYPERTENSION

The Joint National Committee on Prevention, Detection, Evaluation and Treatment of High Blood Pressure (JNC 7) recommends screening patients for OSA when they have:

New onset hypertension

OR

Refractory hypertension[1]



Reference Card From the

Seventh Report of the Joint National Committee on Prevention, Detection, Evaluation, and Treatment of High Blood Pressure (JNC 7)

EVALUATION

Classification of Blood Pressure (BP)*

Category	SBP mmHg		DBP mmHg
Normal	<120	and	<80
Prehypertension	120–139	or	80–89
Hypertension, Stage 1	140–159	or	90–99
Hypertension, Stage 2	≥160	or	≥100

* See Blood Pressure Measurement Technique (reverse side)
Key: SBP = systolic blood pressure DBP = diastolic blood pressure

Diagnostic Workup of Hypertension

- Assess risk factors and comorbidities.
- Reveal identifiable causes of hypertension.
- Assess presence of target organ damage.
- Conduct history and physical examination.
- Obtain laboratory tests: urinalysis, blood glucose, hematocrit and lipid panel, serum potassium, creatinine, and calcium. Optional: urinary albumin/creatinine ratio.
- Obtain electrocardiogram.

Assess for Major Cardiovascular Disease (CVD) Risk Factors

- Hypertension
- Obesity (body mass index ≥30 kg/m²)
- Dyslipidemia
- Diabetes mellitus
- Cigarette smoking
- Physical inactivity
- Microalbuminuria, estimated glomerular filtration rate <60 mL/min
- Age (>55 for men, >65 for women)
- Family history of premature CVD (men age <55, women age <65)

Assess for Identifiable Causes of Hypertension

- Sleep apnea
- Drug induced/related
- Chronic kidney disease
- Primary aldosteronism
- Renovascular disease
- Cushing's syndrome or steroid therapy
- Pheochromocytoma
- Coarctation of aorta
- Thyroid/parathyroid disease

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
National Institutes of Health
National Heart, Lung, and Blood Institute

TREATMENT

Principles of Hypertension Treatment

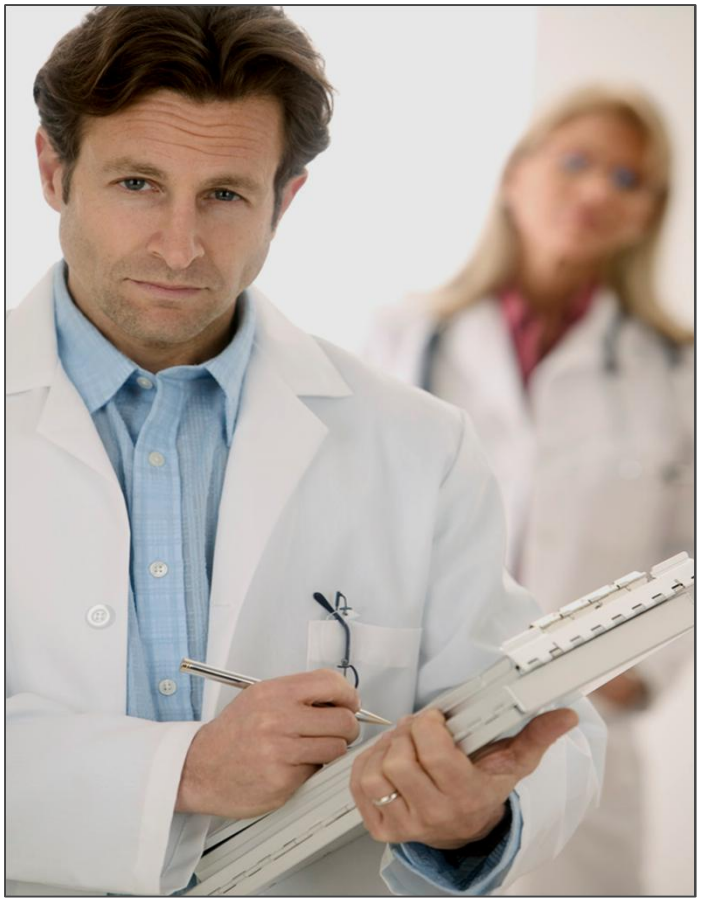
- Treat to BP <140/90 mmHg or BP <130/80 mmHg in patients with diabetes or chronic kidney disease.
- Majority of patients will require two medications to reach goal.

Algorithm for Treatment of Hypertension

1 Chobanian, A., et al., Hypertension 2003; 42:1206-1252

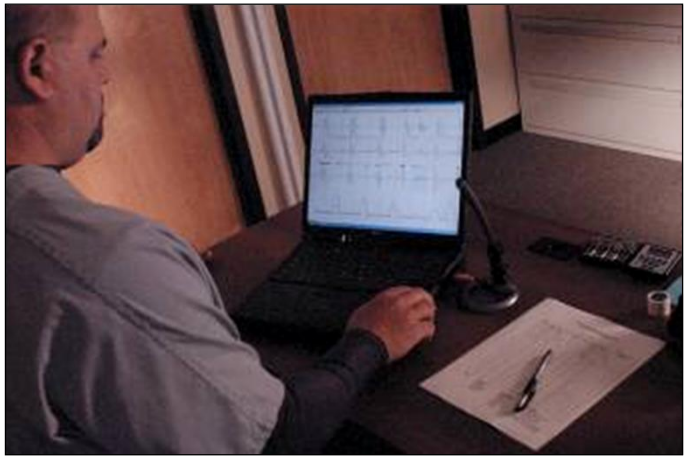
DIAGNOSIS OF SLEEP APNEA

- Physical exam and history
- Questions about sleep & symptoms that may occur during the day, indicating a problem with sleep
- Diagnosed by having a PSG/Lab or portable sleep study performed during drivers normal sleep hours
- Remember, signs and symptoms are poor predictors of disease severity



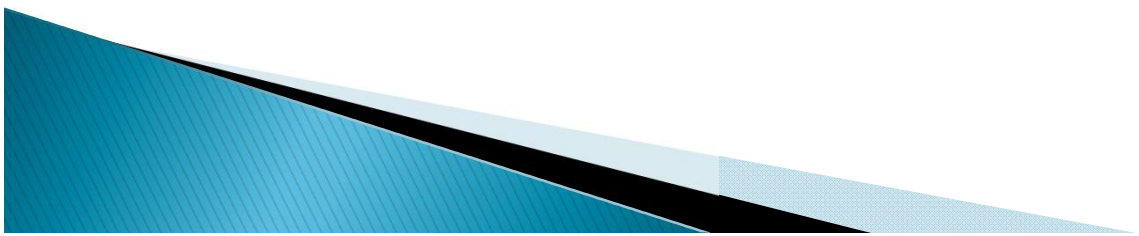
WHAT IS A SLEEP STUDY?

- A sleep study is a painless study that is done in an ambulatory or laboratory setting to monitor patient's sleep and breathing patterns
- The study may record the following during sleep:
  - Brain wave activity
  - Respiratory pattern
  - Heart rate
  - Chest movement
  - Leg movement
  - Eye movement
- Identification and treatment of the sleep disorder is the goal



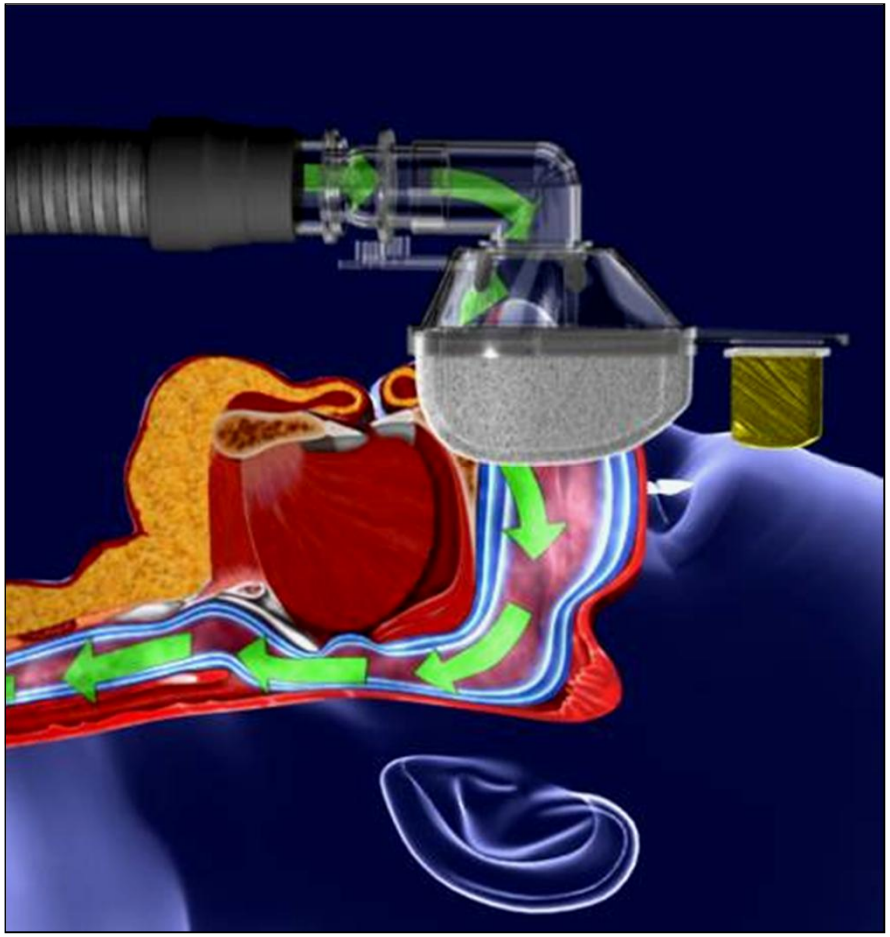
TREATMENT OPTIONS

- Oral appliances
- Positive airway pressure
  - Continuous positive airway pressure
  - Bi-level positive airway pressure
- Other (limited role)
  - Medications
  - Weight loss
  - Behavioral therapy
  - Oxygen



OSA THERAPY

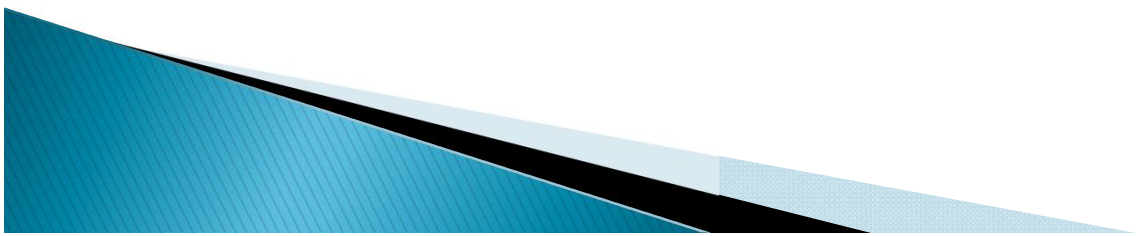
- Of those patients being treated for OSA, 70 – 80% utilize CPAP therapy with a nasal mask[1]
- CPAP provides positive pressure to provide a pneumatic splint for the patient's airway



1 Frost & Sullivan, Sleep Apnea Models, 2001

PAP THERAPY FOR PATIENTS WITH OSA

- CPAP
  - One level of pressure on inspiration and exhalation
  - Device may have the option to provide pressure relief in early exhalation
- Bi-level therapy
  - One level of pressure on inspiration and lower level of pressure on expiration
  - Device may have the option to provide pressure relief in early exhalation
- Auto titration therapy
  - Device pressure is adjusted based on airway dynamics and device algorithm



GOALS OF TREATING OSA WITH PAP

Short Term

- Maintain open airway
- Improve quality of sleep
- Alleviate daytime symptoms
  - Sleepiness
  - Moodiness/Impaired concentration/Memory loss
  - Morning headache

Long Term

- Reduce mortality and morbidity
  - Decrease cardiovascular consequences
  - Reduce sleepiness
- Improve quality of life

Marin, JM et. al Lancet 2005: 365:1046 - 1053

Summary

- 28.1% of truck drivers have sleep apnea
- 3-7x increased risk for crash
- OSA is co-morbid w/other costly & chronic diseases.
- Treatment can not only improve safety and driving performance, but other health outcomes.
- Treating all US drivers suffering from apnea would save $11.1B in collision costs and save 980 lives annually (Sassanai, et al. SLEEP 2004)

What should a sleep program contain?

- Consistency: Screen to Compliance Program
  - Communication and Support of Program: Top Down
  - Screening Criteria
  - Test Criteria
  - Diagnosis Criteria
  - Device Criteria
  - Compliance Criteria
    - Initial and Long-Term
  - Length of Medical Card: short vs. long cards
  - Employee Policies:
    - Pre-employment Criteria
    - "Discipline" Criteria

What should a sleep program contain?

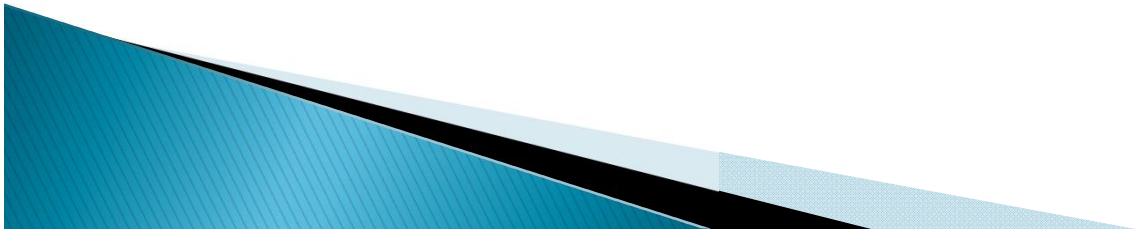
- Screening
- Testing (Home or In-Lab)
- Diagnosis by Physician, NP, PA-C
- Treatment Testing or Apap Titration
- Treatment Device for Drivers to Use
- Compliance Data
  - Hours of Use per day
  - Number of Days Used
  - Effective Treatment? (must show treated AHI)

Solutions for Fleets

- Cost Range for a Complete Program: $1800-$3600
  - (total package, for drivers DX with sleep apnea)
  - estimated at 28% of your total driver count.
  - 672,000 for 1000.00 driver fleet size (assuming middle price point of 2400.00)

- Utilization of low cost sleep apnea resources:
  - Use of sleep apnea companies, that provide turn-key coverage for all driver/medical flow steps.

  - Online or paper Screenings vs. Consults
    - Screen All drivers
    - Take action on: Moderate to Severe Risk
    - Consults for High Risk Drivers who Struggle



Solutions for Fleets

Utilization Continued

- Home Sleep Testing vs. In-Lab Sleep Studies
  - One test, in-home or cab, during driver's normal sleep time. Use APAP for home titration.
- Coaching for Compliance
  - Keep your Drivers Treated
- 24-hour Test to Treatment Turnaround Times
  - Keep your Drivers Driving…..

Solutions for Fleets

- What reimbursement models can be used?
  - Privately Funded by Fleet
  - Privately Funded by Driver
  - Mix of Fleet and Driver
    - Contract with sleep network that has multi-tier contracting in place for many health plans, or has a private pay discount, payment plan options.
    - sleep apnea and pap treatment is already a covered benefit under the majority of health plans
    - Fleet can consider covering co-pay, or deductible assistance, payroll deductions
    - Work with Provider Relations to remove driver portion for sleep codes, * meaning no co pay-deductions applied.

Solutions for Fleets

- Keep " External" Services to Minimum
  - *What internal resources does your Fleet have?*
    - DOT Examiners-talk with their admin team, what scope of practice do they have?
    - Manage the program internally.
      - Internal download capabilities
      - Ability to have non-compliant drivers " pushed" to safety.
      - Purchase DME and Compliance tools, and distribute them to drivers as needed, re-use compliance devices.
      - Use internal coaching, CPAP champions to help new drivers acclimate.
      - Train-the Trainer: minimize setup and operating costs.

Solutions for Fleets

Be wary of hidden, unspoken costs…

- *Avoid the Following:*
  - Unnecessary Consults and Follow-ups
  - In-Lab sleep studies for all Drivers
  - In-lab Titrations studies-followed by APAP Device
  - Testing 100% of drivers
  - Too many re-supplies
    - 2x year, plus cushions/filters, VS, quarterly.

FMCSA OSA REQUIRMENTS:

" likely updated language" from FMCSA

- All Drivers Screened.
- OSA Diagnosis precludes unconditional certification.

A driver with a DX of OSA can be certified if:

- The driver has untreated OSA AHI $\leq$ 20, AND the driver does not admit to experiencing sleepiness during major wake period, OR OSA is being effectively treated.
- Recertified annually through <u>compliance with PAP</u>
  - Compliance entails a minimum of 4 hrs/day 70% of days

Referral for Diagnosis

- Drivers must be referred if:
  - BMI≥35, OR
  - Judged AT RISK by way of:
    - Validated Questionnaire
    - Clinical Evaluation (considering risk factors below)
      - Advancing age
      - BMI≥28
      - Small or recessed jaw
      - Neck size ≥ 17 male, 15.5 female
      - Small airway (Mallampati Scale score of Class 3 or 4)
      - Family History
      - Hypertension (treated or untreated)
      - Type 2 Diabetes (treated or untreated)
      - Hypothyroidism (untreated)

Method of Diagnosis and Treatment

Diagnosed by:

- In-laboratory testing
- At-home polysomnography-with Chain of Custody
- All individuals with OSA should be referred to a clinician with relevant expertise.
- Adequate PAP pressure should be established an auto-titration system.

Conditional Certification

- Have AHI≥20 Compliant with PAP, OR
- Have undergone surgery pending post op findings
- Have BMI≥35 (pending sleep study) May be certified for 60 days
- Upon PAP compliance for 60 days, a 90 day card will be issued.
- Upon 90 days of compliance a one year certification card is issued.

Disqualification and Denied Certification

1. Reporting excessive sleepiness during the major wake period while driving OR
2. Experienced a crash while falling asleep OR
3. Experienced a single-vehicle crash OR
4. Have been found non-compliant in treatment per recommendation 1