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Thank you for joining ISMPP U today!

The program will begin promptly at 11:00 am EST

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Today's Program

- **Presenter**
  - Chris L. Pashos, PhD
- **Moderator**
  - Michael Wittek, MSW
- **Q&A follows the presentation–but feel free to send in questions as you have them**

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REAL WORLD. REAL VALUE.

HEOR 201
How Valuable is this Medical Technology?
The Role of Health Economics and Outcomes Research

Chris L. Pashos, PhD
November 18, 2009
ISMPP U

Outline: The Role of Health Economics & Outcomes Research

I. Linking Clinical Trials to the Real World

II. Understanding the Burden of Disease

III. Projecting the Value of Interventions

IV. Providing Real-World Proof

I. Linking Clinical Trials to the Real World

Marketplace Evolution

- The challenges to achieve market success have changed over time
  - Before the 1980s, regulatory approval assured commercial success of safe and efficacious products
  - In the 1980s and 1990s, regulatory approval with some economic and Patient Reported Outcomes data to support reimbursement assured commercial viability
- The present and future
  - Regulatory approval with data in controlled settings gets sponsors to the starting line
  - To achieve commercial success, sponsors need to marshal resources efficiently and effectively to plan and implement an integrated market access, marketing and sales effort
  - Sponsors must dramatically improve their ability to produce scientifically valid real-world evidence to demonstrate the value of their products

Sir Michael Rawlins' statements in October 2008 to the Royal College of Physicians

- "… we need a new approach to analysing clinical evidence"

- "… RCTs' appearance at the top of the heirarchy of evidence is inappropriate… need a diversity of approaches that involve the totality of the evidence base"

- "…observational studies are also useful… can provide an important source of evidence about both the benefits and harms of therapeutic interventions"

AMCP Format for Formulary Submissions, Version 3.0

- In October 2009, the AMCP released the latest version of its dossier submission guidelines.
- The one substantive change from format v2.1 is the requirement to include published data from retrospective observational studies, meta-analyses, assessments of adherence or persistence, studies of patient preference, and other HEOR analyses.

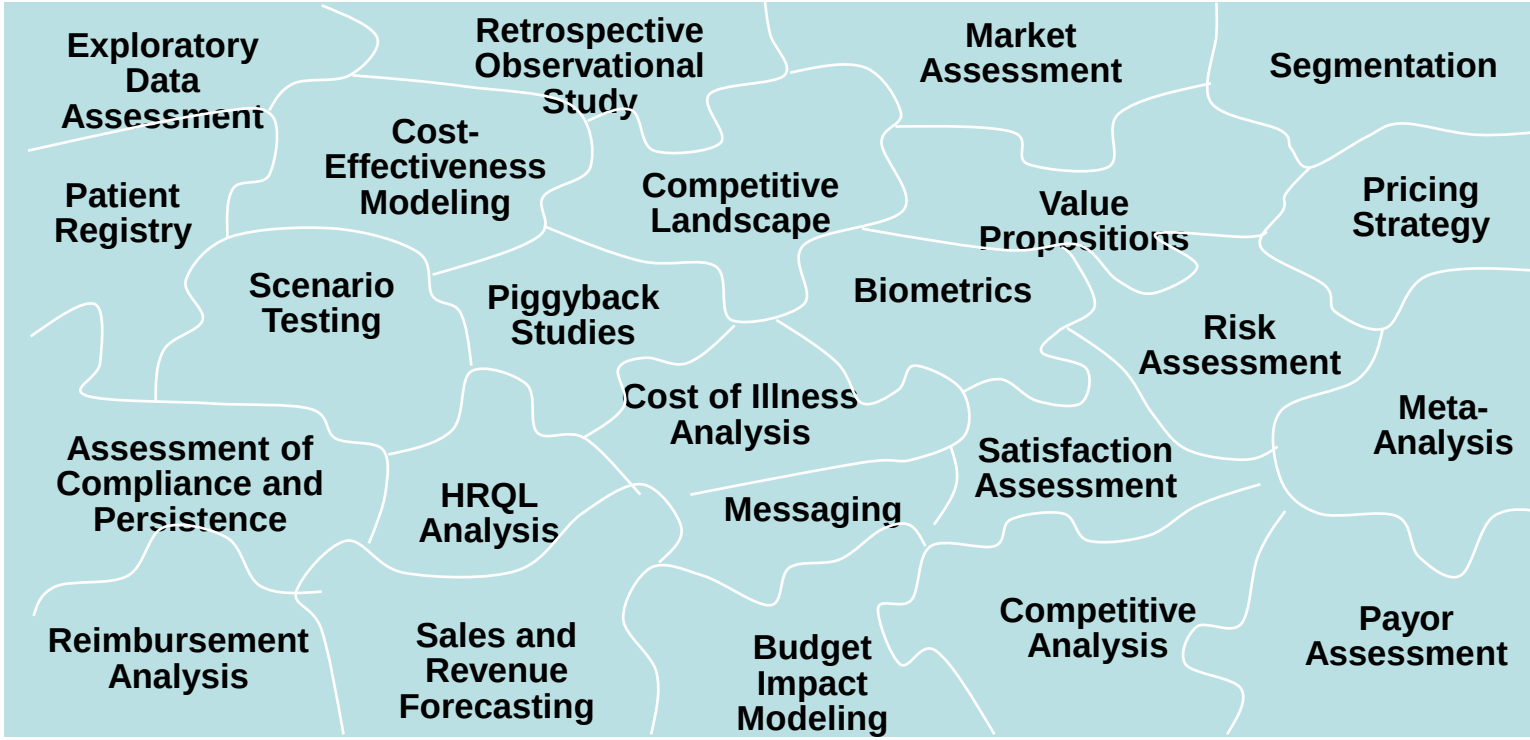
Context: Key Stakeholders

- Clinicians
- Physician and disease organizations
- Health technology industry
- Health technology assessment agencies
- Health insurers / payers
- Regulatory authorities
- Patients

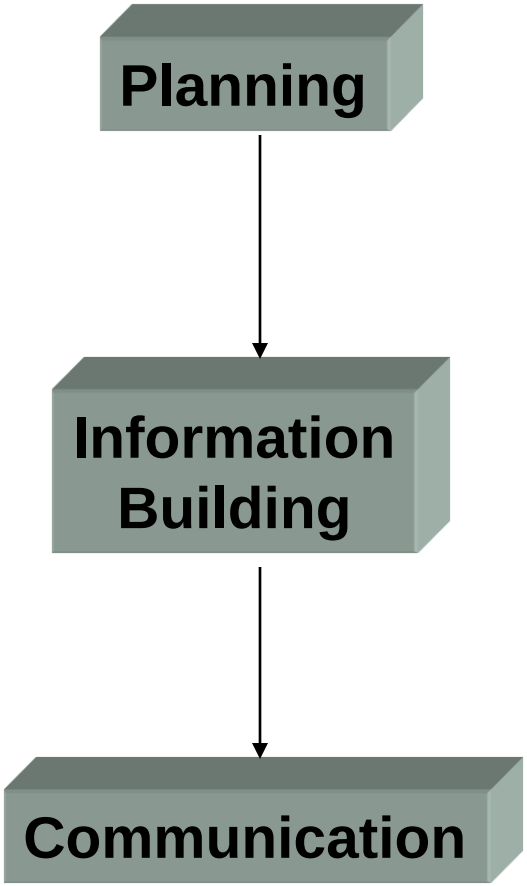
Health Economics and Outcomes Research

- Involves the collection and analysis of data on the use of health care products and services and on their clinical, economic, and patient-reported outcomes.
- Synthesizes both real-world and clinical trial data to provide the sponsor and key stakeholders - physicians, health care providers, regulators, payers and patients – via publications, a comprehensive view of the evidence on the burden of disease and the value of specific products in reducing that burden.

Health Economics and Outcomes Research Involves and Integrates Tools from Multiple Disciplines



Value Demonstration and Risk Management



Strategic value planning and support

- Integrated market research and outcomes research
- Strategic pricing and positioning
- Strategic economic & outcomes research plans

Retrospective analyses & economic modeling

- Assessments of claims, medical chart, and epidemiology data
- Literature synthesis and meta-analysis
- Burden of illness and budget impact evaluations
- Cost effectiveness and cost-utility analyses

Prospective studies

- Patient registries and observational studies
- Piggyback studies in clinical trials
- Surveys of payers, physicians, patients, others

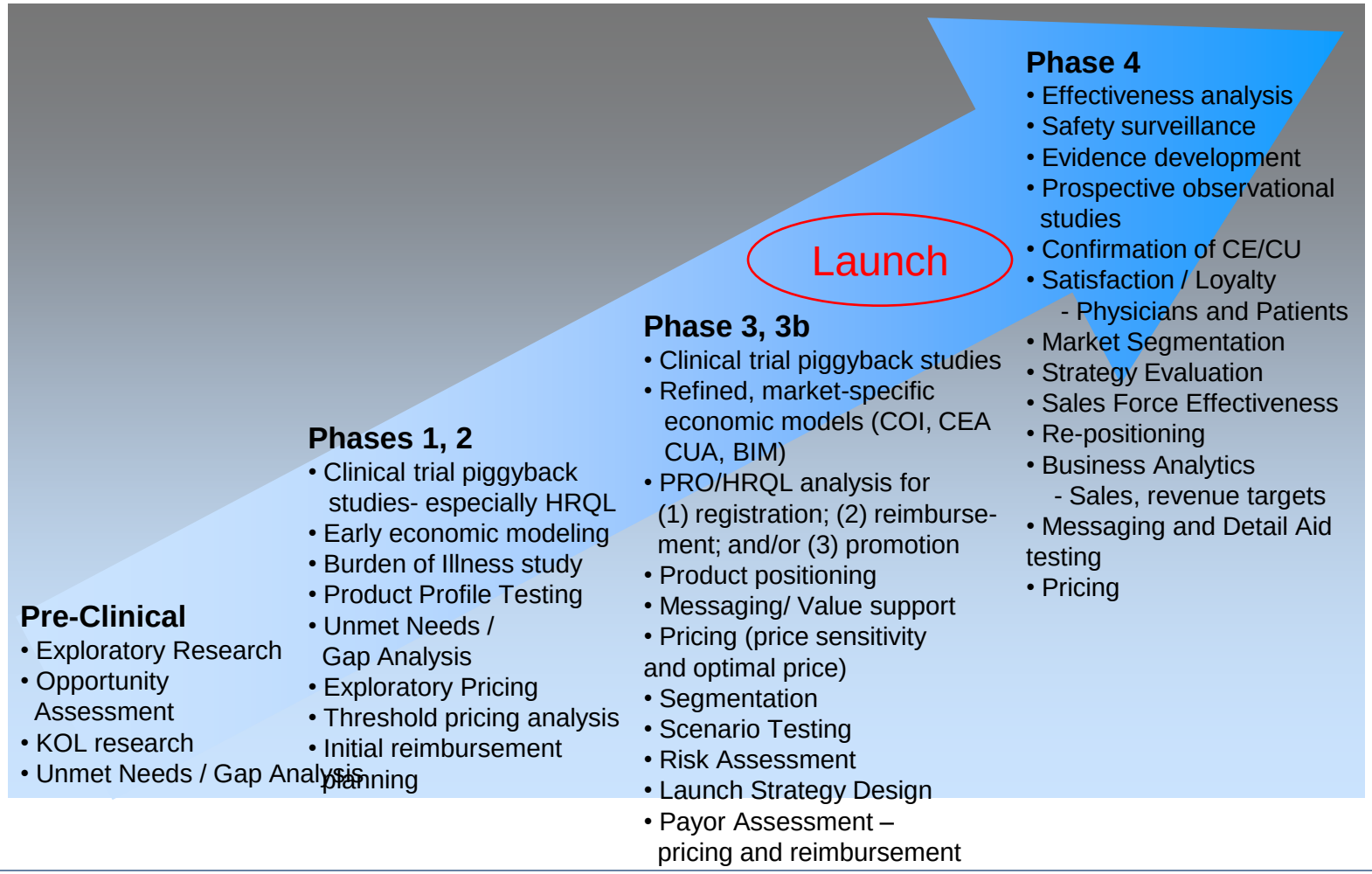
HRQL / PRO assessment

- Instrument development and validation: health-related quality of life, compliance, preference
- Design & analysis in registries, trials and surveys

Publications and presentations

Dossiers – global value and market-specific

Development and Commercialization

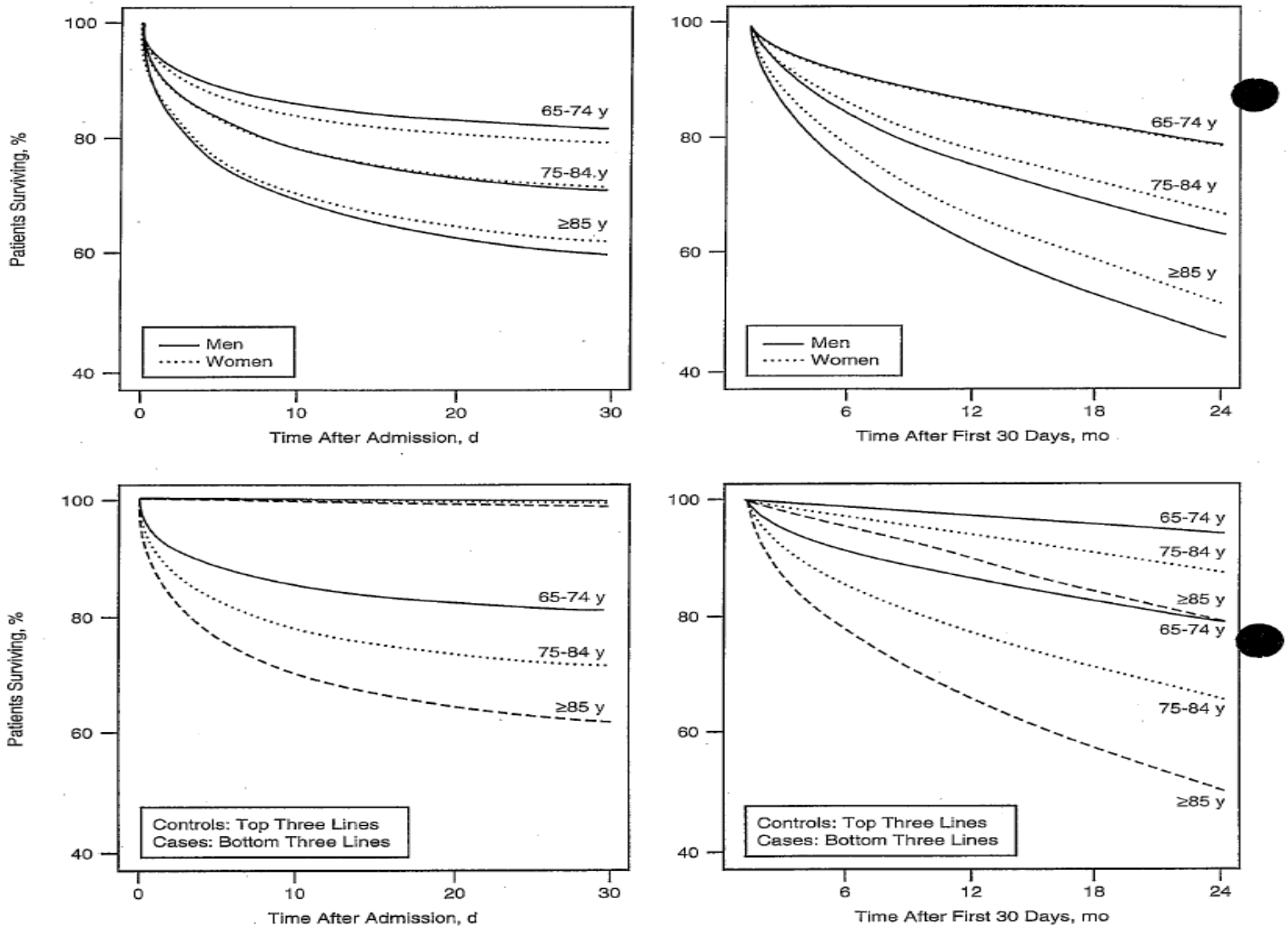


II. Understanding the Burden of Disease

Acute Myocardial Infarction in the Medicare Population

Process of Care and Clinical Outcomes

I. Steven Udvarhelyi, MD, SM; Constantine Gatsonis, PhD; Arnold M. Epstein, MD, MA; Chris L. Pashos, PhD; Joseph P. Newhouse, PhD; Barbara J. McNeil, MD, PhD



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ORIGINAL ARTICLE *Clinical haemophilia*

Physicians' preferences towards coagulation factor concentrates in the treatment of Haemophilia with inhibitors: a discrete choice experiment

WC LEE,* A. V. JOSHI,† S. WOOLFORD,‡ M. SUMNER,† M. BROWN,§ N. HADKER§ and C. L. PASHOS§

**Abt Associates Inc., Bethesda, MD; †Novo Nordisk Inc., Princeton, NJ; ‡Department of Mathematical Sciences, Bentley College, Waltham, MA; and §Abt Associates Inc., Lexington, MA, USA*

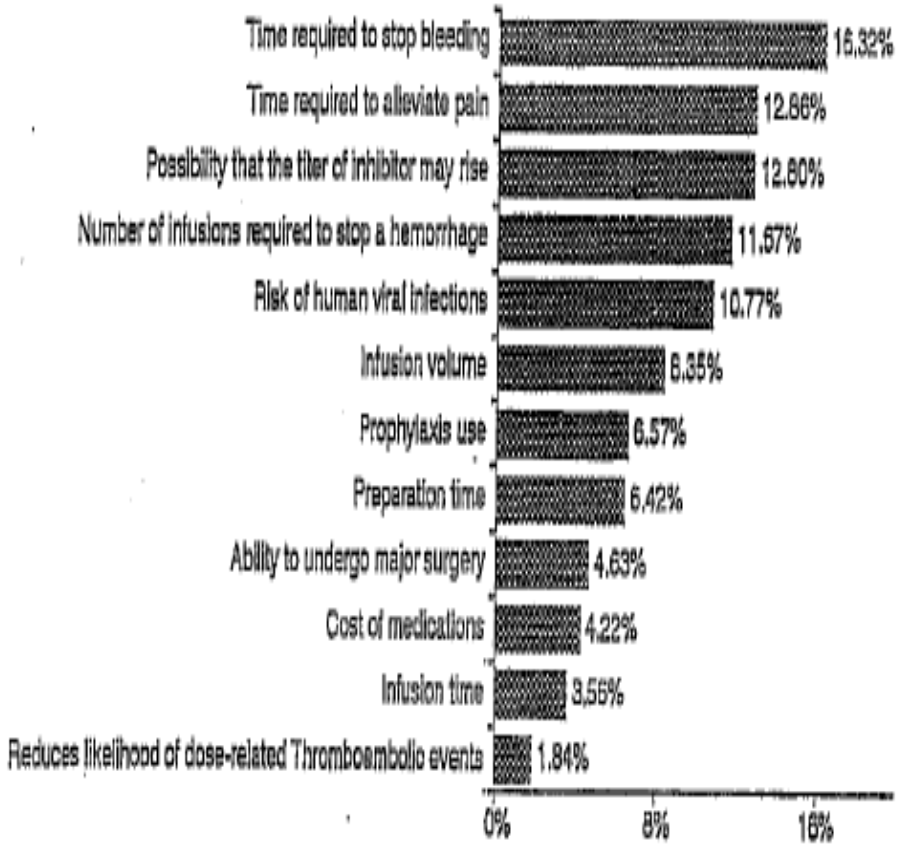

Fig. 1. Relative importance of treatment features.

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Colorectal Cancer Screening Attitudes and Practices in the General Population: A Risk-adjusted Survey

Walter L. Straus, Edward C. Mansley, Karen F. Gold, Qin Wang, Prabashni Reddy, and Chris L. Pashos

TABLE 4 ◎ Rates of "ever received screening" by risk category and screening test

Colorectal cancer screening test	Average-risk subjects ($n = 306$)	Increased-risk subjects ($n = 176$)	p-value
Fecal occult blood test	67.1%*	80.7%*	.003
Flexible sigmoidoscopy	43.0%	69.2%	.0001
Colonoscopy	22.5%	73.6%	.0001
Double-contrast barium enema	28.6%	58.6%	.0001

*$p < .0001$ fecal occult blood test vs other colorectal cancer screening tests.

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Case Study: To Increase Market Awareness

Retrospective Database Analysis PLUS in Oncology	
The Challenge	Company had established evidence in clinical trials that a particular health care intervention preserves bone mineral density in men with prostate cancer. Need to describe the burden of skeletal related events in patients with cancer to build awareness & market.
Approach	Given budget and time constraints, strategy was to use retrospective Medicare data analysis to describe clinical and economic impact of hormonal therapies on fractures in prostate cancer.
Deliverables	Longitudinal Medicare data analysis, thought-leader collaborations, report, presentations, publications
Outcomes	Quantified magnitude of the clinical and economic burden and raised awareness among payer (Medicare) and physicians Multiple presentations at conferences (AUA, ASCO, MASCC) and publications (*Cancer* and *Journal of Clinical Oncology*) Product value dossier for payers, that consolidates evidence

III. Projecting the Value of Interventions

The economic impact of blue-light filtering intraocular lenses on age-related macular degeneration associated with cataract surgery: a third-party payer's perspective

Prabashni Reddy[a], Xin Gao[a], Rod Barnes[b], Carol Fairchild[b], Kreda Boci[a], Curtis Waycaster[b] and Chris Pashos[a]

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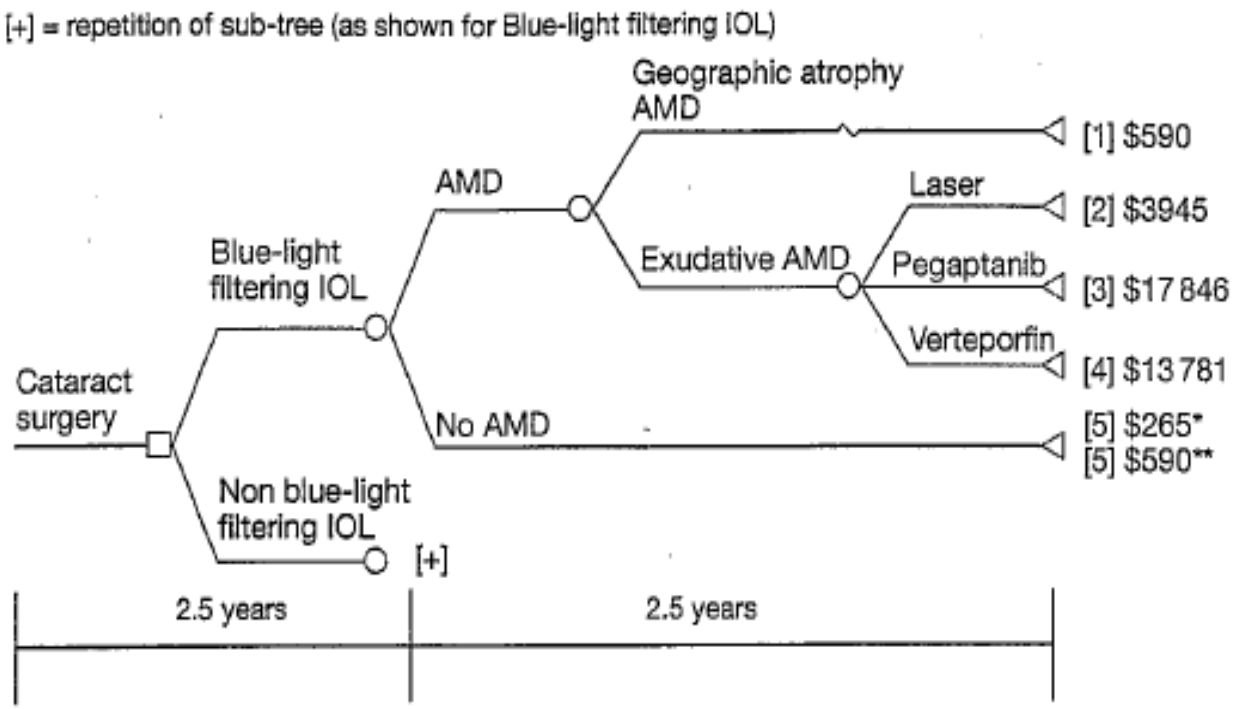
[b] *Alcon Laboratories Inc., Health Economics, 6201 South Freeway, R5-16, Fort Worth, TX 76134-2099, USA*



[¶]Once AMD develops, all patients receive at least an annual ophthalmologic visit
[†]All patients receive vitamin/antioxidant prevention except patients 55 to 64 years in the No AMD group
*55–64 years
**≥ 65 years
AMD = age-related macular degeneration; IOL = intraocular lens

Figure 1. Model structure and costs associated with age-related macular degeneration[¶†]

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A Retrospective Managed Care Claims Data Analysis of Medication Adherence to Vaginal Estrogen Therapy: Implications for Clinical Practice

LEE P. SHULMAN, M.D.,[1] DAVID J. PORTMAN, M.D.,[2] WON CHAN LEE, Ph.D.,[3]
SANJEEV BALU, Ph.D., M.B.A.,[4] ASHISH V. JOSHI, M.S., Ph.D.,[5]
DAVID COBDEN, M.Sc., M.P.H.,[5] QIN WANG, M.A.,[3] and CHRIS L. PASHOS, Ph.D.[4]

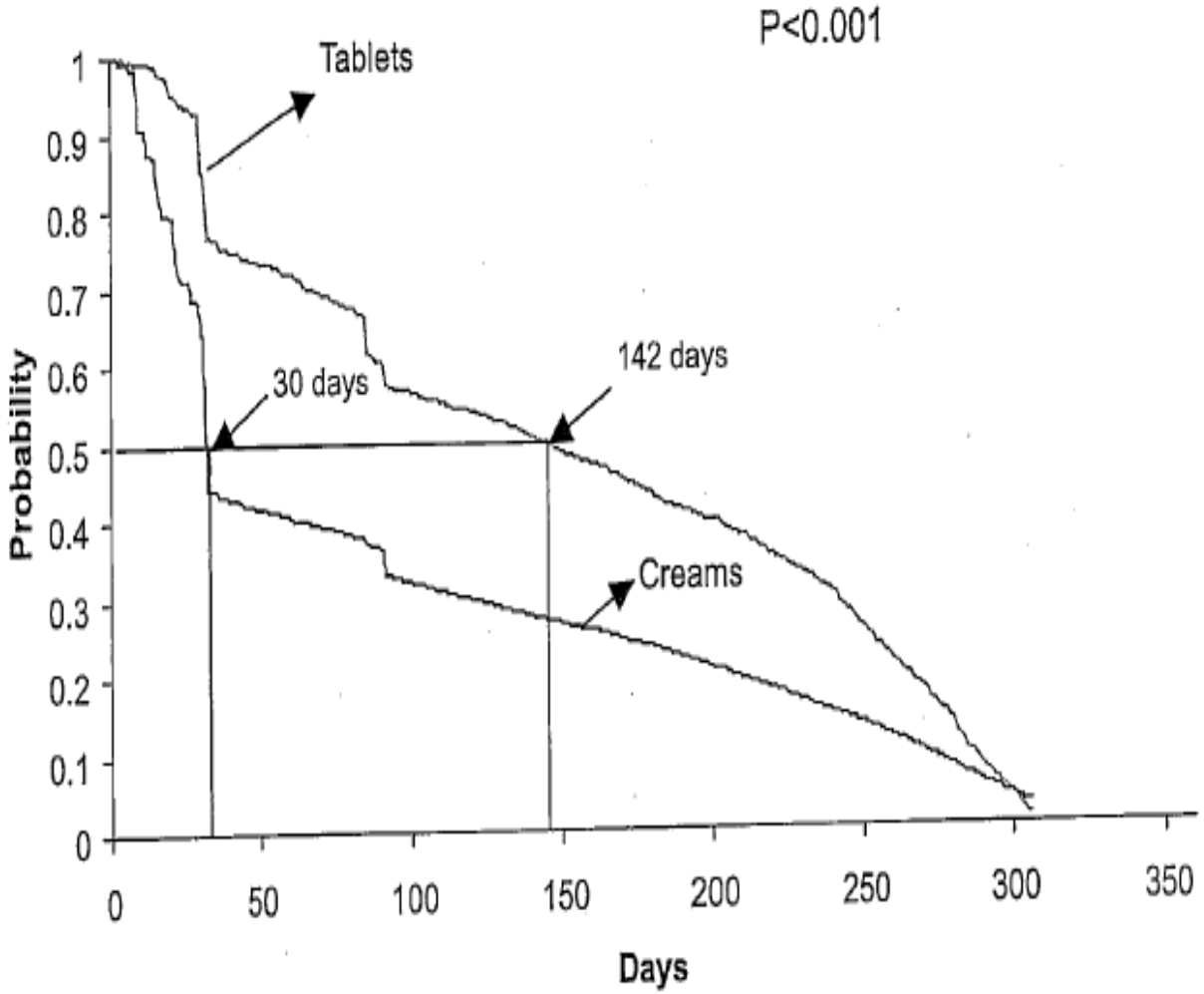

FIG. 1. Time to treatment discontinuation: Kaplan-Meier analysis (n = 13,074).

Case Study: To Provide Innovative Strategic Support

Strategic Modeling Support for Expensive Blood Safety Product	
The Challenge	A new blood transfusion safety product appears doomed as it isn't cost-effective (CER >$250,000/QALY saved) • Is it possible to shape perceptions regarding product value?
Approach	Carefully crafted and implemented a publication plan that "set the stage" and then delivered release of "noteworthy" CEA results
Deliverables	Economic model demonstrates product's cost effectiveness is comparable to that of other common safety interventions • Brochure (for early dissemination) • Publication on economics of transfusion and product's CE • Interactive multi-country model
Outcomes	Sponsor senior management praises creative communication strategy that benefits this and other products

IV. Providing Real World Proof

Trends in the Use of Drug Therapies in Patients With Acute Myocardial Infarction: 1988 to 1992

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JEFFREY B. GARFINKLE, MS,† JOSEPH P. NEWHOUSE, PHD,*‡§
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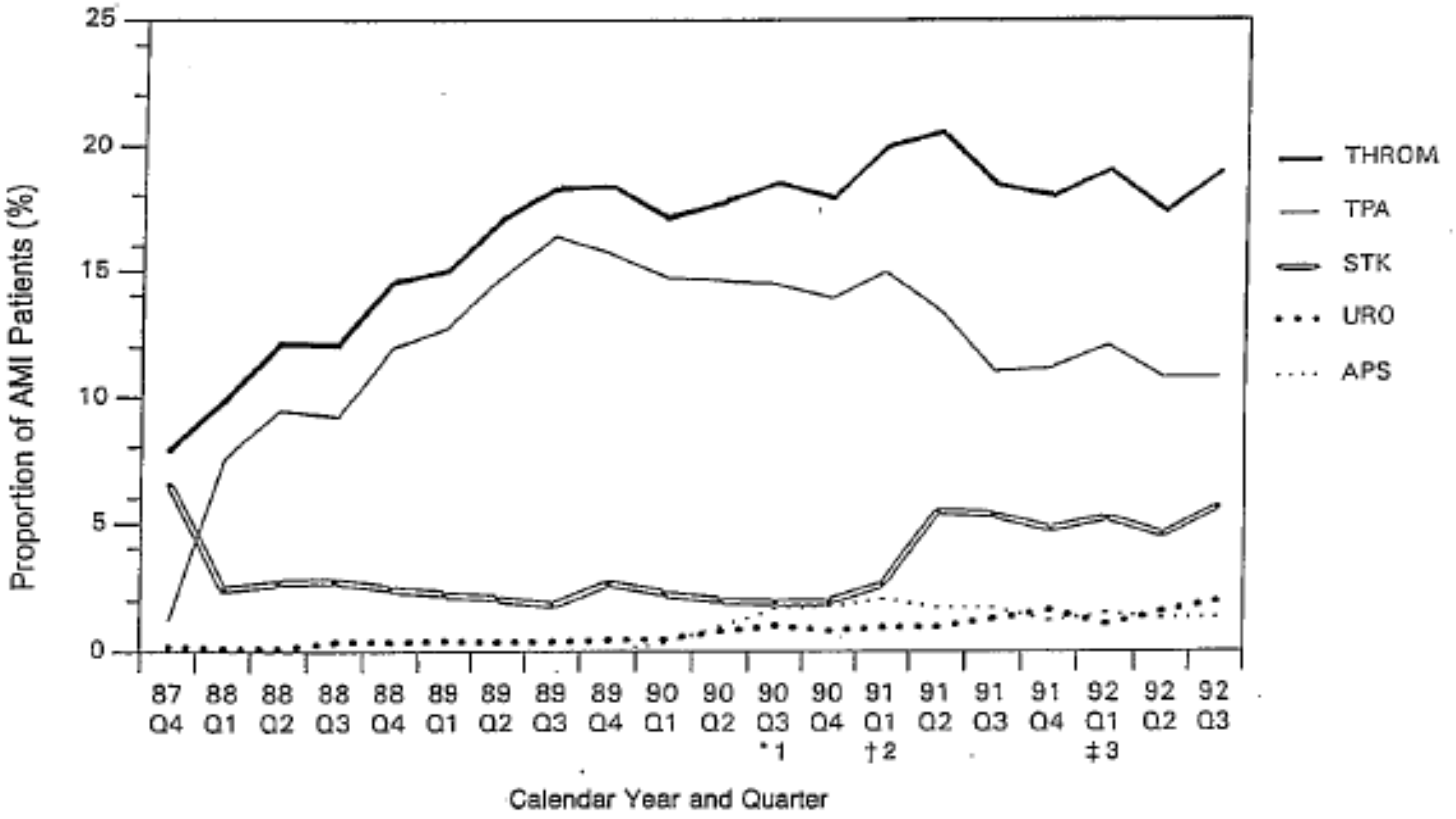

*1 GISSI-2 Published
†2 ISIS-3 Presented
‡3 ISIS-3 Published

Hypertension Program Conference Presentations

Hadker N, Greene B, Brown M, et al. Impact of the BP DownShift Program on Blood Pressure Control among Commercial Driver License Employees: a Managed Care Perspective, **Academy of Managed Care Pharmacy 19th Annual Meeting & Showcase,** San Diego, CA, April 11-14, 2007.

Greene BL, Brown TM, Harshman RS, et al. Impact of the BP DownShift Program on Blood Pressure Control among Commercial Driver License Employees with Diabetes and Obesity, ***American Diabetes Association 67th Scientific Sessions****,* Chicago, June 22-26, 2007.

Greene BL, Brown TM, Harshman RS, et al. Impact of the Change in Department of Transportation (DOT) Guidelines and the BP DownShift Program on Blood Pressure (BP) Control Among Commercial Driver License (CDL) Employees, ***American Occupational Health Conference*****,** New Orleans, May 6-9, 2007.

Greene BL, Brown TM, Miller JD, Harshman R, Richerson G, Doyle JJ, Economic Impact of the BP DownShift Program on Blood Pressure Control among Commercial Driver License Employees, ***Academy of Managed Care Pharmacy Educational Conference*****,** Kansas City, Missouri, October 15-18, 2008.

Presentation at AMCP

Impact of the BP DownShift Program on Blood Pressure Control Among Commercial Driver License Employees: a Managed Care Perspective

Hadker N,[1] Greene B,[1] Brown TM,[1] Harshman R,[2] Richerson G,[2] Turner B,[2] Skrepnek SH,[3] Doyle JP

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ABSTRACT

Background: Rising healthcare costs to large, self-insured employers in the United States have prompted interest in programs to help manage and prevent chronic conditions. The BP DownShift Program was designed to improve blood pressure (BP) outcomes among commercial driver's license (CDL) employees, in light of recent changes in the Department of Transportation's (DOT) Hypertension Guidelines for CDL recertification.

Objective: The goal of this research was to assess the impact of the BP DownShift program on BP outcomes among CDL employees at a large southeastern US utility company.

Methods: This study evaluated the DOT Medical Examination Report for Commercial Driver Fitness Determination prior to and after the BP DownShift program for a random sample of CDL employees. The program consists of various educational materials for use by employers, employees, and physicians. Clinical data included BP measurement, body mass index (BMI), and patient-reported medical history. Guidelines issued by the Seventh Report of the Joint National Committee on Prevention, Detection, Evaluation, and Treatment of High Blood Pressure (JNC-7) were used to classify employees' hypertensive status.

Results: A total of 501 CDL employees were assessed; all were male, most (66%) were aged 40 years or older, and mean BMI was 30 kg/m². Compared with baseline, fewer employees had uncontrolled BP (Stage 1 or 2) following the program (28.3% vs 28.8%, $p<0.01$). Among employees taking antihypertensive (AHY) medication, a significantly smaller percentage had uncontrolled BP (48.0% vs 33.4%, $p<0.05$), while a larger percentage had controlled BP (52.0% vs 66.6%, $p<0.05$).

Conclusions: The BP DownShift Program was associated with a significant reduction in the number of CDL employees with uncontrolled BP. Further investigation is warranted to assess the long-term impact of BP DownShift and associated financial implications.

OBJECTIVE

- To assess whether the BP DownShift Program for commercial drivers improved BP outcomes among CDL employees of a self-insured utility company

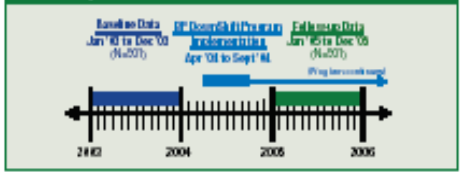
METHODS

- This longitudinal study evaluated the DOT Medical Examination Report for Commercial Driver Fitness Determination[1] before (baseline) and after (follow-up) implementation of the BP DownShift Program for a random sample of CDL employees (see Figure 1)

METHODS (cont.)

- Data collected included BP, body mass index (BMI), self-reported medical history, comorbidities, risk factors, and medication use

Figure 1. Study Timeline.



- Guidelines issued by the Seventh Report of the Joint National Committee on Prevention, Detection, Evaluation, and Treatment of High Blood Pressure[2] (JNC 7) were used to classify employees' hypertensive status; BP control is defined as <140/90 mm Hg and <130/80 for those with diabetes
- Statistical weighting was applied to control for potentially confounding longitudinal effects of changes in age and BMI on the BP of CDL employees at follow-up versus baseline

RESULTS

- The sample consisted of 501 CDL employees; all were male, the majority (66%) were aged 40 years or older, and mean BMI was 29.8 kg/m²

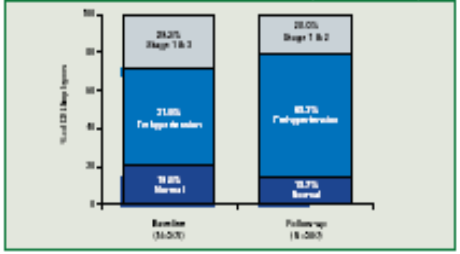
Table 1. CDL Employee Profile.

CDL Employee Profile	Baseline (N=501)	Follow-up (N=500)
Age (mean)	42.5	44.5
BMI (mean)	29.8	30.3
Diabetes, % (n)	6.2% (31)	7.4% (37)
Hypertension, % (n)	25.5% (128)	30.2% (151)
AHY Medication Use, % (n)	25.3% (127)	30.2% (151)

RESULTS (cont.)

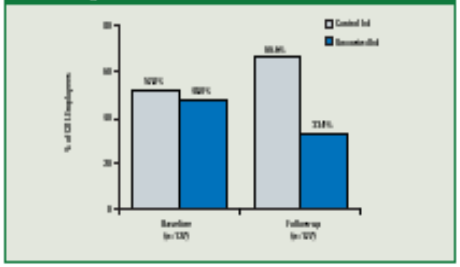
- Compared with baseline, significantly more CDL employees had controlled BP at follow-up (71.7% vs 80.0%, $p<0.01$)

Figure 2. JNC 7 Classification at Baseline and Follow-up Among Total Sample.



- Among CDL employees taking antihypertensive medication, a significantly higher percentage had controlled BP at follow-up (52.0% vs 66.6%, $p<0.05$)

Figure 3. BP Control From Baseline to Follow-up Among CDL Employees Taking AHY Medication.



RESULTS (cont.)

- Among CDL employees with a self-reported diagnosis of hypertension, significantly more had controlled BP at follow-up (52.3% vs 66.9%, $p<0.05$)
- Among CDL employees without a self-reported diagnosis of hypertension, fewer trended toward uncontrolled BP at follow-up (21.7% vs 16.2%, $p<0.10$)

LIMITATIONS

- Data (eg, medical history and medication use) were self-reported
- Data related to lifestyle modifications were not available and, therefore, were not collected

CONCLUSIONS

- The BP DownShift Program was associated with a significant increase in the number of CDL employees with controlled BP
- Further investigation is warranted to assess the long-term impact of BP DownShift Program and associated financial implications for employers

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2. Chobanian AV, Bakris GL, Black HR, et al. The Seventh Report of the Joint National Committee on Prevention, Detection, Evaluation, and Treatment of High Blood Pressure: the JNC 7 Report. *Hypertension*. 2003; 42:1206-1252.

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Presentation at ADA

Impact of the BP DownShift Program on Blood Pressure Control Among Commercial Driver License Employees with Diabetes and Obesity

Beth L. Greene[1], T. Michelle Brown[1], Robert S. Harshman[2], Gerald T. Richardson[2], Beverly H. Turner[2], Samantha H. Skrepnek[2], Joseph J. Doyle[3]
[1]Abt Associates Inc., Lexington, MA, [2]Georgia Power Southern Company, Atlanta, GA, [3]Novartis Pharmaceuticals, East Hanover, NJ

GEORGIA POWER
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ABSTRACT

Background: The risk for multiple coronary disorders, Type II diabetes, and high blood pressure is well documented. The prevalence of hypertension is rising as obese and diabetic populations grow across the US. The BP DownShift Program was designed to improve blood pressure (BP) outcomes among commercial driver license (CDL) employees. We assessed the impact of the program among CDL employees with Type II diabetes and obesity in a large southeastern U.S. utility company.

Methods: We did a retrospective cohort pre-post study of the Department of Transportation for CDL certification exams evaluating before and after program implementation among a random sample of CDL employees. The program consisted of education and materials for nurses, employers, and employees. Exams collected and/or calculated included BP, body mass index (BMI), and patient reported medical history and medication use. Guidelines issued by the Seventh Report of the Joint National Committee on Prevention, Detection, Evaluation, and Treatment of High Blood Pressure[1] were used to classify employees' hypertensive status.

Results: A total of 581 CDL employees were assessed longitudinally at 1 year and 581 (100%) were white and 48 years old. Forty-four percent (n=258) were obese (BMI ≥ 30.0 kg/m²), a significantly higher percentage than the national average (33.9%; P<.0001). Among the total sample, six percent (n=36) reported having Type II diabetes at baseline, consistent with national prevalence (7%). Among these, 69% were obese. Compared to baseline, significantly more Type II diabetics had controlled BP following the program (83% vs. 39%, p<0.05). Among obese CDL employees, significantly more were controlled following the program (42% vs. 74%, p<0.05).

Conclusions: The BP DownShift Program was associated with a significant reduction in the number of diabetics and obese CDL employees classified with hypertension. Further investigation is warranted to assess the long-term clinical and financial impact of BP DownShift Program.

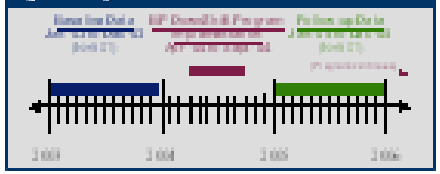
OBJECTIVE

- To assess whether the BP DownShift Program for commercial drivers improved BP outcomes among CDL employees with Type II diabetes and obesity at a utility company.

METHODS

- Medical examination records, required by the Department of Transportation for CDL certification[1], were evaluated before and after program implementation among a random sample of CDL employees.

Figure 1. Study Timeline.



- The program consisted of education and materials for nurses, employers, and employees.
- Examined medical exam data collected, including BP, BMI (Table 1), and patient reported medical history and medication use (ATC).

Table 1. Body Mass Index (BMI) Classification

Underweight	< 18.5
Normal Weight	18.5-24.9
Overweight	25.0-29.9
Obese	≥ 30.0

- Guidelines issued by the Seventh Report of the Joint National Committee on Prevention, Detection, Evaluation, and Treatment of High Blood Pressure[1] were used to classify employees' hypertensive status.

RESULTS

- A total of 581 CDL employees were assessed longitudinally at 1 year and 581 (100%) were white and 48 years old.

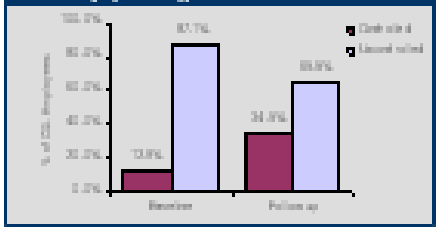
Table 2. CDL Employee Profile

CDL Employee Profile	Baseline (n=581)	Follow-up (n=581)
Age (in years)	42.1	43.1
Obese, % (n)	44.1% (256)	44.8% (260)
Type II Diabetes, % (n)	6.2% (36)	7.4% (43)
Hypertensive, % (n)	20.1% (120)	20.2% (118)
ATC Medication Use, % (n)	20.2% (117)	20.2% (118)

RESULTS (cont.)

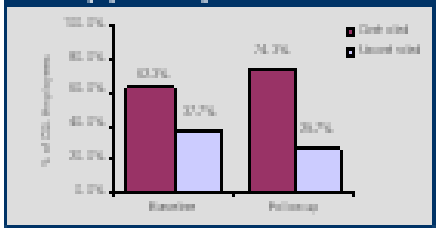
- Forty-four percent (n=258) were obese (BMI ≥ 30.0 kg/m²), a significantly higher percentage than the national average (33.9%; P<.0001).
- Among the total sample, six percent (n=36) reported having Type II diabetes at baseline, consistent with national prevalence (7%). Among these, 69% were obese.
- Compared to baseline, significantly more Type II diabetics had controlled BP following the program (83% vs. 39%, p<0.05).

Figure 2. BP Control Rates Analysis: Follow-up Among CDL Employees with Type II Diabetes.



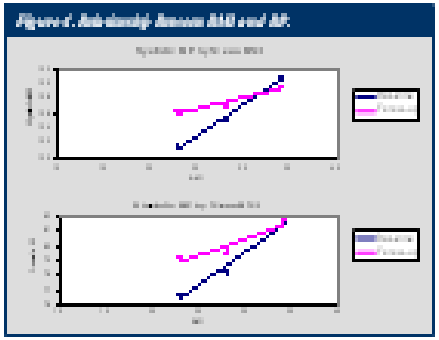
- Despite more CDL employees diagnosed as obese in the follow-up period (44% vs. 49%), significantly more were controlled following the program (42% vs. 74%, p<0.05).

Figure 3. BP Control Rates Analysis: Follow-up Among CDL Employees with Obesity.



RESULTS (cont.)

Figure 4. Relationship Between BMI and BP.



- There is a clear correlation between BMI and BP levels. However, the relationship is the strongest when looking at systolic BP.

LIMITATIONS

- Data (e.g., medical history and medication use) was self-reported.
- Data collected lifestyle modifications were not collected and, therefore, not controlled.

CONCLUSIONS

- The BP DownShift Program was associated with a significant increase in the number of diabetics and obese CDL employees that have controlled BP.
- Further investigation is warranted to assess the long-term clinical and financial impact of BP DownShift Program.

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2. [illegible]
3. [illegible]

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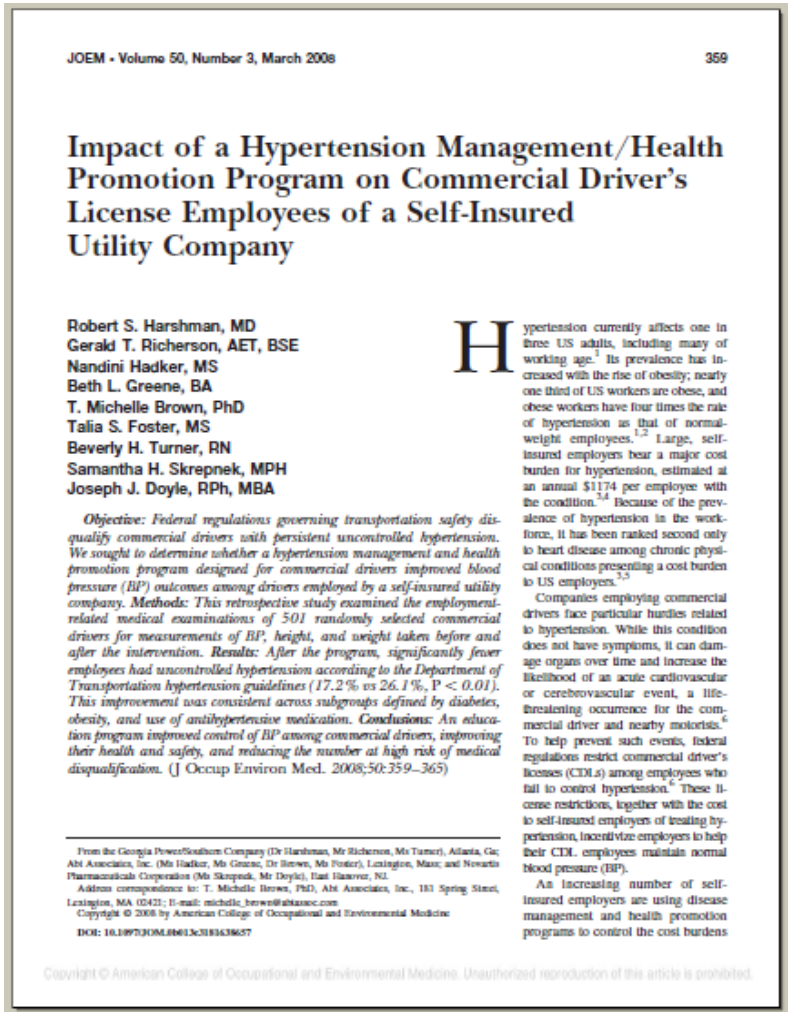
Harshman RS, Richerson GT, Hadker N, et al. Impact of a Hypertension Management/ Health Promotion Program on Commercial Driver's License Employees of a Self-Insured Utility Company, ***Journal of Occupational and Environmental Medicine****;* 2008 (March); 50 (3): 359-365.

Publication in Journal of Occupational and Environmental Medicine



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Impact of a Hypertension Management/Health Promotion Program on Commercial Driver's License Employees of a Self-Insured Utility Company

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T. Michelle Brown, PhD
Talia S. Foster, MS
Beverly H. Turner, RN
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Objective: *Federal regulations governing transportation safety disqualify commercial drivers with persistent uncontrolled hypertension. We sought to determine whether a hypertension management and health promotion program designed for commercial drivers improved blood pressure (BP) outcomes among drivers employed by a self-insured utility company.* *Methods:* *This retrospective study examined the employment-related medical examinations of 501 randomly selected commercial drivers for measurements of BP, height, and weight taken before and after the intervention.* *Results:* *After the program, significantly fewer employees had uncontrolled hypertension according to the Department of Transportation hypertension guidelines (17.2% vs 26.1%, P < 0.01). This improvement was consistent across subgroups defined by diabetes, obesity, and use of antihypertensive medication.* *Conclusions:* *An education program improved control of BP among commercial drivers, improving their health and safety, and reducing the number at high risk of medical disqualification.* (J Occup Environ Med. 2008;50:359–365)

Hypertension currently affects one in three US adults, including many of working age.[1] Its prevalence has increased with the rise of obesity; nearly one third of US workers are obese, and obese workers have four times the rate of hypertension as that of normal-weight employees.[1,2] Large, self-insured employers bear a major cost burden for hypertension, estimated at an annual $1174 per employee with the condition.[3,4] Because of the prevalence of hypertension in the workforce, it has been ranked second only to heart disease among chronic physical conditions presenting a cost burden to US employers.[3,5]

Companies employing commercial drivers face particular hurdles related to hypertension. While this condition does not have symptoms, it can damage organs over time and increase the likelihood of an acute cardiovascular or cerebrovascular event, a life-threatening occurrence for the commercial driver and nearby motorists.[6] To help prevent such events, federal regulations restrict commercial driver's licenses (CDLs) among employees who fail to control hypertension.[6] These license restrictions, together with the cost to self-insured employers of treating hypertension, incentivize employers to help their CDL employees maintain normal blood pressure (BP).

An increasing number of self-insured employers are using disease management and health promotion programs to control the cost burdens

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of hypertension and other chronic illnesses.[7] Many studies suggest that such programs are associated with improved clinical outcomes and quality of patient care.[8–10] In one systematic review, four of eight analyses of disease management programs targeting hypertension found that the programs produced significant reductions in mean systolic BP, by 2 to 12 mm Hg more than controls not provided the program.[9]

For self-insured companies employing commercial drivers, a hypertension management and health promotion program may help maintain or improve health, increase safety, and save costs. We sought to determine whether a hypertension management and health promotion program designed for commercial drivers improved BP outcomes among CDL employees of a self-insured utility company.

Materials and Methods

This retrospective, longitudinal analysis examined the Department of Transportation (DOT) Medical Examination Reports[6] of CDL employees who participated in the BP DownShift Program implemented by their employer, a large electric utility company located in the southeastern United States, between April and September of 2004; all CDL employees were continuously provided educational materials explaining the importance of BP control in lowering their cardiovascular risk and maintaining their CDL certification. Employees also received resources to help them understand and manage hypertension, such as treatment information, suggested questions for their physician, and record-keeping tools. In addition to the materials provided to the employees, the BP DownShift Program also supplied tools to the employer, employee unions, and the physicians caring for CDL employees, to help promote hypertension awareness and participation in the program.

Clinical and demographic data were obtained from the Medical Examination Reports, which are completed as part of each employee's periodic medical examination for CDL certification.[6] CDL employees with a history of normal BP and no major health problems as defined in the DOT Physical Qualifications for Drivers (CFR 391.41 [b] [6]) are examined for recertification every 2 years; those with hypertension or other serious health problems must be examined more frequently.[6] The length of time between examinations for this group of CDL employees varies depending on the severity of hypertension and presence of other health conditions, ranging from 3 months for those classified in Stages 2 or 3 hypertension according to the DOT guidelines, up to 1 year for those classified in Stage 1 hypertension, those taking antihypertension medication, or those who have diabetes. In this analysis, an employee's "baseline" examination was the most recent examination conducted before the implementation of the BP DownShift Program. The "follow-up" examination was defined as the most recent examination administered after the program.

As part of the BP DownShift Program, employees received verbal counseling during their baseline examination, or during multiple employee health fairs within the intervention period. Counseling consisted of 5 to 10 minutes of review of the individual's health and employment status, and discussion of the current DOT regulations, as these regulations were revised in 2004 becoming more stringent. If needed, employees were referred back to their primary care physician or cardiologist, as appropriate, for follow-up.

A random sample of 501 employees (approximately 25%) was selected from the entire CDL employee population (2038). Five hundred of these employees had baseline and follow-up measurements of BP, and 498 had baseline and follow-up measurements of body mass index (BMI).

Data abstracted from Medical Examination Reports[6] included demographics (age, gender, CDL class, and status), employee-reported medical history (cardiovascular conditions/risk factors and other comorbidities and medication use), and the results of the physical evaluation (including assessments of BP and of height and weight used to calculate BMI).

Statistical weighting was used to control for potentially confounding effects of changes in age and BMI on the BP of individuals at follow-up versus baseline. The relative contribution of BP among employees within each age and BMI group (eg, age <30 years, normal BMI) at follow-up was weighted by the change in the percentage of employees classified within that age-BMI group from baseline to follow-up.

CDL employee BMI of less than 25.0 kg/m^2 was classified as "normal." "Overweight" was defined as a BMI between 25.0 kg/m^2 and 29.9 kg/m^2 and "obese" was defined as a BMI of 30.0 kg/m^2 or greater.[11] CDL certification is based upon BP guidelines issued by DOT,[6] and DOT classifications were recorded for each employee. Guidelines issued by the Seventh Report of the Joint National Committee on Prevention, Detection, Evaluation, and Treatment of High Blood Pressure[12] (JNC 7) also were used to classify employees' hypertensive status. "Uncontrolled" BP is defined as Stages 1, 2, and 3 hypertension under DOT Guidelines,[6] and Stages 1 and 2 hypertension under JNC 7.[12] See Fig. 1 for a comparison of these guidelines.

This study received Institutional Review Board approval. The data that were collected for this study are not protected health information, but rather employee medical information that are subject to the Americans with Disabilities Act and Family and Medical Leave Act. All employees signed a release document that allowed the employer to use the data for research purposes. In order to maintain employee confidentiality, the employer coded each CDL employee record using a unique identifier, and then the data were stripped of all personal identifiers. This included the removal of name, social security number, address, height, and weight from each record. The file link-

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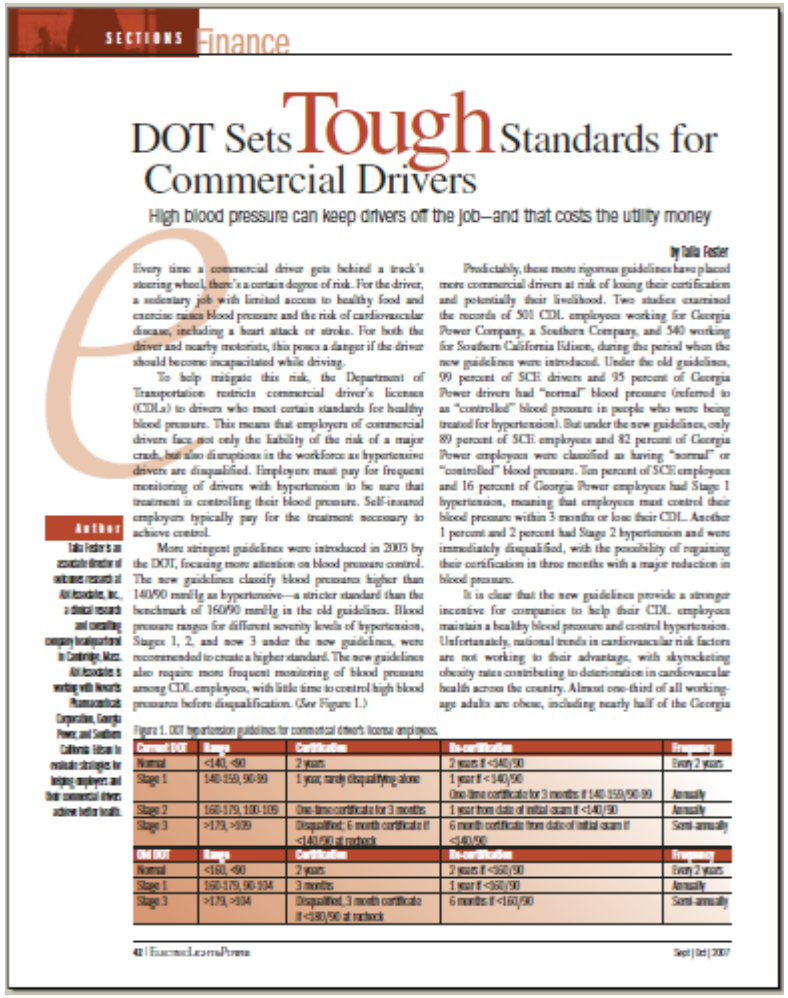

SECTIONS Finance

DOT Sets Tough Standards for Commercial Drivers

High blood pressure can keep drivers off the job—and that costs the utility money

by Talia Foster

Every time a commercial driver gets behind a truck's steering wheel, there's a certain degree of risk. For the driver, a sedentary job with limited access to healthy food and exercise raises blood pressure and the risk of cardiovascular disease, including a heart attack or stroke. For both the driver and nearby motorists, this poses a danger if the driver should become incapacitated while driving.

To help mitigate this risk, the Department of Transportation restricts commercial driver's licenses (CDLs) to drivers who meet certain standards for healthy blood pressure. This means that employers of commercial drivers face not only the liability of the risk of a major crash, but also disruptions in the workforce as hypertensive drivers are disqualified. Employers must pay for frequent monitoring of drivers with hypertension to be sure that treatment is controlling their blood pressure. Self-insured employers typically pay for the treatment necessary to achieve control.

More stringent guidelines were introduced in 2003 by the DOT, focusing more attention on blood pressure control. The new guidelines classify blood pressures higher than 140/90 mmHg as hypertensive—a stricter standard than the benchmark of 160/90 mmHg in the old guidelines. Blood pressure ranges for different severity levels of hypertension, Stages 1, 2, and now 3 under the new guidelines, were recommended to create a higher standard. The new guidelines also require more frequent monitoring of blood pressure among CDL employees, with little time to control high blood pressures before disqualification. (*See* Figure 1.)

Predictably, these more rigorous guidelines have placed more commercial drivers at risk of losing their certification and potentially their livelihood. Two studies examined the records of 501 CDL employees working for Georgia Power Company, a Southern Company, and 540 working for Southern California Edison, during the period when the new guidelines were introduced. Under the old guidelines, 99 percent of SCE drivers and 95 percent of Georgia Power drivers had "normal" blood pressure (referred to as "controlled" blood pressure in people who were being treated for hypertension). But under the new guidelines, only 89 percent of SCE employees and 82 percent of Georgia Power employees were classified as having "normal" or "controlled" blood pressure. Ten percent of SCE employees and 16 percent of Georgia Power employees had Stage 1 hypertension, meaning that employees must control their blood pressure within 3 months or lose their CDL. Another 1 percent and 2 percent had Stage 2 hypertension and were immediately disqualified, with the possibility of regaining their certification in three months with a major reduction in blood pressure.

It is clear that the new guidelines provide a stronger incentive for companies to help their CDL employees maintain a healthy blood pressure and control hypertension. Unfortunately, national trends in cardiovascular risk factors are not working to their advantage, with skyrocketing obesity rates contributing to deterioration in cardiovascular health across the country. Almost one-third of all working-age adults are obese, including nearly half of the Georgia

Figure 1. DOT hypertension guidelines for commercial driver's license employees.

Current DOT	Range	Certification	Re-certification	Frequency
Normal	<140, <90	2 years	2 years if <140/90	Every 2 years
Stage 1	140-159, 90-99	1 year, rarely disqualifying alone	1 year if <140/90 One-time certificate for 3 months if 140-159/90-99	Annually
Stage 2	160-179, 100-109	One-time certificate for 3 months	1 year from date of initial exam if <140/90	Annually
Stage 3	>179, >109	Disqualified; 6 month certificate if <140/90 at recheck	6 month certificate from date of initial exam if <140/90	Semi-annually
DOT/DOT	**Range**	**Certification**	**Re-certification**	**Frequency**
Normal	<160, <90	2 years	2 years if <160/90	Every 2 years
Stage 1	160-179, 90-104	3 months	1 year if <160/90	Annually
Stage 3	>179, >104	Disqualified; 3 month certificate if <180/90 at recheck	6 months if <160/90	Semi-annually

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Conclusions

- Health economics and outcomes research (HEOR) provide empirical evidence that is complementary to that obtained from randomized clinical trials
- HEOR publications create awareness of disease burden and product value among key stakeholders
- HEOR publications are critical for technology registration, reimbursement and promotion

THANK YOU!

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