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Improving Blood Pressure Control in Over-the-Road Truck Drivers: Is Provision of Medication Therapy Management by Pharmacists Feasible?

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Abstract

Purpose *This pilot sought to determine feasibility of studying the impact on hypertension in over-the-road truck drivers who met with pharmacists for Medication Therapy Management (MTM) compared to those who did not.*

Design/methodology/approach *Drivers were randomly assigned to control or treatment (MTM) group for 52 weeks. Drivers assigned to the MTM arm could receive services in person or via secure videoconferencing technology located in a private space at the trucking company. All subjects were provided education and received a blood pressure monitor and log for recording daily blood pressures.*

Findings *Eleven drivers enrolled and seven drivers completed the study. The primary barriers to participation included unpredictable driver schedules and lack of access to MTM provider while on the road.*

Research limitations/implications *This pilot study was limited by small sample size. Pharmacists were not available to meet with truckers "on demand." Therefore, researchers are encouraged to test alternate opportunities to increase enrollment of drivers in studies and access to MTM services while drivers are on the road.*

Practical implications *Hypertension is the second highest health-related cost burden, and over-the-road truck drivers have unique challenges that can make it difficult to attain blood pressure control. Pharmacist-provided MTM has been shown to improve blood pressure control. Improving access to MTM, perhaps using a national network of pharmacists or technology from the road, may decrease morbidity and mortality in drivers.*

Originality/value *This paper fulfills an identified need to study how to improve driver access to care to reduce cardiovascular-related morbidity and mortality.*

Background

Hypertension affects over one-third of adults in the United States ≥ 20 years of age (~ 78 million).[1] Although it is well established that high blood pressure is the biggest contributor to cardiovascular disease (CVD) mortality in the U.S., control remains suboptimal.[1,2] Just over one-half of U.S. adults have their blood pressure (BP) controlled (systolic BP <140 mmHg and diastolic BP <90 mmHg) despite widespread efforts to promote awareness and treatment, along with the availability of low cost, effective antihypertensive agents.[1] In addition, hypertension is a costly condition. An analysis of a multi-employer database of 374,799 employees demonstrated hypertension in the workforce is the second highest cost burden for U.S. employers.[3] Employers and payers of employee health benefits bear a substantial cost for the burden of hypertension in not only direct costs but also in indirect costs including absenteeism and presenteeism, with the overall economic burden of hypertension being slightly under $400 per eligible employee per year.[3,4] According to the National Survey of U.S. Long-Haul Truck Driver Health and Injury the prevalence of hypertension in long-haul truck

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drivers in 2010 is statistically similar to that of the 2010 U.S. adult working population (26.3% vs. 24.1%), yet the prevalence of obesity and current smoking are more than double in long-haul truck drivers (69% vs. 31%, $p < 0.01$; and 51% vs. 19%, $p < 0.01$, respectively), further increasing their overall risk of cardiovascular disease.[5]

Companies providing services using commercial drivers have special challenges related to hypertension. Not only do these companies face costs related to a driver's health, but also specific dangers and liability associated with traffic accidents from impaired employees while driving including the risk of major accidents involving drivers who are suspected to have experienced myocardial infarctions while on the road.[6, 7] In addition, other variables make it more challenging to provide optimal health care to long-haul truck drivers, including erratic and ever-changing driver schedules, access to timely health care services, and health insurance.[6] In two recent surveys of long-haul truck drivers, 33-38% were not covered by health insurance, as opposed to 17% of the U.S. adult working population.[5,6] Other factors impeding the optimal provision of health care to long-haul truck drivers are the lack of regular visits to health care providers (70% had no regular health care visits) and delay in seeking care (up to 20% report waiting to reach home prior to seeking care).[6]

In an effort to reduce risks of transportation mishaps, the U.S. Department of Transportation (DOT) has increased regulatory requirements and restrictions on commercial driver's licenses (CDL).[8] The DOT hypertension qualifications define drivers with systolic blood pressure (SBP) higher than 140 mmHg and/or diastolic blood pressure (DBP) over 90 mmHg as hypertensive. The DOT further classifies qualifications and CDL certification according to severity of hypertension. CDL drivers must undergo frequent monitoring of blood pressure, with time limits for controlling high blood pressure before disqualification. While this is an incentive for companies to maintain healthy employees, there is a cost associated with monitoring, medical visits and tests, and treatment to achieve control of hypertension. As such, there is a need for targeted and novel interventions to improve the provision of optimal health care, including blood pressure management, to long-haul truck drivers.

Medication therapy management (MTM) is a service provided by qualified and credentialed pharmacists. MTM services have demonstrated positive results in identifying and resolving drug therapy problems and improving patient outcomes.[9,10] Several studies have demonstrated that consultation with pharmacists can improve blood pressure control when focused on direct patient-centered care.[11-17] In addition, added attention has been given to the superior prognostic value of out-of-office blood pressure values relative to office-based readings, with the upper limit of normal for home and ambulatory blood pressure being 135/85 mmHg.[18-20] Therefore, interventions which may improve ambulatory blood pressure control are worthy of further investigation, such as the use of "blood pressure load," a novel approach to gauge ambulatory blood pressure control. Systolic and diastolic blood pressure loads are defined as the average probability a person would obtain a home systolic blood pressure reading greater than 135 mmHg and diastolic blood pressure reading greater than 85 mmHg respectively.[21]

This pilot sought to determine feasibility of conducting a study to confirm or refute the operational hypothesis that over-the-road truck drivers who met with pharmacists (face-to-face or through videoconferencing) for MTM would have lower blood pressure load (probability of obtaining a home systolic blood pressure reading greater than 135 mmHg and diastolic blood pressure readings greater than 85 mmHg) than those who did not receive MTM. Feasibility was assessed by evaluating the following questions in a sample of over-the-road drivers:

1) Will over-the-road drivers enroll in and complete a 12-month research study?
2) Will drivers take, record, and submit daily blood pressure readings?
3) To what extent will drivers randomized to receive MTM schedule and attend their appointments?
4) Will drivers randomized to receive MTM elect to attend face-to-face or by video conferencing?
5) What are the demographic and clinical characteristics of drivers enrolling in a study (e.g. caffeine intake, exercise habits, achievement of blood pressure goals, systolic and diastolic blood pressure loads)?

This paper will describe feasibility of conducting a research study designed to confirm or refute the operational hypothesis that long-haul truck drivers who met with pharmacists (face-to-face or through videoconferencing) for MTM would have lower blood pressure load than those who did not receive MTM.

Methods

Study Setting

Halvor Lines, Inc., headquartered in Superior, Wisconsin, is a moderate-sized trucking company that employs approximately 300 over-the-road drivers and operates 310 power units and 850 trailers. They provide transportation and logistics services across the U.S. and Canada. Leadership of Halvor Lines, Inc. has created a focus on driver health in an

effort to sustain a healthy productive workforce, and has previously partnered with the College of Pharmacy at the University of Minnesota Duluth Campus to promote health of drivers through health screenings and education. Essentia Health is a large integrated health system with hospitals and clinics in northern Minnesota, northern Wisconsin, North Dakota, and Idaho. MTM pharmacists participating in this study were located in the Internal Medicine department at Essentia Health First Street Clinic in Duluth, MN.

Inclusion Criteria
Eligible drivers included adults age 24 or older who possessed an active Commercial Driver's License (CDL) by the Department of Transportation, and had a clinical diagnosis of hypertension. Drivers had to be be located or frequently traveled to the Halvor Lines Superior, WI Hub, be able to comply with required study appointments, and be able and willing to sign informed consent.

Exclusion Criteria
Drivers could not be enrolled in any other disease-state management (DSM) or similar program, or be enrolled or participating in any other medication therapy management program.

Study design
Eligible drivers were screened and enrolled by study investigators on site at the Halvor Lines Training Center located in Superior, WI. Target study enrollment was 60 subjects, with 30 subjects randomly assigned to either a treatment or control group for a duration of 52 weeks. Enrollment occurred for the first six months of the study.

All study subjects were seen at the Halvor Lines Superior Hub for initial evaluation by one of the study investigators. Using an unconstrained permuted blocks of random size approach, subjects were randomized to either the MTM group or "usual care" group. Drivers assigned to the MTM group received pharmacist-provided face-to-face MTM services, and could opt to receive MTM in-person at Essentia Health or via secure videoconferencing technology located at the Halvor Lines Training Center, connected to the MTM provider site at Essentia Health. Drivers randomized to "usual care" continued their usual medical care with their primary care physician, and did not receive MTM.

Enrollment Visit
During the enrollment visit the pharmacist investigator thoroughly explained the purpose of the study and study procedures, obtained signed informed consent, and obtained the subject's medication and medical history, vital signs, and anthropometrics in the designated private space in the Halvor Lines Superior Hub training facility. The treatment room was equipped with an Omron BP760 sphygmomanometer, body weight scale, stadiometer (height), and measuring tape. All participants were provided educational materials at enrollment explaining the importance of blood pressure control in lowering their cardiovascular risk and maintaining their CDL certification. They also received resources to help them understand and manage hypertension, such as treatment and lifestyle information, suggested questions for their physician, and record-keeping tools. Subjects in both groups were given an automatic home blood pressure monitor to check their blood pressure daily upon waking and instructed to submit their blood pressure readings to the secured on-site collection box monthly. The investigator then completed all necessary documentation and forwarded findings to the subject's MTM pharmacist provider if assigned to the MTM group. A detailed description of procedures for initial and follow-up MTM visits and data collected can be found in Appendix A. Usual MTM fees were waived for subjects participating in the study.

A survey was administered at the enrollment and final visits for all subjects. The survey measured the following domains: medication adherence; satisfaction with, perceptions of, and preferences for pharmacist-provided MTM; and driver demographic and health status variables.

Recruitment
Drivers were notified about the study through announcements at quarterly driver meetings, posting of study flyers at the Halvor training center, flyers placed in driver mailboxes at Halvor headquarters, and via the monthly driver newsletter. Potential subjects could call or e-mail study investigators to schedule an enrollment visit, and study investigators were available on-site for 4-8 hours per week for walk-in enrollment during the six-month study enrollment period.

Subjects were given a $25 gift card upon enrollment in the study and an additional $50 gift card if they complete the final study visit.

Evaluation Plan
The feasibility of this pilot study was evaluated by collecting driver demographics through case report forms completed at enrollment and final visits, medical records, final visit survey, MTM visit case report forms, and driver blood pressure logs. Had the pilot study enrolled sufficient subjects (n=60) to answer the primary research question, mean systolic blood pressure load would have been compared between the MTM and "usual care" groups.

Statistical Analysis
Data were analyzed using the Statistical Package for the Social Sciences (SPSS, Version 20). Demographic characteristics of the participants were calculated using descriptive statistics. Related-samples Wilcoxon signed rank or McNemar's test were used as appropriate to test for differences between enrollment visit and final visit driver demographic and clinical characteristics.

This study was approved by both the Essentia Health and University of Minnesota Institutional Review Boards, and was funded by a grant from Daiichi Sankyo, LTD.

Results

Enrollment and Retention
Despite a variety of recruitment efforts (attending quarterly driver meetings, posting study flyers, placing study flyers in mailboxes and in the monthly newsletter, and investigator presence on site at least four hours weekly during enrollment), only eleven drivers enrolled in the study, which was an insufficient sample size to answer the primary study question. Seven of the eleven enrolled subjects completed a final study visit.

Subject Demographics and Clinical Characteristics
Demographic and clinical characteristics of subjects at enrollment and final visit are displayed in Table 1. The majority of participants were male with mean age of 56 years at enrollment, ranging from 38 to 73 years old. All participants were on at least one antihypertensive medication, and most had controlled blood pressure, with an average systolic and diastolic blood pressure at enrollment of 129.6 mmHg and 83.6 mmHg respectively. Drivers enrolled in the study ranged from newly diagnosed (11 days prior to enrollment) to having hypertension for 35 years. No differences were found between enrollment and final visit characteristics for the seven individuals who completed the study.

"Home" Blood Pressure Monitoring
Individual results of home blood pressure monitoring are shown in Table 2. Two drivers submitted no logs. Of the nine that did submit blood pressure logs, no driver completed blood pressure logs for all days of the study, with an average completion of 146 days (s.d. 118 days; range 0-296 days). The grand mean of drivers' average home blood pressure readings over the course of the year were 122.8 mmHg (s.d. 9.3) systolic and 76.9 mmHg (s.d. 5.8) diastolic. Of the nine drivers submitting logs, average systolic and diastolic loads were 15.3% (s.d. 19.6%, range 0-61.5%) and 13.7% (s.d. 14.3%, range 0-32.1%) respectively.

Barriers to scheduling/completing MTM and final visits
Per protocol, each of the MTM group subjects should have attended at least one initial and two follow-up MTM appointments. Four out of the six subjects randomized to the MTM group completed an initial MTM appointment; three completed face-to-face visits and one via teleconference. No subjects completed a follow-up MTM visit. An attempt was made at the end of the initial MTM visit to schedule a follow up appointment; however, each subject declined due to variability and uncertainty in work schedule. Three separate attempts were made over several months to contact subjects for initial or follow-up MTM visit. In most attempts to contact subjects, voicemail messages were left but not responded to. One subject discontinued employment at the company and withdrew from the study. The few subjects who were successfully contacted were on the road and either cited uncertainty about when they would be back in the area, or that they would be available on a weekend or evening in which no MTM pharmacist was available. One follow-up MTM visit was scheduled, but the subject did not show up.

Seven out of eleven subjects completed final study visits. Of those who did not complete a final study visit, one subject confirmed he no longer worked for the company, and three others were unreachable and did not return multiple messages left at their preferred contact numbers/emails.

Discussion

This pilot study attempted to enroll long-haul truck drivers in a study comparing pharmacist-provided MTM and usual care to gauge the impact of a pharmacist intervention on blood pressure control. Our results reflect an inability to enroll an adequate size sample of drivers in this type of study, to schedule drivers and have them maintain health care appointments with pharmacists, and to have drivers submit self-monitored blood pressure logs. Barriers to scheduling and enrollment, and the implications for further studies and health care provision for drivers are discussed below.

Scheduling Barriers
Given variability and unpredictability of driver schedules, it was challenging to enroll drivers in the study and schedule any appointment in advance unless a driver was not scheduled to work and was residing in the local area. Many drivers do not live within close proximity of the local hub, so even if they were not on the road for work, many would likely not be in the area. Presumably this scheduling difficulty is not isolated to participation in a research study, but also inhibits drivers accessing health care services efficiently when needed.[22] Providing access through mobile technology (e.g. smart phone) that would allow virtual visits at the driver's convenience while a driver was out on the road may be an

option. The ability to upload pertinent data (e.g. blood pressures or blood sugars) could also aid in the ability to provide care for drivers while on the road. Experience at Kaiser Permanente suggests that connected health technologies have positive impacts on those who otherwise may not access traditional care[23]. Another option could be connecting drivers with a convenient national network of MTM providers with "on call" availability or flexible schedules to meet drivers' needs, given drivers' variable and ever-changing schedules. Rolling Strong is one example of a company aiming to improve driver health through connecting drivers nationally with biometric screenings across a chain of pharmacies, phone health education and coaching, and exercise equipment designed for use in a truck (http://rollingstrong.com/2015/).

Enrollment Barriers

Aside from the scheduling difficulties described above, it is unclear what role that MTM being provided as part of a "study" impeded driver participation, i.e., would drivers have been more likely to enroll in an MTM program if these services were provided outside the realm of a "research study?" Drivers' livelihoods are dependent on maintaining their CDL. Because drivers need to meet blood pressure goals to maintain their CDL, they may experience fear of "being found out" that their blood pressure is not at goal. Despite repeated assurances that information obtained through their participation in the study would be kept in strict confidence and not shared with their employer, this concern may have persisted, leading to driver hesitation to participate in the project.

During the recruitment period of the study to the present, Halvor Lines hired a health and wellness coordinator who is present full time on site at the Superior, WI hub. According to the health and wellness coordinator, the average life expectancy for an over-the-road driver is 61 years old, which is 14 years less than the average worker. The median age for a driver at Halvor Lines is 52 years old. The coordinator's programs at Halvor Lines have been primarily based on diet modification such as eating a balance of macronutrients, watching sodium intake, and increasing water intake, and exercise plans based on what drivers have access to over the road. Most programs are run for twelve weeks. As a company, Halvor Lines employees have lost over 2100 pounds in just over a year, with a total of 111 participants. Out of these 111 participants, over sixty self-report that they have either cut back doses or gone off medications because of improved health. The challenge with this group of participants is getting them to the hub for their initial weigh-in and measurements. Once they do the initial weigh-in, each week the driver will self-report his/her weight via phone. Final measurements and weigh-ins are then done after the 12 weeks is over. Weekly coaching calls are set-up to help with the process. In addition, drivers report they like having access to someone on site and by phone, as it is more convenient for them.[24] It is unclear what impact the wellness programs and availability of an on-site wellness coordinator had on study enrollment, ongoing participation, and in study subjects' data (e.g. BMI, blood pressure). Similar strategies to those used by the health and wellness coach could be beneficial when providing health care services to driver populations.

Limitations

This pilot study was limited by the small pool of potential study subjects available, and that the pool came from only one trucking company. Pharmacists were not available to meet with truckers "on demand" or outside of the MTM pharmacists' normal business hours.

Conclusion

A study protocol that requires truck drivers to schedule appointments at a specific time and place did not prove feasible in this project. Future research using alternative methods of study enrollment, study protocol design, health promotion, subject self-reporting of data and access to care (e.g. telehealth from the road) are needed to determine what interventions are most effective to reduce cardiovascular morbidity and mortality in over-the-road truckers. Alternate strategies to provide health care for over-the-road truckers may improve access and utilization.

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Appendix A

Initial MTM and follow-up visits

Subjects randomized to the MTM group were required to meet with the pharmacist MTM provider at least every four months, or more frequently as clinically indicated. At each visit for subjects in Group 2, the assigned MTM pharmacist conducted a standardized MTM visit and systematic process that:

- Assessed all of the patient's drug-related needs
- Identified drug therapy problems
- Established therapeutic goals
- Designed a medication therapy care plan
- Conducted follow-up visits to evaluate progress
- Communicated information to the patient's physician

During this process each of the patient's medications underwent scrutiny for:

- Assessment of proper indication
  - Is the drug being used unnecessary?
  - Is additional drug therapy needed?
- Effectiveness of treatment
  - Is the current drug therapy is ineffective?
  - Is the dose is too low to produce the desired response?
- Safety
  - Is there an adverse drug reaction present?
  - Is the current drug dosage too high?
- Convenience
  - Is the patient adherent to the therapy?
  - Are there barriers to the patient's ability to comply with therapy, (e.g., physical, and financial)?

Table 1. Demographic and clinical characteristics at enrollment and final visit

Characteristics		Enrollment visit (n=11)	Final visit (n=7)
SBP average		129.6 (s.d. 10.14)	129.1 (s.d. 14.88)
DBP average		83.6 (s.d. 7.56)	79.3 (s.d. 10.65)
Pulse average		71.6 (s.d. 11.02)	63.2 (s.d. 11.04)
DOT HTN Classification	Normal	8 (72.7%)	5 (71.4%)
	Stage 1	3 (27.3%)	2 (28.6%)
BMI		37.7 (s.d. 5.596)	33.1 (s.d. 3.38)
BMI Classification	Normal	0 (0%)	0 (0%)
	Overweight	0 (0%)	1 (14.3%)
	Obese	11 (100%)	6 (85.7%)
Self-reported			
Gender	Male	10 (90.9%)	7 (100%)
	Female	1 (9.1%)	0 (0%)
Age		56 (s.d. 10.173)	61 (s.d. 8.426)
Highest level of education	Less than high school	1 (9.1%)	1 (14.3%)
	High school diploma	4 (36.4%)	2 (28.6%)
	Some college or technical degree	5 (45.5%)	3 (42.9%)
	Professional or graduate degree	1 (9.1%)	1 (14.3%)
Ethnicity	Caucasian	11 (100%)	--
Duration of HTN (years)		12.3 (s.d. 12.42)	--
Average # of hypertension medications		1.6 (s.d. 0.6876)	1.4 (s.d. 0.53)
Self-rated health	Poor	1 (9.1%)	0 (0%)
	Fair	3 (27.3%)	0 (0%)
	Good	5 (45.5%)	4 (57.1%)
	Very good	2 (18.2%)	2 (28.6%)
	Excellent	0 (0%)	1 (14.3%)

Diabetes		3 (27.3%)	4 (57.1%)
Metabolic Syndrome		6 (54.5%)	1 (14.3%)
Kidney Disease		2 (18.2%)	0 (0%)
Smoking	No	4 (36.4%)	3 (42.9%)
	Yes	3 (27.3%)	0 (0%)
	Former	4 (36.4%)	4 (57.1%)
Alcohol Use		8 (72.7%)	5 (71.4%)
Caffeine Use		10 (90.9%)	7 (100%)
Stimulant Use		1 (9.1%)	1 (14.3%)
Aerobic Exercise		8 (72.7%)	6 (85.7%)
Minutes/week for those exercising		146 (s.d. 151.67)	128 (s.d. 88.99)

Table 2. Home blood pressure monitoring for each participant

Participant	% blood pressure readings submitted (days)	Average systolic blood pressure mmHg	Average diastolic blood pressure mmHg	Systolic blood pressure load (% readings above 135 mmHg)	Diastolic blood pressure load (% readings above 85 mmHg)
1	18.9% (69)	117.8	71.9	0%	0%
2	81.1% (296)	115.2	73.6	6.8%	6.1%
3	51.5% (188)	106.9	67.4	1.6%	1.1%
4	0% (0)	--	--	--	--
5	11.2% (41)	129.3	82.1	26.8%	22%
6	91.5% (334)	130.7	75.8	21.3%	1.2%
7	51.2% (187)	125.7	83.0	7%	31%
8	0% (0)	--	--	--	--
9	64.1% (234)	136.6	82.3	61.5%	28.6%
10	53.7% (196)	116.4	82.7	1.5%	32.1%
11	16.7% (61)	126.7	73.5	11.5%	1.6%

Table 3. MTM and Final Visits

Visit Type	Visits Anticipated	Visits Completed	Contact attempts
MTM	18 (6 subjects: 1 initial and 2 follow-ups per protocol)	4 initial visits (3 face-to-face, 1 teleconference), 0 follow-up visits	18
Final (12-month)	11	7	35

Table 4. Final visit contact attempts

Subject	C1	C2	C3	C4	C5	C6	#C	Final visit completed?
1	E	E	E	E	E		5	No
2	P	P	P	P			4	Yes
3	P	P					2	Yes
4	P						1	No - no longer at Halvor
5	P/E	P	P	P	P	P	7	No
6	P	P					2	Yes
7	P	P					2	Yes
8	P	P	P	P	P		5	No
9	P	P	P				3	Yes
10	P	P					2	Yes
11	P	P					2	Yes

C = contact (C1= first contact; C2 = second contact, etc.); #C = total number of contact(s)/contact attempts; P = phone call or voicemail left; E = Email.