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Running head: CARING FOR COMMERCIAL DRIVERS LIVES QUALITY

CARING FOR COMMERCIAL DRIVERS LIVES QUALITY IMPROVEMENT
PROGRAM

by

SUSAN SANFILIPPO, FNP-BC, NP-C, COHN/CM

A DNP PROJECT

Submitted in partial fulfillment of the requirements for the

Degree of Doctor of Nursing Practice

to

To The School of Graduate Studies

of

The University of Alabama in Huntsville

Date of Submission: 07-09-2018

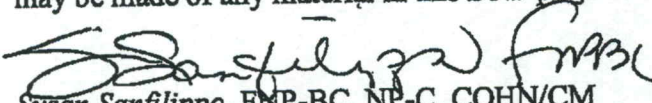
HUNTSVILLE, ALABAMA

2018

~~Dr. Louise O'Keefe~~
Dr. Louise O'Keefe

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Susan Sanfilippo, FNP-BC, NP-C, COHN/CM

Student Signature

07-09-2018

Date

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DNP PROJECT APPROVAL FORM

Submitted by Susan Sanfilippo, MSN, FNP-BC, NP-C, COHN/CM in partial fulfillment of the requirements for the degree of Doctor of Nursing Practice and accepted on behalf of the Faculty of the School of Graduate Studies by the DNP project committee.

We, the undersigned members of the Graduate Faculty of The University of Alabama in Huntsville, certify that we have advised and/or supervised the candidate on the work described in this DNP project. We further certify that we have reviewed the DNP project manuscript and approve it in partial fulfillment of the requirements for the degree of Doctor of Nursing Practice.

7-9-2018 Louise O'Keefe Committee Chair
(Date)

Aun Dahl Committee Member

Missi [Signature] DNP Program Coordinator

Karen Frith College of Nursing, Associate Dean for Graduate Studies

Masha N. Adams College of Nursing, Dean

[Signature] Graduate Dean

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ABSTRACT

The School of Graduate Studies
The University of Alabama in Huntsville

Degree: Doctor of Nursing Practice College: Nursing

Name of Candidate: Susan Sanfilippo, MSN, FNP-BC, NP-C, COHN/CM

Title: CARING FOR COMMERCIAL DRIVERS LIVES QUALITY IMPROVEMENT PROGRAM

Background and Review of Literature: A clinical observation was made during the physicals of local truck drivers with a commercial driver's license that indicated there was an increase in the number of drivers with restricted licenses. Several drivers were unable to obtain the maximum 2-year certification period. Others were temporarily or permanently disqualified due to one or more unstable chronic health conditions.

Purpose: The purpose of the Caring for Commercial Drivers Lives Quality improvement program is to improve truck driver health and ultimately make roadways safe for travel.

Methods: The theoretical framework for the proposed quality improvement program includes the Logic Model and Plan, Do, Study, Act, (PDSA), cycle diagram (W.K. Kellogg 1998; IHI, 2017). The W.K. Kellogg Foundation Logic Model framework provides a framework for the program to outline what needs to be developed, refined, and improved. The proposal PDSA diagram outlines the phases of the improvement process (See Appendix A).

Implementation Plan/Procedure: Drivers were assessed through a formalized quality improvement program that included an Advanced Practice Nurse Practitioner, and a Registered nurse health coach. Biometric measurements, weekly health coaching, and algorithms to refer to primary care.

Implications/Conclusion: In the Doctor of Nursing Practice, the practitioner seeks evidence-

ACKNOWLEDGEMENTS

I would like to acknowledge the commercial trucking industry and the drivers who assiduously work to meet the necessities of the citizens of the United States. Without them the transportation of the nation's food, health supplies, technological equipment, would nose-dive, and the activities of daily living would come to a shrieking halt.

To my husband, Peter, this is a dedication to you. For all the love and support you have given me throughout the years to see this scholarly project to completion. And with never-ending admiration to my brother, Jeffrey, a loving and gentleman, a commercial driver devoted to making our public highways a safer place to drive.

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Caring for Commercial Drivers Lives Quality Improvement Program

Introduction

In the United States, a select population of men and women drive commercial vehicles for the transportation industry. They may be employed by a local or nationally recognized employer or are self-employed. Their licensure identifies the commercial driver. A driver may drive locally or cross-country to deliver supplies to vendors and consumers. The career is challenging, lonely, and isolating with hours of operation averaging 14-hours per day (Layne, Rogers, & Randolph, 2009).

In the United States heart disease, diabetes, and obesity are the leading causes of declining health in Americans (CDC, 2017). The trucking industry's environment involves extended work hours, a sedentary lifestyle, and fast food consumption which are primary risk factors for heart disease (Robinson & Burnette, 2005; Gilson et al., 2017; Olson et al., 2016). The health of the average commercial truck driver is at risk for hypertension, obesity, obstructive lung disease, sleep disorders, and chronic or fatal cardiac conditions (Thiese et al., 2015).

Hartenbaum, 2010 states, "Cardiovascular conditions may be one of the most likely medical problems for sudden incapacitation of a commercial driver" along with other conditions such as diabetes, lung disease, or sleep apnea. "In a 1989 study of 189 fatal-to-driver heavy truck accidents, 10 percent of the accidents were at least in part attributed to medical problems" (Hartenbaum, 2010 p. 101).

Background and Identification of the Problem

Commercial truck drivers aged 21 and over are at risk for chronic health conditions due to extended work days, job pressure, and lack of sleep (Angeles et al., 2014; Apostolopoulos, Sönmez, Shattell, Gonzales, & Fehrenbacher, 2013). Commercial Driver's License, (CDL),

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drivers are sedentary and lack regular exercise, consume a high-fat diet, and use nicotine or smokeless tobacco (Apostolopoulos et al., 2013). The truck driver did not develop the CDL disqualifying condition overnight which complicates the length of recovery. Studies indicate learning healthy habits through early and frequent intervention is needed to decrease the incidence of a disease even though it may be temporary (Ng et al., 2016). Additional studies on commercial drivers' health and preventive care are essential to determine long-term benefits (Ng et al., 2016).

Commercial truck drivers are required to complete a medical evaluation and successfully pass the criteria set by the Department of Transportation (DOT) to drive commercial vehicles (Hartenbaum, 2010). The driver is financially motivated to maintain the CDL license. Without the medical examiner's signature on the certification card, the driver is unable to continue with employment.

The health of the average truck driver can be appalling with inadequately managed chronic conditions. Body image and behaviors observed within the industry include individuals with an elevated body mass index, expanded waistline, large neck circumferences, edema of lower extremities, and shortness of breath with activity, nicotine abuse, and excessive alcohol intake (Sanfilippo, 2016, Professional Observation).

A clinical observation was made during the physicals of local truck drivers with a (CDL), that indicated there was an increase in the number of drivers with restricted licenses. Several drivers were unable to obtain the maximum 2-year certification period. Others were temporarily or permanently disqualified due to one or more unstable chronic health conditions. Chronic health conditions, i.e., uncontrolled diabetes, high blood pressure, and coronary heart endanger road safety if left untreated (Jensen & Dahl, 2009). A second observation noted that care

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coordination is deficient between the Certified Medical Examiner (CME) and primary and specialty providers. Truck drivers require comprehensive assessments and interventions outside of the mandatory licensing requirements. It became clear that assistance was needed to improve the health outcomes of truck drivers.

Review of the Evidence

Databases used for the literature search include, National Library of Medicine, PubMed, Center for Disease Control, CDC, National Institute of Occupational Safety and Health, (NIOSH), Cumulative Index to Nursing and Allied Health Literature, (CINAHL Complete), and Cochrane Review. Key words used were *truck drivers, commercial trucking industry, preventive health, DOT drivers and obesity, health coaching, truck drivers and cardiovascular disease, sleep apnea and DOT, diabetes and commercial truck drivers, weight management programs.*

Studies reviewed included research of weight management programs and benefits for the truck driving industry, self-reported surveys of truck drivers, and health care provider intervention strategies. Health care provider interventions for health care promotion activities for preventive care is beneficial when combined with employer enticements; active employer dedication to the program, ease of access to the screening program best practices guidelines followed (Goetzel & Hearn, 1997).

A clinic in the Rocky Mountains implemented a 12-week study for commercial truck drivers to improve health through weight loss. Thirteen participants started the program and twelve completed it. The program included health coaches, baseline measurements, and clinician intervention. The drivers were recruited from local employers, through advertisement at truck stops, and by contacting individuals who had participated in previous studies. The participants enrolled had to be 21 years of age or older with a BMI over 27. The implementation phase

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started with baseline body and point of care diagnostic measures of lipid profile and blood sugar. eating and exercise, and cooking utensils with a heating element to prepare their meals. Health coaches interacted with the participants throughout the length of the program. The overall success of the study was limited by the sample size, timeframe, and communication difficulties. The participants were surveyed and recommended a longer program with more frequent coaching (Thiese et al., 2015).

The purpose of the study by Apostolopoulos, Sönmez, Shattell, Gonzales, and Fehrenbacher, 2013, was to survey truck drivers for self-reported health conditions and to determine if the working conditions contributed to ill health. A cross-sectional design included surveying truck drivers by utilizing the Healthy Truck driver survey. The sample size of 316 truck drivers had greater than five years' experience as a driver.

The Healthy Truck Driver Survey consists of 82 questions to determine the drivers' overall health, employment history, and ability to obtain health care services. The driver's self-reported the information by completing the survey. Fifty-three percent of the population surveyed had BMI greater than 30, and 70% of the participants did not have a primary care provider. A third of the group did not have health insurance. The study identified the need for ongoing preventive actions to improve truck driver health and for road safety. A study weakness was that the sample did not include female drivers.

Olson and colleagues 2016, used a randomized controlled interventional design for weight reduction in truck drivers to improve their health. The researchers sought out employers to enroll their drivers in a 6-month program. The program design was based on, "The Safety and Health Involvement for Truckers, (SHIFT), model" (Olson et al., 2016, p. 1698). The original

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study was small and nonrandomized, and the researchers wanted to expand the number of participants and include a control group to determine the success of the SHIFT interventions. The interventions included software to assist with weight loss monitoring, a weight loss competition, and coaching by qualified interviewers for behavioral modifications. The findings demonstrated the positive outcomes of motivational interviewing and competitive peer to peer weight loss programs. The drivers were provided an encompassing health promotion program. The outcomes for weight loss for the control and intervention group averaged 7 pounds (Olson et al., 2016). The study reinforces the need for further interventional studies to improve driver health.

In 2005 through 2012, a study performed by These and colleagues evaluated over 88,000 drivers through a database to determine if a higher body mass put them at risk for additional health conditions that may delay or disqualify them from commercial driving. The study demonstrated an inverse relationship between increasing weight and an elevated body mass index and licensure disqualification. The outcome reinforces the necessity for further clinician intervention to assist commercial drivers to a healthier lifestyle.

A study in Australia offered incentives to truck drivers for increasing activity and eating a balanced diet (Gilson, Pavey, Wright, et al., 2017). Pedometers and software applications assisted the driver with monitoring the progress through a 20-week program. The outcomes demonstrated improved physical activity. There was little improvement in the ability to obtain fresh food and maintain a balanced diet using the software, and a nutritional expert was recommended for future studies (Gilson et al., 2017).

In review of the literature, a lifestyle counseling program in Finland for truck and bus drivers demonstrated, “positive changes in lifestyle habits during counseling (Puhkala et al.,

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2016, p.435). The Finland study offered telephonic counseling to drivers while they were on the road. The drivers verbalized the appreciation for the contact to keep them connected and to meet their goals (Puhkala, 2016).

Organizational “Gap” Analysis of Project Site

The organizational gap analysis identified health care disparities in the occupational health setting. High blood pressure, obesity, smoking, lack of exercise, and stress put the CDL driver at risk for diseases. Truck drivers work long stressful hours in a sedentary environment where fast food consumption is the mainstay. The timeframes for transportation of goods and services do not allow the driver to take breaks for healthier meals or permit exercise for 30 minutes 5 or more days per week. The workplace setting does not encourage a healthy lifestyle and the long hours and time away from home do not permit scheduling 1:1 interaction with a health care provider (Greenfield et al., 2016).

The health care facility selected for implementation of this quality improvement program recognizes the gaps in care. One area that needs improvement is the need for a health care provider to assess, facilitate, evaluate, and coordinate the care of the trucking population. There are successful programs within the organization designed for men “The Jordy Nelson” and for women the “WomenHeart.”

The Jordy Nelson program named after a Green Bay Packer football player wide receiver was designed to appeal to males 18 and older without a previous health exam in last 3 years. The screening offers a testing package valued at greater than \$350.00. The laboratory testing includes a comprehensive metabolic panel, liver enzyme testing, blood sugar, and a total cholesterol panel (Bellin, 2017). The participant’s height and weight are measured along with blood pressure measurements. The results are then reviewed with a health care provider. The heart health

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program addresses heart disease prevention in women (Bellin, 2017).

The heart health program offers a support group and screening for heart disease for women. A calcium score screening test is offered for women over 40 at risk for heart disease. If a woman's history includes a positive family history of heart conditions or if their lifestyle includes smoking or little to no exercise, or elevated blood pressure, or high blood cholesterol the screening test is available for \$50.00. The cardiac computed tomography, (CT), scan test takes less than 60 minutes to perform with no prep required and measures plaque build-up to determine coronary artery disease risk (Bellin, 2017).

The stakeholders in occupational health, the medical staff, and the executive management team assimilate evidence-based medicine guidelines into clinical practice by offering screenings for high-risk populations and occupations. The goal is to improve health and save lives.

Evidence Based Practice: Verification of Chosen Option

The evidence-based practice guidelines for diabetes, heart disease, obesity, and hypertension are readily available online. For example, from the American Diabetes Association, (ADA), for diabetes management and the National Institutes of Health, Eighth Joint National Committee, (JNC8), Hypertension guidelines (James et al., 2014). The clinical site's established Health Risk Assessment (HRA), and Reasonable Alternative Standards, (RAS) coaching program guide the clinician on current evidence-based practice guidelines. The RAS program encourages the participant to improve their health by attending coaching sessions offered in 3-month increments. At the end of the RAS sessions, the participants are entitled to a monetary reward by receiving a lower premium rate retroactive to the calendar year.

Theoretical Framework/Evidence Based Practice Model

The theoretical framework for the proposed quality improvement program includes the

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Logic Model and Plan, Do, Study, Act, (PDSA), cycle diagram (W.K. Kellogg 1998; IHI, 2017). The W.K. Kellogg Foundation Logic Model framework provides a framework for the program to outline what needs to be developed, refined, and improved. The proposal PDSA diagram outlines the phases of the improvement process (See Appendix A).

The Proposal- A quality improvement project led by health care providers to improve health outcomes of commercial trucking employees.

Plan-Development of the program and gathering stakeholders to obtain buy-in.

Do- RN Nurse Health Coach/Case Manager coaching sessions begin. Brochure, checklist, algorithm, and consent forms finalized/applied. Participants selected.

Study-Determine if program is making a difference in the health outcomes of truck drivers.

Act-Making changes based on the quality improvement project phase outcomes.

Project Site and Population

The project site is located in rural Marinette County of Wisconsin. The parent company, Bellin Hospital is located in Green Bay. Several satellite clinics reside within Northeastern Green Bay, Marinette County, and Iron Mountain and Escanaba of Michigan. Occupational Health in Marinette is staffed by one advanced practice clinician and a licensed practical nurse. The clinic hours are from 7:30 am to 6:00 pm. A medical director, nurse practitioners, and several physician assistants provide coverage to the satellite clinics. The organizational structure is multi-layered with chief operating officer, team leaders, executive professional, vice presidents, quality, and information technology teams.

The facility in Marinette offers numerous specialties in orthopedics, asthma and allergy, pulmonology, oncology, and cardiology. The organization recognizes quality improvement initiatives and is open to innovative ideas and looking “outside of the box” to improve health of communities and populations.

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Bellin Hospital is a not-for-profit health care facility regionally recognized as a top rated, 8th ranked, hospital in Wisconsin by U.S. News and World Report. The executive, managerial, and health care teams work steadily and consistently to improve services and the health of populations served. The team is located in the Green Bay, Marinette, and Upper Peninsula of Michigan communities. Health care promotion activities for local employers and community stakeholders are offered onsite or within the hospital or clinic settings to improve group health.

Goals, Objectives and Expected Outcomes

The goals of this 2- month program is improved driver health by early recognition and assessment of risk factors that lead to chronic health conditions that may restrict or disqualify them from driving a commercial vehicle. The objectives:

- Promote Preventive Care.
- Recognition of signs and symptoms of disease.
- Prompt referral to primary care.
- Implementation of Advanced Practice Nurse Practitioner Navigator role and,
- Registered Nurse Health Coaching.
- Improved driver health to maintain commercial driver's licensure.

Project Design

The project design encompasses practice intervention and a process improvement project. The Advanced Practice Nurse Practitioner, (APNP), and Registered Nurse, (RN) Health Coach/Case Manager will assess, evaluate, and facilitate care based on the individual's needs. The clinician will utilize evidenced based guidelines for hypertension, diabetes, and weight management to monitor the individual's health.

The RN Health Coach/Case Manager is required to provide health coaching and be a

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certified health coach. The PDSA model provides direction for the APNP and RN to determine successes and weaknesses in the quality improvement program. The proposed program health risk assessment data obtained at baseline and 2 months' post initiation, with IRB approval DOT long form results, and participant surveys will evaluate the program.

Setting facilitators and barriers.

Assumptions are the community and stakeholders will welcome the CDL, preventive health program. In the last 3 years, local employers implemented health risk assessments to drive down health care cost. The benefit outweighs the risk as improved road safety is the concern.

External factors include time constraints, driver reluctance or lack of availability, local competition, staff resistance or failure to buy-in. The organization views the program as a pilot program. One example of a way to assist the driver with time constraints, reluctance, or lack of availability is to work around their schedule and provide 1:1 telephonic intervention with the RN Health Coach/Manager. See Appendix B, Logic Model.

Implementation/Plan/Procedures

Questions for program development:

- 1) What can a health care organization do to assist an individual with a CDL license to improve their health?
- 2) Are there successful weight management or health programs available to commercial drivers?
- 3) How does an implementation of a quality improvement program for weight management, exercise, and nutrition education motivate the individual and employer (stakeholder) to improve the driver's health?

The goals of this 2- month program is improved driver health to serve the occupational

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health needs of the commercial driver population of Marinette County and outlying communities. Marinette County is in northeast Wisconsin. Marinette County's population is greater than 40,000 people evenly distributed between males and females. The majority of inhabitants are between 21 and 61 years of age. Within this age range, the number of employed are working in the business and industrial sector. Employers are commercial trucking, retail, manufacturing, industrial, and lumber mills. Unemployment is high at 6.0% when compared to national average of 4.9% (U.S. Department of Commerce, 2016). Healthcare and commercial trucking are a prominent competitive industry in the county.

Employers desire lower health care cost while maintaining quality health care services for their employees. The quality of care, timeliness of the delivery, and the immediate return to driver activities are of the utmost importance to individuals seeking care and their stakeholders. The stakeholders include employers, community leaders, and the families of the employees.

Given that health problems experienced by commercial drivers can affect their safety, health, and employment, what interventions and/or programs can be implemented to improve the health and wellness of a commercial driver? At an occupational health clinic in central Wisconsin, a program was initiated to improve commercial drivers' health. This program offers assessment, monitoring and health care services such as weight management, counseling, biometric measurements, comprehensive laboratory testing, exercise recommendation, smoking cessation, obstructive sleep apnea evaluation and nutrition education.

Guidance is provided by an APNP and a RN Health Coach/Case manager. Interventions offered are assessment, monitoring, and direction finding health care services to prevent chronic disease from becoming debilitating and restrict or disqualify a CDL licensure. Services include weight management counseling, biometric measurements, comprehensive metabolic laboratory

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testing, exercise recommendations, smoking cessation, obstructive sleep apnea evaluation, and nutrition education.

A program brochure outlines the services, location, and contact information to educate all stakeholders. Program development and support are maintained and communicated to interdepartmental executives and midlevel management during weekly and monthly team leader meetings. A meeting with marketing, the Occupational Health Director and the leadership team, reviewed the program mission, vision, and outcome goal. Through these discussions it was identified that the occupational health department is currently providing the service at no cost. Referrals to primary care providers, (PCP), specialty providers, and the ancillary departments would increase revenue and patient health.

Next Steps

1. IRB, Internal Review Board Approval.
2. Information technology, IT EPIC team, consulted for future utilization of electronic health care record. Mandatory utilization of DOT, long form prohibits electronic version.
3. Arrange conference call with Medical Director. Perform DOT exams per regulatory guidelines. Finalize algorithms for hypertension, diabetes, elevated body mass index, and sleep apnea. Select DOT candidates utilizing the DOT Driver Checklist form (Appendix C). Perform HRA, Health Risk Assessment, free of charge to candidates. Schedule DOT Driver with Case Manager. Charge RN visits 12.50 per quarter hour. Referral numbers to PCPs, captured.
4. A random sample survey distribution to commercial transportation employers to obtain their input on the Department of Transportation Medical Examiners long form and driver health.

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- a. The data collection procedure for surveying the local transportation employer group arranged through an e-mail distribution list located on the Occupational Solutions mail server.
- b. A 10-question survey through the Survey Monkey website addresses the number of employees, the number of drivers, questioned on health risk assessments, and a question on the designated employer representative's opinion on a program to improve and monitor commercial driver's health. Open hyperlink for survey-
<https://www.surveymonkey.com/r/K7YKKRB>
- c. This survey consists of 10 question survey developed on the Survey Monkey website. The vendor charges 25.00 dollars a month or 300 dollars annually to have survey data analyzed. The budget for staff costs includes an advanced practice nurse practitioner's hourly wage-of \$44.00 and the registered nurse wage of \$19.00 an hour. An estimate of 2% of the annual hours or 42 hours per clinical staff. The total cost to initiate the survey is 2,646 dollars.
- d. The timeline for this initiation and analysis of the survey data is four weeks. An introduction letter and hyperlink to the survey was included in the e-mail. Week 1: the APNP delegates the task for sending the survey and introduction letter to the employer group to the registered nurse Week 2: the RN follows up with the designated employer representative, DER, to determine if there are questions or concerns.
- e. Week 3: Tallies the number of responses. Week 4: APNP, Advanced Practice Nurse Practitioner presents the survey results to the marketing team.
- f. The APNP will review the data collection for HRA and results provided by the

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vendor's website. The process will begin with HRA baseline data and repeat HRA analysis in 2 months. The Marinette, WI satellite occupational health department's office, computer, and internet access utilized to develop and expand the CDL program.

- g. The APNP will audit the CDL long form. Electronic Medical Record, EMR, record review for health care outcomes. (HRA results, Vital Flow Sheet-Blood pressure and Body Mass Index, BMI. # of PCP visits. Driver Certification period monitored. APNP and RN case manager hours calculated.
5. The medical examiner's findings derived from the long form determine the driver's length of certification or disqualification or pended status. The data collected from the long form highlights areas of alarm necessitating additional medical review and follow up.
6. History or yes responses to questions about coronary artery disease, smoking, head injuries, sleep apnea testing, kidney, lung, alcohol consumption, and cancer diagnosis categorize drivers at risk incapacitating conditions. The driver's primary care provider or specialists provide input on the stability of the disorder. Example a driver with diabetes and a reported hemoglobin A1c of 9.8 indicates uncontrolled diabetes or elevation of blood pressure above 140/90 will restrict licensure. The individual requires medical intervention and monitoring to monitor blood pressure readings for pharmaceutical management and to stabilize the diabetes and bring down the hemoglobin A1c.

Implementing healthy behavior programs throughout the certification period would add a goal; to provide early intervention strategies. The intervention process includes promotion of wellness through one on one session with a designated healthcare provider, nutritionists, physical

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therapist or personal trainer, and a registered nurse. The individual receives the interventions throughout the year to improve the results of their next scheduled CDL exam.

The proposed quality improvement program is initiated with 1:1 interaction with the advanced practice clinician, APNP, and the patient. The APNP facilitates a health promotion program for commercial truck drivers by identifying at risk individuals during the certification exam. Utilizing a checklist form developed to define chronic conditions or habits that may alter lifestyles or hinder or limit the Department of Transportation, DOT, certification card with algorithms for hypertension, body mass index, and hemoglobin A1c parameters will guide the clinician and nurse case manager/health coach (Appendices G, H and I).

Steps to determine CDL participants:

- 1) Driver schedules a commercial driver's medical exam for initial application or recertification.
- 2) Completes the Driver History section on Form MCSA-5875 (see attached file).
- 3) Provider reviews Driver Health History with individual and performs the examination.
- 4) If Diagnosis/Risk Factors:
 - Hypertension

 - Elevated BMI
 - 25-30 Overweight
 - Greater 30 Obese

 - Diabetes
 - Hemoglobin A1c greater or equal to 10%
 - Hemoglobin A1c greater or equal to 7.5% to 9.99%

 - Nicotine Consumption

 - Neck circumference > than 17 inches in males or 16 inches in females, + above comorbidities or positive Obstructive sleep apnea, OSA, symptoms-daytime sleepiness, snore, apnea.

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Referral to appropriate resources for continued care and monitored by Advanced Nurse Practitioner, APNP, and Registered Nurse Case Manager/Health Coach.

- 5) The provider describes the program with the driver and obtains agreement to participate. Then completes the DOT Driver Checklist and faxes the form to the RN Health Coach at 920-436-8699. Within 7 days the RN coach will contact the driver to schedule an appointment.
- 6) The APNP will schedule the HRA within 2-3 days in order for the driver and the RN Health Coach to meet to discuss the results.
- 7) The driver and RN Health Coach will determine health coaching goals based on the HRA results. After initial Face to Face contact, weekly meetings are recommended over the next 3 months.
- 8) During the health coaching the RN Health Coach and health care provider will maintain communication on the individual's progress or lack of.
- 9) At the end of the program a repeat HRA will be drawn.

Measurement Instruments, Data Collection, Data Procedures, Data Analysis

To determine the success or weakness of the program data is collected pre- and post-initiation of the program. The data measured is the baseline and post health risk assessment biometric and comprehensive laboratory numerical results. A comprehensive analysis of the biometric and metabolic testing is reported in a 0-100 ranking; with a 100 recognized as the maximum number to achieve. The survey for stakeholders is identified on the Survey Monkey website and developed by the author (Appendix D). The driver's satisfaction is measured with the following instruments.

The scale survey Medical Outcomes Study Short Form 36 (MOS SF-36) and Medical Outcomes Study Short Form 12 (MOS SF-12) are instruments for use in evaluating a wide-range of disease states and to assess health statuses in adult populations (Lorentz, 2005; Wukich, 2016; Zengin, 2014). The driver/patient can complete the form individually or a trained health system's designee can interview and document the information (Lorentz, 2005). The time

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requirement averages 15 minutes. The questions are weighted and scored to 100 points. The closer the score is to 100 the healthier the individual (Busija et al., 2011).

Validity:

“The MOS SF-36 and MOS SF-12 are well developed, concise instruments with excellent core descriptions of reliability and validity” (Lorentz, 2005, p. 342). Royse, 2016, states that if an instrument has high validity then it is reliable. The instruments SF-36 and SF-12 is available for viewing in the attached .pdf file.

Reliability:

The survey reliability is more than 0.80 for SF-36 and SF-12 (McHorney et al., 1994). The instrument measures a current health status and is utilized in the future to determine if the program improved outcomes. The ability for the instrument to provide baseline and future measurements are tremendously valuable to the patient, program organizers, and stakeholders.

Suitability:

The instrument is suitable for adults and teenagers older than 14, (Lorentz, 2005). In Royse, 2016, the audience must be considered when surveying groups of individuals. If the questions appear intrusive to the individual because they are asked about income and level of education a negative interaction or response may be felt between the patient and interviewer.

Cost-Benefit Analysis/Budget

The proposed cost-benefit analysis and budget for the program is \$65.00-dollar pre- and post -HRA analysis per participant. The RN Health Coach/Case manager \$19.00 per hour wage and projected to be paid for by \$12.50 per quarter hour fee attached to health coaching. The forms, brochure, and APNP wages are currently provided free of charge beyond the \$73.00 fee

CARING FOR COMMERCIAL DRIVERS LIVES QUALITY

for a DOT examination. The case management services provided by the APNP beyond the DOT examination are currently provided gratis. The organization does not have the means to collect for case management provided by a health care provider. See Cost-Benefit Analysis/Budget Table 2.

Timeline

The timeline for the program is 2 months. The RN Health Coach/Case manager selection required certification and current registered nurse licensure. The enrollees selection is determined by the APNP's assessment and evaluation of the past and current DOT examination forms. A health risk assessment is originated within 2-3 days of the participants' voluntary agreement to enroll in the program. The RN Health Coach will meet with the participant within 7 days of receiving the DOT checklist and the HRA results. See Appendix E for detailed outline.

Process

The quality improvement program began with offering qualifying participants the option to have the health risk assessment with biometric measurements. The biometric measurements obtained at initiation of the program and upon completion. The program includes the weekly meetings with the RN health coach. The first meeting is in person and the remaining via telephonic measurements. The day and time of the meetings is mutually agreed upon between the participant and RN health coach.

At the end of the program a final health risk assessment is measured. The RN health coach and APNP meet to review the program with the participant. The program was implemented the fall of 2017 with Bellin's IRB approval as a quality initiative to improve health and self-care of commercial drivers. Fifty driver's records revealed twenty-four healthy males and twenty-six with chronic or new health conditions identified. One participant successfully

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completed the program. One female accepted admittance to the program and then elected to do home exercises and diet plan independently. An additional 4 male individuals declined to participate due to commitment issues. Limitation of study- limited number of participants and driver's lack of readiness for change. The remaining twenty-five drivers were referred to primary care through utilization of the algorithms for hemoglobin A1c, body mass index, and blood pressure.

Case Study

JD is a new CDL applicant. He is between 31- 40 years of age. The medical examiner's report revealed an excessive intake of sugar laden soda, inactivity, and an increase in urinary output. The urine macro test results demonstrated over 500mg/dl for sugar. JD stated he never had diabetes and does not have a primary care provider. The last physician seen was in the Bellin system over 3 years ago. The remaining portion of the physical exam for heart, lung, skin, and abdominal abnormalities was negative.

The APNP scheduled the health risk assessment and RN health coach meeting within the 2-3-day frame. JD and his wife participated in a 45-minute visit to review the program and expectations.

The weekly meetings started with e-mail and telephonic communications to discuss concerns or questions on his progress.

JD successfully completed the program with improvement in activity, decreased hemoglobin A1c from 9 to below 7, omission of sugar laden soda and replaced with water or no calorie soda, and he qualified for a one-year commercial driver's license. JD did not complete the MOS 36-Item Short-Form Health Survey until the end of the program. JD's HRA score was below 50 at the start of the program and increased by twenty points at the end of the 8-week

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sessions. JD met with the APNP at his final HRA screen and had recommendations for future participants, program flow, and the APNP.

JD stated the weekly telephonic meetings were beneficial but expressed concern for others to follow through, as his wife was a big supporter and reminded him of his commitment to the program and his family to maintain a healthy lifestyle. JD recommended the program offer onsite visits for drivers unable to communicate via telephonic means. Overall, JD rated the program as successful and appreciated the APNP and RN health coach's interventions and would recommend to others. JD stated he would follow with his primary care provider as directed and dietician to improve his eating habits.

The employer surveys were delivered through individual employer identified e-mail broadcasts with a confidential link to survey monkey. Fifty surveys were sent with one response. The company reported over 2000 employed drivers and reported at this time they have no desire to offer health risk assessments, or offer gym memberships, or to receive a call from our facility to discuss the quality program. The respondent did indicate the employer was satisfied with Bellin's Occupational Health program and would continue to utilize the services. Initially it was thought the response rate was low due to undeliverable e-mail addresses. With e-mail address updates and door to door contact the response rate remained unchanged. Two local health care competitors provide gift certificates to employers in order to obtain a survey response. In the future it may be beneficial for the organization to offer a nominal monetary reward to obtain an employer's input.

Ethical Considerations/Protection of Human Subjects

The program requirements include protection of the enrollee's written and electronic medical records. The DOT checklist and personal identifiers of drivers are managed under the

CARING FOR COMMERCIAL DRIVERS LIVES QUALITY

rules and regulations of the Health Insurance Portability and Accountability Act of 1996, (HIPAA). The clinical site's Internal Review Board, IRB, approved the quality improvement program (Appendix F). The University of Alabama-Huntsville IRB approved the submission of the proposed quality improvement program. The consent form for the "The Commercial Driver Lives Quality Improvement Program" and HRA inform the driver of their commitment and responsibilities as a participant (Appendix E).

Clinical Implications to Nursing

In the Doctor of Nursing Practice, DNP, the practitioner seeks evidence-based care protocols and guidelines to provide the best interventions (Reavy, 2016). The population health of commercial drivers warrants early intervention to prevent diseases such as cardiac disease, high blood pressure or high blood sugars, and sleep deprivation. The DNP clinician assesses, manages, and plans care with "The process of shared decision making between, practitioner, patient, and others significant to them based on research evidence, the patient's experiences and preferences, clinical expertise or know-how, and other available robust sources of information" (Polit & Beck, 2012, p.25). The APNP/DNP provider must be willing to offer programs outside of the customary clinical setting and bring health care to the work site.

Approach

The ideal time to intervene with all individuals in safety-sensitive occupations to identify high-risk behaviors or unhealthy lifestyles is upon hiring or during the certification examination. The driver would be assessed and referred to the structured program by certified medical examiners as identified under the Department of Transportation's guidelines.

Expected Outcomes

The expected outcomes are an identified quality improvement program designed for

CARING FOR COMMERCIAL DRIVERS LIVES QUALITY

commercial drivers, improved road safety, and the enhanced long-term health of the driver (Jensen & Dahl, 2009). The long-term outcome is for the driver and employer to be satisfied with the program and the interventions to maintain or improve the driver's state of health.

Conclusion

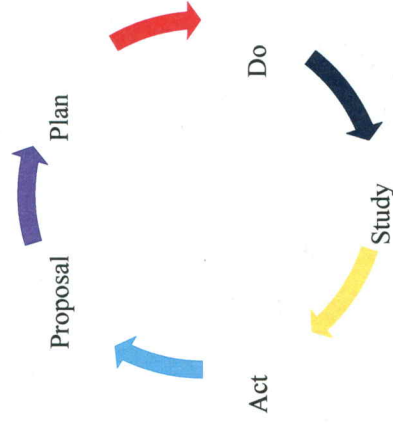
The quality improvements successes and implications for future services revealed the need for ongoing interventions to improve the commercial driver's health. The health care practitioner can provide direction, effective communication, and direction for referrals to primary care when a participant his unable or unwilling to participate in a structured program. The algorithms for BMI, hypertension, and elevated hemoglobin A1c are available to the facilities' practitioners and of benefit to a clinician's practice to refer to primary care and monitor driver's conditions.

The study's greatest limitation is the lack of response to the program. The program is innovative for a rural community. The health care and trucking industry in the northern region of Wisconsin must collaborate regularly to engage commercial drivers to improve health. Interventions for improving participation is promoting the program outside of the organization at community events, employer sites, and sponsored occupational health events.

The long-term goal for improving road safety is far from its goal as many variables for underutilization of health care between driver certification, medical examiners not adhering to DOT guidelines for driver qualifications, and ongoing job stress for drivers being on the road from family or support systems. Further research is required to improve overall driver health and to increase employer and driver participation with structured quality improvement programs.

Caring for Commercial Drivers Lives Quality Improvement Program

Appendix A



The Proposal- A quality improvement project led by health care providers to improve health outcomes of commercial trucking employees.

Plan-Development of the program and gathering stakeholders to obtain buy-in.

Do- RN Nurse Health Coach/Case Manager coaching sessions begin. Brochure, checklist, algorithm, and consent forms finalized/applied. Participants selected.

Study-Determine if program is making a difference in the health outcomes of truck drivers.

Act-Making changes based on the quality improvement project phase outcomes.

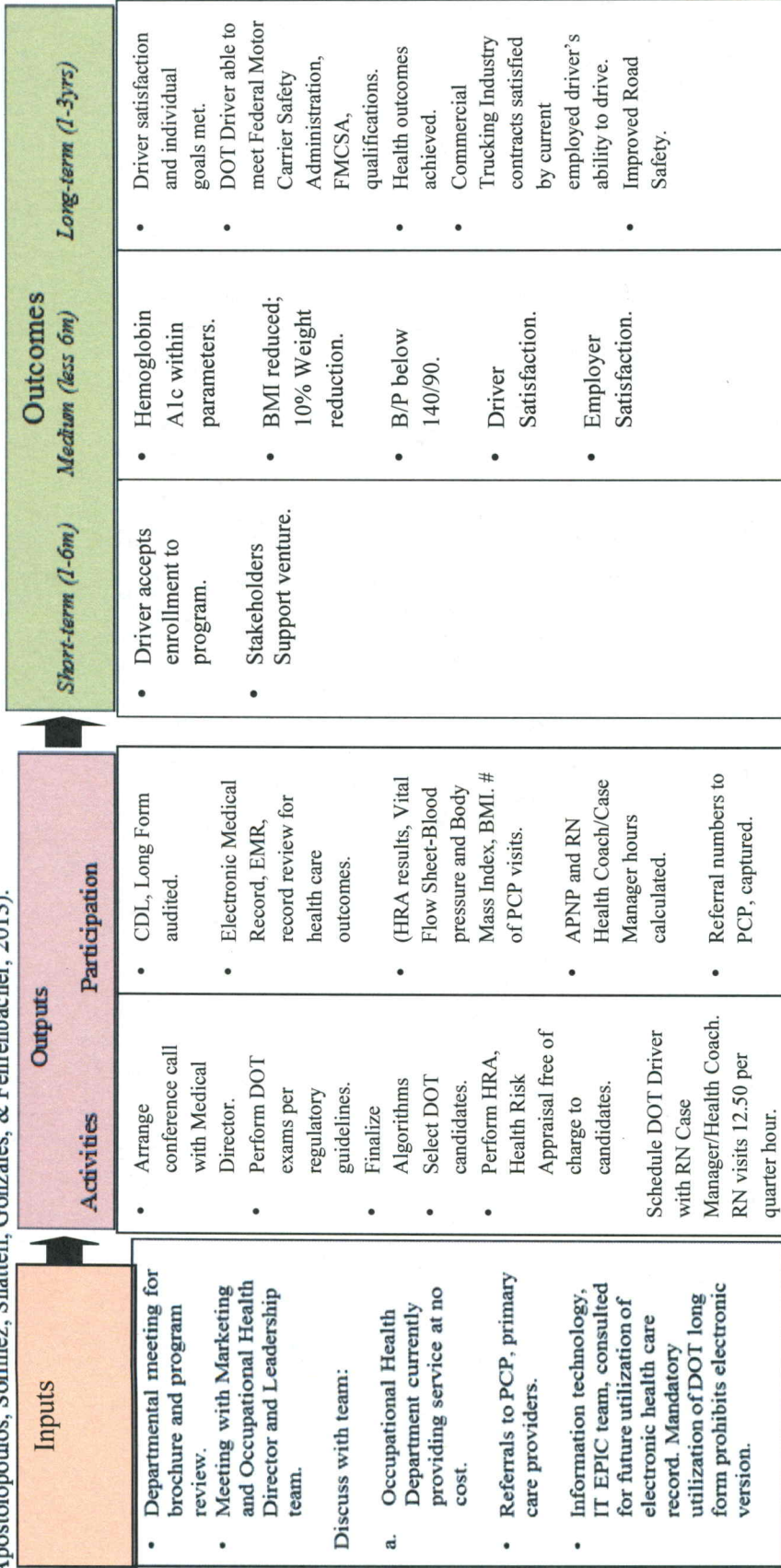
Adapted: Langley GL, Moen R, Nolan KM, Nolan TW, Norman CL, Provost LP. The Improvement Guide: A Practical Approach to Enhancing Organizational Performance (2nd edition). San Francisco: Jossey-Bass Publishers; 2009.

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Program: DOT Driver Logic Model

Appendix B

Situation: The *Caring for Commercial Drivers Lives Program*, based on the fundamentals of health and wellness. The commercial truck driving industry has a high rate of employees with high blood pressure, elevated blood sugars, heart and lung disease, stress-related mental health issues, and sedentary work activity (Apostolopoulos, Sónmez, Shattell, Gonzales, & Fehrenbacher, 2013).



Assumptions

The community and stakeholders will welcome the CDL preventive health program. In the last 3 years, local employers implemented health risk assessments to drive down health care cost. The benefit outweighs the risk as improved road safety is the concern.

External Factors

Time constraints, driver reluctance or lack of availability, local competition, staff resistance or failure to buy-in.

Appendix C



DOT Driver Checklist

Appointment Date ___/___/___

PATIENT INFORMATION

Name: _____ DOB: _____
Employer: _____ CDL Status: _____

Diagnosis/Risk Factors

- Hypertension, Elevated BMI, 25-30 Overweight, Greater 30 Obese, Nicotine Consumption, Diabetes, Hemoglobin A1c greater or equal to 10%, Hemoglobin A1c greater or equal to 7.5% to 9.99%, Neck circumference > than 17 male or 16 female, + above comorbidities or positive symptoms-daytime sleepiness, snore, apnea

Health Risk Assessment Results

- Schedule HRA Date ___/___/___
Review HRA Score ___ Date ___/___/___

Goals

- 1. _____ 2. _____ 3. _____

PROGRAM REFERRALS

- ESTABLISH WITH PCP Healthcare Provider Name: _____
RN CASE MANAGER
PHYSICAL THERAPY
OSA, Obstructive Sleep Apnea Evaluation
DIETARY REFERRAL
DIABETES EDUCATOR

RN Case Manager

- Weekly Telephonic Counseling
1:1 Face to Face Date ___/___/___ Date ___/___/___ Date ___/___/___

OUTCOMES (Measured through Long Form, Chart Audit and Surveys)

- Goals Met: BMI reduced; 10% Weight reduction
B/P below 140/90
Hemoglobin A1c within parameters
Driver Satisfaction
Employer Satisfaction

CARING FOR COMMERCIAL DRIVERS LIVES QUALITY

Appendix D

CDL Employer Survey

1. About how many employees work at your organization?

_____.

2. How many of the employees are commercial truck drivers?

_____.

3. Are majority of the drivers certified to drive for 2 years based on the last medical exam?

Yes

No

4. Do you offer health risk assessment testing?

Yes

No

5. In the past two years how satisfied were you with the exams performed at Bellin Health Occupational Health Marinette?

6. What are your biggest concerns regarding the Commercial Driver's Licensure, CDL, and medical certification requirements?

Too restrictive.

Driver's Health.

Lack of healthcare provider support for trucking industry.

Disqualification of driver, loss of licensure.

7. Do you or would you offer incentives to employees participating in wellness programs?

Yes

No

Maybe

8. Do you have any other comments, questions, or concerns?

_____.

9. Would you like to have a representative contact you regarding our CDL wellness program?

Yes No

10. Do you offer reimbursement for fitness membership? Yes No

Appendix E

Caring for Commercial Drivers Health Coaching Program

Your Occupational Health provider has referred you to this program to improve your personal health. We ask that you commit to completing the following requirements:

Baseline Health Risk Assessment

A Health Risk Assessment is a tool to help individuals to identify personal health risks by completing a health questionnaire and biometric measurements. Measurements include a blood test and physical health measurements (height, weight, waist measurement, blood pressure, etc.). The blood tests include: blood sugar, cholesterol, nicotine, and blood chemistries.

Cost: Free

Health Coaching

Program Description: Meet with a Bellin Personal Health Coach to discuss Health Risk Assessment results, develop a personal wellness plan, and set goals

Initial Meeting: 30-45 minutes in durations

Face to face (unless driver lives > 20 miles from Health Coach Office) or
Telephonic (used if driver lives > 20 miles from Health Coach Office)

- Review Health Risk Assessment results for determination of which areas to focus on
- Develop health and wellness plan-goal setting/motivators/barriers/strategies to overcome, etc.
- Determine follow up coaching schedule

Follow up coaching: Weekly (15-30 minutes) appointments for 4 weeks (4 visits) and every other week over 8 weeks (4 additional visits) for a program total of 8 visits. Days/times for appointments to be determined with Health Coach.

Full coaching time will span 2 months.

Cost: Free

Post Health Risk Assessment

Repeat testing to determine overall progress in the program.

Cost: Free

I understand the requirements of this program.

Participant Name

Date

Appendix F

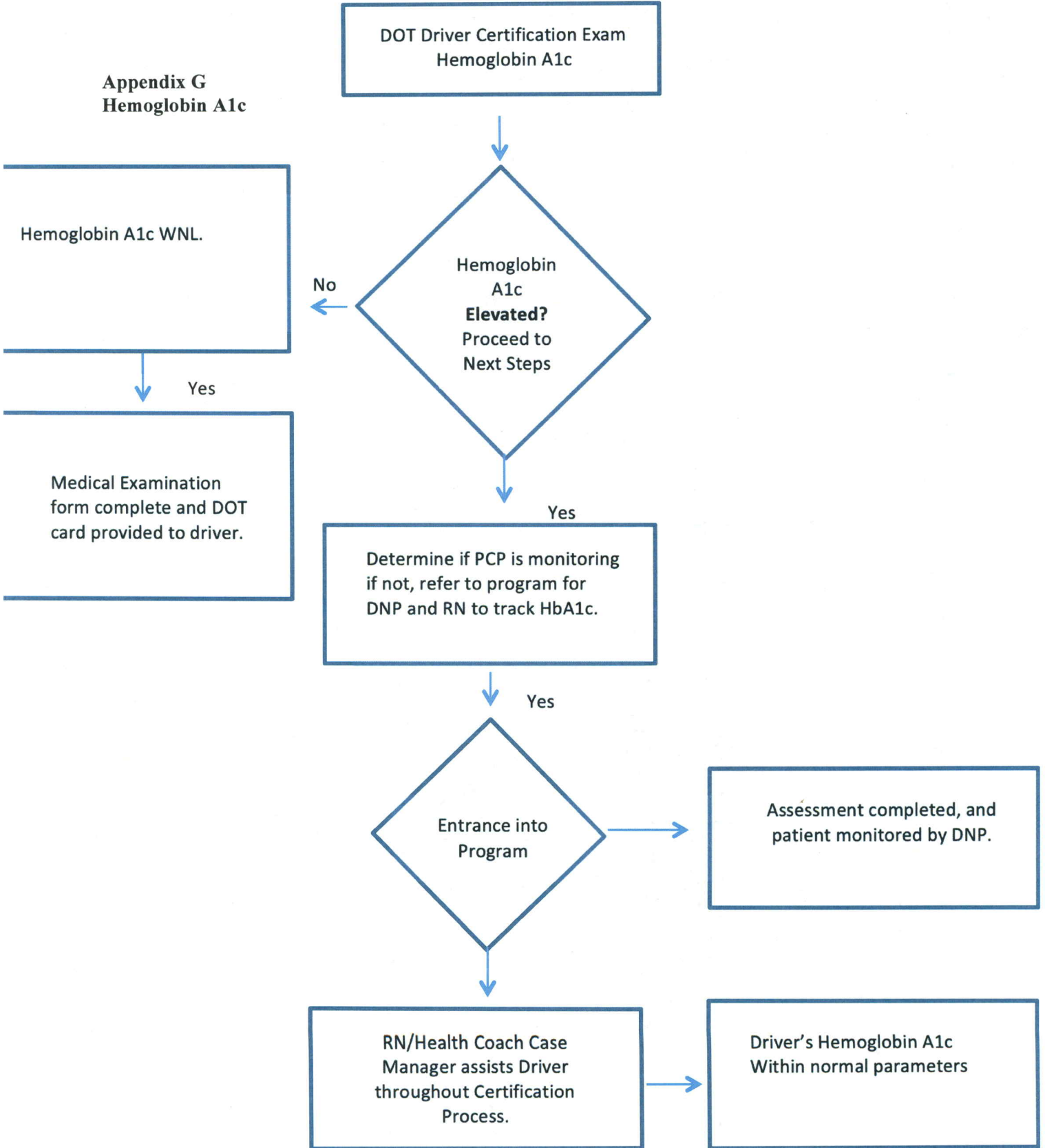
Driver Health Survey

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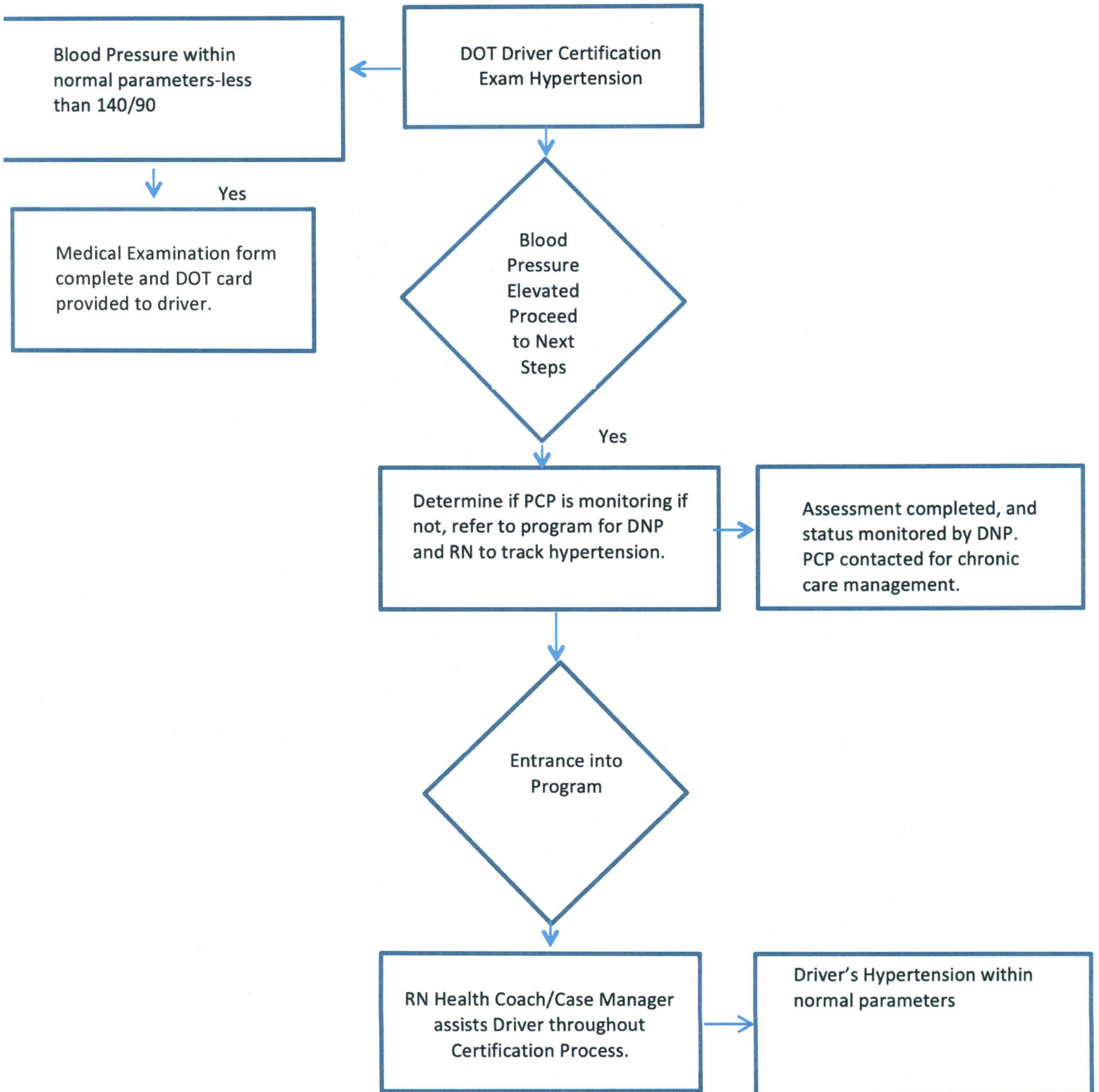
http://www.brandeis.edu/roybal/docs/SF-36_website_PDF.pdf

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Appendix G
Hemoglobin A1c

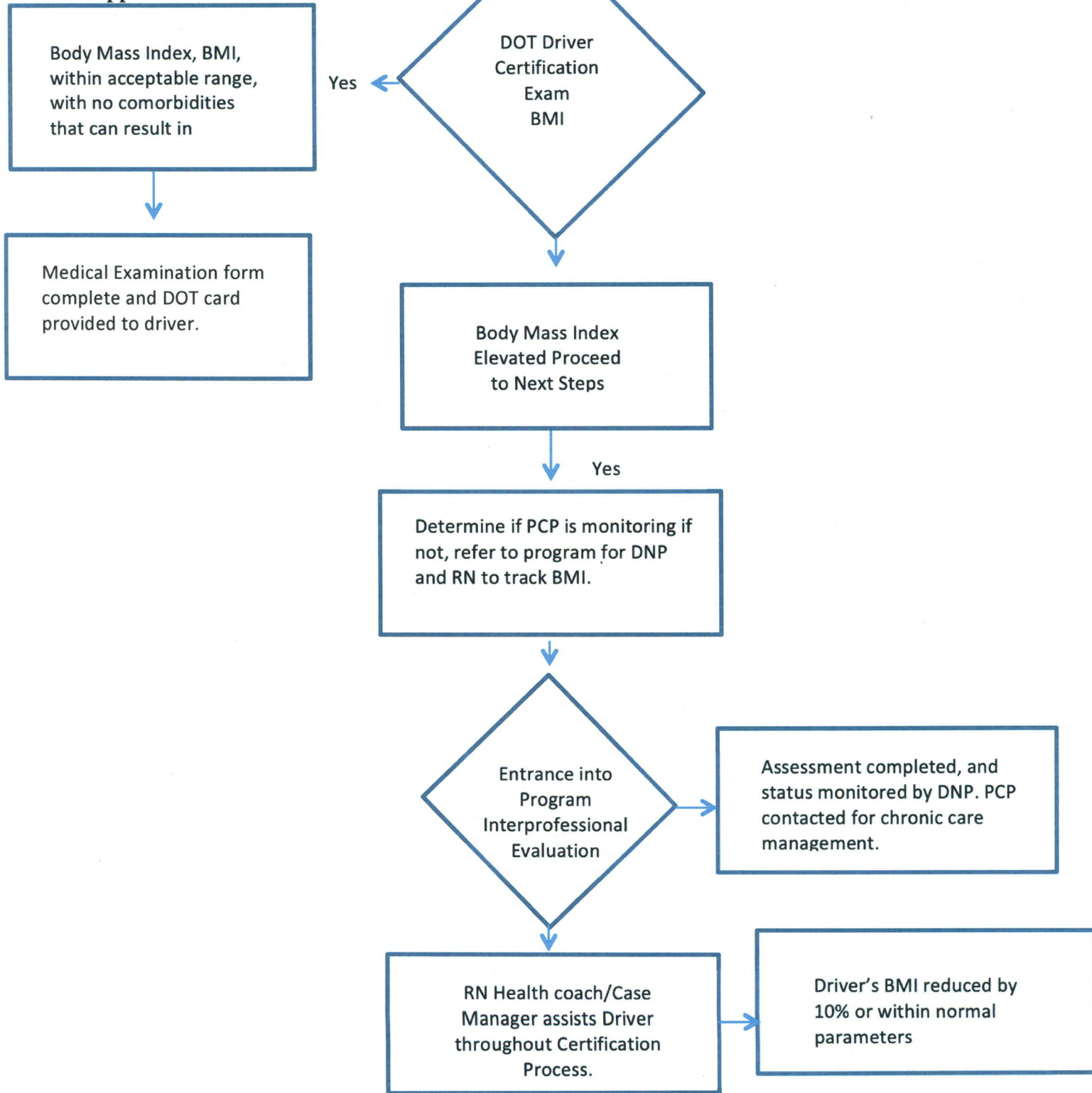


Appendix H Blood Pressure



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Appendix I BMI



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Table 1.

Advantages	Disadvantages
1:1 interaction.	The driver's extended work-hours limit face to face time with provider.
RN Health Coach/Case Management Reimbursement.	RN fee may deter drivers or employers from participation.
Employer "Buy In" to maintain driver CDL licensure.	Lack of employer support because of economic concerns for small transportation carriers.
Interdepartmental support.	Lack of organizational internal support because the Occupational Health department is an ancillary service and not identified as profitable by upper management.

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Table 2. Cost Benefit Analysis

Clinic Staff	Wage/Cost		Services	Fee (*Future fee)
APNP	\$44.00 per hour		DOT exam	\$73.00 per exam
RN Wage	\$19.00 per hour		Case Management	\$50.00 per hour fee (\$12.50 per 15-minute increment*)
5-hour Case Review by APNP - currently waived.	\$220.00 loss per 5-hour increment		HRA	\$65.00 per test=\$120.00*
Total	\$220.00 (loss) per case			\$243.00 Gain Subtract \$44.00 for APNP hourly wage \$199.00 Profit per individual

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Timeline Table 3 Project Timeline

Task	October	November	December	January	February	March	April	May	June
2017-2018									
Develop Algorithms, finalize brochure, program and Health Risk Assessment HRA consent form, and Electronic Medical Record, EMR documentation.	X								
Interview and select RN Health Coach.	X								
Enroll participants-2 - month commitment.	X	X	X	X	X	X	X	X	X
Assessment, Recognition, Intervention, Evaluation; of quality program benefits.	X	X	X	X					
Quality Program Summary.				X					
Results presented to local stakeholders, healthcare providers, community								X	

CARING FOR COMMERCIAL DRIVERS LIVES QUALITY

representatives.									
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Key:	Age Range: 21-30, 31-40, 41-50, 51-60, 61-70, 71-80
BMI: Body Mass Index	Gender: Male or Female
	Certification: 2 Years Maximum

# (1-25)	Gender	Age	Body Mass Index BMI	Dx-Diagnosis	Certification Period	Date Card Expires	Accompanied by Waiver	Disqualified
1	Male	31-40	31.32	Hypertension	5-30-2018	8-30-2018		
2	Male	31-40	26.08	Healthy Male	5-30-2018	5-30-2020		
3	Male	71-80	29.11	CAD, HTN, Stents	06-14-2018	06-14-2019		
4	Male	51-60	39.97	Insulin dependent diabetes, CPAP, CAD	06-13-2018	06-13-2019		
5	Male	41-50	32.78	HTN, OSA hx	06-13-2018	06-13-2019		
6	Male	41-50	26.3	Healthy Male	06-12-2018	06-12-2020		
7	Male	41-50	32.6	HTN	06-15-2018	06-12-2019		
8	Male	31-40	31.32	HTN	05-30-2018	8-30-2018		
9	Male	31-40	26.08	Healthy Male	05-30-18	05-30-2020		
10	Male	21-30	37.78	Healthy Male	03-29-2018	03-29-2020		
11	Male	41-50	46.33	HTN, CPAP	04-03-2018	04-03-2019		
12	Male	51-60	33.70	Healthy Male	03-30-2018	03-30-2018		
13	Male	31-40	32.44	Healthy Male	05-29-2018	05-29-2020		
14	Male	41-50	37.27	Healthy Male	05-25-2018	05-25-2020		
15	Male	71-80	36.03	Diabetes Type II, CPAP, HTN, CAD Medication regime, PAC, PVC	05-25-2018	05-25-2019	Yes	
16	Male	61-70	28.51	OSA, HTN	05-25-2018	05-25-2019		
17	Male	51-60	41.2	HTN	05-22-2018	05-22-2019		
18	Male	51-60	36.76	Diabetes Type II	05-22-2018	08-22-2018		
19	Male	41-50	30.6	OSA, CPAP	05-18-2018	05-18-2019		
20	Male	51-60	33.00	CPAP	05-11-2018	05-11-2019		
21	Male	41-50	38.00	Healthy Male	05-11-2018	05-11-2019		
22	Male	51-60	24.89		05-1-2018	05-01-2020		

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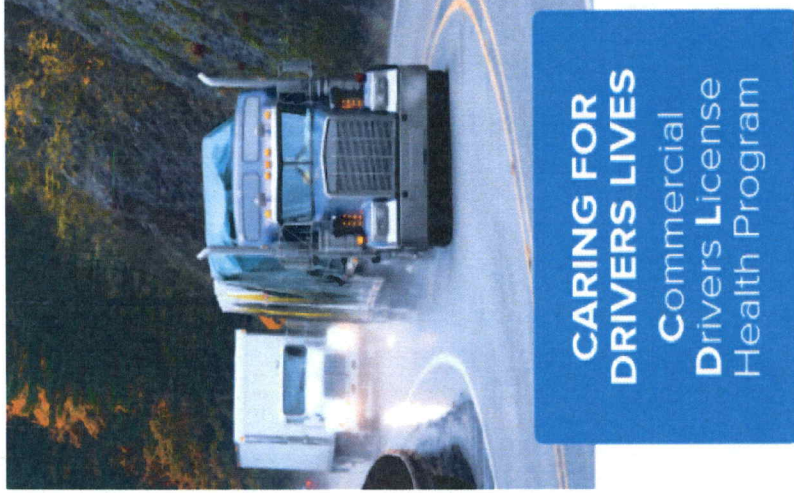
23	Male	51-60	29.03	Healthy Male	4-26-2018	04-26-2020		
24	Male	21-30	23.78	Healthy Male	04-26-2018	04-26-2020		
25	Male	21-30	40.93	Healthy Male	04-19-2018	04-19-2020		

Table 4 Data Analysis Sample

Appendix J

SERVICES OFFERED:

- Pre/Post Dot Certification Assessments to Improve Health and Successful Licensure
- DOT Physicals
- Health Risk Assessments
- Nurse Health Coaching
- Physical Therapy Evaluation and Treatment
- Primary Care and Specialty Referrals
- Weight Management
- Nutrition Counseling
- HMR Diet Program
- Smoking Cessation Program
- Post Offer Functional Assessments
- Obstructive Sleep Apnea, OSA Evaluation



CARING FOR
DRIVERS LIVES
Commercial
Drivers License
Health Program

bellinhealth

Marinette

A Department of Bellin Health Oconto Hospital

2820 Roosevelt Road | 715.735.2200

bellin.org

bellinhealth | Occupational Health



Commercial Driving Profession

The average commercial driver is 45 years of age, male, and overweight. Their health is comprised due to inactivity, poor dietary habits, and high risk behaviors such as smoking. Smoking is a leading cause of high blood pressure, coronary artery disease, and strokes.

Licensure:

In order for commercial drivers to maintain their CDL license a mandatory medical examination is required by a Certified Medical Examiner.

The examiner must determine if the driver meets the Federal Standards to safeguard roadways. The health of the driver is reviewed. Elevated body mass index, BMI, high blood pressure readings greater than 140/90, uncontrolled blood sugars with hemoglobin A1c above 7.0% warrant additional testing or referrals. The untreated condition could limit or disqualify the driver. Our goal is to prevent this from happening.



Our Approach

Our approach is to assist the driver with his or her health throughout the certification period. Bellin Health can offer professional healthcare services with Occupational Healthcare providers, physical therapy to improve fitness and dietary services to educate on proper nutritional intake, along with 1:1 intervention on maintaining or achieving a state of health.

WE WANT OUR PATIENTS TO HAVE A PHENOMENAL EXPERIENCE.

Appendix K

IRB Letter-Bellin



Bellin Health IRB

QI Protocol Notification

To: Susan Sanfilippo
From: Mary Sallenbach, IRB Coordinator
Subject: Protocol #67
Date: 08/02/2017

The protocol **67. Caring for Commercial Driver's Lives Program** has been verified as a **Quality Improvement Project**, and accordingly does not meet the definition of "research" at to 45CFR46.102(d). Your protocol is thus exempt from IRB review.

Please note that changes to your protocol may affect its exempt status. Please contact me directly to discuss any changes you may contemplate.

Thanks,

Mary Sallenbach
IRB Coordinator
mary.sallenbach@bellin.org

CARING FOR COMMERCIAL DRIVERS LIVES QUALITY

Appendix L

IRB Letter-UAH



THE UNIVERSITY OF ALABAMA IN HUNTSVILLE

March 15th 2018

Susan Sanfilippo
Department of Nursing
University of Alabama in Huntsville

<input checked="" type="checkbox"/> Expedited (see pg 2)
<input type="checkbox"/> Exempted (see pg 3)
<input type="checkbox"/> Full Review
<input type="checkbox"/> Extension of Approval

Dear Ms. Sanfilippo,

The UAH Institutional Review Board of Human Subjects Committee has reviewed your proposal, *Caring for Commercial Drivers' Lives Program*, and found it meets the necessary criteria for approval. Your proposal seems to be in compliance with this institutions Federal Wide Assurance (FWA) 00019998 and the DHHS Regulations for the Protection of Human Subjects (45 CFR 46).

Please note that this approval is good for one year from the date on this letter. If data collection continues past this period, you are responsible for processing a renewal application a minimum of 60 days prior to the expiration date.

No changes are to be made to the approved protocol without prior review and approval from the UAH IRB. All changes (e.g. a change in procedure, number of subjects, personnel, study locations, new recruitment materials, study instruments, etc) must be prospectively reviewed and approved by the IRB before they are implemented. You should report any unanticipated problems involving risks to the participants or others to the IRB Chair.

If you have any questions regarding the IRB's decision, please contact me.

Sincerely,

Bruce Stallsmith
IRB Chair

Professor, Biological Sciences

OFFICE OF THE VICE PRESIDENT FOR RESEARCH Von Braun Research Hall M-17
35899

T 256.824.6100

F 256.824.6783

Huntsville, AL

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Expedited:

Clinical studies of drugs and medical devices only when condition (a) or (b) is met. (a) Research on drugs for which an investigational new drug application (21 CFR Part 312) is not required. (Note: Research on marketed drugs that significantly increases the risks or decreases the acceptability of the risks associated with the use of the product is not eligible for expedited review. (b) Research on medical devices for which (i) an investigational device exemption application (21 CFR Part 812) is not required; or (ii) the medical device is cleared/approved for marketing and the medical device is being used in accordance with its cleared/approved labeling.

Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture as follows: (a) from healthy, nonpregnant adults who weigh at least 110 pounds. For these subjects, the amounts drawn may not exceed 550 ml in an 8 week period and collection may not occur more frequently than 2 times per week; or (b) from other adults and children, considering the age, weight, and health of the subjects, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected. For these subjects, the amount drawn may not exceed the lesser of 50 ml or 3 ml per kg in an 8 week period and collection may not occur more frequently than 2 times per week.

Prospective collection of biological specimens for research purposes by noninvasive means. Examples: (a) hair and nail clippings in a nondisfiguring manner; (b) deciduous teeth at time of exfoliation or if routine patient care indicates a need for extraction; (c) permanent teeth if routine patient care indicates a need for extraction; (d) excreta and external secretions (including sweat); (e) uncannulated saliva collected either in an unstimulated fashion or stimulated by chewing gumbase or wax or by applying a dilute citric solution to the tongue; (f) placenta removed at delivery; (g) amniotic fluid obtained at the time of rupture of the membrane prior to or during labor; (h) supra- and subgingival dental plaque and calculus, provided the collection procedure is not more invasive than routine prophylactic scaling of the teeth and the process is accomplished in accordance with accepted prophylactic techniques; (i) mucosal and skin cells collected by buccal scraping or swab, skin swab, or mouth washings; (j) sputum collected after saline mist nebulization.

Collection of data through noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves. Where medical devices are employed, they must be cleared/approved for marketing. (Studies intended to evaluate the safety and effectiveness of the medical device are not generally eligible for expedited review, including studies of cleared medical devices for new indications).

Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for nonresearch purposes (such as medical treatment or diagnosis).

Collection of data from voice, video, digital, or image recordings made for research purposes.

Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies.

OFFICE OF THE VICE PRESIDENT FOR RESEARCH

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256.824.6783

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Exempt

- Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as (a) research on regular and special education instructional strategies, or (b) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods. The research is not FDA regulated and does not involve prisoners as participants.
- Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interviews, or observation of public behavior ¹ in which information is obtained in a manner that human subjects cannot be identified directly or through identifiers linked to the subjects and any disclosure of the human subject's responses outside the research would NOT place the subjects at risk of criminal or civil liability or be damaging to the subject's financial standing, employability, or reputation. The research is not FDA regulated and does not involve prisoners as participants.
- Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement) survey procedures, interview procedures, or observation of public behavior if (a) the human subjects are elected or appointed public officials or candidates for public office, or (b) Federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter. The research is not FDA regulated and does not involve prisoners as participants.
- Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects. The research is not FDA regulated and does not involve prisoners as participants.
- Research and demonstration projects which are conducted by or subject to the approval of department or agency heads, and which are designed to study, evaluate, or otherwise examine: (i) public benefit or service programs; (ii) procedures for obtaining benefits or services under those programs; (iii) possible changes in or alternatives to those programs or procedures; or (iv) possible changes in methods or levels of payment for benefits or services under those programs. The protocol will be conducted pursuant to specific federal statutory authority; has no statutory requirement for IRB review; does not involve significant physical invasions or intrusions upon the privacy interests of the participant; has authorization or concurrent by the funding agency and does not involve prisoners as participants.
- Taste and food quality evaluation and consumer acceptance studies, (i) if wholesome foods without additives are consumed or (ii) if a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture. The research does not involve prisoners as participants.

¹ Surveys, interviews, or observation of public behavior involving children cannot be exempt.

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