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Accurate Documentation of Smoking History through a Clinical Workflow Improvement Project

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ACCURATE DOCUMENTATION OF SMOKING HISTORY THROUGH A CLINICAL WORKFLOW IMPROVEMENT PROJECT

By

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Abstract

For both men and women in the United States (U.S.), lung cancer is the leading cause of cancer-related deaths – more than breast, colon, and prostate cancers, combined (American Cancer Society [ACS], 2017). Not accurately identifying patients at high-risk for lung cancer contributes to high rates of lung cancer-related deaths and late-stage diagnosis. Lung cancer screening (LCS) is the newest preventive cancer screening examination and has been available in the U.S. since 2015 (Sorrie, Cates, & Hill, 2016). Patients who are screened and found to be eligible for LCS, undergo a low-dose computerized tomography (LDCT) of the chest with 90% less ionizing radiation compared to conventional chest computerized tomography (Radiologic Society of North America) [RSNA], 2018). The purpose of this screening examination is to decrease lung cancer mortality by identifying early-stage lung cancers by LDCT (The National Lung Screening Trial Research Team [NLSTRT], 2014). LDCT decreases mortality by 20% compared to chest radiograph (NLSTRT, 2014). Identifying candidates for LCS within the electronic medical record has proven difficult across the U.S. This difficulty is generally attributed to the lack of accurately documented smoking history. In a recent meta-analysis of four large LCS locations, incomplete documentation of tobacco smoking history was identified as an important challenge worth addressing (Gould et al., 2017, July 6). The purpose of this Doctor of Nursing Practice project is: (a) to improve the smoking history intake process, (b) assess the knowledge, attitudes, and procedures of smoking history intake, and (c) provide an increased understanding of the importance of an accurate smoking history intake and LCS.

Keywords: lung cancer screening, low-dose computerized tomography, electronic medical record, smoking history documentation, lung cancer, lung cancer screening trial

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Background and Significance

Statement of Problem

For both men and women in the U.S., lung cancer is the leading cause of cancer-related deaths – more than breast, colon, and prostate cancers, combined (American Cancer Society [ACS], 2017). In 2018, the ACS expects 234,030 new cases of lung cancer nationally and 500 new cases in North Dakota (ND) (ACS, 2018). According to the American Lung Association (ALA), and the National Cancer Institute (NCI) approximately 8.6 million Americans are considered high-risk for lung cancer (ALA, 2017; NCI, 2017). Compared to a non-smoker, those who smoke increase their risk of lung cancer by 15 to 30 times. Smoking is directly attributable to 80% of deaths from lung cancer (ACS, 2017).

Lung cancer screening (LCS) by low-dose computerized tomography (LDCT) is the newest preventive cancer screening examination in the U.S. (Sorrie, Cates, & Hill, 2016). Patients who are screened and found to be eligible for LCS, complete a computerized tomography (CT) of the chest with 90% less ionizing radiation compared to conventional chest CT (Radiologic Society of North America [RSNA], 2018). The purpose of this screening examination is to decrease lung cancer mortality by identifying early-stage lung cancers by LDCT (National Lung Screening Trial Research Team [NLSTRT], 2014). The National Lung Screening Trial was the landmark study that ultimately lead to the development of LCS guidelines (NLSTRT, 2011). The study enrolled 53,454 individuals at high-risk for lung cancer at several U.S. medical centers. The patients were randomized to receive annual chest radiographs or LDCT, for three consecutive years. Adherence to screening was 90%. Deaths

from lung cancer, in the chest radiograph group, was 309 deaths per 100,000 person-years; in the LDCT group there was 247 deaths per 100,000 person-years. This represents a 20% mortality reduction when screened with LDCT compared to chest radiograph.

The ability to identify eligible patients for LCS within the electronic medical record (EMR) has proved challenging. Generally, this is because much of the critical information necessary to accurately document a smoking history is stored as unstructured text that many electronic medical records (EMRs) are unable to abstract. This contributes to missed opportunities to identify patients at high-risk for lung cancer. Barber et al. (2015) noted wide variability in ". . . data content and a high level of missing data" which has led to necessary improvements in EMR efficiencies (p. e570). The authors found that by utilizing a standardized smoking intake tool during vital sign evaluation, it led to a statistically significant increase in documented smoking history from 18.4% to 73.2% ($\boldsymbol{p} < .001$; 95% CI 0.53 to 0.56). This impacts not only how nurses complete the smoking history intake, but also improves the patients' chance of being identified as a candidate for LCS.

In a recent meta-analysis of four large LCS locations, incomplete documentation of tobacco smoking history was identified as an important challenge worth addressing (Gould et al., 2017). The authors recommended minimizing the burden of data-collection and improving clinical workflow; addressing specific eligibility criteria for LCS and facilitating quality improvement for LCS. On May 22, 2018, Davenport noted, in a recent study that was completed based upon Lung Cancer Screening Registry (LCSR) data of the American College of Radiology (ACR), that "one of the biggest obstacles for this has been the lack of an accurate smoking history in patients' records;" supporting this projects purpose (p. 3). The findings of this study

were presented at the annual American Society of Clinical Oncology (ASCO) meeting in June of 2018.

Local and National Data

According to the ACS Statistics Center, in 2018 there will be an estimated 4,110 new cancers in the state of North Dakota (ND) (2018). Nationally, there will be 1,735,350 new cancers (ACS, 2018). Table 1 summarizes the estimated new cancer rate and death rate, in ND and the U.S., for lung, breast, colon, and prostate cancer for 2018 (ACS, 2018). The death rates of lung, breast, prostate, and colorectal cancers have decreased overall since 1991, the ACS attributes this to reductions in smoking, early detection and treatment (ACS, 2018). In ND, that out of 1290 expected cancer deaths in 2018, 310 (24%) will be from lung cancer (ACS, 2018). Additionally, in ND, from 2006-2010, lung cancer had the highest percentage of cancer-related deaths for both men (27%) and women (23%) (North Dakota Cancer Coalition [NDCC], 2013).

Table 1

Estimated New Cancers & Death Rate for ND & U.S.; 2018

	Lung n	Breast n	Colon n	Prostate n
New Cancer Rate				
ND	500	570	350	380
U.S.	234,030	268,670	97,220	164,690
Death Rate				
ND	310	80	110	70
U.S.	154,050	41,400	50,630	29,430

Note. Adapted from "Cancer Facts & Figures 2018," by the ACS, 2018, Retrieved from https://www.cancer.org/content/dam/cancer-org/research/cancer-facts-and-statistics/annual-cancer-facts-and-figures/2018/cancer-facts-and-figures-2018.pdf

The stage in which patients are diagnosed with lung cancer greatly impacts survival rates. According to the ACS (2018), 79% of those patients diagnosed with lung cancer were diagnosed at a late-stage, which greatly reduced their five-year survival rate. From 1999-2006, individuals diagnosed with early-stage lung cancer had a 52.9% survival rate compared to only 3.5% for

late-stage diagnosis (NDCC, 2011). For that same, eight-year time-period, ND females diagnosed with breast cancer at early-stage had a 98% five-year survival rate, and a 23.4% late-stage five-year survival rate (NDCC, 2011). Improved survival rates are directly related to increased awareness of breast cancer and access to care, leading to improved screening to identify early-stage disease (World Health Organization [WHO], 2018).

Individuals screened for breast cancer and colon cancer in ND and the U.S. is significantly higher than screening for lung cancer. Despite aggressive LCS program implementation, however, screening rates remain low. Table 2 demonstrates the screening rates for breast, colorectal, and lung cancer; although lung cancer screening rates are not available for ND. As of June 2018, a recent study found that for 2016, the national LCS rate was only 1.9% (Pham, Bhandari, Oechsli, Pinkston, & Kloecker, 2018).

Table 2

2015 Breast, Colorectal, & Lung Cancer Screening Rates & Rank

	Breast Mammography (women >/=40)	Colorectal Stool Test or Endoscopy (>/=50)	LDCT
ND	71.2%	65.3%	Not available
National Rank	31st	37th	Not available
U.S.	72.4%	68.9%	4%

Note. Percentage = completed screening of those individuals eligible for screening. National Rank 1 = Highest value. LDCT = Low-Dose Computerized Tomography. Adapted from "Cancer Facts & Figures 2018," by the ACS, 2018, Retrieved from https://www.cancer.org/content/dam/cancer-org/research/cancer-facts-and-statistics/annual-cancer-facts-and-figures/2018/cancer-facts-and-figures-2018.pdf

Lung Cancer Screening Program

In February of 2017, a nonprofit community hospital-based health system in the Midwest launched a comprehensive LCS program. A comprehensive LCS program is a process in which patients that qualify for LCS meet with a healthcare provider to complete a shared decision-

making appointment to discuss the risks and benefits of LCS and jointly decide if the patient should undergo LDCT. Patients are screened annually, following a shared decision-making appointment, if the patient remains qualified for LCS. The patient will undergo the LDCT and further treatment or monitoring based upon the LDCT results and monitoring guidelines.

According to the Centers for Medicare & Medicaid Services (CMS), LCS basic requirements include (1) age 55-77, (2) 30 pack-per-year smoking history, and (3) if a previous smoker, quit within the past 15 years (2015). Current EMR technology at the project facility does not accurately identify, through discrete data-capture, patients at high-risk for lung cancer. Thus, the argument could be made that technology needs to be modified to identify the high-risk patient, and trigger either a health maintenance alert, reminder for the healthcare professional (HCP) or provider to discuss LCS, or direct on-line portal messaging to the patient.

Project Purpose

The purpose of this project is to improve the accuracy of the smoking history intake process performed by ambulatory care healthcare professionals (HCPs) in internal medicine (IM), family medicine (FM), and pulmonary medicine (PM) departments, thereby improving the identification of candidates for LCS. To screen individuals for lung cancer, those at high-risk for lung cancer need to be identified, so modifications to the EMR are necessary to provide specific smoking history intake information.

This clinical workflow improvement project (CWIP) is designed to improve the process of smoking history intake, and increase the knowledge of smoking history intake and LCS, of the HCPs evaluating patients in the clinic setting. Additionally, this project will evaluate the attitudes and skills of HCPs obtaining smoking history information, providing support for further research.

Theoretical Foundation

Technological competency as caring in nursing (TCCN) (Appendix A) is a middle-range nursing theory by Rozzano Locsin (2001). TCCN emphasizes the importance of patients being included and integrated within their own care as participants, as nurses strive to meet the needs of the patient. Understanding the natural existence of technology, as it relates to caring in nursing, is important for HCPs to understand the downstream effects of process changes to the smoking history intake. The primary purpose of this theory is to acknowledge the person as the focus of nursing and technology (Locsin, n.d.). The main concepts of the TCCN theory includes; (a) the harmonious coexistence of technology and caring in nursing, (b) how technology enhances nursing practice to provide quality care, (c) technology brings the patient closer to the nurse, and (d) the nurse and patient engage in conversation and develop a plan of care that is mutually satisfying.

Definition of Terminology

- Advanced EMR: Includes electronic clinical information with extensive clinician notes, computerized provider order entry (CPOE) for medications, laboratory, radiology, consultations, and nursing orders, results management, and advanced decision support including guidelines, reminders, allergies, interactions, and dosing support (Charles, King, Patel & Furukawa, 2013).
- Ambulatory HCPs: Medical assistants (MAs), certified nursing assistants (CNAs), licensed practical nurses (LPNs), and registered nurses (RNs) working in ambulatory care IM, PM, and FM; excluding advanced practice registered nurses (APRNs), physician assistants (PAs), medical doctors (MDs) and doctors of osteopathy (DOs).

- Basic EMR: Includes electronic clinical information with or without clinical notes, CPOE for medications, and basic results management (Charles, King, Patel & Furukawa, 2013).
- Deaths per-person years: "A measurement of observation time per person and is often used as the denominator in incidence rates when, for varying periods, individuals are at risk of developing a disease, using a health service, or dying" (University of Manitoba [U of M], 2018, para 1).
- Five-year survival rate: The percentage of people who are alive five years after being diagnosed with a condition such as cancer (National Cancer Institute [NCI], n.d.).
- LDCT: CT and computers produce multiple, cross-sectional images or pictures of the inside of the lungs with 90% less ionizing radiation compared to conventional chest CT (RSNA, 2018).
- Lung cancer death: Lung cancer mortality rate or death rate is the number of deaths per 100,000 persons per year, with lung cancer as the underlying cause of death, occurring in a specified population.

  Mortality Rate = (Cancer Deaths / Population) × *100,000* (NCI, 2017).
- Lung cancer screening examinations: Low-dose computerized tomography (LDCT) completed to evaluate a patient for lung cancer.
- Pack-year smoking history: A calculation of smoking history based upon:

Number of years smoked + number of packs per day smoked = pack-year smoking history.

Literature Review

A comprehensive literature review was conducted using CINAHL, PubMed Central, and MEDLINE/PubMed. The following Medical Subject Headings (MeSH) terms were used; lung cancer screening, low-dose CT, and smoking history documentation. The PubMed Central search resulted in 7,586 articles. This was reduced by selecting academic journals and adding the Boolean phrase "lung cancer screening" resulting in 698 articles. A CINAHL search for smoking history documentation utilizing the Boolean term "record" resulted in nine journal articles. A MEDLINE/PubMed search resulted in 491 journal articles.

Smoking History Documentation & Electronic Medical Records

In a study by Zeliadt, et al. (2018, April), the authors studied the challenges associated with implementing LCS at Federally Qualified Health Centers. While challenges were identified throughout the process, smoking status is reportedly documented for all patient visits, but only 59 (54%) documented a pack-history, which is an essential component of LCS. Also, only 29% of the documented information was considered reliable; meaning able to be used to make patient care decisions. Finally, only 13% of the documented patient histories indicated that the EMR data could be used to identify eligible candidates for LCS.

Cole, Pflugeisen, Schwartz, and Miller (2018), in a cross-sectional study to evaluate the accuracy of EMR data to identify candidates for LCS, found that 30% of medical records had incomplete or inadequate smoking history information to appropriately identify the patient for LCS, Therefore, strategies were implemented to improve EMR documentation among medical assistants to better identify smokers and provide clinician reminders.

Katki, Kovalchik, Berg, Cheung, and Chaturvedi (2016) estimated that nine million Americans may qualify for LCS. *Healthy People 2020* has identified a goal to reduce the lung cancer death rate by 10% (2017). Screening high-risk individuals will improve overall mortality

related to lung cancer by 20%, as patients will be diagnosed with more treatable and potentially curable early-stage disease (NLSTRT, 2011). To screen individuals, HCPs must be able to accurately identify them within the EMR.

Jamal, Dube, Malarcher, Shaw and Engstrom (2012) for the CDC, note that *Healthy People 2020* objectives for tobacco use includes screening for tobacco use within the ambulatory care setting (ACS) for individuals greater than 18 years old. The authors additionally noted between 2005 and 2008, the CDC analyzed data from 96,232 individuals from 771 million outpatient visits and found that 483 million (62.7%) visits included tobacco screening (Jamal, Dube, Malarcher, Shaw and Engstrom, 2012). An estimated 340 million (17.6%) of those visits included active tobacco users, and of those identified as tobacco users, only 20.9% of those individuals were counseled on smoking cessation. Obtaining a complete, accurate smoking history remains the single most important technique in identifying LCS candidates. This fact continues to support the need for high-quality smoking history intake as part of routine intake and assessment.

Barber et al. (2015), noted that accurate smoking intake documentation prior to the implementation of a smoking history tool within the EMR was 18.4%, and following implementation improved to 28.52% (55% increase) ($\boldsymbol{p} < .001$; 95% CI 0.53 to 0.56) in the completion of smoking status. This study is important to this DNP project because it emphasizes the importance of the integration of a standardized tool to assist HCPs obtain accurate information.

Mader et al. (2016) evaluated the effectiveness and feasibility in combining "practice facilitation and academic detailing quality improvement (QI) strategies to help primary care practices increase breast, cervical, and colorectal cancer screening (CRC) among patients" (p.

533). The study evaluated 23 various-sized healthcare organizations, all of which implemented a combination of EMR workflows, patient education and outreach interventions, provider audits and feedback, and streamlining of reminder systems. The intervention increased breast cancer screening rates by 13% (***p*** = .001), and CRC screening rates increased by 5.6% (***p*** = .001). Utilizing evidence-based strategies to modify workflows and policies is stated as an important intervention in QI success (Mader et al., 2016). These results suggest that LCS may incur similar improvements in screening examinations following specific interventions.

In a regression analysis of data from 2007-2010 of the National Ambulatory Medical Care Survey (NAMCS) and 17 clinical trials, Bae, Ford, and Huerta (2016), found that physicians using *advanced* EMR systems, compared to *basic* EMR systems, were much more likely to record, counsel, and document smoking status and offer support. The authors suggest making EMR upgrades with integration of clinical decision-aids into the EMR. This is important given that both QI projects and workflow improvement projects evolve to improve the way we collect patient data and provide high-quality shared-decision making.

Healthcare Professional Impact

In a Cochrane review of 49 randomized control trials by Rice, Hartmann-Boyce, and Stead (2013), the authors reviewed smoking cessation interventions delivered by nurses. Over 17,000 patients' information was utilized in this analysis and the main outcome was abstinence from smoking six-months following the nursing intervention. The review found quality evidence that nurses materially contributed to the success of patients to stop smoking. This study showed that critical decisions and changes need to be made with respect to the method that patient smoking history is not only obtained, but also acted upon with counseling and coordination of care. Therefore, incorporating an intervention – along with the collection of smoking history

information – is necessary to provide the patient with the best possible outcome. This DNP project focuses upon the HCPs that make initial contact with patients in the ACS, as they are a common source of information and support for patients, specifically obtaining smoking history information.

Retrouvey, Patel, and Shaves (2016) found that increasing community awareness and positive perceptions of LCS by LDCT is an important factor in encouraging patients to seek out LCS. In this study, radiology residents screened volunteers at a local health fair for risk factors for lung cancer, where they provided a survey to those participants regarding their knowledge and understanding of LCS. All patients (100%) responded they would seek out screening and would recommend screening to friends and family, which supports the importance of identifying candidates for LCS.

Literature Gaps or Limitations

Research exists studying the effectiveness of LCS but there is an appreciable gap between best-evidence and actual clinical practice related to LCS. Additionally, there is a lack of EMR research pertaining to smoking history intake and its' relationship to LCS. This DNP project is designed to provide new and supporting knowledge to better understand the difficulties in obtaining and documenting an accurate and complete smoking history.

Design and Methods

Population

The population from which the sample data were gathered was ambulatory care HCPs working in IM, FM, and PM in a nonprofit community hospital-based, fully-integrated health system in the Midwest. To recruit participants, from the approximate 45 potential participants, project recruitment flyers (Appendix B) for the research project were posted in the identified

HCPs' work location in non-patient areas. Participants were made aware that participation was not mandatory, and that by opting out of the research project would not result in any repercussions.

Study Design

This DNP project was a quasi-experimental, one-group pretest-posttest design. The HCP education intervention was completed on January 31, February 1, 2, and 8, 2018. This CWIP provided education to HCPs who room patients for a clinic visit. The education interventions were designed (a) to improve HCPs' depth-of-knowledge and understanding related to LCS and smoking history intake, and (b) to provide information to address more precisely organizational needs, and (c) to improve clinical workflows within the ambulatory care-setting. This CWIP provided education to HCPs that included the basics of lung cancer screening, the importance of smoking history documentation, and the identification of LCS candidates and how those factors impact lung cancer screening.

Survey Tool and Demographics

An informed consent was attached to the pre-intervention survey with the instructions for the participants to keep the consent for future reference (Appendix C). Basic, anonymous demographics were included in the pre-intervention survey only, which included (a) age range, (b) gender, (c) range of years-of-service, (d) educational level, (e) work location (IM, FM, or PM), (f) current or former smoker, and (g) employment status. The voluntary survey included information regarding actual and perception of knowledge, attitudes, and procedures of smoking history intake and LCS. Participants had the option not to answer any question with which s/he was not comfortable. The pre-intervention and post-intervention surveys are referenced as Appendices D and E, respectively. To be able to compare the pre-intervention and post-

intervention surveys, a self-assigned, unique, de-personalized identifier linked participants' surveys. Participants needed to remember and provide their self-chosen unique identifier when they completed the post-intervention survey; none of the participants forgot their de-personalized identifier.

Setting and Organizational Analysis

The DNP CWIP was completed at a nonprofit community hospital-based, health system in the Midwest. This regional facility is licensed for 251 inpatient beds, with multiple ambulatory clinics, provides comprehensive healthcare services, and employs 2,907 employees with over 220 providers in over 40 specialties.

Data Collection

Healthcare professionals' data.

The survey instruments (pre-intervention and post-intervention) included 14-questions of six-levels of Likert-type choices. The survey instrument consisted of LCS knowledge questions, the importance of LCS, the importance of the identification of high-risk patients, and the necessity of capturing accurate patient data related to LCS. Additionally, the survey included two questions in which the purpose was to determine if respondents knew the informational data-points that are necessary to identify lung cancer candidates and the method to calculate "pack-year" smoking history. The questions were answered either correctly or incorrectly. Finally, one question evaluated the HCPs' perceived time spent on smoking history intake and documentation. This data was manually entered an excel spreadsheet prior to statistical analysis.

Smoking history documentation data.

There were three time periods: (a) February to April 2017 (pre-intervention), which was compared with (b) October to December 2017 (pre-intervention) and (c) February to April 2018 (post-intervention). Reports were created by information technology and did not include personal, identifiable private health information. The project leader did not access any protected patient information or medical records. Discrete data was obtained in an anonymous aggregated report for each of time periods which included: (a) current or former smoker, (b) if the patient quit smoking what year or age, (c) how many years did the patient smoke, (d) how many packs per day did the patient smoke, and (e) the calculated pack-year smoking history.

A *complete* smoking history (for identifying candidates for LCS) includes:

- Current or former smoker
- Total number of years smoked.
- Total number of packs-per-day smoked.
- Calculated pack-year smoking history.
- If a former smoker, number of years ago (or age) the patient quit smoking.

Lung cancer screening data.

Additional data consisted of the number of actual LCS examinations completed and the location of the referring provider, was obtained from the information technology department in an anonymous aggregated report from February to April 2017, which was compared with October to December 2017 and February to April 2018.

Procedure for Implementation

This DNP project was designed around the *Institute for Healthcare Improvement's* (IHI) plan-do-study-act (PDSA) model for improvement (2018). Within the PDSA cycle, this project *(plan)* was based upon the premise that HCPs lack some of the knowledge, skills, and EMR tools

needed to document a patient's complete smoking history. To conduct (*do*) this doctoral project, the HCPs educational sessions were completed along with the pre-intervention and post-intervention surveys completion and ultimately data collection. Collected data were then studied *(study)* for significant results to provide the opportunity to learn from the data. In summary, the results were summarized to determine the best use of the data and opportunity for additional research project *(act)* (IHI, 2018). Appendix F provides the PDSA timeline for this DNP project.

Budget.

Given that minimal costs were associated with this project, a budget evaluation or proposal was not necessary. The project leader provided the costs of paper and printing. The project intervention (HCP's education) was completed during noon sessions in the conference rooms of the various departments. Staff was paid for their time by the organization. The organizations' Institutional Review Board (IRB) required a *business agreement* (Appendix G) between the organization and project researcher, the purpose of which was to enhance risk management to reduce "liability risks that [may] contribute to financial losses" including (a) legal risk, (b) intangible risk, (c) technical risk and (d) security risk (Reavy, 2016, p. 208).

EMR workflow modification.

In consultation with nursing leadership and nursing informatics the project leader developed a new EMR workflow to more accurately document patient smoking history. After discussion with nursing informatics the original EMR form shown in figure 1 below remained the same; and currently is the first screening form the HCP completes as part of the smoking history intake process. The project leader reviewed the literature and necessity of smoking history documentation for LCS. From this information the new EMR form, as shown in figure 2,

was developed and added into the clinical workflow. This new EMR data collection tool was designed to improve the documentation of patient smoking history.

Clinic smoking history intake procedure.

Patients who present for ambulatory clinical encounters are asked several standard questions by HCPs, utilizing an EMR form, called the *adult clinic intake*. For all clinic areas, *required* clinic intake information includes reason for visit, allergies, medications, vital sign measurements, depression screening, suicide risk assessment, and smoking status. Figure 1 is an image of the smoking history form intake prior to the CWIP. Smoking status did not provide the necessary components to complete an accurate and complete smoking history. HCPs could make comments in blank fields to provide more information; but that type of information cannot be easily abstracted out of the medical record.

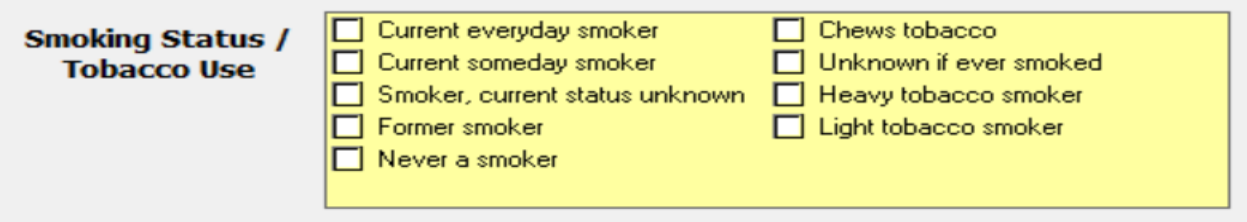

Figure 1. EMR smoking history intake form pre-intervention[1].

Figure 2 is an image of the new, supplemental smoking history intake form which was created as part of this CWIP. This EMR form immediately went-live on the last day of the project educational sessions (intervention). During a patient's clinic visit, the HCP completes the adult clinic intake. The original form in figure 1 is still the required *initial* question regarding smoking history; and if the patient is *never a smoker*, no further action is required. If any of the other fields are selected, in figure 1, the new supplemental form will automatically open; which is noted in figure 2.

Figure 2. Supplemental EMR smoking history intake form post-intervention[1].

It should be noted that none of the fields in figure 2 are mandatory; a mandatory field would be highlighted yellow. At the project facility, all ambulatory clinic settings utilize the same adult clinic intake and there is no current way to only make fields mandatory for specific locations; the same form had to be implemented across the care system. The collection of smoking history information, as above, now creates patient data to abstract, to identifying patients at high-risk for lung cancer and potential candidates for LCS. Additionally, this improved documentation provides a more complete picture of the health history of the patient.

Intervention procedure.

The CWIP, which was intended to improve the accuracy of smoking history intake in ambulatory care, was implemented at the project facility. The HCPs received notification three weeks prior to the project intervention with the distribution and posting of a flyer. Ambulatory care HCPs were educated on the new CWIP for smoking history intake, the process, and the importance of an accurate smoking history intake on the identification of patients at high-risk for lung cancer. The education session included a 15-minute audio-visual presentation with the

opportunity to ask follow-up questions. No printed handouts were given during the presentation. Participants completed a voluntary pre-intervention and post-intervention survey.

Resources.

Resources necessary for this project included 33 HCPs to complete the pre-intervention and post-intervention surveys. Regarding the workflow intervention, resources include, one nursing informatics RN, two information technology data abstractors, two clinic nursing educators and the project leader. The participants took approximately 15 minutes each to complete the surveys, and 30 minutes to attend the intervention. The clinic nursing educators contributed approximately three hours each to facilitate and attend the educational interventions. The informatics RN and information technology data abstractors contributed approximately eight hours each assisting in the collection of anonymous data.

Ethics and Protection of Human Subjects

This DNP project was approved as exempt research by the University of North Dakota IRB on November 21, 2017, as noted as Appendix H. The organizations' IRB approved this project on December 22, 2017. Private health information was not obtained. The data recorded will be stored for a period of three years in a locked cabinet within the project leaders' workplace. Data entered within an electronic source is password protected. This DNP project did not meet the human subjects' research threshold for IRB review as this was a QI project to improve care process at the organization which project does not involve a test article or a Food and Drug Administration (FDA)-regulated product and there are no humans that are recipients of a test article or control. There are no risks in participating in this research beyond those experienced in everyday life.

Outcomes

Objective: HCPs will understand the knowledge and skills necessary to improve the accuracy and completeness of smoking history intake in an ambulatory care setting.

Goal #1: To provide HCPs the knowledge necessary, through a CWIP, to increase the accuracy and completeness of smoking history intake in ambulatory care.

Outcome #1: By April 2018, HCPs will increase by 25% their actual and perception of knowledge and skills necessary related to the importance of accuracy and completeness of smoking history intake in ambulatory care.

Goal #2: To provide HCPs the skills necessary, through a CWIP, to increase the accuracy and completeness of smoking history intake in ambulatory care.

Outcome #2: By April 2018, HCPs will increase by 25% the accuracy and completeness of smoking history intake in ambulatory care**.**

Data Analysis and Interpretation

The following descriptive statistics were analyzed: frequencies, percentages, measures of central tendency, and minimum and maximum values of the demographic and survey results. Due to the design of this project, inferential statistical analysis included a paired-sample ***t***-test, and a one-way ANOVA (Polit & Beck 2017). Statistical analysis was completed using Statistical Package for the Social Sciences.

Results

Demographics.

Thirty-three (73.3%) HCPs voluntarily participated in the CWIP, out of 45 eligible. Most of the HCPs were age 31-40 (n=9; 9.1%) or 41-50 (n=9; 9.1%) and 32 (97%) identified as female. One participant did not respond to gender. Most HCPs had many years of service as a HCP; 21-30 years (n=8; 24.2%) or >30 years (n=8; 24.2%). Most of the HCPs had

an Associate's Degree (n=16; 48.5%) and worked full-time (n=23; 69.7%). Majority of the HCPs worked in family medicine (n=19; 57.6%). There were four (12.1%) HCPs who were active smokers and seven (21.2%) that were former smokers. Table 3 is a complete listing of the HCPs' demographic information.

Table 3

Demographic Characteristics

Characteristic	Frequency (N)	Percentage
Age		
18-25	1	3%
26-40	3	9.1%
31-40	9	27.3%
41-50	9	27.3%
51-60	7	21.2%
61-70	3	9.1%
Gender		
Female	32	100%
Male	0	
Years as HCP		
2-5	4	12.1%
6-10	2	6.1%
11-15	5	15.2%
16-20	5	15.2%
21-30	8	24.2%
>30	8	24.2%
Educational Level		
HSD	6	18.2%
GED	3	9.1%
Associate's Degree	16	48.5%
Bachelor's Degree	7	21.2%
Doctoral Degree	0	
Employment Status		
Full-time	23	74.2%
Part-time	8	25.8%
Employment Location		
Internal Medicine	3	9.1%
Family Medicine	19	57.6%
Pulmonary Medicine	5	15.2%
Float	2	6.1%
IM/FM	1	3%
Current Smoker		
Yes	4	21.1%

No	28	84.8%
Former Smoker		
Yes	7	21.2%
No	22	66.7%

Survey results.

All thirty-three participants responded via the six-levels of Likert-type choices that ranged from "Strongly Disagree" (value = 1) to "Strongly Agree" (value = 6) or Likert-type choices that ranged from "Definitely Not Confident" (value = 1) to "Definitely Confident" (value = 6). The first part of the "knowledge" portion of the survey instrument (both pre-intervention and post- intervention) which consisted of four statements. Table 4 is a summary with results of the pre-intervention and post-intervention survey questions. Paired-samples ***t***-tests were used to compare the results of the intervention; because post-intervention means are subtracted from pre-intervention means, a negative mean difference indicates an increase for a question.

Table 4

Pre- and Post-Intervention Survey Results: Summary

Question Summary	Mean	N	Mean Difference	Std. Deviation	T(33)	Sig. (2-tailed)
Knowledge: I have knowledge of LCS.	Pre: 4.39 Post 5.67	33	-1.273	1.008	-7.250	.000
Attitude: Obtaining an accurate smoking history on my patients is valuable.	Pre: 5.58 Post: 5.85	33	-.273	.574	-2.729	.010
Data Capture: It is important for me to document an accurate smoking history, in order for the provider I work with, identify candidates for LCS.	Pre: 5.36 Post 5.88	33	-.515	.906	-3.268	.003
Data Capture: My patients expect that I gather an accurate smoking history.	Pre: 4.55 Post: 5.39	33	-.848	1.228	-3.970	.000

Note. 6-levels Likert-like choices. Each question represents a different portion of the pre- and post-intervention surveys. Fourteen questions total.

- For Question 1, *"I have knowledge of lung cancer screening."* knowledge increased by an average of $\boldsymbol{M} = -1.27$ points with $\boldsymbol{SD} = 1.0085$. The intervention was statistically significant, $\boldsymbol{t}(33) = -7.2497$, $\boldsymbol{p} = .000$, $\boldsymbol{r}^2 = 62.17\%$.
- For Question 2, *"I am confident in my ability to obtain and document an accurate smoking history."* confidence increased by an average of $\boldsymbol{M} = -1.36$ points with $\boldsymbol{SD} = 1.0252$. The intervention was statistically significant, $\boldsymbol{t}(33) = -7.6406$, $\boldsymbol{p} = .000$, $\boldsymbol{r}^2 = 64.61\%$.
- For Question 3, *"This in-service will enhance my understanding of accurate smoking history intake."* knowledge increased by an average of $\boldsymbol{M} = -0.73$ points with $\boldsymbol{SD} = 0.7191$. The intervention was statistically significant, $\boldsymbol{t}(33) = -5.8102$, $\boldsymbol{p} = .000$, $\boldsymbol{r}^2 = 51.32\%$.
- For Question 4, *"I plan to implement what I have learned from this in-service regarding the importance of accurate smoking history intake."* knowledge increased by an average of $\boldsymbol{M} = -0.54$ points with $\boldsymbol{SD} = 0.7111$. The intervention was statistically significant, $\boldsymbol{t}(33) = -4.4063$, $\boldsymbol{p} = .000$, $\boldsymbol{r}^2 = 37.72\%$.

The next part of the survey instrument consisted of two questions, the purpose of which was to determine if respondents (a) knew the informational data-points that are necessary to identify lung cancer candidates and (b) the method to calculate "pack-year" smoking history. The questions were answered either correctly or incorrectly. Table 5 is a summary of the results for these two questions.

Table 5

Pre-and Post-Intervention Survey Results

Question	Correct Pre-Intervention N=32	Correct Post-Intervention N=32	% Increase	z	Sig. (2-tailed)
What smoking history data points are necessary to gather to accurately identify LCS candidates?	18 (56.3%)	20 (62.5%)	6.2%	-.509	.305
What smoking history information is necessary to obtain to calculate a pack-year smoking history?	23 (71.9%)	25 (78.1%)	6.2%	-.577	.282

Note. Multiple choice questions. Two questions total.

- For Question 5, *"What smoking history data points are necessary to gather to accurately identify lung cancer screening candidates?"* 18 of 32 respondents (56.3%) answered correctly on the pre-intervention survey, and 20 of 32 respondents (62.5%) answered correctly on the post-intervention survey; this 6.2% increase was not statistically significant. $\boldsymbol{z} = -.509$, $\boldsymbol{p} = .305$, 95% CI [−.210, .270].
- For Question 6, *"What smoking history information is necessary to obtain to calculate a pack-year smoking history?"* 23 of 32 respondents (71.9%) answered correctly on the pre-intervention survey, and 25 of 32 respondents (78.1%) answered correctly on the post-intervention survey; this 6.2% increase was not statistically significant. $\boldsymbol{z} = -.577$, $\boldsymbol{p} = .282$, 95% CI [−.274, .149].

Pre-intervention and post-intervention survey instrument questions 7, 8, and 9 asked about the importance of LCS, the importance of LCS in identifying high-risk patients, and HCPs attending LCS educational services, respectively.

- For Question 7, *"How important do you feel that lung cancer screening is?"* opinions increased by an average of $\boldsymbol{M} = -0.364$ points with $\boldsymbol{SD} = 0.5488$. The intervention was statistically significant, $\boldsymbol{t}(33) = -3.8066$, $\boldsymbol{p} = .001$, $\boldsymbol{r}^2 = 31.19\%$.

- For Question 8, *"How important is the identification of patients at high-risk for lung cancer for the purpose of lung cancer screening?"* opinions increased by an average of ***M*** = −0.333 points with ***SD*** = 0.5951. The intervention was statistically significant, ***t***(33) = −3.2176, ***p*** = .003, r^2 = 24.41%.
- For Question 9, *"Generally speaking, attending educational in-services regarding evidence-based practice is important?"* opinions increased by an average of ***M*** = −0.364 points with ***SD*** = 0.4885. The intervention was statistically significant, ***t***(33) = −4.2762, ***p*** = .000, r^2 = 36.41%.

Pre-intervention and post-intervention survey questions 10 through 13 were concerned with the necessity of capturing accurate patient data with respect to LCS.

- For Question 10, *"The provider I work with (NP, PA, MD, DO) values an accurately documented smoking history."* opinions increased by an average of ***M*** = −0.606 points with ***SD*** = 1.0880. The intervention was statistically significant, ***t***(33) = −3.2000, ***p*** = .003, r^2 = 24.24%.
- For Question 11, *"Obtaining an accurate smoking history on my patients is valuable."* opinions increased by an average of ***M*** = −0.273 points with ***SD*** = .5741. The intervention was statistically significant, ***t***(33) = −2.7292, ***p*** = .010, r^2 = 18.91%.
- For Question 12, *"How I obtain and document smoking history impacts our ability to identify candidates for lung cancer screening."* opinions increased by an average of ***M*** = −0.303 points with ***SD*** = .5294. The intervention was statistically significant, ***t***(33) = −3.2880, ***p*** = .002, r^2 = 25.28%.
- For Question 13, *"I believe that accurately documenting an appropriate smoking history, improves patients' access to potentially life-saving cancer screening."* opinions

increased by an average of $\boldsymbol{M} = -0.331$ points with $\boldsymbol{SD} = .5400$. The intervention was statistically significant, $\boldsymbol{t}(33) = -3.5456$, $\boldsymbol{p} = .001$, $\boldsymbol{r}^2 = 27.93\%$.

- Question 14 captured data on the time-difference between pre-intervention ($\boldsymbol{n} = 33$) and post-intervention ($\boldsymbol{n} = 33$) patient screening for accurate smoking history: *"Obtaining an accurate smoking history takes how much time?"* is noted in figure 3.

Interval	Pre-Intervention		Post-Intervention	
	Frequency	Percent	Frequency	Percent
8 to 10 Minutes	2	6.1	1	3.0
4 to 5 Minutes	6	18.2	2	6.1
2 to 3 Minutes	15	45.5	14	42.4
< 1 Minute	10	30.3	16	48.5

Figure 3. Perceived time it takes to obtain an accurate smoking history.

For the less-than one-minute interval, the difference between percentages was 18.2%, but was not statistically significant; $\boldsymbol{z} = 1.51$, $\boldsymbol{p} = .065$, 95% CI [−.414, .050].

- The pre-intervention and post-intervention results of Question 15, *"I am expected to take and document an accurate patient smoking history."* are as follows: opinions increased by an average of $\boldsymbol{M} = -0.515$ points with $\boldsymbol{SD} = .7953$. The intervention was statistically significant, $\boldsymbol{t}(33) = -3.7208$, $\boldsymbol{p} = .001$, $\boldsymbol{r}^2 = 30.20\%$.
- The pre-intervention and post-intervention results of Question 16, *"My patients expect that I gather an accurate smoking history."* are as follows: opinions increased by an average of $\boldsymbol{M} = -0.848$ points with $\boldsymbol{SD} = 1.2278$. The intervention was statistically significant, $\boldsymbol{t}(33) = -3.9697$, $\boldsymbol{p} = .000$, $\boldsymbol{r}^2 = 32.97\%$.
- The pre-intervention and post-intervention results of Question 17, *"It is important for me to document an accurate smoking history, in order for the provider I work with to identify candidates for lung cancer screening."* are as follows: opinions increased by an

average of $\boldsymbol{M} = -0.515$ points with $\boldsymbol{SD} = .9056$. The intervention was statistically significant, $\boldsymbol{t}(33) = -3.2679$, $\boldsymbol{p} = .003$, $\boldsymbol{r}^2 = 24.99\%$.

Smoking history results.

Utilizing the three same time periods, aggregated data was gathered to assess the actual accuracy of collected smoking history during ambulatory clinic encounters in IM, FM, and PM, for patients age 55-77. This resulted in a 57,519 total clinic encounters. Table 6 is the missing, partial, and complete smoking history data. A missing smoking history is characterized by *no response* on any of the smoking history questions and a partial smoking history lacks one or more components of a complete smoking history. Currently, there is no way to know if this information is missing due to patients not providing the requested information, HCPs not asking the question, or a combination of both. A one-way ANOVA was completed to evaluate the mean of the variable "age" for each of the variables "time-period." The age of the patient was statistically significant for different "time-periods" $\boldsymbol{F}(2, 57{,}516) = 119.790$, $\boldsymbol{p} < .005$.

Table 6

Missing, Partial, & Complete Smoking History Documentation

Time-Period	Total Encounters each Period	Frequency & Percentage of Missing Smoking History	Frequency & Percentage of Partial Smoking History	Frequency & Percentage of Complete Smoking History
February – April 2017 Pre-Intervention	18,209	4,869 (26.7%)	41 (.23%)	0
October – December 2017 Pre-Intervention	21,107	6,280 (29.4%)	36 (.17%)	0
February – April 2018 Post-Intervention	18,203	4.849 (26.6%)	1965 (9.26%)	189 (1%)

Note. Note. a. Missing Smoking History = Tobacco use not stated or asked - not documented; b. Locations = Internal Medicine, Pulmonary Medicine, Family Medicine; c. Ambulatory clinic encounters; d. ages 55-77

For each time period, one-third of the patients identified as having *never smoked*. Table 7 notes the frequencies and percentages of patients that were identified as *former smokers* and

those identified as a *current, every day smokers*. Both tables represent many patients that could potentially be considered candidates for LCS. The way in which the current EMR intake system is set up, HCPs may ask smoking status in multiple different ways. HCPs have the option of answering smoking-related questions in multiple areas of the EMR; leading to variability in the assessment of smoking status.

The number of years smoked and the number of pack-per-day smoked provides the necessary information to calculate a pack-year smoking history. For the periods, pre-intervention, February to April of 2017 and October to December of 2017, there was 41 (0.23%) and 36 (0.17%) clinic encounters, respectively, which included a *partial* smoking history (years smoked, packs-per-day smoked, and pack-year smoking history). There were no documented encounters, in which the year or age, the patient quit smoking. Post-intervention, from February to April of 2018, there was 189 encounters which included a complete smoking history as noted above. This represents one percent of all encounters (18,203) for this time period. Further statistics could not be calculated because no complete smoking histories were obtained from the pre-intervention first and second time period.

Table 7

Frequencies and Percentages of Former and Current Smokers

Time Period	Frequency	Percent	Total Encounters Each Period
Feb-April 2017			18,209
Former	5,005	27%	
Current	1809	9.9%	
Oct-Dec 2017			21,107
Former	5,472	25.9%	
Current	2,034	9.6%	
Feb-April 2018			
Former	4,855	26.7%	18,203
Current	1,804	9.9%	

LDCT results.

Since the LCS program began at the project facility in February of 2017, approximately 250 patients have been screened for lung cancer by LDCT. Prior to the intervention and due to the lack of accurately documented smoking history data to abstract from the electronic medical record (EMR), a reasonably accurate number of patients that would have been considered eligible for LCS are nearly impossible to determine. A chi-square test of independence was conducted between "time-period" and "location" of providers who order LDCT. All expected cell frequencies were greater than five. There was a statistically significant association between "time-period" and "location" $\boldsymbol{X^2}$ (4) = 18.324, $\boldsymbol{p}$ <.001. The frequencies and percentages of LDCTs completed, for each time period, are noted in table 8.

Table 8

Frequencies and Percentages of LDCTs Completed

Time Period	Location IM	FM	PM	Cardiology
Feb-April 2017	14 (28.6%)	21 (42.9%)	14 (28.6%)	
Oct-Dec 2017	2 (3.6%)	43 (76.8%)	10 (17.9%)	1 (1.8%)
Feb-April 2018	12 (27.9%)	23 (53.5%)	8 (18.6%)	

The differences between the number of LDCTs completed between the provider groups and three time periods was statistically significant, ($\boldsymbol{F}$ = 5.283, $\boldsymbol{p}$ = .048). Table 9 is a summary to the volume of providers, number of LDCTs completed, and percentage of LDCTs per provider group. The Cramer's V revealed a strong relationship between the variable "location" and the variable "time-period" at $\boldsymbol{V}$ = .250, $\boldsymbol{p}$ = .001. A chi-square goodness-of-fit (GoF) was conducted to determine the difference between the observed frequencies and the expected frequencies of LDCTs completed for each practice location and each time period. The GoF chi-square found

that the number of LDCTs completed for each location and time period were not equal. For the first time-period, GoF chi-square = 2.000, which was not significant ***p*** = .368; indicating that the number of completed LDCTs completed was not statistically significantly different. For the second time-period, GoF chi-square = 51.527, which was significant ***p*** = .000; indicating that the number of completed LDCTs completed was statistically significantly different. For the third time-period, GoF chi-square = 8.418, which was significant ***p*** = .015; indicating that the number of completed LDCTs completed was statistically significantly different.

Table 9

Volume of Providers, Total Number & Percentage of LDCTs

	Number Providers	Number of LDCTs	Percentage of LDCTs	Number of LDCTs per Provider
Internal Medicine	4	28	19%	7
Pulmonary Medicine	4	32	22%	8
Family Medicine	31	87	59.2%	2.8

Note. Based upon known number of providers in each practice location. A provider = advanced practice registered nurse (APRN), physician assistant (PA), medical doctor (MD), or doctor of osteopathy (DO) with a National Provider Identifier (NPI) number. LDCT = Low-Dose Computerized Tomography. Ambulatory IM, PM, FM.

Validity of Results

The main premise of research and project validity is randomization. This project is not randomized so therefore lacks an element of scientific rigor associated with RCTs (Polit & Beck, 2017). Thirty-three out of the 45 (73%) of the eligible HCPs participated in the project intervention and completed surveys. All of IM and PM HCPs were invited to participate; but only FM HCPs working within the local community of the project location were invited to participate. This organization has multiple rural community clinic locations that were not included due to the feasibility of the HCPs attending the same educational intervention and completing surveys. This represents selection bias which can affect the validity of the results

(Polit & Beck 2017). The educational intervention was performed by the project leader utilizing audio-visual technology, following a rehearsed presentation. There were several educational intervention sessions which could potentially lead to intervention bias (Polit & Beck, 2017). Great care was taken to follow the presentation as best as possible for each intervention. Finally, the survey utilized in this DNP project was created by the student with the assistance of university faculty. The validity and reliability of the survey tool has not been established.

Interpretation

Survey results.

Overall, this CWIP demonstrated an increase in the perception of knowledge following the educational intervention. Fourteen of the seventeen survey questions pertaining to the perception knowledge of smoking history intake demonstrated a statistically significant increase. This supports the need to provide HCPs with the educational resources necessary to accurately obtain complete smoking history information. Also, when HCPs are provided with education, regarding the importance of accurate smoking history intake, they demonstrate an overall increased understanding, confidence in obtaining an accurate history, and understanding of importance of the value of LCS and accurate smoking history intake. Questions five *"What smoking history data points are necessary to gather to accurately identify lung cancer screening candidates?"* and six *"What smoking history information is necessary to obtain to calculate a pack-year smoking history?"* of the survey, did not demonstrate statistical significance; although both questions demonstrated an increase in the number of correct answers. The way in which these questions were asked may have been too complicated; requiring adjustment for use in the future.

Smoking history documentation.

There was a significant amount of missing data; it is unknown if the missing data is related to the patient not responding to the questions from the HCP or whether the HCP did not ask the questions. There was less missing data after the educational intervention (third time-period). For the pre-intervention first and second time-periods, there was not a *complete* smoking history obtained at *any* encounter. From February to April 2017 and October to December 2017 *all* encounters lacked the year or age in which the patient quit smoking. This is a necessary component for LCS because one of the requirements to be screened with LDCT is that former smokers must have quit smoking within the past 15 years. After 15 years of abstinence from smoking, patients are no longer considered candidates for LCS. Post-intervention from February to April 2018 there were 189 (1%) encounters that included a complete smoking history. This is an improvement from 0% in the time-periods before the intervention. While there is importance and value in that 189 encounters compared to 0 completed of an accurate smoking history; it is quite evident that additional improvements to the EMR and on-going education are necessary to simplify and streamline the smoking history intake.

Lung cancer screening.

Regarding the data collection of the frequency of LDCTs and ordering provider's location; the group means were statistically significant in their differences ($\boldsymbol{p} < .05$). Understanding that the variation, most likely, is due to group differences (e.g. size of provider group, understanding of LDCT and LCS, and previous experience with LDCT and LCS). Additionally, variations in the volume of LDCTs completed, increased during the pre-intervention time period of October to December 2017 and this could be due to patients including the LDCT at the end of the insurance year once their deductible was met. The opposite

may be true, as the volume decreased quite significantly from February to April of 2018, when co-pays for insurance would be at the highest. This time-period reduction could also be explained by decreasing enthusiasm with the LDCT LCS program. The newness had worn off by that time, and providers may not have been thinking about LCS as regularly. As noted in Table 8 above the number of providers within each specific specialty and the total number of LDCTs for that specialty. Despite having the least number of providers, IM averaged seven LDCTs per provider, PM averaged eight LDCTs per provider, while FM averaged 2.8 LDCTs per provider. This further emphasizes where continuing education needs to be focused.

Project Outcomes

This CWIP met a majority of the projects' outcomes goals. HCPs increased by at least 25% (25.28% - 64.61%) for 11 of 14 questions their perception of knowledge and skills necessary related to the importance of accuracy and completeness of smoking history intake in ambulatory care. Three questions achieved statistical significance but not a 25% improvement (24.24%, 24.41%, and 24.99%) in the perception of knowledge. HCPs partially met this goal, as the actual knowledge of the skills necessary to accurately and completely obtain a smoking history, as correct answers to these two questions improved by 6.2%, but was not statistically significant. Comparing both pre-intervention time periods to the post-intervention time period; HCPs increased accuracy and completeness of smoking history by at least 25%, as noted below.

- February to April 2017: No complete smoking histories
- October to December 2017: No complete smoking histories
- February to April 2018: 189 complete smoking histories

Strengths and Limitations

Strengths

Strengths of this CWIP demonstrates results are likely more genuine due to the natural testing environment and provides results to reinforce further study and analysis. The design of this CWIP removes the concern of assignment bias. Ultimately this QI project is designed to improve HCPs' processes which directly affect clinical patient and health outcomes. The data analysis of this project assists in the identification of strengths and weaknesses of current processes within the organization. With complete and accurate smoking history information, improved patient outcomes are expected by identifying individuals at high-risk for lung cancer and promoting LCS. This CWIP improves the organizations' ability to correctly identify candidates for LCS and to ensure insurance payment of the LDCT and the organizations' ability to correctly report to the Lung CT Screening Reporting & Data System, through the ACR, as mandated by CMS (CMS, 2015). Finally, this CWIP provides an enhanced EMR data collection tool for HCPs across the health system.

Limitations

There are limitations of this CWIP as participants of this project may have prior, personal experience with the subject matter and may have experienced a similar subject matter encounter during the time they participated in the project. Generalizability is limited due to the small, convenience sample of HCPs and providers although there is a significantly large number of clinical encounters. The pre-intervention and post-intervention surveys have not been subjected to reliability and internal validity testing or pilot testing. QI projects are largely based upon experiential learning, local context, and therefore lack of identifiable generalizable truths (Chao, 2007). Additionally, casual inference is limited due to lack of random assignment (Polit & Beck,

2017). The two-actual knowledge-based questions potentially could be re-written. Improving the quality of these questions may make for better understood questions. Due to the large volume of missing completely at random data of smoking history information, the data-set likely underestimates the number of patients whom would be considered candidates for LCS.

Suggestions for Improvement

Suggestions for improvement include: (a) additional EMR modifications to minimize and simplify the questions asked in the adult clinic intake for smoking history, (b) provide printed education for HCPs to keep after the educational intervention, and (c) provide a link to educational resources related to smoking history intake and LCS within the organizations' intranet for on-going education.

Implications and Future Directions

This DNP project has provided useful information for further development of additional QI initiatives for LCS. From this project, recommendations for practice will assist providers and organizational stakeholders to make informed decisions about further project development. Initial efforts will be directed towards the improvement and accuracy of documentation of a complete smoking history intake for all adults across the entire health system. This project demonstrates that the consistent intake of basic smoking status is lacking, thereby making it difficult to obtain a complete history. This project demonstrates a significant improvement in the collection of smoking history information following education and with on-going education, process improvement and refinement, the organization will likely continue to improve smoking history intake.

EMR Modifications

As further modifications are made, focusing on simplification and standardization of smoking history documentation is necessary. Development of a health maintenance reminder or alert system, to identify potential candidates for LCS will commence, once an improved complete smoking history process is finalized. The development of nurse-driven preventive screening protocols for LCS may provide an excellent opportunity to maximize the identification of patients that may quality for LCS. Overall disease management and preventive screening guidance may benefit from further database development to better identify at-risk individuals. To improve the collection of accurate smoking history information, mandatory fields could be utilized to maximize the benefits of smoking history intake. Considering that all adult patients should have their smoking status asked and documented within the EMR, having such large numbers of missing or incomplete smoking history demonstrates an on-going challenge to be addressed.

With complete and accurate smoking history information, improved patient outcomes are expected by identifying individuals at high-risk for lung cancer and promoting LCS. This CWIP improves the organizations' ability to correctly identify candidates for LCS and to ensure insurance payment of the LDCT and the organizations' ability to correctly report to the Lung CT Screening Reporting & Data System, through the ACR, as mandated by CMS (2015). Finally, this CWIP provides an enhanced EMR data collection tool for HCPs across the health system.

EMR Inaccuracies

Inaccuracies within EMR intake is an important concept to discuss. The HCP responsible for documenting within the EMR is obligated to document accurate information. Omission or commission of accurate medical history may lead to improper medical advice; which may

ultimately lead to errors, adverse outcomes, or legal activity (Veteran's Administration, [VA], n.d.). Therefore, improving the overall assessment of smoking history will be important component of organizational initiatives and educational programming.

Sustainability

This project has provided useful insight to better understand which direction efforts need to be focused on to improve smoking history intake and increase the knowledge of HCPs pertaining to smoking history intake and LCS. Upon completion of this DNP project, valuable and important information will provide the project leader and organization with local data to further improve the identification process for patients at high-risk for lung cancer and possibly other conditions. Not only will an accurate smoking history intake impact how patients are identified for LCS but for further population- health data abstraction and disease process management. Utilizing the feasibility, appropriateness, meaningfulness, and effectiveness (FAME) tool, further development of organizational guidelines for practice recommendations may be utilized (Reavy, 2016).

HCPs involved in direct patient care and collection of smoking history information will need on-going education and access to on-line organizational resources for the accurate and complete collection of a smoking history. Recommendations will be intended to provide the best evidence-based guidelines for accurate smoking history intake and LCS. These guidelines will be placed within the electronic nursing policy and procedure manual. As part of the development of organizational guidelines for smoking history intake, providing HCPs with the knowledge and training necessary to provide counseling and care recommendations for active smokers is necessary.

Conclusion

Overall, this project demonstrated statistically significant improvements in the perception of knowledge of LCS and smoking history intake. How these improvements translate into improved accuracy and complete documentation of smoking history and its' impact on the identification of LCS candidates and LCS rates is unknown. Ensuring that HCPs have the knowledge and understanding to utilize current EMR technology to improve the efficiency and accuracy of existing smoking history intake is necessary. Obtaining a complete, accurate smoking history remains the single most important technique in identifying LCS candidates. Further study is needed to fully understand the effects of human factors in the overall accuracy and completeness of smoking history documentation and its' relationship to LCS workflow for the successful enhancement of the EMR and LCS programs.

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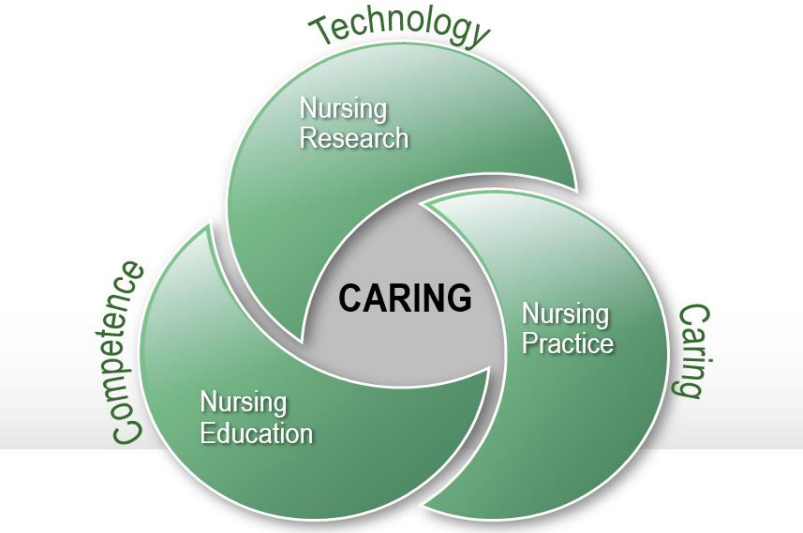
Footnotes

[1]From the electronic medical record by project organization, 2018. Reprinted with permission.

Appendix A

Technological Competency as Caring in Nursing: Middle-Range Nursing Theory
By Rozzano C. Locsin, PhD, RN, FAAN (Locsin, 2001).

Adapted conceptual model of *Technological Competency as Caring in Nursing* MRNT. Adapted from the MRNT *Technological Competency as Caring in Nursing* by Locsin.



Appendix B

Recruitment Flyer

Attention
MAs, CNAs, LPNs, & RNs

In ambulatory care: Internal Medicine, Family Medicine & Pulmonary Medicine.

Prior to a Clinical Workflow Improvement Project you will be asked to participate in a research study. You will complete a survey before and after the implementation.

You are NOT required to participate and choosing to not participate will have no impact on your employment.

Title: **Accurate Documentation of Smoking History through a Clinical Workflow Improvement Project**

Purpose: To improve the smoking history intake process to accurately identify candidates for lung cancer screening.

Protocol: The investigator will develop and implement a clinical workflow improvement project designed to better identify patients at high-risk for lung cancer. MAs, CNAs, LPNs, & RNs will be educated on the new smoking history intake process and the importance of identifying patients at high-risk for lung cancer. The voluntary pre-intervention and post-intervention surveys will study the knowledge, attitudes, and procedures of smoking history intake and lung cancer screening.

1. Develop clinical workflow
2. Educate staff on smoking history intake and lung cancer screening
3. Pre-intervention survey
4. Implement clinical workflow improvement
5. Post-intervention survey

Thank you very much for the assistance in my doctoral project. There will be no financial compensation.

For questions or concerns please contact the principal investigator:
Heidi Bender, MS, APRN, FNP-C, Doctor of Nursing Practice-Student
857-5741 (office); heidi.bender@ndus.edu; heidi.bender@trinityhealth.org
OR
Dr. Mary Jane Rivard, DNP, RN, Faculty 701-367-6408 (office); mary.rivard@und.edu

Appendix C

UNIVERSITY OF NORTH DAKOTA
Institutional Review Board
Informed Consent Statement

Title of Project:	**Accurate Documentation of Smoking History through a Clinical Workflow Improvement Project**
Principal Investigator:	*Heidi Bender, 701-340-0754 (cell); 701-857-5741 (office)*
Advisor:	*Dr. Mary Jane Rivard, College of Nursing and Professional Disciplines, 430 Oxford St. Stop 9025, Grand Forks, ND 58202. Phone: 701-367-6408.*

Purpose of the Study:
The purpose of this research study is to improve the smoking history intake process to have the appropriate information to accurately identify candidates for lung cancer screening.

Procedures to be followed:
The investigator is developing a clinical workflow improvement project to improve identification of patients at high-risk for lung cancer. You will be asked to complete pre- and post-intervention surveys.

Risks:
There are no risks in participating in this research beyond those experienced in everyday life.

Benefits:
You will not benefit personally from being in this study. However, we hope that, in the future, other people might benefit from this study because improved accuracy of smoking history documentation will likely lead to an improved effort and ability to identify patients who are at risk for lung cancer. This identification may allow that patient access to a life-saving cancer screening examination. Patients who are screened for lung cancer with low-dose computerized tomography have a 20% reduction in death rate.

Duration:
It will take approximately 15 minutes to complete each survey.

Statement of Confidentiality:
Surveys will be linked by an anonymous number only. When the surveys are distributed, you will create a unique, de-personalized identifier such as an ID number or code to place on the survey. You will need to remember and provide this unique identifier the next time you complete the survey. The data recorded will be stored for a period of three years in a locked cabinet within the principal investigators workplace. Data entered within an electronic source will be accessed with the data password protected.

Right to Ask Questions:
The researcher conducting this study is Heidi Bender. You may ask any questions you have now. If you later have questions, concerns, or complaints about the research please contact Heidi Bender, 701-857-5741 (office), 701-340-0754 (cell); heidi.bender@ndus.edu; heidi.bender@trinityhealth.org. The faculty advisor is Dr. Mary Jo Rivard and she can be contacted at 701-367-6408.

If you have questions regarding your rights as a research subject, you may contact The University of North Dakota Institutional Review Board at (701) 777-4279. You may also call this number with problems, complaints, or concerns about the research. Please call this number if you cannot reach research staff, or you wish to talk with someone who is an informed individual who is independent of the research team.

General information about being a research subject can be found on the Institutional Review Board website "Information for Research Participants" http://und.edu/research/resources/human-subjects/research-participants.cfm

Compensation:
You will not receive compensation for your participation.

Voluntary Participation:
You do not have to participate in this research. You can stop your participation at any time. You may refuse to participate or choose to discontinue participation at any time without losing any benefits to which you are otherwise entitled. There will be not any repercussions within your place of employment if you choose not to participate.

You do not have to answer any questions you do not want to answer.

You must be 18 years of age older to consent to participate in this research study.

Completion and return of the surveys implies that you have read the information in this form and consent to participate in the research.

Please keep this form for your records or future reference.

Appendix D

KAP Survey

Pre-Intervention Survey: Perception of Knowledge, Attitudes, and Practices (KAP)

Title of the Study: **Accurate Documentation of Smoking History through a Clinical Workflow Improvement Project**

In the U.S., more people die from lung cancer than breast, colon, and prostate cancer combined. Lung cancer screening has been available in the U.S. since 2015. Identifying candidates for lung cancer screening, within the electronic medical record is difficult. To assess the knowledge, attitudes and procedures of smoking history intake, some information is required from you. Your response will significantly contribute this workflow improvement project. Your participation will be kept confidential. The survey does not ask for any information that will identify who submitted the responses to and no individual identifying information will be collected. Therefore, your responses are recorded anonymously. If this research is published, no information that can identify you will be included since your name is in no way linked to your responses. There are no repercussions to you regarding your employment, should you decide not to participate.

KAP Survey

Demographic Information:

Age: 18-25
26-30
31-40
41-50
51-60
61-70

Gender: Male
Female

Years as healthcare provider: <1
2-5
6-10
11-15
16-20
21-30
>30

Highest educational level: High-school diploma
GED
Associate's degree
Bachelor's degree
Master's degree
Doctoral degree

Employment status:
Full-time
Part-time
Casual

Current work location: Internal Medicine
Family Medicine
Pulmonary Medicine

Do you smoke cigarettes: Yes
No

Former smoker? Yes
No

KAP Survey

Knowledge:

1. On a scale of 1-6; with 1 being *strongly disagree* and 6 being *strongly agree*, I have knowledge of lung cancer screening?

Strongly Disagree	Disagree	Somewhat Disagree	Somewhat Agree	Agree	Strongly Agree
1	2	3	4	5	6

2. On a scale of 1-6 with 1 being *definitely not confident* and 6 being *definitely confident*; I am confident in my ability to obtain and document an accurate smoking history.

Definitely Not Confident	Not Confident	Somewhat Not Confident	Somewhat Confident	Confident	Definitely Confident
1	2	3	4	5	6

3. On a scale of 1-6; with 1 being *strongly disagree* and 6 being *strongly agree*; this in-service will enhance my understanding of accurate smoking history intake.

Strongly Disagree	Disagree	Somewhat Disagree	Somewhat Agree	Agree	Strongly Agree
1	2	3	4	5	6

4. On a scale of 1-6; with 1 being *strongly disagree* and 6 being *strongly agree*; I plan to implement what I have learned from this in-service regarding the importance of accurate smoking history intake.

Strongly Disagree	Disagree	Somewhat Disagree	Somewhat Agree	Agree	Strongly Agree
1	2	3	4	5	6

KAP Survey

5. What smoking history data points are necessary to gather to accurately identify lung cancer screening candidates?
    a. Age, is the patient a current or former smoker, what year or age did the patient begin smoking, what year or age did the patient stop smoking, how many packs per day did the patient smoke?
    b. Is the patient a current or former smoker, what year or age did the patient begin smoking, what year or age did the patient stop smoking, how many packs per day did the patient smoke?
    c. Gender, is the patient a current or former smoker, what year or age did the patient begin smoking, what year or age did the patient stop smoking, how many packs per day did the patient smoke?
    d. Is the patient a current or former smoker and how many packs per day did the patient smoke?

6. What smoking history information is necessary to obtain to calculate a *pack-year smoking history?*
    a. Year started smoking, numbers of years smoked, former or current smoker.
    b. Number of years smoked and number of packs per day.
    c. Year quit smoking, numbers of years smoked.
    d. Current or former smoked, numbers of years smoked.

Attitudes:

7. On a scale of 1-6; with 1 being *extremely unimportant* and 6 being *extremely important*; how important do you feel that lung cancer screening is?

Extremely Unimportant	Unimportant	Somewhat Unimportant	Somewhat Important	Important	Extremely Important
1	2	3	4	5	6

8. On a scale of 1-6; with 1 being *extremely unimportant* and 6 being *extremely important*; generally speaking, how important is the identification of patients at high-risk for lung cancer; for the purpose of lung cancer screening?

Extremely Unimportant	Unimportant	Somewhat Unimportant	Somewhat Important	Important	Extremely Important
1	2	3	4	5	6

KAP Survey

9. On a scale of 1-6; with 1 being *strongly disagree* and 6 being *strongly agree*; generally speaking, attending educational in-services regarding evidence-based practice is important?

Strongly Disagree	Disagree	Somewhat Disagree	Somewhat Agree	Agree	Strongly Agree
1	2	3	4	5	6

10. On a scale of 1-6; with 1 being *strongly disagree* and 6 being *strongly agree*; the provider I work with (NP, PA, MD, DO) values an accurate documented smoking history?

Strongly Disagree	Disagree	Somewhat Disagree	Somewhat Agree	Agree	Strongly Agree
1	2	3	4	5	6

11. On a scale of 1-6; with 1 being *strongly disagree* and 6 being *strongly agree*; obtaining an accurate smoking history on my patients is valuable?

Strongly Disagree	Disagree	Somewhat Disagree	Somewhat Agree	Agree	Strongly Agree
1	2	3	4	5	6

Practices:

12. On a scale of 1-6; with 1 being *strongly disagree* and 6 being *strongly agree*; how I obtain and document smoking history impacts our ability to identify candidates for lung cancer screening.

Strongly Disagree	Disagree	Somewhat Disagree	Somewhat Agree	Agree	Strongly Agree
1	2	3	4	5	6

KAP Survey

13. On a scale of 1-6; with 1 being *strongly disagree* and 6 being *strongly agree*; I believe that accurately documenting an appropriate smoking history, improves patients' access to potentially life-saving cancer screening.

Strongly Disagree	Disagree	Somewhat Disagree	Somewhat Agree	Agree	Strongly Agree
1	2	3	4	5	6

14. Obtaining an accurate smoking history takes how much time?

>10 minute	8-10 minutes	6-7 minutes	4-5 minutes	2-3 minutes	<1 minute
1	2	3	4	5	6

15. On a scale of 1-6; with 1 being *strongly disagree* and 6 being *strongly agree*; I am expected to take and document an accurate patient smoking history.

Strongly Disagree	Disagree	Somewhat Disagree	Somewhat Agree	Agree	Strongly Agree
1	2	3	4	5	6

16. On a scale of 1-6; with 1 being *strongly disagree* and 6 being *strongly agree*; my patients expect that I gather an accurate smoking history?

Strongly Disagree	Disagree	Somewhat Disagree	Somewhat Agree	Agree	Strongly Agree
1	2	3	4	5	6

17. On a scale of 1-6; with 1 being *strongly disagree* and 6 being *strongly agree;* it is important for me to document an accurate smoking history, in order for the provider I work with identify candidates for lung cancer screening.

Strongly Disagree	Disagree	Somewhat Disagree	Somewhat Agree	Agree	Strongly Agree
1	2	3	4	5	6

Appendix E

KAP Survey

Post-Intervention Survey: Perception of Knowledge, Attitudes, and Practices (KAP)

Title of the Study: **Accurate Documentation of Smoking History through a Clinical Workflow Improvement Project**

In the U.S., more people die from lung cancer than breast, colon, and prostate cancer combined. Lung cancer screening has been available in the U.S. since 2015. Identifying candidates for lung cancer screening, within the electronic medical record is difficult. To assess the knowledge, attitudes and procedures of smoking history intake, some information is required from you. Your response will significantly contribute this workflow improvement project. Your participation will be kept confidential. The survey does not ask for any information that will identify who submitted the responses to and no individual identifying information will be collected. Therefore, your responses are recorded anonymously. If this research is published, no information that can identify you will be included since your name is in no way linked to your responses. There are no repercussions to you regarding your employment, should you decide not to participate.

KAP Survey

Knowledge:

1. On a scale of 1-6; with 1 being *strongly disagree* and 6 being *strongly agree*, I have knowledge of lung cancer screening?

Strongly Disagree	Disagree	Somewhat Disagree	Somewhat Agree	Agree	Strongly Agree
1	2	3	4	5	6

2. On a scale of 1-6 with 1 being *definitely not confident* and 6 being *definitely confident*; I am confident in my ability to obtain and document an accurate smoking history.

Definitely Not Confident	Not Confident	Somewhat Not Confident	Somewhat Confident	Confident	Definitely Confident
1	2	3	4	5	6

3. On a scale of 1-6; with 1 being *strongly disagree* and 6 being *strongly agree*; this in-service enhanced my understanding of accurate smoking history intake.

Strongly Disagree	Disagree	Somewhat Disagree	Somewhat Agree	Agree	Strongly Agree
1	2	3	4	5	6

4. On a scale of 1-6; with 1 being *strongly disagree* and 6 being *strongly agree*; I plan to implement what I have learned from this in-service regarding the importance of accurate smoking history intake.

Strongly Disagree	Disagree	Somewhat Disagree	Somewhat Agree	Agree	Strongly Agree
1	2	3	4	5	6

KAP Survey

5. What smoking history data points are necessary to gather to accurately identify lung cancer screening candidates?
    a. Age, is the patient a current or former smoker, what year or age did the patient begin smoking, what year or age did the patient stop smoking, how many packs per day did the patient smoke?
    b. Is the patient a current or former smoker, what year or age did the patient begin smoking, what year or age did the patient stop smoking, how many packs per day did the patient smoke?
    c. Gender, is the patient a current or former smoker, what year or age did the patient begin smoking, what year or age did the patient stop smoking, how many packs per day did the patient smoke?
    d. Is the patient a current or former smoker and how many packs per day did the patient smoke?

6. What smoking history information is necessary to obtain to calculate a *pack-year smoking history?*
    a. Year started smoking, numbers of years smoked, former or current smoker.
    b. Number of years smoked and number of packs per day.
    c. Year quit smoking, numbers of years smoked.
    d. Current or former smoked, numbers of years smoked.

Attitudes:

7. On a scale of 1-6; with 1 being *extremely unimportant* and 6 being *extremely important*; how important do you feel that lung cancer screening is?

Extremely Unimportant	Unimportant	Somewhat Unimportant	Somewhat Important	Important	Extremely Important
1	2	3	4	5	6

8. On a scale of 1-6; with 1 being *extremely unimportant* and 6 being *extremely important*; generally speaking, how important is the identification of patients at high-risk for lung cancer; for the purpose of lung cancer screening?

Extremely Unimportant	Unimportant	Somewhat Unimportant	Somewhat Important	Important	Extremely Important
1	2	3	4	5	6

KAP Survey

9. On a scale of 1-6; with 1 being *strongly disagree* and 6 being *strongly agree*; generally speaking, attending educational in-services regarding evidence-based practice is important?

Strongly Disagree	Disagree	Somewhat Disagree	Somewhat Agree	Agree	Strongly Agree
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10. On a scale of 1-6; with 1 being *strongly disagree* and 6 being *strongly agree*; the provider I work with (NP, PA, MD, DO) values an accurate documented smoking history?

Strongly Disagree	Disagree	Somewhat Disagree	Somewhat Agree	Agree	Strongly Agree
1	2	3	4	5	6

11. On a scale of 1-6; with 1 being *strongly disagree* and 6 being *strongly agree*; obtaining an accurate smoking history on my patients is valuable?

Strongly Disagree	Disagree	Somewhat Disagree	Somewhat Agree	Agree	Strongly Agree
1	2	3	4	5	6

Practices:

12. On a scale of 1-6; with 1 being *strongly disagree* and 6 being *strongly agree*; how I obtain and document smoking history impacts our ability to identify candidates for lung cancer screening.

Strongly Disagree	Disagree	Somewhat Disagree	Somewhat Agree	Agree	Strongly Agree
1	2	3	4	5	6

KAP Survey

13. On a scale of 1-6; with 1 being *strongly disagree* and 6 being *strongly agree*; I believe that accurately documenting an appropriate smoking history, improves patients' access to potentially life-saving cancer screening.

Strongly Disagree	Disagree	Somewhat Disagree	Somewhat Agree	Agree	Strongly Agree
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14. Obtaining an accurate smoking history takes how much time?

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15. On a scale of 1-6; with 1 being *strongly disagree* and 6 being *strongly agree*; I am expected to take and document an accurate patient smoking history.

Strongly Disagree	Disagree	Somewhat Disagree	Somewhat Agree	Agree	Strongly Agree
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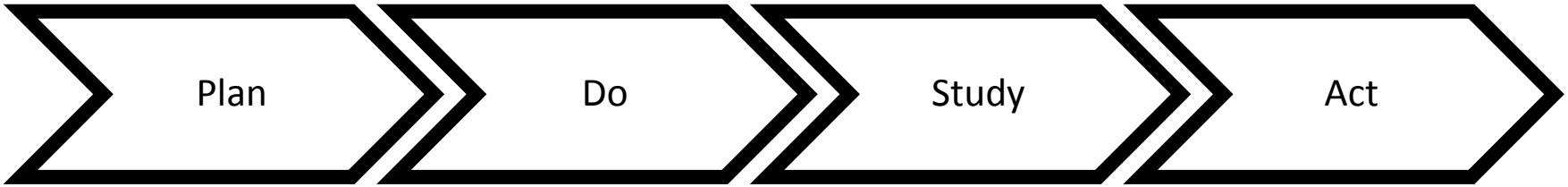
16. On a scale of 1-6; with 1 being *strongly disagree* and 6 being *strongly agree*; my patients expect that I gather an accurate smoking history?

Strongly Disagree	Disagree	Somewhat Disagree	Somewhat Agree	Agree	Strongly Agree
1	2	3	4	5	6

17. On a scale of 1-6; with 1 being *strongly disagree* and 6 being *strongly agree;* it is important for me to document an accurate smoking history, in order for the provider I work with identify candidates for lung cancer screening.

Strongly Disagree	Disagree	Somewhat Disagree	Somewhat Agree	Agree	Strongly Agree
1	2	3	4	5	6

Appendix F



- August-September 2017
- Project Start 9/22/17
- DNP Faculty Presentation 10/10/2017
- Organization Presentation 11/7/2017
- Organization IRB 11/13/2017
- UND IRB Approval 11/21/2017
- DNP Project Draft Due 12/6/2017

- Post Project Flyers 1/8/2018
- Pre-Intervention Survey 1/31-2/8/2018
- Intervention 1/31-2/2/2018
- Post-Intervention Survey 1/31/-2/8/2018
- Data Collection Period 2/15-4/1/2018

- Data Analysis Period 4/2-4/15/2018
- DNP Project Defense 7/12/2018

- Organization Presentation of Findings 8/15/2018

Appendix G

BUSINESS ASSOCIATE AGREEMENT

EFFECTIVE DATE: October 20, 2017 ("Effective Date")

PARTIES:

xxxxxxxxxx ("Covered Entity")

Heidi Bender ("Business Associate")

RECITALS:

A. Covered Entity and Business Associate have entered into one or more agreements (collectively, the "Agreement") in which Business Associate agreed to provide certain services to Covered Entity, which services may involve Business Associate's receipt, use, disclosure or creation of Protected Health Information on behalf of Covered Entity.
B. The parties desire to enter into this Business Associate Agreement (the "BAA") to reflect their understandings and obligations with regard to Protected Health Information.

NOW, THEREFORE, in consideration of the mutual covenants and promises made by and between the parties, the receipt and adequacy of which is acknowledged, the parties agree as follows:

AGREEMENTS:

ARTICLE 1.
DEFINITIONS

1.1) Catch-All Definition. Terms used, but not otherwise defined, in this BAA shall have the same meaning as those terms in the Privacy Rule and Security Rule.

1.2) Specific Definitions.

(a) Breach. "Breach" shall have the same meaning as the term "breach" in 45 CFR 164.402.

(b) Designated Record Set. "Designated Record Set" shall have the same meaning as the term "designated record set" in 45 CFR 164.501.

(c) Electronic Protected Health Information. "Electronic Protected Health Information" shall mean individually identifiable health information that is transmitted in or maintained by electronic media.

(d) Individual. "Individual" shall have the same meaning as the term "individual" in 45 CFR 160.103 and shall include a person who qualifies as a personal representative in accordance with 45 CFR 164.502(g).

(e) Privacy Rule. "Privacy Rule" shall mean the Standards for Privacy of Individually Identifiable Health Information at 45 CFR part 160 and part 164, subparts A, D and E.

(f) Protected Health Information. "Protected Health Information" shall have the same meaning as the term "protected health information" in 45 CFR 160.103, limited to the information created or received by Business Associate from or on behalf of Covered Entity.

(g) Required By Law. "Required By Law" shall have the same meaning as the term "required by law" in 45 CFR 164.103.

(h) Secretary. "Secretary" shall mean the Secretary of the Department of Health and Human Services or his designee.

(i) Security Incident. "Security Incident" shall mean the attempted or successful unauthorized access, use, disclosure, modification, or destruction of information or interference with system operations in an information system.

(j) Security Rule. "Security Rule" shall mean the Security Standards at 45 CFR Parts 160, 162 and 164.

ARTICLE 2.
OBLIGATIONS AND ACTIVITIES OF BUSINESS ASSOCIATE

2.1) Regulatory Compliance. Business Associate agrees that it shall comply with the provisions of the Privacy Rule and Security Rule to the extent such regulations apply directly to Business Associate.

2.2) General. Business Associate agrees not to use or disclose Protected Health Information other than as permitted or required by this BAA or as Required By Law.

2.3) Safeguards. Business Associate agrees to implement and use appropriate safeguards to prevent use or disclosure of the Protected Health Information other than as provided for by this BAA. Business Associate agrees to implement administrative, physical and technical safeguards that reasonably and appropriately protect the confidentiality, integrity and availability of the Electronic Protected Health Information that it creates, receives, maintains or transmits on behalf of Covered Entity.

2.4) Mitigation. Business Associate agrees to mitigate, to the extent practicable, any harmful effect that is known to Business Associate of a use or disclosure of Protected Health

Information by Business Associate in violation of the requirements of this BAA including any Breach.

2.5) Reporting Disclosures and Breaches. Business Associate agrees to report to Covered Entity:

(a) any improper use or disclosure of the Protected Health Information within 10 days of discovery of such improper use or disclosure;

(b) any Security Incident of which it becomes aware, within 5 days of discovery; and

(c) any Breach or probable Breach, within one day of becoming aware of the Breach or probable Breach. Business Associate may make the initial report orally, but shall provide a full written report to Covered Entity within five days of providing oral notice. Each report (oral or written) shall include, to the extent available at the time of the report, a description of the breach, the Protected Health Information disclosed (including names and contact information), and a description of any remedial action(s) taken by Business Associate.

2.6) Agents and Subcontractors. Business Associate agrees to ensure that any agent, including a subcontractor, to whom it provides Protected Health Information or Electronic Protected Health Information received from, or created or received by Business Associate on behalf of Covered Entity agrees to the same restrictions and conditions that apply through this BAA to Business Associate with respect to such information. Business Associate agrees to ensure that any such agent or subcontractor to whom it provides Electronic Protected Health Information agrees to implement reasonable and appropriate safeguards to protect such information.

2.7) Access to Protected Health Information. In the event Business Associate maintains Protected Health Information in a Designated Record Set, Business Associate agrees to provide access, at the request of Covered Entity, and in the time and manner determined by Covered Entity, to Protected Health Information in a Designated Record Set to Covered Entity or, as directed by Covered Entity, to an Individual in order to meet the requirements under 45 CFR 164.524.

2.8) Amendment of Protected Health Information. In the event Business Associate maintains Protected Health Information in a Designated Record Set, Business Associate agrees to make any amendment(s) to Protected Health Information in a Designated Record Set that the Covered Entity directs or agrees to pursuant to 45 CFR 164.526 at the request of Covered Entity or an Individual, and in the time and manner determined by Covered Entity.

2.9) Access and Inspection. Business Associate agrees to make internal practices, books, and records, including policies and procedures and Protected Health Information, relating to the use and disclosure of Protected Health Information received from, or created or received by Business Associate on behalf of, Covered Entity available to Covered Entity, or to the

Secretary, in a time and manner designated by Covered Entity or the Secretary, for purposes of the Secretary determining Covered Entity's compliance with the Privacy Rule.

2.10) Accounting of Disclosures. Business Associate agrees to document such disclosures of Protected Health Information and information related to such disclosures as would be required for Covered Entity to respond to a request by an Individual for an accounting of disclosures of Protected Health Information in accordance with 45 CFR 164.528. Business Associate agrees to provide to Covered Entity or an Individual, in a time and manner designated by Covered Entity, the information collected to permit Covered Entity to respond to a request by an Individual for an accounting of disclosures of Protected Health Information in accordance with 45 CFR 164.528.

ARTICLE 3.
PERMITTED USES AND DISCLOSURES BY BUSINESS ASSOCIATE

3.1) General Use and Disclosure. Except as otherwise limited in this BAA, Business Associate may use or disclose Protected Health Information to perform functions, activities, or services for, or on behalf of, Covered Entity as specified in the Agreement, provided that such use or disclosure would not violate the Privacy Rule if done by Covered Entity or the minimum necessary policies and procedures of Covered Entity.

3.2) Use for Business Purposes. Except as otherwise limited in this BAA, Business Associate may use Protected Health Information for the proper management and administration of Business Associate or to carry out the legal responsibilities of Business Associate.

3.3) Disclosure for Business Purposes. Except as otherwise limited in this BAA, Business Associate may disclose Protected Health Information for the proper management and administration of Business Associate, provided that such disclosures are (a) Required By Law; or (b) Business Associate obtains reasonable assurances, prior to disclosure, from the person to whom the information will be disclosed that it will remain confidential and be used or further disclosed only as Required By Law or for the purpose for which it was disclosed to the person, and the person notifies the Business Associate of any instances of which it is aware in which the confidentiality of the information has been breached.

3.4) Data Aggregation. Except as otherwise limited in this BAA, Business Associate may use Protected Health Information to provide Data Aggregation services to Covered Entity as permitted by 45 CFR 164.504(e)(2)(i)(B) and if so requested by Covered Entity.

ARTICLE 4.
OBLIGATIONS OF COVERED ENTITY

4.1) Notification to Business Associate. Covered Entity shall notify Business Associate of: (i) any limitation(s) in its notice of privacy practices in accordance with 45 CFR 164.520, to the extent that such limitation may affect Business Associate's use or disclosure of Protected Health Information; (ii) any changes in, or revocation of, permission by Individual to use or disclose Protected Health Information, to the extent that such changes may affect Business

Associate's use or disclosure of Protected Health Information; and (iii) any restriction to the use or disclosure of Protected Health Information that Covered Entity has agreed to in accordance with 45 CFR 164.522, to the extent that such restriction may affect Business Associate's use or disclosure of Protected Health Information.

4.2) Requests. Covered Entity shall not request Business Associate to use or disclose Protected Health Information in any manner that would not be permissible under the Privacy Rule if done by Covered Entity.

ARTICLE 5.
TERM AND TERMINATION

5.1) Term. This BAA shall be effective as of the Effective Date, and shall terminate when all of the Protected Health Information provided by Covered Entity to Business Associate, or created or received by Business Associate on behalf of Covered Entity, is destroyed or returned to Covered Entity, or, if it is infeasible to return or destroy Protected Health Information, protections are extended to such information, in accordance with the termination provisions in this Article 5.

5.2) Termination for Cause. Upon Covered Entity's knowledge of a material breach by Business Associate, Covered Entity shall either:

(a) Provide an opportunity for Business Associate to cure the breach or end the violation and terminate the Agreement if Business Associate does not cure the breach or end the violation within the time specified by Covered Entity;

(b) Immediately terminate the Agreement if Business Associate has breached a material term of this BAA and cure is not possible; or

(c) If neither termination nor cure are feasible, report the violation to the Secretary.

5.3) Effect of Termination.

(a) Except as provided in paragraph (b) of this section, upon termination of the Agreement, for any reason, Business Associate shall return or destroy all Protected Health Information received from Covered Entity, or created or received by Business Associate on behalf of Covered Entity. This provision shall apply to Protected Health Information that is in the possession of subcontractors or agents of Business Associate. Business Associate shall retain no copies of the Protected Health Information.

(b) In the event that Business Associate determines that returning or destroying the Protected Health Information is infeasible, Business Associate shall provide to Covered Entity notification of the conditions that make return or destruction infeasible. Upon the mutual agreement of the parties that return or destruction of Protected Health Information is infeasible, Business Associate shall extend the

protections of this BAA to such Protected Health Information and limit further uses and disclosures of such Protected Health Information to those purposes that make the return or destruction infeasible, for so long as Business Associate maintains such Protected Health Information.

ARTICLE 6.
INDEMNIFICATION; INJUNCTIVE RELIEF

6.1) Indemnification. Business Associate agrees to indemnify, defend and hold harmless Covered Entity and its directors, officers, agents, shareholders and employees from and against any and all claims, demands, losses, expenses, costs (including reasonable attorneys' fees), damages and causes of action arising from or relating to Business Associate's breach of this BAA. In the event of a Breach by Business Associate, its agents, employees, or subcontractors, Business Associate will reimburse and indemnify Covered Entity's expenses and costs, including attorney's fees, that are reasonably incurred due to the Breach, including costs associated with the notification of Individuals and the media, as well as credit monitoring and other mitigating actions if determined necessary by Covered Entity.

6.2) Injunctive Relief. The parties acknowledge that the remedy at law for any breach of the terms of this BAA are inadequate and that the damages resulting from such breach are not readily susceptible to being measured in monetary terms. Accordingly, in the event of a breach or threatened breach by Business Associate or any of its subcontractors of the terms of this BAA, Covered Entity shall be entitled to immediate injunctive relief and may obtain a temporary order restraining any threatened or further breach.

ARTICLE 7.
MISCELLANEOUS

7.1) Regulatory References. A reference in this BAA to a section in the Privacy Rule or Security Rule means the section as in effect or as amended.

7.2) Amendment. The Parties agree to take such action as is necessary to amend this BAA from time to time as is necessary for Covered Entity to comply with the requirements of the Privacy Rule and Security Rule.

7.3) Survival. Sections 5.3, 6.1 and 6.2 of this BAA shall survive the termination of the Agreement.

7.4) Interpretation. Any ambiguity in this BAA shall be resolved to permit Covered Entity to comply with the Privacy Rule or Security Rule.

IN WITNESS WHEREOF, the parties hereto have executed this BAA in the manner appropriate to each.

COVERED ENTITY

By: On-file at project organization
Its: Corporate Compliance Officer

BUSINESS ASSOCIATE

By: HEIDI BENDER
Its: Principal Investigator

Appendix H

UNIVERSITY OF NORTH DAKOTA

DIVISION OF RESEARCH & ECONOMIC DEVELOPMENT

UND.edu

Institutional Review Board
Twamley Hall, Room 106
264 Centennial Dr Stop 7134
Grand Forks, ND 58202-7134
Phone: 701.777.4279
Fax: 701.777.6708
Email: UND.irb@research.UND.edu

November 21, 2017

Principal Investigators:	Heidi Bender
Project Title:	Accurate Documentation of Smoking History Through a Clinical Workflow Improvement Project
IRB Project Number:	IRB-201711-123
Project Review Level:	Exempt 1, 2
Date of IRB Approval:	11/21/2017
Expiration Date of This Approval:	11/20/2020

The application form and all included documentation for the above-referenced project have been reviewed and approved via the procedures of the University of North Dakota Institutional Review Board.

Attached is your original informed consent statement that has been stamped with the UND IRB approval and expiration dates. Please maintain this original on file. You must use this original, stamped consent form to make copies for participants. No other consent form should be used, and no signatures should be obtained from participants. Each participant must be given a copy of the informed consent statement to keep for their records.

If you need to make changes to your research, you must submit a Protocol Change Request Form to the IRB for approval. No changes to approved research may take place without prior IRB approval.

This project has been approved for 3 years, as permitted by UND IRB policies for exempt research. You have approval for this project through the above-listed expiration date. When this research is completed, please submit a Termination Form to the IRB.

The forms to assist you in filing your project termination, adverse event/unanticipated problem, protocol change, etc. may be accessed on the IRB website: http://und.edu/research/resources/human-subjects/

Sincerely,

Michelle L. Bowles, M.P.A., CIP
IRB Coordinator

MLB/sb

Enclosure

Cc: Dr. Mary Jane Rivard (w/o attachment)