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AUTOMATED IDENTIFICATION OF TYPE 2 DIABETES MELLITUS: CODE VERSUS TEXT

by

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Submitted in Partial Fulfillment of the Requirements

For the Degree of Master of Science in Public Health in

Epidemiology

The Norman J. Arnold School of Public Health

University of South Carolina

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DEDICATION

This work is dedicated to my family and friends. Thank you all for believing in me and continually encouraging me to achieve my dreams.

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This thesis would not have been possible without the continued support and guidance from a number of people. First I would like thank my committee chair, Dr. Anwar Merchant for his knowledge, guidance, and flexibility to work with me from afar. I am also indebted to my thesis committee members, Dr. Linda Hazlett and Dr. Robert Moran, for their time, honest critiques, and willingness to guide me through the entire process. I would also like to acknowledge my PPRNet mentors, Dr. Steven Ornstein and Dr. Ruth Jenkins for providing me with the PPRNet data and for molding me into a true researcher.

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iv

ABSTRACT

Background: A growing emphasis in the healthcare industry today is being placed on demonstrating meaningful use of one's Electronic Health Record (EHR) system. As rates of chronic disease, including diabetes mellitus (DM) rise, it has become clear that accurate and timely disease surveillance could be greatly improved utilizing the technologies available to clinicians today. As the Centers for Medicare and Medicaid Services (CMS) meaningful use incentive program deadlines fast approach, it remains unclear if their limited attestation criteria clearly reflect their end goal of improving patient care. The objective of this research was to determine the diagnostic accuracy of an automated text- based algorithm for identifying patients with diabetes mellitus from the longitudinal PPRNet Database.

Methods: The longitudinal PPRNet database is comprised of McKesson's Practice Partner, Lytec or Medisoft EHR system users nationwide. The analysis included data from the 115 PPRNet practices that submitted their 4th quarter data extract in January 2014. An unstructured free-text algorithm was used to determine the number of type 2 diabetics among all active adult patients. This algorithm which examines unstructured free-text data documented within the EHR title lines was compared to a previously established protocol which used a combination of ICD-9 diagnostic codes and/or active DM prescriptions. **Results:** Between all algorithm comparisons, the patients identified as having diabetes varied considerably. Using the combination of ICD-9 diagnostic codes and/or active DM prescriptions as comparison method, the resulting sensitivity was 77.8% and specificity was 97.2% for the free-text definition. Using diagnostic codes alone as the standard for comparison resulted in a much higher sensitivity (99.3%), and lower specificity (91.9%). However, when we compared the free-text definition to the ICD-9 diagnostic codes alone, 70% of free-text identified cases were found to be un-coded.

Conclusions: As EHR use continues to rise, it is crucial that we continue to develop ways to accurately translate patient data out of these systems in order to meaningfully utilize these powerful technologies. This thesis has helped clarify the need for further development of accurate data translation platforms in order to capture each patient's full and unique health story as well as for monitoring treatment and outcomes all while minimizing physician burden.

TABLE OF CONTENTS

DEDICATION
ACKNOWLEDGEMENTS iv
Abstractv
LIST OF TABLES ix
LIST OF ABBREVIATIONSx
CHAPTER I – Introduction1
1.1 Statement of the Problem1
1.2 Purpose and Objectives
1.3 Significance of Research
CHAPTER II – Literature Review
2.1 Diabetes Mellitus
2.2 U.S Healthcare's Transition to Electronic Health Record Systems
2.3 Data Structure
CHAPTER III – Methods
3.1 Study Design17
3.2 Measurement
3.3 Statistical Analysis

CHAPTER IV – Results	23
4.1 Sample Characteristics	23
4.2 Sample Characteristics of Test Identified Diabetes Mellitus Population	23
4.3 Algorithm Evaluation: DM Prevalence, Sensitivity and Specificity	24
CHAPTER V – Discussion	27
5.1 Strengths of Study	28
5.2 Limitations of Study	28
5.3 Future Research	29
5.3 Conclusions	29
References	31

LIST OF TABLES

TABLE 2.1: Description of comparative studies that examine the reliability and validity of EHR derived algorithms for clinical quality measurement
TABLE 3.1: Drugs for treatment of Type 2 Diabetes Mellitus 20
TABLE 4.1: Sample Characteristics of PPRNet Population and Adults with Text-Identified Type 2 Diabetes Mellitus
TABLE 4.2: 2-year DM Prevalence among All Active Adult Patients in 115 PPRNet Practice Sites by Algorithm
TABLE 4.3: Sensitivity and Specificity of Unstructured Free-Text Algorithm UsingDifferent Standards of Comparison

LIST OF ABBREVIATIONS

BMI	Body Mass Index
САН	Critical Access Hospitals
CDC	Centers for Disease Control and Prevention
CQM	Clinical Quality Measure
DM	Diabetes Mellitus
EHR	Electronic Health Record
НІТ	Health Information Technology
HITECH	Health Information Technology for Economic and Clinical Health
NLP	Natural Language Processing
PBRN	Primary Care Based Research Network
PHR	Personal Health Record
PPRNet	Practice Partner Research Network

CHAPTER I

Introduction

1.1 Statement of the Problem

Diabetes mellitus (DM) is one of the most prevalent, costly and burdensome, chronic illnesses in the U.S, with nearly 10% of the entire population diagnosed with diabetes and 35% with prediabetes. The American Diabetes Association predicts that as many as 1 in 3 Americans will have diabetes by 2050 (1). As Americans become increasingly plagued by diabetes, accurate and timely disease surveillance is becoming increasingly important for clinicians, clinical researchers, policy makers and health plan administrators. Historically, disease surveillance required manual review of paper charts or large national surveys, both of which are time consuming and costly; however the nationwide shift to electronic health records (EHR) provides the potential for a more efficient alternative.

The Health Information Technology for Economic and Clinical Health (HITECH) Act passed by the U.S Congress in 2009 is investing billions of dollars in incentives to clinicians who can demonstrate meaningful use of their EHR systems over the next several years. This act was set into motion with hopes of molding EHR's from data graveyards into data warehouses. Ideally these warehouses will contain extractable, secure, comprehensive, and standardized health information (2, 3). Meaningful use

includes both a core set and a menu set of objectives that are specific to eligible providers, hospitals and critical access hospitals (CAH). There are a total of 24 meaningful use objectives for eligible providers, and 23 objectives for eligible hospitals and CAHs. To qualify for an incentive payment, 19 of these 24 or 18 of the 23 objectives must be met. Due to the significant requirements for meaningful use attestation, the program is divided into 3 stages for qualification. In the first stage of participation, providers must demonstrate meaningful use for a 90-day EHR reporting period; in subsequent stages, providers will demonstrate meaningful use for a full year EHR reporting period. Programs are not required to demonstrate meaningful use in consecutive years; however, there are deadlines for attesting to each stage. All hospitals and practices that choose not to participate in the program will face reductions in Medicare reimbursement rates (4).

The overarching goals of this meaningful use incentive program are to push the U.S health care system to exploit and expand health information technology; however this major overhaul presents many challenges to all parties involved. As the deadlines for qualifying as a stage 2 meaningful use vendor quickly approach, EHR software companies struggle to keep up, preventing proper usability assessments during development (5). A certified stage 2 meaningful use EHR vendor must enable providers to record data in a structured format, allowing for data to be more easily retrieved and transferred, with hopes of optimizing health technology to improve patient care. Meanwhile, practitioners continue to struggle with current insufficient interfaces, and clinical researchers suffer from lacking standardized terminologies, yet both have little say in future system developments (6). EHRs contain two types of data; structured,

coded data and, unstructured, free text data. Both types of data contain important information about the patient's unique health story. Many providers find that entering standardized data, rather than free text takes more time and effort. Some feel that current software is lacking in standardized matches for many common chronic conditions (2). West et al highlighted that the fragmentation of the US healthcare system hinders chronic disease management as well as longitudinal research on these diseased populations. Because patients see multiple providers in their lifetime, tracking a patient's care remains extremely difficult (7). Researchers advise further validation on electronic database extraction techniques before using them to assess quality of care (8).

Diabetes surveillance remains a top priority of the CDC, who developed and maintains the world's first diabetes surveillance system. These surveillance data rely on national and state-based household, telephone, and hospital-based surveys and vital statistics to monitor diabetes trends. In collaboration with the NIH, the CDC has also initiated the SEARCH for Diabetes in Youth study, the largest major surveillance system to quantify and track the diabetes burden in Americans under 20 years of age. The SEARCH study provides population-based information on the underlying factors, trends, impact and level of care provided as well as allows researchers to clarify the degree to which type 2 diabetes is affecting youth of different racial and ethnic backgrounds. Overall, the CDC's surveillance data is used to understand the diabetes epidemic, identify vulnerable at-risk populations, set prevention objectives and monitor successes of programs over time, all at the national level.

1.2 Purpose and Objectives

The purpose of this thesis is to optimize methods for identification of patients with type 2 diabetes mellitus (DM) from de-identified EHRs of primary care practices in the Practice Partner Research Network (PPRNet). PPRNet is a practice based research network (PBRN) that was established in 1995 as a collaborative effort between the Department of Family Medicine at the Medical University of South Carolina (MUSC), McKesson in Seattle, WA, and participating primary care or internal medicine practices nationwide. The PPRNet database contains historical clinical data from 1987 through 2013 from 340 practices and more than 5 million patients. Currently PPRNet has 151 active member practices who electronically submit quarterly data extracts to PPRNet for aggregation and analysis.

Our structured coded-data algorithm used for comparison was developed from the previously established definition that Miller et al. used in 2004 to auto-identify DM patients in the Department of Veteran Affairs database to calculate best estimates of DM prevalence and incidence rates (9). Our unstructured text data algorithm uses a developed data dictionary based on natural language processing to identify cases of DM through evaluation of unstructured text data from the title lines within the EHR. This thesis will test the diagnostic accuracy of the unstructured text algorithm in comparison with Miller's identification protocol. The specific aims for this thesis are:

Specific Aim 1: Unstructured text data

• Identify cases of DM from de-identified EHR's of primary care practices participating in PPRNet using developed algorithms based on natural

language processing to identify cases of DM through evaluation of unstructured text data from the title lines within the EHR.

Specific Aim 2: Structured coded data

 Identify cases of DM from de-identified EHR's of primary care practices participating in PPRNet using an algorithm established by Miller et al. that assesses ICD-9 codes and diabetes medications from structured diagnostic data fields.

Specific Aim 3: Diagnostic accuracy

• Compare the unstructured text-based algorithm versus Miller's algorithm that assesses ICD-9 codes and diabetes medication prescriptions for identifying patients with diabetes.

1.3 Significance of Research

Specific aims of this thesis will assess the diagnostic accuracy of a new unstructured text-based algorithm in comparison to an established structured code-based algorithm. Several studies have been conducted to evaluate methods for estimating disease prevalence or identifying high-risk patients from structured EHR data, or claims data. Much existing research focuses on the use of automated data retrieval strategies to assess quality of care, although a study comparing the data documented within structured, coded fields with unstructured, narrative fields has yet to be performed. As the goals of the meaningful use EHR incentive program continue to propel the U.S healthcare system forward at a rapid rate, it's important to evaluate the current system operations in order to monitor the impact these changes have on achieving desired long-term outcomes. This thesis intends to not only present the diagnostic accuracy of this proposed diagnostic tool,

but also highlight the fundamental differences between data recorded in structured and unstructured formats.

CHAPTER II

Literature Review

2.1 Diabetes Mellitus

Prevalence of type 2 DM in the United States is increasing at a rapid rate, along with it are health care costs, and other associated complications. From 1980 to 2011, the crude prevalence of diagnosed diabetes rose 176% (from 2.5% - 6.9%) (10). The American Diabetes Association (ADA) reported as of March 2013, 25.8 million (8.3%) Americans have diabetes, listing 7.0 million of those as undiagnosed. The total annual costs attributable to diabetes are estimated to be nearly 245 billion dollars, accounting for 20% of all health care expenditures in the U.S. Another 79 million Americans have prediabetes, of which only 7.3% have been told by their physician (1). Prediabetes, also commonly referred to as impaired glucose tolerance (IGT) or impaired fasting glucose (IFG) almost always precedes the development of type 2 diabetes.

While risk factors such as genetics, ethnicity, birth weight and metabolic syndrome certainly play a role in the development of diabetes, several controllable lifestyle factors, such as one's weight, diet, exercise regimen and smoking status also influence a person's probability of acquiring the disease. The ADA reported 85.2% of people with type 2 diabetes are overweight or obese (1). Given the magnitude of this problem, the U.S healthcare system needs accurate, automated data retrieval methods to estimate and monitor its prevalence and evaluate the quality of care.

2.2 U.S Healthcare's Transition to Electronic Health Record Systems

Many large institutions nationwide have adopted EHR systems, while fewer small clinics and primary care practices, who treat a majority of Americans, have integrated health information technology (HIT) into their practices. Among these early adopters, few properly utilized advanced features such as clinical decision support, point of care alerts, patient activation, and overdue service reminder letter generation (11-13). While clinical decision support has been shown to improve things like preventive care screening rates among primary care doctors, an unintended inverse effect of alert fatigue has surfaced when used too frequently (14, 15). Lacking standard data definitions and interoperability hinder nationwide implementation of comprehensive Personal Health Records (PHR), highlighting the urgent need for clinical informatics (16). These patient portals are currently utilized by less than 1% of the U.S population. The healthcare system recognizes the potential these portals could have on stimulating patient engagement. This platform would allow patients access to their personal health information, as well as educational material and tools, empowering them to become active participants in the management of their own health (17, 18).

The U.S congress enacted the Health Information Technology for Economic and Clinical Health (HITECH) Act as part of the American Reinvestment and Recovery Act of 2009 to allow the Center for Medicare and Medicaid to provide incentives to clinicians and hospitals who demonstrate meaningful use of their EHR system (19). The requirements for participation gradually increase throughout the three stages, qualifying providers that attest to each stage with significant incentive payments, and penalizing

those that don't successfully attest to stage two requirements at least three months before the end of the 2014 payment year.

2.2.1 Electronic Health Records and Quality Clinical Care and Measurement

As clinicians across the country strive to earn these meaningful use incentives, greater emphasis has been placed on the validity of current EHR-derived clinical quality measures. Although the potential rewards are enormous, the accompanying challenges should not be underestimated. Historically, clinical researchers, health plan administrators and policymakers have relied on administrative, claims-based databases, and self-report to deduce clinical context, often producing misleading results that underestimate quality-of-care measures (20, 21). Self-report has been shown to over-estimate diabetes quality of care measures (22).

Claims databases were developed to collect insurance payments, not track clinical information. Consequently, much relevant health information that is unnecessary for processing payments may not be collected or recorded accurately. Pharmacy claims often fail to identify chronic conditions like diabetes and hypertension that are being controlled by diet alone (23). The comparison of claims with medical record data produced complementary information on diabetes quality of care measures, resulting in mixed reliability, the highest being microalbumin testing and the lowest agreement for eye examination (22). A later study compared a claims-based strategy and an EHR-based method with a manual review reference group in the identification of pharyngitis. Overall, a larger proportion of cases were correctly identified by the EHR-based strategy than the administrative data-based strategy. The administrative data-based strategy did however boast a higher specificity than the EHR-based method, emphasizing the need for

more rigorously defined EMR-based retrieval strategies, before utilizing them for quality of care measurement (8). In 2012, Ganz et al extracted structured coded data on falls in the elderly, and compared it with manual review. He found that only 54% of falls were identified within the coded data, and that much documentation regarding the care surrounding each event was recorded in non-structured form. In conclusion, because the accuracy of quality of care measures vary greatly between the types of care process being evaluated, and prevent unique challenges, future validation studies comparing automated algorithms to manual review will be beneficial (24, 25).

2.2.2 Chronic Disease identification within the Electronic Health Record

Accurate chronic disease identification within the EHR is essential to surveillance efforts, the development of patient care plans, and clinical research advancements. Clinician documentation style remains the essential focus for improvement. Chronic disease management often requires the coordination of many physicians. Due to incongruent EHR systems, much treatment documentation from specialists fails to be entered into the EHR utilized by the patient's primary care providers. Most information that is relayed winds up in the free text portion of office notes, which automated searches do not detect (26). Shifting to a more team-based care approach is necessary for improved identification and care of chronic illness.

Strict algorithms for identification also prove to be important. In 2004, a study to estimate DM rates over a three year period within the Department of Veterans Affairs DEpic electronic database was conducted. This study compared varying combinations of EHR derived DM criteria to self-reported DM cases. The algorithm with the highest sensitivity (93%) and specificity (98%) used DM medication prescription records in the

current year and/or 2 diabetes codes from inpatient and/or outpatient visits (VA and Medicare) over a 24 month period. When similar algorithms were applied to claims databases in 2006, Solberg et al reported final positive predictive values (PPV) between 0.965 and 1.0. All algorithms were tested on a small sample population and then adapted, producing a final algorithm with the following inclusion criteria; 2 or more outpatient or 1 inpatient ICD-9 codes for diabetes within one year, or a filled prescription for diabetes-specific medication in the same calendar year. After initial chart review, Metformin was found to be used to treat other conditions, such as polycystic ovary syndrome, infertility and reactive hyperglycemia, and was removed as a diabetes-specific medication from the final algorithm (27).

2.3 Data Structure

The type of data contained in an EHR can be classified into one of two types; structured, coded data, or, unstructured, free-text data. Much recent research has focused on comparing the type of data stored in each form and its relation to clinical quality measurement. The meaningful use incentive program has identified many of the limitations in using unstructured data for these purposes, thus encouraging clinicians to document in structured, coded formats in order to attest in both stage 2 and stage 3. Many structured fields successfully capture all relevant information needed for some quality measures, such as blood pressure recorded in vital signs for hypertension measures (28). Although, much of the literature suggests that the completeness of the medical records and ease of extractability vary greatly depending on the clinical area of focus (29). The literature referenced in the following sections present the positive and negative attributes of both data types.

2.3.1 Unstructured Data

Unstructured, narrative text provides unique insight into the quality of care because it represents a provider's thought process, unrestricted by structured vocabularies. This extensive narrative data is made valuable through the use of natural language processing (NLP). Most challenges in NLP arise in the process of deriving meaning from human or natural language input. Although NLP continues to improve, recall and precision rates vary significantly between systems. Narrowly and consistently defined variables, such as gender, race and test results tend to demonstrate the highest rates of both, while variables with multiple definitions remain difficult to capture and code (30).

Studies that have only evaluated structured data fields have regularly stated that the algorithms missed recognition because relevant information, such as exclusion criteria, was only documented in narrative form (31). Another study found that their NLP system consistently out-performed the use of ICD-9 billing codes in identifying the condition of interest (32). Overall, the condition of interest being evaluated has the largest impact on NLP results.

Existing literature highlights the limitations associated with manual review, the use of administrative data, EHR data structure and format, and extraction procedures (19, 21, 33-35). One major issue with auto-extracted data stems from under recording in reasonably accessible fields such as medication lists (36). This type of automated recognition software has been applied to discharge summaries, radiology reports, and other qualitative data from limited sections of the patient's EHR resulting in a validity ranging from low to high (37-42). When used in combination with ICD-9 codes, Zeng et

al found that accuracy improved. NLP systems have been shown to accurately identify risk factors and diagnostic criteria associated with certain medical conditions. Byrd et al successfully developed NLP algorithms using Framingham criteria for early detection of heart failure patients (43).

2.3.2 Structured Data

Structured, coded data allows for interoperability between systems. This type of data eases the accuracy for secondary use purposes. Readily available and directly analyzable EHR data reduces the need for extensive manual chart review, thus allowing for performance measures to be more easily assessed on a larger proportion of patients in care. When structured data was compared with full chart review results from the Veterans Health Administration's External Peer Review Program (EPRP) on several measures, over 80% of the data on these selected measures was found in a directly analyzable format within the EHR. While the EPRP data were found to be more complete, the correlation of measures between sources was very high (0.89-0.98) (44).

Much focus been placed on standardizing EHR output, while very little emphasis, until recently has been aimed at standardizing EHR data inputs. All clinicians are initially trained on proper documentation techniques in their EHR training. These techniques are often reinforced by quality improvement specialists; however no mechanism within the EHR forces providers to document in a particular location in the chart. Intensive training, automatic prompts and proper feedback are necessary in standardizing their documentation habits to reflect the care given in EHR-derived quality measures (34).

Even standardized data comes with drawbacks. Botsis et al found much inaccuracy within coded data. Often times a non-specific ICD-9 code is selected, such as 250 for diabetes, when a more accurate diagnosis is actually made at the point of care. Inconsistencies within the data also prove to be troublesome, sometimes displaying both 250.01 and 250.02 for type-1 and type-2 diabetes respectively. He also highlights the lack of contextual information the current ICD-9 coding system supports (45).

Table 2.1: Description of Comparative Studies that examine the Reliability and Validity of EHR derived Algorithms for Clinical Quality Measurement

Citation	Attribute Examined	Study Population	Study Design	Results
Baker et al., 2007	Accuracy; measure validity; completeness	N=517; Heart failure patient with 2 or more clinic visits within the 18 month period	Comparative	Automated review of the EHR was comparable to manual review for Left ventricular ejection fraction (LVEF) measurement (94.6% vs. 97.3%), prescription of beta blockers (90.9% vs. 92.8%), and prescription of ACE inhibitors or ARBs (93.9% vs. 98.7%). Performance was lower for prescription of warfarin for atrial fibrillation (70.4% vs. 93.6%).
Baldwin et al., 2008	Accuracy	N= 60; Women ≥ 40 years structured convenience sample from a Women's Health Center in 2001	Comparative	A significant difference between Natural Language Processing (NLP) methods and manual review was found. The NLP method found a false positive rate of 0, and a false negative rate of .035.
Benin et al., 2005	Accuracy	N= 479; possible pharyngitis episodes were analyzed using; (1.) EMR-based, (2.) administrative data- based, and (3.) manual review reference strategies	Comparative	When comparing each group to the reference; 91% of EMR-based strategy episodes were confirmed and 59% of the administrative data-based strategy.
Fowles et al., 1999	Accuracy; comparability	N= 760; Adults with Diabetes, aged 31-64 from a Minnesota health	Cross-sectional	Reliability between primary medical record and claims varied by measure; Eye examination (K= 0.371), Oral agents(K= 0.699), Insulin (K= 0.548), HbA1c (K= 0.678) and Microalbumin (K= 0.748)

		maintenance organization		
Ganz et al., 2012	Accuracy; measure validity and agreement	N=215; Falls data from a quality improvement initiative in primary care medical groups	Comparative	A structured visit note was found in 54% of charts within 3 months of the date patients had been identified as falling. The reliability of the codable-data algorithm was good (K=0.61) compared with full medical record review for three care processes.
Goulet et al., 2007	Accuracy; completeness; comparability	VA patients with hypertension, ischemic heart disease and diabetes	Comparative	Over 80% of the selected measures were found in directly analyzable form within the EMR. The degree of correlation between automated algorithms assessing structured fields in comparison to the Veterans Health Administration's External Peer Review Program(EPRP) was high (0.89-0.98).
Hivert et al., 2009	Accuracy; measure validity; completeness	N=122,715; Active adult patients from 12 primary care practices in eastern Massachusetts	Descriptive	Directly measured EHR-defined MetS had 73% sensitivity and 91% specificity. DM incidence was 1.4% in the No MetS group vs. 4% in the At-Risk-for-MetS group.
Miller et al., 2004	Accuracy; comparability	Department of Veterans Affairs patients recorded in the longitudinal, national database since 1998	Descriptive	The most accurate criterion was a prescription for diabetes medication in the current year and/or 2 + diabetes codes from inpatient and/or outpatient visits (VA and Medicare) over a 24-month period (Se= 93% and Sp= 98%) against patient self-report.
Owen et al., 2004	Accuracy	N=261; Random sample of inpatient and outpatient visits for Schizophrenia patients from the Veterans Health	Comparative	The percent agreement between automated algorithms and manual review among patients with chlorpromazine equivalents < 300, 300-1,000, and > 1,000, are .11, .41, and .21, respectively for inpatients, and .19, .21 and .40 for outpatients. The overall weighted Kappa for inpatients (K=0.55) and outpatients (K= 0.63).

		Administration database (VistA)		
Parsons et al., 2011	Accuracy; measure validity	N=4,081; patient EHR records from 57 practices	Comparative	The majority of diagnoses for chronic conditions had information documented in the problem list (a structured field) and were recognized by the automated quality measures, including diabetes (>91.4% across measures), hypertension (89.3%), ischemic cardiovascular disease (>78.8% across measures) and dyslipidemia (75.1%).
Persell et al., 2006	Accuracy; measure validity	N=1,006; All CAD patients from a large internal medicine practice	Comparative	Performance on 7 quality measures varied from 81.6% for lipid measurement to 97.6% for blood pressure measurement. After including Free-text data, the adherence rate increased, ranging from 87.5% for lipid measurement and low-density lipoprotein cholesterol to 99.2% for blood pressure measurement.

CHAPTER III

Methods

3.1 Study Design

3.1.1 PPRNet

We used a cross-sectional study of diagnostic accuracy design, analyzing data from the longitudinal PPRNet database. PPRNet was established in 1995 as a collaborative effort between the Department of Family Medicine at the Medical University of South Carolina (MUSC), Practice Partner/McKesson in Seattle, WA and participating primary care and internal medicine practices. PPRNet is a practice based research network (PBRN) that strives to improve the quality of healthcare in its member practices by; turning clinical data into actionable information, empirically testing theoretically sound quality improvement interventions, and disseminating successful interventions to primary care providers across the country. Currently PPRNet has 151 physician practices, representing over 1068 health care providers, and approximately 1.4 million patients located in 38 states. All of PPRNet's member practices currently use McKesson's Practice Partner, Lytec or Medisoft's EHR systems. These data are extracted and sent to PPRNet on a quarterly basis. Data are then cleaned, appended to the longitudinal database and analyzed to produce quality improvement reports on 65 clinical quality measures (CQM). These quality measures include ten diabetes mellitus measures and track the quality of care on several other common conditions such as cardiovascular disease, respiratory disease with other focuses on women's health, cancer screening, immunizations, mental health, substance abuse, and medication safety.

3.1.2 Study population

This eligible patient population was comprised of active patients from 115 PPRNet practices that sent their fourth quarter data extract in January 2014. A patient was defined as active if he/she had a visit within 1 year and was not designated with a deceased or inactive status. A visit was determined by a progress note title that did not include text indicating a cancelled appointment or no show. Similarly, in either approach, the recorded data must not be designated with an inactive status or a resolved date.

3.1.3 Inclusion and exclusion criteria

The electronic health record of all active patients ≥ 18 years of age were evaluated for an active diagnosis of type 2 diabetes mellitus made within the last 2 years.

3.2 Measurement

The aims of this study were to assess DM diagnosis in a database of electronic medical records using 3 methods: NLP, Miller's protocol, and ICD-9 codes. NLP is a newer method that uses an algorithm based on unstructured text data, while the other two methods have been used in the past.

3.2.1 Unstructured text evaluation

The unstructured text algorithm utilizes NLP techniques for automated identification of diagnoses. We first developed common text variations of DM, including full diagnosis names, ICD-9 codes, abbreviations, synonyms, and common misspellings. These 341 text string variations were then compared to the free text data, flagging

possible diagnoses of type 2 DM and suggesting a corresponding ICD-9 code. All flagged diagnoses with a frequency of 4 or more were then manually reviewed by a research assistant for correctness. Text strings were then either classified as definite diagnoses of type 2 DM, or excluded from future analysis. These text string classifications were then reviewed by a clinician for accuracy. This review process is conducted on a quarterly basis. Each quarter, only new text variations, with a frequency greater than 3 are flagged for manual review. Currently, the PPRNet database contains 13,231 text variants included as DM.

3.2.2 Structured data evaluation

The coded, structured data evaluation algorithm we used is based on Miller's definition for DM identification in a VA population [Miller 2004]. This criterion included a prescription for a diabetes medication in the current year and/or 2 or more recorded type 2 diabetes ICD-9 diagnostic codes within a 24-month period. As of January, 2014, the PPRNet database contained data through December 31, 2013 from 115A practices. The DM codes included for analysis were comprised of the following ICD-9 codes; 250(excluding type 1 codes), 357.2, 362.01, 362.02, 366.41. These were extracted from the 4 code fields within the EHR. The medications included for DM treatment will be taken from the most current Treatment Guidelines from The Medical Letter. The DM medications included in the analysis are listed in Table 2 (46).

 Table 3.1: Drugs for Treatment of Type 2 Diabetes Mellitus

Drug	Formulation
Biguanide	
Metformin	500,850,1000 mg tabs
Glucophage	500,850,1000 mg tabs
extended- release – generic	500, 750 mg tabs

Glucophage XR	500, 750 mg tabs
Glumetza	500, 1000 mg tabs
Fortamet	500, 1000 mg tabs
Riomet- liquid	500 mg/ 5 mL (4, 16 oz)
Second- Generation Sulfonylureas	
Glimepiride – generic	1, 2, 4, 8 mg tabs
Amaryl	1, 2, 4 mg tabs
Glipizide – generic	5, 10 mg tabs
Glucotrol	5, 10 mg tabs
extended- release – generic	2.5, 5, 10 mg tabs
Glucotrol XL	5, 10 mg tabs
Glyburide – generic	1.25, 1.5, 2.5, 3, 5, 6 mg tabs
DiaBeta	1.25, 2.5, 5 mg tables
Micronase	1.25, 2.5, 5 mg tabs
micronized tablets - generic	1.5, 3, 4.5, 6 mg tabs
Glynase Prestab	1.5, 3, 6 mg tabs
Non-Sulfonylurea Secretagogues	
Nateglinide – generic	60, 120 mg tabs
Starlix	60, 120 mg tabs
Repaglinide Prandin	0.5, 1, 2 mg tabs
Thiazolidinediones	
Pioglitazone – Actos	15, 30, 45 mg tabs
Rosiglitazone Avandia	2,4, 8 mg tabs
Alpha-Glucosidase Inhibitors	
Acarbose – generic	25, 50, 100 mg tabs
Precose	25, 50, 100 mg tabs
Miglitol	25, 50, 100 mg tabs
DPP-4 Inhibitors	
Sitagliptin Januvia	25, 50, 100 mg tabs
Saxagliptin Onglyza	2.5, 5 mg tabs
Linagliptin Tradjenta	5 mg tabs
GLP-1 Agonists	
Exenatide – Byetta	250 mcg/mL (1.2, 2.4 mL
	prefilled pen)
Liraglutide – Victoza	6 mg/mL (3 mL prefilled pen)
Other	
Colesevelam – Welchol	625 mg tabs
Bromocriptine – Cycloset	0.8 mg tabs
Pramlintide Symlin	1000 mcg/mL (1.5, 2.7 mL
	prefilled pens)

Combination Products

Metformin/glipizide – generic	625 mg tabs
Metaglip	0.8 mg tabs
Metformin/glyburide	1000 mcg/mL (1.5, 2.7 mL
Glucovance	prefilled pens)
Metformin/pioglitazone	500/15, 850/15 mg tabs
Actoplus Met	500/15, 850/15 mg tabs
Actoplus Met XR	1000/15, 1000/30 mg tabs
Metformin/repaglinide – Prandimet	500/1, 55/2 mg tabs
Metformin/rosiglitazone – Avandamet	500/2, 55/4, 1000/2, 1000/4
	mg tabs
Glimepiride/rosiglitazone – Anandryl	1/4, 2/4, 4/4, 2/8, 4/8 mg tabs
Glimepiride/pioglitazone – Duetact	2/30, 4/30 mg tabs
Metformin/sitagliptin Janumet	500/50, 1000/50 mg tabs
Metformin/saxagliptin Kombiglyze	500/5, 1000/2.5, 1000/5 mg
	ER tabs

3.3 Statistical analysis

Statistical analysis was performed using SAS software version 9.2 (SAS Institute, Cary, NC). The number of type 2 DM cases was calculated using both algorithms (described above), as well as an algorithm that evaluated ICD-9 diagnostic codes, alone. The accuracy of the unstructured text algorithm was compared to Miller's approach as well as the ICD-9 diagnostic code algorithm by calculating sensitivity and specificity. The unstructured text algorithm was used to calculate the 2-year prevalence of DM in PPRNet. Rates are presented overall and in population subsets defined by patient characteristics: age, sex, body mass index (BMI), as well as practice characteristics, including; practice type, being either internal medicine or family practice, a mix of both, multi-specialty, or "other".

CHAPTER IV

Results

4.1 Sample Characteristics

There were a total of 368,384 active adult patients among the 115 practices who sent their 4th quarter data extracts to PPRNet in January 2014 (Table 3). More than half of the population was female (57.5%). Within the sample, 36.6% were aged 18-44 years old, 18.6% were 45-54 years old, 19.5% were 55-64 years old, 13.9% were 65-74 years old, 7.6% were 75-84 years old, and 3.2% were 85-108 years old. Nearly a quarter of the population was underweight/normal weight (24.7%), while 29.8% were overweight, and 38.9% were obese. A majority of PPRNet practices are family practices, accounting for 70.5% of the patient sample. The majority of remaining patients belong to internal medicine practices (17.1%). A small sample of patients belongs to mixed practices made up of both family practitioners and internists. Rounding out the sample are multispecialty practices (2.6%), and "other" which consists of Rheumatology, Pulmonary, Gynecology, Neurology, Urology and Pediatric practices (4.5%).

4.2 Sample Characteristics of Text-identified Diabetes Mellitus Population

Just over half of adult diabetics are female (51.1%). The percentage of diabetics increases with age before leveling off at age 74 and declining thereafter. As expected, most of these type-2 diabetics fell in the overweight (23.7%) or obese (63.0%) BMI categories. Less than 10% of PPRNet's diabetic patients are underweight (0.8%) or

normal weight (8.6%). The DM patient sample was representative of the full population in regards to practice type as displayed in Table 3.

4.3 Algorithm Evaluation: DM Prevalence, Sensitivity and Specificity

Table 4 presents 2-year DM prevalence estimates based on each of the three algorithms (detailed description provided above in Section 3.2). Both the unstructured free-text algorithm and Miller's algorithm produced the same prevalence (11.1%), while the ICD-9 diagnostic code algorithm identified far fewer cases of DM, resulting in a prevalence of 3.4%.

Between all algorithm comparisons, the patients identified as having diabetes varied considerably. When we compared the unstructured free-text algorithm to Miller's, each protocol found close to 10,000 patients that were missed by the opposing definition. Using Miller's protocol as the standard of comparison, the resulting sensitivity was 77.8% and specificity was 97.2%. However, when we compared the free-text definition to the ICD-9 diagnostic codes alone, 70% of free-text identified cases were found to be un-coded. Only 86 additional patients had 2 or more recoded ICD-9 diagnostic codes but were not identified using the free-text algorithm. All 86 cases identified by the code definition alone were due to the low frequency of the corresponding text string. As described in detail in the methodology, only those unstructured text diagnoses that occur 4 or more times within the data are included for review to be counted as a definite diagnosis of DM. Using diagnostic codes alone as the standard for comparison resulted in a much higher sensitivity (99.3%), and lower specificity (91.9%).

	All Adult patients (≥18)		Diabetes (text)	
	No.	%	No.	%
Overall Number and DM Prevalence	368,384		40,947	11.1
Sex				
Male	156,293	42.4	20,026	48.9
Female	211,897	57.5	20,913	51.1
Age (years)				
18-44	134,828	36.6	4,118	10.1
45-54	68,387	18.6	6,943	17.0
55-64	71,671	19.5	10,972	26.8
65-74	51,314	13.9	10,682	26.1
75-84	27,853	7.6	5,926	14.5
85-108	11,731	3.2	1,911	4.7
BMI				
Underweight (< 18.5)	6,178	1.7	327	0.8
Normal (18.5-25)	84,903	23.0	3,530	8.6
Overweight (25-30)	109,786	29.8	9,716	23.7
Obese (> 30)	143,317	38.9	25,806	63.0
Practice Type				
Family Practice	259,736	70.5	28,712	70.1
Family Practice/Internal Medicine	17,606	4.8	2,069	5.1
Internal Medicine	63,162	17.1	7,830	19.1
Multispecialty	9,724	2.6	589	1.4
Other	16,676	4.5	1,743	4.3

Table 4.1: Sample Characteristics of PPRNet Population and Adults with Text-Identified Type 2 Diabetes Mellitus

Table 4.2: 2-year DM Prevalence among	All Active Adult Patients in 115 PPRNet Practice Site	s by Algorithm

Definition	No. (368,384)	Prevalence (%) (2012-2013)	
Miller's structured-coded: Active medication prescription and/or 2+ ICD-9 codes recorded within the previous 2 years	41,007	11.1	
Unstructured free-text: Active text diagnoses recorded in unstructured title lines within previous 2 years	40,947	11.1	
ICD-9 diagnostic codes: 2+ ICD-9 diagnostic code recorded within previous 2 years	12,354	3.4	

26

Table 4.3: Sensitivity and Specificity of Unstructured Free-Text Algorithm Using Different Standards of Comparison

Standard of Comparison		Compared with unstructured free-text algorithm				
	Agreement: DM = Yes	Text definition alone	Standard of Comparison alone	Agreement: DM = No	Se (%)	Sp (%)
Miller's structured-coded	31,885	9,062	9,122	318,315	77.8	97.2
ICD-9 diagnostic codes	12,268	28,679	86	327,351	99.3	91.9

CHAPTER V

Discussion

The first aim of this study was to replicate, in PPRNet, the best definition for automated DM identification within EHR data from Miller's 2004 study comparing various definitions for DM identification using the Department of Veteran Affairs electronic health record database. We found that while the same overall percentage of diabetic patients were identified using this method as compared to the free-text method, there were several thousand diagnoses that had clear evidence of a free-text diagnoses that were missing a corresponding diagnostic code, and that were not on an active prescription for a DM medication. Similarly, there were close to the same number of diabetic patients identified by Miller's definition alone when compared to the free-text algorithm. Miller's best definition includes an active prescription for DM recorded within the last year, or 2 or more ICD-9 diagnostic codes recorded within the last 2 years. One of the main limitations of this definition is that some commonly used medications for DM, such as Metformin, which is the first-line drug of choice for the treatment of type 2 diabetics who are overweight or obese and with normal kidney function is also used in the treatment of polycystic ovary syndrome and other diseases where insulin resistance may be an important factor.

Secondly, this paper aimed to test a newly developed unstructured free-text based algorithm in accurate identification of DM cases within an active PPRNet patient population. One overarching limitation was due to our inability to access and manually

review each individual patient record, leaving us with no true gold standard for comparison. We chose Miller's definition because it had been found to be quite accurate when compared to patient survey. Using this standard of comparison, the free-text definition resulted in a fair sensitivity and very good specificity. Although we did not manually review each patient record, each unique text string with a frequency of 4 or more that was flagged for review using our automated DM text string dictionary consisting of 341 unique and comprehensive text strings was reviewed by a trained research assistant. Text diagnoses that were unclear were then also reviewed by a physician. While we cannot say with certainty that all cases of DM identified using the text algorithm is an actual case of DM, we are very confident that the rate of misclassification is very low due to this extensive processing. After comparing our algorithm with ICD-9 diagnostic codes alone, it also appears that we are missing very few coded cases of DM, resulting in a very high sensitivity (99.3%) and specificity (91.9%). Several more cases were identified when adding prescriptions for DM to the definition, but as we previously stated, we cannot be sure that the medication is being used to treat DM.

5.1 Strengths of the Study

A major strength of this study is the large sample size. This sample represents the differing documentation styles of hundreds of physicians nationwide treating hundreds of thousands of patients in both urban and rural practice settings.

5.2 Limitations of the Study

PPRNet has very little variation in practice type and practice size, consisting of mostly small to mid-size family practices and internal medicine clinics. Another

limitation is the fact that all PPRNet practices use one common EHR software product in an ever growing market place of products with varying configurations. Lastly, we did not compare our free-text based algorithm with a gold standard (physician diagnosis) preventing the estimation of its sensitivity and specificity. However, the development of the NLP algorithm is an iterative process. After a query is used to identify diabetes cases, a physician reviews the cases that the query identifies for accuracy. The query is then modified and the process is repeated. This happens on an ongoing basis. This rather efficient NLP algorithm was used to identify cases in this study.

5.3 Future Research

We recommend that similar studies in the future use databases that contain data from several EHR software systems to reduce bias. It would be interesting to replicate this study in a more diverse research network; stratifying by practice site characteristics such as size, location and specialty as well as provider characteristics such as degree and specialty. In looking at both practice and provider characteristics, we could get a better understanding of what major factors influence physician EHR documentation styles. It would also be useful to attain patient records for manual chart review to use as a gold standard for comparison when testing new algorithms that could potentially aid in a variety of arena's such as population health. In a similarly large research network, one could collect a randomized sample of a small percentage of the total population rather than manually review the charts of the entire population.

5.4 Conclusions

Our unstructured free-text evaluation performed quite well in accurately identifying Type 2 DM patients within the PPRNet active patient population. As EHR

use is on the rise, it is crucial that we continue to develop ways to accurately translate patient data out of these systems in order to meaningfully utilize these powerful technologies. This paper has helped clarify the need for further development of accurate data translation platforms in order to capture each patient's full and unique health story as well as for monitoring treatment and outcomes all while minimizing physician burden.

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