

The Relationship Between the Adoption of Patient Centered Medical Home and the Quality of  
Medication Use: Results from the National Ambulatory Medical Care Survey

by

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## **DEDICATION**

To My Beloved Parents

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## ABSTRACT

**Background:** Nearly 40% of adults age 65 and over report using five or more medications and one in five prescriptions in primary care are identified as inappropriate. Medication quality of care is a critical healthcare concern. To improve primary care, Patient-Centered Medical Homes (PCMHs) are considered a promising approach with a focus on systems-based quality and safety improvement. Evidence has demonstrated that PCMH adoption has many potential benefits. However, gaps exist in our knowledge regarding the potential benefits of PCMH in improving patient medication quality of care.

**Objectives:** To quantify current ambulatory care practices' level of PCMH adoption and determine practice-based and physician-related factors associated with the degree of PCMH implementation and to explore the association between the level of PCMH adoption in a practice and its impact on medication processes and outcome of care indicators.

**Methods:** This study employed the 2009 and 2010 National Ambulatory Medical Care Survey (NAMCS) dataset, using a cross-sectional study design. For missing data, multiple imputations by chained equations were used to generate five complete data sets to provide improved statistical power. The use of high-risk medication (HRM), drug-disease interaction (DDIS), and the occurrence of adverse drug events (ADEs) were the three selected medication process and outcome quality indicators. The level of PCMH adoption was predicted, controlling for physician and practice characteristics.

**Results:** Half of the ambulatory care settings in NAMCS adopted some aspect of PCMH during the observed study period. Physicians' characteristics had significant associations with PCMH adoption, with older age and being female less likely to adopt PCMH. The prevalence of HRM, DDIS, and ADEs among the target populations were 11.2%, 15.0%, and 4.0%, respectively. The adoption of PCMH was not associated with the selected medication quality indicators.

**Conclusion:** PCMH was adopted by over 50% of practices throughout the United States and medication quality remains of concern. While the results did not support the impact of PCMH on medication use quality, these findings are limited to HRM, DDIS and ADE. Other quality measures, such as prevention and screening or disease-specific measures should be examined in the future studies.

## CHAPTER I. INTRODUCTION

One in five prescriptions in primary care in the United States is inappropriate, which could lead to serious medical consequences and place a substantial economic burden on our health care system.<sup>1</sup> To ensure patient safety and control healthcare costs, it is critical to monitor medication use. This is particularly important if we consider that almost one-half of the U.S. population takes at least one prescription medication and 1 in 10 reports taking more medications in the preceding month.<sup>2</sup> Among the elderly population, inappropriate medication is a particularly important problem, given their pharmacokinetic and pharmacodynamic changes arising from aging and greater use of high-risk medications. A related concern is that patients with higher medication use face an increased risk of inappropriate medication use, and a higher risk of experiencing adverse drug events (ADEs).<sup>3</sup> In order to monitor inappropriate medication use and enhance medication safety, the Center for Medicare and Medicaid Services (CMS) employs quality measures developed by the Pharmacy Quality Alliance (PQA) and the National Committee for Quality Assurance (NCQA). These measures are directed at assuring medication quality which is of interest to the public and determining reimbursements for providers, but more broadly with a view toward enhancing accountability.<sup>4</sup> Aligned with the goal of providing high-quality medication services, the Patient Centered Medical Home (PCMH) model was designed as an innovative transformation in primary care that emphasizes specific medication management approaches aimed at ensuring that medications are distributed to and used appropriately by each patient.<sup>5</sup>

Many primary care practices have begun to implement PCMHs in their settings, yet what remains largely unexplored is how and to what extent this patient care model can impact patients' process-of-care and health outcomes related to medications. The provision of care in a PCMH appears to have the potential to improve health service utilization and patient satisfaction.<sup>6</sup> But, to date no study has investigated the relationship between the degree to which practices have implemented various aspects of PCMH and medication-related quality of care. To have a comparable way to quantify the provided services, many practices depend on the certification as PCMH by the NCQA PCMH recognition program, which is a voluntary program consisting of three levels of achievement, as measured by a scoring rubric.<sup>7</sup>

The long-term goal of this investigator is to improve primary care delivery and elucidate how practices with PCMH processes of care impact the quality of medication use and related outcomes. The study is based on a combined theoretical model, using the well-established framework in the Chronic Care Model, and supplemented with structural and organizational factors. The rationale of this study is that there is a need to determine whether primary care practices using PCMH strategies indeed provide better care that result in better medication-related outcomes. These results may provide insightful information about the value of having medication-related experts, such as pharmacists, in the PCMH care team to strengthen medication services.

## **OBJECTIVES**

The overall objective of this study is to quantify the association between the levels of NCQA PCMH recognition in primary care practices and the quality of care related to medication use. The central hypothesis is that a practice with higher levels of NCQA PCMH recognition will offer better medication quality of care. This central hypothesis, as highlighted by the conceptual framework, will be tested by the following two specific aims:

- (1) Quantify current primary care practices' level of PCMH adoption and determine physician and practice related factors associated with the degree of PCMH implementation.
- (2) Explore the association between the level of PCMH adoption in a practice and its impact on processes and outcomes of care related to medication use.

With these aims in mind, the hypothesized statements are as follows:

- (1) Physician characteristics will have a significant association with the adoption of PCMH.
- (2) A higher level of PCMH adoption will be associated with a lower probability of inappropriate medication use, defined as high-risk medications and disease-drug interactions, among older adults.
- (3) A higher level of PCMH adoption will be associated with less frequently reported ADEs.

## **LITERATURE REVIEW**

This dissertation chapter first offers a general view of the quality of care with a specific focus on medication use. It then examines three medication quality indicators, along with a justification of why these measures were selected for use. Next, it explains the motivation for implementing a PCMH model and provides a systematic analysis of the impact of this model on the quality of care. Finally, the chapter describes the association between the PCMH model and patient medication use, examining the connection between what this current literature review describes and the missed opportunities where improvements can be made. The chapter concludes by proposing a theoretical model that can be used to examine the association between the quality of medication use and the adoption of the PCMH model.

### **Quality of Care**

#### *General Quality of Care*

In the ongoing debates about how to improve the U.S. health care system, a central concern has been how to meet the demand for high quality of care. This demand has grown in response to two factors. First, the delivery of high quality care can no longer be evaluated by expert opinion, namely judged by health care providers who decide what is good or best care. Today, to be labeled as good or better care, health care organizations have to meet criteria or standards, be accredited by validating institutions, and be evaluated by expert panels as well as consumers.<sup>8</sup> Assessments by the validating institutions not only establish consensus on important health care quality issues, but also provide a meaningful seal of quality, as a reliable indicator that an



organization is well-managed and delivers quality care, which is important for both patients and providers. Second, the transformation of the health care environment has prompted interest in examining the quality of care. For example, the growing demand for health care services, rising health care costs, constrained health resources, and evidence of a lack of uniformity in treatments among clinical practices have all led to increased interest in measuring the quality of care.<sup>9</sup>

Quality of care is a concept composed of a variety of elements and is complex as well as multi-dimensional.<sup>10-12</sup> In the health care literature, definitions of quality of care are fragmented and have changed dramatically over the past several decades. One of the early definitions of quality was offered by Donabedian (1968) who described quality as the evaluative dimension of elements and interactions in the medical care process, judging what is “good” or “bad”. Although this definition placed quality in the center of most health care organizations, it has been criticized for failing to consider two important aspects.<sup>13</sup> For one, the definition does not consider practice patterns guided by evidence and for another it does not take into account assessments of patient outcomes.<sup>14</sup> Donabedian refined his original definition and proposed another view of quality, which is now widely endorsed. According to this definition, quality can be examined in terms of three aspects: structure, process, and outcome. Structure refers to the attributes of the settings where care occurs, and it can include material resources, human resources, and organizational structure. Process refers to the duration of giving and receiving care, which would involve, for example, patients’ activities related to seeking care or clinicians’ activities in making a diagnosis or recommendations for treatment or surgery. Outcomes are defined as the effects of care on health status, both at the individual and the population level. A change in a patient’s health behavior, the satisfaction with received care, or the effects of a medication treatment can all be viewed as outcomes of quality of care.<sup>15</sup> Donabedian (1990) also highlighted seven

characteristics that factor into the quality of care: efficacy, effectiveness, efficiency, optimality, acceptability, legitimacy, and equity.<sup>16</sup>

Other scholars have also offered definitions of quality, which center more on patient-care. For instance, Steffen (1998) defined quality as the capacity to achieve legitimate medical and nonmedical goals, determined by the patients.<sup>17</sup> Berwick provided a simple definition for quality of care, describing it as meeting the customer's needs, assuming that patients always have sensible, understandable, and reasonable expectations of health care.<sup>18</sup> These viewpoints stand in opposition to quality of care as viewed from a society's perspective, which aims to have the most efficient and cost-effective care. From this perspective, doing everything medically possible for patients to achieve an improvement in health status without calculating the costs of healthcare providers or societies may create tension between the goals of individuals and those of society. Another scholar, Campbell, took a different approach to defining quality of care. Campbell viewed quality of care both from the individual and population levels. From the individual level, quality is a matter of (1) whether individuals can access the health structures and process of care which they need and (2) whether the care received is effective. On the other hand, quality of care at the population level can also be described as "the ability to access effective care on an efficient and equitable basis for the optimization of health benefit/well-being for the whole population".<sup>9</sup>

Another comprehensive and well-cited definition of quality of care is proposed by the United State Institute of Medicine (IOM). According to the IOM, quality of care is the degree to which health-care services for individuals and populations increase the likelihood of desired health outcomes and are consistent with current professional knowledge.<sup>19</sup> The IOM proposed six different domains of quality of care, including safety, timeliness, effectiveness, efficiency,

equity, and patient-centeredness. This dissertation will adopt the IOM definition of quality of care as the working definition for two reasons. First, this definition of quality care is the most up-to-date in the quality of care literature. Second, this definition of quality of care aligns with the aims of the Patient-Centered Medication Home (PCMH), which is the major focus of this dissertation.

### *The Assessment and Improvement of Quality*

Quality of care can be assessed and improved in several ways, including developing and using standards, guidelines, or indicators. Standards are defined as the level of compliance with a criterion or indicator. It can be divided as target standards and achieved standards. Target standards are set prospectively and stipulate a level of care that providers must strive to meet. Whereas achieved standards are measured retrospectively and elaborated whether providers met predetermined standards.<sup>20</sup> In general, standards play significant roles in the delivery of safe and effective care. One study suggested that standards need to be evidence based and professionally endorsed.<sup>21</sup> Examples of standards refer to hospital quality standards. The definition of standards under the hospital quality context is policies about cleanliness and controlling infections or time to provide treatment for a heart attack. Guidelines, on the other hand, can be viewed as a form of reference, viewing as recommended, non-mandatory controls for helping to support standards,<sup>22</sup> and a clinical practice guideline is one example.<sup>23</sup> Different from standards or guidelines, indicators are specific and explicit approaches that can be used to examine measurable elements of practice. As such, indicators can support the implementation of strategic plans so as to improve health care.<sup>24-26</sup> Indicators considered here are primarily quality indicators (QIs), such as

the number of deaths from major cardiovascular disease (mortality rate) or the number of heart attacks or cases of fatal coronary heart disease (incidence rate). The QIs can mostly be found in two comprehensive annual reports in the United States: the National Healthcare Quality Report and the National Healthcare Disparities Report. These two reports are produced by the Agency for Healthcare Research and Quality (AHRQ), aiming to measure trends in effectiveness of care, patient safety, timeliness of care, patient centeredness, and efficiency of care. These two reports are viewed as the latest available findings on quality of health care in the U.S.

One of the most common chronic diseases, hypertension, can be used to explain the definitions of standard, guideline, and indicator. For example, the general standard states that 90% of the patients in a practice with a blood pressure of more than 160/90 mm Hg should have their blood pressure re-measured within 3 months. The achieved standard may report that 80% of the patients in a practice with a blood pressure of more than 160/90 mm Hg had their blood pressure re-measured within 3 months. *American Society of Hypertension guidelines* follow the standard and suggest that if a blood pressure reading is raised on one occasion, the patient should be followed up on two further occasions within the specific time. The detailed indicators define more specifically how to calculate a quantitative measure for the standard. The indicator numerator is the number of patients with a blood pressure of more than 160/90 mm Hg having had re-measured their blood pressure within 3 months. The indicator denominator includes patients with a blood pressure of more than 160/90 mm Hg.<sup>27</sup>

Quality indicators are widely-used measures, and their use has several advantages, such as the ability to (1) identify health care improvement on a quantitative basis, (2) measure the efficacy of specific interventions, and (3) provide a quantitative link between quality of care and cost effectiveness.<sup>26,28</sup> Quality indicators can be examined in relation to quality of care in stages,

namely structure, process and outcome.<sup>15,29</sup> Process measures have the advantages that they are more sensitive to the differences in the quality of care and they are direct measures of quality. Quality indicators are also widely used in evaluations of structure and outcome; however, there are some limitations with regard to considering these two stages, specifically for two reasons. For one, quality indicators in structure of care are regarded as less than ideal forms of predictors of quality because of the inconsistencies across different health care settings. For another, quality indicators have been criticized in relation to outcome of care because they are an indirect measure, meaning that quality of care in patient outcomes may be influenced by many factors and require a large amount of data for analysis.<sup>30</sup> For example, physicians can provide the exact same high quality processes of care to a set of patients and achieve different outcomes, which is attributable to the numerous personal and societal factors that may impact health outcomes.

Although quality indicators have some disadvantages when used in evaluations of structure or outcome of care, it is worth noticing that many quality indicators have been implemented by different organizations. To date, quality measures mainly are all evidence-based and are developed by government agencies (e.g., Centers for Medicare and Medicaid Service (CMS) and the Agency for Health Care Research and Quality (AHRQ)) and private nonprofit organizations (e.g., the Joint Commission on Accreditation of Health Care Research and Quality (AHRQ) and the National Committee for Quality Assurance (NCQA)). Among all the organizations, the Healthcare Effectiveness Data and Information Set (HEDIS) of the NCQA is one of the most widely-used tools in the U.S. health care system for measuring, reporting and improving healthcare quality. HEDIS offers a wide range of measures aiming to help employers and patients know how well their care follows the standards. Nearly 90% of health plans in the U.S.

have adopted HEDIS as a common tool to evaluate the quality of care and these plans also include Medicare and Medicaid.<sup>31</sup>

Given the importance and widespread use of HEDIS indicators, this dissertation will use three representative quality indicators related to medication quality of care, representing our outcome variables from HEDIS including two of process of care and one of outcome of care. The following section will first explain why the dissertation focuses on the quality indicators related to medication use, justify what these three medication-related quality indicators are, and provide support for why these three medication-related quality indicators were selected.

### **Quality in Medication Use**

While quality of care is important for all aspects of health service provision, it is particularly important in the realm of patient medication use. This heightened importance of medication quality of care can be attributed to three serious issues. First, the growth in medication expenditures is considerable. According to a 2011 CDC report, spending on prescription drugs was \$263 billion, representing nearly 10% of all national health care spending.<sup>32</sup> Studies have also projected that the expenditures on medications will continue to increase for reasons related to the following second issue.<sup>33</sup> A second issue is the demand for medications in our health care system. As the aging population increases in number, there will be an associated increase in the demand for medications that will delay the onset of disease, treat disease, and improve quality of life. One study reported that almost 40% of older Americans used five or more prescription drugs in the past month.<sup>34</sup> A more recent study also found that the demand for medication has expanded to all the populations. Accordingly, the use of prescription

medications has continued to climb annually for individuals of all ages: 25% of children and 90% of adults aged 65 and over have taken one or more prescription medications in the past 30 days.<sup>2</sup> The third issue leading to a heightened increase in medication use quality is the potential for harm.

As the use of medications grows, the probability of inappropriate medication use also increases. Inappropriate medication use can then lead to serious medical consequences (e.g., adverse drug events), which in turn could create a substantial economic burden on the health care system (e.g., more expenditures on emergency room visits or hospitalizations).<sup>1</sup> Previous studies have demonstrated that inappropriate medication use is highly prevalent among older adults, affecting approximately 24% of the community-dwelling elderly and 40% of nursing home residents in the United States.<sup>35,36</sup> This inappropriate medication use has also been shown to have a strong association with the increased risks of adverse drug events as well as morbidity, mortality, and increased health care utilization.<sup>37</sup> Indeed, adverse drug events annually account for more than 175,000 emergency room visits among Americans age 65 years and over.<sup>38</sup> Therefore, examining the medication quality of care is an urgent issue.

In order to examine the medication quality of care among the population, a clear definition of the construct is needed, along with an understanding of the approaches to examining medication use. Roth Et al. defined quality of medication use as “the degree to which medication use for individuals and populations increases the likelihood of desired health outcomes and is consistent with current professional knowledge”.<sup>39</sup> Roth Et al. also identified inappropriate medication use as underuse, overuse, and misuse. Underuse refers to failure to provide a medication when it could have a positive outcome for a patient. Overuse refers to the provision of a medication to such a degree that it has harmful consequences rather than beneficial ones.

Misuse applies when there is a medication failure of a planned action to be completed as intended.<sup>40</sup>

Among these three types of inappropriate medication use, the focus of this dissertation will be the misuse of medication, including high-risk medication use and drug-disease interactions. Further, most causes of inappropriate medication use can be attributed to the responsibility of prescribers.<sup>41</sup> To evaluate the performance of prescribers, several organizations, from non-profit alliances to government agencies, have devoted their efforts to establishing medication-related indicators at the population level to estimate the level of variation in potentially inappropriate prescribing (PIP) across different health care settings.<sup>42</sup> The dual goal of having quality indicators is to provide a consensus as to what constitutes exceptional pharmacy quality and to improve patients' medication quality of care through developing and implementing performance measures. Examples of the most well-known organizations developing medication-related indicators include the Pharmacy Quality Alliance (PQA), the NCQA, and the Center for Medicare and Medicaid Services (CMS).<sup>43-45</sup>

The PQA is a consensus-based, multi-stakeholder membership organization, whose focus is on the appropriate use of medication with the goal of optimizing patients' health by improving the quality of medication use.<sup>43</sup> Its mission is to develop strategies for measuring and reporting medication utilization and pharmacy services. The PQA measures were developed to include several areas such as medication safety, medication adherence, and medication appropriateness. These measures are widely employed in the health care insurance marketplace, and have also been adopted by the CMS in Medicare Part D star rating plans. Examples of medication performance measures include the use of high-risk medications in the elderly, drug-drug interactions, or cholesterol management in coronary artery disease.



Another organization which is devoted to establishing the medication quality measures is the NCQA. The NCQA is a well-known private non-profit organization whose mission is to assure, improve, and elevate healthcare quality. As a major national organization, the NCQA has reviewed and accredited healthcare quality throughout the U.S. healthcare system since 1990. The NCQA has two major functions: (1) to inform choices and pursuit of the best available care for stakeholders through offering a series of quality measurements, and (2) to assist healthcare organizations to make informed decisions that can drive quality improvement via providing a range of evaluative programs, such as accreditation, certification, and recognition. Among these quality measurements and programs in the NCQA, the HEDIS is one of the most widely used tools that help health organizations to measure quality in several important dimensions of care and services. In particular, the HEDIS offers several measures that address patient medication use in a variety of ways such as antibiotic utilization, potentially harmful drug-disease interactions in the elderly, and use of high-risk medications in the elderly.<sup>44</sup>

CMS, on the other hand, is a government agency that primarily implements quality initiatives to assure quality for Medicare Beneficiaries via public disclosure. CMS has an interest in establishing quality measure to achieve the following three aims: (1) improve quality of care services, (2) pay for quality of care reporting, and (3) provide public quality of care reporting. With regard to medication use, the CMS has implemented an innovative project, called the Medication Measures Special Innovation, with specific medication measures. The aims of this project are to create a more comprehensive means for detecting and preventing medication errors, adverse drug reactions, and other harmful patient safety events. Examples of measures within the project include adherence to antiplatelet therapy after stent implantation and adherence to ACEIs/ARBs for individuals with diabetes mellitus.

After reviewing all the medication quality of care indicators put forth by these organizations and considering how they may be assessed in a nationally representative manner, three representative medication related QIs for evaluating the prevalence of inappropriate medication use were selected including (1) the use of high-risk medications, (2) the existence of drug-disease interactions, and (3) the prevalence of Adverse Drug Events (ADEs). The first two indicators are classified as medication process of care indicators, whereas the last is considered to be a medication outcome of care indicator. These three medication-related quality indicators were chosen for three reasons. First, these selected indicators are widely used in assessing medication quality of care among practices. Second, the definition of these quality indicators can be adapted for examination in the proposed dataset. Third, no previous studies have investigated whether an association exists between these medication-related quality indicators and the implementation of the transformed delivery model (which will be explained further in the later sections). The following sections explore these indicators individually.

Medication use constitutes a sizeable portion of U.S. healthcare. On average, 75% of U.S. outpatient visits involve medication therapies and it is estimated that 2.6 billion medications were ordered or provided in 2010.<sup>46</sup> Along with the increasing demand for medications is the likelihood that potentially inappropriate prescribing (PIP) is also rising. One study reported that one in five prescriptions in primary care in the United States is inappropriate (e.g., overused, underused, or high-risk), which can lead to serious medical consequences, and place a substantial economic burden on our healthcare system.<sup>1</sup> This is particularly important if we consider that almost one-half of the U.S. population takes at least one prescription medication and 1 in 10 reports taking more medications in the preceding month.<sup>2</sup> Therefore, the assessment of PIP and the assurance of medication quality are critical in today's health care system.

PIP is defined as the use of a medication where the risk of ADEs outweighs the clinical benefit, especially when a safer or more effective alternative medication is available for the same condition.<sup>47</sup> PIP, in fact, is a major, well-documented public health concern. In general, PIP consists of seven types, including, high risk medication use, inappropriate drug dose, drug duplication, drug-drug interaction, drug duration, drug-disease interaction, and any other inappropriate medications.<sup>41</sup> This dissertation will focus on two of the most common types of PIP: high risk medications (HRMs) and Drug-Disease interaction (DDIS). The following paragraphs will introduce these two commonly used medication quality of care measures and one medication outcome measure (i.e., Adverse Drug Events) individually.

### ***The Use of High Risk Medications (HRMs)***

#### *Definition and criteria*

The use of HRMs is defined as medications that are prescribed for the elderly population without a clear evidence-based indication, which leads to a substantially higher risk of adverse side-effects compared to the risk among younger people.<sup>48</sup> Generally, the use of HRMs can be detected in one of two ways. One is through implicit criteria and the other is via explicit criteria. Implicit approaches rely on clinician judgment of appropriateness for each case, which is a time-consuming process and inconvenient for population-based studies, whereas explicit approaches are relatively standardized and quantifiable.<sup>49</sup> Since this dissertation proposes to use national survey data to estimate the prevalence of HRMs, an explicit measure is the most suitable approach to examine the occurrence of HRMs. Current explicit measures of HRM are important quality measures that are included in the CMS based Medicare Part D, the NCQA HEDIS and

the PQA. To date, the three most widely-used, validated, and explicit measures of HRM among the elderly population are Beers, Zhan, and HEDIS criteria.

The Beers criteria was proposed and developed by Dr. Mark Beers in 1991. It is currently the most widely described and used screening tool for inappropriate medication use among the elderly population.<sup>1</sup> The criteria were rated by an expert panel that determined the effects of risk outweigh the potential benefit among the elderly population.<sup>47</sup> The original Beers criteria listed 30 medications to be avoided among the elderly population residing in nursing homes, regardless of their diagnosis. Beers criteria were subsequently expanded and revised in 1997, 2002, and 2012 to include all geriatric care settings.<sup>47,50,51</sup> Despite the widespread use of Beers criteria, the Beers criteria remain controversial. The first concern is that the medication lists based on Beers criteria are not absolutely contraindicated among elderly population. The second concern is whether the Beers medication list is comprehensive and up to date. The final concern is that Beers criteria are difficult for clinicians to use.<sup>48,52</sup>

The second widely used criteria for determining inappropriate medication use are Zhan criteria. Zhan criteria, proposed in 2001, were developed by a panel of experts who were familiar with the original Beers criteria, the updates, and the measures in the National Medical Expenditure Survey. Based on the expert panel's opinions, Zhan criteria are more specific and organized. The selected 33 drugs identified using Zhan criteria are classified into 3 categories: (1) should always be avoided, (2) are rarely appropriate, and (3) have some indications, but are often misused.<sup>53</sup> Even though Zhan criteria for identifying inappropriate medication use among the elderly are also widely used in the literature and have been regarded as the best available clinical tool for the screening of inappropriate medication use, they have been criticized by

several studies for not providing the most up-to-date lists.<sup>53,54</sup> A further criticism is that Zhan criteria do not consider patient doses, frequency of administration, or duration.<sup>55</sup>

Given the drawbacks of Beers and Zhan criteria, the NCQA HEDIS are often used to determine inappropriate medication for the elderly population and are the third most widely used lists. Initiated in 2006, the NCQA HEDIS established inappropriate medication use indicators based on recommendations from an expert panel and references to the most recent version of Beers criteria. The NCQA HEDIS categorized in detail inappropriate medication use on the basis of two measures: drugs to avoid in elderly populations (i.e., the use of HRMs) and drugs that have the potential to cause a harmful DDIS in the elderly. Given the importance of HRM and DDIS use among the elderly, these issues will be taken up in the next sections.

To identify the prevalence of HRMs among the elderly population, this dissertation will employ the NCQA HEDIS criteria, specifically those used to identify high-risk medications.<sup>56</sup> The NCQA HEDIS was chosen for three reasons. First, the NCQA HEDIS criteria apply morerefined measures for benchmarking the quality of medication management among the elderly population. Second, the lists are used among nearly 90% of health organizations and are frequently employed in studies.<sup>44,52,57</sup> Third, the lists were developed in 2006 and are updated annually. Compared to Beers criteria and Zhan criteria, the NCQA lists include the most up-to-date and comprehensive drug information. The full list of each set of criteria is provided in Appendix A.

### *Prevalence of HRMs*

Two review papers systematically reported that the prevalence of HRMs among elderly populations varies widely from 2.9% to 62.5%.<sup>1,54</sup> The broad range of the incidence of HRMs is important to consider and can be attributed to three reasons. First, the studies were conducted in

different countries. Physicians in different countries may have distinct prescribing behavior, which might account for the HRMs rate. Second, the studies were completed in different practice settings, e.g., primary care practices, long-term care facilities, or hospitals, which might also be a factor that leads to the variation in HRMs prevalence. For example, a higher prevalence of HRMs might be found among hospitalized patients than among those who are seen in primary care practices, as the former may have more serious health conditions that require more medications for treating conditions, exposing them to higher rates of HRMs. Third, the reviewed studies may have applied different “criteria” to identify HRMs. Given the differences among the available criteria, it is inevitable that HRM prevalence will also differ. Despite their important findings, the two reviews have other limitations in terms of exploring HRM rates. First, the studies are not up-to-date and may overlook recent efforts (e.g., health care reform or the rearrangement of other non-physician professionals) to prevent the occurrence of HRMs. Second, not all the selected articles in the reviews investigated the actual factors affecting HRMs; instead, the selected articles in the reviews took into account only patient-related factors that may affect the use of HRMs.

#### *Factors related to HRMs*

Generally, previous articles have concluded that three major patient-related factors were associated with HRMs, including gender (female), age (older), and the number (higher) of medications.<sup>58-64</sup> However, these studies were not comprehensive in that they did not consider practice-level characteristics and attributed the use of inappropriate medication mostly to the patients themselves. Indeed, it is worthwhile to consider that often exposure to inappropriate medication is attributable to the prescribing behavior of the providers. Therefore, an examination of studies related to HRMs is needed to consider practice-level characteristics that serve as

factors. Practice-level characteristics (e.g., practice type, practice level) are important because these characteristics represent the extent to which care may be accessed or offered. This issue was not fully discussed/investigated in the review articles.

To deal more fully with these gaps in previous studies, this dissertation will offer a more comprehensive literature review of the prevalence of HRMs and an investigation of factors related to this issue (e.g., practice-level characteristics). The selection process for the articles is described as follows. The Ovid Medline In-Process was used to search up to 2015, aiming to search relevant articles in English by using terms and keywords in the title and abstract. The search included terms related to “high risk medication”, “factors”, “inappropriate prescription”, “high risk medication” “primary care”, “ambulatory care”, “general practice”, “office practice” or “outpatient care”. To be included, studies must have also reported the rate of HRMs and other factors of interests (either individual and/or practice level characteristics) affecting HRMs.

Overall, 16 articles met the inclusion criteria for the detailed analysis. The results of the literature search are systematically presented in Table 1.1. Five major themes emerged from the selected articles. First, the majority (11 of 16) of the studies of HRMs were conducted in the U.S. Second, all the papers included used explicit criteria but the majority (9 of 16) employed various forms of the Beers, namely four versions in 1991, 1997, 2002, and 2012. The remaining studies used Zhan criteria, NCQA HEDIS, and others (McLeod criteria, Germany’s publish list, and Miao criteria). Third, all of the studies focused on elderly populations; they also employed data from either large administrative data sets or surveys of a restricted geographic location. A small number of studies even narrowly focused on a specific subsample, such as elderly veterans.<sup>52,57,59,65</sup>

Fourth, the reported prevalence of HRMs was revealed to vary even more widely than the previous two reviews studies reported, ranging from 3.7% (Zhan criteria) to 59.2% (2012 Beers criteria). Two explanations are offered for this widely reported variation in HRMs. For one, different data sets were employed in the studies and these different data sets differ with regard to the composition of their samples. For example, the prevalence of HRM reported as 57% in Kondo Et al. study since their study used Beers criteria and the population was targeted at adults aged 65 and over and with hemodialysis treatment record in hospital; Whereas the prevalence of HRM recorded as approximately 13% in the study of Pugh Et al. using the NCQA HEDIS criteria and focused on Veteran population. For another, different criteria to identify HRMs were adopted with studies that used Beers criteria, resulting in a higher prevalence of HRMs than did studies using other criteria. Most of the studies that adopted Beers criteria to determine the prevalence of HRMs found high rates (more than 30%) and might have overestimated HRMs. This possible overestimation implies that other criteria would be better options for examining HRMs. For the final theme, half of the studies identified factors affecting HRMs at the practice level. These findings indicate that increasingly researchers are aware that not only can HRMs be attributed to patients' characteristics, but they can also be explained by the characteristics of the healthcare providers as well as the environment in which they work.

Generally, two research trajectories have examined HRMs. One is based on individual characteristics of patients, which have been widely investigated. The other takes both individual characteristics of patients and practice characteristics into account. The first line of research (i.e., investigation of individual characteristics), has mainly adopted the view of inappropriate medication use attributable to patients. Most of the studies in this category have revealed both consistent and inconsistent results regarding the factors that affect inappropriate medication use.



Studies have consistently reported higher levels of inappropriate medication use among patient who are female,<sup>57,59,65-72</sup> are age 65 and over,<sup>57,70,72</sup> have demonstrated comorbidity conditions,<sup>52,57,59,65,73</sup> and take more medications.<sup>52,53,57,59,65,66,68-71,74,75</sup> One area of disagreement at the individual level, however, is race. Two out of five studies found that white Caucasians are more likely to be prescribed inappropriate medications,<sup>59,65</sup> whereas the remaining three studies reported the opposite results, where non-white populations experienced higher rates of HRMs.<sup>52,57,68</sup>

Additionally, other factors that can affect HRMs appear only once, such as having poor health status,<sup>53</sup> residing in metropolitan areas,<sup>76</sup> having payment sources of either Medicare or Medicaid,<sup>5</sup> having been hospitalized in the previous year,<sup>57,68</sup> having a higher number of outpatient visits,<sup>70</sup> using a higher number of over-the-counter drugs,<sup>71</sup> and being illiterate.<sup>74</sup> Overall, because these individual factors have been reported to have associations with HRMs, all these factors should be considered as significant covariates for the present analysis. The second line of HRM research explores both individual and practice characteristics by examining five major factors that contribute to HRMs: specialty of the practice,<sup>52,57,59</sup> type of the practice,<sup>72</sup> numbers of prescribers,<sup>68,75</sup> age of prescribers,<sup>70,72</sup> and gender of the physicians.<sup>72</sup>

This section has described two major features of this dissertation. First, the NCQA HEDIS criteria have been selected as the standardized measure for HRMs. Second, this dissertation will explore the association between quality of care at the practice level and potentially inappropriate medication use among the elderly age 65 and over, controlling for both patient and practice characteristics. The investigations of practice-level characteristics in the current literature are not comprehensive. A variety of factors at the practice level should be considered, such as the ownership of the practice (physician group or health care cooperation). Most important of all, no

current studies examine whether practice transformation, such as adopting the PCMH, may also affect HRMs. Since the PCMH emphasizes the importance of providing better health services to patients, it is important to know whether practices transformed into PCMH may enhance the medication quality of care (i.e., lower onset of HRMs). Overall, this approach is important because most of the relevant studies did not link such a timely issue with the occurrence of HRMs.

Table 1.1. Factors Associated with HRM Use, the Reported Prevalence of HRM with Adopted Criteria, and the Characteristics of Studies (2001-2015)

<b>Reference</b>	<b>Factor affecting HRM (individual level)</b>	<b>Factor affecting HRM (practice level)</b>	<b>Prevalence</b>	<b>Criteria</b>	<b>Study Population</b>	<b>Data Resource</b>	<b>Top most frequently prescribed HRM</b>
Zhan, 2001	Health Status (Poor health) and Number of Medication use (More)	N/A	21.3%	Zhan	Community-dwelling elderly	MEPS	Propoxyphene, Amitriptyline, Dipyridamole, Promethazine, and Hydroxyzine
Goulding, 2004	Gender (Female), Number of Medication use (More)	N/A	7.8% / 3.7%	Beers/ Zhan	Adults age 65 and over	NAMCS + NHAMCS	(Drug class) Pain relievers and central nervous system drugs
Pugh, 2005	Gender (Female), Race (White), Comorbidity condition (psychiatric), and Number of Medication use (More)	N/A	23%	Zhan	Veteran	National Veteran inpatient and outpatient administrative and outpatient pharmacy data	(Drug class) Pain relievers, Benzodiazepines, Antidepressants, and Musculoskeletal agents
Viswanathan, 2005	Referred patient, Location in metropolitan area	N/A	13.4% 8.8% 4.2%	2002 Beers 1997 Beers  Zhan	Adults age 65 and over	NAMCS+NHAMCS	Propoxyphene, Doxazosin, Amiodarone, Nitrofurantoin, Amitriptyline

<b>Reference</b>	<b>Factor affecting HRM (individual level)</b>	<b>Factor affecting HRM (practice level)</b>	<b>Prevalence</b>	<b>Criteria</b>	<b>Study Population</b>	<b>Data Resource</b>	<b>Top most frequently prescribed HRM</b>
Pugh, 2008	Gender (Female), Race (White), Comorbidity condition, and Number of Medication use (More)	Specialty of the practice (Geriatric care)	26.2 %	Zhan	Veteran	National Veteran inpatient and outpatient administrative data	Not report
Pugh, 2011	Gender (male), Ethnicity (Hispanics), Number of Medication Use (More), Comorbidity condition	Specialty of the practice (Geriatric care)	Range from 12.3% to 13.1%	NCQA HEDIS	Veteran	National veteran outpatient and pharmacy data	Endocrine Drug, Gastrointestinal Antispasmodics, Cardiac Medications, Antibiotics
Bao, 2011	Number of Medication (more), Payment source (Medicare or Medicaid)	None of the predictors were significant	38%	2002 Beers criteria	Healthy patients 65 years of age or older on at least one medication	National Home and Hospice Care Survey	Narcotics, Antiadrenergics, Antihistamines, Antiarrhythmics, Tricyclic antidepressants,
Stafford, 2011	Number of Medication (more), Take psychotropic medication, Health Status (illness)	N/A	35.3%/18.7%	2003 Beers criteria McLeod criteria	Adults age 65 and over	Survey of residents of care homes across Tasmania in Australia	Benzodiazepines, Amitriptyline, Oxybutynin, Non-steroidal anti-inflammatory drugs.

<b>Reference</b>	<b>Factor affecting HRM (individual level)</b>	<b>Factor affecting HRM (practice level)</b>	<b>Prevalence</b>	<b>Criteria</b>	<b>Study Population</b>	<b>Data Resource</b>	<b>Top most frequently prescribed HRM</b>
Gellad, 2012	Age (older), Gender (female), Race (non-white), Number of Medication Use (More), Comorbidity condition (More), ER/Hospitalization in previous year (yes)	Specialty of the practice (Geriatric care)	4.7%	NCQA HEDIS	Veteran	National veteran outpatient and pharmacy data	(Drug class) Opioid, Antihistamine, Skeletal muscle relaxant
Oliveira, 2012	Patient literacy status (illiteracy), Number of Medication (more)	N/A	34.5%	Beers criteria	Adults age 65 and over	Prospective survey of the medication use	Short-acting nifedipine and Methyldopa
Holmes, 2013	Gender (female), Ethnicity (black), Income status (low), Hospitalization status, and Number of Medication Use (More)	Numbers of prescribers	31.9%	2003 Beers criteria	Texas Medicare Part D beneficiaries	Medicare claims and Medicare Part D event files	Propoxyphene, Nitrofurantoin, Clonidine, Cyclobenzaprine, Amitriptyline
Schubert, 2013	Gender (female), Number of Medication Use (More)	N/A	22.0%	Germany's recently published list	Adults age 65 and over	Health Insurance claim data in Germany	Amitriptyline, Tetrazepam, Doxepin, Acetyldigoxin, Doxazosin

<b>Reference</b>	<b>Factor affecting HRM (individual level)</b>	<b>Factor affecting HRM (practice level)</b>	<b>Prevalence</b>	<b>Criteria</b>	<b>Study Population</b>	<b>Data Resource</b>	<b>Top most frequently prescribed HRM</b>
Pannoi, 2014	Age (older), Number of Medication Use (More), outpatient visit (less)	Age of the prescribers (older)	28.1 %	2012 Beers criteria	Adults age 65 and over	From a district hospital in Southern Thailand	(Drug class) Benzodiazepine, Non-Cox-selective NSAIDs, Alpha-1-blockers, Tertiary Tricyclic Antidepressants
Kondo, 2014	Number of Medication Use (More), Comorbidity condition (More)	Number of Provider (more), Without multidisciplinary professionals, Practice type (clinic)	57 %	Beers criteria	Adults age 65 and over and received hemodialysis treatment at a hospital or clinic.	The Japan Dialysis Outcomes and Practice Patterns Study	(Drug class) H2 blockers, Antiplatelet agents, and $\alpha$ -blockers
Baldoni, 2014	Gender (female), Self-medication, use of OTC medication, use of psychotropic medication, Number of Medication Use (More)	N/A	48.0 % / 59.2 %	2003/2012 Beers criteria	Adults age 65 and over		Clonidine, Amitriptyline, Metformin, Fluoxetine, Dexchlorpheniramine
Amos, 2015	Age (older), Gender (Female)	Age of physician (older), Gender of physician (male), and practice type (Solo)	28 %	2011 Miao criteria	Adults age 65 and over	Large database in Italy	Ticlopidine, NSAIDs, Doxazosin, Digoxin, Antiarrhythmics

## *Drug-disease interactions (DDIS)*

### *Definition and criteria*

While most studies typically have adopted the use of high-risk medications as an indicator of PIP, studies are beginning to expand their scope to include other indicators, such as DDI and DDIS.<sup>77</sup> DDI is defined as an occurrence when two drugs known to interact are concurrently prescribed. Further, DDIS is defined as a condition in which a prescribed medication subsequently exacerbates a coexisting chronic condition.<sup>41,78</sup>

Both DDI and DDIS have in fact become critical risks for the elderly population.<sup>79-81</sup> Two reasons can explain why the elderly population is more likely to experience these two types of PIP. First, the elderly population has a higher prevalence of comorbidity conditions, which are associated with greater demands for pharmacotherapy. Second, the greater demand for pharmacotherapy leads to a higher probability of polypharmacy, which could induce both DDI and DDIS and increase the risk of adverse effects.<sup>82</sup> Given the prevalence of DDI and DDIS and the importance of their association with potential adverse health outcomes among the elderly population, these two indicators can be significant proxies for inappropriate medication use.<sup>77</sup> As such, DDIS has been selected as one indicator of PIP in this dissertation. Another motivation for this choice is that while a number of studies have assessed the prevalence of DDI, the prevalence of DDIS is relatively less investigated.<sup>77</sup> Similar to HRMs, DDIS also can be estimated by using explicit or implicit measures of potentially inappropriate medication prescribing.<sup>83</sup> Since this dissertation will depend on a large data set to explore the research questions, an explicit measure will be adopted to investigate the prevalence of DDIS.

Among the explicit measures of DDIS, six tools are widely used in the current literature for determining DDIS, including McLeod's criteria,<sup>84</sup> the Improving Prescribing in the Elderly Tool (IPET),<sup>85</sup> Updated Beers criteria,<sup>50</sup> Zhan criteria,<sup>86</sup> the NCQA HEDIS criteria,<sup>31</sup> and the Screening Tool of Older Person's Prescriptions (STOPP).<sup>87</sup> In order to maintain the clarity of the meaning of tools for determining DDIS, two points should be clarified before introducing these six tools. First, the following paragraph will use "criteria" to represent the explicit measures for determining the DDIS. The rationale for using this terminology for DDIS explicit measures is that all the DDIS related studies employ "criteria". Second, the names of some criteria (i.e., Beers criteria, Zhan criteria, and the NCQA HEDIS criteria) are exactly the same as some discussed in the previous section for high-risk medications. However, the contexts are completely different. For Beers and the NCQA HEDIS criteria, the reference articles are the same as in the previous section, but only focus on the DDIS. For Zhan criteria, the medication lists for DDIS are not the same as those on the list of high-risk medication. The Zhan criteria for high-risk medication were published in 2001, whereas the criteria for DDIS were released in 2005.

McLeod's criteria are the first consensus-based PIP list created by a Canadian expert panel that mentioned DDIS. According to McLeod Et al., 38 PIP criteria were classified into three groups: 16 drugs generally to be avoided, 11 DDI, and 11 DDIS. Six diseases are included in the discussion of DDIS including cardiovascular diseases (i.e., hypertension, angina, and atrial fibrillation), insomnia, depression, dementia, osteoarthritis, and gout.<sup>84</sup>

IPET is a revised version of McLeod's criteria also developed by several Canadian scholars.<sup>88</sup> IPET has several advantages over McLeod's criteria including (1) a more up-to-date medication list, (2) relative conciseness as a tool, and (3) widespread acceptability and use in Canada and Ireland.<sup>83</sup> IPET consists of 14 questions to identify PIP along with 8 types of disease for assessing the DDIS, namely chronic obstructive airways disease,



cardiovascular disease (i.e., congestive heart failure, heart block, and hypertension), gout, glaucoma, active metabolites, peptic ulcer disease, osteoarthritis, and diarrhea.

The first updated Beers criteria included DDIS classifications, whereas the original Beers criteria did not consider the inappropriateness of diagnosis or concurrent use of medications.<sup>50</sup> With the work of Fick and his research team, the updated Beers criteria identified 20 diseases/conditions linked to medication/medication classes that patients should avoid. These diseases/conditions were heart failure, hypertension, gastric, seizures, blood clotting disorders, bladder outflow obstruction, stress incontinence, arrhythmias, insomnia, Parkinson disease, cognitive impairment, depression, anorexia and malnutrition, syncope or falls, hyponatremia, seizure disorder, obesity, chronic obstructive pulmonary disease, and chronic constipation.

The next tool for detecting DDIS is Zhan criteria.<sup>86</sup> The 2005 Zhan criteria focused on inappropriate DDI and DDIS, identified by evaluations of an expert panel. The 2005 Zhan criteria, which incorporated both McLeod and Beers criteria, identified six DDI combinations and fifty DDIS combinations along with more detailed clinical significance. Clinical significance was categorized into three levels including high, moderate, and lower or uncertain. Based on the review and discussion of the expert panel, three of the six DDI were regarded as high clinical significance, one of moderate clinical significance, and two of lower or uncertain clinical significance. High or moderate clinical significance implies that evidence of the interactions is well established or an altered pharmacological response is possibly to occur, whereas low or uncertain clinical significance means the evidence of the interaction is not well established. Among the DDIS, fifteen are considered high; twenty-one DDIS are classified moderate; and thirteen DDIS are viewed as low or uncertain clinical significance. Fifteen types of diseases or conditions are mentioned in the Zhan's DDIS classification, including cardiovascular disease (i.e., hypertension, postural hypotension, heart

failure, peripheral vascular disease, arrhythmia, and heart block), urinary incontinence, benign prostatic hypertrophy, constipation, glaucoma, peptic ulcer, dementia, syncope/falls, insomnia, asthma/chronic obstructive pulmonary disease, diabetes, raynaud disease, seizures, chronic renal failure, and gout.

The NCQA HEDIS criteria are the most widely used criteria and have been adopted by more than 90 percent of health plans in the United States. The DDIS criteria of the NCQA HEDIS are relatively concise and sufficient. Developed in 2007 and updated annually, the NCQA HEDIS criteria are based on modifications of the McLeod and Beers criteria.<sup>78</sup>

According to NCQA HEDIS criteria, a patient will be identified as having been exposed to DDIS if he/she meets the following three conditions: (1) a patient is 65 years old and over, (2) a patient must have one of the following health conditions, including fall/fractures, dementia, and chronic renal failure, and (3) a patient has an ambulatory prescription for a contraindicated medication concurrent with or after a diagnosis. The three conditions linked to the corresponding medication groups are as follows: (a) fall/fractures: tricyclic antidepressants, conventional or atypical antipsychotics, and specific sleep agents (e.g., zolpidem), (b) dementia: high anticholinergic agents (i.e., gastrointestinal antispasmodics, skeletal muscle relaxants), and (c) chronic kidney disease: nonsteroidal anti-inflammatory drugs (NSAID). Finally, the STOPP is another tool for detecting DDIS. Proposed by Gallagher and his research team, STOPP is based on Beers criteria and was designed to estimate the PIP for community dwelling older adults as well as hospitalized patients in Ireland in 2008.<sup>87</sup> The STOPP includes 17 diseases/conditions that may cause drug interactions. These diseases/conditions includes heart failure, hypertension, duodenal ulcers, epilepsy, blood-clotting disorders, stress incontinence, arrhythmias, insomnia, cognitive impairment, depression, anorexia and malnutrition, syncope or falls, hyponatraemia, seizure disorder, obesity, chronic obstructive pulmonary disease, and constipation.

Despite the many criteria, this dissertation will adopt the NCQA HEDIS criteria as the working definition of DDIS for three reasons. First, the NCQA HEDIS criteria are a national quality measure and can be easily applied in large administrative datasets. Second, the NCQA version is the most widely used measure to monitor quality of prescribing by most of managed care organizations in the United States, providing important context for the findings in this study.<sup>89</sup> Third, the criteria contain the most up-to-date DDIS (Appendix B). In order to have an advanced understanding of DDIS, the following two sections (1) summarize the prevalence of DDIS according to relevant studies, and (2) explore factors that affect the occurrence of DDIS.

### *Prevalence of DDIS*

The Ovid Medline In-Process was used to identify up-to-date relevant articles written in English using specific terms and keywords in the title and abstract. The key terms include “drug-disease interaction”, “medication prescribing”, “inappropriate prescription”, and “factors”. The selected articles contained the information about the prevalence of DDIS as well as the exploration of factors that affect the DDIS. Seven articles met the inclusion criteria and the findings of these 7 articles are summarized in Table 1.2.

The median rate of reported DDIS among the elderly was 22.4% with a range from 2.6% to 64.0%. This wide variation has three possible explanations. First, the studies used different explicit criteria to determine the prevalence, which is likely to produce different estimates of the extent of the problem. The different types of criteria have various definitions of DDIS, which can cause varying prevalence. For example, the Beers criteria contain 20 types of DDIS, Zhan criteria have 50 types of DDIS, and NCQA HEDIS has 3 types. Indeed, the highest prevalence of DDIS among all the selected articles used Zhan criteria, whereas the lowest prevalence of DDIS employed NCQA HEDIS criteria. This finding strongly suggests that including more criteria for DDIS will result in a higher prevalence of DDIS. The Zhan

and NCQA HEIDS criteria are the most two common methods in the selected papers (i.e. four out of seven articles),<sup>52,57,79,86</sup> while the remaining criteria, e.g., Beers criteria or others, appear only once.<sup>78,80,81</sup>

The second reason for the DDIS range is the different populations in the selected papers. Three out of seven articles reported the prevalence of DDIS at more than 20%, and two of these three articles were centered on hospitalized populations.<sup>78-80</sup> Since the inpatient population normally has greater medications demands, the likelihood of being exposed to DDIS risk might also increase.

Finally, the third reason for the high discrepancy of DDIS may be the use of different data sources. For the studies using national data sets, the prevalence of DDIS was generally less than 5%.<sup>52,57,86</sup> For the other studies, which employed regional data sets, reported rates were all more than 10%.<sup>78-81</sup> This difference implies that the use of national datasets might result in having lower rates of DDIS because it may provide data that are more representative.

Based on the above reasons for explaining the potential dissimilarity of drug-disease interaction rates, two outcomes are expected in this dissertation. First, the rate of drug-disease interaction is expected to be low because the target sample of this dissertation will be general individuals age 65 and older who use outpatient visits as opposed to inpatients and HEDIS NCQA has criteria for three DDIS. Second, the rate of drug-disease interaction may range between 2.6% and 15.2%, which was reported by Zhan (2005) and Pugh (2011), respectively. Zhan employed NAMCS data and different criteria while Pugh explored Veteran data using the NCQA HEDIS.

#### *Factors related to DDIS*

Similar to the exploration of HRMs, two research trajectories have explored the use-related factors that affect the prevalence of drug-disease interactions. One is based on the individual perspective exclusively and the other considers both individual and practice

perspectives together. As to the former approach, six of seven articles focused on individual characteristics. The results of these studies are consistent, showing that patients with higher numbers of medications,<sup>52,78-81,86</sup> older age,<sup>57,78-80</sup> being married,<sup>78</sup> Hispanic race,<sup>52</sup> having more chronic diseases,<sup>52,78,79</sup> and having no co-payments<sup>52</sup> were more likely to have drug-disease interactions. Although this dissertation focuses on how practice-level characteristics affect the prevalence of drug-disease interactions, these identified individual characteristics are still valuable references for inclusion in the model as covariates.

As to the focus on patient and practice characteristics, only one out of seven articles considered both of these factors. This study showed that if a patient was seen in a facility with geriatric education, then he/she has lower odds of having drug-disease interactions, suggesting that such practices enhance medication quality.<sup>57</sup> The results also indicated that if a patient is seen in a facility caring for fewer older veteran patients (over 65), then the odds of a patient receiving a drug-disease interaction will increase. This implies that the capacity of a facility can affect the occurrence of inappropriate medication prescribing. In other words, the results suggest that if the size of a facility is larger (i.e., caring for more patients), then the exposure to DDIS may be lower. The rationale is that a larger practice has more healthcare professionals/staff, which in turn may translate to high quality medication gate keepers to monitor appropriate medication use.

The review of the relevant literature revealed two noticeable limitations, which can be improved upon in this dissertation. First, few studies recognized DDIS as a significant area of inappropriate medication use beyond HRMs. Exploring factors that affect the prevalence of DDIS is indeed a critical issue to investigate, particularly as the population ages, has multiple chronic conditions, and takes more prescribed medications. Second, few practice-level characteristics were examined, even though other practice-level characteristics, such as practice type, location, ownership, and the composition of staffs within a practice could also

affect prescribing practices. Previous studies indicate that the characteristics of healthcare professionals, e.g., physicians or pharmacists, can affect patients' medication use because these professionals have complete authority and responsibility for prescribing behavior.<sup>90,91</sup> In other words, they have a direct impact on patient medication use, as well as patient drug-disease interaction. What is more, other practice characteristics, e.g., the types or the adoption of a new model for delivering enhanced primary care, may also influence patient disease treatment and outcomes.<sup>92-94</sup> For the purposes of this dissertation, if a practice provides a better quality of care environment, this should enhance patients' appropriate medication use (i.e., lower the chances of drug-disease interactions). In this dissertation, having a PCMH model will serve as an innovative proxy of improving the quality of care.

The review of the relevant literature revealed three gaps in our current knowledge of DDIS. These gaps can be addressed/filled in this dissertation. First, few studies have recognized DDIS as a significant and unexplored area within the issue of inappropriate medication prescribing and use apart from HRM. An exploration of factors affecting the prevalence of DDIS is indeed a critical issue that needs to be investigated as the U.S. population is aging and is being diagnosed with multiple chronic conditions that require prescribed medications. Additionally, the higher demand for prescribed medication among the elderly population may induce polypharmacy, which is a harmful public health issue due to its potential to cause adverse drug effects and DDIS.<sup>95</sup> Two points need to be highlighted here. First, the NCQA HEDIS measure of DDIS will be served as one of the medication quality of care indicators. Second, the models analyzed in this study will consider more individual characteristics and add more practice-level characteristics to expand our understanding of the factors impacting DDIS. The individual characteristics will include (1) patient socio-demographic information, (2) patient clinical characteristics, and (3) patient medication use. The practice characteristics will contain (1) the organizational structure of a

practice, (2) the type of office setting, (3) the average number of physicians in a practice, (4) the ownership of the practice, (5) the primary expected source of payment, and (6) the region of the practice. Most important of all, the degree of quality of service (i.e., the implementation of a PCMH model) which a practice offers will be examined.

Table 1.2 Factors associated with DDIS, reported prevalence with adopted criteria, and the characteristics of studies (2001-2015)

<b>Reference</b>	<b>Factor affect DDIS (individual level)</b>	<b>Factor affect DDIS (practice level)</b>	<b>Prevalence</b>	<b>Criteria</b>	<b>Study Population</b>	<b>Data Resource</b>	<b>Top most frequently prescribed DDIS</b>
Goldberg (1996)	Number of medication use, age (older)	N/A	21.5%	SOAP computer software program	Patients either receive 3 or more medication or any patients age 50 and over and at least have two medications	From a community hospital, Emergency department and a general hospital teaching facility	(1) Albuterol, Prednisone, Ibuprofen with hypertension (2) Furosemide, Albuterol, Prednisone with diabetes
Zhan (2005)	Number of medication use	N/A	2.6% of visits	Zhan criteria	Outpatient visits by patients aged 65 and older	NAMCS and NHAMCS	Patients with benign prostatic hypertrophy had at least one of six drugs that should be avoided.
Lindblad (2005)	Number of medication use (more), age (older), marriage status (being married), and comorbidity conditions (more)	N/A	40.1%	Combine Beers and McLeod criteria	397 frail veteran age 65 and over and has an inpatient visit	The 11 Veterans Affairs Medical Centers	Heart failure and calcium-channel blockers; Diabetes and $\beta$ -blockers



<b>Reference</b>	<b>Factor affect DDIS (individual level)</b>	<b>Factor affect DDIS (practice level)</b>	<b>Prevalence</b>	<b>Criteria</b>	<b>Study Population</b>	<b>Data Resource</b>	<b>Top most frequently prescribed DDIS</b>
Doubova (2007)	Number of medicines use (5 more), age (older), suffering from cardiovascular diseases	N/A	64.0%	Zhan criteria	Ambulatory patients over 50 years of age, with non-malignant pain	Two family medicine clinics in Mexico City	N/A
Pugh (2011)	High disease burden (physical, psychiatric, number of medications), Race (Hispanics), and individuals with no copayments	N/A	15.2%	NCQA HEDIS	Age 65 and over who received Veteran outpatient care	National Veteran inpatient, outpatient and pharmacy data	N/A
Gellad (2012)	Age (older)	Without formal geriatric education; With practices accommodate fewer older adults	3.2%	NCQA HEDIS	Veterans age 65 and over with received either one outpatient or inpatient care; with history of falls or hip fractures,	National Veteran outpatient and inpatient data	<ol style="list-style-type: none"> <li>1. Dementia/anticholinergic</li> <li>2. Chronic renal failure/non-steroidal anti-inflammatory drug</li> </ol>

Reference	Factor affect DDIS (individual level)	Factor affect DDIS (practice level)	Prevalence	Criteria	Study Population	Data Resource	Top most frequently prescribed DDIS
Mand (2014)	Number of medication, age (older)	N/A	10.4%	Beers criteria	dementia, or chronic renal failure Age 65 and over with at least one diagnosis named in Beers criteria	From a total of 148 family practitioners' practices in Germany	Patients who take hypertension medication, using central acting sympathomimetic drug

## *Adverse Drug Events*

Adverse drug events (ADEs) have been highlighted as a national patient safety and public health concern in today's healthcare system.<sup>96</sup> The aging population and their growing demand for medications have raised the prevalence of ADEs.<sup>97</sup> Existing studies indicate that approximately 20% of individuals experience ADEs in ambulatory care settings, and 50% of individuals experience ADEs in hospitalization settings.<sup>98</sup> The prevalence of ADEs is a cause for concern because of the economic and health burdens they impose. It is estimated that annually ADEs account for \$3.5 billion spent on extra medication expenditures.<sup>99</sup> The annual emergency department and inpatient visits related to ADEs are estimated to be 700,000 and 120,000, respectively.<sup>38</sup> ADEs are also associated with greater healthcare utilization, causing individuals to have longer hospitalizations and higher health expenditures.<sup>100</sup> The serious effects of ADEs have been investigated in inpatient settings; however, relatively few studies are reported in ambulatory settings.

Due to concerns surrounding ADEs and the limited findings in ambulatory settings, this dissertation will include ADEs as one measure of medication use quality. To begin, a definition of ADEs will be provided, followed by methods of ADE detection. This will be followed by a discussion of ADE prevalence and an exploration of risk factors. Finally, a critique of ADE studies will be given followed by the introduction of a new approach to examining ADEs.

### *Definition and Detection of ADEs*

The definition of ADE is simple and straightforward: an injury resulting from medical intervention related to a drug.<sup>101</sup> In the current ADE literature, there are two major approaches to examining the incidence of ADEs: one is preventability and the second is

severity. From the preventability perspective, two types of ADEs are discussed where one is preventable and the other is non-preventable. Preventable ADEs arise as a result of medication used in error, and the events are considered preventable. According to the National Coordinating Council for Medication Error Reporting and Prevention, medication errors can be defined as “any preventable event that may cause or lead to inappropriate medication use or patient harm while the medication is in the control of the health care professional, patient, or consumer. Such events may occur in any one of the following procedures, including prescribing; order communication; product labeling, packaging, and nomenclature; compounding; dispensing; distribution; administration; education; monitoring; and use.”<sup>102</sup> Previous studies have shown that nearly one-third of ADEs that occur in primary care settings are preventable.<sup>103,104</sup> Non-preventable ADEs, on the other hand, are considered adverse drug reactions (ADR), and are defined as injuries resulting from the use of a medication but not associated with any errors.<sup>101,105</sup> WHO also defines ADRs as “an effect that is noxious and unintended which occurs at doses used in man for prophylaxis, diagnosis, or therapy.”<sup>106</sup> In the current literature, ADEs are commonly refers to both the occurrence of preventable ADEs and ADRs.<sup>107</sup>

The severity of ADEs is classified as one of two types, with either four levels of severity (i.e., fatal, life-threatening, serious, and significant)<sup>101,108</sup> or three levels of severity (i.e., minor, moderate, and severe).<sup>99,109</sup> The events leading to an ADE can include errors in ordering (by physicians or pharmacists), transcribing (by a secretary, a nurse, a physician assistant, depends on the unit and time of day), dispensing (by pharmacy), and administering (by nursing).<sup>101</sup> There is also an alternative ADE topic to explore the incidence of potential adverse drug events (pADEs). pADEs are defined as medication errors with the potential to cause an injury but do not necessarily cause any harm.<sup>101</sup> This type of ADE is also an important research area in which efforts are needed, and studies have shown that the

occurrence of pADEs are more likely in pediatric inpatients.<sup>105,110</sup>

Generally, four major methods for detecting ADEs have been described in the current literature including (1) voluntary reporting, (2) chart review, (3) computerized monitoring, and (4) claim data screening. Since the methods are complementary, some studies have used multiple methods to identify ADEs, while others use only one approach.<sup>102</sup>

The first strategy to detect ADEs is via voluntary reporting, including spontaneous and stimulated reporting. Spontaneous reporting depends on healthcare providers, such as physicians, nurses or pharmacists, to report any ADE occurrence that is identified in daily practice. Stimulated reporting is based on prompting healthcare providers via interviews to solicit ADE information.<sup>99</sup> The advantage of using voluntary reporting lies in its low cost. This disadvantage of both spontaneous and stimulated strategies is that they heavily rely on providers' verbal reports, which may cause under-reporting.

The second strategy to identify ADEs is by retrospective chart review, in which ADEs are identified through examination of patient medical charts. This method detects ADEs in a more comprehensive manner than voluntary reporting can. Studies that use chart review to detect ADEs typically report a higher prevalence of ADEs compared to other approaches.<sup>98</sup> However, this approach can be costly and time consuming, as well as require medical professionals training/involving for proper identification of ADEs. Furthermore, chart review is often a more subjective approach since the process highly depends upon reviewers' judgments.<sup>111</sup>

The third strategy to identify ADEs is through computerized monitoring, which is regarded as a promising comprehensive technique.<sup>112</sup> Through the use of computer tools that include certain rules and events such as medication stop orders, antidote ordering, and certain abnormal laboratory values,<sup>113</sup> ADEs can be easily detected. These processes of computerized monitoring produce relatively sensitive results that can calculate the occurrence

of ADEs automatically. A further advantage is that studies have reported that using computerized monitoring can be more cost-effective than other alternatives and cover a larger population.<sup>3,99,114</sup> However, the pitfalls of using computerized monitoring include the cost of implementing the information system and the lack of consistency for ADE identification criteria in different information systems.

The fourth strategy to detect ADEs is screening using ICD-9-CM diagnosis codes. The ICD-9-CM is the International Classification of Diseases, Ninth Revision, Clinical Modification, which is based on the World Health Organization's Ninth Revision. The ICD-9-CM code is defined as the official system of assigning codes to represent patients' diagnoses and procedures.<sup>115</sup> The ICD-9-CM code mainly consists of three sections: (a) a tabular list containing a numerical list of the disease code numbers in tabular form, (b) an alphabetical index to the disease entries, and (c) a classification system for surgical, diagnostic, and therapeutic procedures (alphabetic index and tabular list). The E code is one part of the ICD-9-CM code sections (the third one), which is an index that represents external causes of injury and poisonings along with the extent and the place where the adverse events occurred. The RFV code is a unique classification in the NAMCS and NHAMCS data sets to determine whether a visit is injury related. The definition of injury includes not only physical injury but also poisoning and adverse effects (e.g., carpal tunnel syndrome, allergic reactions, alcohol and drug abuse, birth trauma, and others were all viewed as injury-related visits). The identifying codes for ICD-9-CM and RFV are not identical. Coding is determined by researchers' judgment.

This is the most common approach for studies which use large datasets to detect the incidence of ADEs.<sup>116</sup> The advantages of adopting this approach are that it is inexpensive, does not require advanced information systems, and can be used in a large scale observation. However, this approach has been criticized because it is much less sensitive than chart review

or computerized monitoring and fewer rules can be applied to detect ADEs. Considering that each approach to ADEs detection has drawbacks, there is no gold standard for tracking ADEs, and the approach to ADE detection depends on the researchers' study design and resources. Among the selected studies that investigated the prevalence of ADEs via large-scale datasets, all of them used the ICD-9-CM and E codes to infer the role of medications which patients used that may be indicative of ADEs. Sarkar's study employed the most intricate approach to define ADEs.<sup>117</sup> Using the NAMCS dataset, the authors selected one survey question "Is this visit related to: adverse effect of medical/surgical care or adverse effect of medicinal drug?" to identify candidate ADE visits. The second step that the authors applied was based on experts' clinical review and consensus through reviewing all the potential diagnostic (ICD-9-CM code) and RFV codes for all ADE candidate visits. According to their study, the potential ADE visits were counted if both approaches are identified the visits as ADEs. This dissertation will adopt Sarkar's survey question approach to identify potential ADE visits. Furthermore, in order to have a more comprehensive inclusion of ADE visits, this study will also include the other codes shown in the remaining papers.

### *Prevalence of ADEs*

According to previous studies, the prevalence of ADEs ranges from 1.6% to 52.9%.<sup>98,118</sup> This range in prevalence can be attributed to different detection methods, clinical settings, and subjects, consistent with the variability in HRM and DDIS. ADEs reported by patients/family members or identified by medical record/chart review detect many more ADEs compared to voluntary reporting. Most reported rates of ADEs are lower in ambulatory care-based studies than hospital-based studies. The prevalence of ADEs has been reported to be the highest among the elderly population, which is reasonable considering the health issues of this population.<sup>98</sup>

### *Factors related to ADEs*

Since this dissertation focuses on the medication quality of care in ambulatory care settings, the explorations of ADE prevalence and associated factors will center on the ambulatory care-based studies. The Ovid Medline In-Process was used to identify relevant studies published from 1995 to 2015. The key search terms included “ADE,” “prevalence,” “primary care,” “ambulatory care,” and “factors.” The selected articles contained information on the prevalence of ADEs as well as explorations of factors that affected ADEs. Nine articles met the inclusion criteria and are considered (in Table 1.3). The number of articles that focus on children, adults, elderly, or all ages are two, one, three, and three, respectively.

Three key points emerged from these papers. First, studies that target the elderly population reported the highest prevalence (50.1 per 1000 person years) among all targeted groups. While the unit of analysis differs slightly among the selected papers, those that used national survey data reported the rate of ADEs per 1000 person years, whereas the other studies employing regional data used actual ADE prevalence. Second, the prevalence was higher if the methods for identification used patient self-report or chart review.<sup>99,110</sup> For those studies that used nationally representative data, the reported prevalence of ADEs was found to be relatively lower than self-reported or chart review. Third, for those studies which used nationally representative data, the diagnostic codes (e.g., E codes and/or ICD-9-CM codes) and the Reason for Visit codes (RFV) were applied to identify ADEs.

In considering the factors associated with ADEs, four of nine studies found several significant factors that were associated with the onset of ADEs. The explored factors included patient age, gender, race, region, number of chronic conditions, education level, number of medications taken, whether the patient used natural health products, disability status, type of practice or type of prescribing that a patient received, and the duration of continuous care. Generally, the findings of these studies have consistently shown that patients with a higher



number of medications,<sup>99,117,119</sup> being older,<sup>119,120</sup> being female,<sup>119</sup> having disability status (particularly cognitive impairment),<sup>120</sup> using less natural health products,<sup>120</sup> and using more primary care visits<sup>117</sup> are more likely to experience ADEs. Among those factors, the number of medications taken is the factor that appears the most frequent. Besides examining the prevalence of ADEs and its related factors, this study will report the most commonly used medications that are associated with ADEs. Considering these articles, the most commonly medications associated with ADEs include antimicrobial agents, central nervous system agents, psychotropic agents, anticonvulsants, hormones, analgesics and gastrointestinal agents.

Compared to previous studies focused on individual-level characteristics associated with ADEs, this dissertation takes into account practice-level characteristics for a more comprehensive consideration. Most importantly, this dissertation will use ADEs as a medication outcome indicator and examine whether recent implementation of the PCMH model may reduce ADEs in primary care settings. This assumption has not been explored in previous literature and is expected to have two aims. The first is to examine whether the prevalence of ADEs has been improved in recent years. The other contribution is to inform how the PCMH may impact patient medication use.

Table 1.3 Prevalence, assessment criteria, factors associated with ADEs, and drug group associated ADEs, in outpatient ambulatory care settings

<b>Reference</b>	<b>Prevalence, n/N (%)</b>	<b>Method of ADEs identification</b>	<b>Factors associated with ADEs</b>	<b>Medication (the most frequent drug categories)</b>	<b>Correspond Codes</b>	<b>Data Resource</b>
<b>Pediatric</b>						
Kaushal (2007)	13% with non preventable ADEs, 3% with preventable ADEs	Determine ADEs by prescription review, survey, and chart review	Not discussed - ADEs occurred most at the drug administration stage. Improved patient communication appears to have strong potential as prevention strategies.	Penicillin or derivatives, Inhaled drugs – steroids, antifungal, bronchodilators Topical antihistamine	No information	6 office practices in Boston area
Bourgeois (2009)	7.78 visits with ADEs per 1000 children	E code and ICD-9-CM code	Present national estimates and demographic characteristics of patients with ADEs: age, gender, race, payment source, clinical settings, and region	Antimicrobial agents, Central nervous system agents, and Hormones	E930–E949/ E850–E858* ICD-9-CM code 995.0, 995.2, 945.4, 535.4, 692.3, 693.0, 779.4, 292.1–292.9, 708.0, 357.6, 960 –979	NAMCS+ NHAMCS
<b>Adults (including elderly)</b>						
Gandhi (2003)	24.5%, (162/221)	Patients self-report, physician-independent review, physician chart review, and patient	Only number of medications taken was significantly associated with ADEs	Selective serotonin-reuptake inhibitors, Beta- blockers, Angiotensin-converting-enzyme inhibitors, Non-steroidal anti-inflammatory agents,	No information	Regional survey in Boston Area

Reference	Prevalence, n/N (%)	Method of ADEs identification	Factors associated with ADEs	Medication (the most frequent drug categories)	Correspond Codes	Data Resource
		telephone survey		Calcium-channel blockers		
<b>Elderly only</b>						
Hanlon (1997)	35%	Patient self-reported study	Not show any significant difference in age, race, education, self-perceived health, number of prescriber, and previous ADEs history	Cardiovascular and central nervous system medication classes were the most commonly implicated	No information	General Medicine Clinic at the Durham Veteran Medical Center
Gurwitz (2003)	50.1 per 1000 person-years (1523/30397)  27.6% of ADEs are preventable	Multiple resources	Present characteristics of patients that observed in the study: age, gender, number of outpatient visits, number of prescription medications,	Cardiovascular, antibiotics, diuretics, nonopioid analgesics, anticoagulants	ICD-9-CM code 960-977 (except 963), 909, 692, 693, 357, 708, 535	Within a multispecialty group of practice
Ganjavi (2007)	9.9% (24/242)	Depends on the report of patients and caregivers and the assessment	Older age and greater cognitive impairment were associated with ADEs; the use of Natural health	Central nervous system, cardiovascular system, analgesic, anticholinergics, gastrointestinal	No information	Two clinics in Toronto

Reference	Prevalence, n/N (%)	Method of ADEs identification	Factors associated with ADEs	Medication (the most frequent drug categories)	Correspond Codes	Data Resource
		of clinical reviewers	products predicted a lower risk of ADEs.			
<b>All ages</b>						
Zhan (2005)	15 visits per 1,000 population	E code and ICD-9-CM code	Not discussed	Antibiotics and other anti-infective, hormones and synthetic substitutes, analgesics, antipyretics, and antirheumatics	E930-E947 E850-E858 (excluding E935)  ICD-9-CM code 292, 692, 6930, 760, 763, 779, 782, 60-969, 909, 970-979	NAMCS+ NHAMCS
Bourgeois (2010)	9.1 per 1000 persons in 1995  16.9 per 1000 persons in 2005	E code and ICD-9-CM code	-Age older (65 years and older), Greater number of medications taken by patient, Gender female	antihypertensives, estrogen/ progesterones, nonopioid-based analgesics/ antipyretics, antidepressants, and mood stabilizers.	E930 –E949* E850 –E858  ICD-9-CM code 995, 945, 535, 692, 693, 779, 292, 708, 357, 960- –979*	NAMCS+ NHAMCS
Sarkar (2011)	0.5 percent of all visits	RFV code and ICD-9-CM code	-Number of prescribed medications, With more primary care visits		RFV** code 5905.0  ICD-9-CM code 960-979*, 995, 692, 693, 292, 708, 357	NAMCS+ NHAMCS

## **Patient Centered Medical Home**

The Patient-Centered Primary Care Collaborative (PCPCC) defines the Patient Centered Medical Home (PCMH) as “ a model or philosophy of primary care that is patient-centered , comprehensive, team-based, coordinated, accessible, and focused on quality and safety.”<sup>121</sup> The emergence of the Patient Centered Medical Home (PCMH) was considered a highly innovative transformation in U.S. primary care.<sup>122</sup> As an important innovation, the PCMH is also regarded as a promising approach to addressing the recent fragmentation, poor quality, and high costs of the health care system. With endorsements from several accredited organizations, such as the PCPCC, and support in the Patient Protection and Affordable Care Act of 2010, numerous PCMH initiatives have been established in a wide variety of practice settings across the country.<sup>123</sup> According to several studies, PCMH initiatives have demonstrated the potential to improve patient-related care quality/outcomes (e.g., patient satisfaction or quality of care) and reduce costs/utilizations.<sup>124-126</sup> Despite the potential benefits in these areas, what remains largely unexplored is how and to what extent this PCMH implementation can affect patients’ medication quality of care.

The following section is divided into three parts. First, the concept and the evolution of the PCMH are presented, including several different PCMH definitions. Second, the current literature related to the PCMH adoption is explored. Third, a systematic review of the current literature related to the effect of PCMH implementation is also presented. The final section will draw general conclusions, identify gaps in the current literature, and propose a new contribution to examine the adoption of the PCMH.

## *The Concept and Evolvement of the PCMH*

The PCMH is defined as a transformative healthcare model that (1) aims to provide more accessible, high-quality, and comprehensive patient care, led by a specific physician, and (2) emphasizes a team-based approach as well as whole-person orientation during all stages of care, including primary, secondary, and tertiary care.<sup>121</sup> The concept of the PCMH has its origins in pediatrics in the 1960s. As most physicians caring for patients, pediatricians generally have two purposes. One is to undertake a first-contact role solving any concerns related to vulnerable children with chronic conditions and their caregivers needed. The other is to act as a referral agent to pass relatively seriously ill patients to appropriate specialists.<sup>127</sup> This PCMH concept has gradually evolved, emphasizing general patient-centered care within physician practices. In the PCMH, physicians are expected to be leaders of a group of non-physician professionals in practice, to facilitate collaborative care, to provide continuous, comprehensive care, and to meet all types of patients' health needs. Additionally, this concept specifically aims to personalize, prioritize and integrate care for whole-person care rather than focusing on disease treatment.

During the past decade, the PCMH model has evolved and been modified by several organizations. In 2007, the original features of the PCMH were first described by several primary care physician associations, also referred to as the Patient-Centered Primary Care Collaborative (PCPCC). These physician associations endorsed a PCMH model, known as the Joint Principles (also known as the Seven Joint Principles), outlining seven significant areas for effective PCMH care: (1) Personal physician, (2) Physicians directing the medical practices, (3) Whole-person orientation, (4) Coordinated care, (5) Quality and safety care, (6) Enhanced access to care, and (7) Payment reform. The original Seven Joint Principles were modified by the Agency for Health Research and Quality (AHRQ) into the five principles of

the PCMH, encompassing: (1) Comprehensive Care, (2) Patient-Centered Care, (3) Coordinated Care, (4) Accessible Services, and (5) Quality and Safety. AHRQ asserts that the modification is more efficient and clear than the original PCMH model.<sup>128</sup> Further modifications to the model were made in 2010 by a prominent private foundation, the Commonwealth Fund, which drew from the Seven Joint Principles of the PCPCC to establish its approach to define and measure the PCMH. Their model consists of four concepts including (a) the fundamental tenets of primary care (accessibility, comprehensiveness, integration, and relationship), (b) new ways to reform the organizational setting, (c) the development of practices' internal capabilities, and (d) changes of the health care system and reimbursement.<sup>129</sup> Shortly after this modification, in 2011, the National Committee for Quality Assurance (NCQA) further framed a series of PCMH recognition standards with detailed rating scores and supplemental elements for each evaluated domain. The NCQA PCMH standard includes six domains: (1) Enhancing access and continuity, (2) Identifying and managing patient population, (3) Planning and managing care, (4) Providing self-care support and community resources (5) Tracking and coordinating care, and (6) Measuring and improving performance. Each domain is further divided into three to seven sub elements.<sup>130</sup>

Despite the different definitions of the PCMH, the original Seven Joint Principles will be used as the fundamental PCMH concept for the following two reasons. First, the PCPCC-defined Seven Joint Principles remains the most commonly used framework in examinations of PCMH implementation in practices.<sup>131</sup> Second, the seven domains covered in the Seven Joint Principles are comprehensive and concise relative to the modified models. Specifically, compared to the initial Seven Joint Principles, the remaining models either focus too narrowly on a specific domain, such as patient safety and quality, or neglect one significant aspect, such as the importance of redesigning financial reimbursement systems. In reality, each domain is crucial and should be equally examined. In the current literature, two lines of

research have evaluated the implementation of the PCMH. One investigates the extent to which practices adopt the PCMH, and the other demonstrates the effects of PCMH implementation.

### ***Evaluating PCMH***

The establishment of PCMH in practices is expensive and time consuming but the effectiveness of PCMH is worthy to explore. Apart from financial resources needed for technology to integrate information into the care delivery system, significant efforts are required to engage all the healthcare professionals in collaborative work as well as to establish trust between patients and providers.<sup>132</sup> Explorations of the extent to which primary care practices have implemented the PCMH are critical for two reasons. First, many PCMH pilot projects have been implemented. For example, several major national health plans/organizations have numerous PCMH demonstration pilot projects in 18 states.<sup>123</sup> Furthermore, in 2008, CMS also conducted Medicare Medical Home Demonstration pilot projects in 400 practices in 8 states, aiming to provide targeted, accessible, continuous, and coordinated care to Medicare beneficiaries with chronic or prolonged diseases.<sup>133</sup> Second, whether these PCMH programs have evolved past the pilot stage is unknown. Many stakeholders, such as the federal government and private organizations, have a considerable interest in evaluating whether the PCMH represents an effective model for transforming the delivery of health care.

To determine the extent of PCMH adoption, appropriate methods or measures must be chosen. Since PCMH is a multi-dimensional concept, evaluating its effectiveness is challenging. PCMH evaluation must be comprehensive, taking both the context of transformation and experiences of diverse stakeholders into account.<sup>134</sup> The context of



transformation consists of the major components of PCMH, namely practice information, team-work environment, culture of trust, and the degree of communication, whereas the experiences of diverse stakeholders can be derived directly from a survey of patient, staff, and clinician satisfaction. Generally, two research methods are employed to evaluate PCMH effectiveness. One approach involves qualitative methods and the other is quantitative. Qualitative methods have two advantages. They allow for the exploration of a contextualized and comprehensive examination of what occurs in practices that may influence the implementation of PCMH, and they complete or explain the findings obtained through quantitative methods.<sup>135</sup>

Currently, two types of qualitative methods have been used in PCMH-related studies. One involves observational evaluation and the other is the interview evaluation. Observational evaluation includes direct observation of staff, patients, or caregivers within the practice environment, allowing researchers to directly observe how a practice functions.<sup>134</sup> Using this approach, Nutting and his research team investigated a national project to observe the transformation of family practices into PCMHs.<sup>136</sup> The findings showed that transforming a practice to a PCMH requires strong willingness and efforts from both professionals and practices. The study also concluded that although most practices are equipped with basic core functions of PCMH, few of them had a systematic strategy to transform their practices to the more comprehensive care characteristics of a PCMH.

Interview evaluation generally consists of in-person individual interviews, aiming to elicit information or attitudes in interviewees' own words.<sup>137-139</sup> Individual baseline interviews, follow-up interviews with clinicians, or patient interviews are examples of interview evaluation methods. This type of qualitative research is conducted to probe more deeply into providers or patients' experiences and opinions about the implementation of PCMH.<sup>140-142</sup> In their 2015 interview study, Aysola and his research group used patient-

reported results to characterize patients' experiences with care after PCMH adoption and their understanding and perceptions of the PCMH model. The aim in collecting this information was to compare patient responses in relation to the degree of practice-level PCMH adoption. The results demonstrated that patients generally were aware of the PCMH concept, yet they perceived no PCMH-related structural changes, regardless of the extent to which their practice had implemented PCMHs.

Although qualitative methods have advantages for examining PCMH implementation, these approaches are not ideal for conducting larger-scale investigations. For such studies, quantitative methods or mixed methods are more suitable.<sup>143</sup> A quantitative method generally follows one of three approaches. First, a survey of the practice, clinician, and staff can collect demographic information of the providers and staff and allow for an analysis of the extent to which providers perceive transformations within the PCMH.<sup>126</sup> For example, Baxter Et al. conducted a national survey of nearly 200 physicians to explore the potential of PCMH implementation for small medical practices as well as to examine physicians' perceptions of the PCMHs.<sup>144</sup> Embedded in the survey instrument were three components: a survey of practice characteristics (e.g., practice size or ownership), a survey of physicians' perceptions of the PCMH (containing 16 specific questions), and a validated culture rating instrument (consisting of 45 items examining 9 dimensions of organizational culture). The findings of the study indicated that physicians were aware that a PCMH might improve the quality of primary care; however, they also highlighted tension that existed between societal benefits and rising costs for practices, which was a challenge for PCMH implementation.

The second quantitative approach used in studies involves patient surveys. In the PCMH literature, exploration of patient satisfaction and reviews of patient-report outcomes are the two major types of patient surveys.<sup>94,124,145,146</sup> In their 2010 survey research, Jaén and his research team used patient-reported outcome questionnaires administered to patients from 36

family medicine practices across the United States to evaluate whether PCMH implementation could improve patient outcomes (e.g., access to care, patient empowerment, and self-rated health status). The results showed that implementation of the PCMH was positively associated with patients' condition-specific quality of care, but not with patients' experiences with the services offered by a PCMH. While most other studies of PCMH have revealed positive patient-report outcomes, some studies found inconsistent results in patient satisfaction with PCMHs.<sup>147,148</sup>

The third quantitative approach is the meta-measurement of PCMH. Meta-measures are a well-established tool that can assess baseline needs of practices and monitor transformation. Examples of this technique include the NCQA PCMH guidelines and the practice self-evaluation PCMH assessment. To date, many studies have already used the guidelines or modification of them published by the NCQA to define a PCMH practice.<sup>125,142,149-160</sup>

The NCQA PCMH program consists of three levels of achievement, as measured by a scoring rubric. In the 2008 NCQA PCMH evaluation, the scoring system was designed to evaluate how well a practice was performing on nine standards that aligned with the core components of primary care: (1) access and communication, (2) patient tracking and registry functions, (3) care management, (4) self-management support, (5) electronic prescribing, (6) test tracking, (7) referral tracking, (8) performance reporting and improvement, and (9) advanced electronic communication. Subsumed under these nine standards were 30 specific elements including 10 designated as "must pass" elements for purposes of medical home recognition. The detailed list is provided in Appendix C. An example is the ninth standard, advanced electronic communication, which consists of three elements and is worth a total score of 4 points. Element A of this standard focuses on the availability of an interactive web site for patients and their families (1 point). Element B centers on whether the practice has

electronic patient identification (2 points), while Element C assesses whether the practice care management team uses electronic communication to manage patient chronic conditions.

The scoring for PCMH designation involves two parts: (1) the degree to which the procedure meets the standard and (2) the level of performance. The former is determined directly by the score each practice receives, whereas the latter is based on a combination of the number of “must pass” elements and “the scores” for those items. Based on the NCQA PCMH recognition program, to be certified as a Level 1 PCMH, a practice has to meet 4 of the 10 must-pass elements and have a score of 25 - 49. Level 2 practices have to pass all 10 must-pass elements with the score of 50 - 74. Likewise, Level 3 practices have to pass all 10 must-pass elements with the score over 75. A higher score/level is indicative of a more comprehensive PCMH.<sup>89</sup> To be evaluated for the NCQA PCMH recognition program, practices first should voluntarily complete a Web-based survey and attach documentation to support their responses. This documentation is reviewed by a certified NCQA PCMH trainer, and 5% of applications will go through an on-site audit. These applications will undergo three rounds of internal review. After the review, the practice will receive a level of recognition based on both their total evaluated scores and their performance on 10 “must pass” elements.

Among the various types of techniques described above, this dissertation will adopt the meta-measure, specifically, the approach implemented for the NCQA PCMH recognition for three reasons. First, the NCQA PCMH recognition program is currently the most widely used evaluation method, although there is no required official accreditation for practices to brand themselves as PCMHs. The second reason for choosing the NCQA PCMH accredited program is because it is a well validated and updated program. The very first NCQA PCMH recognition program was developed in 2006 with guidance from the American College of Physicians, the American Academy of Family Physicians, the American Academy of Pediatrics and the American Osteopathic Association. It is reviewed, updated, and published

every 5 years in response to a joint effort of related professionals. The final reason for choosing the NCQA PCMH recognition program is that it has a well-defined scoring system and standardized guidelines. This well-designed program allows practices managers/owners to assess the operation of their practices in relation to the NCQA PCMH standards. This well-used program also allows health services researchers to evaluate and compare the adoption of PCMH at a national level. Based on the research findings, only Hollingsworth's study employed the NCQA PCMH scoring rubric to map the survey items from a nationally representative dataset to demonstrate the actual implementation of PCMHs across the United States.<sup>156</sup> Their study found that nearly half of the practices nationwide lacked sufficient PCMH infrastructure. To extend the knowledge of PCMH in primary care practices, this dissertation will build on Hollingsworth's study and advance their work to examine the effectiveness of PCMH with regard to medication quality of care.

## *The Effect of Implementing PCMH*

Apart from examining the extent of PCMH implementation among practices, another interest of the PCMH literature is to evaluate the effects of PCMH implementation and to compare results of PCMH implementation across practices. Generally, four domains of PCMH outcomes are well explored, including patient experience, economic outcomes, process measure and clinical outcomes.

The first domain is experience outcomes, including both patient and staff experience with PCMH implementation. Studies related to patient experience outcomes have reported consistent results. Specifically, patients have generally reported higher satisfaction with the care they received, reported positive relationships with providers and overall good experiences based on the results from after PCMH adoption or comparisons of pre-post time periods.<sup>94,142,145,161,162</sup> Findings, however, are mixed for staff experiences with PCMH implementation. Some studies of PCMH implementation have examined physicians' experiences, whereas other studies have investigated the opinions of non-physician professionals.<sup>145,163-165</sup> For instance, Richardson Et al. surveyed physicians to determine their satisfaction with the PCMH. The results indicated that the physicians' satisfaction was notably lower than expected (i.e. nearly two-third of the interviewees reported being only somewhat or very satisfied overall with their practice after PCMH transformation). Fontaine and his research team used a qualitative approach to interview thirty-one administrative and clinical leaders to explore their experiences with PCMH implementation in Minnesota. The findings showed that interviewees regarded the implementation of PCMH as beneficial for patients, even though barriers existed, such as the lack of quality in electronic medical records and unclear reimbursement plans.<sup>153,164</sup> Additionally, Reid Et al. used the 22-item

Maslach Burnout Inventory to measure the level of emotional exhaustion, depersonalization, and sense of personal accomplishment among staff in practices with a recognized PCMH program. The results showed positive evidence that implementing PCMH reduced staff burnout at 12 months post implementation.<sup>145</sup>

The second outcome domain is the economic outcomes of PCMH, including utilization and cost. This focus is the most common in current PCMH-related studies.<sup>125,150-152,154,157,158,166-171</sup> To measure economic outcomes, studies have investigated primary care visits,<sup>125</sup> specialty care visits,<sup>154</sup> telephone visits,<sup>151</sup> 30-day readmission rates,<sup>170</sup> inpatient admissions,<sup>125,154,157,158,160,168,172,173</sup> and emergency department visits.<sup>122,125,160,172</sup> Likewise, the measures of cost in the PCMH literature are total costs,<sup>125,160,166,168,169</sup> inpatient costs,<sup>154,157,160,168,174</sup> outpatient costs,<sup>150</sup> emergency room costs,<sup>157,160,174</sup> specialty care costs,<sup>154,157,174</sup> and medication costs.<sup>174</sup> The findings of the economic outcomes for practices adopting the model have been inconsistent. Many of the studies provided empirical evidence to show that practices which had adopted PCMH could reduce utilization and cost of high-cost medical interventions, such as emergency room visits, hospitalization and 30-day readmission.<sup>173,175</sup> On the other hand, some preliminary studies showed opposite results and practices that adopted PCMH did not experience reductions in utilization of hospitalization, emergency room visits, or total costs.<sup>125,151,173</sup> These mixed findings can be attributed to two reasons, namely the selected population and the observation time. The choice of a cohort with chronic diseases that does not need intensive care to control their diseases might not yield a significant improvement in utilization. Furthermore, a lag between PCMH implementation and observations of effects on patients' outcomes may be another reason for explaining the mixed results.

The third domain of exploring PCMH outcome is the assessment of process-of-care indicators. This domain can be divided into two categories: preventive services and chronic

illness care services. The measures of preventive services which have been used or recommended as the outcome of PCMH-related studies include adult weight screening and follow-up, cancer screening (breast and cervical), chlamydia screening in women, lipid screening, influenza vaccination, and behavioral counseling.<sup>92,159,169,176</sup> Studies of preventive services have consistently reported positive effects of PCMH, in that screening or vaccination rates have increased. As to the chronic illness care services, measures listed/suggested by the types of chronic conditions, such as respiratory, cardiovascular, and diabetes have all been used to evaluate PCMH outcomes.<sup>122,145</sup> Compared to the measures for respiratory and cardiovascular conditions, diabetes care is the most common proxy for chronic illness care services in the PCMH context. The recommended measures for diabetes care include Hemoglobin A1<sub>c</sub> (H<sub>b</sub>A1<sub>c</sub>) testing, body mass index (BMI) record, eye exam performed, LDL-C screening, and medical attention for nephropathy.<sup>122,177</sup> Studies have reported consistent, positive results in regard to the effect of PCMH implementation on diabetes care management.<sup>155,178-180</sup> Interestingly, the majority of preventive service and chronic illness care service measures are adapted from HEDIS.

The final domain of PCMH exploration is clinical outcomes. Clinical outcome measures that have been used for examining the implementation of PCMH include hemoglobin A1<sub>c</sub> values, blood pressure control, low density-lipoprotein cholesterol control and high-density lipoprotein cholesterol control.<sup>160,180,181</sup> Studies using these outcome measures have consistently found positive results among the PCMH-related studies, particularly when the PCMH provided pharmacist-involved services. However, none of these studies have investigated the quality of medication use more generally. To fill the gap, this dissertation will investigate the association between the PCMH adoption and several medication-related quality measures.



## **Theoretical Considerations**

The focus of this dissertation is a series of explorations and analyses of two areas in PCMH adoption: (1) the factors affecting the level of PCMH implementation in practices and (2) the influence of PCMH implementation on the use of medications. The goals of healthcare reform are to improve the quality, safety, efficiency, and effectiveness of U.S. health care, and it is important to know the extent that practices implement PCMH and how that implementation affects medication use. This study will be based on a theoretical framework that incorporates elements from two widely used behavioral theories, namely Wagner's Chronic Care Model and Hogg's primary care organization model.<sup>182,183</sup> The following section provides an overview of each theoretical model and elaborates on the rationale for their selection in this study. Finally, the modified merged conceptual framework is presented.

### ***Wagner's Chronic Care Model***

Wagner's Chronic Care Model, also known as the Chronic Care Model (CCM), was developed in 1996 by the MacColl Institute for Healthcare Innovation, led by the director, Dr. Edward Wagner. This model emerged in response to the increasing burden of chronic diseases and the apparent disparity of approaches for disease management. The CCM was designed to help practices improve patient health outcomes, particularly for those patients with chronic diseases. The CCM does not offer a quick and easy solution; instead, it provides a multidimensional solution to complex health situations in primary care. The ultimate goal of the CCM is to transform daily care for patients with chronic conditions from acute and reactive to proactive and planned care.

Generally, six essential, interrelated elements constitute the CCM.<sup>182</sup> The first element is community resources and policies. This element emphasizes the linkages between providers or organizations and community-based resources, which can be a means for practices with limited resources to improve patients' chronic care. Examples of community-based resources include exercise programs at community centers or meals at senior centers. The second element is the healthcare organization, addressing the structure, goals, and values of a provider organization and its relationship with purchasers, insurers and other providers.

The third element is self-management support. Since the CCM model centers on the development of effective chronic care guidelines, teaching patients about disease management and following major management strategies such as diet, exercise, and medication use are all important issues. The fourth element is delivery system design. This element stresses the importance of redesigning the care approach to one of a team-based care to serve patients for both acute and chronic care. To achieve this goal, physicians should help patients with acute problems and intervene in stubbornly difficult chronic cases. Non-physicians should also have direct patient care services, and their goals are to offer expert support to patients with chronic disease who need to maintain a self-care protocol and the other is to arrange routine periodic planned visits for patients.

The fifth element is decision support, which underlines the significance of evidence-based clinical guidelines. Evidence-based guidelines are expected to provide the most up-to-date standards for optimal chronic care. The final element is the clinical information system, which highlights the importance of implementing computerized electronic medical systems within practices. The rationale for implementing clinical information systems is that they serve as reminder systems that assist healthcare professionals to adhere to guidelines and as registries for planning individual patient care and conducting population-level care. All six

elements must be inter-related to improve interactions between providers and patients and to improve outcomes.

The CCM was chosen as one of the behavioral models for this dissertation for the following three reasons. First, the CCM can be viewed as part of the PCMH model. In other words, the concepts of CCM are fundamental elements of the PCMH model.<sup>184</sup> However, there exist some dissimilarities between the CCM and the PCMH model. For example, the CCM is centered on care for patients with chronic conditions, whereas the focus of PCMH is on direct patient care as well as population health management. Furthermore, the PCMH model emphasizes a whole person orientation, offering care ranging from preventive services to tertiary care and this differs from the CCM which targets chronic disease management. Additionally, the PCMH model allows an examination of some specific mechanisms within practices, such as the collaboration between physicians and non-physicians and EMR functionality, while the CMM is more general. In order to develop a comprehensive theoretical model, this dissertation added concepts from Hogg's primary care organization model and merged them with CCM for the research framework.

### ***Hogg's Primary Care Organization Model***

The primary care organization model (PCOM) was proposed by Dr. Hogg and his research team in 2008. This model consists of blended perspectives of organizational theory and other primary care models to establish a comprehensive primary care model with a focus on delivery of services.<sup>185</sup> Generally, the PCOM can be viewed from two perspectives including structure and performance domains. The structure domain has three significant components, namely the healthcare system, the context of practices and the organization of practices. The healthcare system can be regarded as a system level structure that includes

policies, stakeholders, and other components that influence primary care organizations and providers. Other aspects of the healthcare system are governance and accountability as well as resources and technical provisions. The context of practices refers to the characteristics of the surrounding communities and the availability of connecting other medical resources or services in the area. Examples of context include local medical and social services or population and community characteristics. Finally, the organization of the practices is related to the characteristics of practices that might affect performance and include health human resources, office infrastructure, organizational structure and practice integration.

Within the performance domain are two subcategories: healthcare service delivery and technical quality of clinical care. The healthcare service delivery depicts and evaluates the provision of healthcare services. The following six features summarize the health care services delivery: access, patient-provider relationship, continuity, service integration, comprehensiveness, and provider satisfaction. The technical quality of clinical care, on the other hand, is defined as “the degree to which clinical procedures reflect current research evidence and/or meet commonly accepted standards for technical content or skill.”<sup>28</sup> There are four subcomponents of technical quality of care including health promotion and primary prevention, secondary prevention, care of chronic conditions and care of acute conditions.

### ***The Modified Conceptual Framework***

In order to examine the level of PCMH implementation in practices, as measured by the NCQA, and to fully explore the influence of this level of care on medication quality of care, the chronic care model and PCOM were merged to create a new model. In this modified framework, the PCOM was adopted as the grounded model for two reasons. One is that the mechanism of the PCOM emphasizes the processes of structure and performance.

Additionally, the PCOM outlines specifically how the structure domain influences primary care performance. The other reason is that the model focuses on exploring the factors that affect the extent to which quality services are delivered. However, because the PCOM does not highlight or explain how the performance of primary care affects patient outcomes, the outcome domain was borrowed from CCM. The modified theoretical framework is shown in Figure 1.1.

In this modified model, three domains constitute the general framework: structure, performance or process and outcomes. In the structure domain, two components are embedded, namely the practice context and organization of the practice. Similar to the PCOM, factors such as type of practice, office type, practice size, ownership status, geographic region of the practice, metropolitan status of the practice, and Medicare/Medicaid penetration of the practice are taken into account as the practice context. In addition, physician demographic characteristics, including age, gender, specialty, and identity are considered as part of the organization.

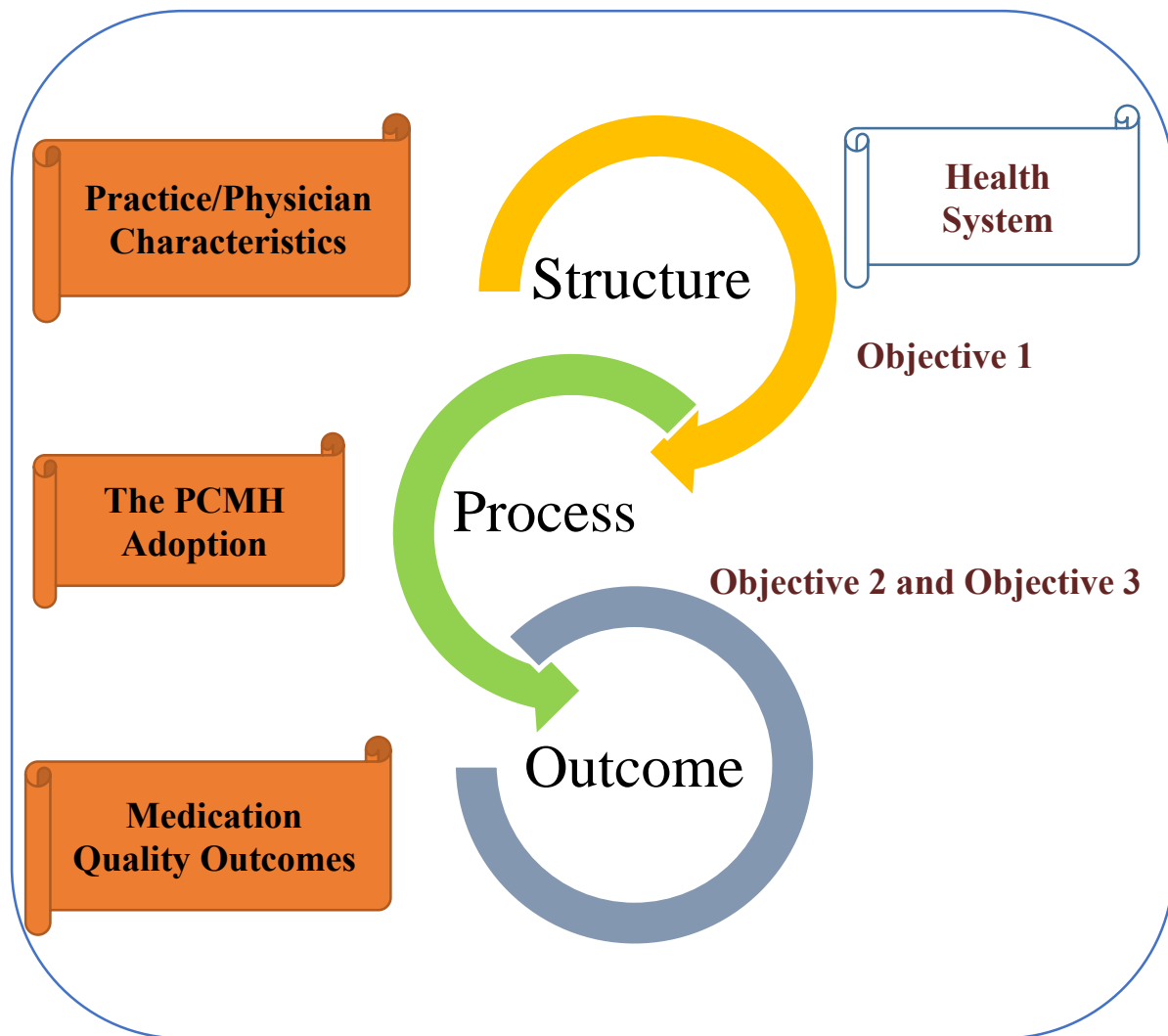
As to the performance or process domain, the level of PCMH recognition will be used as the proxy of how a practice provides care. Specifically, each practice will be categorized into four different level of the PCMH. The evaluation method used by Hollingsworth Et al. to determine whether a practice offers services beyond the traditional primary care service offerings (e.g., provide more team-based care or accessible care to the patients) will be expanded. Building on the Hollingsworth study, this dissertation includes three important features: (1) it uses the most up-to-date national data and medication quality indicator lists, (2) it determines the adoption of PCMH with a more restricted criteria (i.e., categorization of different levels of PCMH in terms of must-pass elements), and (3) it investigates the association between the adoption of PCMH and medication quality of care. The outcomes of our new model are the medication use quality indicators, namely quality indicators

categorized as process of care and outcome of care. To determine medication process of care, (1) the use of high risk medication and (2) the use of DDIS were chosen. As to the medication outcome of care indicator, ADEs were selected for the evaluation. Finally, patient characteristics are added as covariates for these models, as they play a crucial role in the quality of medication use. Examples of patient characteristics include age, gender, race, comorbidity conditions, number of medications used, and household income.

## **CONCLUSION**

This dissertation will examine the relationship between level of PCMH and quality of medication use. This relationship will be explored using a nationally representative dataset. This important policy question will help us understand how quality of medication use may be affected by this healthcare reform.

Figure 1.1 Conceptual Framework



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## **CHAPTER II. PAPER 1: PHYSICIAN-RELATED CHARACTERISTICS AND THE ADOPTION OF PATIENT-CENTERED MEDICAL HOME: RESULTS FROM A POPULATION-BASED NATIONAL SURVEY**

### **Introduction**

The Patient-Centered Medical Home (PCMH) is one important innovation in today's healthcare reform. The emergence of the PCMH model can be viewed as a partial solution for the fragmented primary care system and the challenge of providing more accessible, continuous, comprehensive, and collaborative services to patients.<sup>1</sup> Despite the increased focus on the adoption of PCMH and its effect on health utilization and quality of care, the adoption of PCMH has remained below fifty percent of overall primary care practices.<sup>2,3</sup> In seeking to understand PCMH adoption, many studies have targeted the characteristics of practices that have pursued this healthcare model. For example, practice size,<sup>2,4</sup> ownership,<sup>3,4</sup> and location<sup>4,5</sup> have all been linked to PCMH adoption. Other factors related specifically to physicians have been investigated, and results show that physician specialty, particular primary care physician, does have a positive association with the adoption of PCMH.<sup>3,4,6</sup> Despite this focus, explorations of physician demographic characteristics that might influence the adoption of PCMH have not been

undertaken. To address this gap in knowledge, this study is the first in the PCMH literature to evaluate a broad set of physician-related factors that are associated with PCMH adoption.

Exploration of physician characteristics is important in understanding PCMH adoption for three reasons. First, personal demographic characteristics of physicians may determine the diffusion of PCMH adoption, especially when considering Roger's diffusion of innovation theory, which assumes that individual characteristics affect the spread of new ideas.<sup>7</sup> For example, this theoretical model has been applied in health services research to explore the adoption of electronic medical records (EMR).<sup>8,9</sup> These findings show that older age of physicians who work in smaller-size practices lag in their adoption of electronic medical records.<sup>10</sup> Whether a similar association between physician characteristics and practice size exists for PCMH adoption is not known because the theory has not yet been applied to the PCMH context. Furthermore, individual characteristics such as physician gender and type have been associated with adopting technological and administrative innovations such as new drug prescribing and EMR.<sup>11-13</sup>

A second reason to explore individual characteristics in relation to PCMH adoption is that provider characteristics have been relevant in studies applying Hogg's primary care model.<sup>14,15</sup> In Hogg's model, the structural domain includes provider characteristics, infrastructure of practices, and healthcare system characteristics. These factors have been shown to impact primary care, as the value of having non-physician professionals participating in primary care added to the improvement of primary care delivery services in Canadian's' community health centers.<sup>16</sup> Studies have concluded that understanding the specific components of the structural domain may facilitate improvement in primary care sector performance.



Finally, the third reason to investigate physician characteristics is because the role of physicians currently has a greater influence on adoption of PCMH than other non-physician professionals in medical practices. Specifically, the Seven Joint Principles, which is one of the most popular definitions of PCMH, emphasizes the important role of the physician.<sup>17</sup> Among these principles, including enhanced access, whole person orientation, coordination of care, personal physician, physician-directed practice, safety and quality, as well as the payment reform, the physician role is particularly highlighted.<sup>18</sup> Thus, physicians often play significant roles as leaders of non-physician professionals as well as first-line providers in the PCMH model. Previous studies have emphasized physician knowledge and attitudes as invaluable in supporting healthcare reform, yet the association between their demographic characteristics and the adoption of PCMH has not been examined thoroughly.<sup>19-21</sup> In summary, population-based national estimates about the impact of physician characteristics on the adoption of PCMH will be important in its continued adoption.

In order to study the extent of PCMH adoption, a suitable measure to quantify the adoption of PCMH is needed. To date, there is no single, national measure to determine whether practices have appropriately branded themselves as PCMHs. To explore the extent to which practices adopt PCMH, however, it is possible to use an accreditation approach. Accreditation standards primarily evaluate the structural, technological and process components of PCMH and have stated measurements of each component.<sup>22</sup> Of these accreditation approaches, the Physician Practice Connections-PCMH tool from the National Committee for Quality Assurance (NCQA) is the most widely used in the PCMH literature to measure the adoption of PCMH among practices.<sup>23-27</sup> This NCQA PCMH recognition program is a self-reported, well validated, and

regularly updated voluntary program that results in four levels of achievement (not accredited, level 1, level 2, and level 3), as measured by a complicated scoring rubric.<sup>28</sup>

An exploration of factors related to PCMH adoption may aid in the further adoption of PCMH among other practices, which may improve patient quality of care and reduce unnecessary healthcare utilization. This study has merged diffusion of innovation theory and Hogg's primary care model to explore the adoption of PMCH (Figure 2.1). The purpose of this study was to (1) determine the prevalence of PCMH adoption among practices using a nationally representative survey and (2) quantify the relationships between extent of PCMH adoption and physician and practice characteristics.

## **Methods**

### **Study Design and Data Sources**

This study is a cross-sectional study using two years of data (2009-2010) from the National Ambulatory Medical Care Survey (NAMCS). The NAMCS is a complex, multistage, stratified probability sample representative of the national provision and use of ambulatory medical services in the U.S. All results from this study are based on a sample of visits to non-federal, employed, office-based physicians. Detailed descriptions of NAMCS can be found in previous studies.<sup>29</sup> This study used both publicly available and restricted NAMCS survey questions. The publically available survey includes a series of NAMCS questions designed to capture the characteristics about service delivery, visits, practices and physicians and can be found on the

Centers for Disease Control and Prevention/National Center for Health Statistics' (NCHS) website at <http://www.cdc.gov/nchs/namcs.htm> and practice characteristics. The remaining restricted data were collected through a series of questions focused on practice organizational structure (single or multi practices), numbers of physicians within a practice, physician age and physician gender. All data were accessed through the Research Data Center (RDC) at the University of Michigan and in a process approved by the NCHS Research Ethics Review Board (ERB). Analysis of restricted data available at the Research Data Center was also approved by the NCHS ERB, and this study was designated as exempt by the University Of Michigan Institutional Review Board.

## **Measures**

### ***Determining PCMH***

The primary variable of interest in this study was the extent to which practices adopted PCMH, as measured by the NCQA PCMH recognition program. The NCQA PCMH recognition program has clear scoring algorithm and has been widely used in previous studies to determine the extent of practices' PCMH adoption.<sup>3,4</sup> The NCQA scoring method is designed to capture the essential characteristics of PCMH including nine standards, thirty elements, and ten must pass elements to result in four levels of PCMH. Since there is no single question in the NAMCS that can identify whether a practice has implemented PCMH or not, this study adopted an innovative mapping technique which was employed in a previous study using NAMCS data.<sup>3</sup>

The determination of the level of PCMH adoption required a two-step process: (1) determination of the PCMH score and (2) categorization of the PCMH level. The first step used survey items from 2009 and 2010 NAMCS, which were compared and mapped to the 2008 NCQA PCMH guidelines so as to determine whether a practice was a medical home. Hollingsworth mapped NAMCS survey items to the NCQA rubric to estimate the extent to which a practice was recognized as a medical home.<sup>3</sup> Unlike Hollingsworth, we employed the most recent year to capture the PCMH adoption, while also adding the must-pass elements to define the level of PCMH and exploring additional relevant variables affecting the PCMH adoption. Extending this work, our study mapped 15 elements of the NCQA PCMH standards, representing seven standards in the 2009 NAMCS, and 15 elements of the NCQA PCMH standards, representing six standards in the 2010 NAMCS. Each practice received a “passed” (1=yes) point for each measurable element and a cumulative point total by summing points across all passed elements. A PCMH infrastructure score for each practice was calculated by dividing the cumulative points by the total number of available points. This number was expressed as a percentage. The maximum denominators for this score were 55 points and 60 points in the 2009 and 2010 NAMCS, respectively. The reason that 2009 and 2010 have different denominators is because some items were added and some were eliminated by the design of the survey. The detailed mapping technique is shown in Appendix E. Note that even though the PCMH scores were first calculated using visit-level data, these data were aggregated to practice level estimates by using appropriate practice-level weights.

The second step involved categorizing the percentage into the different levels of PCMH. Once the score for each practice was determined, each practice was assigned to an NCQA PCMH level of recognition, determined by the cut-off of cumulative points and numbers of

“MUST PASS” elements that each practice received, consistent with the NCQA PCMH guideline. The original NCQA PCMH guideline contained three levels of PCMH recognition including not accredited (less than 25% of total points), Level 1 (25 to 49 percent of the total points and 5 of 10 must-pass elements passed), Level 2 (59-74 percent of the total points and all 10 must-pass elements passed), and Level 3 (75 percent and more of the total points and all 10 must-pass elements passed). Because not all of the elements of the NCQA PCMH were captured in NAMCS, this study defined the classification of the NCQA PCMH level recognition as follows: not recognized (less than 25 percent of total points), Level 1 (25-49 percent of the total points and 2 out of 4 must-pass elements pass), Level 2 (50-74 percent of the total points and all 4 must-pass elements pass), and Level 3 (over 75 percent of the total points and all 4 must-pass elements pass). The comparison between the original NCQA PCMH criteria and the modified version based on NAMCS survey items is shown in Appendix E.

### ***Physician and Practice Characteristics***

In considering Roger’s diffusion of innovation theory and Hogg’s primary care model, five physician characteristics and six practice characteristics were selected to examine the level of PCMH adoption. Physician variables included age (less than 40/40-54/55-64/65 and over), gender (female/male), employment status (employee or contractor/owner), specialty (primary care/medical care/surgical care), and type (doctor of osteopathy/doctor of medicine). Practice-level characteristics focused on region (Northeast/Midwest/West/South), metropolitan status (Non-MSA/MSA), organizational structure (single/multi-specialty practices), organizational type

(public/private), ownership (physician group/ HMO or else), and size (solo/small group/medium group/large group).

## **Statistical Methods**

All analyses used appropriate NAMCS sampling weights to compute unbiased population estimates of the descriptive and regression parameters of interest. Codes in the NAMCS public-use data sets identifying sampling strata and sampling clusters were also employed in all analyses to compute appropriate design-based estimates of standard errors for the weighted estimates. Some variables were missing about 50% of their values, and multiple imputation by chained equations was used to provide more statistical power to analyze the relationships of interest.<sup>29</sup> These imputations generated five completed data sets with all missing values imputed based on other observed variables. The five completed sets of analyses were combined with the original data set to generate a final overall set of multiple-imputation estimates for each analysis.

Because the purpose of this study was to investigate adoption of PCMH at the practice level, the unit of analysis was practice and the practice-level estimates were used based on a previous paper published by NCHS.<sup>30</sup> Practice-level estimates were determined by dividing the physician sample weight by the number of physicians in the practice.<sup>29</sup> Physician estimates were also used for the description of physician characteristics. With the appropriate weights for different levels of estimates, the data can reflect accurate national practice or physician estimates.

Descriptive statistics were used to determine the proportion of practices that met NCQA PCMH criteria. Design-adjusted Rao-Scott chi-square tests were employed to test the bivariate

associations between the level of PCMH variable and physician characteristics. Two sets of analyses were conducted. Because of the exploratory nature of these analyses, a backward selection approach was used when fitting the regression models to determine the subsets of predictors having significant associations with the dependent variable. First, a multivariate logistic regression model was employed to quantify the associations between baseline physician and practice characteristics with adoption of any level of PCMH (not accredited versus Level 1, Level 2, and Level 3). Second, a multinomial logistic regression was fitted to study the associations among the four levels of PCMH classifications and baseline physician and practice variables, with “not accredited” specified as a reference category. A two-tailed *p*-value less than 0.05 indicated statistical significance. The *-svy-* commands in Stata version 13.0 were used for all analyses.

## **Results**

These estimates presented here are nationally representative, as appropriately weighted estimates and multiple imputation procedures were used. About 60% of all physicians were age 54 years or younger; nearly three-quarters were male (74.5%); 66% were owners; half (49.8%) were primary care physicians, and most (93.7%) held doctor of medicine degrees (Table 2.1). As to the practice characteristics, 36.4% of practices were in the South geographic region; most of the practices (88.6%) were located in a metropolitan area; almost all of the practice type was private (90.9%); the ownership of the practices were physician groups (84.9%), and slightly more than half of the practice sizes (56.5%) were solo or having fewer than 3 partners (Table 2.1).

More than half of the practices (54.3%) were classified as having some level of PCMH implementation, whereas less than half of the practices (45.7%) met none of the PCMH criteria (Table 2.2). A small number of physician characteristics varied by level of PCMH adoption including physician age, employment status, and specialty. Practice characteristics including organizational structure, and practice size also varied by level of PCMH adoption. As expected, for the practices with the highest accredited PCMH recognition, the reporting physicians were younger, with more employees or contractor status, identified as primary care physicians, and worked in multiple specialties as well as larger practices.

Results of a multinomial logistic regression considering the four specific levels of PCMH as the dependent variable are presented in Table 2.3. In general, three physician variables and one practice variable were associated with the adoption of PCMH. Female physicians were found to be less likely to adopt PCMH. The adjusted odds ratio (AOR) was statistically significant when comparing PCMH level 2 to the not accredited PCMH (AOR= 0.6; 95% CI, 0.43, 0.93). Being an older age physician (i.e., age 55 and over) was found to significantly decrease the odds of participation in the PCMH implementation. Physician specialty also was associated with the adoption of PCMH; in particular, being a primary care physician was found to significantly increase the odds of having a higher level of PCMH. As to practice characteristics, larger practices had statistically significant higher odds of adopting the PCMH model.

Table 2.4 displays the specific PCMH elements with four physician characteristics, including gender, age, employment status, and specialty individually. As shown, three out of seven PCMH elements had statistically significant differences in relation to gender: access and communication; offer advanced self-management support, and performance reporting and improvement. Female physicians received higher scores for the three PCMH elements. As to the



other characteristics, a clear pattern emerged where younger age physicians and employee/contractor physicians had significantly higher scores in most of the PCMH elements. The results also indicate that primary care physicians have higher scores than do medical or surgical physicians on the following elements: the elements of proving patient tracking and registry, offering better care management, and using electronic prescribing, and elevating test tracking.

## **Discussion**

The main contribution of this study is the examination of PCMH adoption on the basis of a composite PCMH measure and the exploration of associations in a large, representative sample of U.S. physicians. While previous studies have focused on practice characteristics and their associations with PCMH adoption<sup>3,4,5</sup>, this study is the first using national data to incorporate physician characteristics to examine the relationship with PCMH adoption. The results showed that PCMH adoption was influenced by physician characteristics (i.e., being female, being age fifty-five and younger, and being a primary care physician). The results of physician characteristics corresponded to previous studies using the diffusion of innovation theory that female physicians and older physicians were relatively slower to adopt innovative ideas in practices.<sup>7,8,9</sup> As to the physician specialty, this is the first study that demonstrated that primary care physicians were more likely affected by new ideas than other specialties. For the remaining covariates, larger practice size significantly increased the rate of PCMH adoption, and this result was similar to results reported by Hollingsworth Et al.<sup>3</sup>

The greater prevalence of PCMH adoption in 2010 is positive and may be greater than the overall prevalence conveys. Although the study followed an approach similar to that of Hollingsworth Et al., which mapped the 2008 NCQA PCMH guideline with the 2007 and 2008 NAMCS survey items, this study used the most recent data and employed more restrictive criteria by including four must-pass elements for evaluating the PCMH adoption.<sup>3</sup> Having the additional requirements with four must-pass elements, including whether a practice had enhanced access and communication, used electronic systems to take clinical notes, identified patient medication problem lists, and viewed lab results with out-of-range values highlighted, has significant implications. The present study showed that PCMH adoption (i.e., PCMH adoption rate was 54.3% in this study) was similar but more in-depth, as the distribution was shifted toward a higher level of adoption (level 2) versus a basic level of PCMH adoption (level 1) in the previous study (i.e., PCMH adoption rate in Hollingsworth was 54.0%).<sup>3</sup> In addition, the definition used in this study was stricter, suggesting greater adoption of PCMH.

The PCMH elements that were mapped in the NAMCS are important to note. The mapped items emphasized the importance of establishing electronic medical systems within practices. Specifically, 12 of 15 mapped items related to the adoption of PCMH variables were focused on EMR. This implies that fewer items in the PCMH adoption variables were related to other components of PCMH, such as coordination of care and team-based care. If other NCQA PCMH items could have been mapped, the estimate for PCMH adoption may have been affected. Overall, the adoption of PCMH still has room for improvement as 45% of practices were not identified as PCMH.

Diffusion of innovation theory suggests that characteristics differentiate individuals who adopt innovations earlier versus later.<sup>31,32,33</sup> However, this theory does not explicitly consider the

influence of external environments, such as practice infrastructure or organizational structure, which could also affect the adoption of innovations. With the combination of the Hogg's primary care model, this study can more comprehensively explain the factors that affect the rate of PCMH adoption from four perspectives. First, this study found that older physicians lagged in their adoption of PCMH in their practices. This finding is consistent with previous research that applied diffusion of innovation theory to explain the adoption of electronic medical systems and to investigate physicians' support of recent health care reform,<sup>8,34</sup> where older physicians lagged behind their younger counterparts in the adoption of innovation.

Second, the results of this study showed that gender plays a significant role in PCMH adoption. In particular, male physicians were more likely to adopt the PCMH model, and this result aligns with previous studies showing that male physicians favored new medication treatments or other novel interventions, whereas female physicians were relatively conservative, spending more time on patient counseling and ordering laboratory tests for their patients.<sup>12,35</sup> The authors of each study suggest that male physicians might be more confident than female physicians to initiate new medical treatments. Other studies have also supported findings of gender disparity in clinical decision-making.<sup>36</sup> Whether female physicians are indeed more conservative in the case of PCMH adoption is still debatable since the PCMH is not a completely new concept. The PCMH model blends both traditional attributes of primary care (i.e., first contact access, comprehensiveness of care, integration/coordination of care, and continuity of care) and new approaches (i.e., organizing practice and development of practices' internal capabilities) of healthcare delivery.<sup>37</sup> Ottmar Et al. showed that female family physicians were more likely to review patient records and contact patients to invite them in for care (i.e., population management).<sup>38</sup> In the present study, the sub-analysis also demonstrated that female

physicians obtained better scores in four of the NCQA PCMH elements, including enhancing access and communication, offering better care management and advanced self-management support, elevating test tracking, and performing reports and improvements. However, the composite measure of PCMH adoption included 15 items and the overall scores were cumulative. Therefore, the final multinomial logistic regression suggested that male physicians may be more capable of practice transformations (e.g., using the electronic medical systems), but female physicians were more focused on comprehensive care for patients.

Third, with respect to physician types, the results of this study provided interesting findings, wherein primary care physicians were more likely to adopt PCMH than surgical care or medical care physicians. From a policy perspective, primary care practices have been targeted by payers to implement PCMH, so this finding is not surprising.<sup>3,39,40,41</sup> However, these findings are inconsistent with three earlier studies that showed physician specialty was not associated with practices' adoption of either electronic medical systems or PCMH.<sup>3,13,42</sup> Hollingsworth's study, which investigated the adoption of PCMH, showed that physicians who resided in multi-specialty practices had a greater rate of PCMH adoption than those in single-specialty practices. One explanation for the inconsistent findings is that this current study included more physician demographic characteristics than previous studies. This study included age and gender while Hollingsworth Et al. did not. To the extent, that age and gender may be confounded with specialty, e.g., specialty physicians may be older and more likely to be male, the inclusion of age and gender in this analysis allows the effect of specialty to be quantified independently. Additionally, previous studies also indicated that compared to specialist physicians, primary care physicians have more knowledge and awareness of patient-centered care; therefore, it may be easier for them to accept the PCMH concept and apply this model in their regular daily care.<sup>43</sup>

Last but not least, the results are consistent with previous studies in terms of practice size.<sup>3,39</sup>

This study found clear evidence that larger practices were more likely to adopt PCMH, and this is anticipated as larger practices may have more capacity to accommodate the PCMH adoption.

The findings of this study should be evaluated in light of certain limitations. First, the NAMCS is a cross-sectional survey, but the data provides national estimates of PCMH adoption, extending previous studies that had a regional focus. Second, physician factors were limited to demographic characteristics; the NAMCS does not include questions focused on attitudes, intentions, beliefs, or motivation of physicians. Therefore, we cannot evaluate the adoption of PCMH from physicians' attitudinal perspectives. Previous studies using a qualitative approach or surveys showed that physicians' decisions to pursue NCQA PCMH recognition program were mainly determined by financial incentives.<sup>44</sup> Although we cannot assess physicians' intentions toward financial incentives for adopting the PCMH, we provide more generalizable results to identify physician factors that were associated with the adoption of PCMH at a national level in the United States.

Third, the study relied on self-reported information, as NAMCS is a physician/office-reported survey. Despite this limitation, the results reflect the most up-to-date PCMH adoption scenario at the national level. Finally, the inability to capture all the NCQA PCMH elements in NAMCS is another concern. Because the survey questions in NAMCS cannot perfectly map onto the NCQA PCMH elements, the raw scores and level of PCMH adoption was refined based on the limited data. The approach used in this study was conservative, using the most must-pass criteria as possible for the available data. Furthermore, the measure of PCMH adoption emphasized the implementation of EMR. This systematic error of measuring the composition of PCMH may not reflect all the significant components of PCMH. This mapping approach was

consistent with previous research and used all available data in NAMCES so that national estimates could be determined.

As policymakers and stakeholders work to stimulate PCMH adoption in today's healthcare delivery system, the exploration of how to increase this uptake is important. Policy makers may consider promoting PCMH adoption among physicians with the identified characteristics. For example, policy makers should target older and female physicians who are more likely to resist adapting to new transformative care for patients. Furthermore, health policy makers should keep in mind that the transformation of practices cannot be completed quickly. This process requires the cooperation of practices and time for physicians to change their clinical behaviors. For physician practices, adoption of the model may require them to give more authority to non-physician professionals to care for their patients. For example, one previous study has shown that physicians can transfer the authority for handling chronic medication management to medication professionals such as pharmacists, allowing the physicians to work on more acute and/or serious patient concerns.<sup>45</sup> Additionally, the incorporation of other non-physician professionals may also mitigate the estimated shortage of primary care physicians.<sup>46</sup> It is also important to educate physician students/trainees about the importance of both collaborative work with other non-physician professionals and the adoption of new practice innovations such as PCMH.

In terms of future work, important changes to the questions in NAMCS will provide additional opportunity to continue to study the adoption of PCMH.<sup>47</sup> Questions specifically asking the whether the practice is certified as a patient-centered medical home and what types of non-physician professionals are on staff at the office location were added in the 2013 survey, providing an important opportunity to study the uptake of non-physician personnel into physician

practices. In addition, the findings from this study suggest that the interaction between physician age and practice size or physician gender and practice size are two important interaction effects that future studies could consider.

## **Conclusion**

An estimated 54% of physician practices in the United States have adopted some aspect of PCMH, and 12% have achieved Level 3 status according to NCQA PCMH accreditation standards, given data that are available in the NAMCS. Several characteristics of physicians were associated with PCMH adoption. Consistent with the diffusion of innovation framework, physicians who are female, older, and specialists were less likely to adopt PCMH into their practices. Physicians working in larger practices were also more likely to adopt PCMH.

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Table 2.1 Weighted Multiple Imputation Estimates of Physician and Practice Characteristics (n=15,468)<sup>1</sup>

Physician Characteristics <sup>2</sup>		Practice Characteristics <sup>3</sup>	
	% [95 % C.I.]		% [95 % C.I.]
Physician Age		Practice Region	
Less than 40	13.0 (11.3-14.6)	Northeast	20.8 (17.4-24.2)
40-54	46.7 (44.2-49.1)	Midwest	19.4 (17.0-21.8)
55-64	28.7 (26.6-30.8)	West	36.4 (33.3-39.5)
65 and Over	11.7 (10.2-13.2)	South	23.4 (20.8-26.1)
Physician Gender		Practice Metropolitan Status	
Female	25.5 (23.3-27.6)	Non-MSA	11.4 ( 7.7-15.1)
Male	74.5 (72.4-76.7)	MSA	88.6 (84.9-92.3)
Employment Status		Organizational Structure	
		Single Specialty Practice	
Employee/Contractor	33.8 (31.0-36.6)		31.6 (29.2-34.0)
Owner	66.2 (63.4-69.0)	Multi Specialty Practice	11.9(10.5-13.3)
Physician Specialty		Solo	56.5 (53.7-59.3)
Primary Care	49.8 (48.8-51.9)	Practice Type	
Medical Care	28.9 (27.2-30.7)	Public	9.1( 7.8-10.5)
Surgical Care	21.2 (19.6-22.8)	Private	90.9(89.5-92.2)
Physician Type		Practice Ownership	
Doctor of		Physician Group	
Osteopathy	6.3 ( 5.4- 7.3)		84.9 (82.9-87.0)
Doctor of Medicine	93.7 (92.7-94.6)	HMO/Else	15.1 (13.0-17.1)
Interviewed Year		Practice Size	
2009	50.7 (48.4-52.9)	Solo/Partner	56.5 (53.7-59.3)
2010	49.3 (47.1-51.6)	Small Group (3-5)	23.9 (21.6-26.2)
		Medium Group (6-10)	13.5 (12.0-15.0)
		Large Group (+11)	6.1( 5.1- 7.0)

(Source: 2009-2010 NAMCS restricted data)

<sup>1</sup> Based on the results of a multiple imputation analysis with M=5 imputed datasets

<sup>2</sup>.Based on physician sample weight

<sup>3</sup>.Based on practice weight = (Physician sample weight)<sub>ij</sub>/S<sub>ij</sub>, Where S<sub>ij</sub> = number of physicians within practice j reported by physician i (Hing, 2007)



Table 2.2 Weighted Multiple Imputation Estimates of Bivariate Associations Between Physician and Practice Characteristics and Level of PCMH

	Not Accredited n=179,694 (45.7%)	PCMH Level 1 n=75,637 (19.2%)	PCMH Level 2 n=90,313 (22.9%)	PCMH Level 3 n=47,984 (12.2%)	p <sup>1</sup>
Physician Age					<0.01
Less than 40	9.1	12.0	15.7	19.1	
40-54	40.7	48.8	49.9	53.7	
55-64	31.9	29.0	27.5	22.2	
65 and Over	18.3	10.2	6.9	5.0	
Physician Gender					0.05
Female	24.0	26.7	23.0	32.3	
Employment Status					<0.01
Employee/Contractor	23.7	31.8	40.0	51.6	
Owner	76.3	68.2	60.0	48.4	
Physician Specialty					<0.01
Primary Care	42.0	47.4	49.8	73.5	
Medical Care	34.0	25.8	29.8	18.0	
Surgical Care	24.0	26.8	20.4	8.4	
Physician Type					0.49
D.O.	8.0	5.1	4.8	6.3	
M.O.	92.0	94.9	95.2	93.7	
Interviewed Year					<0.00
2009	54.1	52.2	52.1	37.2	
2010	45.9	47.8	47.9	62.8	
Practice Region					0.05
Northeast	21.5	24.0	17.0	20.1	
Midwest	18.4	21.5	20.6	17.7	
West	38.6	32.6	38.6	30.0	
South	21.5	21.9	23.9	32.2	
Metropolitan Status					0.62
Non- MSA	10.1	14.9	11.0	11.4	
MSA	89.9	85.1	89.0	88.6	
Organizational Structure					<0.01
Single Specialty	24.2	32.1	40.2	42.4	
Multi Specialty	6.6	10.2	19.1	20.7	
Solo	69.2	57.6	40.7	36.9	
Practice Type					<0.01
Public	5.3	7.1	12.6	20.5	
Private	94.7	92.9	87.4	79.5	
Practice Ownership					<0.01
Physician Group	91.2	86.5	76.9	74.3	
HMO/ Else	8.8	13.5	23.1	25.7	
Practice Size					<0.01
Solo/Partner	69.2	57.6	40.7	36.9	

Small Group (3-5)	19.7	23.2	29.2	30.8
Medium Group (6-10)	8.6	12.8	19.2	22.0
Large Group (11 +)	2.4	6.4	10.8	10.3

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(Source: 2009-2010 NAMCS restricted data)

Note. <sup>1</sup> p-values correspond to Rao-Scott chi-square test statistics

Table 2.3 Weighted Multiple Imputation Estimates of Adjusted Odds Ratios (AOR) and Design-Based 95% CIs for the Multinomial Logistic Regression Model for Factors Associated with Different Levels of PCMH

	PCMH Level 1			PCMH Level 2			PCMH Level 3		
	AOR	95 % CI	p-value	AOR	95 % CI	p-value	AOR	95 % CI	p-value
<b>Physician Characteristics</b>									
Physician Gender (referent: Male)									
Female	0.9	0.63-1.35	0.68	0.6	0.43-0.93	0.02	0.7	0.44-1.06	0.09
Physician Age Group (referent: age less than 55)									
55 and Over	0.7	0.49-0.95	0.02	0.6	0.42-0.79	0.00	0.4	0.24-0.59	<0.01
Employment Status (referent: Employee or Contractor)									
Owner	0.7	0.43-1.06	0.09	0.9	0.58-1.32	0.52	0.7	0.45-1.16	0.18
Physician Specialty (referent: Surgical Care)									
Primary Care	1.0	0.66-1.38	0.80	1.5	1.06-2.10	0.02	4.4	2.53-7.49	<0.01
Medical Care	0.7	0.46-0.98	0.04	1.1	0.74-1.55	0.72	1.5	0.73-2.92	0.28
<b>Practice Characteristics</b>									
Practice Region (referent: Northeast)									
Midwest	0.9	0.55-1.52	0.74	1.1	0.71-1.79	0.61	0.7	0.40-1.37	0.33
South	0.7	0.45-1.15	0.17	1.2	0.77-1.86	0.42	0.7	0.39-1.38	0.34
West	0.9	0.54-1.43	0.60	1.3	0.79-2.22	0.28	1.3	0.78-2.30	0.28
Practice Ownership (referent: Physician or Physician Group)									
HMO or Else	0.9	0.54-1.64	0.84	1.7	0.90-3.11	0.10	1.1	0.53-2.21	0.83
Practice Type (referent: Public)									
Private	1.0	0.64-1.59	0.98	0.8	0.48-1.46	0.53	0.4	0.19-1.02	0.06
Practice Size (referent: Solo/Partner)									
Small Group (3-5)	1.2	0.83-1.71	0.35	2.1	1.46-3.07	0.00	2.2	1.34-3.50	<0.01
Medium Group (6-10)	1.4	0.96-2.09	0.08	3.0	2.03-4.32	0.00	3.0	1.81-4.86	<0.01
Large Group (11 +)	2.6	1.62-4.14	<0.01	5.7	3.65-8.94	0.00	4.9	2.73-8.67	<0.01

Note: Baseline outcome category: Not accredited PCMH

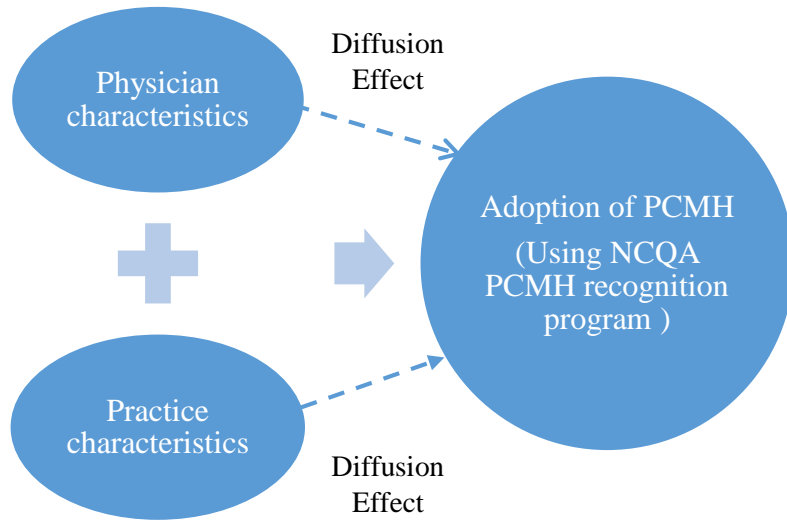
Table 2.4 Primary Care Practice Attainment of Individual NCQA Elements, Stratified by Physician Characteristics

NCQA Elements	Physician Gender			Physician Age Category		
	Male	Female	p-value	less than 55	55 and over	p-value
<b>Enhance access and communication</b>						
Allow same day appointments	61.1	69.1	<0.00	65.6	59.5	0.03
<b>Improve patient tracking and registry</b>						
Has system for managing patient data	80.2	81.7	0.51	84.0	75.4	<0.00
Has electronic system for clinical data	51.6	52	0.89	58.8	41.3	<0.00
Use electronic clinical data	50.6	45	0.06	53.3	43.1	<0.00
Able to organize clinical data	52.8	50.9	0.49	59.8	41.3	<0.00
Identify patient important diagnosis/conditions	46.6	46.1	0.86	51.8	38.7	<0.00
Track patient medication lists	50.5	53.1	0.48	58.8	39.7	<0.00
<b>Provide better care management</b>						
Has preventive services reminders	37.2	42.1	0.07	44.0	30.3	0.00
Has other non-physician assistance	29.9	26.3	0.21	30.7	26.3	0.08
Visits patients besides outpatient visits	54.9	61.3	0.02	55.9	57.6	0.48
<b>Offer advanced self-management support</b>						
Provide health education	41.4	49.4	<0.00	44.9	41.4	0.15
<b>Prescribing electronically</b>						
Has computerized systems for prescribing	49.4	50.6	0.68	55.1	41.7	<0.00
Prescribing with warning signs	39.4	42.2	0.29	45.4	32.3	<0.00
<b>Elevate test tracking</b>						
Has out-of-range levels highlighted	44.5	49.7	0.07	50.2	39.4	<0.00
System sends tests electronically	30.2	35.4	0.05	36.3	24.3	<0.00
Can view the results electronically	55.6	58.9	0.25	62.2	48.0	0.04
<b>Performance reporting and improvement</b>						
Has electronic public health report	15.6	23.6	0.01	17.2	11.3	0.04

Continue

NCQA Elements	Employment Status			Specialty			
	Employee/Contractor	owner	p-value	Primary care	Surgical	Medical	p-value
<b>Enhance access and communication</b>							
Allow same day appointments	67.8	59.0	<0.00	79.0	46.3	43.4	<0.00
<b>Improve patient tracking and registry</b>							
Has system for managing patient data	86.7	71.8	<0.00	77.1	81.3	69.1	0.10
Has electronic system for clinical data	61.7	39.8	<0.00	49.7	43.1	39.9	0.05
Use electronic clinical data	57.6	37.1	<0.00	42.1	51.2	36.1	0.01
Able to organize clinical data	61.8	39.9	<0.00	46.4	47.2	42.5	0.79
Identify patient conditions	55.2	36.2	<0.00	45.1	39.8	35.4	0.11
Track patient medication lists	63.8	35.1	<0.00	47.1	36.9	40.7	0.04
<b>Provide better care management</b>							
Has preventive services reminders	43.8	29.6	<0.00	40.4	27.5	25.8	<0.00
Has other non-physician assistance	34.7	24.0	<0.00	32.0	23.4	20.5	0.01
Visits patients besides outpatient visits	52.9	60.4	0.01	65.8	50.8	52.4	<0.00
<b>Offer advanced self-management support</b>							
Provide health education	46.6	42.9	0.14	46.7	32.7	47.1	<0.00
<b>Prescribing electronically</b>							
Has computerized systems for prescribing	56.5	37.8	<0.00	47.2	37.1	38.7	<0.00
Prescribing with warning signs	46.7	29.2	<0.00	39.2	23.8	31.6	<0.00
<b>Elevate test tracking</b>							
Has out-of-range levels highlighted	55.2	34.7	<0.00	47.3	30.0	34.9	<0.00
System sends tests electronically	38.9	22.0	<0.00	33.9	17.6	20.2	<0.00
Can view the results electronically	65.8	44.1	<0.00	55.7	45.1	42.7	<0.00
<b>Performance reporting and improvement</b>							
Has electronic public health report	24.3	11.5	<0.00	21.1	10.0	6.8	<0.00

Figure 2.1. Proposed Theoretical Framework



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**CHAPTER III. PAPER 2: DOES THE EXTENT OF PATIENT CENTERED MEDICAL  
HOME ADOPTION REDUCE THE USE OF INAPPROPRIATE MEDICATION  
AMONG OLDER ADULTS?**

**Introduction**

Almost one-half of the U.S. population takes at least one prescription medication, leading to nearly \$326 billion in prescription sales.<sup>1</sup> It is critical to ensure the appropriateness of medications so that adverse events can be minimized. A medication is considered inappropriate if the risk of harm from the medication is judged to outweigh the potential clinical benefit after considering the patient's clinical circumstances.<sup>2</sup> Moreover, previous studies indicate that one in five prescriptions ordered in the primary care setting in the United States is considered inappropriate.<sup>3</sup> This high prevalence of inappropriate medication use suggests a high likelihood of poor medication quality of care, which is a major public health concern.<sup>4,5</sup> The inappropriate use of medications may lead to serious medical consequences that place a substantial economic burden on our health care system. Evidence for this is provided by studies revealing that on average \$7.2 billion in healthcare expenditures is associated with inappropriate medication use among older adults age 65 and older each year. Further, nearly 17% of U.S. emergency room visits are related to at least one potentially inappropriate medication (PIM).<sup>6</sup>

Apart from the economic burden, appropriate medication prescribing and use is especially critical among adults, given that nearly 40% of adults age 65 and over reported being on five or more medications.<sup>7</sup> Evidence shows that greater numbers of medications are associated with a greater risk of having a potentially inappropriate medication (PIM).<sup>3</sup> PIM is defined as medications that are deemed potentially harmful to the elderly population. The growing concern about PIM has caused both the Federal government and quality organizations to address medication quality of care through the development of national action plans as well as establishing standardized medication indicators. For example, the National Action Plan for Adverse Drug Event Prevention aims to promote and coordinate Federal resources to prevent adverse drug events (ADEs), which are associated with PIMs.<sup>8</sup> Similarly, medication indicators, such as the use of high-risk medications and the potentially harmful drug-disease interactions, have been developed in the Healthcare Effectiveness Data and Information Set (HEDIS) for stakeholders to evaluate the appropriateness of medication use.<sup>9</sup> In fact, previous studies have demonstrated that several PIM medication indicators (e.g., Beers criteria, Zhan criteria, and HEDIS) can serve as proxies to evaluate the quality of appropriate medication use in various settings and populations.<sup>10-14</sup> These studies have not only reported the prevalence of PIM, but also examined the associated factors.<sup>15-19</sup> These studies have focused on patient characteristics, revealing that being female, older age, poorer health condition, poorer health literacy, greater number of chronic diseases, greater number of medications, greater number of visits, greater number of prescribers, and living in the south region were more likely to be associated with PIM. Although patient factors are not the only predictors of PIM, a few studies have examined structural characteristics, such as practice size and type. These studies have shown that physician characteristics also affect the occurrence of PIM, including physicians residing in solo practice,

and those identified as geriatric specialties, older age, and being female.<sup>19,20</sup> Indeed, the cause of PIM can be attributed to prescribing behaviors among providers and the types of practices in which patients reside. Surprisingly, no studies have considered the occurrence of PIM within the context of healthcare reform, which has introduced new models of integrated healthcare delivery and promised improved quality of care. One such model is the Patient-Centered Medical Home (PCMH).

The PCMH is defined as a transformative and innovative model, aiming to provide comprehensive, patient-centered, team-based, accessible and coordinated primary care with a focus on systems-based quality and safety improvement.<sup>24,25</sup> By adopting the PCMH model, practices are expected to increase access to care, improve the quality of delivered care and reduce overall health care expenditures.<sup>26</sup> The NCQA PCMH standards and guidelines are the most widely used voluntary program to assess primary care practices as medical homes in the current literature.<sup>27</sup> Importantly, these guidelines have been used in several national PCMH projects.<sup>28</sup> The NCQA PCMH guideline program identifies three levels of PCMH attainment, as measured by a complex scoring rubric, to evaluate the extent to which a practice adopts a PCMH approach to care. When the level of achievement is high, the practice has a relatively more comprehensive care environment and is expected to offer a better quality of care, reduced cost of care, enhanced experience of care and better professional experience.<sup>29</sup> Thus, the level of PCMH adoption should be related to the quality of care, as assessed by a variety of processes and outcomes of care. Process indicators for medication use quality may include those specified by the HEDIS, such as routine high blood pressure checking, HbA1C, LDL-C and persistent medication monitoring among patients with diabetes.<sup>30,31</sup> Along with these types of process

indicators, outcome indicators, such as diabetes outcome measures, are also recommended by the Commonwealth Fund to evaluate PCMH adoption among practices.<sup>32</sup>

Several studies of PCMH have demonstrated that the integration of non-physician professionals, such as pharmacists, can strengthen the PCMH. This is because pharmacists provide a range of critical services, including medication management (e.g. Medication Therapy Management, or Collaborative Drug Therapy Management), which are essential to improve medication quality of care.<sup>33,34</sup> There are mixed results supporting the impact of PCMH, and the potential benefits of PCMH in relation to appropriate medication use remain largely unexplored. It is important to consider appropriate medication use in the context of PCMH adoption, as medications are the mainstay of treatment in primary care, and pharmacists may be able to improve medication management among patients with chronic diseases such as diabetes and hypertension.<sup>35</sup> No study has examined the value of adopting PCMH on the quality of patient medication use.

To address these gaps in knowledge, the objective of this study was to explore the association between the PCMH adoption and its impact on PIM among older adults. In order to evaluate the extent to which a practice may impact medication use, this study employed features of the NCQA PCMH recognition program and used a nationally representative database. Two medication indicators were selected to represent the extent of PIM associated with a patient visit, including the use of high-risk medications (HRM) and potentially harmful drug-disease interactions (DDIS), which are expected to be lower in prevalence for practices with higher levels of PCMH adoption.

## Methods

### Study Design and Data Sources

In this retrospective study, the extent of PCMH adoption was the exposure variable and inappropriate medication use was the outcome. Data for this study came from the National Ambulatory Medical Care Survey (NAMCS). The NAMCS is a nationally representative, multistage probability sample survey, which was originally created by the National Center for Health Statistics (NCHS), Centers for Disease Control and Prevention. The NAMCS is designed to provide objective, reliable information about the provision and use of ambulatory medical care services among patients of all ages in the United States. The data in the survey are weighted to produce national estimates of the utilization of ambulatory services. All of the responses in the NAMCS are based on a sample of visits to non-federally employed office-based physicians who are primarily engaged in direct patient care.

The NAMCS randomly selects those physicians, assigns them to one of 52 weeks in a year, and expects them to report information on a systematic random sample of patients treated during their assigned week.<sup>36</sup> For the sampling, the NAMCS utilizes a multistage probability sample design that involves 3 stages: (1) sampling of geographic locations (or primary sampling units [PSUs]), (2) sampling of physician practices within sampled geographic locations (stratified by physician specialty), and (3) sampling of visits within sampled physician practices.

Patient, clinical, physician, and practice information are collected for each selected visit and then recorded on patient record forms by participating physicians or office staff. This study included data from surveys conducted in 2009 and 2010, which are the most recently released publicly available NAMCS data. Each patient visit recorded up to 8 medications prescribed,



administered, injected or provided. The patient visit was the unit of analysis. Patient visits were in scope if the patient was aged 65 and over and without any medication records, based on HEDIS criteria.<sup>9</sup> This study was declared exempt by the Institutional Review Board of the University of Michigan.

## **Measures**

### ***Determining Level of PCMH Adoption***

To designate levels of PCMH adoption in the NAMCS, this study builds on a calculation method reported in Hollingsworth Et al. that mapped the 2009 and 2010 NAMCS survey items to the 2008 NCQA PCMH guidelines so as to designate a practice as a medical home.<sup>37</sup> We further advanced their work to generate a stricter PCMH recognition calculation method by adding the must-pass elements to define the level of PCMH, and examined the relationship of level of PCMH adoption with the extent of PIM prescribing.

The original NCQA PCMH guidelines contain nine standards with thirty subsumed elements, and for each element “passed”, specific points are awarded. Among the thirty elements, ten were designated as “MUST PASS” elements for the purpose of categorizing different levels of PCMH.<sup>38</sup> Using survey items from the 2009-2010 NAMCS, we mapped the 2008 NCQA PCMH guideline elements for medical home recognition. This approach allowed for the derivation of nationally representative estimates of the proportion of practices that qualify as medical homes. Due to the frequent changes of NAMCS instruments, we mapped 15 elements of the 2008 NCQA PCMH standards, representing seven and six standards for the 2009 and 2010

NAMCS items individually. The unit of observation in NAMCS is patient visit. The level of PCMH adoption for each visit was determined by using the practice characteristic variables in each visit record, and the PCMH scores will be the same for the visits from the same practice. Each visit received a “passed” (1=yes) point for each measurable element and a cumulative point total by summing points across all passed elements. A PCMH infrastructure score was calculated by dividing the cumulative point total by the total number of available points, expressed as a percentage. The maximum denominators for this score were 55 points and 60 points in 2009 and 2010, respectively. The reason that 2009 and 2010 have different denominators is because some items were added and some were eliminated for those years. The detailed mapping technique is shown in Appendix E.

Once the score for PCMH adoption was determined, the score was assigned to an NCQA PCMH level of recognition, determined by a cut-off of cumulative points and numbers of “MUST PASS” elements, consistent with the NCQA PCMH guidelines. In the original NCQA PCMH guidelines, there were three levels of PCMH recognition: not accredited (fewer than 25 percent of total points), Level 1 (25 to 49 percent of points and a pass on 5 of 10 MUST PASS elements), Level 2 (59-74 percent of total points and a pass on all 10 MUST PASS elements), and Level 3 (points more than 75 percent and a pass on all 10 MUST PASS elements). Because not all elements of the NCQA PCMH were included in the NAMCS, this study defined the classification of the NCQA PCMH level recognition as follows: not recognized (fewer than 25 percent of total points), Level 1 (25-49 percent of total points and a pass on 2 out of 4 MUST PASS elements), Level 2 (50-74 percent of total points and a pass on all 4 MUST PASS elements), and Level 3 (over 75 percent of total points and a pass on all 4 MUST PASS elements). The comparison between original NCQA PCMH criteria and the modified version

based on NAMCS survey items is shown in Appendix E.

### *Defining Potentially Inappropriate Medications*

The outcomes for this study were two age-appropriate medication quality of care indicators (1 = yes, 0 = no) coded for each visit, including (1) the use of high-risk medications (HRM) and (2) potentially harmful drug-disease interactions (DDIS), which were both defined by NCQA for HEDIS. The prevalence of HRM was measured as the proportion of patient visits where the record designated an individual age 65 and over and received at least one medication which was on a list of medications to be avoided.<sup>9</sup> To identify whether older adult visits in NAMCS involved exposures to any HRM medications, the Multum drug codes were employed to match the medication lists in NAMCS with the high risk medication lists provided by NCQA. DDIS prevalence was measured as the proportion of patient visits where the record contained information about the individual that indicated a diagnosis of dementia (ICD-9-CM codes 290, 294, 331, and 046), falls (ICD-9-CM codes 226, 340, 820, and 821), or chronic renal failure (ICD-9-CM codes 585), and a contraindicated medication for any of these diagnoses.<sup>21</sup> The contraindicated medication groups included: (a) dementia: high anticholinergic agents (i.e., gastrointestinal antispasmodics, skeletal muscle relaxants), (b) fall/ hip fractures: tricyclic antidepressants, conventional or atypical antipsychotics, and specific sleep agents (e.g., zolpidem), and (c) chronic kidney disease: nonsteroidal anti-inflammatory drugs (NSAID). These two outcome measures were coded for each visit as two dummy variables (0 = no, 1 = yes) and were used to represent the extent of PIM, which was expected to be lower for practices with higher levels of PCMH adoption.

### *Other Covariates*

This study focused on examining the impact of transforming traditional care to PCMH (i.e., process of care) on medication quality (i.e., outcomes) based on the proposed theoretical model (i.e., the Wagner's chronic care model and the Hogg's primary care organization model). Yet, patient individual characteristics and other structure elements needed to be considered.

Based on the previous HRM and DDIS related literature, patient individual-level characteristics played significant roles on the exposure of inappropriate medication use.<sup>4,5,6</sup> Therefore, variables including (1) age, (2) gender (female/male), (3) race (White/Black/Other), (4) number of chronic diseases (sum of fourteen chronic conditions including arthritis, asthma, cancer, cerebrovascular disease, chronic renal failure, congestive heart failure, chronic obstructive pulmonary disease, depression, diabetes, hyperlipidemia, hypertension, ischemic heart disease, obesity, osteoporosis), (5) number of medications (sum of up to 8 listed medications), (6) number of past visits within the last year, (7) household income in patient's zip code, and (8) primary expected source of payment for the visit (Private insurance /Medicare/Medicaid/Others) were included.

Since the modified theoretical model considered practice organizational structure into account for its influence on outcome, several system-level covariates were included in this study. These variables included (1) practice type (Solo/Non Solo), (2) practice region (Northeast/South/West/Midwest), (3) practice metropolitan status (Metropolitan Statistical Area/non-Metropolitan Statistical Area), (4) physician specialty group (Primary care specialty/Surgical care specialty/Medical care specialty), (5) employment status of physician (Owner/Employee/Contractor), and (6) type of physician (Doctor of Medicine/Doctor of Osteopathy).

## Statistical Methods

All analyses used appropriate NAMCS sampling weights to compute unbiased population estimates of the descriptive and regression parameters of interest. Codes in the NAMCS public-use data sets identifying sampling strata and sampling clusters were also employed in all analyses to compute appropriate design-based estimates of standard errors for the weighted estimates. Some variables were missing about 50% of their values, and multiple imputation by chained equations was used to provide more statistical power to analyze the relationships of interest.<sup>39</sup> These imputations generated five completed data sets with all missing values imputed based on other observed variables. The five completed sets of analyses were combined with the original data set to generate a final overall set of multiple-imputation estimates for each analysis.

Design-based Rao-Scott Chi-square tests and Wald tests were employed to test the bivariate associations between the dichotomous outcomes (high risk medication use and DDIS) and patient/provider characteristics. Design-based multivariate logistic regression models were used to examine the associations between PCMH adoption and the use of inappropriate medication, controlling for the aforementioned covariates. An investigation of interaction between patient age and number of medication uses was employed as an exploratory analysis. The Archer–Lemeshow goodness-of-fit tests were used to assess the fits of the logistic regression models in each of the five imputed data sets.<sup>40</sup> All data management and analysis was conducted using Stata (Version 13.0), and the Stata code used is available upon request.

## Results

The NAMCS data provide information for a total of 63,150 sampled outpatient clinic visits, which are representative of approximately two billion ambulatory visits between 2009 and 2010. Of these visits, 13,156 outpatient clinic visits met the selection criteria, namely patients being 65 and over and prescribed at least one medication at the outpatient visit. This sample provides population estimates for 432 million outpatient visits from 2009 to 2010 for the target population. Nearly 11% (95% confidence interval [CI] = 10.0% to 12.4%) of the visits in the target population involved prescription of an HRM. Approximately 15% (95% CI = 15.8% to 25.5%) of the visits in the target population with specific diseases indicated involved exposure to drug-disease interactions. The characteristics of the target population of visits, those with HRM, and those with DDIS are reported in Table 3.1. Based on this sample of 13,156 visits, an estimated 58% (95% CI = 53.2% to 62.8%) of visits in the target population occurred in practices without any PCMH accreditation. For the visits associated with HRMs and DDIS, the rate of occurrence in practices without any PCMH accreditations was 53% (95% CI = 46.6% to 59.4%) and 55 % (95% CI = 40.0% to 71.0%), respectively. The rates of HRM-associated and DDIS-associated visits were particularly higher for visits when patient gender was female with lower household income and private insurance, when the visit was to a solo practice, and when the visit was conducted by primary care physicians.

For HRM, the 10 most frequent medications were (in descending order): Acetaminophen-Propoxyphene Napsylate, Conjugated estrogens, Nifedipine, Cyclobenzaprine, Diazepam, Nitrofurantoin macrocrystals, Diphenhydramine, Thyroid desiccated, Hydroxyine hydrochloride, and Dicyclomine. For DDIS, Quetiapine with fall or fracture was the most common combination documented in the patient visits, followed by (medication/condition) quetiapine (Dementia), zolpidem (Fall/Hip fracture), cyclobenzaprine (Dementia), naproxen

(CKD), olanzapine (Fall/Hip fracture), oxybutynin (Dementia), ibuprofen (CKD), risperidone (Fall/Hip fracture), and celecoxib (CKD) (Tables 3.2 and 3.3). For HRM, most of the listed medications were identified as continued ones, whereas three out of ten DDIS medication were newly administered.

The multiple imputation estimates of bivariate associations between level of PCMH, other covariates, and use of HRM during a patient visit demonstrated that patient age (younger than 75), gender (female), race (black), number of medications used (greater), income (lower), region (residence in South), and physician specialty (seen by primary care doctor) were significantly associated with a higher risk of HRM (Table 3.4). For the DDIS-related visits, the results of the Wald tests showed that number of chronic conditions (less) and number of medications used (greater) were statistically associated with higher risk of DDIS during a patient visit.

The final multiple imputation estimates of logistic regression models with adjusted odds ratios (ORs) for HRM and DDIS are presented in Table 3.5. The level of PCMH was not associated with the odds of the patient visit involving HRM when adjusting for the other covariates.

However, for the HRM model, visits where the gender was female ([OR]=2.00, [95% CI]=1.64-2.43), had more past visits ([OR] =1.02, [CI] =1.00-1.03), had more medications ([OR] =1.26, [CI] =1.20-1.32), lived in the southern region ([OR] =1.59, [CI] =1.06-2.39), and was seen by primary care physicians ([OR]=1.27, [CI]=1.05-1.53) were significantly more likely to involve HRMs. Visits with age being younger ([OR] = 0.98, [CI] =0.97-0.99) and with more than two coexisting chronic conditions ([OR] =0.62, [CI] =0.48-0.80) were significantly less likely to involve HRMs.

For the logistic regression for DDIS-related visits, the level of PCMH was not associated with the odds of the patient visit involving DDIS. The odds of receiving DDIS medications

increased for each additional medication use by a factor of 1.27 ([OR] =1.27, [CI] =1.12-1.45), or decreased for those patients visits reported having two and more chronic conditions with an OR of 0.23 ([OR] =0.23, [CI]=0.08-0.67). The fits of the two logistic regression models were assessed using the Archer–Lemeshow goodness-of-fit test for each of the five imputed data sets. The range of goodness-of-fit test statistics for the HRM and DDIS models suggested that the fits were good in each imputed data set, with the range of p-values always greater than 0.05.

Sensitivity analyses were conducted to assess whether different definitions of outcomes, PCMH categorizations, and physician types substantially changed the predictive models. Specifically, we redefined and reran the following analyses: (1) the medication quality indicators were limited to new HRM and new DDIS medications; (2) we redefined the PCMH categorizations, using the Hollingsworth Et al. approach (i.e., without having must pass criteria) and dichotomizing it into a binary variable (e.g., meet none versus some PCMH criteria); and (3) we limited analyses to primary care physicians. For the sensitivity analysis and the model with interaction terms for both HRM and DDIS models, there were no substantial changes. Therefore, only the results for primary analysis are presented.

## **Discussion**

This study is one of the first to use the NAMCS database to determine if adoption of PCMH model is associated with better clinical performance in terms of medication use among older adults. Data were analyzed applying several NCQA HEDIS measurements, namely the high risk medication and drug-disease interaction indicators. These two medication quality of care indicators were selected as important quality indicators of the adoption of PCMH.<sup>32,41</sup> After



adjusting for patient- and practice-level characteristics, our findings showed that the level of PCMH adoption was not associated with the quality of medication use indicators. For the remaining covariates, our study found that number of medications used was the most significant factor that affected the occurrence of HRM and DDIS.

Although it was anticipated that adopting PCMH would be associated with quality of medication use, the lack of association is consistent with two previous studies.<sup>42,43</sup> Holmboe et al used a web-based survey of 254 physicians chosen from metropolitan regions of eighteen cities in thirteen states to investigate the relationship of practices' "systemness" as PCMH and the quality of care they provided. They developed a series of survey questions that captured the primary characteristics of PCMH based on the NCQA scoring algorithm and generated a risk-adjusted composite measure of quality for chronic, acute, and preventive care. Their initial findings demonstrated that overall scores were a composite of several structural elements of PCMH and was not associated with higher quality of patient care. Likewise, Shi Et al. employed the Safety Net Medical Home Scale (SNMHS) to capture the features of PCMH and to assess the relationship between PCMH adoption in the Health Resources and Services Administration-funded safety net health centers and four clinical measures (vaccination rates among children, pap smear rates among eligible women, HbA1c values among patients with diabetes, and blood pressure rates among patients with hypertension). Employing the SNMHS algorithms and generating total PCMH and subscale scores (i.e., accumulated by each domain), they also found no associations between the aggregated total PCMH scores and any of the four performance measured outcomes.

Several reasons may explain these discouraging results. One reason is whether the design of the PCMH recognition program can appropriately assess the right PCMH elements that

practices tend to offer. In other words, the NCQA PCMH is one of the tools that aims to evaluate practices' quantify the delivery of care using principles embodied in the PCMH. With regard to this issue, we may question whether the NCQA PCMH guidelines or the SNMHS scoring method fully capture the essence of PCMH characteristics so as to allow for an accurate evaluation of healthcare delivery. The NCQA PCMH guidelines can identify the presence or absence of structural and process elements of practices and at best assess only the potential capability that practices can draw on to serve patients. However, the NCQA PCMH guidelines are the most common approach in the literature for assessing PCMH. A second reason is that our mapping approach of the NCQA guidelines to the NAMCS may have lost some important concepts of PCMH, such as referral tracking and advanced electronic communication elements. This concern highlights the pitfall of assessing the PCMH components thoroughly. Furthermore, several significant elements are not included in the NCQA PCMH recognition guideline but emphasized in previous studies as necessary to provide better-quality of care, including (a) the interpersonal relationships among providers and patients as well as within professionals, (b) the skills and interdependence of the health professionals working in various practice settings, and (c) physicians' leadership, attitudes and interactions within complex adaptive systems.<sup>44</sup> The failure to capture such measurements of practice structure may prevent an accurate assessment of the quality of patient care.

Another reason for the lack of association between the adoption of PCMH and the quality of medication use may be related to the selection of the two inappropriate medication quality indicators. A growing number of PCMH demonstration projects have shown improvements in healthcare access and quality of care, yet most of the previous studies reported inconclusive results and/or rarely focused on the quality of medication use.<sup>29,45</sup> Indeed, previous

studies that demonstrated the effectiveness of PCMH in relation to quality of care generally focused on preventive services, disease specific medication indicators (e.g. rates of immunization, cancer screening, ACE or ARB prescribed for diabetes/chronic heart failure patients, or narcotics prescribed for patients with low back pain), or medication adherence rates in chronic disease conditions.<sup>29,45</sup> No previous study has investigated the overall use of medications for all the population, without targeting in specific chronic diseases. In other words, our study is more advanced in that it hypothesizes the PCMH can be beneficial for a more general population, i.e., older adults.

Despite the findings of our study, our results deliver an important message, namely that patients need improved medication use in the PCMH model. Particularly, more and more studies are emphasizing the importance of whether patients are taking medication appropriately. Additionally, the selection of appropriate medications has already become as an important issue for primary care settings.<sup>32,41</sup> Our study findings also suggest that medication experts such as clinical pharmacists may be needed to participate in the PCMH collaborative team. Previous studies have shown some positive results when pharmacists are included in the PCMH. For example, studies have shown improvements in blood pressure outcomes and diabetes control, and patients also had a significantly lower rate of hospitalizations utilization.<sup>33,46, 47</sup> The findings of our study signal an opportunity to pharmacists that there is still a need for ensuring the appropriate medication use within the PCMH model.

This study showed that the prevalence of HRM and DDIS in outpatient visits involving older U.S. adults were 11.2% and 15.0%, respectively. These findings were in accordance with a previous study that used the same criteria (i.e., HEDIS HRM and DDIS measures) to define the list of inappropriate medication use.<sup>21</sup> Pugh Et al. reported that the prevalence of HRM and

DDIS were 12.3% and 15.2%, respectively, in 2006. No comparison can be made to other studies that used other criteria for defining inappropriate medication, such as Beers or Zhan Criteria, because of differences in the medication lists. Apart from this general finding of potentially harmful medications, we also identified the top 10 inappropriate prescribed HRM and DDIS medications in the U.S, which has rarely been reported in previous studies.<sup>12,16</sup> This finding provides valuable information to clinicians and/or prescribers who need to be aware of which specific inappropriate medications should be targeted. For HRM, propoxyphene and nifedipine were the most prescribed inappropriate medications, which were consistent with previous literature.<sup>10</sup> Additionally, our results identified that most of the high risk medications were reported as continued medications, implying that either the risks outweigh the benefits or that prescribers engaged in poor prescribing quality in an ongoing manner.<sup>48</sup> With regard to the top list of DDIS, our study was the first to describe the specific drug-disease interactions. Our findings showed that patient visits with fall/hip fracture recorded the most medication interactions. These results can be an important reference for clinicians to consider when prescribing for this subpopulation.

This study offers an up-to-date analysis of risk factors for potentially inappropriate medication use. For HRM, we found that visits where the individuals were female gender and had more medications were more likely to be exposed to risks, which is consistent with prior studies.<sup>5,16,20,21,23,49</sup> Additionally, the number of past outpatient visits, the type of physicians that the patient contacted, and region are three variables that have not been investigated in the inappropriate medication use literature. It is plausible that patients with a greater number of visits and seen by primary care physicians are the ones who are more vulnerable and have greater need for medications, leading to higher chances of HRM exposure. As to the south

region being a factor for higher exposure to HRM, this may indicate regional disparity in medication quality of care.<sup>50</sup> In our study, it was somewhat surprising that the finding of the effect of comorbidity conditions was inconsistent with that reported in previous studies.<sup>11,14,49</sup> One possible explanation for that was the number of medications in the dataset was restricted to eight medications per visit; this restriction may have failed to capture all medications on the HRM lists. This is reasonable in light of a previous study using national representative survey and reporting that the average prescription medication used for older adults is five or more.<sup>51</sup> As for the exposure to DDIS, only the number of medication used variable shown significant association with the exposure.

A number of potential limitations should be noted. First, we acknowledge that mapping technique of measured NAMCS items to NCQA elements was subjective. For example, not all the NCQA elements are contained in the NAMCS database. In addition, the measure of PCMH adoption variables centered on the evaluation of EMR and with few items for other important elements, such as collaborative and coordinated care. However, we used an approach similar to Hollingsworth Et al.. As well, there is currently no national database in the United States that can measure PCMH infrastructure across a variety of practices.

Another potential limitation was the limited medication history in NAMCS. The medication history of each patient visits were up to eight medications. However, this medication list would then provide an under-estimate of these indicators, as medications may be missing that would qualify for the outcome. Third, the data are from a systematic random sample, but physician or office staff may misrepresent data and data were missing. NAMCS provides specific instructions in terms of the way to collect the data; nevertheless, respondent bias may exist. Strong imputation methods were used to reduce the impact of missing data. Finally, this

analysis used a cross-sectional study design and causality cannot be made. Using a longitudinal study design may enable investigators to observe the patterns of the use of inappropriate medication and the PCMH adoption over time, but the design of NAMCS precluded this approach.

Future studies of this topic are still needed. Examining PCMH sub-elements and the quality of medication use may be insightful to identify whether specific aspects of PCMH are related to medication quality. As well, qualitative studies focused on healthcare professionals' opinions of medication use to understand why HRM and DDIS occur would be helpful. The latter is an important consideration as HRM is a star measure for Part D plans and a HEDIS measure.

## **Conclusion**

Our study found no association between adoption of PCMH and medication quality of care. The most prevalent high risk medications were propoxyphene and nifedipine. Individual physician characteristics were more important than practice characteristics in predicting the quality of medication use.

Table 3.1 Weighted Multiple Imputation Estimates of Patient and Practice Characteristics of Target Population, of Population with HRM, and of Population with DDIS

	Total population <sup>a</sup> [N=432,284,932] [100 %]	With HRM <sup>b</sup> [N=48,430,635] [11.2 %]	With DDIS <sup>c</sup> [N=8,865,883] [15.0 %]
<b>Patient Characteristics</b>	Est. % [95% CI]	Est. % [95% CI]	Est. % [95% CI]
Mean age [95 % CI]	75.5 [75.3-75.8]	74.8 [74.2-75.5]	79.7 [78.1-81.2]
Gender			
Female	57.7 [56.3-59.1]	72.1 [68.6-75.7]	62.4 [50.5-74.2]
Race			
White	88.4 [86.5-90.3]	86.7 [82.7-90.7]	79.9 [68.3-91.6]
Black	8.2 [ 6.5 - 9.9]	10.9 [7.0 -14.8]	16.9 [ 5.5 -28.2]
Others	3.4 [ 2.5 - 4.3]	2.4 [1.0 - 3.8]	3.2 [ 0.0 - 6.9]
Number of Chronic disease <sup>1</sup>			
None	13.9 [12.5-15.3]	13.9 [11.2-16.6]	9.2 [ 3.1 -15.4]
One	23.7 [22.2-25.1]	21.4 [17.9-24.9]	15.1 [ 7.2-23.1]
Two and over	62.4 [60.0-64.9]	64.7 [60.4-70.0]	75.7 [63.6-87.7]
Total number of visit medications	4.6 [ 4.4- 4.8]	5.9 [ 5.6 - 6.3]	6.3 [ 5.7- 6.8]
Number of visits last year	4.7 [ 4.4- 4.9]	5.2 [ 4.6- 5.7]	4.9 [ 3.7- 6.1]
Reported Household income			
Below \$ 40,627	44.3 [40.0-48.6]	50.0 [43.8-56.1]	56.1 [41.1-71.1]
\$ 40,627 and over	55.7 [51.4-60.1]	50.0 [43.9-56.2]	43.9 [28.9-58.9]
Insurance Type			
private insurance	15.7 [13.9-17.5]	16.0 [12.6-19.4]	21.4 [10.2-32.5]
Medicare/Medicaid	82.8 [80.8-84.7]	82.3 [78.9-85.7]	77.8 [66.8-88.9]
Else	1.5 [ 1.1- 2.0]	1.7 [ 0.6 - 2.9]	0.8 [ 0.0- 1.7]
<b>Practice Characteristics Among Visits</b>			
PCMH Level			
Not accredited	58.0 [53.2-62.8]	53.0 [46.6-59.4]	55.5 [40.0-71.0]
Level 1	14.7 [11.8-17.5]	16.5 [11.7-21.4]	9.6 [ 1.1-18.1]
Level 2	10.5 [ 7.8 -13.2]	12.2 [ 7.1-17.2]	14.0 [ 4.6-23.4]
Level 3	16.8 [13.7-20.0]	18.3 [14.1-22.6]	20.9 [ 7.9-33.9]
Region			
Northeast	15.8 [12.6-19.0]	11.8 [ 7.7-15.9]	15.3 [ 4.3-26.3]
Midwest	25.0 [19.8-30.1]	23.3 [16.5-30.0]	16.9 [ 6.3-27.5]
South	38.5 [32.8-44.0]	45.5 [36.4-54.6]	48.0 [31.9-64.1]
West	20.7 [17.0-24.5]	19.4 [13.0-25.8]	19.8 [ 9.0-30.6]
Metropolitan Statistical Area			
No	13.0 [ 5.9- 20.1]	13.9 [ 5.1-19.9]	11.5 [ 1.8-21.2]
Yes	87.0 [79.9-94.1]	86.1 [77.4-94.9]	88.5 [78.8-98.2]
Type of Practice			
Solo	31.4 [27.7-35.2]	68.0 [62.3-73.7]	55.3 [40.9-69.7]
Group practice	68.6 [64.8-72.3]	32.0 [26.3-37.7]	44.7 [30.3-59.1]

Type of Physician						
Doctor of Medicine	94.6	[93.3-95.9]	94.6	[92.4-96.9]	97.5	[95.1-100.0]
Doctor of Osteopathy	5.4	[ 4.1- 6.7]	5.4	[ 3.1 - 7.6]	2.5	[ 0.0 - 4.9]
Physician Specialty Group						
Primary Care Specialty	47.3	[43.4-51.1]	55.1	[49.8-60.4]	48.4	[33.3-63.4]
Surgical Care Specialty	21.4	[19.1-23.8]	16.5	[13.3-19.8]	6.7	[ 2.2 -11.1]
Medical Care Specialty	31.3	[28.1-34.5]	28.4	[23.5-33.3]	44.9	[30.0-59.8]
Employment Status of Physician						
Owner	73.9	[69.7-78.1]	72.4	[66.1-78.6]	76.3	[63.6-89.0]
Employee or Contractor	26.1	[21.9-30.3]	27.6	[21.4-33.9]	23.7	[11.0-36.4]

(Source: NAMCS 2009-2010)

Data reported as mean or proportion (%). Estimates of means and proportions are based on patient visits in U.S. Reported Estimates at top of table represent:

- (1) Weighted estimate of % of visits recording age 65 and over, at least have one medication record,
- (2) Weighted estimate of % of visits recording age 65 and over, at least have one medication record with HRM,
- (3) Weighted estimate of % of visits recording age 65 and over, at least have one medication record with DDIS.

<sup>a</sup> Original unweighted sample size of visits= 13,156;

<sup>b</sup> Original unweighted sample size of visits with HRM=1,320;

<sup>c</sup> Original unweighted sample size of visits with DDIS= 135.

<sup>1</sup> For the target population and HRM, 13 different types of chronic conditions were included. These chronic diseases included Arthritis, Asthma, Cancer, Cerebrovascular disease, Chronic renal failure, Congestive heart failure, Chronic obstructive pulmonary disease, Depression, Diabetes, Hyperlipidemia, Hypertension, Ischemic heart disease, and Osteoporosis. For individuals with DDIS, 3 chronic conditions were excluded from the sum (i.e., Chronic Renal Failure, Depression, and Osteoporosis).



Table 3.2 Ten Most Commonly Administered High Risk Medications in Visits (Among the Target Population)

Medication	Total Estimated Number of Visits where the Rx were Used	Continued Medication (%)	New Medication (%)	Blank (%)	% of Visits	95 % CI
Acetaminophen-Propoxyphene Napsylate	7,187,089	5,573,347 (77.0)	1,613,742 (22.3)	53,464 (0.7)	15.0	11.9-18.6
Conjugated estrogens	6,563,599	6,045,738 (91.5)	517,861 ( 7.8)	40,483 (0.6)	13.6	11.1-16.7
Nifedipine	5,809,907	5,489,176 (92.3)	320,731 ( 5.4)	137,842 (2.3)	12.3	9.4-15.9
Cyclobenzaprine	5,111,934	3,758,842 (73.4)	1,353,092 (26.4)	9,058 (0.1)	10.6	8.4-13.2
Diazepam	3,012,241	2,318,850 (73.9)	693,391 (22.1)	124,652 (4.0)	6.5	4.4 -9.5
Nitrofurantoin macrocrystals	2,347,120	1,733,868 (68.2)	613,252 (24.1)	193,761 (7.6)	5.2	4.0 -6.9
Diphenhydramine	2,475,483	1,867,297 (74.7)	608,186 (24.3)	24,012 (1.0)	5.2	3.6 -7.4
Thyroid desiccated	1,450,073	1,450,073 (86.8)	N/A (0.0)	220,295 (13.2)	3.4	2.4 -5.0
Hydroxyine hydrochloride	1,701,400	1,390,988 (78.3)	310,412 (17.5)	75,349 (4.2)	3.7	2.5 -5.3
Dicyclomine	1,536,760	1,156,656 (75.3)	380,104 (24.7)	N/A (0.0)	3.2	2.1 -4.7

(Source: NAMCS 2009-2010)

Table 3.3 Ten Most Commonly Administered DDIS combinations in Visits (Among the Target Population with specific diseases, including Fall/Hip Fracture, Dementia, and CKD)

Medication	Total Estimated Number of Visits where the Rx were Used	Identify as Continued Medication (%)	Identify as New Medication (%)	Blank (%)	% of Visits	95 % CI
Quetiapine +Fall/Hip Fracture	712,276	611,980 (85.9)	100,296 (14.1)	N/A (0.0)	16.7	9.1-28.6
Tolterodine +Dementia	592,925	566,374 (95.5)	26,551 (4.5)	N/A (0.0)	13.9	7.7-23.8
Zolpidem +Fall/Hip Fracture	385,001	309,055 (80.3)	25,508 (6.6)	50,438 (13.1)	9.0	4.8-16.3
Cyclobenzaprine+ Dementia	371,237	183,038 (49.3)	188,199 (50.7)	N/A (0.0)	8.7	2.9-23.1
Naproxen + CKD	288,075	137,733 (47.8)	150,342 (52.2)	N/A (0.0)	6.8	2.2-19.0
Olanzapine +Fall/Hip Fracture	241,652	201,997 (83.6)	39,655 (16.4)	N/A (0.0)	5.7	2.5-12.1
Oxybutynin + Dementia	199,857	199,857 (100.0)	N/A (0.0)	N/A (0.0)	4.7	1.8-11.4
Ibuprofen + CKD	160,949	69,069 (42.9)	91,880 (57.1)	N/A (0.0)	3.8	1.2-11.4
Risperidone + Fall/Hip Fracture	160,592	133,852 (83.3)	26,740 (16.7)	N/A (0.0)	3.8	1.6-8.9
Celecoxib + CKD	143,038	143,038 (100.0)	N/A (0.0)	N/A (0.0)	3.4	1.1-9.8

(Source: NAMCS 2009-2010)

Table 3.4 Weighted Multiple Imputation Estimates of Bivariate Associations Between Patient and Practice Variables and Use of HRM/ DDIS

Patient Characteristics	HRM		DDIS	
	OR	95 % CI	OR	95 % CI
Age (referent: 65-74 years)	Wald X <sup>2</sup> (1)= 7.7, p<0.05			
75 and older	0.80*	0.68-0.94	1.33	0.76-2.35
Gender	Wald X <sup>2</sup> (1)= 57.6, p<0.05			
Female	2.04*	1.70-2.45	1.39	0.87-2.34
Race (referent: White)	Wald X <sup>2</sup> (2)= 3.59, p<0.05			
Black	1.41*	1.05-1.91	2.06*	1.03-4.15
Others	0.70	0.41-1.17	1.34	0.37-4.89
Number of Chronic Condition (referent: None)			Wald X <sup>2</sup> (2)= 4.42, p<0.05	
One	0.89	0.68-1.17	0.34*	0.16-0.71
Two and over	1.04	0.82-1.31	0.45*	0.21-0.97
Number of Medication Use (referent: Two or Less Rx )	Wald X <sup>2</sup> (2)= 35.06, p<0.05		Wald X <sup>2</sup> (2)= 3.82, p<0.05	
3-6 Rx	1.9*	1.4-2.6	2.18	0.90-5.28
7-8 Rx	3.7*	2.7-5.1	3.09*	1.36-7.00
Reported Household Income (referent: Income below \$40,627)	Wald X <sup>2</sup> (1)= 8.67, p<0.05			
\$ 40,627 and over	0.77*	0.65-0.92	0.68	0.38-1.23
Insurance Type (referent: Private insurance)				
Medicare/Medicaid	0.97	0.78-1.20	0.46	0.19-1.09
Else	1.06	0.57-1.99	0.35	0.08-1.45
<b>Practice Characteristics</b>				
PCMH Level (referent: Not accredited)				
Level 1	1.27	0.94-1.71	0.72	0.29-1.81
Level 2	1.31	0.89-1.92	0.66	0.35-1.24
Level 3	1.22*	1.01-1.47	0.98	0.51-1.90
Region (referent: Northeast)	Wald X <sup>2</sup> (3)= 2.97, p<0.05			
Midwest	1.27	0.88-1.85	0.58	0.26-1.30
South	1.67*	1.16-2.42	1.16	0.63-2.14
West	1.28	0.87-1.89	0.91	0.46-1.78
Location of practice (referent: Non-Metropolitan Statistical Area)				
Yes	0.92	0.67-1.26	0.91	0.50-1.67
Type of Practice (referent: Group practice)				
Solo	1.03	0.84-1.27	1.42	0.85-2.35
Type of Physician (referent: Doctor of Medicine)				
Doctor of Osteopathy	1.01	0.69-1.46	2.07	0.69-6.26
Physician Specialty Group (referent: Surgical Care)	Wald X <sup>2</sup> (2)=10.35, p<0.05			
Primary Care Specialty	1.58*	1.30-1.94	0.97	0.44-2.12

Medical Care Specialty	1.19	0.94-1.51	1.11	0.53-2.36
Employment Status of Physician (referent: Owner)				
Employee or Contractor	1.09	0.89-1.35	0.99	0.52-1.89

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(Source: NAMCS 2009-2010)

Note. \*  $p < 0.05$

Table 3.5 Final Weighted Multiple Imputation Estimates of Odds Ratios in Logistic Regression Models for the Probability of HRM or DDIS

Parameter	HRM			DDIS		
	OR	95 % CI	p-value	OR	95 % CI	p-value
Age	0.98	0.97-0.99	<0.001	1.02	0.99-1.06	0.223
Gender						
Female	2.00	1.64-2.43	<0.001	1.26	0.74-2.14	0.395
Race (referent: White)						
Black	1.22	0.94-1.60	0.140	1.95	0.94-4.07	0.075
Others	0.78	0.46-1.31	0.350	1.91	0.54-6.78	0.316
Number of Chronic Condition (referent: None)						
One	0.72	0.54-0.96	0.026	0.81	0.30-2.21	0.679
Two and more	0.62	0.48-0.80	<0.001	0.23	0.08-0.67	0.008
Reported Household income (referent: Income below \$40,627)						
\$ 40,627 and over	0.86	0.70-1.05	0.143	0.74	0.37-1.47	0.390
Total number of past visits	1.02	1.00-1.03	0.005	0.99	0.92-1.07	0.866
Total number of visit medications	1.26	1.20-1.32	<0.001	1.27	1.12-1.45	<0.001
Insurance Type (referent: Private Insurance)						
Medicare/Medicaid	0.92	0.74-1.15	0.457	0.38	0.15-0.96	0.041
Else	1.17	0.63-2.17	0.613	0.24	0.05-1.18	0.079
PCMH (referent: Not accredited)						
Level 1	1.20	0.86-1.69	0.280	0.90	0.30-2.74	0.855
Level 2	1.10	0.77-1.55	0.617	0.85	0.40-1.81	0.679
Level 3	1.18	0.96-1.45	0.108	0.96	0.44-2.11	0.928
Region (referent: Northeast)						
Midwest	1.10	0.76-1.58	0.617	0.69	0.26-1.84	0.454
South	1.59	1.06-2.39	0.025	1.27	0.64-2.53	0.492
West	1.30	0.88-1.93	0.185	1.02	0.48-2.13	0.966
Metropolitan Statistical Area						
Yes	1.07	0.81-1.41	0.640	0.90	0.44-1.83	0.764
Type of Practice (referent: Group practice)						
Solo	1.08	0.88-1.34	0.457	1.53	0.78-3.01	0.221
Type of Physician (referent: Doctor of Medicine)						
Doctor of Osteopathy	1.04	0.74-1.48	0.811	1.67	0.52-5.51	0.378
Physician Specialty Group (referent: Surgical Care Specialty)						
Primary Care	1.27	1.05-1.53	0.016	0.85	0.32-2.27	0.743
Medical Care Specialty	0.94	0.74-1.19	0.596	0.94	0.37-2.37	0.887
Employment Status of Physician (referent: Owner)						
Employee or Contractor	0.92	0.75-1.12	0.404	1.38	0.63-3.03	0.416

(Source: NAMCS 2009-2010)

Results of the final logistic regression model provide adjusted ORs for associations between variables of interest and HRM/DDIS prescription. The Archer-Lemeshow goodness-of-fit statistics range from 0.31-0.59 (p value= 0.81-0.97) for HRM and 0.54-1.96 (p value =0.05-0.84) for DDIS, suggesting that the models fit well across the imputed datasets.

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## **CHAPTER IV. PAPER 3: DOES THE EXTENT OF PATIENT CENTERED MEDICAL HOME ADOPTION REDUCE THE OCCURRENCE OF ADVERSE DRUG EVENTS?**

### **Introduction**

Adverse drug events (ADEs) pose a large risk to patient medication quality of care and have been regarded as one of the most important patient safety and public health concerns in today's healthcare system.<sup>1</sup> ADEs are simply defined as injury resulting from medication intervention related to a drug.<sup>2</sup> ADEs can occur in either the medication use process (i.e., prescribing, dispensing, administering, or monitoring) or as a result of an undesirable clinical manifestation that is consequent to and caused by the administration or omission of medication. Previous studies have indicated that ADEs are extremely common in medical practices.<sup>2,3</sup> For example, the prevalence of ADEs is known to be high in both ambulatory care as well as inpatient care, with median ADE prevalence rates of 20% and 50%, respectively.<sup>4</sup> To further illustrate the scope of ADEs, another study focused on inpatient care reported that the annual ADE-related emergency department and inpatient visits were estimated to be 700,000 and 120,000, respectively.<sup>5</sup> Most ADE-related studies have been conducted in the in-patient setting and additional research is needed in the ambulatory setting. In addition, ADEs affect individuals at all ages whenever the treatment of disease condition involves medication use.<sup>6,7</sup> Yet, the

youngest (0 to 4 years old) and oldest (age 65 years old) individuals are the most vulnerable populations to the adverse outcomes of ADEs.<sup>8,9</sup>

The high prevalence of ADEs is of concern not only because of their impact on health but also because of their contribution to higher overall healthcare costs including hospitalizations and prolonged hospital stays.<sup>10-12</sup> National surveillance data have shown that ADEs account for \$3.5 billion spent on extra medical expenditures annually.<sup>13</sup> The financial impact of ADEs even influences indirect healthcare costs, such as lost productivity.<sup>14-16</sup> Given the large and ever-increasing magnitude of the development of new medications, discovery of new uses for older medications, the rising aging population, the demand of using medications for disease prevention, and increased coverage for prescription medications in the U.S., ADEs represent a major public health challenge.<sup>17</sup>

The growing concern about ADEs has caused both government institutions and professional organizations to seek a reduction in ADE prevalence through the development of national ADE Action Plan as well as prioritizing healthcare delivery strategies for their prevention.<sup>1,13</sup> Despite the need to prevent ADEs, few studies have investigated individual-level characteristics associated with their occurrence. In the limited literature available, studies have reported that patients with a greater amount of medication use,<sup>8,9,18</sup> being of older age,<sup>8,19</sup> being female,<sup>8</sup> and having cognitive disability<sup>19</sup> were more likely to experience ADEs. Surprisingly, no studies have considered whether the occurrence of ADEs can be reduced in response to the transformation of healthcare settings, in which promising new models of integrated delivery services have emerged for ensuring quality of care. One such model is the Patient-Centered Medical Home (PCMH).

The PCMH is defined as a model or philosophy of primary care that is patient-centered, comprehensive, team-based, coordinated, accessible, and focused on quality safety by the

Patient-Centered Primary Care Collaborative (PCPCC). With the adoption of the PCMH model, practices are expected to comprehensively improve access to care, quality of care services, and overall health care utilization.<sup>20</sup> To be recognized as a PCMH practice, there are three common options through which practices can be certified, including the Accreditation Association for Ambulatory Health (AAAH), the Joint Commission, and the National Committee for Quality Assurance (NCQA).<sup>21</sup> Among the options, the NCQA PCMH guideline is the most widely used voluntary program to evaluate the adoption of PCMH in the current literature.<sup>22</sup> The NCQA PCMH guideline program has a complex scoring rubric that comprises different domains of evaluations and identifies three general levels in PCMH attainment of practices. When the level of achievement is high, the practice has a relatively more comprehensive care environment and is expected to offer a better quality of care, reduced cost of care, enhanced experience of care, and a better professional experience.

Previous PCMH related studies have demonstrated mixed results in terms of the impact of PCMH on healthcare utilization and quality improvement.<sup>23-25</sup> A further weakness in the literature is the lack of comprehensiveness in terms of outcome assessment. In this regard, it is notable that the potential benefits of adopting PCMH in relation to the occurrence of ADEs remain largely unexplored. Given the efforts to reduce the incidence of ADEs, it is important to consider whether a reduction can be achieved in the context of PCMH adoption. This is because ADEs can be viewed as one of the significant health outcomes related to quality of medication use, which is consistent with the PCMH goal of improving the overall quality of care for patients.<sup>23</sup>

To our knowledge, no study has examined the value of PCMH adoption in relation to the occurrence of ADEs and the potential for reducing their numbers. To fill this void, the objective

of this study was to explore the association between the level of PCMH adoption and ADE prevalence. In order to have generalizable estimates, this study employed features of the NCQA PCMH recognition program and used a nationally representative database to investigate the influence of PCMH adoption on ADE-related visits. The study hypothesized that a higher level of PCMH adoption of practices will be associated with less frequently reported ADEs.

## **Methods**

### **Study Design and Data Sources**

This study consists of cross-sectional analyses utilizing data from the National Ambulatory Medical Care Survey (NAMCS). The patient visit was the unit of analysis. The selection criteria for the sample of analysis included individuals of all ages who had at least one medication record. The study was approved by the Institutional Review Board of University of Michigan.

The 2009 and 2010 NAMCS were the primary data sources. The NAMCS is a nationally representative survey, designed as a multistage probability sample survey with appropriate weighting methods. The weights are designed to produce national estimates of the provision and use of ambulatory medical care services in the United States. Non-federal employed office-based physicians are randomly selected to respond to the NAMCS questionnaires. The content of the NAMCS includes patient, clinical, and practice information for each selected visit and is classified into patient and physician related forms. The selection criteria for visits into this study

were that visits were for patients of all ages who had at least one medication record in the outpatient visit.<sup>26</sup>

## **Measures**

### ***Determining Level of PCMH Adoption***

The main variable of interest was the level of PCMH adoption in physician practices. Since no direct measure exists in the NAMCS to measure PCMH adoption, the 2009-2010 NAMCS data were mapped onto the 2008 NCQA PCMH guideline elements for PCMH recognition. This mapping technique involved two steps. The first step was to calculate the score of PCMH adoption that was determined by the practice characteristics on each patient visit. That is, each patient-level/visit record was assigned to a practice-level PCMH adoption status, and the PCMH score was the same for all visits from the same practice. The scoring method was determined by a complex mapping approach based on a calculation method used in a previous study.<sup>27</sup> In Hollingsworth's study, the authors mapped the 2007-2008 NAMCS survey items to the NCQA PCMH guidelines, which contained detail scoring criteria to determine PCMH scores for primary care practices. This study further advanced Hollingsworth's investigation by adding the must-pass elements criteria to designate medical home scores. In the original NCQA PCMH guidelines, nine standards with thirty subsumed elements have specific points awarded. Ten out of thirty elements were designated as "MUST PASS" elements for the purpose of categorizing different levels of PCMH. However, not all elements could be mapped in NAMCS and some items were added or eliminated in the 2009 and 2010 NAMCS. This study first identified seven



standards with 15 elements of the NCQA PCMH standards that could be mapped in NAMCS 2009, and six standards with 15 elements of the NCQA PCMH standards that can be mapped in 2010 NAMCS. The unit of observation in NAMCS is patient visit, and the level of PCMH adoption that each patient visit was assigned was determined from the characteristics in each visit record. Each visit received a “passed” (1=yes) point for each measurable element and a cumulative point total by summing points across all passed elements. A PCMH infrastructure score on each visit record was calculated by dividing its cumulative point total by the total number of available points, expressed as a percentage. The maximum denominators for this score were 55 points and 60 points in 2009 and 2010, respectively. The detailed mapping technique can be visualized in Appendix E.

The second step to measure PCMH adoption was to categorize the level of PCMH. In the original NCQA PCMH guidelines, the scores and number of “MUST PASS” elements determined the levels of PCMH. The scores were then classified into four categories: not accredited (fewer than 25 percent of total points), Level 1 (25 to 49 percent of points and a pass on 5 of 10 MUST PASS elements), Level 2 (59-74 percent of total points and a pass on all 10 MUST PASS elements), and Level 3 (points more than 75 percent and pass all 10 MUST PASS elements). Since not all the NCQA PCMH elements were included in the NMACS, this study defined the classification of the NCQA PCMH level recognition as follows: not recognized, (fewer than 25 percent of total points), Level 1 (25-49 percent of total points and a pass on 2 out of 4 MUST PASS elements), Level 2 (50-74 percent of total points and a pass on all 4 MUST PASS elements), and Level 3 (over 75 percent of total points and a pass on all 4 MUST PASS elements). The comparison between original NCQA PCMH criteria and the modified version based on NAMCS survey items is shown in Appendix E.

### *Defining Adverse Drug Events*

The outcome for this study was the occurrence of ADEs in a patient visit. To identify whether a patient visit in NAMCS involved ADEs, two approaches were used to code dummy variables (1 = yes, 0 = no) for each visit. Visits were identified as having ADEs if one of the approaches was confirmed. The first approach depended on a single question that physicians were instructed to mark: “whether this visit of the patient is related to adverse effect of medical/surgical care or adverse effect of medicinal drug.” The response was coded as yes or no. The second approach to identify whether the visit was ADEs related was determined by a review of diagnostic codes and reasons for visit codes. Since this study included all age levels for investigating ADE-related visits, all the diagnostics and reasons for visit codes that had been important in previous studies were used. For the diagnostic codes, the International Classification of Disease, Ninth Revision, Clinical Modification (ICD-9-CM) codes were used as follows, 960-979, (poisoning by antibiotics, sedatives and hypnotics, and poisoning by agents primarily affecting the cardiovascular system), 995 (unspecified adverse effect of unspecified drug, medicinal, and biological substance, anesthesia shock), 535 (aspirin gastritis), 692 (dermatitis due to drugs and medications in contact with skin), 693 (dermatitis due to drugs and medications taken internally), 779 (drug reaction in newborn), 292 (drug-induced mental disorders), 708 (allergic urticaria), and 357 (polyneuropathy due to drugs). As to the reason for visit codes, if a patient’s visit was coded as 5905 (allergy to medication, anaphylactic shock, and bad reaction to prescribed medication), a visit was viewed as related to an ADE. In summary, if the single question or an ICD-9 code indicated an ADE, the visit was coded as 1=yes. If not, the visit was coded as 0=no.

### *Other Covariates*

Based on the proposed merged theoretical model (i.e., the Wagner's chronic care and the Hogg's primary care organization model), this study examined the impact of PCMH adoption (i.e., process of care) on quality (i.e., the occurrence of ADEs represented medication-related outcomes) and other covariates are necessary to be included.

Previous ADE-related studies showed that several patient characteristics are significantly associated with the occurrence of ADEs.<sup>4</sup> Therefore, the following variables were considered in this study: age, gender (female/male), race (White/Black/Other), number of chronic disease (sum of fourteen chronic conditions including arthritis, asthma, cancer, cerebrovascular disease, chronic renal failure, congestive heart failure, chronic obstructive pulmonary disease, depression, diabetes, hyperlipidemia, hypertension, ischemic heart disease, obesity, osteoporosis), number of medications used (sum of up to 8 listed medications), number of past visits in last year, household income in patient's zip code, and primary payment for visits (Private insurance /Medicare/Medicaid/Others).

In addition, the modified theoretical model also included practice structure as an indirect effect on outcome. Therefore several physician and practice related variables were used in this study for representing the structure domain, such as physician specialty group (Primary care specialty/Surgical care specialty/Medical care specialty), physician employment status (Owner/Employee/Contractor), physician type (Doctor of Medicine/Doctor of Osteopathy), practice type (Solo/Non Solo), region (Northeast, South/ West/ Midwest), and metropolitan status (Metropolitan Statistical Area/non- Metropolitan Statistical Area).

## Statistical Methods

All analyses used appropriate NAMCS sampling weights to compute unbiased population estimates of the descriptive and regression parameters of interest. Codes in the NAMCS public-use data sets identifying sampling strata and sampling clusters were also employed in all analyses to compute appropriate design-based estimates of standard errors for the weighted estimates. Some variables were missing about 50% of their values, and multiple imputation by chained equations was used to provide more statistical power to analyze the relationships of interest.<sup>39</sup> These imputations generated five completed data sets with all missing values imputed based on other observed variables. The five completed sets of analyses were combined with the original data set to generate a final overall set of multiple-imputation estimates for each analysis.

Descriptive statistics were used to determine the proportion of patient visits with occurrence of ADEs. Chi-square tests and Wald tests were employed to test the bivariate association between the dichotomous outcomes (i.e., ADE) and patient/provider characteristics. Multivariate logistic regression was used to examine the association between PCMH adoption and experiencing an ADE, controlling other covariates. The Archer–Lemeshow goodness-of-fit tests were used to detect whether the model is a good fit or not. Since the analysis is survey-based, the `-svy-` commands in Stata version 13.0 were used for all analyses.

This study took missing data into account. About 50% of the patient visits had complete data for all the individual analysis variables. Multiple imputations by chained equations was used for imputing the missing data and aimed to provide more statistical power.<sup>28</sup> The Stata commands `- mi impute chained-` were used to perform the multiple imputations. Five imputed datasets offered an opportunity to adjust the missing information for each analysis.<sup>28</sup>

## Results

The original NAMCS data contain information for a total of 63,150 sampled outpatient clinic visits, which are representative of 2,046,598,491 ambulatory visits during 2009 and 2010. Of these visits, 46,641 outpatient clinic visits met the inclusion criteria, and this sample provided population estimates for 85 million outpatient ADE-related visits, accounting for 4.2% during 2009 and 2010. The majority of ADE visits were identified via the ICD-9 codes.

As to characteristics of the visits with an ADE (Table 4.1), the majority of the visits were by adults between the ages of 18 and 64 years (51.2%; CI: 47.9-54.5%), women (62.7%; CI: 59.9-65.5%), persons who were white (82.3%; CI: 79.3-85.2%), those with one and more chronic diseases (51.6%; CI: 45.9-57.1%), those with three or more medication records (52.3%; CI: 48.3-56.2%), those with one or two patient visits last year (32.1%; CI: 29.2-35.1%), those with income \$40,627 and over (55.8%; CI: 50.9-60.6%), and those with private insurance (55.6%; CI: 52.2-59.0%). Considering the system-level characteristics (Table 4.1), the majority of ADEs occurred in not accredited PCMH practices (57.8%; CI: 53.6-61.0%), practices resided in the South (34.9%; CI: 28.9-40.9%), practices located in metropolitan area (86.9%; CI: 79.5-94.3%), practices recognized as group practice (66.3%; CI: 61.8-70.9%), where physician type was Doctor of Medicine (94.9%; CI: 93.1-96.7%), where physician specialty group was primary care (59.7%; CI: 54.9-64.5%), and where physician employment status was owner (66.8%; CI: 61.4-72.1%). Approximately 60% of ADEs was due to drug dermatitis and rash or spontaneous ecchymosis, whereas the remaining ADEs visits were related to aspirin gastritis, drug neuropathy, or unspecified medicinal substance use (Table 4.2).

The multiple imputation estimates of bivariate associations between level of PCMH, patient-level characteristics, system-level characteristics, and the exposure of ADEs are shown in

Table 4.3. The Wald tests show that patient age (less than 18-years-old), gender (female), number of chronic conditions (fewer), physician with Doctor of Osteopathy degree and primary care physician during a patient visits were significantly associated with a higher risk of having ADEs. The level of PCMH, however, did not demonstrate a significant bivariate association with the occurrence of ADEs during a patient visit.

According to the final multiple imputation estimates of the logistic regression model coefficients and the adjusted odds ratios (AORs) for ADE-related visits, the level of PCMH was not associated with the odds of the patient visits involving ADEs when adjusting for the other covariates (Table 4.4). Patient visits where the gender was female (AOR = 1.20; CI = 1.06-1.36), being black (AOR = 1.25; CI = 1.05-1.49), having more medication records (AOR = 1.05; CI = 1.01-1.08), being seen by Osteopathy physicians (AOR = 1.35; CI = 1.00-1.81) or being seen by primary care physicians (AOR = 1.45; CI = 1.13-1.86) were significantly associated with a greater odds of having an ADE-related visit. Visits where the patients had more than two coexisting chronic conditions (AOR = 0.63; CI = 0.52-0.76) or with other insurance coverage (AOR = 0.74; CI = 0.57-0.95) were significantly less likely to involve ADEs. The Archer-Lemeshow tests for all five imputed data sets demonstrated good fits of the model. The test statistics range between 1.12 and 1.50 and the p-values of these five tests were all greater than 0.05.

Sensitivity analyses were used to examine whether different PCMH categorizations and physician types substantially changed the results of the predictive models. Specifically, two analyses were done. First, the PCMH categorization was re-categorized, using the Hollingsworth Et al. approach (i.e., without having must pass criteria) as well as dichotomizing it into a binary variable, i.e., meeting none versus meeting some PCMH criteria. Second, the visits included in

the analyses were limited to visits with primary care physicians. The results of the sensitivity analyses did not show substantial changes, and the results for primary analysis are presented.

## **Discussion**

The negative effects of ADEs have already become a major public health concern, prompting efforts to reduce ADE occurrence and investigate factors that influence the onset of ADEs. In an effort to contribute to the strategies to address the issue, this study is the first to explore whether higher adoption of PCMH would impact the prevalence of ADEs-related patient visits. After adjusting for both individual and practice level characteristics, the adoption of PCMH was not associated with whether a visit was ADE-related. The study further found that other covariates, including patient gender, race, medication records, chronic condition status, insurance type, and physician specialties types were significantly associated with the odds of experiencing an ADE-related visit.

Although this study found no association between the adoption of PCMH and individuals having an ADE-related visit, the findings here are consistent with the results of our previous work (Chapter 3) and three other studies, where receiving care in a PCMH was not associated with better process or outcomes of care.<sup>29-31</sup> These previous, consistent findings give rise to concerns regarding the effectiveness of PCMH adoption on patient quality of care. Particularly, these studies employed various quality of care measures, such as vaccination rates among children, pap smear rates among eligible women, HbA1c values among patients with diabetes, blood pressure rates among patients with hypertension, and patient with inappropriate medication use, and none of the measures were significantly improved. The findings of this study are

consistent, in that this healthcare reform model was not associated with an the expected reduction in prevalence of ADE-related visits

Three reasons may explain the unexpected results. The first is related to the definition of what a PCMH means for practices. Although previous studies have shown that the NCQA PCMH recognition program is the most common approach to evaluate the delivery services that practices can provide, some studies have criticized the measurement of this NCQA PCMH recognition program.<sup>32,33</sup> Ho Et al. viewed the NCQA PCMH recognition program as costly, requiring excessive documentation, and imposing rigid structural and process requirements for practices, especially for smaller practices that face more financial and personnel pressure to achieve NCQA PCMH recognition. The authors stated that the NCQA PCMH recognition program overemphasized documentation (which cannot be equated with the actual services that practices can offer), forms (which do not capture the patient-centered collaborative care), and technology (which does not correspond to utility and distracts physicians from patient care). They suggested a better way to measure PCMH attainment, such as using patient experience of care, population health and costs.<sup>34-36</sup> The issues surrounding technology have also been explored by Miller Et al., who also concluded that the NCQA PCMH recognition program only partially recognized the innovation of practices related to information technology (i.e., the adoption of electronic medical system) and overlooked the importance of other significant elements that are emphasized in the Joint Principles, such as team-based care or the incentives.<sup>33</sup> In other words, the 2008 NCQA PCMH measure that was used in this study may not adequately represent care provided in a PCMH.

The second reason that could explain these discouraging results is the mapping technique of NCQA PCMH recognition program to the NAMCS. As described in the methods section,



some elements of PCMH could be fully captured due to the data limitation, such as referral tracking and advanced electronic communication elements. This unavoidable pitfall may lead to concerns in terms of comprehensive assessment of the PCMH components. The final explanation for the lack of association between the adoption of PCMH and the reductions in rates ADEs may be attributed to the overly broad definition of ADEs. This study defined the occurrence of ADEs as including heterogeneous event types, such as healthcare-acquired infections, fall-related injuries, and postoperative complications. This broad definition may have led to the inclusion of events that should have been excluded, thus decreasing the sensitivity to detect ADEs of relevant interest. For example, one previous study recommended that if the aim of patient safety interventions is to decrease the onset of ADEs, it is necessary to measure specific ADEs instead of identifying all sorts of ADEs.<sup>37</sup> However, targeting at specific ADEs requires relatively larger amount of sample which was the limit of this study.

Indeed, despite the results presented here, a growing number of PCMH demonstration projects have shown improvements in patient medication quality and safety via the involvement of medication experts, such as pharmacists, to the PCMH collaborative team. However, these studies did not focus on the outcome of patient safety in medication use.<sup>38-50</sup> Furthermore, no previous study has explored the medication outcomes, such as high risk medication or drug-disease interaction conditions, for patients receiving care under the PCMH context. This study was based on the hypothesis that PCMH will benefit patients, particularly on the basis of providing better quality of care.<sup>51</sup> Yet, the assumption may be too optimistic regarding the influence of the PCMH model. One explanation is because the original PCMH has been focused on the quality of disease management rather than the outcomes of medication safety efforts.

Overall, this study suggests that there remains a need to be vigilant about medication use and safety, as 4% of visits were related to an ADE. This finding is particularly important, given the ever increasing complexity of care for patients, as new diagnoses, tests, and medications and new types of errors and harms are emerging.<sup>52</sup> Opportunities for other non-physician medication experts, such as pharmacists, to actively participate in the PCMH team to ensure the medication safety may be needed within the PCMH model.

Future studies may undertake more in-depth investigations through two approaches. First, studies could examine the association between PCMH sub-elements and the occurrence of ADEs. This would be valuable for stakeholders or researchers who need to be aware of which the piece of the PCMH infrastructure may actually improve patient medication use outcomes. Second, studies could investigate more specific ADEs during patient visits in order to have a relatively targeted evidence-based intervention plan to ensure better patient medication safety.

The findings of this study should be considered in light of two limitations, which can mostly be attributed to the data constraints. First, the technique for mapping NCQA PCMH criteria to the 2009 and 2010 NAMCS was subjective and did not capture all the elements of PCMH due to the data limitation. Furthermore, the measures in the NCQA PCMH criteria stressed the importance of EMR, other significant components of PCMH were missing, such as collaborative and coordinated care. However, this mapping approach is the optimizing one at that point of time when using the 2009 and 2010 NAMCS data. Second, the definition of ADEs via the ICD-9-CM codes may not be comprehensive enough to detect all ADEs since previous studies showed that the prevalence of ADEs is much lower via ICD-9-CM codes than via chart review or other approaches.<sup>4</sup> More complex detection strategies appear to be needed to capture thoroughly the onset of ADEs, such as the use of chart reviews or voluntary reported from

clinicians. Despite the value of using other approaches to identify ADEs, this information cannot be found in NAMCS, which only records patient medication use, but lacks further detailed care records. Second, this analysis used a cross-sectional study design due to the design of NAMCS and causality cannot be inferred. A longitudinal study design may enable researchers to observe the trend of PCMH adoption as well as the occurrence of ADEs during the study period, yet this study design could not be done using the NAMCS datasets.

## **Conclusion**

This study showed that 4.2% of patient visits or 85 million visits were defined as ADE related in ambulatory care settings in the United States. The adoption of the PCMH model was not associated with patient medication safety in the reduction of ADEs. Individual-level characteristics were found to have a greater impact than practice-level characteristics on the occurrences of ADE-related visits.

Table 4.1 U.S. Population Estimates of Visits Among <sup>1</sup> the Target Population, <sup>2</sup> ADE-related Visits during 2009 and 2010

	Target Population (N=2,046,598,491)* (100 %)	With ADEs (N=85,957,137)** (4.2 %)
<b>Patient Characteristics</b>	Proportion (%) [95 % CI]	Proportion (%) [95 % CI]
Age		
Less than 18 Years	16.9 [15.3-18.4]	21.1 [17.8-24.4]
Between 18 and 64 Years	54.9 [53.4-56.4]	51.2 [47.9-54.5]
65 Years and Over	28.3 [26.9-29.6]	27.7 [24.7-30.6]
Gender		
Female	58.6 [57.7-59.5]	62.7 [59.9-65.5]
Race		
White	84.3 [82.6-86.1]	82.3 [79.3-85.2]
Black	11.4 [ 9.8-13.1]	13.5 [10.8-16.2]
Others	4.2 [ 3.6- 4.9]	4.2 [ 2.6- 5.8]
Number of Chronic disease <sup>2</sup>		
None	40.5 [38.9-42.1]	48.4 [44.7-52.1]
One	25.5 [24.6-26.4]	22.0 [19.8-24.1]
Two and over	34.0 [32.2-35.9]	29.6 [26.1-33.1]
Total number medications of visits		
One	29.8 [28.1-31.6]	28.3 [25.4-31.2]
Two	19.4 [18.5-20.2]	19.4 [17.0-21.8]
Three or more	50.8 [48.6-53.0]	52.3 [48.3-56.2]
Number of visits last year		
None	9.0 [ 8.4- 9.6]	8.5 [ 6.7-10.4]
Between 1 and 2 visits	32.2 [31.2-33.3]	32.1 [29.2-35.1]
Between 3 and 5 visits	30.6 [29.8-31.5]	31.8 [29.0-34.6]
6 Visits or over	28.1 [26.9-29.4]	27.5 [24.4-30.7]
Reported Household income		
Below \$ 40,627	43.1 [39.2-46.9]	44.2 [39.4-49.0]
\$ 40,627 and over	56.9 [53.1-60.8]	55.8 [50.9-60.6]
Insurance Type		
Private insurance	53.6 [51.7-55.6]	55.6 [52.2-59.0]
Medicare/Medicaid	39.6 [37.8-41.4]	39.6 [36.1-42.6]
Else	6.8 [ 6.0- 7.5]	5.1 [ 3.8- 6.4]
<b>Practice Characteristics</b>		
PCMH Level		
Not accredited	57.3 [53.7-61.0]	57.8 [53.6-61.0]
Level	12.9 [10.9-14.9]	11.5 [ 8.7-14.3]
Level 2	10.3 [ 8.4-12.2]	10.3 [ 7.5-13.1]
Level 3	19.5 [16.7-22.2]	20.4 [16.3-24.5]
Region		
Northeast	17.4 [14.5-20.5]	17.5 [13.0-22.0]
Midwest	23.4 [19.0-27.8]	26.6 [21.0-32.2]

South	38.7 [33.6-43.7]	34.9 [28.9-40.9]
West	20.5 [16.9-24.1]	21.0 [16.9-25.2]
Metropolitan Statistical Area		
No	12.3 [ 5.9-18.8]	13.1 [ 5.7-20.5]
Yes	87.7 [81.2-94.1]	86.9 [79.5-94.3]
Type of Practice		
Solo	31.0 [27.8-34.2]	33.7 [29.1-38.2]
Group practice	70.0 [65.8-72.2]	66.3 [61.8-70.9]
Type of Physician		
Doctor of Medicine	93.1 [91.7-94.5]	94.9 [93.1-96.7]
Doctor of Osteopathy	6.9 [ 5.5- 8.3]	5.1 [ 3.3- 6.9]
Physician Specialty Group		
Primary Care Specialty	59.8 [56.7-62.9]	59.7 [54.9-64.5]
Surgical Care Specialty	14.3 [12.7-15.8]	9.3 [ 7.2- 11.5]
Medical Care Specialty	26.0 [23.4-28.5]	30.9 [26.1-35.7]
Employment Status of Physician		
Owner	67.4 [64.0-70.7]	66.8 [61.4-72.1]
Employee or Contractor	32.6 [29.3-36.0]	33.2 [27.8-38.6]

(Source: NAMCS 2009-2010)

\*original unweighted sample size of the patient visits n=46,641

\*\*original unweighted sample size of the patient visits with ADEs n=2,574

Data are reported as mean or percentage (with 95 % CI) with survey weights incorporated. These are weighted Multiple Imputation Estimates of means and proportion of patient and practice characteristics for all target population office visits in U.S. from 2009-2010.

<sup>1</sup> Patient visit has at least one medication record.

<sup>2</sup> Overall, 13 different types of chronic conditions were included. These chronic diseases included Arthritis, Asthma, Cancer, Cerebrovascular disease, Chronic renal failure, Congestive heart failure, Chronic obstructive pulmonary disease, Depression, Diabetes, Hyperlipidemia, Hypertension, Ischemic heart disease, and Osteoporosis.

Table 4.2 Five Most Commonly Identified ADEs by ICD-9-CM code in the Population of Visits (Weighted MI Estimates)

Symptoms	ICD-9- CM code	Total Estimated Number of Patient Visits	% of ADE Visits	95 % CI
Drug Dermatitis	629,623	27,039,685	31.7	23,008,590- 31,070,780
Rash and Spontaneous Ecchymosis	782	26,446,201	31.0	22,435,814-30,456,588
Unspecified Adverse Effect of Medicinal Substance	995	6,243,904	7.3	4,354,480 - 8,133,328
Aspirin Gastritis	535	5,954,273	7.0	4,362,977 - 7,545,569
Neuropathy due to Drugs	357	2,397,187	2.8	1,242,813 - 3,551,561

(Source: NAMCS 2009-2010)

Table 4.3 Weighted Multiple Imputation Estimates of Bivariate Associations Between All Independent variables and ADE-related Visits during 2009 and 2010

<b>Patient Visits Characteristics</b>	ADE Visit	
	OR	95 % CI
Age (referent: Less than 18 Years)**		
Between 18 and 64 Years	0.73*	0.62-0.87
65 Years and Over	0.77*	0.64-0.93
Gender*		
Female	1.20*	1.06-1.35
Race (referent: White)		
Black	1.22*	1.02-1.46
Others	1.02	0.72-1.45
Number of Chronic Condition (referent: None)**		
One	0.71*	0.61-0.83
Two and over	0.72*	0.61-0.84
Reported Household Income (referent: Income below \$40,627)		
\$ 40,627 and over	0.95	0.83-1.09
Insurance Type (referent: Private insurance)**		
Medicare/Medicaid	0.96	0.83-1.10
Else	0.71*	0.55-0.93
<b>Practice Characteristics</b>		
PCMH Level (referent: Not accredited)		
Level 1	0.88	0.69-1.12
Level 2	0.99	0.79-1.24
Level 3	1.04	0.84-1.29
Region (referent: Northeast)		
Midwest	1.14	0.84-1.56
South	0.90	0.68-1.19
West	1.03	0.78-1.36
Metropolitan Statistical Area		
Yes	0.93	0.71-1.22
Type of Practice (referent: Group practice)		
Solo	1.14	0.96-1.35
Type of Physician (referent: Doctor of Medicine)**		
Doctor of Osteopathy	1.40*	1.04-1.87
Physician Specialty Group (referent: Primary Care)**		
Surgical Care Specialty	0.65*	0.52-0.81
Medical Care Specialty	1.20	0.98-1.49
Employment Status of Physician (referent: Owner)		
Employee or Contractor	1.03	0.85-1.25

(Source: NAMCS 2009-2010)

Note.

\*\* The p-value of the Wald test is  $<0.05$ , meaning that the specific variable has significant association with ADE-related visits.

\* The p-value of the Design-based Rao-Scott Chi-square tests is  $<0.05$ , meaning the specific value of the variable has a significant association with ADE-related visits



Table 4.4 Final Weighted Multiple Imputation Estimates of Adjusted Odds Ratios in the Logistic Regression Model for ADE-related Visits

Parameter	ADE-Visits		
	OR	95 % CI	p-value
Age (referent: Age under 18 years)			
Between 18 and 64 years	0.79	0.66-0.96	0.924
Age 65 and over	0.97	0.44-0.98	0.041
Gender			
Female	1.20*	1.06-1.36	0.005
Race (referent: White)			
Black	1.25*	1.05-1.49	0.012
Others	1.00	0.69-1.43	0.984
Number of Chronic Condition (referent: None)			
One	0.69*	0.58-0.81	<0.000
Two and more	0.63*	0.52-0.76	<0.000
Reported Household income (referent: Income below \$40,627)			
\$ 40,627 and over	0.92	0.80-1.04	0.183
Total number of past visits	0.99	0.98-1.00	0.264
Total number of visit medications	1.05*	1.01-1.08	0.005
Insurance Type (referent: Private Insurance)			
Medicare/Medicaid	0.89	0.74-1.06	0.152
Else (Worker's compensation, Self-Pay, Charity)	0.74*	0.57-0.95	0.022
PCMH (referent: Not accredited)			
Level 1	0.89	0.69-1.12	0.298
Level 2	0.94	0.74-1.20	0.630
Level 3	1.03	0.82-1.28	0.811
Region (referent: Northeast)			
Midwest	1.16	0.86-1.57	0.319
South	0.85	0.64-1.14	0.275
West	1.06	0.81-1.39	0.689
Metropolitan Statistical Area			
Yes	0.95	0.73-1.23	0.684
Type of Practice (referent: Group practice)			
Solo	1.19	0.99-1.44	0.060
Type of Physician (referent: Doctor of Medicine)			
Doctor of Osteopathy	1.35*	1.00-1.81	0.048
Physician Specialty Group* (referent: Surgical Care)			
Primary Care	1.45*	1.13-1.86	0.003
Medical Care Specialty	1.89*	1.40-2.56	<0.000
Employment Status of Physician (referent: Owner)			
Employee or Contractor	1.03	0.85-1.25	0.757

(Source: NAMCS 2009-2010)

The results of Archer-Lemeshow goodness-of-fit statistics for the completed five imputed data sets range from 1.12-1.50 and the p-values of these five tests were all greater than 0.05. These results suggest that the fits of all models were acceptable.

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## **CHAPTER V. DISCUSSION**

The objective of this dissertation was to evaluate primary care delivery and elucidate how PCMH has been adopted in practices and how their subsequent processes of care impact the quality of medication use. This dissertation aimed to quantify the association between the levels of NCQA PCMH recognition in primary care practices and the quality of care related to medication use. The central hypothesis of this dissertation was that a practice achieving higher levels of NCQA PCMH recognition, as determined by the NCQA PCMH scoring system, will offer better quality care and have higher levels of safe medication prescription, as determined by three medication quality indicators.

This dissertation was categorized into 5 chapters. Chapter 1 provided a complete review of the literature on medication quality and current understanding of PCMH. This review specifically included (1) analysis of current existing literature focused on quality, medication quality and an overview of the PCMH, and (2) identification of the gaps in our knowledge of the association between PCMH implementation and specific medication quality indicators. Chapters Two, Three, and Four presented three separate papers with different aims and each analysis contributed to the overall objective of the study. Although statistical analyses were conducted separately and reported in these different chapters, together the chapters aimed to assess the factors associated with the PCMH implementation and impact on patient medication use. The study in Chapter 2 applied the proposed PCMH framework to determine whether a significant

association existed between physician characteristics and PCMH implementation across the nation. Chapter 3 and Chapter 4 then examined whether adopting a PCMH model resulted in a noticeable improvement in quality of medication process and outcomes for individuals in the United States.

The present chapter, which built on the results and conclusions from the previous three chapters, draws a picture of PCMH adoption and its association with medication quality of care. Specifically, this chapter consists of five sections. First, the gaps of past PCMH studies are presented. Second, a discussion of how the three chapters address the gap in PCMH knowledge is offered. Third, the overall findings of the present studies are compared to those of past literature. Fourth, the limitations of this dissertation are discussed. Lastly, the implications of these studies for research and policy as well as future research directions are described in detail.

### **Gap in Current PCMH Research**

As discussed in the first chapter, numerous studies have emphasized the importance of patient medication quality of care and the impact of adopting PCMH for practices, yet three major limitations exist in the current literature. First, the approach of *how* PCMH adoption affects medication quality of care has not been examined. While many studies have demonstrated that receiving care in a PCMH can improve overall health services utilization, patient satisfaction, and some quality of care measures (e.g., having better rates of using preventive services, including cancer screening tests or seasonal flu shots),<sup>1-3</sup> what remains largely unexplored is how and to what extent this promising patient care model can affect patients' process-of-care and health outcomes related to medications. It is important to know whether this

promising patient care model can facilitate, ensure, and monitor medication quality of care. This process is particularly important if we consider that almost one-half of the U.S. population takes at least one medication and more than forty percent of adults age 65 and older use five or more different medications per week.<sup>4,5</sup> Indeed, previous studies have shown that when medication experts, such as pharmacists, are involved in collaborative PCMH team care there is a positive impact on several medication-related clinical outcomes for patients with chronic diseases, such as an improvement in glycated hemoglobin (HbA1c) and low-density lipoprotein (LDL) tests, or blood pressure.<sup>6-10</sup> Although PCMH studies of the above selected measures have indicated that patients did improve their clinical measures after taking medications, the studies were narrowly focused on patients with chronic diseases and failed to consider monitoring of direct medication use and medication use consequences.

A second limitation of previous studies is related to where the data on PCMH adoption has been collected. Although PCMH can provide comprehensive, patient-centered, coordinated, and accessible care aimed at achieving meaningful quality improvements for patients and has become a hot topic in today's healthcare delivery reform, most of the relevant literature is limited to state-level projects.<sup>11,12</sup> In other words, most of the results in the current PCMH literature reflect only partial success of the implementation of PCMH with no comprehensive assessment across the nation. Chapter 1 revealed that nationwide assessments of the factors associated with PCMH adoption are lacking, yet PCMH is one of the significant tools of today's Affordable Care Act. Few studies have evaluated PCMH adoption via a nationally representative database to clearly identify the extent of PCMH adoption.<sup>13-15</sup> To our knowledge, only the paper by Hollingsworth Et al. employed and described how to use the NCQA PCMH recognition program to assess the adoption of PCMH practices across the nation.

A third limitation in previous studies is related to the comprehensiveness of examination of *what* factors might be associated with the adoption of PCMH. Most of the past studies have found that practice characteristics, such as size and type, have the most significant influence on the extent to which practices have transformed traditional care into a collaborative team-oriented care. Missing from these studies are practice-level characteristics and the characteristics of physicians who theoretically have a great capacity to determine the extent to which an organization (i.e., practice) can transform itself into a PCMH.

Thus, these three limitations indicate clear gaps in the literature, that, if addressed, would offer a more comprehensive view of *how* the adoption of PCMH affects patient medication quality as well as *what* factors are associated with the practice decision-making in terms of transforming care into a PCMH at the national level.

In an attempt to more comprehensively examine PCMH adoption, this dissertation used a modified theoretical framework, considering two models from health services research, and applied these in three separate, but interrelated papers (Chapter 2, Chapter 3, and Chapter 4). The objectives of these three papers were to (1) explore the association between the level of PCMH adoption in a practice and its impact on processes and outcomes of care related to medication use and (2) quantify current primary care practices' level of PCMH adoption and determine practice-based and physician-related factors associated with the degree of PCMH implementation.

## **Filling the Gaps in Previous PCMH Research**

### **Proposed PCMH Framework**

Past literature has centered on evaluating the implementation of PCMH via various avenues. However, there are missed opportunities in the exploration of PCMH adoption to improve medication-related quality of care as well as expanding our understanding what factors might influence the PCMH adoption. As discussed in detail in Chapter 1, Wagner's Chronic Care Model serves as the central feature for the proposed framework, while the Hogg's primary care model provides a more structured skeleton to interpret the effect of PCMH on medication quality of care. Combining these models offers a more complete theoretical framework to examine the PCMH infrastructure and impact on the delivery of care.

The new theoretical framework is shown in Figure 1.1. In this combined model, the environmental, structural, and organizational factors of primary care are emphasized, and factors from different perspectives are classified into structural, performance, and outcome domains. For example, the original structural domain proposed by Hogg Et al. included three perspectives (1) health care system, (2) practice context, and (3) organization of the practice. Our study differs from Hogg's original primary care model and investigates only the last two perspectives, which are viewed as the structural domain. As to the performance domain, the level of NCQA PCMH recognition will quantify the performance of each practice. Since the outcome domain was not proposed in Hogg's primary care model, it was adopted from Wagner's chronic care model. The outcomes of the newly proposed model were three medication use quality indicators. These three quality indicators were classified into two categories: (1) process of care, and (2) outcome of care. For medication process of care outcomes, the high-risk medication and drug-disease

interaction lists were selected to represent the extent of medication-related process of care. The occurrence of adverse drug events, on the other hand, was selected as the medication outcome quality.

## **Overview of Findings**

*Factors Associated with PCMH adoption.* In Chapter 2, the study used the structural domain of Hogg's primary care model and merged it with the Roger's diffusion of innovation theory to build a basic conceptual framework, aiming to explore the factors associated with the adoption of the PCMH. Based on the notion of diffusion of innovation theory (i.e., assuming that specific individual characteristics would affect the spread of new ideas) and the evidence from literature review, this study hypothesized that besides practice-level characteristics, physician-related characteristics would play significant roles in the extent of PCMH adoption among practices.

The classification of different levels of PCMH for practices integrated aspects from the NCQA PCMH recognition program and mapped it to the appropriate and available survey items listed in the NAMCS. This mapping technique was based on Hollingsworth Et al., the first paper to delineate the mapping procedures, including multiple imputations based on chained equations to correct for the item-missing data. This study advanced the previous work by updating the data sources as well as assigning more restrictive criteria (i.e., taking must-pass elements into account) to classify the different levels of PCMH.

While applying design-based practice-level weights to the 2009 and 2010 NAMCS data, it was found that around 54% of practices were recognized as having some level of PCMH

implementation. Five physician characteristics (age, gender, employment status, specialty, and type) and six practice characteristics (region, metropolitan status, organizational structure, type, ownership, and size) were selected to examine the association with the level of PCMH adoption. The results showed that younger, male, primary care physicians and larger practices have higher odds of being associated with the PCMH adoption. The findings were consistent with the diffusion of innovation theory and previous work, wherein physicians with younger age, male, and belonging to larger practices had quicker adoption of new ideas. As to the type of physicians, this study indicated that primary care physicians were more likely to adopt the PCMH than specialties. One reason for explaining this phenomenon is because PCMH tends to be based on primary care settings rather than other specialty ones.

*Association Between PCMH and Medication Quality.* Chapters 3 and 4 focused on the effect of the PCMH model on the process and outcome domains of care. The overall objective of these two chapters was to investigate whether the transformation of primary care (i.e., the extent to which practices adopt PCMH) would lead to better medication quality of care. The adoption of the PCMH model was expected to be associated with the extent to which practices improved their process of care for patients. To investigate this hypothesis and the hypothesis related to an improved outcome domain of the model, three medication-related indicators were chosen. The approach for defining the level of PCMH for practices is the same as that in previous chapter (Chapter 2).

Using the 2009 and 2010 NAMCS data, Chapter 3 examined whether PCMH adoption would improve medication process of care quality using two well-representative medication quality of care indicators (i.e., high risk medication and drug-disease interaction).. The targeted population was limited to adults aged 65 and over because this population is likely to take

medications that allow the indication criteria to be met. With the appropriate patient visit weights, Chapter 3 demonstrated nationally representative results. Based on the sample of 13,156 outpatient clinic visits, nearly 11% of older adult visits involved prescription of high risk medication, and approximately 15% of older adult visits involved drug-disease interactions, including the use of medications that should be avoided with diagnoses of dementia, falls or chronic renal failure. Contrary to the hypothesis, the level of PCMH was not associated with the odds of older adults visit having either high-risk medication or drug-disease interactions, while adjusting for the other covariates.

Unlike practice characteristics, individual characteristics had an influence on the exposure to both high-risk medication and drug-disease interactions. For the high risk medication model, elderly visits where the patient was recognized as female, older, had more past visits, used more medications, lived in the southern region, and were seen by primary care physicians was significantly associated with inappropriate medications. For drug disease interaction lists, only two individual characteristics had a significant influence: the number of medication use and the number of chronic diseases. The results demonstrated that additional medication use or having fewer chronic diseases would increase the odds experiencing a drug disease interaction.

Chapter 4 also showed similar findings. In Chapter 4, the aim was to assess whether the adoption of PCMH would reduce the occurrence of adverse drug events, which represented a proxy of medication outcome quality. The data resource (i.e., 2009 and 2010 NAMCS) was the same as in Chapter 3. The targeted population of this Chapter included a sample of all ages with those having at least one medication record. The results showed that 4.2% of patient visits were related to ADEs. Additionally, whether an ADE related patient-visit occurred in a PCMH or a non-PCMH practice setting did not show any significant associations, after controlling for other



covariates, including both practice-level and individual-level characteristics. The results of this chapter were also consistent with Chapter 3 in that individual-level characteristics were more significantly associated with the occurrence of ADEs. Patients' gender female, being black, having more medication used, having fewer chronic conditions, and with insurance other than private or public were significantly associated with a greater odds of an ADE-related visit. Overall, neither analysis found a significant association between PCMH adoption and the selected medication process and outcome quality measures.

### **Findings Compared to Past PCMH Research**

Findings across the chapters (2, 3, and 4) utilized two innovative approaches which have not been investigated in previous studies. The following paragraphs explain the approaches in two subsections, as in the previous section.

*Factors Associated with PCMH adoption.* While previous studies centered on practice-level characteristics to explain the extent to which practices adopt the PCMH model, Chapter 2 offered a more advanced, theoretical, and behavioral-based approach to explore whether physician characteristics might also influence PCMH adoption among practices. First, this question has never been explored in previous studies, due in part to the restricted access to most of the physician-related variables in the NAMCS dataset. If researchers have an interest in investigating the physician-related variables, the process of applying for and gaining permission to access the variables and the data is quite burdensome. Second, the approach to explain the relation between physician characteristics and the adoption of PCMH is novel. None of the current literature has combined Hoggs' primary care theory and Roger's innovation of diffusion

theory to hypothesize that physician characteristic might play significant roles in the extent of PCMH adoption in practices (i.e., representing an acceptance of recent health reform) that they reside in. To explore more detail association between structure and process domains of the proposed conceptual framework, this study even used the diffusion effect within the diffusion of innovation theory to explain how the individual characteristics would have influence on adopting new ideas. This study did show that the results were consistent with what the diffusion of innovation theory hypothesized. And it is important to use a theoretical approach which may help further research to explain physician behavior by specifying relations among the selected variables.

***Association Between PCMH and Medication Quality.*** Compared to previous studies that have examined the association between the PCMH adoption and the quality of care that practices offered, the studies in Chapter 3 and 4 provided a relatively specific investigation of patient medication quality. Particularly, this study used the process and outcome domains in the conceptual theoretical framework to examine whether the transformation of PCMH among practices would affect the medication quality of care, using HRM, DDIS, and ADEs as examples. The findings of previous studies investigating the adoption of PCMH and its effect on improving quality of care have been mixed.<sup>16,17</sup> Although it was anticipated that PCMH adoption would be associated with improved medication quality of care, the results presented in the two chapters did not support this conclusion. This discouraging outcome raises the concerns about how to improve patient health through better monitoring of medication use. In particular past studies have advocated two approaches to optimize patient medication quality of care: (1) the integration of comprehensive medication management under the PCMH model and (2) the

involvement of clinical pharmacists to be part of the PCMH team members to help patients engage in medication related issues. All of these studies demonstrated positive results.

Two reasons might explain why the findings were inconsistent with previous studies. First, the analysis of medication management integration under the PCMH context was not comprehensive. Although several studies have indicated that a PCMH model could improve patient medication management, it benefits only specific patients, namely those who are not reaching their therapy goals, having trouble understanding/following medication regimen, or having frequent readmissions to the hospital.<sup>18-20</sup> However, for those patients who do not belong to these vulnerable populations, there is no evidence.

Second, the expansion of pharmacists' roles in PCMH is still at a very early stage. Over the past decade, the pharmacists' role has generally been shifting from traditional product-oriented/dispensing activities to a boarder range of patient-centered services. Only in the last five years, with the emergence of the PCMH, has the door been opened in primary care to introduce patients to the financed roles for other non-physician disciplines to the patient care team, creating opportunities and a demand for pharmacists to be involved in patient quality of care to ensure safe, effective, and evidence-based medication use. During this time, pharmacists have begun to be regarded as significant medication gatekeepers for PCMH to optimize medication use.<sup>7</sup> Yet, it appears that pharmacists' efforts under the PCMH are still limited to a small number of tasks, including collaborative drug therapy management and medication therapy management for chronic diseases.<sup>7</sup> What is not known is whether these activities are effective because previous studies have lacked thorough assessments of patient medication use on the basis of different types of quality indicators, such as those (i.e., high risk medication /drug-disease interaction lists and the occurrence of ADEs) used in this dissertation or recommended from previous literature.<sup>21</sup>

Overall, the results of this dissertation imply that there remain roles for pharmacists to participate in monitoring medication quality of care within the PCMH.

### **Implications and Future Research**

This dissertation is one of the first studies following a theoretical model to explore physician-related factors associated with the PCMH adoption and its impact on medication quality of care. Several significant implications have emerged from the findings of this dissertation and can be considered at both policy and practice levels.

Two take-away messages are important for policy makers. First, health policy makers should not abandon the PCMH. While the results of this study did not provide positive support to prove that PCMH was an effective model for controlling/enhancing the medication quality of care, the evidence only reflects that from the three medication quality measures. Other prevention and screening or disease specific quality measures, such as cervical cancer screening, breast cancer screening, adult BMI assessment, or disease modifying anti-rheumatic drug therapy for rheumatoid arthritis, should be examined for the effectiveness of PCMH.

Second, the inclusion criteria or indicators to identify a PCMH may need to be reconsidered, especially in the context of its impact on medication use. For example, a criteria such as, “are medications reviewed by clinical pharmacist?” may be especially relevant in future work. The current NCQA PCMH criteria do not emphasize the quality of medication use in the list. Based on the results of this study, it is important to suggest that medication quality is still a concern for PCMH practices. The scenario might improve if the NCQA PCMH criteria clearly indicated the importance of medication quality in its definition of PCMH.

As for practice, two significant implications are offered. First, there is a need to promote the PCMH adoption focusing on specific physician groups. Based on the results of this study, physicians of older age, being female, and identified as medical specialties in ambulatory care settings were less likely to adopt the PCMH. In order to increase the adoption of PCMH, healthcare organizations might design a practical incentive plan that targets these specific populations. Second, there is another need for improving medication use in the PCMH. This study did not find significant associations between the adoption of PCMH and specific medication quality measures. It is critical for medication experts, such as pharmacists, to design interventions for improving these quality indicators in PCMH practices. As well, it may be important to measure and provide incentives for these particular measures to facilitate their improvement.

For the future research, two directions can be pursued to expand the results of this investigation. The first is to acquire more information about physicians, such as their knowledge, skills, and attitudes toward supporting the adoption of PCMH. To determine physician attitudes toward the transformation of traditional care into a PCMH, smaller scale studies using qualitative methods need to be conducted. The findings of such studies could result in a deeper understanding of variation in PCMH adoption across different primary care settings.

The second direction is to investigate whether the involvement of specific healthcare professionals can increase the PCMH adoption rate or the outcomes of care delivered in PCMH. This work is possible in the near future because, beginning in 2013, the NAMCS dataset included a series of checkboxes for interviewees (i.e., physicians) to indicate directly whether (1) their practices adopt PCMH and (2) the presence of any other non-physician professionals (e.g., pharmacists, nurse, and social workers) involved in care. This updated dataset may eliminate the

mapping bias that this study encountered and provide an opportunity to identify whether a more diverse collaboration with other health care professionals can facilitate PCMH adoption as well as offer better quality of care to patients.

## **Limitations**

Similar to other studies, this dissertation has some limitations, which can generally be divided into design and data considerations. First, the design limitations of this dissertation include (1) cross-sectional study design, (2) the selection of the three medication quality indicators, and (3) the inclusion of physician characteristics in Chapter 3 and Chapter 4. Indeed, there are limitations in using a cross-sectional study design, as it is impossible to make causal inferences. In future, the use of longitudinal surveys or study designs comparing pre-post study periods for the adoption of PCMH and medication use outcomes would provide an opportunity to identify trends in PCMH adoption. As well, results from a longitudinal study would reflect not only the scenario at a given time but allow investigators to observe changes over time. However, there are still advantages in conducting cross-sectional studies. For example, it can (a) provide an indication of the magnitude of an issue because the data are often taken from the whole population, (b) include many outcomes and risk factors, and (c) be used for public health planning.<sup>22</sup>

As mentioned earlier, HRM, DDIS, and ADEs were chosen to represent medication process and outcome indicators. The choice of the three indicators may have resulted in selection bias, as they are only a subset of the many medication indicators that can be used to examine the provision of medications in the context of a PCMH. Other medication-related quality indicators,

such as the avoidance of antibiotic treatment for adults with acute bronchitis, the use of angiotensin converting enzyme inhibitors (ACE inhibitors) and angiotensin receptor blockers (ARBs) among patients with diabetes, the use of appropriate medications for patients with asthma, were other available medication-related quality indicators in the NAMCS dataset. Future studies may examine these indicators. Another related drawback of the studies in Chapter 3 and Chapter 4 is that they did not control for several restricted physician-related variables in the examination of the association with patient medication quality of care outcomes. Access to these data was limited to the original models and modifications to the datasets could not be done. Therefore, the studies in Chapter 3 and Chapter 4 did not include the physician characteristics as the control covariates. Future studies can add these physician characteristics to derive unbiased estimates.

Second, the PCMH mapping technique has limitations, and NAMCS does not contain all physician characteristics that may be considered. The mapping technique used to define the PCMH may be questioned in terms of how well it captured actual PCMH environments in practices. This is because the NCQA PCMH recognition program emphasized the implementation of health information technology in practices rather than physician-led care or the collaboration of care delivered to patients. Despite this limitation, the mapping technique employed here is the most commonly used approach in today's literature involving a nationally representative dataset to reflect the results from a macro-level perspective. Furthermore, some of the physician characteristics, such as physician race, years since receiving the medical degree, years in practice, participation in any special courses, are not available in the NAMCS data. These characteristics may be significant determinants of whether practices adopt a PCMH and should be examined.

Third, there was an issue in terms of missing data while analyzing the selected variable in the NAMCS. Based on the results of the table of fraction of missing information (Appendix F), nearly 50% of the patient visits had complete data information. Therefore, the use of multiple imputation of chain equation technique was applied to replace missing values with multiple sets of simulated values and to adjust the parameter estimates for missing data uncertainty. The approach represents a sound scientific approach to manage missing data.

## **Conclusion**

Medication quality of care remains an unsolved public health problem and innovative ways to solve it are still needed. Three medication quality indicators (HRM, DDIS, and ADEs) were not significantly improved in the PCMH context. The findings regarding the adoption of PCMH by physician practices were consistent with previous studies that showed individual/physician-related characteristics had a greater influence than did practice-level characteristics. Policymakers need to be aware that effective strategies are needed to improve the medication quality of care for patients under the promising PCMH model.



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## APPENDICES

### APPENDIX A. BEERS CRITERIA, ZHAN CRITERIA AND NCQA LISTS

Criteria	Medications	Pros	Cons
Beers (1997)	Propoxyphene and combination products, Indomethacin (Indocin, Indocin SR), Phenylbutazone (Butazolldln), Pentazocine (Talwin), Trimethobenzamide (Tlgan), Methocarbamol (Robaxin), carlsoprodol (Soma), oxybutynin (Dltropan), chlorzoxazone (Paraflex), metaxalone (Skelaxin), and cyclobenzaprine (Flexeril) Flurazepam (Dalmane), Amitrlptyline (Elavil), chlordiazepoxldeamitriptyline (Limbitrol), and perphenazlne-amltlptyline (Triavil) Doxepin (Slnequan), Meprobamate (Miltown, Equanll), Lorazepam (Ativan), 3 mg; oxazepam (Serax), 60 mg; alprazolam (Xanax), 2 mg; temazepam (Restoril), 15 mg; zolpidem (Amblen), 5 mg; triazolam (Halcion), 0.25 mg, Chlordiazepoxlde (Librlum), chlordiazepoxide-amltlptyline (Limbitrol), clldlnlum-chlordlazepoxide (Librax), and diazepam (Vallum), Disopyramide (Norpace, Norpace CR), Digoxin (Lanoxln), Dlpyridamole (Persantlne), Methyldopa (Aldomet); methyldopa/ hydrochlorothlazide (Aldoril), Reserpine (Serpasil); reserplne hydrochlorothlazide (Hydropres) Chlorpropamide (Diablnese), Dlcydomine (Bentyl); hyoscyamine (Levsin, Levsinex); propantheline (Pro-Banthine); belladonna alkaloids (Donnatal and others); and clldinium-chlordiazepoxide (Librax), Examples include single and combination preparations containing chlorphenramine (Chlor-Trimeton), diphenhydramine (Benadryl), hydroxyzine (Vistaril, Atarax), cyproheptadine (Periactln), promethazlne (Phenergan), tripeleennamine, and dexchlorphenramlne	*First medication list for the use of inappropriate medication among the elderly population.  *Add the severity noting high or low risk	Quantified the appropriateness of medications mostly for nursing home residents, and added the severity noting high or low risk in 1997

(Polaramine), Diphenhydramine (Benadryl), Ergot mesyloids (Hydergine),  
cyclospasmol, Iron supplements, >325 mg, All barbiturates except phenobarbital,  
Meperidne, Ticlopidine

Beers  
(2002)

**Medicines Modified Since 1997 Beers Criteria:** Reserpine (Serpasil and Hydropres), Extended-release oxybutynin (Ditropan XL), Iron supplements >325 mg, Short-acting dipyridamole (Persantine)

**Medicines Added Since 1997 Beers Criteria:**

Independent of Diagnoses: Ketorolac tromethamine (Toradol), Desiccated thyroid, Orphenadrine (Norflex), Ferrous sulfate 325 mg, Guanethidine (Ismelin), Amphetamines (excluding methylphenidate and anorexics), Guanadrel (Hylorol), Thioridazine (Mellaril), Cyclandelate (Cyclospasmol), Short-acting nifedipine (Procardia and Adalat), Isoxsuprine (Vasodilan), Daily fluoxetine (Prozac), Nitrofurantoin (Macrochantin), Stimulant laxatives may exacerbate bowel dysfunction (except in presence) Doxazosin (Cardura) of chronic pain requiring opiate analgesics), Methyltestosterone (Android, Virilon, and Testrad), Amiodarone (Cordarone), Non-COX-selective NSAIDs (naproxen [Naprosyn], oxaprozin, and piroxicam), Mesoridazine (Serentil), Reserpine doses 0.25 mg/d, Clonidine (Catapres), Estrogens in older women, Mineral oil, Cimetidine (Tagamet), Ethacrynic acid (Edecrin)

Considering Diagnoses: Long-acting benzodiazepines: chlordiazepoxide (Librium), chlordiazepoxide-amitriptyline (Limbitrol), clidinium-chlordiazepoxide (Librax), diazepam (Valium), quazepam (Doral), halazepam (Paxipam), and chlorazepate (Tranxene) with COPD, stress incontinence, depression, and falls; Decongestants with bladder outflow obstruction; Calcium channel blockers with constipation; Phenylpropanolamine with hypertension; Bupropion (Wellbutrin) with seizure disorder; Olanzapine (Zyprexa) with obesity; Metoclopramide (Reglan) with Parkinson disease; Conventional antipsychotics with Parkinson disease; Propranolol with COPD/asthma; Tacrine (Cognex) with Parkinson disease; Anticholinergics with stress incontinence; Barbiturates with cognitive impairment; Tricyclic antidepressants (imipramine hydrochloride, doxepine hydrochloride, and amitriptyline hydrochloride) with syncope or falls and stress incontinence; Antispasmodics with cognitive impairment; Muscle relaxants with cognitive

\* Classified medications into 2 types:  
(1) 48 medications that should generally be avoided, and  
(2) medications that should not be used under 20 specific medical conditions.

n/a

impairment; CNS stimulants with anorexia, malnutrition, and cognitive impairment; Short to intermediate and long-acting benzodiazepines with syncope or falls; Clopidogrel (Plavix) with blood-clotting disorders receiving anticoagulant therapy; Tolterodine (Detrol) with bladder outflow obstruction

Zhan (2001)	<p><b>Always avoid-</b> Barbiturate, Flurazepam, Meprobamate, Chlorpropamide, Meperidine, Pentazocine, Trimethobenzamide, Belladonna alkaloids, Dicyclomine, Hyoscyamine, Propantheline</p> <p><b>Rarely appropriate-</b> Chlordiazepoxide, Diazepam, Propoxyphene, Carisoprodol, Chlorzoxazone, Cyclobenzaprine, Metaxalone, Methocarbamol</p> <p><b>Have some indications but are often misused-</b> Amitriptyline, Doxepin, Indomethacin, Dipyridamole, Ticlopidine, Methyldopa, Reserpine, Disopyramide, Oxybutynin, Chlorpheniramine, Cyproheptadine, Diphenhydramine, Hydroxyzine, Promethazine</p>	Classified 33 drugs into 3 categories.	n/a
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NCQA (2010)	<p>aspirin-meprobamate, meprobamate, scopolamine, trimethobenzamide, ketorolac, APAP/dextromethorphan/diphenhydramine, APAP/diphenhydramine/phenylephrine, APAP/diphenhydramine/pseudoephedrine, acetaminophen-diphenhydramine, carbetapentane/diphenhydramine/phenylephrine, codeine/phenylephrine/promethazine, codeine-promethazine, cyproheptadine, Dexchlorpheniramine, dexchlorpheniramine/dextromethorphan/PSE, dexchlorpheniramine/guaifenesin/PSE, dexchlorpheniramine/hydrocodone/phenylephrine, dexchlorpheniramine/methscopolamine/PSE, dexchlorpheniramine-pseudoephedrine, dextromethorphan-promethazine, diphenhydramine, diphenhydramine/hydrocodone/phenylephrine, diphenhydramine-magnesium salicylate, diphenhydramine-phenylephrine, diphenhydramine-pseudoephedrine, hydroxyzine hydrochloride, hydroxyzine pamoate, phenylephrine-promethazine, promethazine, thioridazine, amphetamine-dextroamphetamine, benzphetamine, dexmethylphenidate, dextroamphetamine, diethylpropion, methamphetamine, methylphenidate, phendimetrazine, phentermine, butabarbital, mephobarbital, pentobarbital, phenobarbital, secobarbital, amitriptyline-chlordiazepoxide, chlordiazepoxide, chlordiazepoxide-clidinium diazepam, flurazepam, nifedipine—short-acting only, dicyclomine, propantheline, atropine, atropine/CPM/hyoscyamine/PE/scopolamine, atropine/hyoscyamine/PB/scopolamine, atropine-difenoxin, atropine-diphenoxylate, atropine-edrophonium, belladonna, belladonna/ergotamine/phenobarbital, butabarbital/hyoscyamine/phenazopyridine, hyoscyamine, hyoscyamine/methenam/m-blue/phenyl salicyl, ASA/caffeine/orphenadrine, ASA/carisoprodol/codeine, aspirin-carisoprodol, aspirin-methocarbamol, carisoprodol, Chlorzoxazone, cyclobenzaprine metaxalone, methocarbamol, orphenadrine, conjugated estrogen, conjugated estrogen-medroxyprogesterone, esterified estrogen, esterified estrogen-methyltestosterone, estropipate, chlorpropamide, ASA/caffeine/propoxyphene, acetaminophen-pentazocine, acetaminophen-propoxyphene, belladonna-opium, meperidine, meperidine-promethazine, naloxone-pentazocine, pentazocine, propoxyphene hydrochloride, propoxyphene napsylate, dipyrindamole—short-acting only, ergot mesyloid, isoxsuprine, methyltestosterone,</p>	An updated and comprehensive lists	Not shown too often in research literature but is adopted common in health plans
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nitrofurantoin, nitrofurantoin macrocrystals, nitrofurantoin macrocrystals-  
monohydrate, thyroid desiccated

## APPENDIX B. DESCRIPTION OF DDIS IDENTIFIED BY THE HEDIS MEASURE

Disease States	Drugs Class	Drugs to Avoid
Dementia	Anticholinergics , Tricyclic Antidepressants	Alavert, Alkabel-SR, Allerman, Altaryl, Ambien, Amrix, Anaspaz, Antihistamine, Antivert, Arbinoxa, Atreza, Atropine, Axid, Banaril, Banflex, Belladonna, Bellatal, Benadryl, Bentyl, Bidhist, Bonine, Bromaphen, Bromax, BroveX, Carbinoxamine, Carisoprodol, Chlorpheniramine, Cimetidine, Claritin, Clemastine, Cogentin, Cyclobenzaprine, Cystospaz, Darcalma, Darpaz, Detrol, Dicyclomine, Dimenhydrinate, Diphedryl, Diphenhydramine, Diphenmax, Ditropan, Donnatal, Dramamine, Driminate, Edluar, Enablex, Famotidine, Fexmid, Flavoxate, Flexeril, Genahist, Histaprin, Homatropine, Hycodan, Hydramine, Hydromet, HyoMax, Hyophen, Hyoscyamine, Intermezzo, Levbid, Levsin, Lodrane, Lomotil, Loratadine, Maldemar, Meclizine, Nizatidine, Orphenadrine, Oscimin, Oxybutynin, Palgic, PediaTan, Pepcid, Periactin, Pharbedryl, Phosename, Phosphasal, Probanthine, Quadrapax, Quenalin, Ranitidine, Sanctura, Scopace, Servira, Siladryl, Siltane, Soma, Sominex, Stahist, Taladine, Tavist, Tolterodine , Toviaz, Tranquil, Trihexyphenidyl, Triptone, Trospium, Tussigon, Twilite, Urelle, Uribel, Uta, Valudryl, Vanadom, Vazol, Verticalm, Vesicare, Vistaril, Wal-finate, Wal-itin, Wal-Zan, Zanaflex, Zantac, Zolpidem, Zzzquil
Fall or Hip Fracture	Antipsychotics, Tricyclic Antidepressants, Sleep Agents	Abilify, Adgan, Alprazolam, Amitriptyline, Amoxapine, Anafranil, Anergan, Ativan, Chlordiazepoxide, Chlorpromazine, Clonazepam, Clorazepate Dipotassium, Clozapine, Clozaril, Compazine, Compro, Dalmane, Desipramine, Diastat Acudial, Diastat Pediatric, Diazepam, Doral, Doxepin, Estazolam, Fanapt, FazaClo, Fluphenazine, Geodon, Halcion, Haldol, Haloperidol, Haloperidol, Imipramine, Invega, Klonopin, Latuda, Librax, Librium, Limbitrol, Lorazepam, Loxapine, Midazolam, Moban, Navane, Niravam, Norpramin, Nortriptyline, Olanzapine, Orap, Oxazepam, Pamelor, Permitil, Perphenazine, Phenadoz, Phenergan, Prochlorperazine, Promethegan, Protriptyline, Quetiapine Fumarate, Restoril, Risperdal, Risperidone, Saphris, Seroquel, Surmontil, Temazepam, Thioridazine, Thiothixene, Tofranil, Tranxene, Triazolam, Trifluoperazine, Trilafon, Trimipramine Maleate. Valium, Vanatrip, Vivactil, Xanax, Ziprasidone, Zyprexa

Chronic Renal Failure	NSAIDS (nonsteroidal anti-inflammatory drugs)	Advil, Aleve, Anaprox, Cambia, Cataflam, Celebrex, Clinoril, Daypro, Diclofenac, EC-Naprosyn, Etodolac, Feldene, Flurbiprofen, Genpril, IBU, Ibuprofen, Ibuprohm, Indocin, Indomethacin, Ketoprofen, Ketorolac Tromethamine, Meclofenamate Sodium, Mefenamic Acid, Meloxicam, Mobic, Motrin, Nabumetone, Nalfon, Naprelan, Naprosyn, Naproxen, Nuprin, Oxaprozin, Piroxicam, Ponstel, Sprix, Sulindac, Tolmetin, Voltaren, Wal-Profen, Zipsor
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APPENDIX C. NCQA 2008 STANDARDS AND GUIDELINES FOR PHYSICIAN PRACTICE CONNECTIONS ®

PATIENT-CENTERED MEDICAL HOME (PPC-PCMH™)

**Table 1: PPC 2006 to PPC-PCMH  
Crosswalk**

**SCORING IN PPC-PCMH:**

1. The number of overall points is the same but in some cases the distribution has changed:
  - The number of points increased for some elements.
  - As indicated below, some standards and elements have been added and others have been deleted.
2. One of the scoring options at the element level changed:
  - Increased from 20%–25%.
3. The number of factors increased in some elements but this did not change the scoring for those elements.

PPC 2006 and PPC-PCMH Standards	PPC 2006 and PPC-PCMH Element Titles	PPC 2006 Points	PPC-PCMH Points	Description of Change	PPC-PCMH Changes, Additions or Deletions				
					Standards	Elements	Factors	Explanation	Examples
PPC 1: Access and Communication	PPC 1A : Access and communication processes	4	4 <b>Must-Pass</b>	Added factor: Identifying health insurance resources for patients without insurance.			✓		
	PPC 1B: Access and communication results	4	5 <b>Must-Pass</b>	None					
PPC 2: Patient Tracking and Registry Functions	PPC 2A: Basic system for managing patient data	2	2	Added factors: Legal guardian, health insurance coverage and preferred method of communication			✓		
	PPC 2B: Electronic system for clinical data	3	3	Added factor: Head circumference for patients ≤2 years			✓	✓	
	PPC 2C: Use of electronic clinical data	3	3	None					
	PPC 2D: Organizing clinical data	6	6 <b>Must-Pass</b>	Added factor: Screening tool for developmental testing and growth charts.			✓	✓	
	PPC 2E: Identifying important conditions	4	4 <b>Must-Pass</b>	Added explanation for risk factors associated with practice's demographics.				✓	
	PPC 2F: Use of system for population management	2	3	Added factor: Patients who might benefit from care management. Added explanation for pediatrics.			✓	✓	

Continued

PPC 2006 and PPC-PCMH Standards	PPC 2006 and PPC-PCMH Element Titles	PPC 2006 Points	PPC-PCMH Points	Description of Change	PPC-PCMH Changes, Additions or Deletions				
					Standards	Elements	Factors	Explanation	Examples
PPC 3: Care Management	PPC 3A: Guidelines for important conditions	3	3 Must-Pass	Added to element: ... evidence-based <i>diagnosis and</i> treatment guidelines...		✓			
	PPC 3B: Preventive service clinician reminders	4	4	Added examples for pediatric practices.				✓	
	PPC 3C: Practice organization	3	3	Expanded explanation of team of physicians and staff related to handling patient care responsibilities.			✓	✓	
	PPC 3D: Care management of important conditions	5 Must-Pass	5	Changed factors from setting to <i>writing</i> individualized care plans and treatment goals.			✓	✓	
	PPC 3E: Continuity of care	5	5	Added to element: ... patients transitioning to other care. Added factors: written transition plan and help identifying new PCP or specialist.		✓	✓	✓	
PPC 4: Patient Self-Management Support	PPC 4A: Documenting communication needs	2	2	None					
	PPC 4B: Self-management support	4	4 Must-Pass	Added factor: provides written care plan to patient/family. Added to explanation: written materials appropriate for patients. Added to examples: referrals to community resources.			✓	✓	✓
PPC 5: Electronic Prescribing	PPC 5A: Electronic prescription writing	3	3	None					
	Electronic prescribing interoperability	3	Deleted	Deleted					
	PPC 5C (B): Prescribing decision support—safety	3	3	None					
	PPC 5D (C): Prescribing decision support—efficiency	2	2	None					

Continued

PPC 2006 and PPC-PCMH Standards	PPC 2006 and PPC-PCMH Element Titles	PPC 2006 Points	PPC-PCMH Points	Description of Change	PPC-PCMH Changes, Additions or Deletions				
					Standards	Elements	Factors	Explanation	Examples
PPC 6: Test Tracking	PPC 6A: Test tracking and follow-up	6	7 Must-Pass	Added factor: follow-up to get results on in-patient pediatric screening tests.			✓		
	PPC 6B: Electronic system for managing tests	6	6	None					
PPC 7: Referral Tracking	PPC 7A: Referral tracking	4	4 Must-Pass	Added to element: <i>Specialist or consultant report</i> . Added to explanation: clinical details to include in referral.		✓		✓	
	PPC 7B: Referral decision support	3	Deleted	Deleted					
PPC 8: Performance Reporting and Improvement	PPC 8A: Measures of performance	3 Must-Pass	3 Must-Pass	Added to factor: examples for pediatric practices.			✓		
	PPC 8B: Patient experience data		3	New	✓	✓	✓	✓	✓
	PPC 8C (8B): Reporting to physicians	3	3 Must-Pass	Added to explanation: staff meetings.				✓	
	PPC 8D (8C): Setting goals and taking action	3	3	Added family involvement.				✓	
	PPC 8E (8D): Reporting standardized measures	2	2	None					
	PPC 8F (8E): Electronic reporting—external entities	1	1	None					
PPC 9: Advanced Electronic Communications	PPC 9A: Availability of interactive Web site		1	New	✓	✓	✓	✓	✓
	PPC 9B: Electronic patient identification		2	New	✓	✓	✓	✓	✓
	PPC 9C: Electronic care management support		1	New	✓	✓	✓	✓	✓

The National Committee for Quality Assurance. Patient-centered medical home recognition. <http://www.ncqa.org/Programs/Recognition/Practices/PatientCenteredMedicalHomePCMH.aspx>. Accessed 07/15, 2014.

**APPENDIX D. MAPPING THE 2008 NCQA PCMH ELEMENTS TO THE 2009 2010 NAMCS Survey Items**

Variable Name	Corresponding question from NAMCS	Response	Point
<b>Standard 1: Access and communication</b>			
Element 1. Access and Communication Processes			
SASDAPPT	Does your practice set time aside for same day appointments? (MUST PASS)	(a)No (b)Yes	4
Element 2: Access and Communication Results (MUST PASS)			5
(No correspond questions from NAMCS)			
<b>Standard 2. Patient tracking and registry functions</b>			
Element 1. Basic System for Managing Patient Data			
EDEMOG	Does your practice have a computerized system for Patient history & demographic information?	(a)No (b)Yes	2
Element 2. Electronic System for Clinical Data			
EMEDREC	Does your practice use an EMR or EHR system (not including billing records)?	(a)No (b)Yes	3
Element 3. Use of Electronic Clinical Data			
EIMGRES	Does your practice have a computerized system for viewing imaging results?	(a)No (b)Yes	3
Element 4. Organizing Clinical Data			
EPNOTES	Does your practice have a computerized system for clinical notes? (MUST PASS)	(a)No (b)Yes	6
Element 5. Identifying Important Conditions			
EPROLST	If practice has a computerized system for patient demographic information, does it include patient problem lists? (MUST PASS)	(a)No (b)Yes	4
Element 6. Use of System for Population Management			
EMEDS	If practice has a computerized system for patient demographic information, does it include a list of medications that patient taking? (2010)	(a)No (b)Yes	3
<b>Standard 3. Care Management</b>			
Element 1. Guidelines for Important Conditions (MUST PASS)			3
(No correspond questions from NAMCS)			
Element 2. Preventive Service Clinician Reminders			
EREMIND	Does your practice have a computerized system for reminders for guideline-based interventions and/or screening tests?	(a)No (b)Yes	4
Element 3. Practice Organization			

PHYSASST, NPNMW, RNLPN	Was a PA seen at this visit? Was a Nurse practitioner/Midwife seen at this visit? Was a RN/LPN seen at this visit?	(a)No (b)Yes	3
<b>Element 4. Care Management Of Important Conditions</b>			
NHVISR, HOMVISR, TELCONR,E CONR	Did you make encounters of the following types with patients? (nursing home visits/other home visits/ hospital visits/ telephone consults/ email consults)	(a)No (b)Yes	5
<b>Element 5. Continuity of Care</b>		(No correspond questions from NAMCS)	5
<b>Standard 4. Self-management support</b>			
<b>Element 1. Documenting Communication Needs (MUST PASS)</b>		(No correspond questions from NAMCS)	2
<b>Element 2. Self-Management Support</b>			
HEALTHED	Was any health education ordered or provided at the visit?	(a)No (b)Yes	4
<b>Standard 5. Electronic prescribing</b>			
<b>Element 1. Electronic Prescription Writing</b>			
ECPOE	Does your practice have a computerized system for orders for prescriptions?	(a)No (b)Yes	3
<b>Element 2. Prescribing Decision Support—Safety</b>			
EWARN	If practice has a computerized system for orders for prescriptions, are there warnings of drug interactions or contraindications provided?	(a)No (b)Yes	3
<b>Element 3. Prescribing Decision Support—Efficiency</b>		(No correspond questions from NAMCS)	3
<b>Standard 6. Test tracking</b>			
<b>Element 1. Test Tracking and Follow-Up</b>			
ERANGE	If your practice has a system for viewing lab results, are out of range levels highlighted? (MUST PASS)	(a)No (b)Yes	7
<b>Element 2. Electronic System for Managing Tests</b>			
EORDER	(1)If your practice has a computerized system for orders for test, are orders sent electronically	(a)No (b)Yes	6
<b>Standard 7. Referral Tracking</b>			
<b>Element 1. Referral Tracking (MUST PASS)</b>		(No correspond questions from NAMCS)	4
<b>Standard 8. Performance reporting and improvement</b>			
<b>Element 1. Measures of performance (MUST PASS)</b>		(No correspond questions from NAMCS)	3
<b>Element 2. Patient Experience Data</b>		(No correspond questions from NAMCS)	3
<b>Element 3. Reporting to Physicians (MUST PASS)</b>		(No correspond questions from NAMCS)	3



Element 4. Setting Goals and Taking Action	(No correspond questions from NAMCS)	3
Element 5. Reporting Standardized Measures	(No correspond questions from NAMCS)	2
Element 6. Electronic Reporting External Entities		
EPUBHLTH Does your practice have a computerized system for electronic public health reporting? (2009)	(a)No (b)Yes	1
<b>Standard 9. Advanced electronic communications</b>		
Element 1. Availability of Interactive Web Site	(No correspond questions from NAMCS)	1
Element 2. Electronic Patient Identification	(No correspond questions from NAMCS)	2
Element 3. Electronic Care Management Support	(No correspond questions from NAMCS)	1

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## APPENDIX E. COMPARISON BETWEEN ORIGINAL NCQA PCMH CRITERIA AND SURVEY ITEMS

	Original 2008 NCQA PCMH criteria	Mapping Results from 2009 2010 NAMCS
Standards	9	7
Elements	30	20/21
Must Pass Elements	10	4
Scores	100	55/60
Level of PCMH		Relative scores (the number of available points/cumulative total scores)
Not Accredited	Less than 25 points	Less than 25 %
Level 1	25 points–49 points + Must-pass elements = 5 of 10	Between 25-49 % + Must-pass elements = 2 of 4
Level 2	50 points–74 points + Must-pass elements = 10 of 10	Between 50-74 % + Must-pass elements = 4 of 4
Level 3	75 points or more + Must-pass elements = 10 of 10	75 % or more + Must-pass elements = 4 of 4

**APPENDIX F. FRACTION OF MISSING INFORMATION ESTIMATES FROM MULTIPLE IMPUTATION ANALYSES**

Variable Name	Explanation	Mean %	Fraction of Missing Information %	Missing Proportion %
<b>Variables for composing the PCMH</b>				
SASDAPPT	Does practice set time aside for same day appointments?	64.28	2.76	3.68
EDEMOG	Does practice have computerized system for patient history & demographic info?	85.44	0.34	0.70
EMEDREC	Does practice use EMR or EHR system (not Including billing records systems)?	54.22	0.20	6.4
EIMGRES	Does practice have computerized system for viewing imaging results?	52.20	0.05	1.74
EPNOTES	Does practice have computerized system for clinical notes?	54.50	0.31	9.6
EPROLST	If yes, does this include a patient problem list?	54.06	4.50	7.98
EMEDS	If yes, do they include list of medications patient is currently taking?	55.30	0.06	1.92
EREMIND	Does practice have computerized system for reminders for interventions /tests?	39.77	2.73	5.55
PHYSASST	Physician assistant seen	6.05	0.00	0.00
NPNMW	Nurse Practice/ Midwife seen	1.81	0.00	0.00
RNLPN	RN/LPN seen	24.62	0.00	0.00
NHVISR	During last normal week of practice, nursing home visits?	15.35	0.75	2.64
HOMVISR	During last normal week of practice, other home visits?	6.30	1.46	2.91
TELCONR	During last normal week of practice, telephone consults w/pats?	52.84	2.18	4.35
ECONR	In last normal week of practice, internet/email consults w/pats?	7.97	1.03	4.07
HOSVISR	During last normal week of practice, hospital visits?	55.52	3.52	4.36
HEALTHED	Was health education ordered or provided?	39.93	0.08	1.44
ECPOE	Does practice have computerized system for orders for prescriptions?	49.39	0.04	1.09
EWARN	If yes, are warnings of drug interactions/ contraindications provided?	48.44	3.45	4.41
ERANGE	If yes, are out of range levels highlighted?	51.36	3.88	5.79
EORDER	If yes, are orders sent electronically?	34.26	1.67	3.15
EPUBHLTH	Practice has computerized system for public health reporting?	16.27	2.16	6.82

<b>Variables for practice characteristics</b>				
RETYPOFF	Type of office setting	100	0.00	0.00
REGION	Geographic region	100	0.00	0.00
MSA	MSA or non-MSA area	100	0.00	0.00
MDDO	MD or DO	100	0.00	0.00
SPECCAT	Physician specialty	100	0.00	0.00
SOLO	Solo or group practice	31.44	0.01	1.30
OWNS	Who owns the practice?	97.60	0.07	2.40
EMPSTAT	Employment status of physician	96.20	0.09	3.80
PAYTYPER	Recoded type of payment	92.30	4.50	7.70
<b>Variables for patient characteristics</b>				
AGE	Patient age	100	0.00	0.00
SEX	Patient gender	100	0.00	0.00
RACER	Patient race	100	0.00	0.00
NUMMED	Patient number of medication use	100	0.00	0.00
PASTVIS	How many visits in past 12 months?	100	0.00	0.00
ARTHRTIS	Does patient now have arthritis?	100	0.00	0.00
ASTHMA	Does patient now have asthma?	100	0.00	0.00
CANCER	Does patient now have cancer?	100	0.00	0.00
CEBVD	Does patient now have cerebrovascular disease?	100	0.00	0.00
CRF	Does patient now have chronic renal failure?	100	0.00	0.00
CHF	Does patient now have congestive heart failure?	100	0.00	0.00
COPD	Does patient now have COPD?	100	0.00	0.00
DIABETES	Does patient now have diabetes?	100	0.00	0.00
HYPLIPID	Does patient now have hyperlipidemia?	100	0.00	0.00
HTN	Does patient now have hypertension?	100	0.00	0.00
IHD	Does patient now have ischemic heart disease?	100	0.00	0.00
HINCOMER	Median household income in patient's ZIP	94.61	3.84	5.39
PAYTYPER	Recoded type of payment	92.30	5.11	7.70

## APPENDIX G. IRB DOCUMENTATION



Health Sciences and Behavioral Sciences Institutional Review Board (IRB-HSBS) • 2800 Plymouth Rd., Building 520, Room 1170, Ann Arbor, MI 48109-2800 • phone (734) 936-0933 • fax (734) 998-9171 • irbhsbs@umich.edu

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**To:** Chi-Mei Liu

**From:**

Thad Polk

**Cc:**

Chi-Mei Liu  
Brady West  
Steven Erickson  
Karen Farris  
Richard Bagozzi

**Subject:**Initial Study Approval for [HUM00096464]

**SUBMISSION INFORMATION:**

Study Title: Extent of PCMH adoption and medication use quality  
Full Study Title (if applicable): Extent of PCMH adoption and medication use quality: results from a nationally representative sample  
Study eResearch ID: [HUM00096464](https://erresearch.umich.edu/HUM00096464)  
Date of this Notification from IRB:3/25/2015  
Review:Expedited  
Initial IRB Approval Date: 3/25/2015  
**Current IRB Approval Period:3/25/2015 - 3/24/2016**  
**Expiration Date:** Approval for this expires at **11:59 p.m. on 3/24/2016**  
**UM Federalwide Assurance (FWA): FWA00004969 (For the current FWA expiration date, please visit the [UM HRPP Webpage](#))**  
**OHRP IRB Registration Number(s): IRB00000246**

**Approved Risk Level(s):**

<https://errm.umich.edu/ERRM/Doc/0/IV48P8O4QKDKV/FORDGLJDQJBCD/fromString.html>

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**MORE INFORMATION:**

You can find additional information about UM's Human Research Protection Program (HRPP) in the Operations Manual and other documents available at: <http://hrpp.umich.edu>.

A handwritten signature in black ink that reads "Thad A. Polk". The signature is written in a cursive style with a long horizontal stroke at the beginning.

**Thad Polk**  
Chair, IRB HSBS