

Increasing Capacity to Conduct Research with Electronic Health Records (EHR) across Diverse Sites in a Practice Based Research Network

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Abstract

Increasing Capacity to Conduct Research with Electronic Health Records (EHR) across Diverse Sites in a Practice Based Research Network

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Background: Electronic health records (EHRs) have been widely adopted in clinical settings for patient care and billing purposes, creating a large repository of patient data. However, many clinical organizations and clinicians are unable to access this data for quality improvement or research purposes. The WWAMI region Practice and Research Network (WPRN), a collaborative Practice Based Research Network (PBRN), developed a successful process to use EHRs to answer a research and quality improvement question

Methods: The WPRN used a collaborative process to develop the study. Project steps included: topic selection, parameter development, participant training, data collection, analysis, and results dissemination. Sites used EHR data to calculate the number of adult patients who were

prescribed sleep medications in 4 medication groups in a 1-year time period. Data was reported in aggregate which eliminated the need for Human Subjects review

Results: Seven sites in three states, with over 44,000 adult patients, participated in the primary data collection. The WPRN was able to demonstrate wide variation in prescribing practices across sites. The proportion of adult patients receiving a prescription for sleep medications containing Zolpidem ranged from 0.25% to 5.81% across practices.

Discussion: The use of tools, clear processes, collaborative study development enable diverse practices with varying levels of EHR sophistication and utilization capacity to participate in studies using EHRs for quality improvement and research purposes. Participating in such projects helps build site confidence and capacity for using the EHR for future research projects.

Introduction

Electronic Health Records (EHRs) have been widely adopted in a variety of settings including outpatient clinics, hospitals, and health systems. Uptake of EHRs has increased rapidly with the passage of the 2009 Health Information Technology for Economic and Clinical Health (HITECH) Act, which incentivized EHR adoption [1]. Since the enactment of HITECH, EHR use amongst office-based physicians increased over 62% between 2009 and 2013, growing from 48% using EHRs to over 78% [2]. The rapid adoption of EHRs has created large repositories of data that clinicians and clinical organizations are eager to tap into, yet many have struggled to use this clinical tool for benchmarking, quality improvement, or research purposes [3] [4] [5].

In the WWAMI region Practice and Research Network (WPRN), a collaborative Practice Based Research Network (PBRN) consisting of 55 primary care clinics across 23 organizations in the five-state WWAMI region (Washington, Wyoming, Alaska, Montana, and Idaho), we sought to increase capacity for clinicians and clinical organizations to use EHRs for quality improvement and research purposes. The WPRN has a participatory governance structure whereby member sites provide feedback on every aspect of operations, from research priorities to study design. This bi-directionality gives the WPRN a deep understanding of sites' capacities and limitations, which allowed the WPRN Coordinating Center to develop a methodology with which diverse practices can conduct EHR data-based studies.

The objective of this paper is to describe a successful process that the WPRN developed in order to use EHRs to measure variation in a clinical outcome across sites, and to return the findings of the resulting study back to the sites. This process demonstrates how clinicians can build their confidence and capacity to use EHRs for secondary purposes such as benchmarking,

quality improvement, and research rather than solely for patient care and billing, which are the primary uses for EHRs [6] [7]. This approach may also be generalizable to diverse PBRNs or consortia, which represent a wide variety of practice and patient populations [8].

Methods

Setting

The WPRN receives support from the Institute for Translational Health Sciences (ITHS), a Clinical and Translational Science Award (CTSA) funded by the National Institutes of Health (NIH), the University of Washington's Department of Family Medicine, and the participating clinical practices. The CTSA program has expressly prioritized engaging clinicians and communities in the full spectrum of translational research [9]. The WPRN exemplifies this mission through its diverse partnerships and depth of collaborations. Member practices range in type, from federally qualified health centers and private practices to university-affiliated and government-operated clinics. These diverse settings allow the WPRN to address a wide range of issues facing practitioners in real-world settings, and allow the WPRN to reach many rural and underserved populations. The WPRN is led by a Coordinating Center of investigators and research scientists dedicated to facilitating research studies and building research capacity within the network. The Coordinating Center plays a key administrative role in developing research protocols and bringing research opportunities to the clinics.

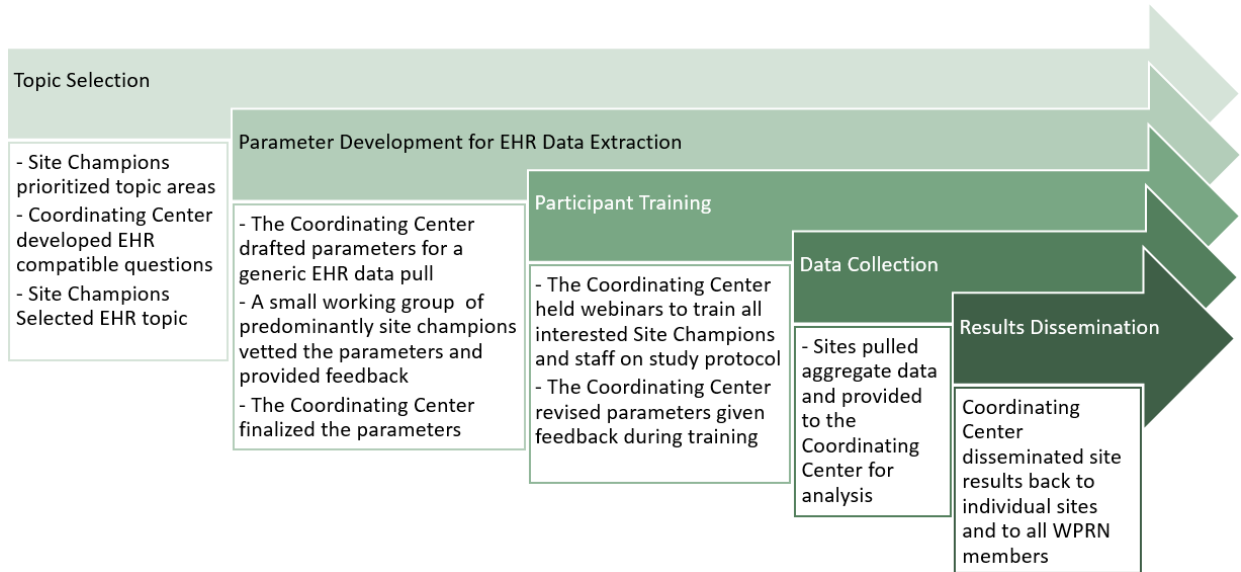
WPRN member practices are represented by site research champions (from here on, they will be referred to as site champions) who are engaged clinicians working in member sites. The WPRN values collaboration and bi-directionality in its membership and governance;

clinicians and clinical organizations' goals and concerns help shape research priorities, design, and implementation in the research network [10]. Site champions are provided with opportunities to participate as co-investigators in studies (e.g., contribute to study design, grant applications, and study implementation), and to share the clinical questions of concern to them and their clinics. Most participating site champions are clinicians with no dedicated funding for research. The network is highly collaborative, and is governed by a Steering Committee comprising a subset of regional site champions and Coordinating Center members. All major research and governance decisions must be approved by the Steering Committee.

Each year, the WPRN holds an in-person Annual Meeting in order to bring members together from across the region to identify priorities, develop research projects, and disseminate information. At the 2014 Annual Meeting, the Coordinating Center held a pre-conference session with site champions who were interested in developing a new project: to build a benchmarking process within the WPRN that could inform practice improvement across primary care practices. This project was designed to meet the dual interests of member practices, which expressed interest in learning to better use their EHR data for quality improvement purposes, and the WPRN's goal of building research capacity within sites. The collaborative process that the WPRN used to develop the project from inception to results dissemination is outlined below (see Figure 1). There were three stages: 1) study development, which included topic selection, parameter development, and participant training; 2) data collection and analysis; and 3) results dissemination which involved presentation of de-identified results to participating sites and across the entire network in order to inform site practice.

Process Overview

Figure 1: EHR Project Process



Topic Selection

During the Annual Meeting pre-conference session, site champions worked together to identify a prioritized list of 6 research questions that they believed EHR data could answer.

These data could be used to compare practice performance across the member practices. The Coordinating Center reviewed the prioritized list of questions, identified which questions were feasible to answer with EHR data, and modified others to fit a simple EHR query.

Site champions noted that the Food and Drug Administration (FDA) had recently lowered the recommended dosage and required warnings on labels of sleep medications containing Zolpidem, as they may be particularly risky in certain populations, especially in women and older adults. These groups are more likely to experience next day impairment and for elderly adults a higher risk of risk of fracture [11] [12] [13]. Two of the 6 questions from the

pre-conference session were related to sleep medications. The first asked, *what percent of women prescribed Ambien are receiving the FDA recommended dose?* The second question asked, *what percent of patients have received a prescription for a sleep medicine? Has this changed over time?* Neither of these questions were answerable in their original form, as a simple EHR query cannot provide dosing information, and examining change over time was deemed outside of the scope of this project due to its complexity.

The Coordinating Center identified themes in the questions and modified the questions, narrowing to 3 that could be answered given EHR data constraints, and would only require aggregate data. Reporting of only aggregate data eliminated the need for Human Subjects review, which reduced barriers to participation.

Questions included:

- What percent of adult patients seen during a 1-year period were prescribed testosterone?
- What percent of adult patients with Hepatitis C positive diagnosis have had a Hepatitis A immunization? Hepatitis B immunization?
- What percent of adult patients (all, men, women) seen during a 1-year period have received a prescription for a sleep medicine?

All pre-conference session participants were asked to rank these three questions in order of preference. Use of sleep medications in primary care received the highest overall ranking among respondents.

Parameter Development

The Coordinating Center conducted a literature review on use of sleep medications in primary care practice and drafted the parameters for the EHR query. All site champions were offered the opportunity to join a working group to review and refine the list of sleep medications and the data categories; eight site champions volunteered. The working group was sent the draft parameters along with relevant articles that the Coordinating Center used to develop medication categories and asked for their feedback.

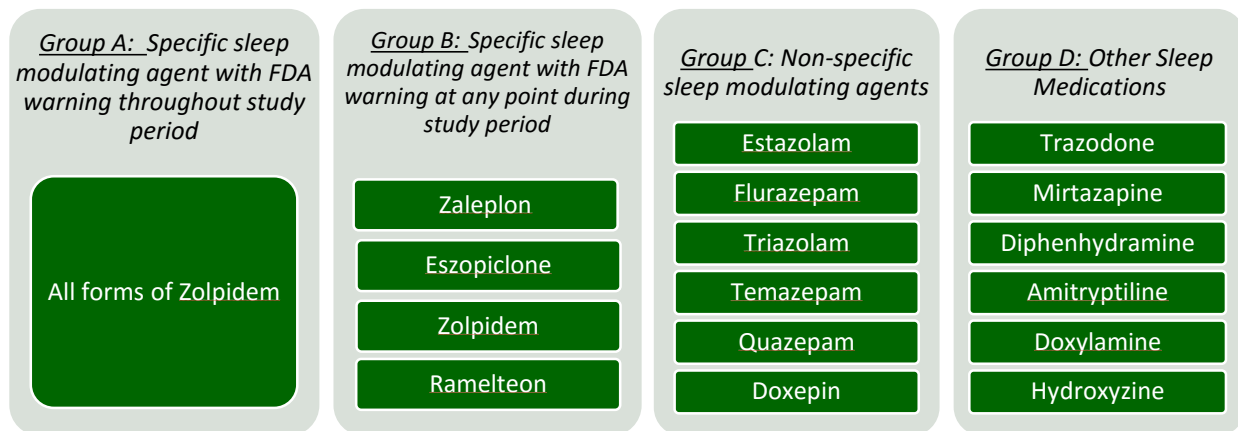
The Coordinating Center revised the parameters given the feedback from site champions. Some examples of modifications include the addition of an additional group of medications (Group D) which includes over the counter (OTC) sleep aids and prescription medications that were not approved by the FDA as a specific sleep modulating agent, yet the group and the literature reported that there is often off label prescribing of these medications for insomnia (see Figure 2) [14] [15] [16]. The modified reference list of sleep medications, which sites would use in their EHR query, was then reviewed by a pharmacist site champion to ensure that medications were categorized effectively and to ensure that the list was not missing any regularly used sleep medications then finalized.

Medications were grouped into four categories to facilitate further analysis by sites (Refer to Figure 2).

- Sleep medications with FDA warning of next day impairment throughout the study period [16] [17] (Group A).

- Any specific sleep modulating agent that had an FDA warning of next day impairment at any point during the study period [16] [18] (Group B. Note that Group A is a subset of Group B).
- Non-specific sleep modulating agents, which have been approved by the FDA to treat insomnia, but they have other indications as well, such as anxiety and depression [15] [16] [19] (Group C).
- Other sleep medications that were either available as OTC sleep aids or prescription medications that were not approved by the FDA as a specific sleep modulating agent, yet they have off-label use for insomnia [14] [15] [16] (Group D).

Figure 2: Medication Groups



The study population included all patients in participating sites, aged 18 years or over as of July 1, 2013, who had an in person office visit with a medical provider during a one year study period from July 1, 2013 –June 30, 2014. All sites were asked to report counts of adults, separated by gender, who were prescribed medications in each of the four medication groups.

Patients with multiple prescriptions across groups would be recorded in each of the medication groups for which they had a prescription; thus they could be counted more than once. Sites were also given the option of measuring these counts by age groups and gender if they were able to do so. (See Appendix 1 for WPRN EHR project query data table).

Training

The Coordinating Center offered four webinars at various times and dates to accommodate the schedules of site champions and information technology (IT) staff in three different time zones. The first half of the webinar explained the context for the project, including objectives, background on sleep disorders and medications, and a description of the process that the WPRN used to develop the study question and parameters. The second half of the webinar explained project implementation, including the methodology, parameters, and data collection process. The webinar was interactive so that participants could ask questions or receive clarification at any time. The webinars also allowed the Coordinating Center to identify parameters that were unclear, which led to further parameter modification to improve clarity and ease of use.

Data Collection

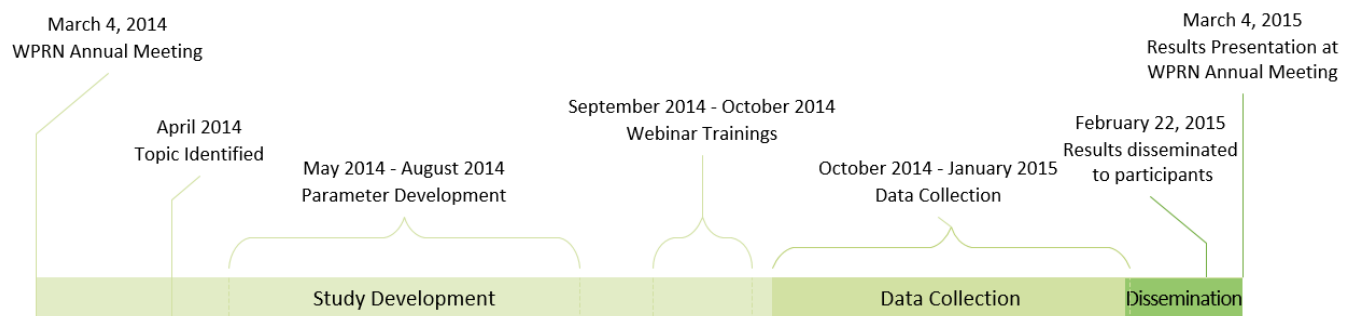
Site champions were given approximately three months to collect their site's data. Data collection processes varied by site. Several site champions provided IT staff with parameters to collect and compile into the data collection spreadsheet (Appendix 1). Some site champions were given raw, de-identified data from the clinic IT staff and compiled counts themselves.

Analysis and Dissemination

The Coordinating Center collected all sites' data, then analyzed and disseminated results to participating sites in the form of a one page results sheet showing variation across practices (see Appendix 2). Site level data were displayed by site ID number, with each participating site given only their own identifying number in order to keep their site level results anonymous. After obtaining sites' permission, the WPRN Coordinating Center distributed the de-identified results sheet to all WPRN member sites and presented the results at the 2015 Annual Meeting to all attendees. We were unable to calculate statistics, as we did not have data at the level of the individual.

The project was expected to take approximately one year from development to dissemination with the WPRN Annual Meetings book-ending the project (see Figure 3.

Figure 3: Project Timeline



Results

Seven sites that cared for over 44,000 adult patients between 7.1.2013 and 6.30.2013 in the study year participated in the primary data collection. Sites were spread across three states and represented a wide variety of practice types and sizes. The smallest clinic cared for fewer

than 4,000 adult patients in the study year and the largest had nearly 13,000 adult patients (See Figure 4 for more detail). Practice types included two each of Federally Qualified Health Centers, hospital-affiliated practices, and University-affiliated practices, and one office practice.

Figure 4: Size of Participating Sites

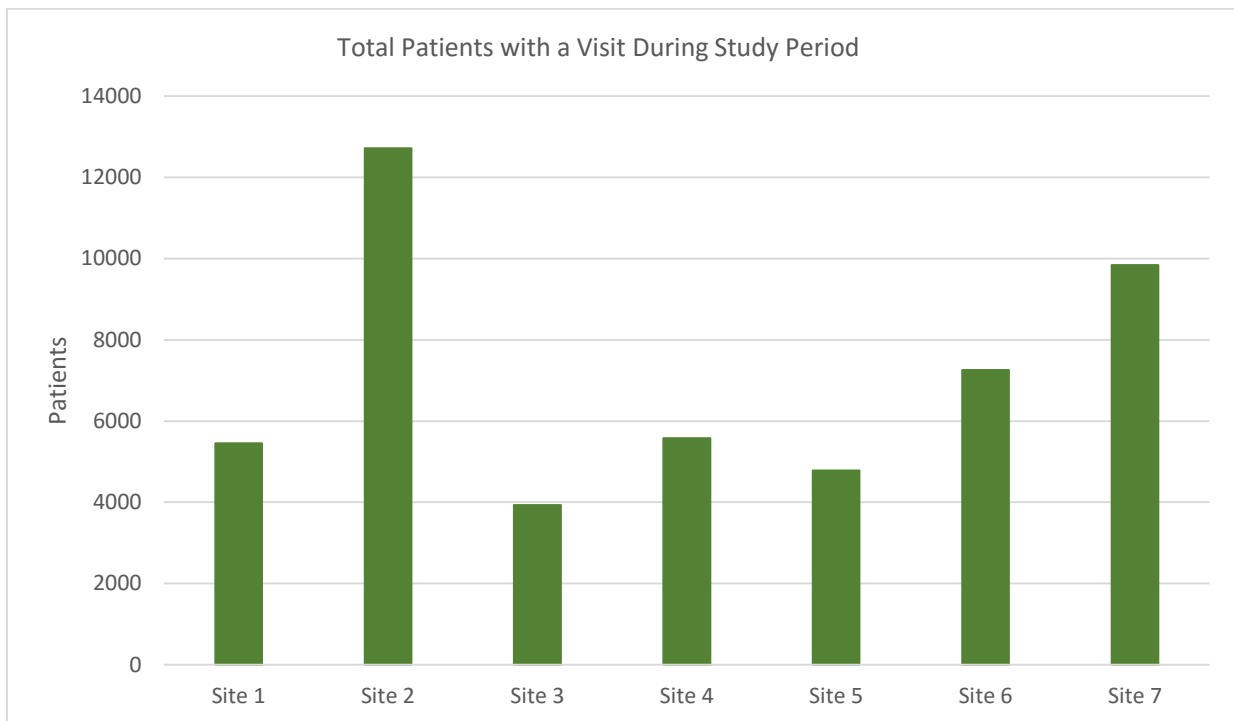
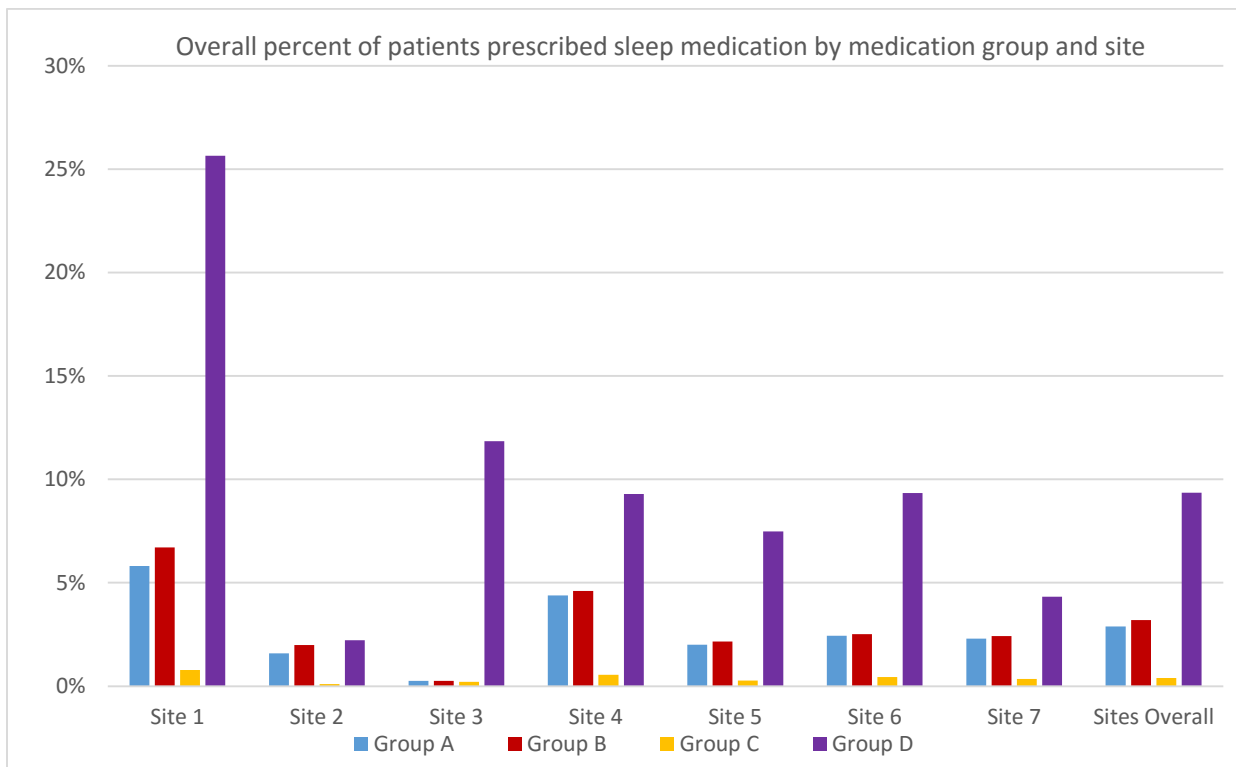


Figure 5 demonstrates the variation in prescribing practices between sites. The proportion of adult patients receiving a prescription for sleep medications with an FDA warning of next day impairment throughout the entire study period (Group A) ranged from 0.25% to 5.81% across practices. The proportion of adult patients receiving a prescription for sleep medications that had an FDA warning of next day impairment in part or all of the study period (Group B) ranged from 0.25% to 6.71%. The proportion of adult patients receiving a

prescription for non-specific sleep modulating agents approved by the FDA to treat insomnia (Group C) was lower, ranging from 0.10% to 0.79%. The variation in the proportion of adult patients receiving a prescription for sleep medications that were not on the FDA approved list as a specific sleep modulating agent (Group D) was greatest, ranging from 4.23% to 25.64% across practices.

Figure 5: Proportion of adult patients prescribed sleep medication by medication group and site



Discussion

The WPRN used a participatory process to develop and implement a network wide study that leveraged EHR data across diverse practices with varying levels of EHR sophistication and utilization capacity. The WPRN’s understanding of EHR systems and of site capacity and

limitations led to development of a simple study process and standardized tools. This allowed the Coordinating Center to compare sites' data without the need for extensive paperwork, data use agreements, or in-depth trainings. Since this project also used aggregated, anonymized data whose primary purpose was quality improvement, it eliminated the need for IRB approval, which has been noted as a barrier to research participation in other settings [20]. This project demonstrates how a PBRN that has developed trusted relationships with member practices and that draws on the expertise of its partners can design a study that is responsive to member's needs and capabilities. This study provided useful clinical information to participating practices while generating preliminary data that may be useful in developing further research studies.

The use of tools, such as simple data collection forms (Appendix 1), encouraged participation from sites as it eliminated issues of compatibility between different EHR systems and allowed sites to use their own coding structures to capture data. While this method of inquiry requires research parameters to be kept simple, it allows diverse sites to share data. This optimizes participation from sites, including smaller sites with fewer resources, and allows them the opportunity to build internal capacity and expand their ability to use EHR systems for quality improvement and research. The iterative and bi-directional process of the project taught site champions how to develop a question that is feasible to answer using EHR data and how to develop parameters to query their EHRs. Not only does this increased capacity have implications for future quality improvement efforts, but the WPRN has demonstrated its capacity to gather EHR data across sites, which can be support the collection of pilot data for grant applications.

This type of study was successful due to its simplicity, clear instructions, and step-by-step facilitation and support from the Coordinating Center. The limited data that studies like this produce are likely appropriate primarily for quality improvement or preliminary studies for grant applications. Cohort discovery and more complex and detailed data extractions require the capabilities of formal data sharing networks. For example, the WPRN has developed Data QUEST, a federated network of sites with data sharing infrastructure which allows a vendor to extract semantically aligned EHR data from multiple distinct primary care health systems simultaneously. [21]. However, this infrastructure is costly and it requires substantial buy-in from clinical organizations.

Benchmarking projects that create reports to allow practices and providers to compare performance to peers can provide valuable information to clinics about how their practice compares to others. Research suggests that using health indicators can be helpful to improve quality, as benchmarks offer a clear starting-point upon which to improve [22]. Benchmarking reports have been shown in some cases to motivate clinicians to emulate top performers and can lead to improved patient care and cost savings [23]. The results of this study demonstrated the utility of EHR data extraction for measuring clinical care variations across diverse practices. Sites displayed wide variation, with one site prescribing one quarter of patients Group D sleep medications and other sites prescribing merely a fraction of that number. However, it should be kept in mind that benchmarks are limited inasmuch as they are unable to reflect the larger setting and complexity in which providers work. Some case studies have demonstrated opposing reactions to benchmarking data, whereby low-prescribing clinicians have increased prescriptions toward the average. Thus, careful thought should be put into how to use the data

for quality improvement [24]. The identification of variation in prescribing practices between sites should serve as a starting point for further investigating opportunities for quality improvement within practices. Following the conclusion of this project, the WPRN offered a webinar to help sites take the next steps for using aggregated benchmarking data like these to improve quality at their own sites.

Limitations

This project was implemented without funding for the clinical sites. This limited the number of sites that were able to participate, and likely contributed to the extended timeline for data collection for some participating sites, which slowed our results dissemination. Three site champions out of seven were unable to return the data within the original data collection timeframe of three months. While we were able to identify some challenges to data collection, such as competing clinic priorities and no dedicated time for research, the WPRN did not do a systematic evaluation of this process.

We did not assess the diagnostic codes associated with the sleep medication prescriptions. This has implications for future quality improvement efforts within sites, insofar as sites will need to further investigate the reasons for sleep medication prescriptions of different types to determine a more accurate picture of clinic-wide prescribing practices. The inclusion of sleep medication prescriptions for diagnoses other than sleep disorders has particular significance for Group C and D medications, which can also be used to treat other conditions such as anxiety and depression, and are not primarily indicated for treating insomnia or other sleep disorders. This may have led us to overestimate the rate of prescriptions for

treatment of sleep disorders. Overestimates might be particularly high in clinics that have patient populations with more anxiety, depression, or other conditions that medication groups C and D are primarily indicated for. While this study included an expansive list of medications used for modulating sleep, it is not exhaustive. Other medications and supplements such as opioids, lorazepam and melatonin, sometimes used for sleep, were not included, which could have underestimated sleep medication prescription.

Another limitation to the study design was that the Coordinating Center did not verify that the algorithms individual practices used would extract the expected data from the EHR, nor did we put data validation measures in place to ensure that the data were free of errors. While sites may have their own internal data validation processes to ensure that data captured from the EHR reliably represents the patient population, we did not verify these processes nor standardize them across practices. However, data collection parameters were intentionally kept simple in order to reduce barriers to participation, and to provide a broad picture of prescribing practices for future efforts. Despite these limitations, we found that the tradeoff of increased participation and capacity building was worthwhile.

Conclusions

The WPRN Coordinating Center demonstrated that by creating simple tools and a structured process, diverse practices can participate in a study that allows comparison of clinical outcomes across a PBRN. Sites with high rates of prescribing can use these data as a point of reference for quality improvement activities within practices. Because this took place in a network with multiple sites, those wishing to use the results to improve care could use the

network as a learning community for identifying best practice that they can apply in their own clinics.

PBRN infrastructure is crucial for developing projects like this one that incorporate real-world clinical priorities into study design and development. Current Clinical and Translational Science Award (CTSA) funding allows the practice-based research networks like the WPRN to develop methodologies that meet diverse clinical organizations where they are, and pave the way for clinical organizations of all shapes and sizes to introduce research into their practice.

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Appendix 1: WPRN Sleep Medication Project Data Table

See definitions for bolded terms

Measure	Result
1) <u>Denominator</u> : Total number of adult patients with a visit to the clinic during the study period	
For Group A Sleep Medications	
2) <u>Total patients</u> : Number of adult patients with a visit to the clinic during the study period who had a prescription (during the study period) for at least 1 Group A sleep medication	
3) <u>Male patients</u> : Number of adult male patients with a visit to the clinic during the study period who had a prescription (during the study period) for at least 1 Group A sleep medication	
4) <u>Female patients</u> : Number of adult male patients with a visit to the clinic during the study period who had a prescription (during the study period) for at least 1 Group A sleep medication	
For Group B Sleep Medications	
5) <u>Total patients</u> : Number of adult patients with a visit to the clinic during the study period who had a prescription (during the study period) for at least 1 Group B sleep medication	
6) <u>Male patients</u> : Number of adult male patients with a visit to the clinic during the study period who had a prescription (during the study period) for at least 1 Group B sleep medication	
7) <u>Female patients</u> : Number of adult male patients with a visit to the clinic during the study period who had a prescription (during the study period) for at least 1 Group B sleep medication	
For Group C Sleep Medications	
8) <u>Total patients</u> : Number of adult patients with a visit to the clinic during the study period who had a prescription (during the study period) for at least 1 Group C sleep medication	
9) <u>Male patients</u> : Number of adult male patients with a visit to the clinic during the study period who had a prescription (during the study period) for at least 1 Group C sleep medication	
10) <u>Female patients</u> : Number of adult male patients with a visit to the clinic during the study period who had a prescription (during the study period) for at least 1 Group C sleep medication	
For Group D Sleep Medications	

11) <u>Total patients</u> : Number of adult patients with a visit to the clinic during the study period who had a prescription (during the study period) for at least 1 Group D sleep medication	
12) <u>Male patients</u> : Number of adult male patients with a visit to the clinic during the study period who had a prescription (during the study period) for at least 1 Group D sleep medication	
13) <u>Female patients</u> : Number of adult female patients with a visit to the clinic during the study period who had a prescription (during the study period) for at least 1 Group D sleep medication	

DEFINITIONS

Patients	Age 18 or over as of 7.1.2013	Birthdate 6.30.1995 or earlier
Study Period	7.1.2013 – 6.30.2014	
Visit	In person (office) visit with medical provider (MD, DO, NP, PA) during the study period	
Prescription	Prescription for selected medication ordered DURING the study period	

Appendix 2: Information Sheet Disseminated to Sites



Institute of Translational Health Sciences
Accelerating Research. Improving Health.

SLEEP MEDICATION IN PRIMARY CARE PRACTICES

Results for 44,102 patients at 7 sites



PROJECT CONTRIBUTORS: RESULTS

PROJECT CONTRIBUTORS:

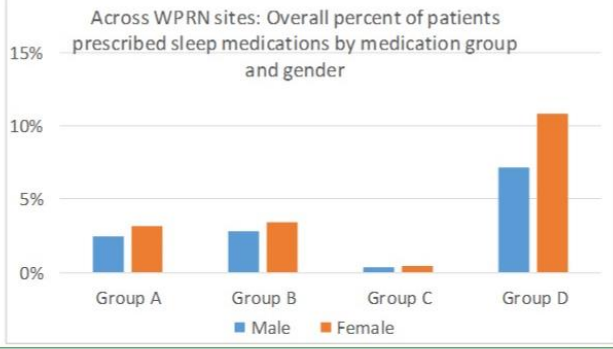
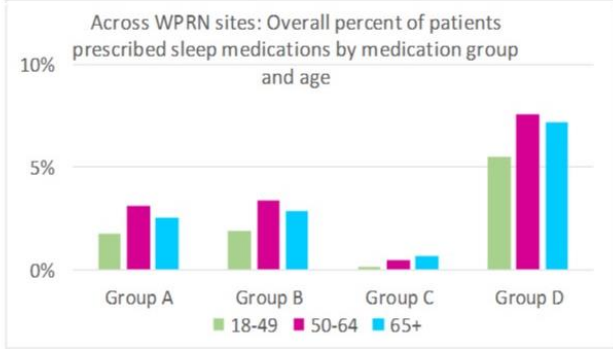
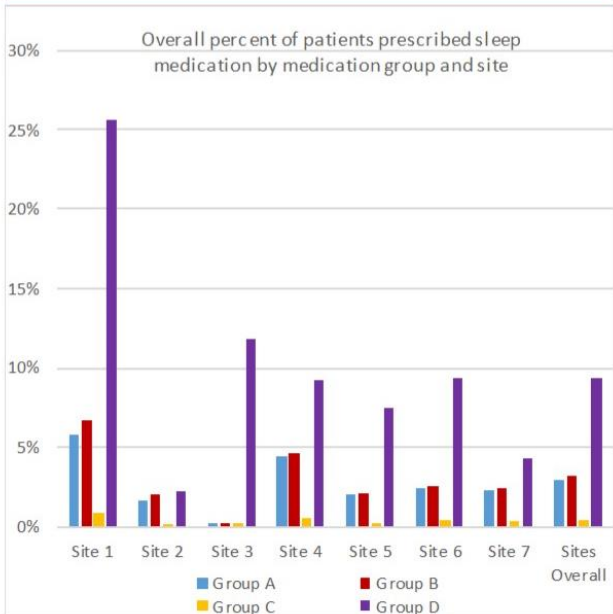
Bill Alto	Ryan Gilles	Adriana Linares
Laura-Mae Baldwin	Deb Gould	Brenda Mollis
Andrea Bishop	Jessica Guh	Jon Neher
Allison Cole	John Holmes	Alex Reed
Sarah Dewane	Jaime Hornecker	Sonja Ronning
Rex Force	Bill Kriegsman	

BACKGROUND:
Pharmacologic treatments for sleep disorders have been found to be effective. However, medications used to treat sleep disorders are associated with increased risk of adverse events, especially in women and older adults.

STUDY QUESTION:
What percent of adult patients with a primary care visit during a 1-year period have received a prescription for a sleep medicine?

STUDY PARAMETERS:
Study period: July 1, 2013 – June 30, 2014
Patients: Adults: ages 18 and over as of July 1, 2013, with an in person office visit with a medical provider (MD, DO, NP, PA) during the study period.

RESULTS



SLEEP MEDICATION GROUPS

Group A: Specific sleep modulating agent with FDA warning throughout study period	Group B: Specific sleep modulating agent with FDA warning in part of study period	Group C: Non-specific sleep modulating agents	Group D: Other Sleep Medications
All forms of Zolpidem	Zaleplon	Estazolam	Trazodone
	Eszopiclone	Flurazepam	Mirtazapine
	Zolpidem	Triazolam	Diphenhydramine
	Ramelteon	Temazepam	Amitryptiline
		Quazepam	Doxylamine
	Doxepin	Hydroxyzine	

*Generics listed. Groups also include brand name medicines

The **WWAMI region Practice and Research Network (WPRN)** is a collaborative group of 50 primary care practices in the WWAMI region (WA, WY, AK, MT, ID) committed to research and practice improvement. This study was supported by the WPRN Coordinating Center based at the University of Washington in Seattle, WA, and supported by the Institute of Translational Health Sciences through a grant from the National Center for Advancing Translational Sciences at the National Institutes of Health.

