

***Grant Final Report***

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**Examination of the Use of Electronic Health Record  
Data for Measuring Performance in Diabetes Care**

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**Principal Investigator:**

Annemarie Gregory Hirsch, MPH, BA

**Team Members:**

Ann S. McAlearney, ScD

Eric E. Seiber, PhD

Walter F. Stewart, PhD, MPH

**Performing Organization:**

Ohio State University

**Federal Project Officer:**

Brenda Harding

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**540 Gaither Road**

**Rockville, MD 20850**

**[www.ahrq.gov](http://www.ahrq.gov)**

## Structured Abstract

**Purpose:** The purpose of this study was to assess the validity of using electronic health record (EHR) data for diabetes performance measures.

**Scope:** The government is providing incentives for providers to use EHR data for performance measurement. However, the use of EHR data for performance measurement and the consequences are poorly understood.

**Methods:** The first part of the study consisted of interviews with clinicians to learn how data is entered into the EHR and what factors influence data entry practices. The second part assessed the validity of eight different EHR-based methods of identifying patients with diabetes. We assessed the sensitivity and specificity of each method and calculated performance measure scores to determine whether the method of identifying the patients was associated with performance measure outcomes.

**Results:** Clinicians endorsed the use of the problem list to identify the target population for diabetes measures. Clinicians indicated that organizational factors impact how they enter diagnoses in the EHR and identified unintended consequences of using EHR data for performance measurement.

The EHR-based methods for identifying patients with diabetes had high specificity (>99.5%) and moderate to high sensitivity (65% to 100%). The use of certain data elements selectively identified patients who had higher performance scores.

**Key Words:** diabetes; performance measurement; electronic health record; EHR

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# Final Report

## Purpose

The purpose of this study was to assess the validity of using EHR data for performance measurement. Diabetes measures were used as examples throughout the project. The project had the following aims: 1) To gain deeper knowledge of how data is entered and processed in the EHR; 2) To evaluate the validity of different approaches to using EHR data to identify patients with diabetes; 3) To evaluate the impact of these approaches on diabetes performance measures. The next section provides background information on EHR adoption, performance measurement, and the challenges of using EHR data in performance measurement.

## Scope

Over the past few years, policymakers have hailed the electronic health record (EHR) as the answer to the health care quality crisis in America.<sup>1</sup> However, simply increasing EHR adoption will be inadequate to substantially improve care.<sup>2</sup> EHR data must be leveraged for secondary purposes, such as performance measurement, in order to make strides in quality improvement. The focus of this paper is on the use of EHR data for measuring performance.

Valid performance measurement is essential to the success of health reform.<sup>3</sup> Performance measures drive quality initiatives such as public reporting of physician performance and pay-for-performance (P4P) programs.<sup>4,5</sup> Performance measures help identify gaps in healthcare delivery and target areas for improvement. Invalid performance measures could undermine potentially effective quality initiatives and misinform providers and hospital leaders regarding the quality of care they are providing. As a result, health care providers may become overconfident about the quality of care provided and reduce improvement efforts, introducing harm.<sup>4</sup>

With the federal government's recent push to increase adoption of EHR systems, more organizations are turning to the EHR data as a source for performance measurement.<sup>2</sup>

However, there are important issues to consider when using EHR data for quality reporting. This paper focuses on three of these issues. First, the accuracy of EHR data is dependent on the providers who enter the data. Second, there is a range of data elements from which to choose to identify the target population for the quality reporting. Third, as with any new application of health information technology (HIT), there is the potential for negative unintended consequences. These issues are discussed in more detail below.

The accuracy of EHR data is dependent on the health care providers entering data into the medical record. How providers enter data in the EHR can be influenced by factors such as workflow, billing processes, and reimbursement policies and user-interface of the EHR system.<sup>6-13</sup> Even with the availability of uniform and discrete data fields within the same EHR system, physicians tend to use the diverse features of an EHR system in many different ways.<sup>14,15</sup> As a result, clinical information is recorded in different physical locations of the record (e.g. problem list, progress notes).<sup>15</sup> When choosing what aspects of the EHR can be used for quality reporting,

one needs to consider the variation in how physicians use the record and what motivates their documentation patterns. To date, there is little information regarding whether EHR data entry and data processing influence performance measures for quality reporting.

The EHR has a range of data elements available and many of these elements can be used to identify a target population for a performance measure, the population of patients whose quality you are trying to measure.<sup>16</sup> The method for identifying the target population should have high sensitivity and specificity. Misclassifying patients as not having a disease could result in missed opportunities for quality improvement, while misclassifying patients as having disease could result in unnecessary clinical tests and interventions. In addition, the method for defining the target population should not influence the outcome of the performance assessment. In other words, the method should not selectively identify patients who are more or less likely to meet performance goals, as this could result in under or overestimating performance.<sup>27</sup>

Given the abundance of data in the EHR, it is not always clear what data elements should be used to identify a target population. Diagnoses are recorded in a number of sections, including the problem list and encounter diagnoses. In some cases, medications indicated for only one disease or abnormal lab values could be used to identify patients with a particular disease. The validity of using these data elements, or a combination of these data elements, to identify a target population is unknown. There are no standards for identifying disease populations using EHR data. In moving to EHR-based measures, The Center for Medicare and Medicaid Services (CMS) has developed specifications for identifying disease populations for their Physician Quality Reporting Initiative (PQRI), however CMS provides little data supporting the validity of these specifications.<sup>17</sup>

Finally, as the use of EHR data for quality measures is a relatively new application of health information technology (HIT), it is important to assess the potential for unintended consequences. There is extensive literature describing the unintended consequences of a range of HIT applications.<sup>18-26</sup> The negative consequences of this technology range from inefficient workflows to the extreme of patient death.<sup>18,20-23</sup> Illustrating the potential seriousness of HIT unintended consequences, Weiner and colleagues coined the term “e-iatrogenesis” defined as patient harm caused at least in part by the application of HIT.<sup>22</sup> There is little information in the literature about the unintended consequences or the potential for e-iatrogenesis when using EHR for performance measures in quality reporting.

Diabetes is a condition frequently included in the performance assessment and performance improvement activities. A recent review of diabetes performance measures identified 146 distinct measures spanning 31 clinical processes or outcomes.<sup>26</sup> Diabetes was one of only three diseases for which PQRI originally permitted the use of EHR data for quality reporting when making the transition to EHR-based reporting in 2010.<sup>17</sup> Table 1 presents the diabetes-related PQRI measures. There have been a few studies exploring how to use EHR data to identify patients with diabetes. Researchers have used different combinations of the following data elements to identify patients with diabetes: problem list diagnosis, abnormal plasma glucose levels, elevated hemoglobin A1c (HbA1c) levels, diabetes-specific medication prescriptions, encounter diagnoses, and diabetes-related phrases in free-text physician notes.<sup>27-29</sup> The specific criteria for each of these data elements varies across studies. To date there is no standard algorithm for identifying patients with diabetes in the EHR.

## Methods

We used a mixed method approach to investigate the validity of using EHR data for diabetes performance measures. The first component consisted of one-on-one telephone interviews with primary care clinicians employed by Geisinger Health System. Geisinger Health System (GHS) is an integrated health care system in Pennsylvania that began implementing its EHR in outpatient clinics in 1996. The purpose of these key informant interviews was to gain an understanding of how clinicians use the EHR to document diagnosis and of what motivates their documentation behavior. The second component of the study consisted of an extraction of EHR data to identify primary care patients with diabetes using eight different EHR-based methods of identification. We assessed the validity of the eight methods by comparing them to gold standard of a manual medical record review. We then determined whether the method of identifying patients with diabetes could impact performance measurement scores. Additional details about these study components are described below.

**Table 1. PQRI 2010 EHR specifications (abridged) for diabetes quality measures<sup>33</sup>**

Measure	Description	Denominator (Target Population)	Numerator	Rationale
Hemoglobin A1c (HbA1c) Poor Control	Percentage of patients with diabetes mellitus who had most recent HbA1c greater than 9%	Patients with a diagnosis of diabetes: All patients with a documented diagnosis of diabetes at any time in the patient's medical record. To be eligible for performance calculations, patients must have at least two face-to-face office visits with the physician, PA, or NP during the measurement period.	Patients with most recent HbA1c > 9% during the measurement period	Intensive therapy of glycosylated hemoglobin (A1c) reduces the risk of microvascular complications.
Low Density Lipoprotein (LDL) Control	Percentage of patients with diabetes mellitus who had most recent LDL level in control (less than 100 mg/dL)	Same as above.	Patients with most recent LDL < 100mg/dL	Persons with diabetes are at increased risk of coronary heart disease (CHD). Lowering serum cholesterol levels can reduce the risk for CHD events.
High blood pressure control	Percentage of patients with diabetes mellitus who had most recent blood pressure in control (less than 140/80 mm Hg)	Same as above.	Patients whose most recent blood pressure <140/80mmHg	Intensive control of blood pressure in patients with diabetes reduces diabetes complications, diabetes-related deaths, strokes, heart failure, etc.

## Clinician Interviews

**Research design.** We conducted an exploratory qualitative study, using a grounded theory approach, to learn how clinicians document diabetes diagnoses in the EHR and what factors influence their documentation patterns.<sup>30</sup> We conducted key informant interviews with clinicians working in the GHS. Clinicians were eligible to participate if they were primary care providers and had been employed by the health system for at least six months. We used a maximum variation strategy to identify clinicians with a broad range of perspectives on EHR-based quality measures and diabetes care.<sup>31</sup> We sought referrals from the quality improvement department of the health system to identify clinicians with a range of levels of participation in the system's quality improvement initiatives and EHR system. We recruited participants via e-mail and reimbursed participants at a rate equivalent to the cost of an existing level 4 visit, determined by the health system, which was the same rate for all participants.<sup>32</sup>

**Study participants.** Seventeen of thirty-seven clinicians (46%) contacted agreed to participate in the study. The remaining 20 clinicians did not actively decline participation, but failed to respond to the recruitment e-mail. After 15 interviews, investigators felt they reached saturation.<sup>33</sup> Fourteen participants were primary care physicians (9 family medicine, 5 internal medicine), two participants were physician assistants and one participant was a nurse practitioner. Participants reported seeing 36 to 450 patients per month. The number of patients seen was largely dependent upon whether respondents had other roles in the health system (e.g., administrative) in addition to patient care roles. On average, clinicians who participated in this study reported that nearly 20 percent of their patients had a diagnosis of diabetes. Six respondents indicated that, in addition to their clinical work, they had some role in quality improvement initiatives or EHR optimization projects for the institution.

**Measures.** We used a semi-structured interview instrument that explored how clinicians enter data in the EHR when diagnosing and treating patients with a diagnosis of diabetes. The interview guide included four primary sections 1) Clinician's professional history/background; 2) How does the diagnosis of diabetes get entered into the EHR? (e.g., What EHR fields are used?, Who enters the diagnosis?, When is the diagnosis entered?); 3) What factors influence documentation behavior?; and 4) What EHR data fields would you recommend for use in identifying patients with diabetes? The interview guide included a combination of open-ended questions and follow-up question probes to allow for flexibility during the interview. Interviews were conducted one-on-one and administered over the telephone. Each interview lasted approximately 30 minutes.

**Analysis.** A team of two investigators coded the interview transcripts to identify broad themes across the data. The investigators used both inductive and deductive methods to code the data. Using the deductive approach, the investigators developed a coding frame based on the questions asked in the interview guide as well as from concepts supported in the literature.<sup>34</sup> Investigators also applied an inductive approach, identifying themes that emerged from the interviewees' comments. Investigators defined codes for these emergent themes and the new codes were added to the original coding frame. All transcripts were then reread and recoded according to the modified coding frame. To ensure consistency, investigators met to discuss the emergent themes and make final coding decisions. Final decisions about coding and themes were

made when investigators reached consensus. We used the qualitative data analysis software program Atlas.ti (version 6.0) to support our coding and analysis process.

As themes emerged during the data collection period, the interviewer would add questions to the interview guide for future interviews. Two themes emerged early in data collection. First, interviewees identified organizational factors that influenced how clinicians documented in the EHR. Second, interviewees reported concerns about the unintended consequences of using an EHR algorithm to identify patients with diabetes for quality reporting. As a result, after the first few interviews, the interviewer added questions relevant to these themes.

## EHR Data Extraction

**Setting and recruitment.** We extracted EHR data on all GHS primary care patients, 18 years of age and older, who had at least one outpatient encounter prior to 2007 and at least two outpatient encounters in 2009.

**Diabetes definitions.** We created eight different definitions for diabetes using different combinations of the following EHR data elements: problem list diagnoses, encounter diagnoses, diabetes-specific medications, elevated HbA1c levels. (Table 2) Three definitions were derived from the CMS specifications for identifying patients with diabetes as well as other definitions used in previous literature.<sup>17,27-29</sup> We used a manual medical record review for our gold standard definition of a diabetes diagnosis. A trained, non-physician reviewer analyzed a subset of medical records randomly selected from the eligible primary care population. The reviewer categorized a patient as diabetic if, during the manual review, she found a diagnosis of diabetes on the problem list, a diagnosis of diabetes associated with a medication or lab order, or found evidence of diabetes in the free-text notes documented by physicians in the Progress Note section of the EHR.<sup>27</sup>

**Table 2 EHR-based definitions for identifying primary care patients with diabetes**

Def. #	Data Element	Data Element Description <sup>12</sup>	Definition Criteria
1	Encounter diagnosis	Encounter diagnoses consist of a list of all conditions co-existing at the time of the encounter that affect the treatment received or length of stay. A condition of sufficient significance to warrant inclusion for investigative medical studies.	At least one diabetes ICD-code associated with at least two encounters between January 1, 2007 and December 31, 2009: 250.xx, 362.01-362.07, 366.41, 648.01-648.04
2	Problem list diagnosis	The problem list constitutes a master list of all a patient's diagnoses. This list includes clinical problems, a diagnosis summary and stressor exposure, an ongoing list of clinically significant health status events, resolved and unresolved, in a patient's life.	At least one diabetes ICD-9 code on the problem list: 250.xx, 362.01-362.07, 366.41, 648.01-648.04
3	Lab Value: Elevated HbA1c	Documentation of theHbA1c test results from the clinical laboratory.	At least two HbA1c levels $\geq$ 6.5 (on separate days)
4	Medication: Diabetes-specific medication	Documentation of diabetes-specific medication prescribed in the course of an encounter.	Prescription for an anti-hyperglycemic medication between January 1, 2007 and December 31, 2009 <sup>1</sup>
5	Meet criteria for definitions 1 OR 2	See descriptions for definitions 1 and 2.	See criteria for definitions 1 and 2.

Def. #	Data Element	Data Element Description <sup>12</sup>	Definition Criteria
6	Meet criteria for definitions 1 or 2 or 3	See descriptions for definitions 1, 2, and 3	See criteria for definitions 1, 2, and 3
7	Meet criteria for definitions 1,2 or 4	See descriptions for definitions 1, 2, and 4	See criteria for definitions 1, 2, and 4
8	Meet criteria for definitions 1, 2, 3, or 4	See descriptions for definitions 1-4.	See criteria for definitions 1-4.

Patients only prescribed metformin, thiazolidine, or exenatide needed to also meet criteria for at least one of Definition 1-3 as these medications are indicated for diseases other than diabetes.

**Performance measures.** CMS has provided EHR specifications for three diabetes performance measures: HbA1c control, blood pressure control, and cholesterol control<sup>17</sup> (See Table 1). For our analysis, we looked at the last of these values reported in 2009. When calculating the performance scores, CMS specifies that the denominator include all patients meeting the diabetes criteria, whether or not they had a record of the clinical test (i.e., blood pressure reading, LDL lab result, HbA1c lab result) in their medical record for the year being studied.<sup>33</sup> The numerator includes all the patients whose clinical outcome measure met the quality threshold defined by CMS.<sup>17</sup>

**Analysis.** We extracted data from the EHR on the primary care patients. Next, we determined which patients met the criteria for diabetes, according to each of the eight definitions. We estimated the prevalence of diabetes for each of the diabetes definitions and for the gold standard. We calculated the sensitivity and specificity of each of the 8 definitions by comparing them to the gold standard of a manual medical record review. For this part of the analysis, we looked at a randomly selected subset of 499 of the eligible primary care patients.

Next, we calculated the proportion of patients identified by each of the eight definitions who met the CMS quality standards. To determine whether a definition selectively identified patients with better or worse performance scores, we used the definition with the highest combination of sensitivity and specificity to identify the “true diabetics” in the primary care population. We then used the chi-square test to determine whether quality performance of the “true diabetics” identified by each of the other seven definitions differed from the quality performance of the “true diabetics” excluded by each of the definitions. In comparing quality scores we controlled for age and diabetes severity using logistic regression analysis.

## Results

### Results of Clinician Interviews

In this section, we report on four themes that emerged during our discussions with respondents. First, clinicians identified two data fields, the problem list diagnosis field and the encounter diagnosis field, as the locations in the EHR where clinicians most frequently document a diagnosis of diabetes. Second, clinicians endorsed the use of a problem list diagnosis for

identifying patients with diabetes for quality measures, while clinicians expressed concern that depending on an encounter diagnosis could result in over- or under-identifying patients. Third, while clinicians were not specifically asked about organizational influences on their documentation behavior, it emerged that organizational factors have an influence over how diagnosis data is entered into the EHR. The sections below provide additional details on these findings. Fourth, discussions with interviewees revealed concerns about the unintended consequences of using EHR data for performance measurement.

**Documenting diabetes diagnoses.** All respondents were asked where in the EHR they document a diagnosis of diabetes. For sixteen of the seventeen respondents (94%), the problem list was the first data field mentioned. While encounter diagnosis was only mentioned first by one respondent, all respondents reported that they also record diabetes as an encounter diagnosis during encounters when treating a patient with diabetes. About one-third of respondents also mentioned adding the diabetes diagnosis to the Past Medical History. (Respondents were not specifically asked about Past Medical History fields).

**Clinician recommendations for EHR fields to use in identifying patients with diabetes.** Respondents were asked to comment on whether or not specific parts of the EHR would be useful in identifying patients with diabetes. As presented in Table 3, all clinicians agreed that using problem list diagnoses would be a good way to identify patients with diabetes. Most clinicians also agreed that finding patients with an encounter diagnosis of diabetes would be another good way to find all the patients with diabetes in the health system, but expressed some concerns regarding the potential for this method to lead to over and under-identification of patients with diabetes.

All clinicians endorsed the use of the problem list to identify patients with diabetes. Clinicians reported that they believed that diabetes was consistently and correctly entered on the problem list. When probed to think of an example when diabetes had been on the problem list incorrectly or incorrectly missing from the problem list, few clinicians could recall an example. One physician noted he recalls diabetes missing from the problem list about three times in his 16 years at the health system.

The support for the problem list was specific for diabetes. Many clinicians reported that while the problem list is used consistently for diabetes, it is used less consistently for other conditions, particularly acute conditions. One respondent noted, “Your acute disease wouldn’t always be transferred to the problem list. You know, if you come in with a cellulitis you’re not going to transfer that over to the problem list, but if you have emphysema, diabetes, yes, they’re going to pull over to the problem list because that’s going to be an ongoing problem.”

The majority of respondents felt that using encounter diagnosis to identify patients with diabetes would also be a good method of identification. However, unlike the endorsement of the problem list diagnosis, the support for using the encounter diagnosis was not unanimous. Clinicians noted the potential for over-identifying and under-identifying patients when using the encounter diagnosis. Clinicians stated that the risk of under-identifying was because the encounter diagnosis was dependent upon a patient coming into the office for their diabetes. A clinician explained, “Let’s say that this particular patient doesn’t belong to me, they belong to another physician, and they happen to be seen for episodic visits, which are unrelated to a diagnosis of diabetes, then diabetes could be theoretically be not dealt with that entire time that they’re absent from their primary care physician.” Over-identification was attributed to clinicians

using a diagnosis of diabetes in place of other diagnosis codes (e.g. impaired fasting glucose) when attempting to rule out a diagnosis of diabetes. One clinician noted, “There are some physicians who, they don't think to put elevated sugar or something like that. So they are not officially diabetic, and you just use diabetic to quickly get the orders in.”

**Organizational factors influencing EHR data entry.** During the interviews, we asked clinicians to explain how and why they enter data into the problem list and encounter diagnosis fields. When explaining how and why they use these fields, it emerged that there are a number of organizational factors that drive how data is entered into these EHR fields. As presented in Table 4, internal quality performance programs, workflow, and leadership pressure all play a role in how these fields are used when documenting a diagnosis of diabetes.

*Workflow.* When discussing how encounter diagnoses of diabetes are entered into the EHR, respondents reported that nurses, physician assistants, nurse practitioners, and physicians enter the diagnosis codes. In addition to manually entering the encounter diagnosis, it emerged during the interviews that the institution’s EHR system offers a number of options for having a diagnosis code automatically listed as an encounter diagnosis. According to the clinicians, all medication, lab, and procedure orders require a link to a diagnosis. When an order is linked to a diagnosis code, that code is automatically listed as an encounter diagnosis. For example, if a physician orders insulin during a visit and links the insulin to diabetes, diabetes will be listed as an encounter diagnosis for that visit.

Clinicians also described EHR tools, such as smartsets, that result in automatically creating an encounter diagnosis. A smartset is an EHR tool used to complete routine encounters all on one form (orders, diagnosis, etc.)<sup>35</sup> Some respondents reported using diabetes smartsets to place orders, such as a hemoglobin A1c lab order. According to respondents, the diabetes smartsets automatically link the hemoglobin A1c order to a diagnosis of diabetes. Respondents also described best practice alerts, such as reminders for diabetes foot exams. These best practice alerts are sometimes linked to smartsets. Once again, some of these smartsets automatically link the resulting orders to diabetes, ultimately resulting in diabetes as an encounter diagnosis. Use of these EHR tools varied by clinicians. Some clinicians noted they frequently use smartsets while others reported never using smartsets.

As a result of the automated entries of diagnosis codes, patients with diabetes whose clinician ordered a lab, medication, or procedure are more likely to have an encounter diagnosis of diabetes in the EHR system than a patient whose physician has not placed any of these orders. Alternatively, patients whose clinicians did not place an order linked to diabetes would be less likely to have an encounter diagnosis of diabetes.

*Internal quality improvement program.* When discussing the problem list, it emerged that an internal quality improvement program for diabetes, referred to as the diabetes bundle, was driven off of the problem list. If a patient has a diagnosis of diabetes listed on their problem list, the patient will be included in the denominator for the diabetes bundle quality measures.

Because of this link between the quality improvement program and the problem list, clinicians indicated they were more conscientious about adding diabetes to the problem list saying, “because of the bundle, we try to make it look good.” An interview with the physician who developed the diabetes bundle indicated that the link between the bundle and the problem list was intentional. “We wanted to put them (physicians) in control of the accuracy of the data.

And so they are the ones that populate the problem list and so they are the ones who tell me who their patients are with diabetes. And so it gives them the responsibility of making sure that the registry information is up-to-date and accurate.”

*Organizational pressure.* Clinicians reported feeling pressure from leaders in their healthcare institution to keep their problem lists accurate and up-to-date. When asked how leadership exerted this pressure to maintain the problem list, most respondents cited the organization’s regular distribution of quality reports. In addition, respondents working in newer clinics noted that when they were integrated into the system, leadership emphasized the general importance of maintaining accurate and up-to-date problem lists. One respondent noted that the pressure to maintain the problem list has resulted in a problem list that is stronger than lists at other institutions. He explained, “So we have started to work with other organizations around the country, who are working with diabetes and have registries as well, and the biggest difference or the biggest debate is whether or not you use problem list data or not. Many EHR groups are not sure how accurate it is... and concerns come up over using problem list data.”

**Unintended consequences.** The section below describes four types of unintended consequences that emerged from the interviews. Not all of the unintended consequences were negative. Moreover, while respondents identified some negative consequences, respondents overwhelmingly supported the use of EHR data in quality reporting. The major categories of unintended consequences were: 1) Improved documentation in the EHR; 2) Negative impact on care process; 3) Insurance coverage issues; 4) Unnecessary patient anxiety. We present supporting quotes in Table 5.

*Improved documentation.* When discussing how to use EHR data to identify patients with diabetes, nearly all respondents drew on their experience with the existing diabetes improvement program described in Section 3.1.3.2. It emerged that clinicians are more conscientious about how they enter and manage the data in the EHR system with the knowledge that the data will be used in quality reporting. One clinician noted that there is more of an effort to obtain and document relevant lab values that might not normally make it into the record, such as lab results from institutions outside of the health system. He noted, “because of the quality program, we call (for the labs) and all that.” Multiple respondents also noted that they are more careful to document a diabetes diagnosis on the problem list. One clinician explained, “With the quality program, usually there’s a pressure to put the diagnosis in and you think about it more.”

*Care process.* In general, clinicians supported the use of EHR data for identifying patients with diabetes for quality reporting. However, clinicians did express concern about a lack of refinement in the EHR algorithms used to identify these patients. Specifically, clinicians felt that some patients with diabetes are inappropriately included in denominators when measuring quality of care. For example, a physician might be told to apply a quality standard, such as keeping an HbA1c level below 7.0, when that level is not appropriate to the specific patient. One clinician explained, “One thing we have not done, in any kind of sophisticated way, is really think about how to really identify the population we want to treat this way and defining who really, genuinely qualifies. The country got excited about keeping HbA1c below 7. But we got data that said for older adults keeping HbA1c that low actually increases the risks associated with hypoglycemia more than having risks of slightly elevated numbers.”

In addition to inappropriately applying treatment guidelines to patients who should not qualify (e.g. elderly, terminally ill, etc), respondents reported that the lack of sophistication of the EHR algorithms impacts clinician time. Clinicians reported that identifying those patients for whom the quality measures do not apply is time consuming for nurses and doctors. Clinicians must go through the EHR manually to determine whether or not the quality standard should be applied to the patient in question. One clinician reported, “One of my colleagues says it takes him 5 to 6 minutes per patient to find out what’s happening. ‘This patient is 92. I don’t think a colonoscopy is necessary.’ And then you scroll down through the report and find that you discussed the colonoscopy and the patient doesn’t want it. So it is a tremendous amount of extra work for the physician with no additional help at all. “

Overall, clinicians emphasized the importance of treating the individual patient, rather than depending on an EHR-based algorithm. One physician summarized this sentiment saying, “I think algorithms can be used, but you need to be very conscientious that you keep the patient at the center of it and not the algorithm at the center of care and evaluation.”

*Insurance issues.* The most frequently mentioned unintended consequence was regarding insurance coverage. Clinicians felt that, in the rare event that the EHR data generates an incorrect diagnosis and documents the diagnosis in the record, patients could be denied insurance coverage or made to pay higher premiums. Respondents felt such misdiagnoses in the record could impact life insurance, long term care insurance, and health insurance coverage. “The insurance company gets wind of that with the record and says, ‘Oh my god, you’re diabetic, we’re going to triple your premiums on your life insurance policy’ or ‘you’re not going to get health insurance because of this.’” In most cases, respondents were speaking hypothetically. However, a few clinicians told stories of insurance companies denying coverage based on incorrect diagnoses in the medical record, highlighting the importance of accurate diagnosis information in the record.

**Table 3. Clinician comments regarding documentation of diabetes diagnoses in the problem list and encounter diagnoses fields**

EHR Data	Comments
Problem List Diagnosis	<p>If it's not on the problem list then usually that patient's not being followed for diabetes.</p> <p>I think we're fairly consistent here with how we use the problem list for diabetes.</p> <p>If I was seeing a patient that I didn't know and I wanted to get an idea of what their medical problems were, that's (the problem list) where I'd look.</p> <p>I know the EPIC team, when we're doing quality assurance ... we will generate a list from the problem list and its accurate.</p> <p>There's quite a variety. There are some that put every little thing on there. And there are others that only put real significant things on there. And there are others that the same thing in on there forever. You know, even though the acute problem is gone.</p> <p>Yeah, I mean, I would say the problem list is always accurate and, if I was going to have a problem with the problem list it is that there are too many things on there. You know, people just put all sorts of extraneous stuff on there.</p>

EHR Data	Comments
Encounter Diagnosis	<p>Sometimes physicians use diabetes as a rule-out diagnosis in their claims based information. You know, they're ordering a glucose or they're ordering a glucometer for a patients and they'll put diabetes down. The patient really doesn't have diabetes, but to rule-out diabetes. It's not the way you're supposed to do it. You're supposed to enter hyperglycemia or something like that, but that's not in practice the way it's sometimes done. So we are very skeptical about a patient who only has one encounter level diagnosis of diabetes.</p> <p>If a person's blood sugars are ranging high, instead of putting something like abnormal chemistry or impaired fasting glucose, people will just stick diabetes on there. Its almost kind of like a rule-out diagnosis but there is no rule-out diagnosis in EPIC</p> <p>If they have impaired fasting glucose and they want diabetes-testing supplies to be paid for, you have to label them as having diabetes.</p> <p>It depends upon your patient panel. If it's an urgent care population, where people come and go, then you would under-diagnose. If it is a fairly stable panel, and people come back or they get the system involved multiple times, you'll eventually catch them.</p> <p>You might miss a fair amount with that because they may be in for blood pressure, cholesterol, and not really there for the diabetes management. I tell you, we would probably put that on the encounter list that day, probably 70 to 80 to 90% of the time, but there would be times when they are in for other reasons. So, the problem list would probably be more accurate than the encounter list.</p>

**Table 4. Clinician comments regarding organizational influences on problem list and encounter diagnoses**

Factor	Comment
Workflow	<p>If a nurse is ordering a medication or procedure for a patient, they will link that medication or procedure to an encounter diagnosis.</p> <p>You have to correlate the test with the diagnosis so that you move that from your problem list into your encounter list and its addressed then and your orders are entered to that diagnosis.</p> <p>As long as diabetes was associated with that medication, it would automatically come over.</p> <p>Yeah, you can use smartsets and pre-set up notes that make it very easy to document diabetic care.</p> <p>Mostly using smartsets for foot exams, for ordering it and a lot of the orders come through smartsets through nursing. HbA1c is on it. So all of that's pended before I even get in the room. You know, it's like pended, ready for me to sign.</p> <p>Most of my ordering is done from smartsets and I already have the diagnosis linked through the smartsets.</p> <p>Well, any time your order something and it's associated with any one particular diagnosis it's on the diagnosis for that particular encounter. So, if I saw you today for depression, for example, and you happen to have diagnosis for diabetes for a medication that has been refilled, even if we didn't talk about it, diabetes is not the reason you're there, we are talking about depression, diabetes would be on the encounter visit that day.</p>

Factor	Comment
Quality Imprvmt.	<p>In the EHR our quality measures are driven off of the problem list. So, I tend to use the problem list to put in the diabetes diagnosis and then all the reminders start firing</p> <p>With the bundles (quality program), usually there's a pressure to put the diagnosis in and you think about it more.</p> <p>I think if there's a bundle (quality program) it really emanates from the problem list. I don't think we get a bundle unless it, you know, is on the problem list.</p> <p>In general, I would say, since its part of the bundles (quality program) its there (on the problem list) more frequently.</p> <p>To some degree, (<i>physicians are using the problem list</i>) more so than before the bundle. Definitely, more so than before the bundle.</p>
Organiz. Pressure	<p>Everybody within the system is very aware that the numbers are looked at. With all the Medicare issues and quality assurance out there, I think everybody is pretty much aware of it. They break it down according to clinics, they break it down according to providers, and share it with us.</p> <p>It's one of the things that the system has made a priority so you're more focused on things that are out there in front where you are getting measured and looked at for.</p> <p>We were very compulsive about putting our diagnosis in...we were told to do that.</p> <p>There's a system level push to actually add the correct diagnosis to the problem list.</p>

*Patient anxiety.* Clinicians also expressed concerns about a patient learning of their diagnosis before a physician has the opportunity to discuss the diagnosis, if the diagnosis derived from the EHR algorithm is automatically inserted into the record. Clinicians agreed this scenario could result in unnecessary patient anxiety. Participants described three different ways a patient could learn of a diagnosis before the physician has notified the patient. First, clinicians explained that many of their patients access their EHR via a patient portal. They noted that if a computer algorithm adds a diagnosis to the problem list, there is potential for a patient to view a diagnosis via the patient portal before a clinician has the opportunity to contact the patient, particularly if the clinician is not made aware that the diagnosis has been added to the record. One clinician recalled a few instances when this scenario occurred with a chronic kidney disease (CKD) quality program, in which diagnosis of CKD is automatically added to the problem list based on lab measures in the EHR.

Second, clinicians reported there is also potential for a patient to be notified of their diagnosis via letter, before the physician has the opportunity to discuss the diagnosis. Clinicians described a quality initiative in their health system in which a letter is automatically sent to patients regarding a diagnosis of CKD when an EHR algorithm automatically adds the diagnosis to the problem list. Third, one physician felt that it was possible that a patient could discover a diagnosis after a medical record review by an insurance company. The respondent explained, "There have been times where people had a diagnosis and maybe were denied insurance, especially life insurance. So they go to buy a house, and they need to have life insurance to cover the mortgage, and they end up getting denied because they have diabetes and they didn't fully realize that or whatever."

The unintended consequences are more severe when the EHR-generated diagnosis is incorrect. Two respondents told stories of patients who incorrectly received automated letters notifying them that they had CKD. In both cases, the patients did not have CKD and the

physicians were not told the letters were being sent. One physician described the fall-out. “It was a mess that took 6 months to clean up. Doctors were accused of neglecting patients. Yeah, so I think we need to be very cautious. One day we are going to get sued.”

## Results of EHR Data Extraction

We identified 125,102 primary care patients who met the initial inclusion criteria. About 17 percent of these patients met at least one of the eight definitions for diabetes, as shown in Table 6. The prevalence estimate of diabetes in the primary care population was highest, (17.2%) when the minimum criteria for diabetes was whether a patient had either a problem list diagnosis, encounter diagnosis, diabetes medication order, or elevated HbA1c levels (definition 8) and lowest (12.2%) when the minimum criteria was having at least two elevated HbA1cs (definition 3). Among those definitions that required the presence of one specific data element to identify patients with diabetes (definitions 1-4), defining diabetes as having at least two encounters with diabetes (definition 1) resulted in the highest prevalence rate (16.3%).

Sensitivity and specificity analysis was conducted on a subset of 499 patients randomly selected from primary care patients. The manual record review (gold standard) identified 80 of these individuals as having a diagnosis of diabetes. Definitions for diabetes that used encounter diagnoses (definitions 1, 5, 6, 7, 8) had sensitivity over 95%. (Table 6). The definition that required an order for a diabetes-specific medication (definition 4) had a sensitivity of 83.8% and the definition that required a problem list diagnosis (definition 2) had a sensitivity of 75%.

**Table 5. Comments regarding negative unintended consequences of using an EHR algorithm to identify diabetes patients for quality measures**

Topic	Comments
Care Process	<p>So certain types of things we should make exceptions for. So something like obviously terminally ill people we would just try to keep their sugar in a range that they're not in the hospital. We don't need to treat them down to 5.6 or 6.0 or whatever. If they're 8, that's ok.</p> <p>I think for some elderly frail people its too aggressive. They are too likely to get dizzy and fall and have other problems. And also, I should mention the A1c target of 7 is too aggressive for a certain number of diabetics.</p> <p>Patients are individual and not everybody fits into a nice, tidy box... Yes, I mean some patients can't tolerate a blood sugar under 160, so you treat the individual.</p> <p>But at the same time, with data mining, you are just looking at numbers and there are lots of other things you have to consider. There are a lot of serious implications.</p> <p>Say there's a dialysis patient, and they don't make any urine and they are diabetic and their microalbumin alert flags. Well, they're already on dialysis anyway. Even if you can make a little bit of urine, what's the point?</p> <p>I mean, it's frustrating at times and it's frustrating with some of the very elderly. We probably shouldn't be bringing their blood pressures down to what our goal is for all our diabetics right now, less than 130 over less than 80.</p>

Topic	Comments
Insurance	<p>I had somebody that got denied for long term care insurance... And they used an encounter diagnoses from 2007 that were used to order some vascular studies. You know, he comes in with this letter and says, 'I don't have this.' I couldn't find it anywhere. I ended up doing a search through all the encounters and eventually found it. So, some of these insurance companies go through those records with a fine-toothed comb.</p> <p>I guess in terms of life insurance and health insurance for people, you know, now they have this label put on them.</p> <p>So, if you use it as a criteria for putting a name of a person and a diagnosis together for insurance purposes, so that their premiums are high because of that, I don't think that's right.</p>
Patient Anxiety	<p>That's huge because now, with patients having access to the problem list because they have access through the patient portal, and they see that, forget about it. I don't want it creating anxiety for them, which, in some cases, chronic kidney disease has. It creates a lot of unnecessary anxiety.</p> <p>Well patients not being aware of it and suddenly becoming aware of it. If they've got access to the patient portal and all the sudden it says they've got diabetes, you know, 'I didn't know I had diabetes.'</p> <p>You're going to be on that list and nobody's contacted the patient, so that would be an issue.</p> <p>No patient should actually get a letter without the physician knowing about it. And the letter is signed "your physician" or even the physician's name on it. And the patient is saying, "You sent me the letter." And there's nothing in EPIC that tells us a letter was sent. And it makes a very complex discussion with the patient.</p>

Requiring at least two elevated HbA1c levels (definition 3) resulted in the lowest sensitivity (65%). Of the 80 patients who had a diagnosis of diabetes according to the gold standard definition, requiring that the patient have two encounters associated with diabetes (definition 1) identified all but 3 patients as having diabetes. One of the patients not identified was not diagnosed with diabetes until December of 2009, the last month in the study period.

**Table 6. Sensitivity and specificity of definitions for diabetes**

Def. #	Definition Description	# patients		Yes	No	Total	Sensitivity	Specificity
1	At least 2 encounter diagnoses	20431	Yes	77	2	79	96.3%	99.5%
1	(% of pc pts)	(16.3%)	No	3	417	420		
2	Problem List (PL)	16322	Yes	60	0	60	75.0%	100%
2	(% of pc pts)	(13.1%)	No	20	419	439		
3	Two A1c >6.5 (on separate days)	15281	Yes	52	0	52	65.0%	100%
3	(% of pc pts)	(12.2%)	No	28	419	447		
4	Medication*	18399	Yes	67	1	68	83.8%	99.8%
4	(% of pc pts)	(14.7%)	No	13	418	431		
5	2 Encounter dx OR Problem List	20570	Yes	77	2	79	96.3%	99.5%
5	(% of pc pts)	(16.4%)	No	3	417	420		
6	2 Encounter dx OR PL OR A1c	20881	Yes	79	2	81	98.8%	99.5%

Def. #	Definition Description	# patients		Yes	No	Total	Sensitivity	Specificity
6	(% of pc pts)	(16.7%)	No	1	417	418		
7	2 Encounter dx OR PL OR Med	21418	Yes	78	2	80	97.5%	99.5%
7	(% of pc pts)	(17.1%)	No	2	417	419		
8	At least one of the above	21555	Yes	79	2	81	98.8%	99.5%
8	(% of pc pts)	(17.2%)	No	1	417	418		

All definitions had specificity over 99.4%. Two patients of the 419 who did not have diabetes, per the gold standard, had at least two encounter diagnoses of diabetes (definition 1). One of these patients also had a diabetes-specific medication ordered (definition 4). While these patients were documented as at risk of getting diabetes in the progress notes, a diagnosis of diabetes was ruled out, per the progress notes, as of the end of the study period.

Approximately 65% of patients identified by each of the definitions met the CMS quality standard for blood pressure control, as shown in Table 7. The proportions ranged from 64.8% when definition 3 was used to 65.5% when definition 2 was used. There was a slightly larger range in the proportion of patients meeting the LDL quality standard. The proportion of patients meeting the standard ranged from 67.1% identified by definition 8 to 71.3% identified by definition 3. For each definition, more than 80% of patients met the quality standard for HbA1c control. The proportions ranged from 82.9% among those identified by definition 8 to 85.1% among those identified by definition 3.

Based on the combination of high sensitivity and specificity, we used definition 8 to identify the “true diabetics” in the population. Definition 8 was also the most inclusive definition, classifying a patient as diabetic if they met the criteria for any of the first seven definitions. Each of definitions 1 through 7 missed a portion of the true diabetics. (See Table 3) In all but one case, the patient group that the definition classified as diabetic performed better on the LDL and HbA1c quality measures than the patient group the definition excluded. This was particularly true among definitions that classified patients as diabetic if they had 2 or more encounter diagnoses of diabetes (definitions 1, 5, 6, and 7).

**Table 7. Proportion of patients identified by diabetes definitions meeting CMS quality standards: patients identified by definitions and patients missed by definitions**

		Number of patients		Percent meeting BP Standard		Percent meeting LDL Standard		Percent meeting HbA1c Standard	
		Identifd.	Missed	Identifd.	Missed	Identifd.	Missed	Identifd.	Missed
1	At least 2 encounter diagnoses	20431	1124	65.1%	64.2%	68.7%	37.8% <sup>1</sup>	84.6%	52.2% <sup>1</sup>
2	Problem List	16322	5233	65.5%	63.7%	70.2%	57.4% <sup>1</sup>	84.3%	78.7% <sup>1</sup>
3	Two A1c >6.5 (on separate days)	15281	6262	64.8%	65.8% <sup>2</sup>	71.3%	56.8% <sup>1</sup>	85.1%	77.4% <sup>1</sup>
4	Medication	18399	3156	65.3%	63.9%	68.4%	59.7% <sup>1</sup>	82.4%	86.1% <sup>2</sup>
5	2 Encounter dx OR Problem List	20570	985	65.1%	64.6%	68.4%	39.6% <sup>1</sup>	84.3%	54.2% <sup>1</sup>

		Number of patients		Percent meeting BP Standard		Percent meeting LDL Standard		Percent meeting HbA1c Standard	
		Identifd.	Missed	Identifd.	Missed	Identifd.	Missed	Identifd.	Missed
6	2 Encounter dx OR PL OR A1c	20881	674	65.0%	67.7% <sup>3</sup>	68.1%	34.1% <sup>1</sup>	84.3%	37.6% <sup>1</sup>
7	2 Encounter dx OR PL OR Med	21418	137	65.1%	59.9%	67.2%	49.6% <sup>1</sup>	82.9%	90.5% <sup>2</sup>
8	At least one of the above	21555		65.1%		67.1%		82.9%	

<sup>1</sup> p<0.0001 – Controlled for age and diabetes severity

<sup>2</sup> p<0.05 – Controlled for age and diabetes severity

<sup>3</sup> p<0.01 – Controlled for age and diabetes severity

Approximately 69% of diabetics identified by definition 1 (2+ encounter diagnoses) met the LDL standard, compared with 37.8% of diabetics who were not classified as diabetic by definition 1 (p<0.0001). Close to 85% of patients who met the criteria for definition 1 met the HbA1c standard compared with 52.2% of patients who did not meet the definition criteria. Over 84% of patients classified as diabetic by definition 5 (2+ encounter diagnoses OR problem list diagnosis) met the HbA1c quality standard, compared to 54.2% of patients excluded by the definition criteria (p<0.0001). All differences remained significant after controlling for age and diabetes complication severity.

## Discussion

The findings from this study provide important information to administrators of quality reporting programs; health system leaders participating in EHR-based performance measurement; and patients, providers and payers viewing performance data. Moreover, health services researchers and epidemiologists using EHR data can benefit from a better understanding of EHR data and its use in identifying disease populations.

One of the key findings of this project is that the method used to identify patients with diabetes in the EHR can be associated with diabetes care performance. Specifically, we found that the use of certain criteria (e.g. 2+ encounter diagnoses) excluded patients from the target population who performed poorly on performance measures. To date, only one other study has evaluated EHR-based diabetes performance measures for selection bias, and this study looked only at encounter diagnoses counts and was confined to Medicare beneficiaries.<sup>27</sup> Our new finding has important implications for performance measurement, particularly for performance measurement used in public reporting of health performance.<sup>5</sup> First, when comparing health systems on performance in diabetes care, it is essential that participating providers use the same method for identifying diabetes patients. Second, when developing performance measures, administrators of quality reporting programs must provide detailed information as to how to identify patients with diabetes. Finally, when a provider or health care organization reports performance measures, the health care provider should be detailed in describing the methods used to identify the target population.

Another key finding of our study was the influence that organizational factors have on EHR data entry and the impact this can have on performance measures. This finding is essential to consider as organizations such as CMS move towards standardizing EHR-based performance

metrics.<sup>36</sup> Whenever possible, organizations developing these standards should attempt to use EHR data elements that are not sensitive to organizational influence. Given that it is unlikely that many data elements will be completely free from the influence of organizational factors, comparisons of performance across organizations should be made with caution.

The relevance of these findings goes beyond performance measurement. The EHR is being increasingly used for secondary purposes such as clinical trials, comparative effectiveness research (CER), and general epidemiological and health services research. The Federal Coordinating Council for Comparative Effectiveness Research acknowledged in its 2009 annual report that the success of CER is largely dependent on health information technology.<sup>37</sup> As with performance measures, CER requires the identification of a target population to answer research questions. If treatments for diabetes are compared in a population that excludes diabetics with poorer cholesterol or blood pressure control, results of the research can not necessarily be generalized to that excluded group. Researchers should consider the findings in this report when using EHR data to identify patients for research.

## Concluding Thoughts

There is much, and frequently well deserved, enthusiasm for the potential for EHR systems to drive improvements in health care quality. One of the proposed paths towards this achievement in quality improvement is through the application of EHR data to performance measurement. However, in the rush to solve the quality problems of our health system, it is imperative we take the time to fully understand EHR data and the consequences of its use in performance measurement. Only after we apply this knowledge can we fully reap the benefits of EHR technology.

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## List of Publications and Products

None at this time.