

Prevalence and Access of Secondary Source Medication Data: Evaluation of the Southeastern Diabetes Initiative (SEDI)

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Abstract

Medication non-adherence is a major public health issue, and measuring non-adherence is a crucial step toward improving it. A paucity of retrievable data prevents researchers from effectively measuring, tracking and sharing outcomes on medication management. High quality data derived from prescribing patterns, including behavioral and technology-based interventions, is necessary to support meaningful use, improve publicly reported quality metrics, and develop strategies to improve medication management. Electronic health records make medication data more numerous and accessible, yet the reliability and utility of electronically available data elements that reflect adherence has not been well established. We sought to explore the types of medication-related data captured over time in a series of patient encounters (n=5500) in a population-based intervention in four U.S. counties in the SouthEastern Diabetes Initiative (SEDI). The purpose was to evaluate data generated through routine healthcare delivery that are repurposed (ie, “secondary use”) for research/QI/population health.

Introduction and Background

Adherence to evidence-based medications is a meaningful goal for patients with chronic illness, to decrease acute clinical events, hospitalizations, and symptoms, and to improve life expectancy. Despite the importance of these outcomes, life-long medication taking is fraught with well-documented cognitive, emotional, social and financial burdens.(1, 2) On a national and international scale, 50% of the population is unable or unwilling to take medications as prescribed.(3, 4) Patients have asked for help to manage chronic medications, in focus groups (5), interviews(6) and social network chat rooms.(7) Significant investment in research to improve adherence has not yielded measureable improvements in medication adherence at the population level, and research that indicates increasingly poor rates of adherence to life-saving medicines over time.(8)

Currently, data collection, curation, preservation and linkages are insufficient for the study and evaluation of interventions to improve medication use and meet the needs of patients, providers and payers. Across almost every level of study design – from descriptive evaluation of medication fill-rate patterns and trends(9) to complex predictive modeling of the association of medication adherence with clinical outcomes(10, 11) – the quality of accessible data for analysis of medication adherence falls short. The variability in data definitions and inconsistency in terms used in practice and research prevent successful scaling of interventions from controlled research settings to real-world populations.(12, 13) In addition, data elements reflecting patients’ most commonly reported challenges in managing medications have not been collected and curated (Table 1).(14, 15)

Table 1. What Patients Want to Know to Manage Meds
Theme

1. When to resume a missed dose of medicine?
2. What to do when the medicine “doesn’t seem to help me”?
3. How to respond if medicine “sometimes makes me worse”?
4. What if my daily schedule conflicts with my medicine schedule?
5. How to get information from my provider when I need it?
6. How to find the least expensive medicine for me?

Challenges in collecting and curating common data elements that are meaningful to patients stem from the etymological origin of the terms used in research and practice to reflect “medication-taking.” Terms that are most commonly used and most likely to be defined and standardized (16), such as medication possession ratio or proportion of days covered, do not reflect aspects of medication-taking that are considered important or useful to patients.

As a result, data capture from the many entities that contribute to management of adherence over time, including patients, caregivers, providers, communities, and health systems, are inaccessible or absent.(17) For example, the data elements reflecting daily management of medications, such as the implementation of routines and reminders to facilitate medication-taking, the monitoring of daily physiologic indicators that drive dose, such as blood sugar in diabetes or daily weight in heart failure, or the access to pharmacies with home delivery; these details and logistics

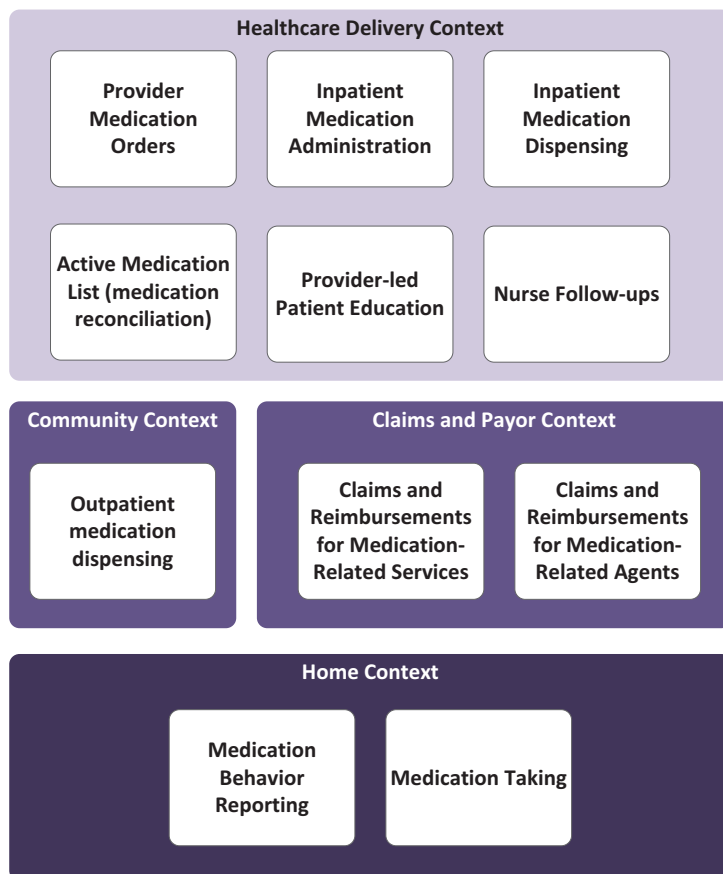
of daily management significantly alter the ability of patients to manage medicines. Yet most are not captured, or if captured are not curated and connected to providers in a way that enables feedback using real-time data.

The purpose of this study was to evaluate: 1) what workflow activities in standard healthcare delivery represent key components of medication management; and 2) what gaps in data collection, curation and preservation prevent data sharing within and across health systems, care settings and institutions?

Methods

We applied a taxonomic approach (18) to identify domains captured in the electronic health records (EHR) to gain a comprehensive understanding of the feasibility of variables reflecting medication adherence. Next, using the same taxonomic approach, we explored the domains captured by non-EHR (un-linked) outpatient and community workflows related to medication use, such as community-based pharmacies, home drug delivery services, home-health and short term skilled nursing facility medication management. In addition we evaluated common un-linked electronic data sources used by patients for self-management or medication monitoring, such as sliding-scale insulin dosing, electronic pill bottles, smart phone applications to monitor pill-taking, and e-messaging systems to monitor pill-associated symptom response.

Figure 1. Contexts for medication-related data.



data sources as shown here in Figure 1.

The SouthEastern Diabetes Initiative (SEDI) houses a multi-dimensional datamart, which includes clinic and hospital electronic health record (EHR) data from 4 counties in the southeastern United States. The project provides opportunities for development of the proposed data framework because it allows us to: 1) Harvest data from electronic sources in each county to create a comprehensive, integrated data warehouse to accurately reflect clinical and social data elements that can be represented at the individual, neighborhood, and community level; 2) Use those data to risk stratify patients and neighborhoods, allowing implementation of an intense clinical intervention from a multi-disciplinary team that provides care to the highest risk patients as well as additional individual and neighborhood interventions to moderate risk patients and neighborhoods; and 3) Implement interventions informed by spatially-enabled informatics systems to longitudinally monitor individuals and populations with T2DM, thereby serving as the basis for decision support and evaluation of chronic illness interventions. Cumulatively, these data sources constitute a broad-scoped, connected data framework, the axis of which revolves on patient-centric activities for medication use. We developed a workflow algorithm to depict activities and

Next, we evaluated the conceptual data framework using our existing SEDI datamart. We conducted four activities to evaluate the framework: 1) Obtained patient perspectives on challenges of managing medicines through systematic literature review; interview and focus groups; review of EHR; and evaluation of medication-related patient reported outcome measures; 2) Matched data sources with the activity model for medication management (Figure 1); 3) Applied the activity model to our SEDI datamart; and 4) Performed a gap analysis to evaluate data collection, curation, preservation and linkages.

Results

Results of our study are shown in Table 2. We examined electronic data from four SEDI counties to develop a data framework that captures the patient experience of medication self-management and the clinical documentation that supports shared decision-making for medication management.

Table 2. Common medication-related activities and workflows with their associated data capture.

Data Domain	Activity Comments	Data Collection and Structuring	Vrijens Taxonomy Classification
Provider medication orders	Provider prescriptions and associated instructions	Tends to be very precise (exact dosage, formulary) especially where medium is Computerized Physician Order Entry (CPOE). This activity does not indicate actual dispensing.	Management of adherence
Inpatient medication dispensing	Health system pharmacy basis	Tends to be very precise with details associated from formulary. Not available in strictly ambulatory settings.	Adherence to medication
Inpatient medication administration	Often a nurse-driven activity	Depending on institute's workflow, may serve as a de facto witness to medication taking.	Management of adherence
Outpatient medication dispensing	Pharmacies (eg, Walgreen's, Walmart, Express Scripts)	Encompasses both direct dispensing agencies and pharmacies, and also claims filed and processed by payors.	Adherence to medication
Active medication list	Healthcare medication reconciliation	Although an important communication medium between patients and providers, process may have less accuracy and precision of recall.	Adherence to medication
Provider-led patient education	Often occurs in hospital settings just prior to discharge	Still in early stages of adoption as formal systems; performed by nurses, pharmacists, and others in various settings.	Management of adherence
Nurse follow-ups	Often a post-discharge activity	High variability, often captured in clinical follow-up notes.	Management of adherence
Patient medication behavior reporting	Eg, apps, survey instruments	High variability across many settings, including direct patient-reported and patient-generated settings.	Adherence to medication
Patient medication taking	Patient ingests the agent	Almost all data are proxies except for direct supervision	Adherence to medication

Discussion

Results of this study support the established medication adherence taxonomy, which is comprised of two overarching constructs, Adherence to Medications and Management of Adherence.(18) The first construct, Adherence To Medication is well developed and is comprised of four domains: initiation, implementation, discontinuation, and persistence. Distinct representative data elements provide multiple options for measuring, assessing, and evaluating each domain. Data elements are measurable components of variables, such as "medication name," "dose," "frequency of administration," and "duration" of prescribed medication dosing. The definition of a discrete data element is constant, but the availability of data elements that represent a variable of interest in a given study context may vary. Each has unique limitations in terms of accessibility, reliability, and

validity. For instance, prescription fill date offers an accessible surrogate for initiation, but its reliability and validity with regard to actual implementation of medication-taking are limited. Other, more sensitive data elements in this domain include MEMS electronic cap removal time stamps, blister pack documentation, or self-report; each has its respective advantages and limitations. However, the second construct, Management of Adherence, is underdeveloped and lacks the organizational framework to formalize a repository of data elements and standard definitions for each element.(19) The World Health Organization (WHO) has defined medication adherence as “the extent to which a person’s medication-taking behavior corresponds with the prescribed therapeutic regimen,” yet, for researchers attempting to measure and evaluate these behaviors in relation to clinical outcomes, this broad definition entails a conundrum of choices and decisions regarding variable selection, with each option varying widely across studies. As a result of this variability, the ability to identify standard data elements in an electronic health record (EHR), case report form, or data warehouse is lost, and opportunities to scale interventions or generalize study findings across settings and populations are sacrificed.

Use of a framework creates fresh possibilities for both research and practice.(18) Importantly, the framework distinguishes between the work associated with taking prescribed medication (Adherence to Medication) and the work that supports management of medication (Management of Adherence). The former refers to initiating the medication, persisting in taking the medicine over time, and discontinuing the medicine at the appropriate time. The latter encompasses prescribing accurately, facilitating accessibility, and ensuring the understanding of instructions for administration. The need to establish these two distinct areas that both contribute to a shared goal is at the heart of achieving improved patient-centered clinical outcomes.

Decisions that patients, providers and researchers need to make related to managing medications and medication-associated data, such as those described in Table 2, are supported by the framework, including decisions regarding modification of prescribed medication regimens, adapting medication regimens to patient-specific symptom responses, or identifying how best to communicate patient-centered outcome data such as blood glucose values to a provider for feedback. Because the framework serves to identify data elements associated with key medication-related activities, patients, providers and researchers can use the framework to identify and exchange key data for feedback and clinical responsiveness, without questioning the source, definition or quality of the data elements being used. For example, data from a home or community pharmacy blood pressure cuff could be used to transmit blood pressure measures and reliably direct dosing changes for antihypertensive medications, without requiring the patient to travel for validation of the data in a hospital or clinic setting.

Conclusion

In summary, this study demonstrates the development and evaluation of a new comprehensive conceptual data framework to improve the collection, curation and preservation of data elements, and the use of secondary data sources commonly used in medication adherence research. The approach allows for future standardization of conceptually valid data elements and definitions that reflect patient management of medications, and measurable opportunities for caregivers, providers, health systems and communities to support the patient to more effectively manage medications. As a result of this project, data architects and system developers will be able to use the conceptual data model to improve the ability to achieve completeness, comprehensiveness, accuracy, efficiency and more integrated clinical use of data collected regarding management of medications across healthcare systems and clinical data networks. In addition, researchers can use the data model to query registries or design longitudinal studies of management of medications using health system, community or payer databases, and the utility, performance and efficiency of these data for conducting studies of patient outcomes will be improved.

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