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Application Notes

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Development of REDCap-based architecture for a clinical decision support tool linked to the electronic health record for assessment of medication appropriateness

Peter A. Charpentier[1], Marcia C. Mecca[2,3], Cynthia Brandt[3,4], and Terri R. Fried [2,3,*]

[1]Program on Aging, Yale School of Medicine, New Haven, Connecticut, USA
[2]Department of Medicine, Yale School of Medicine, New Haven, Connecticut, USA
[3]PRIME Center, VA Connecticut Healthcare System, New Haven, Connecticut, USA
[4]Center for Medical Informatics, Department of Emergency Medicine, Yale School of Medicine, New Haven, Connecticut, USA
*Corresponding Author: Terri R. Fried, MD, P.O. Box 208025, New Haven, CT 06520-8025, USA; terri.fried@yale.edu

ABSTRACT

Objective: To develop the architecture for a clinical decision support system (CDSS) linked to the electronic health record (EHR) using the tools provided by Research Electronic Data Capture (REDCap) to assess medication appropriateness in older adults with polypharmacy.

Materials and Methods: The tools available in REDCap were used to create the architecture for replicating a previously developed stand-alone system while overcoming its limitations.

Results: The architecture consists of data input forms, drug- and disease-mapper, rules engine, and report generator. The input forms integrate medication and health condition data from the EHR with patient assessment data. The rules engine evaluates medication appropriateness through rules built through a series of drop-down menus. The rules generate output, which are a set of recommendations to the clinician.

Discussion and conclusion: This architecture successfully replicates the stand-alone CDSS while addressing its limitations. It is compatible with several EHRs, easily shared among the large community using REDCap, and readily modifiable.

LAY SUMMARY

Specialized electronic programs known as computerized clinical decision support systems can incorporate individual patient risk factors from electronic health records (EHRs) and provide automated guidance to clinicians to assist them in medical decision making for patients. Many of these tools designed to assist with medication prescribing decisions focus on one medication or a group of similar medications. Older adults with multiple chronic conditions are prescribed many medications that may or may not be appropriate based on a wide variety of criteria. Effective tools for such patients are complex, and stand-alone systems are limited in the ability to integrate information from more than one EHR, modify based on new research findings, and disseminate to other healthcare institutions. We developed a novel resource using Research Electronic Data Capture (REDCap) architecture which addresses some of these challenges. The tool integrates medication and health data from EHRs with patient assessment data and, using a system of modifiable rules, allows users to select from a series of drop-down menus and generate an output of clinical recommendations. The REDCap interface is user friendly for nonprogrammers, compatible with several EHRs, easily shared among the large community using REDCap, and readily modifiable to incorporate new findings.

Key words: polypharmacy, potentially inappropriate medication list, decision support systems, clinical, electronic health records

BACKGROUND AND SIGNIFICANCE

Computerized clinical decision support systems (CDSS) providing specific, actionable care recommendations, or management options have been shown to improve the process of care delivery.[1] Increasingly, CDSS are being embedded in the electronic health record (EHR) in order to automate the provision of recommendations based on data abstracted from the EHR. CDSS-EHR linked systems hold particular promise for improving medication prescribing quality and safety. Polypharmacy is highly prevalent among older persons.[2] Polypharmacy is associated with the prescription of potentially inappropriate medications (PIMs), which are medications individually associated with risk of harm,[3] and, deprescribing PIMS has been identified as a key element of good prescribing.[4]

CDSS successfully promote deprescribing.[5] However, many of the systems embedded in the EHR focus on a single medication or single class of medications.[6] In contrast, older persons with multiple medical conditions are prescribed many medications, and these may be inappropriate based on a wide variety of criteria.[7] CDSS that include a more comprehensive set of appropriateness criteria are most often free-standing systems that are not linked to the EHR and are built on a variety of different platforms.[8,9] Ideal decision support systems for deprescribing would link more sophisticated CDSS tools to the EHR, be built on platforms that can be used across multiple EHR systems, and be flexible enough to allow for easy updating of rules for assessing appropriateness as new knowledge develops. The features of Research Electronic Data Capture (REDCap) make it an ideal platform for the

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development of such systems. REDCap is a secure, open-source web application for building and managing databases and is supported and utilized by a large network of experts, the REDCap Consortium.[10]

OBJECTIVE

The purpose of this article is to describe the use of the tools provided by REDCap to create the framework for a CDSS-EHR to assess medication appropriateness in older adults with polypharmacy. The goal of the new framework was to overcome limitations found in the development and testing of a medication appropriateness assessment tool built to identify a broad range of PIMs, the Tool to Reduce Inappropriate Medications (TRIM).[11]

MATERIALS AND METHODS

Description of TRIM

TRIM was developed for use within the Veterans Affairs (VA) health system. TRIM consists of 2 software applications. The first application is a program to extract age, chronic conditions, and medications from the EHR using the Veterans Health Information Systems Technology Architecture's (VistA) EHR Web Services. These data elements allow for the identification of patients with polypharmacy and provide inputs for the algorithms in the second application.

The second application is a web-based medication evaluation tool consisting of 3 components. The first component is an interface for chart review and telephone assessment of health and psychosocial status variables. These variables, along with the EHR-extracted data serve as inputs for the second component, which employs a collection of clinical algorithms to generate indicators of appropriateness. These indicators drive the third component, which is a patient-specific medication management feedback report for the clinician.

The algorithms were developed to provide an automated assessment of appropriateness. The algorithms identify: (1) patients with poor adherence and/or executive dysfunction; (2) potential overtreatment of diabetes mellitus and/or hypertension (HTN); (3) PIMs based on consensus medication lists; and (4) inappropriate renal dosing. In addition to these automated algorithms, there is a manual medication reconciliation evaluation.

Each algorithm consists of an if/then statement. The "if" statements look for markers of inappropriateness and the "then" statements are the feedback for clinicians if the markers are present. The if-then statements were operationalized according to a pseudocode construct into a text "knowledge base" document, which in turn was compiled by the TRIM application into Hypertext Preprocessor (PHP) code and executed.

Limitations of TRIM

The implementation of TRIM revealed important limitations and weaknesses. First, the system could only be used with the VA EHR. Second, the knowledge base document pseudocode was cumbersome for nonprogrammers to work with. Typographical errors and errors in formulating logical expressions would result in the algorithm failing to execute. Debugging required the application developer to analyze system logs and exception reports. Third, the knowledge base rule syntax was limited to simple expressions, resulting in many rules generating the same feedback, advisories, and recommendations. These had to be reconciled by the report generator. Finally, because TRIM is a stand-alone web application, every element except the knowledge base is hard-coded and relies on the original developer for modification. We sought to overcome these limitations with a REDCap-based framework.

RESULTS

Data sources

As shown in Figure 1, there are 4 data sources for the CDSS evaluation and reports. Patient observation data are provided by 2 study-designed REDCap forms: a *Medication Reconciliation Form* and a *Patient Assessment Form*. EHR data may be input through a REDCap *EHR Abstraction Form* and/or through the REDCap Clinical Data Interoperability Services (CDIS) module.[12] This module provides data exchange between the REDCap system and any EHR system with a Health Level Seven Fast Healthcare Interoperability Resource (FHIR) application programming interface (API).

The Medication Reconciliation form is populated with the medications abstracted through the EHR Abstraction Form or imported into REDCap through the CDIS module and has an additional reconciliation field. The completion of the form requires contacting the patient at home. The caller reviews each medication on the form with the patient and selects 1 of 3 drop-down options: taking medication as prescribed, not taking medication, dose, and/or schedule different from prescription. The caller also enters any medications that the patient has at home and is taking but which are not in the EHR.

The Patient Assessment form includes patient characteristics that are not routinely recorded in the EHR. This form can be edited to add, delete, or modify measures.

Architecture

The CDSS is implemented as a REDCap External Module (EM).[13] No CDSS-specific database tables are required; rather, the specialized CDSS data structures are encoded to JavaScript Object Notation (JSON) strings and stored in the REDCap database (back end) as ordinary REDCap EM configuration settings. These are retrieved by the browser client (front end) via Asynchronous JavaScript And XML (AJAX) calls and native REDCap functions, then parsed and stored as arrays of Javascript objects. The CDSS data structures include enumerations of study fields, disease classifications, and medication classifications, as well as bridging tables to manage the many-to-many relationships between fields and classifications. The user-designed rule logic for all reports is also represented as an array of objects encoded to JSON and stored as a single EM configuration setting.

Drug and disease mappings

The CDSS toolkit includes 2 components that map Patient Assessment and EHR-derived REDCap data to one or more classifications, which are the specific data structures used in the CDSS Rule Engine (see below) by means of bridging tables. The *CDSS medication mapper* converts specific medications into *CDSS drugs*, which are the medication classifications used in the rules. The mapping may be to a single drug name or to a drug class. The mapping mechanism is through

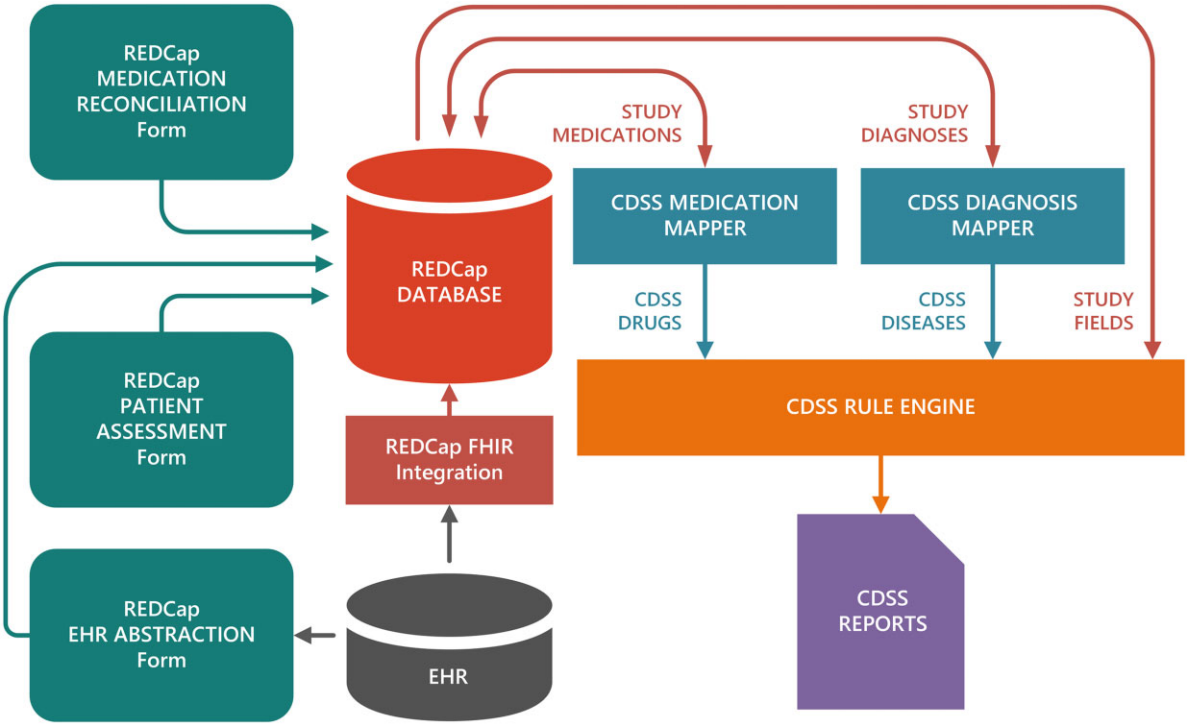

Figure 1. CDSS architecture and data flow. The green boxes represent the forms through which data are entered into the database, along with the data directly exported from the EHR via the Health Level Seven FHIR API. The 2 blue boxes represent mappers that translate medications and diagnosis into study-defined classifications that, along with additional study fields defined in the database, serve as inputs for the CDSS Rule Engine (orange box). The outputs are exported to a print feedback report (purple box).

simple string pattern matching, for example, a REDCap medication value containing "Plavix" can be mapped to a CDSS drug classification, "Clopidogrel," and/or to "Antiplatelet agent." The first classification would be used in a rule referring to the specific medication and the second in a rule referring to the entire class of medications. In a similar manner, the *CDSS diagnosis mapper* converts ICD codes derived from the EHR to *CDSS diseases*, which are the disease categories used in the rules. The CDSS medication and diagnosis mappers save results to (1,0) indicators—one for each drug or disease classification—stored as REDCap fields, as indicated by the bidirectional connectors in Figure 2.

The CDSS rule engine

Each CDSS rule consists of one or more *conditions* and evaluates these as true or false. A true outcome for a CDSS rule will trigger a single *action*, which is a payload (a recommendation and associated data) sent to 1 of the 5 CDSS-supported reports. A CDSS rule condition is a logic expression that must resolve to true or false, and the expression must adhere to a "grammar." This formalization requires a *subject* that is a single CDSS drug, a CDSS disease or a study field, and a *predicate clause* that depends upon the subject class and which may include a threshold *value*.

The CDSS *Rule Editor* (Figure 2) guides the construction of each condition expression. To illustrate how the CDSS Rule Editor guides the construction of a condition expression, consider the renal dosing rule for metformin, which identifies patients with impaired kidney and a metformin daily dose of >2000 mg/day. This rule includes the condition "Metformin dose is greater than or equal to 2000." The subject of this condition is the CDSS drug "Metformin" which is itself a construct determined by EHR data and the CDSS medication mapper. The CDSS rule designer first locates the CDSS drug "Metformin" using a single autocomplete input field that searches all possible condition subjects (CDSS drugs, CDSS diseases, study fields). The CDSS condition expression builder will then offer the following predicate clauses: "is prescribed," "is not prescribed," "dose is less than (value)," "dose is less than or equal to (value)," "dose is greater than (value)," and "dose is greater than or equal to (value)." The user selects "dose is greater than or equal to" and enters "2000" into the value field that the selected predicate clause generates. The conditions that comprise a CDSS rule are combined using the logical operators AND, OR, and NOT, and a single level of parentheses.

The subjects of the condition expressions are restricted to a single REDCap field or mapped disease/medication classification. If a calculated expression is required—for example, a total or mean score—it must be added to the project using the sophisticated and well-documented REDCap calculated field feature. That field will then become the subject for the condition expression.

The CDSS interpreter and CDSS reports

The *CDSS rule interpreter* applies all CDSS rules to the selected patient record and provides payload for CDSS reports in a single step. These payloads consist of a recommendation generated by each condition resolving to "true" for the selected patient and a data summary. A design goal was to avoid a separate "compiling" step for the rule engine, not only to reduce the coding and operational complexity of the system but to ensure that any change to a rule is immediately available to the reports. By carefully developing use-

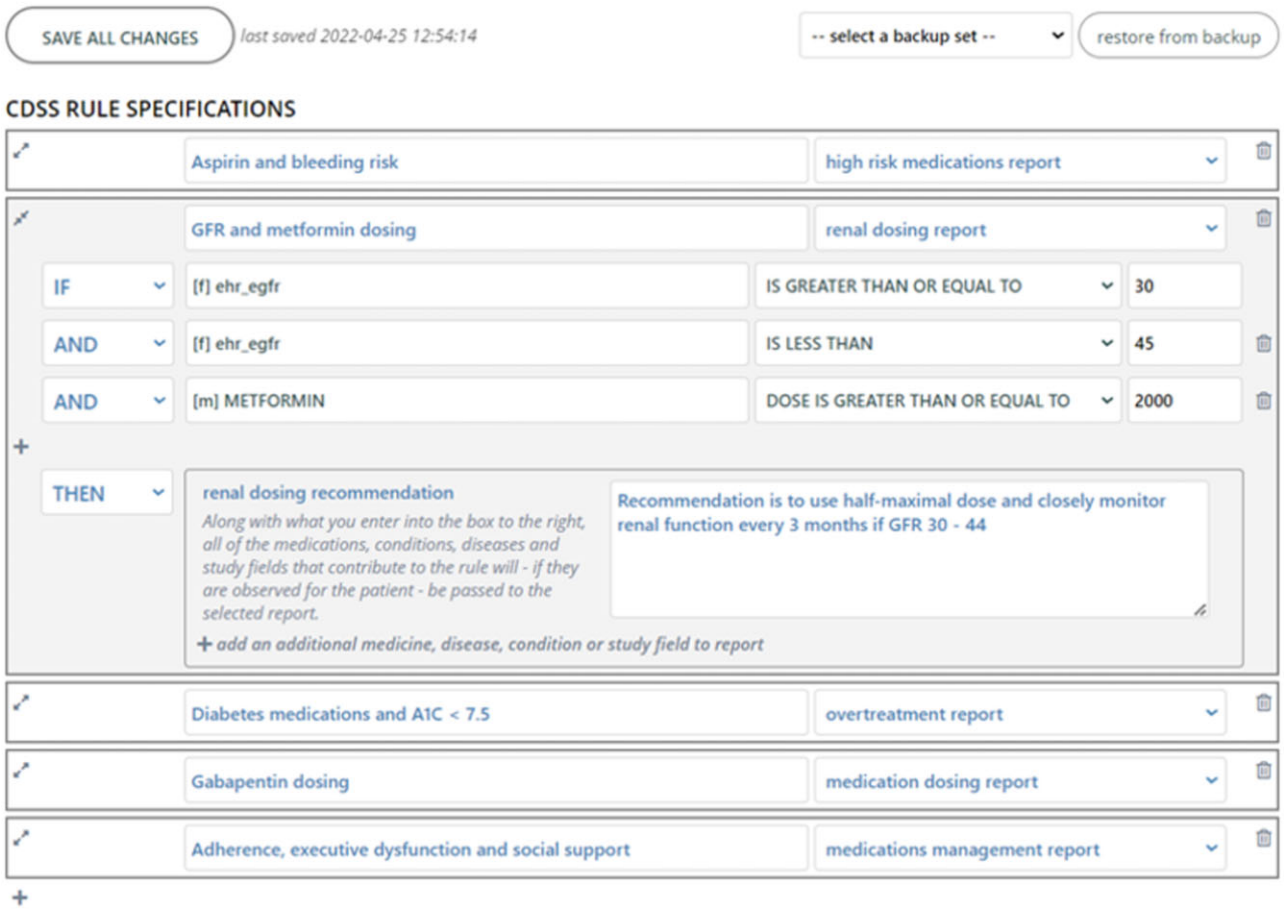

Figure 2. CDSS rule editor. Screen shot of an example of creating a rule to assess appropriateness of dosing of metformin in renal failure.

cases for each rule, an investigator can quickly debug the rule logic and validate the system without programming. Since rules are immediately resolved, combined with data, and executed, we refer to the core of the rule engine as an interpreter and not a compiler.

Rules are designed in the browser client (Javascript, Cascading Style Sheets [CSS]) and executed in the host environment (PHP, Structured Query Language [SQL]). It is therefore important for the 2 environments to have mirrored states regarding all data structures associated with rules. This is accomplished as follows: when any rule component is saved in the browser client, it is sent via AJAX for storage on the REDCap database. The server-side code then queries the database for the same data and sends it back to the browser in the AJAX response. The equivalent Javascript data structure is updated and the affected user interface component—usually an editor—is refreshed. The data manager will therefore know immediately of any data corruption on the host.

There are 5 rule-based reports built into the CDSS, corresponding to the areas of appropriateness assessment described in the "Methods" section. Each report is sent a payload consisting of all recommendations triggered by rules evaluated as true, along with the data associated with each rule. The first report alerts the clinician to patients who have evidence of cognitive impairment and/or medication nonadherence in the context of their available social support, with recommendations to simplify the regimen and, as possible, utilize available support. The second alerts the clinician to patients who are being overtreated for HTN and/or diabetes and provides an alternative blood pressure or blood sugar target. The third is a listing of PIMs based on consensus criteria with recommendations based on the specific medication. The fourth is a list of medications inappropriately dosed for renal function and the fifth a list of medications inappropriately dosed for advanced age, with recommendations for alternative dosing. Several examples are provided in Figure 3. In addition to the rule-based reports, a medication reconciliation summary is provided that indicates discrepancies between medications being taken by the patient and medications noted in the EHR. All of the reports for the selected patient are assembled into a single document that may be viewed and printed.

A report is initiated by an AJAX request originating in the REDCap user interface, specifically by submitting a form injected into the REDCap record home page at load time. The SQL scripts and server-side (PHP) code required to generate the requested report are built from the rule metadata and executed immediately. The payloads are returned to the client, where the combined report is assembled and displayed in a popup browser window (or tab, if popups are blocked).

CDSS toolkit dissemination and sharing rules

The development code of this EM is available to developers as open-source software.[14] The software repository includes a sample REDCap project based on TRIM, with a subset of TRIM rules predefined and all of the CDSS forms. CDSS rules and mappings may be shared between similarly structured REDCap projects using a built-in REDCap EM configuration transfer tool, or even by copying and pasting, since all of the

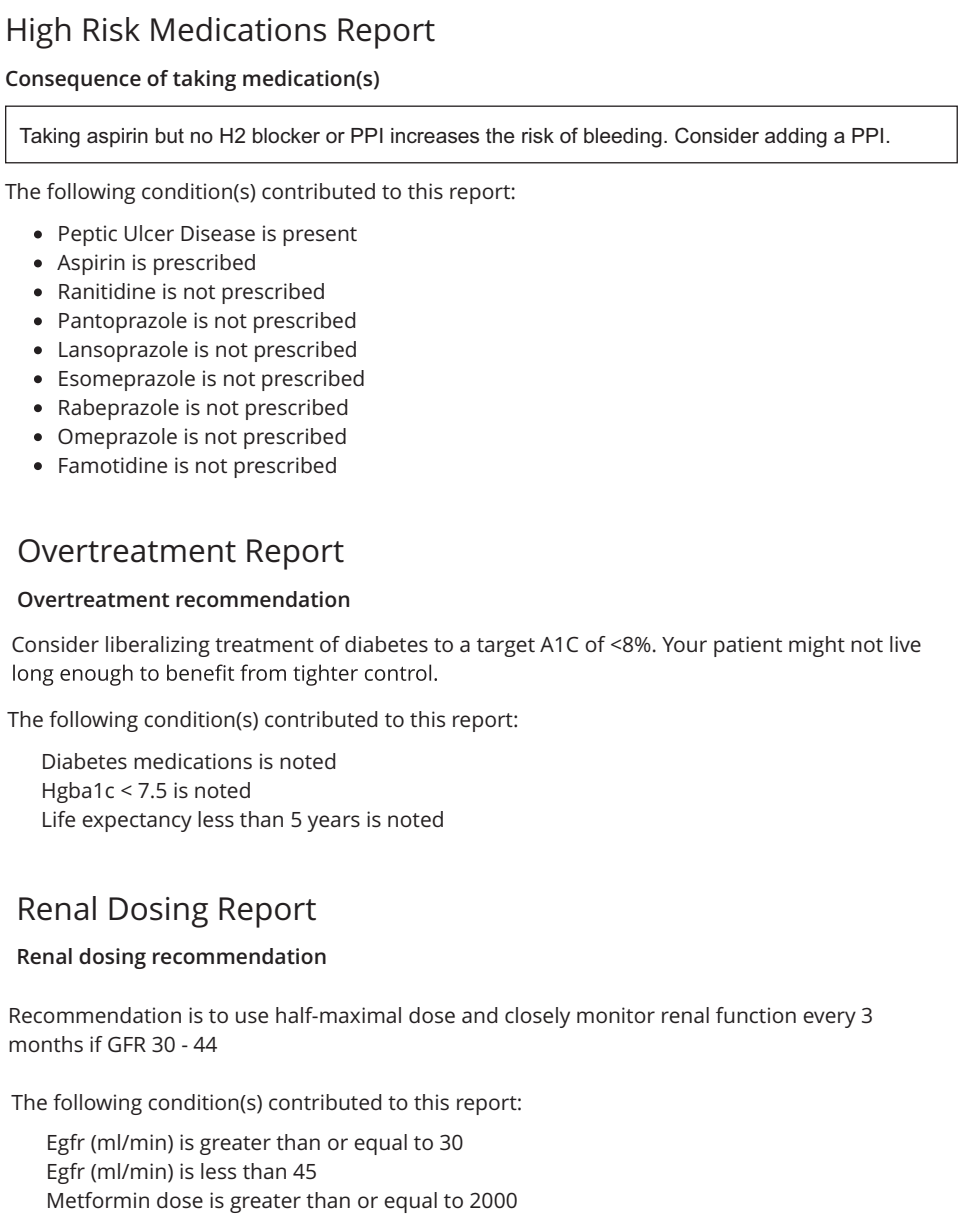

Figure 3. Examples of reports. Examples of reports addressing: (1) high-risk medications; (2) potential overtreatment of diabetes and/or HTN; and (3) inappropriate renal dosing.

stored JSON strings are exposed on the REDCap EM configuration page.

DISCUSSION

We have developed a REDCap software External Module (EM) as the architecture for an EHR-CDSS to evaluate medication appropriateness. This EM uses data imported from the EHR and additional patient assessment data as the inputs for a set of rules that evaluate the appropriateness of medications according to specific patient characteristics and output a set of recommendations. The development code of the CDSS toolkit EM is available to developers as open-source software.

The use of REDCap is an ideal platform for encouraging collaboration among investigators and for dissemination. The CDSS toolkit Rule Engine, by establishing a framework for creating rules based on drop-down menus and simple logic, facilitates the updating of rules to assess medication appropriateness without the need for specialized programming skills. The CDSS toolkit also facilitates expansion of data collection and creation of data elements necessary to support new and revised rules. REDCap forms, including CDSS field definitions, are easily sharable between investigators, as are CDSS rules, which are stored as JSON strings. The desirability of increasing the portability of CDSS is reflected in the development of standards for the representation of clinical knowledge allowing logic to be shared across CDSS, such as Clinical

Quality Language (CQL).[15] With development of a mapper analogous to those described in the CDSS toolkit, it would be possible to incorporate the specifications of CQL into this REDCap-based platform by mapping elements of CQL onto the REDCap fields used in the toolkit.

CDSS toolkit-based projects can take advantage of the significant and evolving informatics capabilities of the REDCap platform. These include a data exchange module based on the FHIR standard that allows for direct data transfer between a local EHR and a locally hosted REDCap installation. This module is currently available for both EPIC and Cerner EHR environments, and work is ongoing to expand to other systems. While the CDSS toolkit also provides a system for manual EHR abstraction, it is expected that the need for manual abstraction will diminish as FHIR support improves REDCap's open platform and allows the integration of additional external tools as they become available. For example, with the increasing sophistication of machine-based learning, the diagnosis and medication mappers in the toolkit could be replaced by a machine-based learning module. However, despite the capabilities of this platform, projects would still be subject to a common problem; namely, errors in output with new medication names for medications included in the rules if the mapper or module was not appropriately updated.[16]

While the toolkit includes a template project based on the evaluation of medication appropriateness, it can also serve as the initial architecture for any CDSS that uses patient data as inputs for evaluation generating output or recommendations. This architecture is particularly well suited for more complex CDSS encompassing a range of inputs, decision rules, and outputs that can calculate and present a broad range of individualized benefits and harms for interventions such as cancer screening[17] and antihypertensive treatment.[18]

CONCLUSION

The CDSS REDCap EM contains all the elements necessary to recreate TRIM, a CDSS-EHR to evaluate medication appropriateness in older persons with polypharmacy. With its focus on standardization and shareability, the REDCap platform provides the basis for collaborative efforts to update and improve upon TRIM and, longer term, to create other complex CDSS.

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AUTHOR CONTRIBUTIONS

All authors contributed to the conception of the manuscript. PAC and TRF designed the CDSS. PAC performed the programming to create the CDSS. All authors participated in drafting and revising the manuscript. All authors agree to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

CONFLICT OF INTEREST STATEMENT

The authors have no competing interests to declare.

DATA AVAILABILITY STATEMENT

No new data were generated or analyzed in support of this research.

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