Implementation of a Novel Multi-Platform Evidence-Based Clinical Decision Support System,

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Organization: Feinstein Institutes for Medical Research

Inclusive Dates of Project: 03/01/2019 – 06/30/2022

Federal Project Officer: Edwin Lomotan, MD, FAMIA

Support for this award was provide by the Agency for Healthcare Research and Quality (AHRQ)

Grant Award Number: 5R18HS026196

Structured Abstract

Purpose: We sought to develop an EHR-independent CDS software platform that can provide a suite of individual CDS solutions capable of being integrated into clinical workflows within various EHRs. The purpose of the supplement was to investigate the effectiveness of the IMPROVE-DD and Wells' Criteria CDS applications on COVID-positive patients compared to patients without COVID.

Scope: We deployed the NOCOS, IMPROVE-DD, and Wells' Criteria CDS on our EHR-independent CDS software platform, EvidencePoint. Despite the limitation of our ability to demonstrate cross-platform operation, the EvidencePoint system was still developed in an EHR-agnostic manner and retains those full capabilities.

Methods: EvidencePoint was designed using a web-based, EHR-agnostic approach. The CDS apps and EvidencePoint application programming interface (API) run on separate servers from the Northwell EHRs and communicate through narrow channels. The platform can be configured to launch from any health system's EHR.

We also conducted a clinical trial based on the IMPROVE-DD application. We hypothesized that universal EHR-integrated CDS utilizing a validated venous thromboembolism risk tool (the IMPROVE-DD application) would increase appropriate thromboprophylaxis and reduce thromboembolism.

Results: Our findings validated the underlying concept of an EHR-agnostic CDS software platform and demonstrated its feasibility in three unique clinical settings and deployments. We have laid the foundation for important CDS applications in the short term and developed a system capable of bringing those applications, and others, to health systems beyond Northwell Health, regardless of which EHR they use.

Key Words: Clinical Decision Support, CDS, Clinical Decision Support System, CDSS, Wells' Criteria, IMPROVE-DD, Evidence-based Medicine

Purpose (Objectives of the Study)

The practice of evidence-based medicine (EBM) at the point of care has well established benefits, particularly when implemented in the form of software-based clinical decision support (CDS) that has been smoothly integrated into clinical workflows within electronic health record (EHR) software systems.

Our prior work in this field demonstrated the impact that CDS can have in helping to promote the active practice of EBM. However, we also identified technical challenges to effectively scaling CDS solutions.

To enable software-based CDS that is directly integrated into EHR-based clinical workflows, early solutions were typically implemented by customizing a particular EHR environment to provide the desired CDS functionality. This was effective when the CDS solution was only required at a single clinical site, but because the software was built "into" the EHR at each specific site, it was not practical to re-implement the same solution at additional sites or on EHR systems from different vendors.

The purpose of *this* research study was to develop an EHR-independent CDS software *platform* that can provide a suite of individual CDS solutions capable of being integrated into clinical workflows within various EHRs, at various clinical sites, without requiring the solutions to be "rebuilt" for each deployment.

The goal of this work is to make it easier to create and disseminate software-based CDS solutions that help promote the practice of EBM at the point of care.

The scope of the study included the conceptualization and development of EvidencePoint, our EHR-independent CDS software platform that can address the fundamental technical barriers mentioned above and in turn facilitate wider dissemination of EHR-integrated CDS.

There were three unique EvidencePoint use cases that served as proofs-of-concept for the study: (1) the Northwell COVID-19 Survival (NOCOS) CDS application; (2) the IMPROVE-DD CDS application for venous thromboembolism (VTE) risk assessment; and (3) the Wells' Criteria CDS[1] application for pulmonary embolism (PE) diagnosis risk stratification.

In addition to the study's foundational research goals, in 2020 we were awarded a supplement to this R18 grant specifically focused on COVID-19. The purpose of the supplement was to investigate the effectiveness of the IMPROVE-DD[2] and Wells' Criteria CDS applications on COVID-positive patients, as compared to a control group of patients who did not have COVID.

Scope (Background, Context, Settings, Participants, Incidence, Prevalence)

Since our goals for the project were to test CDS applications running on the EvidencePoint platform in as broad a manner as possible, Northwell Health provided an ideal context for this study due to its large, diverse patient population and number of hospitals (over 20). From a demographics perspective, approximately 28% of patients were White, 16% Black, 26% Asian and 24% Hispanic.

When the COVID-19 pandemic hit in spring 2020, we were able to quickly deploy the NOCOS survival prediction model across all of Northwell's hospitals, where it was available for easy access to providers in the emergency department directly through the EHR.

In December 2020, we deployed the IMPROVE-DD CDS application for VTE risk assessment to two of Northwell's largest tertiary hospitals, where it was configured as a mandatory component of the VTE prophylaxis process for all hospitalized patients. We also selected two similarly-sized hospitals to serve as controls, where usual care (i.e. no CDS application) was maintained. Over the course of a one-year pilot study, the application was used with 5,249 unique patients at the intervention sites.

In September 2021, we deployed the Wells' Criteria CDS application for PE diagnostic risk assessment to the same two tertiary hospitals that were using the IMPROVE-DD application. One hospital used the Wells' Criteria application with a standard user interface. The other hospital utilized an added feature in the user interface that offered a behavioral economics "nudge" designed to increase user adoption of the tool. Over the course of a six-month pilot study, the application was used during 1,735 patient encounters.

The most significant limitation of the study related to our ability to demonstrate EvidencePoint's capacity to function with EHRs from multiple vendors. When we had originally conceived of the study, Northwell employed multiple EHRs and our plan was to deploy EvidencePoint's tools in similar clinical scenarios, on different systems, to demonstrate its EHR agnostic capabilities.

Shortly after we received our grant award, Northwell announced its intention to migrate all EHRs to a single platform: the Sunrise Clinical Manager (SCM) EHR from Allscripts. Because of this, there were no longer any clinical sites capable of supporting a non-Allscripts deployment, and we lost our ability to perform that sort of comparison.

Despite this limitation of our ability to demonstrate cross-platform operation, the EvidencePoint system was still developed in an EHR-agnostic manner and retains those full capabilities. We are hopeful that subsequent research grants (including an R01 for which we are currently applying) will provide us the opportunity to demonstrate the platform's EHR-agnostic flexibility.

Methods (Study Design, Data Sources/Collection, Interventions, Measures, Limitations)

Over the course of the CDS software platform's design and implementation process, considerations of scalability, portability, workflow, and user experience were paramount. To address the modular implementation

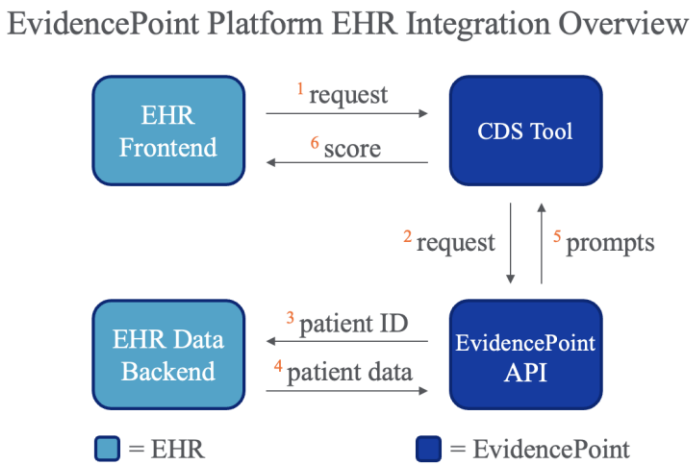
requirement for this initiative, it was critical to enable the platform to easily add CDS apps without the need for major platform modifications. From a dissemination perspective, the platform also had to be modular enough to work across a multitude of health systems and EHRs. Third, the platform had to be easy for clinicians to use.

To address portability and encourage widespread dissemination, the platform was designed using a web-based, EHR-agnostic approach. The CDS apps and EvidencePoint application programming interface (API) run on separate servers from the Northwell EHRs and communicate through narrow channels. The platform can be configured to launch from any health system's EHR and the only limitations are restricted to the EHR's ability to launch and supply data to the platform.

From an architectural perspective, the system is split into four components that make up a front-end interface and a back-end data exchange. The front-end interface consists of clinician-facing EHRs and the CDS apps. These front-end EHRs are responsible for launching and running the browser based CDS apps. These apps are hosted on a server and can calculate a score based on the CPR; however, the CDS assessment is generated and prepopulated with patient data in the back-end data exchange.

The back-end data exchange consists of the EvidencePoint API and the back end EHRs. Given the desired CDS, the EvidencePoint API translates patient health information (e.g., test results and codes) from the back end EHRs to the relevant assessment questions for pre-population. Then, the API sends the prepopulated prompts and assessment-scoring scheme back to the CDS app, where the doctor fills out the remainder of the assessment, corrects for errors, and calculates a score. The software system thus bridges front-end, back-end, pre-existing, and entirely bespoke software to bring CDS assessments to clinician workflows.

Figure: EvidencePoint Platform EHR Integration Overview



Users launch the CDS tool from a typical EHR workflow, or the tool is triggered automatically. The launch request includes the patient's visit-specific ID [1]. The CDS tool forwards the request to the EvidencePoint API [2], which retrieves the patient's data from the EHR data backend [3, 4] and pre-populates the tool with patient data where possible. [5] The user fills in any remaining information and the tool calculates a personalized risk score for the patient, which is in turn sent back to the EHR [6] to be incorporated into the patient's medical record, as well as trigger any resulting next steps in the EHR, such as opening an order set.

In addition to developing and deploying CDS applications based on EvidencePoint to demonstrate the platform's feasibility, we conducted an extensive yearlong clinical trial based on the IMPROVE-DD application. For this trial, we hypothesized that universal EHR-integrated CDS utilizing a validated venous thromboembolism risk tool (the IMPROVE-DD application) would increase appropriate thromboprophylaxis and reduce thromboembolism.

We implemented the IMPROVE-DD application at admission and discharge with thromboprophylaxis order entry following established cut-offs (score 2-3: at-risk, ≥ 4: high-risk). Medically-ill inpatients over age 60 were

randomized to two groups of two tertiary hospitals. Intervention sites utilized the tool; control sites continued usual medical care. The primary outcome was rate of appropriate thromboprophylaxis for at-risk and high-risk patients. Secondary outcomes included venous, arterial, and total thromboembolism, major bleeding, and all-cause mortality 30 days post-discharge.

We extracted weekly data reports from the electronic health record stored in Northwell Health's database through web links provided by the IT team. The SSRS reports were built with the study team based on the inclusion/exclusion criteria and ICD codes listed in the protocol. There were two reports created: one for the intervention hospitals where the tool was implemented, and the other report for the control hospitals. The unique number of patients was used to calculate the total sample size for the study. The study team programmed the control report so that the same inclusion/exclusion criteria would apply.

Once the reports were created, the study team reviewed charts from all four hospitals to validate the data and ensure all patients met the inclusion and exclusion criteria.

The validation process led to the next step of retrieving meaningful statistics from the Excel reports. The data would be downloaded to a secure PHI location, and the following steps were followed:

1. Filter report for inclusion and exclusion criteria
2. Remove duplicate patients (patients that are re-admitted at any of the four hospital sites)
3. For both intervention and control reports: Calculate the number of **unique patients** and provide statistics for study criteria such as:
    a. low risk vs. high risk (only for intervention hospitals)
    b. COVID visits vs. regular visits
    c. total visits and unique visits

The reports were presented at study meetings on a bi-weekly basis to ensure that the project was on track to meet the recruitment goal. Our team made changes consistent with the criteria listed in the protocol and reports were frequently validated to ensure accurate data reporting.

Results (Principal Findings, Outcomes, Discussion, Conclusions, Significance, Implications)

The principal findings from this study validated the underlying concept of an EHR-agnostic CDS software platform and demonstrated its feasibility in three unique clinical settings and deployments.

The first– the NOCOS COVID-19 survival calculator– provided an unanticipated opportunity to demonstrate how EvidencePoint facilitates the rapid development and deployment of CDS applications. While COVID-19 was not part of our study's original design (and did not exist at the time our grant was awarded), we were able to tap into our CDS platform's flexibility and customizability to create a COVID-19 CDS solution within days of the pandemic's outbreak in spring 2020. Because of EvidencePoint's capability for bi-directionally integrating with EHRs, we were able to plug NOCOS directly into the digital flow of care and incorporate patient-specific data from the EHR and write the results of NOCOS risk calculations back into the EHR.

With the IMPROVE-DD VTE risk assessment and prophylaxis application, we were able to develop and deploy a CDS application that formed the backbone of a significant (10,000+ patient) clinical trial. For the IMPROVE-DD trial, appropriate thromboprophylaxis rates were higher at intervention sites, both inpatient (80.1% versus 72.5%, Odds Ratio (OR) 1.52, 95% Confidence Interval (CI) 1.39-1.67, $p<0.001$), and post-discharge (13.6% versus 7.5%, OR 1.93, 95% CI 1.60-2.33, $p<0.001$). There were fewer venous (2.7% versus 3.3%, OR 0.80, 95% CI 0.64-1.00), arterial (0.25% versus 0.70%, OR 0.35, 95% CI 0.19-0.67), and total thromboembolic events (2.9% versus 4.0%, OR 0.71, 95% CI 0.58-0.88) at intervention versus control sites. Major bleeding was rare and did not differ between groups. Mortality was higher at intervention sites (9.1% versus 7.0%, OR 1.32, 95% CI 1.15-1.53). *(Please note, this study has been accepted as a Late Breaking Science Abstract for*

the 2022 American Heart Association Annual Scientific Sessions, and as such is embargoed for release until after that time.)

With the Wells' Criteria PE diagnostic risk assessment application, incorporating behavioral economics "nudges", our preliminary pilot study revealed some promising early results. As illustrated in the table below, at the ED site where the tool with nudges was deployed, providers adopted the tool's CDS recommendations 46.3% of the time, compared with a 23.2% adoption rate for the ED site that used the standard, no-nudge version of the tool. This virtual *doubling* of provider adoption is an indication that nudges have the potential to dramatically increase CDS adoption rates, and we are using this preliminary study as background data for a new R01 we are seeking from AHRQ.

Figure: Comparing Adoption of Wells' Criteria App With and Without Nudges

1,735 patient encounters (provider initiated an order for CTPA)

	ED #1 (Tool ONLY) N, n(%)	ED #2 (Tool with Nudges) N, n(%)	p-value
Total Initiated Orders for CTPA	820	915	
CDS Tool Displayed	148 (18%)	220 (24%)	
CDS Tool Finalized	138 (93.2%)	214 (97.3%)	
CDS Provider Adoption	32 (23.2%)	99 (46.3%)	P<0.001

With regard to our work related to the COVID-19 supplement we received for this grant, we aimed to externally validate the IMPROVE-DD VTE RAM in medical patients hospitalized with COVID-19. This retrospective cohort study evaluated the IMPROVE-DD VTE RAM in adult patients with COVID-19 admitted to one of thirteen Northwell Health hospitals in the New York metropolitan area between March 1, 2020 and April 27, 2020. VTE was defined as new-onset symptomatic deep venous thrombosis or pulmonary embolism. To assess the predictive value of the RAM, the receiver operating characteristic (ROC) curve was plotted and the area under the curve (AUC) was calculated. Sensitivity, specificity, positive predictive value (PPV), and negative predictive value (NPV) were calculated. Of 9407 patients who met study criteria, 274 patients developed VTE with a prevalence of 2.91%. The VTE rate was 0.41% for IMPROVE-DD score 0–1 (low risk), 1.21% for score 2–3 (moderate risk), and 5.30% for score ≥ 4 (high risk). Approximately 45.7% of patients were classified as high VTE risk, 33.3% moderate risk, and 21.0% low risk. Discrimination of low versus moderate-high VTE risk demonstrated sensitivity 0.971, specificity 0.215, PPV 0.036, and NPV 0.996. ROC AUC was 0.703. In this external validation study, the IMPROVE-DD VTE RAM demonstrated very good discrimination to identify hospitalized COVID-19 patients at low, moderate, and high VTE risk[2].

With regard to the Wells' Criteria, we ultimately found that different thresholds of the Well's score accompanied by different thresholds of d-dimer values were not significantly different in ruling out PE in COVID (+) patients compared to COVID (-) patients. The combination of the Well's score with d-dimer thresholds even at the highest thresholds was not useful in ruling in PE in COVID (+) patients or COVID (-) patients.

Ultimately, this research project accomplished important goals with regard to furthering the dissemination of evidence-based practices at the point of care. By demonstrating the feasibility of an EHR-agnostic, workflow-integrated CDS platform, we laid the foundation for important CDS applications in the short term (the NOCOS app, the IMPROVE-DD app, and the Wells' Criteria app) and developed a system that is capable of bringing those applications, and others, to health systems beyond Northwell Health running on a variety of EHR systems.

By integrating behavioral economics and nudge theory into the user interface of the select CDS apps, we were able to demonstrate a notable improvement in clinician adoption of CDS tools, virtually doubling the adoption of apps without nudges.

By validating the effectiveness of the IMPROVE-DD[2] and Wells' Criteria prediction models in the COVID (+) population, we confirmed that these important clinical tools remain useful and viable in the new world in which we now find ourselves.

We are excited and inspired by the work and results we have generated over the past three years of this project. We are actively applying for a follow-up R01 grant and look forward to future opportunities to collaborate with AHRQ and others to further the dissemination of evidence-based medicine practices at the point of care.

List of Publications and Products

Published Works:

1. Zhang NJ, Rameau P, Julemis M, Liu Y, Solomon J, Khan S, McGinn T, Richardson S. Automated Pulmonary Embolism Risk Assessment Using the Wells Criteria: Validation Study. JMIR Form Res. 2022 Feb 28;6(2):e32230. doi: 10.2196/32230. PMID: 35225812; PMCID: PMC8922138.

2. Goldin M, Lin SK, Kohn N, Qiu M, Cohen SL, Barish MA, Gianos E, Diaz A, Richardson S, Giannis D, Chatterjee S, Coppa K, Hirsch JS, Ngu S, Firoozan S, McGinn T, Spyropoulos AC. External validation of the IMPROVE-DD risk assessment model for venous thromboembolism among inpatients with COVID-19. J Thromb Thrombolysis. 2021 Nov;52(4):1032-1035. doi: 10.1007/s11239-021-02504-5. Epub 2021 Jun 19. PMID: 34146235; PMCID: PMC8214061.

Products:

Northwell Health EvidencePoint Website. https://predictivemedicine.northwell.edu. Accessed 9/23/2022.

Abstracts and Presentations:

Spyropoulos A, Goldin M, Koulas I, Solomon J, Qiu M, Ngu S, Smith K, Leung TM, Ochani K, Malik F, Cohen SI, Giannis D, Khan S, McGinn T. A Multicenter Clustered Randomized Trial of a Universal Electronic Health Record-Based Venous Thromboembolism Risk Assessment Model as Integrated Clinical Decision Support for Prevention of Thromboembolism in Hospitalized Medically-Ill Patients. American Heart Association Annual Scientific Sessions, Accepted Late-Breaking Abstract Presentation, November 2022.

Dauber-Decker K, Solomon J, Khan S, Malik F, Ilyas A, Coleman B, Paradis M, Zanos T, Hirsch J, Barnaby D, Richardson S, Goldin M, Spyropoulos A, McGinn T. EvidencePoint: a clinical decision support system (CDSS) for the rapid development and implementation of electronic health record (EHR)-integrated evidence-based CDS applications. AMIA 2021 Clinical Informatics Conference, Accepted Presentation, Virtual, May 2021.

Dauber-Decker K, Khan S, Solomon J, Malik F, Ilyas A, Goldin M, Spyropoulos A, McGinn T. Optimizing IMPROVE-DD, a clinical decision support (CDS) web application (app) to assess venous thromboembolism (VTE) risk. AMIA 2021 Clinical Informatics Conference, Accepted Poster, Virtual, May 2021.