FINAL PROTOCOL

Title: Assessing the Risk of Wrong-Patient Errors in an EMR that Allows Multiple Records Open
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BACKGROUND AND SIGNIFICANCE

Frequency of wrong-patient orders. At least 70,000 U.S. physicians use computerized provider order entry (CPOE) to place orders.[1,2] Although CPOE is associated with a reduction in medical errors,[3-7] when orders are placed electronically certain types of errors, including placing orders on the wrong patient, may occur more frequently.[8-13]

The danger of wrong-patient electronic orders was highlighted by one hospital's report that after implementing CPOE, medications were prescribed for the wrong patient several times per month.[14] In 2003, the United States Pharmacopeia analyzed 7,029 voluntarily reported medication errors over a 7-month period and found a mean of 9 wrong-patient orders at each of 120 participating institutions using CPOE.[15] This report likely under-estimated the extent of wrong-patient electronic orders, as voluntary reporting is known to be an unreliable method for identifying errors.[16-17] Dr. Jason Adelman, the Principal Investigator of this proposal, developed an automated surveillance tool, the Wrong-Patient Retract-and Reorder measure, that identified 5,246 orders placed on the wrong patient in one year at a single academic medical center, with a rate of 58 wrong-patient orders per 100,000 orders.[18] In that year, 1 in 6 providers placed an order on the wrong-patient, and 1 in 37 hospitalized patients had an order placed for them in error. This was the first study using automated surveillance to identify wrong-patient orders, and it demonstrated the prevalence of wrong-patient orders to be significantly higher than previously thought.

Potential risk of placing an order on the wrong patient when multiple medical records are open at once. Although there have been no studies quantifying (or even establishing) an increased risk of wrong-patient errors when providers have multiple records open at once, there have been several articles and expert opinions that warn of this potential risk. In an abstract presented at the 2012 American Medical Informatics Association (AMIA) conference, researchers presented a survey of Chief Medical Information Officers (CMIOs) evaluating the causes of wrong-patient errors in CPOE systems, and reported "[CMIO respondents] attributed wrong-patient errors to the ability to view multiple charts on one computer simultaneously and poor screen design."[19] In a 2012 study, Hyman et al hypothesized that having multiple records open at once increased the rate of wrong-patient errors, but reported they were "unable to determine whether there was any link between the reported errors and multiple records having been open."[20]

A 2013 study published in *JAMIA* evaluated 32 wrong-patient errors, and noted that 60% of these errors occurred in systems that allowed at least two charts open simultaneously. Investigators did not measure total orders, and therefore could not determine error rates and quantify the relationship between the number of records open at a time and the risk of wrong-patient errors.[21] A 2013 white paper titled, How to Identify and Address Unsafe Conditions Associated with Health Information Technology published by the Office of the National Coordinator for Health Information Technology (ONC) claimed that data can be entered "incorrectly into the electronic record due to multiple records being open," but no reference was provided supporting this statement.[22]

The mechanism by which multiple patient records open simultaneously can lead to a wrong-patient error may be related to the ease with which users can toggle between patient records and the similar looking computer screens. The magnitude of this risk needs to be established to help IT leadership decide on how to safely implement CPOE systems. There have been no studies that have evaluated whether multiple records open increase the risk of wrong-patient errors, by how much, and if any increase is dependent on the number of records open (i.e., is four records open simultaneously more dangerous than three? Is three worse than two?). Our research is an important first step in quantifying this risk.

Practice of allowing multiple records opens at once. Investigators on this protocol conducted a national survey of Chief Medical Informatics Officers (CMIOs) via the American Medical Informatics Association listserv and the Association of Medical Directors of Information Systems listserv in March 2014.[23] The survey assessed the practice of allowing multiple records open at once, as well as CMIOs' experiences and perceptions of the risks and gains in efficiencies of having multiple records open. There was a wide range of configuration of this feature across facilities. Of 167 facilities with CPOE systems capable of simultaneously displaying multiple patient records at once, 44.3% allowed three or more records open (unrestricted environment), and 38.3% limited the system to only one record open at a time (restricted environment). It is interesting to note that a number of respondents changed their settings some time after their initial configuration: three hospitals decreased the number of records allowed open at once; two hospitals increased the number of records allowed open at once; and one hospital went from allowing four records open at once down to one, and then back up to two.**Table 1** provides some comments from CMIOs explaining why they chose to establish an unrestricted environment or restricted environment, and why some hospitals decided to switch configurations after the initial instillation. The results of this survey demonstrate that IT leadership is lacking objective data to guide their decision on how many patient records allowed open at once in EHRs.

Table 1. CMIO considerations in configuring an restricted vs unrestricted EHR environment.

Examples of comments from CMIOs who established a restricted environment.
• My organization chose to allow only one EHR open at a time…. We feel that multiple records open and in use by the same person is not good practice and is an error waiting to happen. • Our software vendor allows three records to be opened at once. We made the decision to only allow one record to be opened. We also analyzed our facility in terms of noise levels and distractions and decided that having multiple charts open had the potential of a significant patient safety issue.
Examples of comments from CMIOs who established an unrestricted environment.
• The need to multitask is inherit in today's practice of medicine. We are commonly called to provide coverage for patients for a simple task. To leave a chart and then return becomes a high burden. • I think the efficiency benefits are such that this is justified. There are other ways to prevent wrong-patient problems.
Examples of comments from CMIOs who changed configurations after the initial installation.
• We had wrong-patient errors when we let users access up to three charts at one time, which is why we now limit to just one. • Our system for many years only allowed one patient chart to be open. Due to some complaints and arguments that it would increase efficiency, a decision was made to allow more than one chart to be opened. Less than a year later, it got reverted back because of the increase in documentation errors as reported by the HIMS department.

The feasibility of this study is a result of developing a validated and reliable measure of wrong-patient errors. Adelman et al developed the Wrong-Patient Retract-and-Reorder (RAR) measure as an automated method for identifying wrong-patient electronic orders.[18] This measure will be used to identify the primary outcome in this study. It works by identifying orders placed for a patient that are retracted within 10 minutes and then placed by the same provider for a different patient within the next 10 minutes (**Figure 1**). We performed real-time confirmatory telephone interviews with providers who placed and retracted orders to validate the RAR measure. These phone interviews with ordering providers demonstrated that the RAR measure correctly identified near-miss errors in 170 of 223 cases (positive predictive value 76.2%).

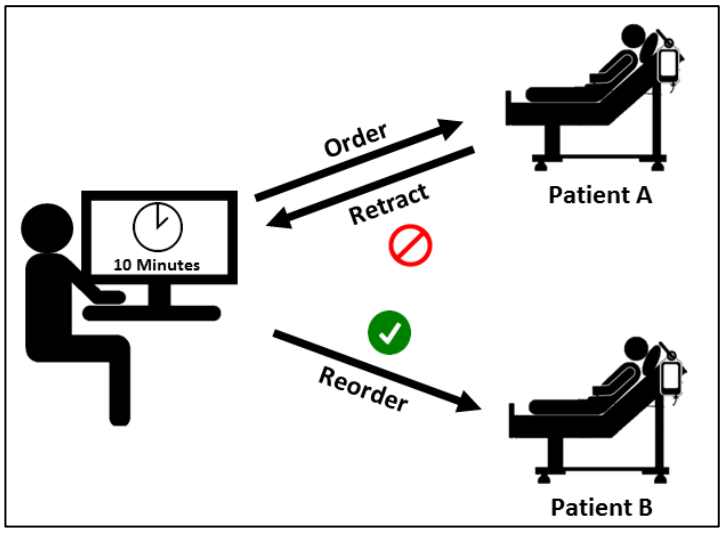

Figure 1. Wrong-Patient Retract-and-Reorder Measure.

Near-miss errors in patient safety research. The Wrong-Patient RAR measure identifies near-miss errors rather than errors that reach the patient and cause harm. Near-miss errors are also referred to as "close calls" by the Department of Veterans Affairs,[24] "good catches" by the National Association for Healthcare Quality,[25] and "free lessons" by the safety expert James Reason.[26] The use of near-miss errors to test safety improvements in healthcare is encouraged by every major patient safety organization including the Agency for Healthcare Research and Quality (AHRQ), Institute of Medicine (IOM), World Health Organization (WHO), Institute for Healthcare Improvement (IHI), and The Joint Commission (JCAHO) because they have been shown by safety experts to have the same causal pathway as errors that cause harm.[27-31]

The link in the causal pathways is demonstrated graphically in the Incident Causation Model first described by industrial safety expert T.W. Van der Schaaf (Figure 2).[27] In this model, the key distinction between an adverse event and a near-miss error is that in the latter a "human recovery" occurs, just before the error reaches a patient and causes harm. This principle is the foundation for the RAR measure, which identifies self-caught errors. In a study by Bates et al of 4,031 randomly selected patient records, 247 adverse drug events and 194 near-miss drug events had similar underlying causes.[32] Because near-miss and actual errors have similar proximate causes, interventions that reduce near-miss errors should also reduce actual errors. In fact, in the seminal article that first demonstrated that CPOE systems prevent medication errors, Bates et al demonstrated that CPOE systems decreased both serious errors and near-miss errors.[4]

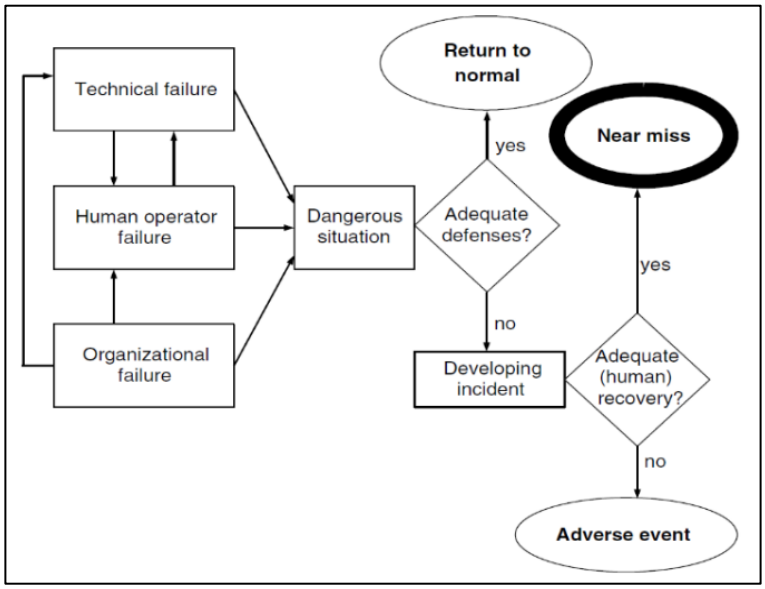

Figure 2. Incident Causation Model.

AHRQ's position on the use of

near-miss errors. AHRQ has supported the use of near-miss errors in patient safety initiatives. The AHRQ National Resource Center for Health Information Technology developed the *Health Information Technology Evaluation Toolkit*, and lists near-miss errors as a particularly useful outcome measure for the evaluation of the effectiveness and safety of Health Information Technology (HIT) projects.[33] Since 2005, AHRQ has coordinated the development and maintenance of the "Common Formats" for national reporting of patient safety events to Patient Safety Organizations (PSOs), and has included near-miss errors as important patient safety data to be collected and analyzed.[34] In addition, AHRQ currently has 141 articles under the "Near-Miss Collection" on the AHRQ Patient Safety Network website, which reviews research and lessons learned specifically related to near-miss errors.[35]

Harm from wrong-patient orders. Until recently, most knowledge about harm from wrong-patient orders came from anecdotal reports. For example, in March 2011 the Institute for Safe Medication Practices (ISMP) published a case report of a physician who used CPOE and accidentally ordered a sedative and paralytic agent for the wrong patient, resulting in respiratory arrest and death.[36] Prior to the Montefiore study, there were no publications that attempted to quantify harm or potential harm from wrong-patient orders. To examine the potential for harm associated with wrong-patient orders, we examined 5,246 near-miss errors identified using the RAR tool and classified 971 errors as clinically significant, 264 as serious, and 126 as life threatening.[18]

Preliminary Studies

Determining the rate of wrong-patient orders. Adelman and colleagues developed and validated the Wrong-Patient RAR measure as an automated tool for capturing wrong-patient orders. After validating the Wrong-Patient RAR measure, we applied it to the complete data set of over 9 million electronic orders placed at a large academic medical center in one year.[18] The Wrong-Patient RAR measure found that 1,388 providers placed 6,885 orders that were retracted and reordered. Multiplying the proportion of retracted orders identified by the positive predictive value of 76.2%, we estimated that 5,246 wrong-patient orders were placed, with an average of 14 retracted orders per day, 1 in 6 providers placed an order on the wrong-patient and retracted it, and 1 in 37 hospitalized patients had an order placed for them in error.

Using the Wrong-Patient RAR measure in a randomized controlled trial evaluating two interventions for preventing wrong-patient orders. We conducted a three-arm randomized controlled trial to test two interventions designed to prevent wrong-patient orders: an ID-verify alert that displayed the patient's name, gender, and age for the provider to verify with one click; and an ID-reentry function that blocked access to the order entry screen until the provider entered the patient's initials, gender, and age.[18] Over 4,000 providers who placed inpatient orders were randomly assigned to receive the ID-verify alert, the ID-reentry function, or neither. Over one million orders were placed in each arm of the study. Compared with the control condition, the ID-verify alert reduced the odds of a wrong-patient order by 16% and the ID-reentry function reduced the odds of a wrong-patient order by 41%. The study found that wrong-patient orders are common, and that interventions like the ID-verify alert and the ID-reentry function can lower the frequency of wrong-patient orders. Although a 41% reduction of wrong-patient errors is substantial, additional safety measures are needed to achieve more complete protection for patients.

SPECIFIC AIMS

Aim 1. Compare the rate of wrong-patient orders in a *restricted* environment that limits providers to one patient record open at a time in an electronic health record to an *unrestricted* environment that allows providers to open a maximum of four records at once.

Aim 2. Conduct subgroup analyses to examine the rate of wrong-patient orders stratified by clinical location, including emergency department, outpatient, and inpatient settings.

STUDY DESIGN

Two-arm Randomized Trial. In a randomized comparative effectiveness trial, we propose to randomly assign providers to one of two configurations of the electronic health record (EHR) system: 1) a *restricted* mode that limits providers to open one record at a time; or 2) an *unrestricted* mode that allows providers to open a maximum of four records open at once. The trial will compare the rate of wrong-patient orders between trial arms, identified by the Wrong-Patient Retract-and-Reorder (RAR) measure.

Role of Columbia University Medical Center (CUMC). CUMC will act as the lead institution and have oversight over study implementation and data analysis. No data will be collected for CUMC patients. Final de-identified data sets will be transferred using a secure file transfer protocol to the principal investigator at CUMC from the study biostatistician at Albert Einstein College of Medicine.

Study Sites. The trial will be conducted at Albert Einstein College of Medicine/Montefiore Medical Center, an integrated regional health system and academic medical center in New York. Study sites include four hospitals, five emergency departments, and more than 100 ambulatory facilities. The health system will use the EpicCare EHR system during this study; Epic has committed to support the project in implementing the Wrong-Patient RAR measure as well as developing and programming a log to capture the number of records open at the time of placing each order. Montefiore met the following six criteria for inclusion as a study site: (1) the capability to implement the Wrong-Patient RAR measure and the log to record the number of records open at the time of placing each order; (2) the capability to merge the results of the Wrong-Patient RAR measure with a table indicating patient, provider, and order characteristics; (3) a minimum of 30,000 admissions per year; (4) a minimum of 50,000 emergency department visits per year; (5) a minimum of 500,000 outpatient visits per year; and (6) patients representing low-income groups, minority groups, the elderly, and individuals with special health care needs (**Table 2**).

Table 2. Characteristics of Study Site.

Systems	
Location	Bronx, NY
Inpatient beds	1536
Annual admissions	90,000
Emergency department visits	306,000
Outpatient visits	2,000,000
Priority Populations	
% Minority	72%
% Medicaid/uninsured	60%
% Medicare	11%

METHODS

Orders versus Order Sessions. If a provider begins placing orders in the wrong patient's record, there is the possibility that several such orders will be placed and then retracted together. Therefore, individual orders do not

represent independent opportunities for errors to occur. Orders are clustered within order sessions, defined as a series of orders placed consecutively by a single provider for a single patient that begins with opening that patient's order file and terminates when an order is placed on another patient or after 60 minutes, whichever comes first. Thus the order session, rather than each order, represents an independent opportunity for a wrong-patient error to occur.

Unit of Analysis. The unit of analysis will be the order session.

Primary Outcome. The primary outcome measure, the Wrong-Patient RAR measure, is an electronic query run retrospectively against every order placed during the study period to identify instances in which one or more orders placed for a patient were retracted (cancelled) by the same provider within 10 minutes, and then reordered by the same provider for a different patient within the next 10 minutes (RAR events). In the validation study, phone interviews with ordering providers confirmed that the RAR measure correctly identified wrong-patient orders in 170 of 223 events, yielding a positive predictive value of 76.2% (95% confidence interval, 70.6% to 81.9%).[18] The primary outcome is wrong-patient order sessions, defined as order sessions that include a wrong-patient RAR event identified by the Wrong-Patient RAR measure.

Provider Level, Patient Level, Order-Session, and Order Level Covariates. The data will have a nested, hierarchical structure with order sessions clustered within providers. The analysis will account for this hierarchical structure and we will gather from the electronic medical record attributes of the provider, patient, order session, and order.

Provider-level covariates: type of ordering provider (attending, resident, physician assistant, nurse practitioner, pharmacist, or other), and total number of orders placed during the study period (a measure of the frequency with which the provider uses the system).

Patient-level covariates: age, race, ethnicity, sex, unit, and date and time of admission.

Order-session level covariates: location of the order session (emergency department, medical-surgical unit, intensive care unit, labor and delivery, pediatrics, other specialty units).

Order level covariates: type of order (medication, imaging, nursing order, procedure, other), date and time of order, date and time of retraction, and number of patient records open at the time the order was placed.

Inclusion and Exclusion Criteria

Patient Inclusion and Exclusion Criteria. All patients are at risk for wrong-patient orders, so all orders placed for all patients will be included in the study. We will ask to waive informed consent to patient inclusion in this study, as it poses no more than minimal risk to patients. To enhance confidentiality, we will replace medical record numbers with pseudo-identifiers in the analytic data sets prior to analysis.

Provider Inclusion and Exclusion Criteria. Any provider who can place an electronic order can potentially place an order on the wrong patient. Prior work showed that wrong-patient errors are made by physicians (60 errors per 100,000 orders), nurse practitioners and physician assistants (74 errors per 100,000 orders), nurses (33 errors per 100,000 orders) and pharmacists (67 errors per 100,000 orders).[18] We will therefore include in the study all providers with the authority to place electronic orders. Providers will be excluded only if their workflow either 1) has a defined requirement to open two patient

records simultaneously (eg, mother-infant services), or 2) bypasses the standard order entry process and therefore would not be captured by the outcome measure (eg, radiologists).

To protect providers' identities, all provider identifiers will be replaced with pseudo-identifiers in the analytic data sets prior to analysis. We will request a waiver of consent from the Institutional Review Board (IRB) as this study poses no more than minimal risk for providers (see Protection of Human Subjects).

Randomization

All inpatient, emergency department, and outpatient providers will be randomized in a 1:1 ratio to either a maximum of one patient record open at a time (restricted mode), or a maximum of four records open at once (unrestricted mode). Assignments will be made prior to the start of the study, and will remain constant throughout the study. A computer programmer working in the information technology (IT) department, who is not an investigator on this study, will use a computerized random number generator and assign one random number to each provider. Providers assigned odd numbers will be assigned to the restricted arm, and those assigned even numbers will be assigned to the unrestricted arm. Providers will be manually assigned per randomization to EHR user-role templates that differ only in the number of patient records allowed open. Providers newly hired after the start of the study will be assigned a random number when assigned a new user logon for the EHR from a computer programmer not affiliated with the study, and will be added to the appropriate arm based on their assigned random number. The study methodology has been approved by the Senior Vice President and Chief Medical Officer at Montefiore, as well as the Executive Lead for the Epic EHR.

Data Capture

The data required to define orders, orders sessions, and the number of open patient records, patient and provider characteristics, and RAR events is automatically captured by the Epic EHR system. Investigators will collaborate with information technology personnel at the study sites and with Epic throughout the implementation phase of the study to develop the methodology for extracting the required data. At the end of the data collection period, data for all orders placed by study providers during the study period will be extracted, de-identified, encrypted, and transmitted electronically to the investigators for analysis. Preset batch orders (eg, for vaccines) will be excluded from the analysis, as these orders are not under the control of individual providers. These data sets will provide all of the information needed to carry out the analyses.

To examine the rate of wrong-patient orders and proportion of orders placed when one, two, three, or four records were open, an electronic log will be developed and programmed into the Epic system to record the number of records open at the time each order was placed.

Protection of Human Subjects

Confidentiality and Consent. Study data will be extracted retrospectively at the midpoint and at the end of the study period. All data sets, reports, and other study records will be de-identified for analysis. Patient medical record numbers and provider ID numbers will be replaced with pseudo-identifiers, and other personal identifiable information (PII) will be deleted from the data sets. The randomized trial will examine two EHR configurations that are both in wide use, with neither representing an established best practice. The randomized trial also does not involve any procedures for which written consent is normally required, and also does not present more than minimal risk to either patients or providers. All near-miss errors will be evaluated in the aggregate and no PII will be used in presentations, publications, or reports. Information will not be released except as necessary for monitoring by the IRB.

As such, per the Code of Federal Regulations Title 45, Parts 160 and 164a, we seek an exemption to the requirement for use of the HIPAA Authorization form, and have completed the HIPAA Authorization Exemption request form. Per the code of Federal Regulations Title 45, Part 46.116 (d), we ask the IRB to waive informed consent, and have completed the Informed Consent Waiver request form.

Data Security and Integrity. All files will be kept on password-protected HIPAA-compliant computers in locked offices. Only will research personnel, namely the computer programmer, biostatistician, and prinicipal investigator, will have access to the study data. Analytic data sets will be de-identified, with patient and provider identifiers replaced with pseudo-identifiers. Data files will be imported into the native format of the statistical program to be used for analysis. The data will be checked for internal consistency. Identified anomalies will be examined, and corrections to the data will be made and documented as necessary.

Communication with providers. At the start of the randomized trial, investigators will explain the purpose of the study to clinical staff via email and directly from within the IT system, using a message crafted by the study team. The message will assure providers that data will be kept confidential and cooperation will carry no risk to them.

Unintended consequences. All unintended consequences and confidentially breaches detected will be brought to the attention of the Chief Medical Information Officer, the Chief Medical Officer, and overseeing IRB.

Study Limitations

First, the Wrong-Patient RAR measure is designed to identify near-miss errors and does not capture wrong-patient errors that reach patients. However, near-miss errors follow the same causal pathways as errors that reach the patient and cause harm, occur more frequently, and can be reliably measured without the biases inherent in voluntary self-reports by providers. National and international patient safety and regulatory agencies endorse the use of near-miss errors to evaluate safety interventions.[27-31] Second, orders that are retracted and reordered beyond the 10-minute timeframe (10 minutes to retraction, 10 minutes to reorder) will not be identified by the RAR measure. However, prior work demonstrated that the average retract-and-reorder time was less than 2 minutes; the 10-minute timeframe will detect the majority of retracted near-miss order errors and identify a sufficient number of outcome events to power this study. Finally, this research is limited to only one EHR vendor system. However, when fully rolled out, Epic's clients will provide care for 45%-55% of the U.S. population.

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FINAL STATISTICAL ANALYSIS PLAN

Descriptive Analysis. We will use descriptive analysis to examine provider-level, patient-level, order session-level, and order-level covariates for the orders placed in the restricted versus unrestricted mode. Descriptive statistics will be reported as mean and standard deviation for continuous variables, and as count and percentages for categories.

Orders versus Order Sessions. If a provider begins placing orders in the wrong patient's record, there is the possibility that several such orders will be placed and then retracted together. Therefore, individual orders do not represent independent opportunities for errors to occur. Orders are clustered within order sessions, defined as a series of orders placed consecutively by a single provider for a single patient that begins with opening that patient's order file and terminates when an order is placed on another patient or after 60 minutes, whichever comes first. Thus the order session, rather than each order, represents an independent opportunity for a wrong-patient error to occur.

Primary Outcome. The primary outcome measure, the Wrong-Patient RAR measure, is an electronic query run retrospectively against every order placed during the study period to identify instances in which one or more orders placed for a patient were retracted (cancelled) by the same provider within 10 minutes, and then reordered by the same provider for a different patient within the next 10 minutes (RAR events). The primary outcome is wrong-patient order sessions, defined as order sessions that include a wrong-patient RAR event identified by the Wrong-Patient RAR measure.

Primary Analysis (Aim 1). The primary analysis of the randomized trial is intention-to-treat, with each provider generating a cluster of order sessions. Hence, the order session will be used as the unit of analysis. The primary outcome variable is dichotomous, indicating whether or not each order session contains a wrong-patient RAR event. To determine the effect of trial arm on wrong-patient orders, we will construct a random effects logistic regression model with wrong-patient order sessions as the outcome, and randomization arm as the independent variable, using provider as a random intercept to account for clusters of order sessions within providers. We will estimate the effect of the restricted mode versus the unrestricted mode on the rate of RAR events using the odds ratio and its 95% confidence interval (CI), and will test the null hypothesis using the Wald test with a two-tailed significance level of 0.05. The primary outcome is reported as the number of wrong-patient order sessions per 100,000 order sessions.

Subgroup Analysis (Aim 2). Additional analyses of the effect of the restricted mode versus the unrestricted mode in specified clinical locations will be carried out by including indicators for the locations and location-study arm interaction terms in the model. For subgroup analyses, we will compare the rate of RAR events in emergency department, outpatient, and inpatient settings, and more specifically in inpatient units, including medical/surgical, critical care, pediatrics, and obstetrics units. We will construct similar mixed-effects logistic regression models for each predefined subgroup, with a separate model including an interaction term to test the significance of treatment effects across subgroups, using the Wald test for significance.

As-Treated Analysis. Because of administrative errors, some providers were not assigned to the trial arm to which they were randomized. Therefore, we will repeat all assessments in as-treated analyses (ie, according to treatment received) such that each order or order session was characterized by the provider's configuration at the time the orders were placed.

For orders placed in the unrestricted mode, we will examine the rate of RAR events and the percentage of orders placed when one, two, three, or four records were open at the time of ordering,

overall and stratified by clinical setting. For these analyses the order will be used as the unit of analysis (rather than the order session), because a provider may open or close patient records while placing a series of orders during a single order session. We will report the number of RAR events per 100,000 orders along with 95% binomial confidence intervals, as well as the percentage of all orders placed under those conditions. These results will be presented for the unrestricted arm overall, and disaggregated by clinical location.

Sample Size. For pragmatic reasons, sample size is not determined by the investigators but will represent the data that is available during the study period. Moreover, as noted, orders do not represent independent events, but are clustered within order sessions that, in turn, are clustered within providers. The magnitude of the effects at these levels are not currently known. Based on prior experience in this setting, in 1 year of data collection we expected to obtain approximately 9,000,000 orders in 2,400,000 order sessions, placed by 3,200 distinct providers for 440,000 distinct patients. We assumed 100 wrong-patient order sessions per 100,000 order sessions in the Unrestricted arm, and an intra-provider correlation of 0.01. With accrual of approximately 1,600 providers in each randomization arm, and a trial duration yielding an average of approximately 1,300 order sessions per provider with a coefficient of variation of 1.2, the trial would have >99% power to detect an odds ratio of 0.5 (or lower), 96% power to detect an odds ratio of 0.6, and 76% power to detect an odds ratio of 0.7.

Missing Data. Due to the automatic functioning of the electronic health record, we do not anticipate that there will be missing data concerning RAR events, the system configuration of restricted mode vs. unrestricted mode, the number of records open at the time of placing an order, or provider-level covariates. There may be sporadic missing information regarding the patient-level covariates. In preliminary data, in a data set of more than 11.6 million orders, there were no missing observations for patient age, sex, or race. An indicator for Hispanic ethnicity was missing in just 4 records. With similar levels of missing data, we feel comfortable that restricting regression models to only include cases with complete data will not introduce appreciable levels of bias. If we find that any variables are missing for more than 1 record per 1,000 (after backfilling based on other records involving the same patient), we will extend our analyses to address this. We will presume that data are missing at random and will apply multiple imputation with chained equations.

Interim Analysis. To safeguard against the possibility that our intervention actually worsens (increases) the rate of RAR events, and to prevent unnecessary continuation of a study that is already conclusive, we will have a data safety monitoring committee conduct one interim review of the data in the randomized trial. After 6 months, we expect 50% of the data to have been accrued. Using the Lan-Demets alpha spending procedure with symmetric O'Brien-Fleming boundaries, the stopping rule at the interim review will be a z-statistic of magnitude 3.0318 or greater.[1] The associated nominal p-value is 0.0024. Combined with a final analysis using a critical z-value of 1.9669 (nominal P=0.0492), we will have spent our overall alpha of 0.05 at the end of the study. The effects of this interim analysis procedure on nominal statistical power (see above) is negligible, less than 0.5 percentage points, so no adjustments to data collection need be made to account for this.

Reference

1. Demets DL, Lan KK. Interim analysis: the alpha spending function approach. *Stat Med*. 1994;13:15e30.