# Final Progress Report to Agency for Healthcare Research and Quality

## Title of Project

Develop and Validate Health IT Safety Measures to Capture Violations of the 5 Rights of Medication Safety

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## 1. STRUCTURED ABSTRACT

**Purpose**: To develop and validate novel Health Information Technology (IT) Safety measures to identify medication and other types of electronic order errors.

**Scope**: Despite near universal adoption of Health IT, order errors remain a threat to patient safety. Regulatory bodies call for development of standardized measures to monitor and improve the safety of Health IT systems.

**Methods**: Using the Retract-and-Reorder (RAR) methodology, we developed new measures to capture instances where an order was placed, retracted by the ordering clinician, and subsequently reordered by the same clinician for the same patient with an order parameter changed (e.g., dose, route, frequency). Queries ran every 30 minutes and details of events that met measure criteria were populated in a web-based survey tool. Research personnel then conducted near real-time confirmatory telephone interviews with clinicians who triggered the measures. Positive predictive value (PPV) and 95% confidence intervals were calculated for each measure, with a target PPV of >75%. We conducted qualitative content analysis of reasons for errors using the Skills, Rules, Knowledge Framework.

**Results:** Target PPV was achieved for new measures: Wrong-Dose 76.7% (71.3–81.5), Wrong-Route 85.2% (77.1–91.3), Wrong Frequency 87.3% (79.9–92.7), Wrong-PRN 78.4% (64.7–88.7), and Retract All 75.6% (71.0–80.1). Qualitative analysis found variation in reasons for errors depending on error type. This new set of measures enables epidemiologic analysis of electronic order errors, informs design of preventive strategies, and provides robust numbers of events to test safety interventions.

**Key Words**: Health IT Safety measures, medication errors, computerized clinician order entry.

## 2. PURPOSE

### Objectives of Study

The purpose of this study was to use the Retract-and-Reorder (RAR) automated detection method[1] to develop and validate novel measures of medication and other types of electronic order errors in Health Information Technology (IT) systems. A set of automated, validated, and reliable Health IT Safety measures that capture a range of order error types will accomplish several objectives: 1) systematically and objectively quantify order errors without reliance on voluntarily reported errors or labor-intensive chart review; 2) enable detailed epidemiologic analyses of electronic medication order errors; 3) inform the design of intervention strategies aimed at preventing these errors; 4) provide sufficient numbers of events to power intervention trials; and 5) serve regulatory and federal agency mandates for ongoing Health IT Surveillance and post-implementation evaluation.

The study pursued the following specific aims:

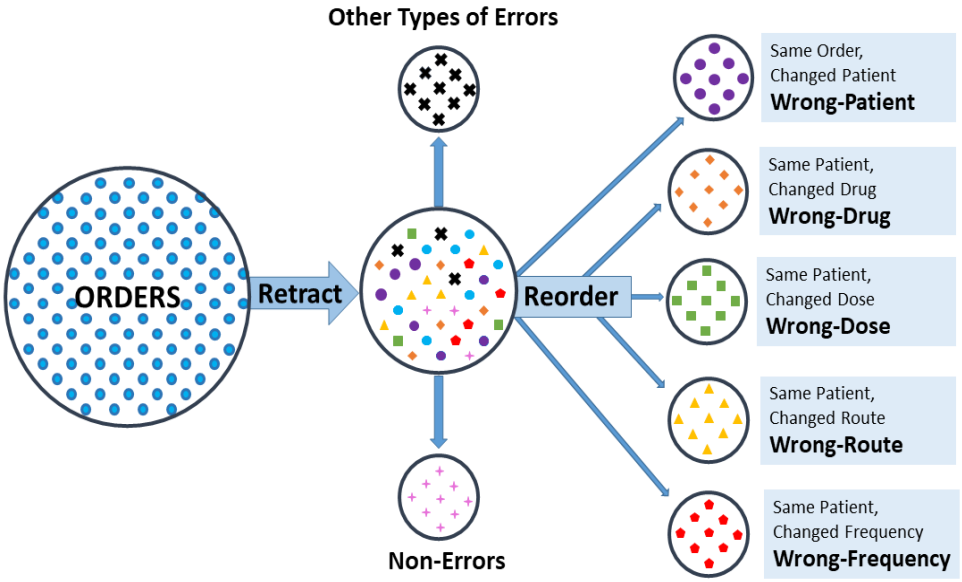
**Aim 1**: Develop and pilot effective and valid measures (positive predictive value >75%) for detecting wrong-dose, wrong-medication, wrong-route, and wrong-frequency electronic orders in an acute care setting, by extending the wrong-patient Retract-and-Reorder automated detection method.

**Aim 2**: Implement the automated measures developed in Aim 1, using a different Electronic Health Record (EHR), to evaluate the reliability (external validity) of the measures.

**Aim 3**: Conduct a multi-site observational study describing the overall frequency of wrong-patient, wrong-dose, wrong-medication, wrong-route, and wrong-frequency electronic orders, and describe the frequency in subgroups characterized by clinician, patient, and system factors.

Our hypothesis was that the theoretical model used to create and validate the Wrong-Patient Retract-and-Reorder measure can be applied to detect wrong-dose, wrong-medication, wrong-route, wrong-frequency, and other types of electronic order errors (**Figure 1**).

**Figure 1. Theoretical model for using the Retract-and-Reorder automated detection method to capture violations of the 5 Rights of Medication Safety and other electronic order errors**.




## 3. SCOPE

### Background

Policymakers have embraced Health Information Technology (IT) as an essential component of high-quality and high-reliability healthcare; however, studies have demonstrated that unintended consequences of computerized clinician order entry (CPOE) can cause serious medication errors and patient harm.[2-6] In a study published in *BMJ Quality & Safety,* Schiff et al conducted an in-depth review and analysis of 10,060 medication errors reported to MEDMARX from 2003-2010 where CPOE was indicated to be a "contributing cause" of the error.[7] Among these errors, 7,171 (71%) occurred during medication ordering, and 67.7% were violations of the 5 Rights of Medication Safety (right patient, right drug, right dose, right route, right timing). Data reported to AHRQ's National Patient Safety Database from 2008-2021 showed that wrong dose, drug, and timing errors remain the most common types of medication errors.[8] These analyses were conducted using errors reported from hundreds of hospitals over several years. While these numbers are large in the aggregate, any one hospital reported only a few Health IT errors per year, which has made it difficult to conduct research aimed at preventing these errors. The scarcity of reported events is not due to a lack of errors, but attributable to voluntary reporting systems that fail to capture the vast majority of errors.[9] More comprehensive measurement of these errors involves intensive chart review, which is not feasible across large healthcare systems. A recent systematic review of CPOE-related medication errors found that wrong dose, drug, route, and timing errors were most frequently reported across studies, with a wide range of prevalence estimates due to inconsistent definitions, measures, and data collection methods.[10]

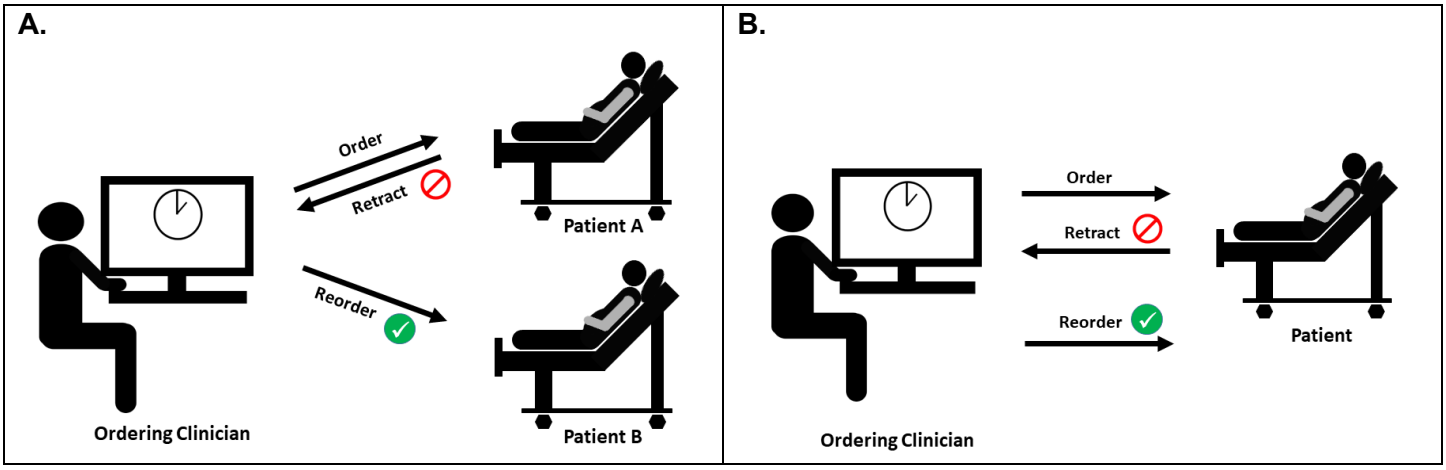
For these reasons, the development of the automated Wrong-Patient Retract-and-Reorder (RAR) measure was an important breakthrough in patient safety research, enabling systematic and objective identification of wrong-patient orders in electronic health record (EHR) data.[1] The Wrong-Patient RAR measure was the first Health IT Safety measure endorsed by National Quality Forum (NQF 2723).[11] Prior to the development of the Wrong-Patient RAR measure, the United States Pharmacopeia used the MEDMARX database to estimate the frequency of wrong-patient electronic orders and found a mean of 9 errors per hospital per year,[12] too few to provide adequate power for rigorous research. In contrast, studies using the Wrong-Patient RAR measure have identified thousands of wrong-patient electronic orders per year, ranging from 85 to 88 events per 100,000 orders in inpatient settings.[1,13] The measure has been used as the primary outcome in several observational studies to examine the epidemiology of wrong-patient orders and in quasi-experimental and randomized controlled trials to evaluate intervention strategies to reduce wrong-patient errors.[1,13-19] Informed by these studies, the Office of the National Coordinator for Health IT (ONC) *SAFER Guides* recommend using the Wrong-Patient RAR measure for hospital monitoring and surveillance as part of an annual EHR

assessment,[20] which as of 2022 is required by Centers for Medicare & Medicaid Services (CMS).[21] In addition, studies using the Wrong-Patient RAR measure showed a significant reduction in identification errors in neonatal intensive care units after implementing a distinct newborn naming convention.[16,17] Based on these results, The Joint Commission requires all hospitals to use distinct methods of newborn identification as part of its National Patient Safety Goals.[22] Using the RAR error detection method to systematically quantify common medication and other types of electronic order errors has potential far-reaching impact, as demonstrated by the experience with the Wrong-Patient RAR measure.

**Context**

The theoretical model that underlies the Wrong-Patient RAR measure suggests the potential to create additional automated measures to detect other types of order errors (**Figure 1**). The Retract-and-Reorder model posits that a rapidly retracted order is likely to contain an error, and the order placed immediately after the retraction, with an element of the initial order changed, is the corrected order. The element changed between the two orders indicates the type of error. The utility of the Wrong-Patient RAR measure served as proof of principle that the RAR theoretical model captures wrong-patient order errors (**Figure 2A**). Many other types of measures of medication and non-medication order errors (e.g., imaging, labs, procedures) could be developed using the model shown in **Figure 2B.** For example, a Wrong-Dose RAR measure that identifies medication orders that are rapidly retracted and reordered by the same clinician for the same patient after changing the dose (e.g., same patient, same drug, different dose), or a Wrong-Site Imaging RAR measure that identifies imaging orders that are rapidly retracted and reordered by the same clinician for the same patient after changing from left side to right side (eg, same patient, same imaging study, different site).

**Figure 2. Retract-and-Reorder (RAR) sequence. A.** Wrong-patient order error, in which an order is placed for Patient A, retracted by the same clinician, then reordered for a different Patient B by the same clinician. **B.** Other types of order errors, in which an order is placed for a patient, retracted by the same clinician, then reordered for the same patient by the same clinician with a parameter of the order changed.




The near-universal transition to EHRs has created an opportunity to develop Health IT Safety measures by leveraging the large volume of electronic data generated in clinical care. The EHR audit log, which contains records of user activity, has demonstrated utility for error detection.[23,24] As part of our preliminary work, we conducted an analysis of electronic orders and audit log data at a large healthcare system to identify error types to target for the new measures. Over a 1-year period, clinicians placed a total of 21,401,986 orders, of which 385,965 orders (1.8%), or more than 1,000 per day, were retracted (canceled) within 30 minutes.[25] Among all retracted orders, 112,114 (29.1%) were RAR events, i.e., reordered within 30 minutes after the retraction by the same clinician with one or more elements of the order changed, and of these 85,567 (76.3%) were medication orders (**Table 1**). Notably, wrong-patient RAR events represented a small proportion (3.6%) of all RAR events, demonstrating the potential to create many more RAR measures to capture a range of different error types.

**Table 1. Medication Orders Retracted and Reordered in a Large Health System in 1 Year (N=21,401,986 orders)**

| Error Type | RAR Orders, n | RAR Orders, % | RAR Rate per 100,000 Orders |
|---|---|---|---|
| Overall Medications | 85,567 | | 1566.6 |
| Wrong Dose | 20,153 | 23.6 | 369.0 |
| Wrong Frequency | 12,353 | 14.4 | 226.2 |
| Wrong Route | 5,556 | 6.5 | 101.7 |
| Wrong PRN | 1,626 | 1.9 | 29.8 |
| Wrong Duration | 418 | 0.5 | 7.7 |
| Other/unknown | 45,461 | 53.1 | 758.0 |

Automated RAR measures overcome many of the limitations of traditional methods used to quantify medical errors, such as chart review and voluntary reporting. RAR measures have the advantage of being 1) objective, eliminating biases introduced by relying on voluntary reporting of patient safety events or documentation in the medical record; 2) immediate, capturing patient safety events in near-real time and providing the unique opportunity to investigate events shortly after they occur; 3) systematic, increasing identification of patient safety events compared to other modalities and providing a robust volume of outcome events to power intervention studies; and 4) generalizable, applicable across EHRs, healthcare systems, and settings.

### Settings

The study was conducted from October 2017 to 2022. Data were collected at Columbia University Irving Medical Center, Weill Cornell Medical Center, and NewYork-Presbyterian Queens Hospital, affiliated with NewYork-Presbyterian, a large integrated academic healthcare system. Study sites included seven hospitals with over 3000 inpatient beds and six emergency departments. Study sites utilized Allscripts and then transitioned to Epic during the study period (Columbia January 2020, Weill Cornell October 2020, Queens Hospital June 2021). Dr. Clyde Schechter served as biostatistician at Albert Einstein College of Medicine; Dr. Hojjat Salmasian served as informatics and technical consultant at Brigham and Women's Hospital. The study protocol was approved by the Institutional Review Boards of all participating sites.

### Participants

**Clinicians.** All clinicians with the authority to place electronic orders (attending, resident, physician assistant, nurse practitioner) were eligible for inclusion in the study. A convenience sample of clinicians who triggered the RAR measures were contacted within 6 hours of the event for a brief interview to verify the error (or false positive) and elicit details of the circumstances that triggered the measure.

**Patients.** Since all patients are at risk for an order error, orders placed for all patients during the study period were eligible for inclusion in the analysis.

## 4. METHODS

### Study Design

The study had two components: a prospective validation study (Aims 1 and 2), and a retrospective cross-sectional observational study (Aim 3). The study design and methods were based on the initial validation of the Wrong-Patient RAR Measure.[1]

For **Aims 1 and 2**, we conducted a prospective study in a convenience sample of clinicians who triggered the RAR measures in development, as described under Data Sources/Collection. First, the measures were developed and validated in Allscripts (Aim 1). We used an iterative process to improve the performance of each measure, for example programming the queries to eliminate false positive events. When the target positive predictive value was reached (see **Measures** below), the new measures were validated in Epic to demonstrate reliability (Aim 2). In addition, we conducted a re-validation of the Wrong-Patient RAR Measure in Allscripts. We specified queries to validate the following new electronic order error measures:

- **Wrong-Dose RAR Measure**: detects medication orders that are placed, retracted by the same clinician within 30 minutes, then reordered by the same clinician for the same patient within the next 10 minutes with only a change in dose (e.g., 20 mg to 40 mg). The measure was validated overall and in a subset of pediatric patients (age ≤21 years).
- **Wrong-Frequency RAR Measure**: detects medication orders that are placed, retracted by the same clinician within 30 minutes, then reordered by the same clinician for the same patient within the next 10 minutes with only a change in frequency (e.g., q4h to q24h).
- **Wrong-PRN RAR Measure**: detects medication orders that are placed, retracted by the same clinician within 30 minutes, then reordered by the same clinician for the same patient within the next 10 minutes with a change from standing to PRN (as needed) or vice versa.
- **Wrong-Route RAR Measure**: detects medication orders that are placed, retracted by the same clinician within 30 minutes, then reordered by the same clinician for the same patient within the next 10 minutes with a change in route of administration (e.g., oral to IV).
- **Retract All Measure**: detects medication and non-medication orders placed, then retracted by the same clinician within 30 minutes. Eliciting the actions taken by the clinician around the event indicates the type of error (e.g., duplicate order, wrong instructions).

For **Aim 3**, we will conduct a retrospective cross-sectional observational study to examine the epidemiology of each type of error over a 1-year period in a large healthcare system comprising approximately 20 million orders. While the measures have been validated, this analysis will be conducted when the measure specifications are finalized (see **Measures** below).

**Data Sources/Collection**

**Aims 1 and 2**. The query for each RAR measure ran every 30 minutes in a live replica server. For each run, details of RAR events that met the measure criteria were populated into a secure, HIPAA-compliant, web-based survey platform with a survey instrument for each measure. Each survey contained detailed information about the ordering clinician, patient, and order. A unique survey link for each event was sent automatically to a secure central email inbox accessed only by the research team. Both the survey instrument and inbox were organized by error type so that each measure was validated separately. Research personnel then reviewed the event information and contacted the clinician involved to conduct a near real-time phone interview to confirm whether the RAR event was an error and to elicit details about the circumstances leading to the event.

Clinicians were contacted within 6 hours of the RAR event. After explaining the study and obtaining the clinician's verbal consent, research personnel conducted a brief interview using a semi-structured interview guide embedded in the survey tool. To create a safe space to discuss potential errors, we based the interview guide on a framework developed by Schiff and colleagues to identify reasons for order errors.[7,26] This approach uses non-leading questions to elicit what happened, why the event happened, and what could have prevented the event. Interviewers asked open-ended and semi-structured questions, including why the initial order was placed, why the order was canceled, who prompted the cancelation, and why the medication was reordered with a parameter changed (e.g., dose, frequency, route). Responses were transcribed into the survey instrument; after each interview, interviewers checked responses for accuracy and completeness.

For each measure, two clinician researchers independently reviewed the responses and classified each event as true positive (error) or false positive. To standardize the classification of events, we developed a tool that detailed criteria for the definition of errors and false-positive events. Criteria used to classify errors in our validation studies were based on a review of patient safety literature, expert opinion, and preliminary review of pilot validation data.[10,27-35] Errors were defined as orders that were retracted and reordered because placement of the initial order was inadvertent or unintentional (execution errors) or due to lack of knowledge, failure to follow protocols, or clinically inappropriate (planning errors).[32,35] In many cases, the clinician acknowledged the error or it was clear by description. False positives were defined as changes made based on clinical judgment, new clinical information, or formulary-related reasons including availability or ease of administration. Disagreements regarding classification were adjudicated by a third clinician. For each measure, inter-rater reliability was assessed using Cohen's Kappa statistic.

**Aim 3**. All orders were extracted from the healthcare system data warehouse for the 1-year period 1/1/2019-12/31/2019 to examine the epidemiology of each error type. Variables included the following:

**Encounter-level characteristics**: location (inpatient, outpatient, emergency department).

**Provider-level characteristics**: type of ordering clinician (attending, resident, physician assistant, nurse practitioner, pharmacist, or other).

**Patient-level characteristics**: age, gender, race, ethnicity, insurance status.

**Order-level characteristics**: medication, therapeutic class, order details, other order types (labs, imaging, procedures) as applicable for non-medication measures, time of day (day, night, weekend), retract time, reorder time.

**Measures**

**Primary Outcome. Aims 1 and 2.** The primary outcome for the validation studies was positive predictive value (PPV), calculated as follows: PPV = number of true-positive events (errors) divided by the total number of events investigated (true-positive + false-positive events) for each measure. PPV was calculated as a percentage with exact binomial confidence intervals (CIs). A target PPV of >75%, with a lower bound of 95% CI of 70%, was chosen based on validation of the Wrong-Patient RAR measure.[1] Based on these assumptions, we estimated a sample size of 200 events for each measure.

The analysis aims to optimize the measures by examining the effect on PPV of varying the following measure parameters: retract and reorder time intervals, magnitude of change (for dose measures only), prevalence of RAR events in 1-year of order data, and sample size required for studies using the measure as the outcome. For Wrong-Dose measures, magnitude of change was calculated as the ratio of the larger to the smaller dose. Based on these analyses, the final specifications for each measure will maximize the PPV and the number of RAR events detected, while minimizing the number of events required to power intervention studies.

**Secondary Outcomes. Aims 1 and 2.** Using the validation data for each RAR measure, we conducted qualitative content analysis of clinician interview responses to describe the underlying reasons why errors occurred.[36] The coding scheme was derived from the Skills, Rules, Knowledge framework for classification of human error,[33,34] adapted by Ferner-Aronson et al[35] for application to medication order errors. This framework distinguishes between Planning Errors, defined as errors in which the intended action is incorrect, and Execution Errors, defined as errors in which a correctly planned action is executed incorrectly.[35] and Execution Errors, defined as errors in which a correctly planned action is executed incorrectly.[35] Planning Errors were further classified as Knowledge Errors, which occur because of practical or clinical knowledge gaps, and Rule-Based Errors, which occur as a result of failure to follow standard protocols or procedures.[35] Execution Errors consist of Slips, defined as unintended actions (eg, clicking on the wrong drug), and Lapses, defined as cognitive errors or errors of memory (eg, forgetting to hold medication pending lab values).[35] We also categorized reasons for false-positive events that triggered the measure queries.

**Aim 3**. Using a data set of all electronic orders placed over a 1-year period across study sites, we will examine the frequency of each error type captured by the new measures, overall and in subgroups by encounter-, clinician-, patient-, and order-level characteristics. Frequency is reported as a rate, calculated as the number of RAR events per 100,000 orders per year.

**Limitations**

First, we used a convenience sample when contacting clinicians to verify whether a Retract-and-Reorder error occurred. The sample to validate the measures was not a random sample and interviews were conducted Monday-Friday during standard business hours. Thus, the sample may not be representative of the universe of events that occurred. Second, the validation results are dependent upon the narrative of the interviewed clinicians. Although the interview guide was created with the intention to minimize fault and blame, and is organized to be concise, some clinicians may have been reluctant to admit placing an order in error or lacked the time to fully explain the event. Third, although the measures were tested in two different EHRs, the validation studies were conducted within a single multi-site healthcare system.

## 5. RESULTS

### Principal Findings and Primary Outcomes

**Aims 1 and 2**. We developed and validated five new RAR medication error measures: Wrong-Dose (all age groups combined), Wrong-Dose Pediatrics (age ≤21 years), Wrong-Frequency, Wrong-PRN, and Wrong-Route RAR measures. For validation, we specified the measures to a maximum retract time of up to 30 minutes and reorder time up to 10 minutes (30/10). Based on early analysis, we found that when an ordering clinician retracts and replaces an order, the corrected order is placed within a short time frame.

There were a total of 885 RAR events that occurred within the 30/10 timeframe included in the analysis. Results of preliminary analysis of PPV with 95% CIs are presented in **Table 2**. PPV for new RAR measures reached the target of >75%. Because Wrong-PRN RAR events were less frequent and the number of events investigated was small, the lower bound of the 95% CI did not reach 70%. For the Wrong-Dose and Wrong-Dose Pediatrics measures, PPV was analyzed for events in which the change in the magnitude of dose from initial order to reorder was at least ±10%.

In addition, we completed the revalidation of the Wrong-Patient RAR measure. In the revalidation, we specified the query to retract and reorder time of 30/10 to determine the effect on PPV, as compared with the original validated measure specified at 10/10. As shown in **Table 2**, when extended to 30/10, the PPV was 64.4% (95% CI 59.0–69.6). For the 10/10-minute timeframe, the PPV for the revalidated measure was 76.7% (95% CI 70.9–81.9), remarkably similar to that of the NQF-endorsed measure at 76.2% (95% CI 70.6% to 81.8%) validated in a different EHR and healthcare system.

**Table 2. Results of Measure Validation in Allscripts (Aim 1)**

| New RAR Measure | Time to Retract/Reorder, min | Total Events, N | Errors, n | Positive Predictive Value, % | 95% CI |
|---|---|---|---|---|---|
| Wrong Dose[1] | 30/10 | 279 | 214 | 76.7 | 71.3–81.5 |
| Wrong Dose Pediatrics[1,2] | 30/10 | 72 | 61 | 84.7 | 74.3–92.1 |
| Wrong Frequency | 30/10 | 118 | 103 | 87.3 | 79.9–92.7 |
| Wrong PRN | 30/10 | 51 | 40 | 78.4 | 64.7–88.7 |
| Wrong Route | 30/10 | 108 | 92 | 85.2 | 77.1–91.3 |
| **Revalidation** | | | | | |
| Wrong Patient | 30/10 | 329 | 212 | 64.4 | 59.0–69.6 |
| Wrong Patient subset[3] | 10/10 | 245 | 188 | 76.7 | 70.9–81.9 |

[1]With a magnitude of dose change of at least ±10%. [2]Subset of Wrong Dose. [3]Subset of Wrong Patient.

For the Retract All Measure, clinician interviews were conducted for 344 events. Results show an overall PPV of 75.6% (95% CI 71.0–80.1) (**Table 3**). We calculated the PPV for medication order errors and non-medication order errors separately and found that both had a high PPV of 72.3% and 80.0%, respectively.

**Table 3. Results of Retract All Measure in Allscripts (Aim 1)**

| | Total Events, N | Errors, n | Positive Predictive Value, % | 95% CI |
|---|---|---|---|---|
| Overall | 344 | 260 | 75.6 | 71.0–80.1 |
| Retract All Meds | 214 | 156 | 72.3 | 66.9–78.9 |
| Retract All Non-Meds | 130 | 104 | 80.0 | 73.1–86.9 |

Time to Retract = 30 min.

Preliminary results of validation of the new RAR measures in Epic EHR yielded PPVs similar to the validation results in Allscripts, demonstrating the reliability of the measures (**Table 4**)**.** Validation of the Wrong-PRN measure in Epic is in process.

**Table 4. Preliminary Results of RAR Measure Validation in Epic (Aim 2)**

| | Total Events, N | Errors, n | Positive Predictive Value, % | 95% CI |
|---|---|---|---|---|
| Wrong-Dose | 209 | 156 | 74.6 | 68.7–80.5 |
| Wrong-Frequency | 198 | 160 | 80.8 | 75.3–86.3 |
| Wong-Route | 130 | 104 | 80.0 | 73.4–86.6 |

Time to Retract/Reorder = 30/10 min.

## Secondary Outcomes

### Qualitative Analysis

Results of the qualitative content analysis classifying reasons for errors is summarized in **Figure 3.** We found substantial variation based on error type. For example, 97% of Wrong-Patient order errors were execution errors, resulting from slips such as clicking on the wrong patient and lapses when clinicians were interrupted or multitasking then realized they were placing orders in the wrong patient's record. Similarly, 70% of Wrong-PRN errors were execution errors, resulting from misclicking or lapses in which clinicians failed to change a default schedule autopopulated by the EHR. In contrast, most Wrong-Dose, Wrong-Frequency, and Wrong-Route order errors (62% to 69%) were planning errors, predominantly resulting from rule-based errors in which clinicians failed to adjust for the clinical status of the patient (based on labs, weight, age, comorbidities, etc.).

**Figure 3. Proportion of Planning and Execution Order Errors in RAR Measure Validation.**

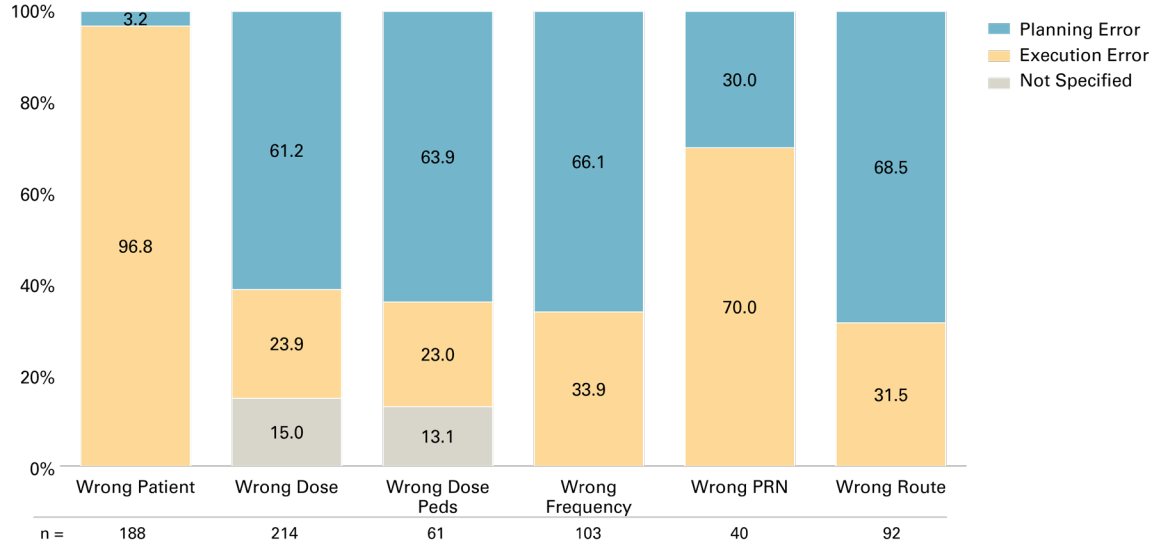
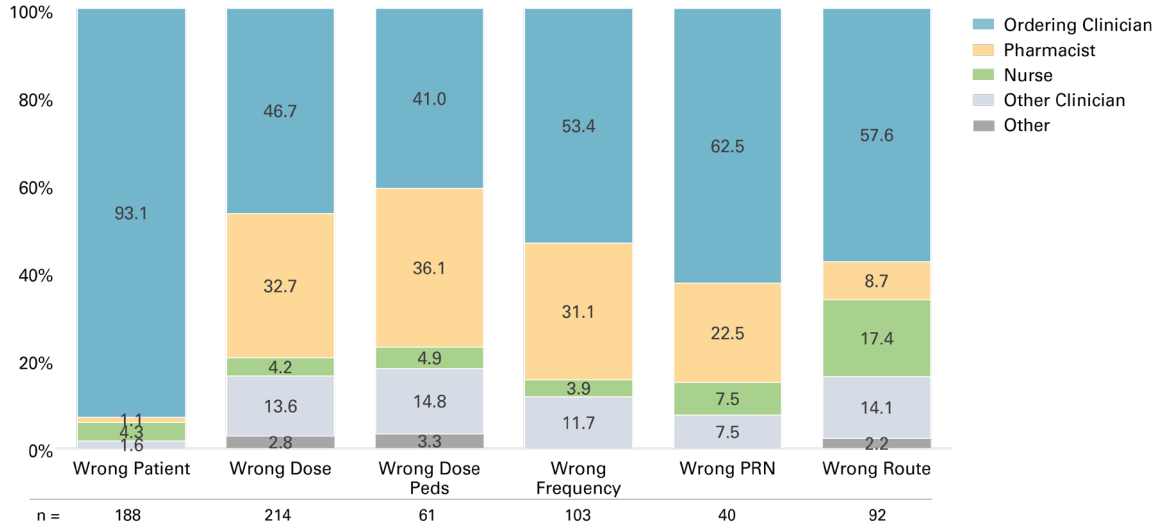



**Figure 4. Who Caught the Error?**



We also analyzed who caught the error or prompted the cancelation of the initial order among RAR events determined to be errors. Consistent with results of reasons for order errors above, the vast majority of Wrong-Patient (93%) and Wrong-PRN (58%) order errors were self-caught by the ordering clinician. In contrast, a substantial proportion of Wrong-Dose, Wrong-Frequency, and Wrong-Route order errors were caught by pharmacists and other clinicians. Results of who caught the order errors are summarized in **Figure 4** above.

**Epidemiology of Ordering Errors. Aim 3.** As described in **Measures** above, the final PPV for each measure will be determined based on analysis to optimize each measure by examining the effect on PPV of varying measure parameters (e.g., retract and reorder times, prevalence of RAR events, and magnitude of change for dose measures). The final specifications for each measure will maximize the PPV and the number of RAR events detected, while minimizing the number of events needed to power intervention studies. This analysis is pending, while thorough data cleaning and checking is being conducted to ensure data accuracy and integrity. Analysis of the epidemiology of order errors will be conducted when optimal measures specifications are final.

**Discussion**

Our study successfully used the novel Retract-and-Reorder (RAR) methodology for detecting Wrong-Patient near-miss order errors to develop and validate Wrong-Dose, Wrong-Frequency, Wrong-PRN, and Wrong-Route order error measures. The PPV for detecting each type of order error reached the target of >75%. When revalidated in another EHR, the PPV of the new measures was similar to results achieved in the initial validation, demonstrating a high degree of reliability. Moreover, the Retract All measure, created to identify all orders cancelled within 30 minutes of ordering, had a PPV for detecting errors of 75.6% and may serve as an overall Health IT Safety measure of order entry errors.

It has been estimated that preventable harm among hospitalized patients results in more than 400,000 deaths per year.[37] A report published in 2022 by the Office of the Inspector General found that 1 in 4 hospitalized Medicare patients experienced an adverse event that caused harm. Nearly half of these adverse events were categorized as preventable and the most common type of patient harm events were medication errors (43%).[38] However, historically order errors have been measured mainly based on voluntary reporting or chart review, methods which have many inherent limitations. Therefore, innovative methods to measure medication order errors are critical to prevent harm. The novel measures validated in this study detect near-miss order errors, intercepted before reaching the patient. The use of near-miss errors to test safety improvements in healthcare is endorsed by major organizations dedicated to improving patient safety, including AHRQ, World Health Organization, Institute for Healthcare Improvement, and The Joint Commission. This is because near-miss errors have been posited by safety experts to have the same causal pathway as errors that cause harm.[39-42] The key distinction between an adverse event and a near-miss error is that, in the latter, “human recovery” occurs before the error reaches a patient and causes harm. In our study, identifying reasons for errors and mechanisms of recovery provides information essential to design effective preventive interventions.

To our knowledge, this is the first rigorous validation of novel, automated measures for detecting several types of near-miss medication order errors. A pilot study applied the RAR methodology to all medication orders and found a PPV for near-miss order errors of 85% (71/84 events); however, all error types were combined in a single measure such that numbers of each event type were very small.[43] Other studies to detect electronic order errors have used methodology similar to our Retract All measure. One study looked at all medications ordered and retracted within 2 hours found an overall PPV of 66%.[44] Another study looked at all “voided” orders and found a PPV as high as 93%.[26] However, these mechanisms for detecting order errors are non-specific and not all EHRs allow a “voided” option. Our unique measures for detecting errors are widely applicable, easy to use, non-labor intensive, and specific. These characteristics make them ideal for outcome measures in interventional studies. For example, the Wrong-Patient RAR measure has been used to examine the effect of the number of open charts in the EHR on wrong-patient order errors.[13] Similarly, these new measures can serve in post-implementation evaluation analysis.

Furthermore, as of 2021, CMS requires healthcare systems to perform a safety assessment of their CPOE annually using the ONC *SAFER Guides*, which may help identify system vulnerabilities.[45] Our queries enabled us to identify near-miss errors and interview clinicians in real time. This gave us a unique opportunity to identify

areas for improvements. Specifically, our qualitative analysis provided insight into reasons for errors and identified possible intervention targets. For example, we found wrong-dose errors were primarily secondary to planning errors, with many clinicians noting an error with weight-based or lab-based dosing. Therefore, autopopulated labs and automated weight-based dosing could help clinicians with error-prone medication dosing, such as antimicrobials. Specific interventions can be targeted to each error type and then tested using the novel measures validated in this study. Our study is ongoing to determine patient and clinician characteristics that are associated with order errors. Additional order error measures are in process, including a Wrong-Drug RAR measure.

**Conclusions**
Our study successfully used the Retract-and-Reorder methodology for detecting Wrong-Patient near-miss errors in order to develop and validate measures to detect Wrong-Dose, Wrong-Frequency, Wrong-PNR, and Wrong-Route order errors. All measures achieved a high PPV, reaching the target of >75%, validated in two different EHR systems. This automated measurement of electronic order errors can be readily integrated into health system EHRs to study the epidemiology of order errors and test the effectiveness of proposed EHR improvements on order error outcomes.

**Significance**
Despite the focus on reducing medical errors over the past two decades, and the substantial investment in improving patient safety, order errors in CPOE systems remain a persistent source of patient harm. Medication errors have been consistently shown to be the most common and preventable type of errors. Lack of standardized methods to systematically and objectively measure order errors has hampered efforts aimed at prevention. The set of electronic order error measures developed in the this study represents a major advance in patient safety. As demonstrated by the utility of the Wrong-Patient RAR measure, these novel measures have the capacity to identify high-risk populations and serve as valid and reliable outcome measures for studies to prevent these types of errors across settings and systems.

**Implications**
The use of the RAR method to develop a set of valid and reliable measures demonstrates the potential to develop many other measures to detect a range of error types. The process we have described provides a framework for other investigators to develop and validate additional RAR measures. The specifications for the novel measures developed in this study will be publicly shared so that the measures can be readily and widely used by other healthcare systems. Finally, a distintive feature of our methodology was the ability of RAR measures to detect order errors shortly after they occurred and enable near real-time phone interviews with ordering clinicians. Our validation process provided a unique opportunity to elicit reasons for order errors from clinicians directly and the identify the mechanisms of recovery, which will inform the development of targeted patient safety interventions to prevent these errors.

## 6. LIST OF PUBLICATIONS

### Published Works and Electronic Resources from Study

Kern-Goldberger AR, Kneifati-Hayek J, Fernandes Y, Applebaum JR, Schechter CB, Adelman JS, Goffman D. Wrong-patient orders in obstetrics. *Obstet Gynecol.* 2021;138(2):229-235. PMID: 34237762. Recipient Roy M. Pitkin Award, 2021.

### Publications in Development

Reddy Spector P, Kneifati-Hayek JZ, Grauer A, Renard BL, Applebaum JR, Fernandes Y, Salmasian H, Southern WN, Schechter CB, Crossman D, Zhang Y, Cooke J, Barchi D, Kumaraiah D, Adelman JS. Methodology for developing and validating automated health information technology safety measures using the Retract-and-Reorder model.

Manuscripts for each measure are in process reporting the validation results and epidemiology of each order error type.

### Presentations

Hyman N, Wright G, Grauer A, Rojas C, Fernandes Y, Kneifati-Hayek J, et al. Validation of automated wrong-dose and wrong-frequency medication error measures: Preliminary results. Poster presentation: Society of General Internal Medicine 2022 Annual Meeting; April 6-9, 2022; Orlando, FL.

Reddy P, Applebaum J, Lobritto S, Adelman J. Understanding the risk of wrong-dose errors in liver transplant recipients using a validated automated measurement tool: a proposal. Poster presentation: SPLIT 25th Annual Meeting; September 30-October 1, 2021; Pittsburgh, PA.*Transplantation.* 2021;105(12S2):S4.

Redman C, Kneifati-Hayek J, Reddy P, Rosen A, Fernandes Y, Applebaum J, Adelman J. Reasons for order errors identified by automated health IT safety measures: preliminary results. Poster presentation: AcademyHealth Annual Research Meeting, June 14-17, 2021. Virtual Event.

Reddy P, Fernandes Y, Applebaum J, Adelman J. Understanding the impact of the COVID-19 pandemic on wrong patient errors using a validated automated measurement tool. Oral presentation: 27th Annual AHRQ National Research Service Award (NRSA) Trainees Research Conference; June 7-8, 2021; Virtual Event.

Grauer A, Reddy P, Rojas C, Fernandes Y, Redman C, Kneifati-Hayek J, Applebaum J, Adelman J. Development and validation of an automated wrong-PRN medication error measure: preliminary results. Poster presentation: Society of General Internal Medicine 2021 Annual Meeting, April 20-23, 2021; Virtual Event.

Rojas C, Reddy P, Fernandes Y, Applebaum J, Adelman J. Using the Wrong-Route Retract-and-Reorder Measure to estimate wrong-route medication errors in patients with enteral tubes. Oral presentation: ASPEN Nutrition Science & Practice Conference; March 20-23, 2021; Virtual Event. Recipient of Distinction Award.

Goffman D, Kern-Goldberger A, Kneifati-Hayek J, Fernandes Y, Applebaum J, Adelman J. Wrong patient orders in obstetrics: an unrecognized patient safety risk. Oral presentation: SMFM 40th Annual Pregnancy Meeting; February 3-8, 2020; Grapevine, TX. *Am J Obstet Gynecology*. 2020;222:S39.

Reddy P, Kneifati-Hayek J, Applebaum J, Adelman J. Development and validation of an automated wrong-dose detection measure at a large tertiary care academic center: preliminary results. Poster presentation: 26th Annual AHRQ National Research Service Award (NRSA) Trainees Research Conference; June 13, 2020; Boston, MA.

Reddy P, Kneifati-Hayek J, Robles P, Rojas C, Ortuno-Garcia C, Huebner J, Stringer W, Kosber R, Applebaum J, Adelman J. Development and validation of an automated wrong-dose detection measure in a pediatric population: preliminary results. Poster presentation: Pediatric Academic Societies Meeting; April 29-May 6, 2020; Philadelphia, PA.

Kneifati-Hayek J, Salmasian H, Fernandes Y, Robles P, Redman C, Green R, Vawdrey D, Applebaum J, Southern W, Adelman J. Validation and enhancement of a National Quality Forum measure for wrong-patient orders. Poster presentation: 25th Annual AHRQ National Research Service Award (NRSA) Trainees Research Conference; June 1, 2019; Washington DC.

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