# A Randomized Controlled Trial Evaluating the Effectiveness of Displaying Patient Photographs in an Electronic Health Record to Prevent Wrong-Patient Electronic Orders

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**NCT:** NCT03626766

**Date**: 10/01/2024

## BACKGROUND

**The problem of wrong-patient orders.** Although computerized clinician order entry (CPOE) systems are associated with a reduction in medical errors,[1-4] when orders are placed electronically certain types of errors, including placing orders on the wrong patient, may occur more frequently.[5-10] The danger of wrong-patient electronic orders was highlighted by one hospital's report of over 5,000 wrong-patient orders in 1 year.[11] All types of orders can be placed on the wrong patient including medications, lab and imaging tests, and nursing orders. If an order is carried out on the wrong patient, it may lead to significant patient harm.

**How patient photographs in electronic health records (EHRs) can prevent wrong-patient electronic orders.** Prior research has shown that cognitively processing a photograph (face recognition) requires significantly less effort than reading a patient's name.[12] As such, prominently displaying a patient photograph has the potential to be a fast and accurate method for verifying a patient's identity when placing electronic orders. Limited evidence suggests that patient photographs may be a promising strategy for reducing wrong-patient orders.[13] In a 2012 study conducted by Hyman et al, researchers asked clinicians to voluntarily report wrong-patient ordering errors before and after patient photographs were implemented in an EHR. Wrong-patient orders declined from the year pre- to the year post-implementation from 12 to 3. While encouraging, this study was limited by small sample size, quasi-experimental design, and reliance on voluntary reporting of errors. We hypothesize that a large randomized controlled trial using an automated and reliable measure of wrong-patient errors instead of voluntary reporting will demonstrate that patient photographs can significantly prevent wrong-patient orders.

**Current use of patient photographs in EHRs.** In 2013, Adelman et al conducted a national survey of hospitals to assess the use of patient photographs in EHRs (unpublished data). This study found that although over 80% of the 131 responding hospitals reported having the capability to display patient photographs in their inpatient EHR, only 17.6% used this function. A study that establishes the effectiveness of prominently displayed patient photographs for preventing wrong-patient errors will provide hospitals with the evidence needed to overcome obstacles and adopt this safety practice.

**Retract-and-Reorder Measure for identifying wrong-patient errors.** The Retract-and-Reorder (RAR) measure is a validated, reliable, and automated mechanism for identifying wrong-patient errors.[11] The RAR measure identifies orders placed on a patient that are retracted within 10 minutes, and then placed by the same clinician on a different patient within the next 10 minutes. These are near-miss errors, self-caught by the clinician before they reach the patient and cause harm. In one study, the RAR measure identified more than 5,000 wrong-patient orders in 1 year, with a rate of 58 wrong-patient orders per 100,000 orders.[11] Real-time telephone interviews with clinicians who placed and retracted the orders determined that the RAR measure correctly identified near-miss errors in 170 of 223 cases (positive predictive value 76.2%).[11] Thus, the RAR measure can provide reliable outcome data for this study.

**Why are near-miss errors important in patient safety research?** The RAR measure captures self-caught wrong-patient errors, which are near-miss errors. 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 (TJC) because they have been shown to share the same causal pathway as errors that cause harm.[14-20]

## SPECIFIC AIMS

The main hypothesis of this study is that an EHR system that prominently displays patient photographs will be more effective for preventing wrong-patient errors than a system that does not display photographs. We will test our hypothesis using randomized controlled trials and pursue the following specific aims:

**Aim 1:** Test the effectiveness of displaying patient photographs in EHR systems for preventing wrong-patient orders, using the Retract-and-Reorder measure to identify the outcome.

**Aim 2:** Identify characteristics of clinicians, patients, and order sessions that impact the effectiveness of patient photographs displayed in an EHR system to prevent wrong-patient orders.

**Aim 3**: Conduct an evaluation of the implementation of patient photographs in the different EHR systems, including staff and patients.

## METHODS

**Research Personnel.** The study will be led by principal investigator (PI) Jason Adelman, MD, MS, Chief Patient Safety Officer and Associate Chief Quality Officer for Columbia University Medical Center/NewYork-Presbyterian (NYP) Hospital. Along with Dr. Adelman, the research team consists of co-investigators from Columbia University, Weill Cornell Medicine, Johns Hopkins Medicine, Albert Einstein College of Medicine/Montefiore Medical Center, and Harvard University/Brigham and Women's Hospital. The collaborating Site Leads include the following:

- Donald Dietz, MD, Assistant Professor of Medicine, Weill Cornell Medicine.
- Joseph Cooke, MD, Chairman, Department of Medicine, New York-Presbyterian/Queens.
- Brenna Farmer, MD, Chief, Department of Emergency Medicine, New York-Presbyterian Brooklyn Methodist Hospital.
- Allen Chen, MD, PhD, MHS, Health IT Patient Safety Officer, Armstrong Institute for Patient Safety and Quality, Associate Professor Department of Oncology and Department of Pediatrics, Johns Hopkins Medicine.
- Clyde Schechter, MD, MA, Professor, Department of Family and Social Medicine, Albert Einstein College of Medicine.
- Hojjat Salmasian, MD, PhD, Vice President for Operational Data Science, Brigham and Women's Hospital.

**Study Sites**. Study sites include Columbia University Irving Medical Center, Weill Cornell Medicine, Johns Hopkins Medicine, Albert Einstein College of Medicine (for data analysis only), and Brigham & Women's Hospital. Data collection for the study will be conducted in two leading electronic health record (EHR) systems, Allscripts and Epic. For the study in Allscripts, two NYP/Columbia University Irving Medical Center campuses that utilize Allscripts EHR will be included: Milstein Hospital and Allen Hospital. Because of NYP's transition to Epic at Columbia University Irving Medical Center in January 2020, Weill Cornell Medicine in October 2020, and remaining NYP hospitals by December 2021, we will evaluate the effectiveness of patient photographs in Epic at Columbia (Milstein Hospital, Allen Hospital, Hudson Valley Hospital, Morgan Stanley Children's Hospital, and Lawrence Hospital) and Weill Cornell (Weill Cornell Medical Center, Lower Manhattan Hospital, NYP/Queens Hospital, NYP/Brooklyn Methodist Hospital, and Westchester Behavioral Health Center). Hudson Valley Hospital staff and employees will not be involved in research activities; all research activities at Hudson Valley Hospital will be conducted by Columbia employees. In addition, we plan to include

NYP's affiliated Ambulatory Care Network. Data collection for the study will also be conducted in Epic at Johns Hopkins Medicine locations, including Johns Hopkins Hospital (Inpatient) and Johns Hopkins Community Physicians sites (Outpatient). Data analysis will be conducted at Albert Einstein College of Medicine. Limited data sets will be securely transferred to the study biostatistician, Dr. Schechter (see Human Subjects Protection). Dr. Salmasian at Brigham & Women's Hospital will serve as consultant and technical advisor for the study.

**Institutional Review Board (IRB) Approval**. As the Lead Institution, the PI at Columbia University Irving Medical Center will work with Site Leads at Weill Cornell Medicine, Johns Hopkins Medicine, Albert Einstein College of Medicine, and Brigham and Women's Hospital to obtain IRB approval to implement study-related activities. Site Leads are responsible for obtaining approval from their respective IRB and are aware that human subjects research cannot commence until their institutional IRB is approved. The PI will work with Site Leads to ensure that all modifications and renewals are reviewed and approved appropriately.

**Research Design.**

**Aims 1 and 2—**The hypothesis of the study is that displaying patient photographs in an EHR at the time of placing electronic orders will significantly decrease the frequency of wrong-patient orders. We will test this hypothesis with a randomized controlled trial using a 2-arm design in Allscripts, and a randomized 2x2 factorial design in Epic to determine the optimal configuration of patient photographs (Figure 1). The design at the different sites is based on the functionality of the EHR systems. In Allscripts, clinicians randomized to the intervention arm will be shown a verification alert with a patient photograph at the time of placing orders; clinicians randomized to the control arm will be shown the alert with an avatar indicating the patient's sex (Figure 2). Epic has the functionality to display a patient photograph in the banner at the side of the screen (called Storyboard in Epic) and in a verification alert at the time of placing orders (Figure 3). Therefore, in Epic clinicians will be randomized to one of four conditions: 1) no photo; 2) photo displayed in Storyboard only; 3) photo displayed in the alert only; or 4) photo displayed in both Storyboard and in the alert.

| 2-Arm Randomized Trial in Allscripts | |
|---|---|
| **Alert with No Photo** | **Alert with Photo** |
| **2X2 Factorial Randomized Trial in Epic** | |
| **No Photo in Storyboard/ No Alert** | **Photo in Storyboard/ No Alert** |
| **No Photo in Storyboard/ Alert with Photo** | **Photo in Storyboard + Alert with Photo** |

**Figure 1. Photo Study Designs**

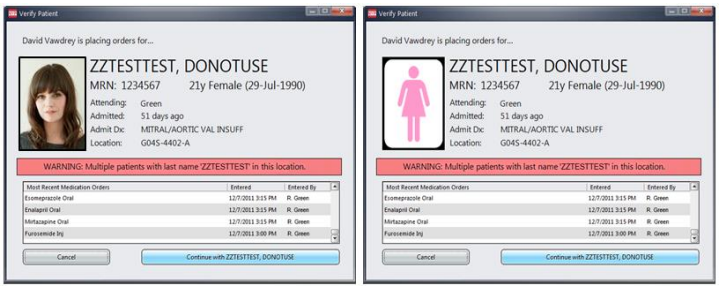


**Figure 2. Verification Alert With vs Without Patient Photo.** (not an actual patient)

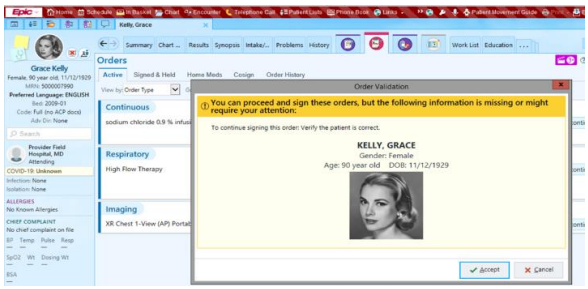


**Figure 3. Patient Photo in Storyboard and Alert.** (not an actual patient)

**Patient Inclusion Criteria.** In this study, we will include all patients for whom an electronic order is placed during the study period at the study sites. At all study sites, all patients aged 1 year and older will be included. Obtaining a photograph at registration is standard procedure at the participating study sites. Patients are not required to provide written or oral consent to have their photograph taken, as the photographs are used as part of routine care. However, patients or their legal guardians may refuse.

**Clinician Inclusion Criteria.** Any clinician who can place an electronic order can potentially place an order on the wrong patient. We will therefore include in the study all clinicians who place an electronic order at the study sites during the course of the study period.

**Randomization.** For the Patient Photo study in Allscripts at NYP Hospital, a simple random allocation scheme to intervention or control (1:1 per the 2-arm design) will be utilized. A computerized random number generator allocates a unique identifier to each EHR user when the user's account is created. Numbers are divided into two groups (even and odd), which are expected to have an equal frequency. For the Patient Photo study in Epic, a simple random allocation scheme will be utilized to assign clinicians to one of four study groups (1:1:1:1 per the 2x2 design). Each study site will generate a list of ordering clinicians to be randomized, replace identifiers with coded pseudo-identifiers, then transfer the de-identified list to the study biostatistician at Columbia for randomization. Randomization will be performed centrally using a statistical software program. De-identified lists for the four study groups will be transferred to each study site to be re-identified and uploaded into study groups in Epic using the Grouper function. Custom functionality has been built within Epic to enable randomization to the four study groups and the corresponding configuration of photos for each group. Randomization procedures will be repeated periodically throughout the study period to assign new clinicians to study groups.

Clinician types whose prior ordering volumes are not representative of their future ordering volume (e.g., low ordering clinicians anticipated to be high ordering clinicians) will be placed in one of two strata (anticipated high orderers or anticipated low orderers) and similarly randomized. Clinician type is associated with anticipated ordering pattern, i.e., attending physicians place few orders, advanced practice clinicians place the most orders, and trainees place a relatively high volume of orders. New clinicians will be randomized by clinician type, within site, without differentiating anticipated high or low order volume.

For the duration of the study, once randomized, clinicians will not be able to switch study groups or withdraw from the study.

**Primary Outcome.** The primary outcome is the frequency of Retract-and-Reorder (RAR) events, identified using the RAR measure, defined as an order that is placed for a patient, then retracted within 10 minutes, and then placed by the same clinician for a different patient within 10 minutes of the retraction.

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

**Clustering of Orders within Order Sessions.** If a clinician begins placing orders in the wrong patient's record, there is the possibility that several such orders will be placed consecutively and then all retracted together. Therefore, individual orders do not represent *independent* opportunities for RAR events to occur. Rather, orders are clustered within order sessions. An order session is defined as a series of orders placed by a clinician for a single patient that begins with opening that patient's order file and terminates when an order is placed for another patient or after 60 minutes, whichever comes first.

**Clinician Level, Patient Level, Order-Session Level, and Order Level Covariates.** The data for this study will have a nested, hierarchical structure with orders clustered within order sessions, and order sessions clustered within clinicians. The analysis will account for this hierarchical structure. We will also extract from the electronic medical record attributes of the clinician, patient, order session, and order.

Clinician level covariates: type of ordering clinician (attending, resident, medical student, physician assistant, nurse practitioner, or other), department, and total number of orders placed during the study period (a measure of the frequency with which the clinician uses the system).

Patient level covariates: date of birth, age, race, ethnicity, sex, insurance status, unit, date and time of admission, and date and time of discharge.

Order-session level covariates: location of the order session (medical-surgical unit, intensive care unit, labor and delivery, pediatrics, other specialty floors), date and time of the start of the order session and date and time of the first retracted order, and duration of the order session.

Order level covariates: type of order placed (medication, radiology, lab, nursing, other).

**Primary Analysis.** The dependent variable is the proportion of order sessions that contain at least one order that was retracted and reordered (an RAR event). Inference about effectiveness of the intervention will be based on a Wald test of the coefficient of an interaction term between study-arm assignment and an indicator of pre- or post-intervention time period. The estimate of effectiveness will be the odds ratio (exponentiated coefficient) reported with its 95% confidence interval. With randomization at the clinician level, patient and order session level attributes may not be evenly distributed across groups. To reduce confounding bias, covariates at these levels that are both differentially distributed in the study groups and associated with the outcome will be included in this primary analysis. Clinician-level covariates will likely be balanced across study groups by randomization and will be included in this primary analysis only if descriptive statistics show otherwise.

**Missing Data.** Due to the automatic functioning of the EHR, we expect there will be no missing data concerning Retract-and-Reorder events, the mode of intervention group vs. control group, or the clinician-level covariates. There may be sporadic missing information regarding the patient-level covariates. In a prior RAR data set consisting of 11.6 million order sessions, 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 believe 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 the data are missing at random and will apply multiple imputation with chained equations.

## Methods for Aim 1 and 2: Photograph Study

**2-Arm RCT: Statistical Power/Sample Size.** The overall design is a randomized trial, with order-session observations nested within randomized clinicians. The number of clinicians is a fixed attribute of the study site and is not subject to investigator control. Based on preliminary data, we assume that we will obtain data on 12,000 clinicians, with half randomized to each study arm.

Over 2.5 years of observation, we will accrue an average of 5,000 order sessions per clinician, with a coefficient of variation of 1.27. We anticipate that the intra-clinician correlation for the outcome will be about 0.001. The most recently available analyses from NYP suggest that the wrong-patient order session rate (a weighted average of inpatient and outpatient rates) is about 130 per 100,000 order

sessions. Using a two-tailed test at the 0.05 significance level, this will provide >90% power to detect a 25% reduction in the wrong-patient order-session rate in the intervention group in the primary analysis.

**2x2 Factorial RCT: Statistical Power/Sample Size**. For our 2x2 factorial study, we did a statistical power simulation. We assumed, based on prior information from our studies and information reported by our collaborators elsewhere that approximately 8,268 clinicians would be randomized in 1:1:1:1 ratio to the four study arms (no photo, photo in Storyboard only, alert with photo only, photo in both Storyboard and alert). We assumed that clinicians would generate an average of 74 order sessions per month, with a Poisson distribution, and that data collection would continue for 1 year. We assumed based on our previous studies that the variance component (in the log-odds metric) at the clinician level would be 1.9 (corresponding to an intra-clinician correlation of 0.52). We assumed that the base rate of RAR events is 9 per 10,000 order sessions. We ran 400 simulations of our study under these assumptions to determine that we would have 91% power (95% CI 88%-94%) to detect an odds ratio of 0.75 (i.e., 25% reduction in RAR events) for either photo intervention (in Storyboard or in alert) compared to no intervention. Our power to detect an additional 15% reduction by the combination of photo interventions (both in Storyboard and in alert) compared to either alone is 99.8% (95% CI 98.6%-99.9%).

**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, a data safety monitoring committee will conduct one interim review of the data. At the midpoint of the study, 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.[21] 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 are needed to account for this.

## Methods for Aim 3

**Observations/Surveys**. We propose conducting an evaluation to assess barriers and facilitators that impact the implementation of patient photos in the EHR system. We will use anonymous surveys and observations; no individual identifiers will be collected. The purpose of this evaluation is to 1) elicit staff feedback about their experience during the photo implementation and registration process, 2) elicit patient feedback on their reasons for declining to be a part of the photo implementation process in the EHR, and 3) document observations of the photo implementation and registration process. Staff and patients will be assured that participating in the study is completely voluntary and will not affect staff's professional standing in any way or the standard quality of care the patient receives. All responses will be shared only with research personnel and will have no identifying information. The surveys and observation tool are attached in the Documents section.

**Focus Groups/Interviews**. We propose conducting a qualitative evaluation consisting of focus groups or interviews at participating study sites to elicit user experience of the photograph feature in the different EHRs, benefits of patient photographs, and barriers to adoption. Lena Mamykina, PhD, Assistant Professor of Biomedical Informatics at Columbia University, will lead the user experience and usability evaluation. The focus groups/interviews will be facilitated using semi-structured interview guides. Dr. Mamykina will conduct separate focus groups/interviews for clinicians and registrars at the three participating study sites. As a result of the activities proposed in this Aim, we will develop a rich understanding of user experiences with different patient photograph features and

local factors that impact adoption.
**Recruitment**. For the staff survey, an electronic survey link will be sent to all registration staff by email providing information about the study and asking them to complete the anonymous survey. The Recruitment Email is attached in the Documents section. For the patient survey, patients who decline to have their photograph taken and uploaded into the EHR system will be approached by a Research Assistant and asked to participate in a brief survey about why they declined. For the observation component, a Research Assistant will use an observation tool to record a sample of registrations and document the process.

For focus groups and interviews, we will recruit approximately 75 individuals (25 at each study site: Columbia, Weill Cornell, Johns Hopkins) exposed to patient photograph features or involved in implementation in two EHR systems (Allscripts and Epic). We will recruit the following individuals: 1) patients, 2) clinicians, and 3) registration staff who experienced patient photographs during the study period. For the three participating sites, we plan to recruit 2-5 individuals in each category. Recruitment will be conducted by email using information sheets to describe the study. Verbal consent will be obtained for those who agree to participate (see Protection of Human Subjects addendum).

**Data Collection, Management, and Analysis**. All data for observations and surveys will be collected using Qualtrics, an online survey and research tool available at Columbia. The survey items will be analyzed using descriptive statistics. The data will use dummy subject ID numbers and will have no identifiers that can be traced back to an individual.

Focus group/interview guides will be designed to address relevant questions for each group; a preliminary semi-structured interview guide for clinicians and registration staff is attached. For clinicians, the focus will be on experience using the photograph features, perceived benefits, limitations in their design, and impact on clinical workflows. For registrars, the main focus will be on the perceived impact of taking photographs on time, patient triage, and workflows. All interviews will be audio recorded and transcribed verbatim for analysis, with identifiers deleted.

To analyze the interviews, we will use inductive thematic analysis. With supervision by Dr. Mamykina, members of the research team with experience in qualitative research will review and code all transcripts. The investigators will initially code data collectively, discussing emerging categories and resolving any disagreements, and develop a preliminary coding scheme. Then, investigators will code independently, and meet to review the transcripts and selected codes to resolve any inconsistencies. Once coding is complete, an independent investigator will review and code a subset of data (5%-10%) to assess inter-rater reliability. We will use triangulation and member checks to increase validity and decrease bias.

## PROTECTION OF HUMAN SUBJECTS

**Potential Risk**. This randomized controlled trial does not present more than minimal risk to either patients or clinicians and does not involve any additional procedures for which verbal or written consent is normally required. Patients will be receiving clinical care in accordance with best practices and their clinicians' discretion. On admission, patients have the option of having their photograph taken as part of the hospital's identification registration system. Patients who participate are not required to provide written or oral consent to have their photograph taken, as the photographs are used as part of routine care. To ensure confidentiality, the analytic data set will not include patient names or patient photographs, and patient medical record numbers and account numbers will be replaced with pseudo-identifiers. In addition, all clinician identifiers will be removed from data sets prior to analysis to protect clinicians' identities; a pseudo-identifier will be used instead.

**Consent**. The proposed research project does not present more than minimal risk of harm to subjects, and the research does not involve any procedures for which written consent is normally required. As such, per the code of Federal Regulations Title 45, Part 46.116 (d), we ask the IRB to waive informed consent for Aims 1, 2, and 3, and have completed the Waiver of Consent form for clinicians and patients regarding the analysis of primary outcome data.

For Aim 3, our approach to informed consent includes verbal consent from clinicians to participate in focus groups and written consent from patients for usage of photos from their EHR.

**Data Security.** Identifying information, including patient medical record numbers and clinician ID numbers, will be replaced by pseudo-identifiers. Dates may be retained, including order dates and discharge dates, in Limited Data Sets. Data will be stored in password-protected computers in locked offices, and all computers are encrypted to meet the security standards set forth by Columbia University and NYP. Data files will be imported into the native format of the statistical program used for analysis. Only the PI and co-investigators will have access to the data. All data transfers between study sites will occur using secure file transfer protocols. Columbia University Medical Center Patient Safety Research, Division of General Medicine will receive the data. Data will be transferred for analysis to the study biostatistician, Dr. Clyde Schechter, at Albert Einstein College of Medicine. Information will not be released except as necessary for monitoring by the Institutional Review Board. As such, per the Code of Federal Regulations Title 45, Parts 160 and 164 (a), we seek an exemption to the requirement for use of the HIPAA Authorization form and have completed the HIPAA Waiver of Authorization (Form B).

**Adverse Events.** Any events that are brought to the investigators' attention during the course of the study will be investigated and reviewed by the data safety monitoring committee (DSMC) and brought to the attention of the IRB.

**Communication with Clinicians.** At the start of the randomized controlled trial, investigators will explain the purpose of the study to clinical staff via email using a message crafted by the study team. The message will assure clinicians that data will be kept confidential and participation carries no risk to them. It will also note that for the duration of the study, clinicians will not be able to switch study groups.

One of the study sites, Johns Hopkins Medicine's IRB, recommended that the study team not send out a communication in advance informing clinicians of the study, and also recommended not allowing clinicians to withdraw from the study, so as not to introduce a significant bias to the study results.

At Columbia University Irving Medical Center and Weill Cornell Medicine, an IRB-approved communication informing all ordering clinicians of the study was disseminated prior to the start of the intervention. However, because this is not a blinded study, and because the intervention is a visual cue aimed at preventing wrong patient errors, we do not believe Columbia and Cornell opting to disseminate a communication and Johns Hopkins opting not to send a communication will affect the results of the study.

**Potential Benefit**. There is no anticipated benefit of participation in this study for patients or clinicians. However, we hypothesize that this randomized controlled study will demonstrate that an EHR system displaying patient photographs significantly reduces the frequency of wrong-patient orders. Because many EHR systems have the capability to display patient photos, results that clearly establish their effectiveness to prevent wrong-patient errors will provide hospitals with the evidence

needed to adopt this safety practice.

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