HIC#2000025786

Information Sheet
YALE UNIVERSITY

Participating centers include:
YALE UNIVERSITY SCHOOL OF MEDICINE – YALE-NEW HAVEN HOSPITAL
YALE UNIVERSITY SCHOOL OF MEDICINE – YALE-NEW HAVEN HOSPITAL: SAINT RAPHAEL CAMPUS
GREENWICH HOSPITAL
LAWRENCE AND MEMORIAL HOSPITAL
BRIDGEPORT HOSPITAL
WESTERLY HOSPITAL

Title: Electronic Alerts for Acute Kidney Injury Amelioration (ELAIA-2): A Multi-Center, Randomized, Controlled Trial

Principal Investigator: F. Perry Wilson, MD MSCE

Funding Source: National Institutes of Health, National Institute of Diabetes and Digestive and Kidney Diseases

Research Study Summary:

- We are asking you to join a research study.
- The purpose of this research study is to determine whether an automated alert system for patients who develop Acute Kidney Injury (AKI) while taking a targeted nephrotoxin will improve the rates of nephrotoxin medication cessation and/or reduce the rates of AKI progression, dialysis, or mortality versus standard care.
- Study procedures will include: Any inpatient that meets KDIGO creatinine criteria for AKI development who has also received at least one dose of a targeted nephrotoxic medication (NSAID, ACE/ARB, and/or PPI) within 24 hours of AKI onset will be randomized to the alert group or usual care (no alert fired). Those in the alert group will have an alert generated within the electronic medical record system, which will consist of a "pop-up" within Epic when any provider accesses the patient's record. This alert will notify providers that the patient has AKI and has recently been given at least one dose of a nephrotoxic medication(s), which are listed. A link to the medication entry system is provided. Please note that because of the randomized nature of this trial, an alert will not fire for all patients with AKI receiving a nephrotoxic agent.
- While it is impossible to opt out of receiving alerts, following its recommendations is completely voluntary and subject to your own clinical judgement. Any data collected on provider actions and behaviors will not be linked to any individual clinicians, and no data will be collected that will tie an individual clinician to any specific outcome.

APPROVED BY THE YALE UNIVERSITY IRB 7/9/2020

- There are some risks from participating in this study. The presence of an additional alert within the medical record may contribute to alert fatigue. However, by accepting, rather than dismissing, the alert, the alert will be suppressed for the individual for 48 hours, thus reducing the number of alerts seen. Additionally, while we will be collecting data on provider behavior, such as continuation or discontinuation of targeted medications, the risk for loss of confidentiality of this information is minimal, as we will NOT link any data to individual clinicians. All such data will be stored on a secure server and only analyzed in aggregate. No study information that identifies you will be available to your supervisor.
- The study may have no immediate benefits to you. However, regardless of the outcome for patient participants, the results of these studies may lead to significant long-term benefit to both patients and providers. Positive results would lead to broader adoption of an effective alerting system that would result in improved treatment for AKI patients. A negative study would result in less enthusiastic adoption of an ineffective alerting system that would otherwise contribute to alert fatigue. We hope to encourage similarly rigorous testing of other alert systems to prevent incorporation of or altogether eliminate those that are ineffective or harmful. •

Privacy / Confidentiality

To protect your confidentiality, your name and other identifying information will not be recorded on any study documents. We will only collect information that is needed for research. Only the researchers involved in this study and those responsible for research oversight will have access to the information you provide. This research is covered by a Certificate of Confidentiality from the National Institutes of Health. The researchers with this Certificate may not disclose or use information or documents that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other action, suit, or proceeding, or be used as evidence, for example, if there is a court subpoena, unless you have consented for this use. Information or documents protected by this Certificate cannot be disclosed to anyone else who is not connected with the research except if there is a federal, state, or local law that requires disclosure or if you have consented to the disclosure, or if it is used for other scientific research, as allowed by federal regulations protecting research subjects.

Questions

If you have any further questions about this study, you may contact the investigator, F. Perry Wilson (203-737-1704). If you would like to talk with someone other than the researchers to discuss problems, concerns, and questions you may have concerning this research, or to discuss your rights as a research subject, you may contact the Yale Human Investigation Committee at (203) 785-4688.