nature portfolio

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Reporting Summary

Nature Portfolio wishes to improve the reproducibility of the work that we publish. This form provides structure for consistency and transparency in reporting. For further information on Nature Portfolio policies, see our Editorial Policies and the Editorial Policy Checklist.

Statistics

For all statistical analyses, confirm that the following items are present in the figure legend, table legend, main text, or Methods section.

n/a	Confirmed	
☐	☒	The exact sample size (*n*) for each experimental group/condition, given as a discrete number and unit of measurement
☐	☒	A statement on whether measurements were taken from distinct samples or whether the same sample was measured repeatedly
☐	☒	The statistical test(s) used AND whether they are one- or two-sided *Only common tests should be described solely by name; describe more complex techniques in the Methods section.*
☐	☒	A description of all covariates tested
☐	☒	A description of any assumptions or corrections, such as tests of normality and adjustment for multiple comparisons
☐	☒	A full description of the statistical parameters including central tendency (e.g. means) or other basic estimates (e.g. regression coefficient) AND variation (e.g. standard deviation) or associated estimates of uncertainty (e.g. confidence intervals)
☐	☒	For null hypothesis testing, the test statistic (e.g. *F*, *t*, *r*) with confidence intervals, effect sizes, degrees of freedom and *P* value noted *Give P values as exact values whenever suitable.*
☒	☐	For Bayesian analysis, information on the choice of priors and Markov chain Monte Carlo settings
☐	☒	For hierarchical and complex designs, identification of the appropriate level for tests and full reporting of outcomes
☐	☒	Estimates of effect sizes (e.g. Cohen's *d*, Pearson's *r*), indicating how they were calculated

Our web collection on statistics for biologists contains articles on many of the points above.

Software and code

Policy information about availability of computer code

Data collection	SQL queries to EHR data warehouse
Data analysis	SAS 9.4 Copyright(c) 2002-2012 by SAS Institute Inc, Cary, NC, USA. We will share our SAS statistical analysis code, along with our data as mentioned below, within 6 months of publication on a public repository such as PhysioNet that provides functionality for users to register, agree to terms of use, and provide evidence of human subjects research training prior to downloading. Site A used MS SQL server 2012 and site B used MS SQL server 2014.

For manuscripts utilizing custom algorithms or software that are central to the research but not yet described in published literature, software must be made available to editors and reviewers. We strongly encourage code deposition in a community repository (e.g. GitHub). See the Nature Portfolio guidelines for submitting code & software for further information.

Data

Policy information about availability of data

All manuscripts must include a data availability statement. This statement should provide the following information, where applicable:

- Accession codes, unique identifiers, or web links for publicly available datasets
- A description of any restrictions on data availability
- For clinical datasets or third party data, please ensure that the statement adheres to our policy

Data Availability: We will make our de-identified outcomes data publicly available within 6 months of publication with no anticipated end date. This will include data dictionaries and de-identified individual shift level and encounter level data for our primary and secondary outcomes. We will make the data available on a public repository, such as PhysioNet, that provides functionality for users to register, agree to terms of use, and provide evidence of human subjects research training prior to downloading. The CONCERN EWS algorithm is considered intellectual property that will not be shared but is described in our online supplement.

Research involving human participants, their data, or biological material

Policy information about studies with human participants or human data. See also policy information about sex, gender (identity/presentation), and sexual orientation and race, ethnicity and racism.

Reporting on sex and gender	Sex is reported per intervention arm in Table 1 Characteristics of Hospital Encounters During the Trial. Patients' sex data was derived from each patient's EHR record data on our EHR data warehouse (and therefore the provenance of sex data includes both self-reported and assigned) and was used as a covariate in the analysis. These data are also reported in extended data eTable1 broken down per site and intervention arm. Gender was not used in the analysis due to the inconsistent unavailability of data in the EHR for the patient population.
Reporting on race, ethnicity, or other socially relevant groupings	Race, ethnicity, and primary language (English or not English) are reported per intervention arm in Table 1 Characteristics of Hospital Encounters During the Trial. These data were derived from each patients' EHR record data on our EHR data warehouse. These data are also reported in extended data eTable1 broken down per site and intervention arm.
Population characteristics	Age, Charlson comorbidity scores and discharge disposition are reported in Table1 Characteristics of Hospital Encounters During the Trial. These data are also reported in extended data eTable1 broken down per site and intervention arm. We also report extended data eTabel2 the Top Admission and Principal Diagnoses across sites.
Recruitment	Individual study units across the 4 hospitals included all non-specialty acute care units (ACUs) and ICUs. Specialty ACUs, such as oncology, psychiatric, and rehabilitation, were excluded. Randomization was performed at the unit level and stratified by site prior to trial initiation. Each study unit (ACU or ICU) was randomly allocated to one of 2 groups (CONCERN EWS intervention or usual-care) using a computer-generated randomization scheme. The trial included 74 clinical units (37 intervention, 37 usual-care) with the following distribution: Site A intervention-19 ACUs and 5 ICUs; Site A usual-care-17 ACUs and 7 ICUs; Site B intervention-9 ACUs and 4 ICUs; Site B usual-care-8ACUs and 5 ICUs (eTable1).
Ethics oversight	Columbia University and Brigham and Women's Hospital

Note that full information on the approval of the study protocol must also be provided in the manuscript.

Field-specific reporting

Please select the one below that is the best fit for your research. If you are not sure, read the appropriate sections before making your selection.

☐ Life sciences ☒ Behavioural & social sciences ☐ Ecological, evolutionary & environmental sciences

For a reference copy of the document with all sections, see nature.com/documents/nr-reporting-summary-flat.pdf

Behavioural & social sciences study design

All studies must disclose on these points even when the disclosure is negative.

Study description	1-year multi site, pragmatic, cluster-randomized clinical trial at 2 large health systems in the Northeastern United States. The objective of this study was to determine at the individual patient level whether CONCERN EWS led to a decrease in primary outcomes (in-hosptial mortality and LOS) and influenced secondary outcomes (cardiopulmonary arrest, sepsis, unanticipated ICU transfers, and 30-day readmission). We hypothesized a priori that patients whose care team received CONCERN EWS risk scores would have lower mortality and LOS than a control group of patients with non-EWS informed teams.
Research sample	This clinical trial took place at 2 large health systems in the Northeastern United States. Each system was a study site (A and B), and sites A and B each comprise 1 academic medical center and 1 community hospital. Individual study units across 4 hospitals included all non-specialty acute care units (ACUs) and ICUs. Specialty ACUs, such as oncology, psychiatric, and rehabilitation, were excluded. The research sample consisted of 60,893 hospital encounters from two large U.S. health systems, including 33,024 encounters in the CONCERN intervention group and 27,869 in the usual-care group. Participants were adult patients (aged ≥18 years) admitted to

acute and intensive care units, with exclusions for those receiving hospice, palliative care, or with pre-existing Do Not Resuscitate/Do Not Intubate orders

• Age: Mean age was 62.62 years (SD = 17.56) in the intervention group and 63.67 years (SD = 17.10) in the usual-care group.
• Sex: The sample was nearly balanced by sex, with 48.62% male in the intervention group and 50.11% male in the usual-care group.
• Race: Race of patients included White (57.30% intervention; 58.41% usual-care), Black (14.77% intervention; 15.16% usual-care), Asian (2.13% intervention; 2.27% usual-care), and Other or Missing (25.80% intervention; 24.16% usual-care).
• Ethnicity: Not Hispanic or Latino (71.52% intervention; 72.86% usual-care), Hispanic or Latino (22.54% intervention; 21.18% usual-care), and Unknown/Not Reported (5.95% intervention; 5.96% usual-care).
• Primary Language: Approximately 81% of patients in both groups spoke English as their primary language.

The sample is broadly representative of hospitalized adult inpatients in urban U.S. healthcare settings but may not be fully generalizable to rural hospitals or smaller community health systems due to potential differences in patient demographics.

Sampling strategy

Randomization was performed at the unit level and stratified by site prior to trial initiation. Power analysis comparing mortality rates between groups estimated a 1-year trial on the targeted units at our 2 sites would result in sufficient sample size for at least 80% statistical power to detect a difference of less than 1% relative difference in mortality rates (2-sided; alpha=.05)(eTable4).

Data collection

Primary outcomes were in-hospital mortality rate and LOS. Secondary outcomes were rates of cardiopulmonary arrest, sepsis, unanticipated ICU transfer, and 30-day hospital readmission. See Table1 for definitions. All data were collected from the EHR and evaluated and reported across study sites. More than one author (Cato, Rossetti, Lowenthal, Jia, Tran, Withall, Lee) have directly accessed and verified the underlying data reported in the manuscript. In addition, we performed randomly selected chart reviews on 10% of the sample per outcome per site to validate our outcome definitions and extractions. The researchers were not blinded to the experimental condition or the study hypothesis. As a pragmatic cluster-randomized controlled trial, the allocation of units to either the intervention or usual care group was known to the study team.

Timing

Outcomes data were collected for all patients admitted to our study units during the trial dates: At Site A, the first inpatient hospital admission for the cohort was October 1, 2020, the last inpatient hospital admission of the cohort was October 31, 2021, and the last inpatient hospital discharge of the cohort was March 30, 2022. At Site B, the first inpatient hospital admission was October 1, 2021, the last inpatient hospital admission was October 30, 2022, and the last inpatient hospital discharge was December 26, 2022.

Data exclusions

Patients on study units were included in the analyses if they were 18 years of age and older, hospitalized for greater than 24 hours (EWS score begins displaying after 24 hours), admitted to a study unit for a minimum of 12 hours, and free from any in-hospital event (including discharge) until at least 6 hours after study unit admission. Hospice and palliative care patients and patients with do not resuscitate/do not intubate and comfort care orders activated prior to any trial outcome event were excluded.

Non-participation

N/A; this field is not applicable to the study because the research was conducted as a pragmatic cluster-randomized controlled trial with waived individual patient consent.

Randomization

Randomization was performed at the unit level and stratified by site prior to trial initiation. Each study unit (ACU or ICU) was randomly allocated to one of the 2 groups (CONCERN EWS Intervention or usual-care) using a computer-generated randomization scheme.The trial included 74 clinical units (37 intervention, 37 usual-care) with the following distribution: Site A intervention-19 ACUs and 5 ICUs; Site A usual-care-17 ACUs and 7 ICUs; Site B intervention-9 ACUs and 4 ICUs; Site B usual-care-8ACUs and 5 ICUs (eTable1). The intervention (CONCERN EWS prediction risk score) was displayed to a patient's care team consisting of nurses and prescribing providers (i.e., physician, nurse practitioners, physician assistants) only if that patient was admitted to an intervention-assigned unit. The intervention was not displayed to care teams of patients admitted to usual-care assigned units.

Reporting for specific materials, systems and methods

We require information from authors about some types of materials, experimental systems and methods used in many studies. Here, indicate whether each material, system or method listed is relevant to your study. If you are not sure if a list item applies to your research, read the appropriate section before selecting a response.

Materials & experimental systems

n/a	Involved in the study
☒	☐ Antibodies
☒	☐ Eukaryotic cell lines
☒	☐ Palaeontology and archaeology
☒	☐ Animals and other organisms
☐	☒ Clinical data
☒	☐ Dual use research of concern
☒	☐ Plants

Methods

n/a	Involved in the study
☒	☐ ChIP-seq
☒	☐ Flow cytometry
☒	☐ MRI-based neuroimaging

Clinical data

Policy information about clinical studies

All manuscripts should comply with the ICMJE guidelines for publication of clinical research and a completed CONSORT checklist must be included with all submissions.

Clinical trial registration	NCT03911687
Study protocol	Please see in our Supplement materials submitted online section sMethods1 which provides a summary of changes in our final analysis plan. Our original study protocol was published here: https://pubmed.ncbi.nlm.nih.gov/34889766/
Data collection	Primary outcomes were in-hospital mortality rate and LOS. Secondary outcomes were rates of cardiopulmonary arrest, sepsis, unanticipated ICU transfer, and 30-day hospital readmission. See Table 1 for definitions. All data were collected from the EHR and evaluated and reported across study sites. More than one author (Cato, Rossetti, Lowenthal, Jia, Tran, Withall, Lee) have directly accessed and verified the underlying data reported in the manuscript. In addition, we performed randomly selected chart reviews on 10% of the sample per outcome per site to validate our outcome definitions and extractions. Outcomes data were collected for all patients admitted to our study units during the trial dates: At Site A, the first inpatient hospital admission for the cohort was October 1, 2020, the last inpatient hospital admission of the cohort was October 31, 2021, and the last inpatient hospital discharge of the cohort was March 30, 2022. At Site B, the first inpatient hospital admission was October 1, 2021, the last inpatient hospital admission was October 30, 2022, and the last inpatient hospital discharge was December 26, 2022.
Outcomes	Primary outcomes were in-hospital mortality rate and length of stay. Secondary outcomes were rates of cardiopulmonary arrest, sepsis, unanticipated ICU transfer, and 30-day hospital readmission. See Table 1 for definitions. All data were collected from the EHR and evaluated and reported across study sites.

Plants

Seed stocks	N/A
Novel plant genotypes	N/A
Authentication	N/A