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STATE-OF-THE-ART REVIEW

REVeAL-HF

Design and Rationale of a Pragmatic Randomized Controlled Trial Embedded Within Routine Clinical Practice

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HIGHLIGHTS

- The large gap between accurate prognostication and clinical decision making in HF is an important cause of misutilization of therapies and potential adverse events.
- Giving providers accurate information about their hospitalized patient's prognosis can improve appropriate clinical interventions and result in better patient outcomes.
- Treatment decisions in HF should be rooted in accurate prognostication to appropriately inform patients about the risk and benefits of recommendations.
- The EHR can be used highly effectively, even in times of a pandemic, to automate enrollment and follow-up of patients with HF.

ABSTRACT

Heart failure (HF) is one of the most common causes of hospitalization in the United States and carries a significant risk of morbidity and mortality. Use of evidence-based interventions may improve outcomes, but their use is encumbered in part by limitations in accurate prognostication. The REVeAL-HF (Risk EValuation And its Impact on ClinicAL Decision Making and Outcomes in Heart Failure) trial is the first to definitively evaluate the impact of knowledge about prognosis on clinical decision making and patient outcomes. The REVeAL-HF trial is a pragmatic, completely electronic, randomized controlled trial that has completed enrollment of 3,124 adults hospitalized for HF, defined as having an N-terminal pro-B-type natriuretic peptide level of >500 pg/ml and receiving intravenous diuretic agents within 24 h of admission. Patients randomized to the intervention had their risk of 1-year mortality generated with information in the electronic health record and presented to their providers, who had the option to give feedback on their impression of this risk assessment. The authors are examining the impact of this information on clinical decision-making (use of HF pharmacotherapies, referral to electrophysiology, palliative care referral, and referral for advanced therapies like heart transplantation or mechanical circulatory support) and patient outcomes (length of stay, post-discharge 30-day rehospitalizations, and 1-year mortality). The REVeAL-HF trial will definitively examine whether knowledge about prognosis in HF has an impact on clinical decision making and patient outcomes. It will also examine the relationship between calculated, perceived, and real risk of mortality in this patient population. (Risk EValuation And Its Impact on ClinicAL Decision Making and Outcomes in Heart Failure [REVeAL-HF]; NCT03845660).
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ABBREVIATIONS AND ACRONYMS

BPA = best practice alert

EHR = electronic health record

HF = heart failure

NT-proBNP = N-terminal pro-B-type natriuretic peptide

The majority of clinical interventions for heart failure (HF) are anchored in assessments of individual patient risk. Societal guidelines, however, do not contain risk-based recommendations; rather, they base them on classification schemata risk such as the New York Association functional classification system or left ventricular ejection fraction, both of which are widely recognized as highly imprecise predictors of disease progression and adverse clinical outcomes (1,2). Numerous risk scores for patients with HF have been developed but they are almost never used clinically for a variety of reasons: being burdensome to calculate, lack of generalizability, outdatedness, outputs that are not clinically meaningful, and absence of integration into the clinical workflow (3–8). As a result, the onus for risk prediction is placed on the subjective estimations of individual clinicians.

This gap between accurate prognostication and clinical decision making at the bedside is in part responsible for the dismal outcomes among patients with HF; the syndrome remains the most common cause of hospitalizations in the United States—nearly 50% patients are hospitalized within 6 months of discharge—and carries a risk of death that exceeds most cancers (9,10). These poor outcomes have persisted despite the emergence of several highly effective therapies that can lead to large decreases in rates of adverse outcomes; despite this, use of these therapies remains remarkably low (11). Accurate risk stratification can lead to improved delivery of individualized care by tailoring therapies, strategies of care, and post-discharge follow-up plans. Closing the gap between prediction and clinical care is postulated to be an important cause of misutilization of therapies that contribute to the high rates of adverse events in this this patient population.

CHALLENGES WITH RISK SCORES IN PATIENTS HOSPITALIZED FOR HF

Numerous risk scores have been developed for patients with HF, a subset of them for those who are hospitalized. These scores—derived from large clinical trials and registries—are rarely used at the bedside for several reasons. First, most of them are more than a decade old, rendering their applicability outmoded for current practice. Second, they include variables cannot be directly calculated from variables in the electronic health record (EHR), adding a degree of inconvenience that clinicians have not wanted to negotiate (12–15). Third, their output has generally not been in terms that are understandable to frontline clinician who prefer straightforward categorizations to complex ones, even at the expense of lower discrimination (16). We aimed to finally traverse these by designing and carrying out the first randomized controlled trial examining the clinical impact of risk stratification at the bedside of patients hospitalized for HF.

THE REVeAL-HF CLINICAL TRIAL

We hypothesized that giving providers accurate information about their hospitalized HF patient's prognosis during the usual course of clinical care will improve use of appropriate clinical interventions and result in better patient outcomes. For this reason, we are undertaking the REVeAL-HF (Risk EValuation And its Impact on ClinicAL Decision Making and Outcomes in Heart Failure) clinical trial. The REVeAL-HF trial is a pragmatic randomized controlled trial testing an electronic alert system that informs practitioners about their hospitalized HF patient's 1-year predicted mortality using validated data from the EHR. We are examining the impact of this information on clinical decision making via use of pharmacotherapies, referral to electrophysiology, palliative care referral, and use of advanced therapies like heart transplantation or mechanical circulatory support, as well as clinical outcomes including length of stay, rates of post-discharge hospitalizations, and mortality. The primary outcome will be a composite of 30-day hospital readmissions and all-cause mortality at 1 year. The secondary endpoints will be length of stay, discharge doses of HF therapies, palliative care referral, referral to electrophysiology, and referral for advanced HF therapies.

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The authors attest they are in compliance with human studies committees and animal welfare regulations of the authors' institutions and Food and Drug Administration guidelines, including patient consent where appropriate. For more information, visit the Author Center.

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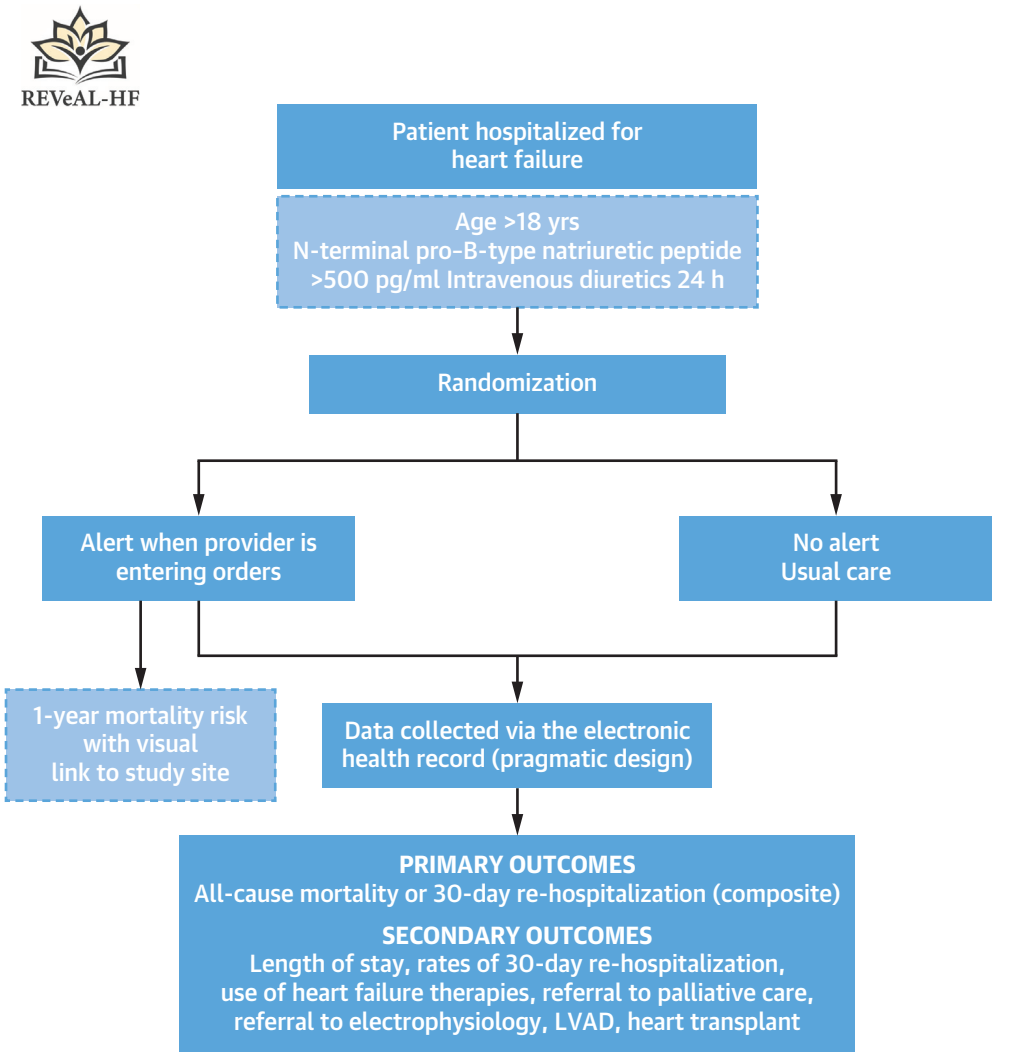
CENTRAL ILLUSTRATION Study Flow of the REVeAL-HF Clinical Trial



Ahmad, T. et al. J Am Coll Cardiol HF. 2021;9(6):409–19.

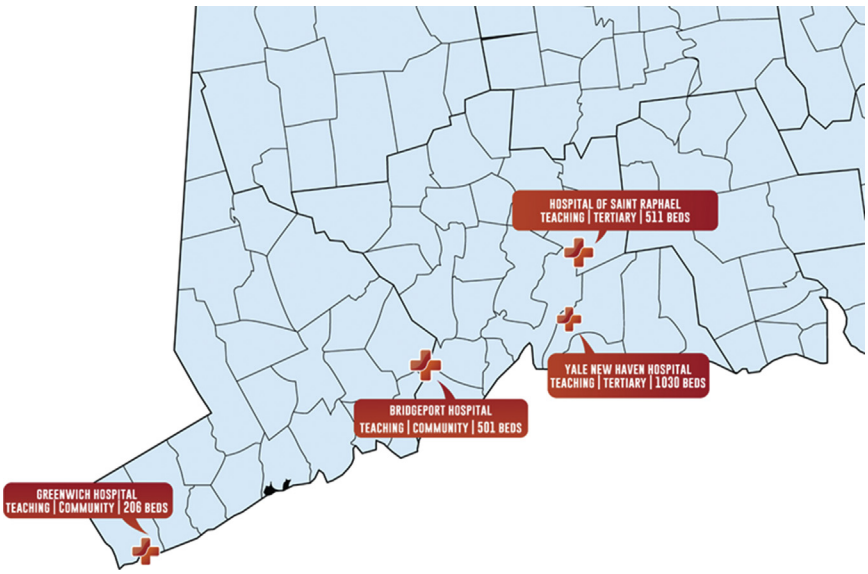
REVeAL-HF is entirely automated with study enrollment done entirely via the electronic health record and providers randomized to an informational risk alert versus usual care. The trial will examine the impact of this information about 1-year prognosis on clinical decision making and patient outcomes. EP = electrophysiology; IV = intravenous; LVAD = left ventricular assist device; NT-proBNP = N-terminal pro-B-type natriuretic peptide; REVeAL-HF = Risk EValuation And its Impact on ClinicAL Decision Making and Outcomes in Heart Failure.

The full study protocol is accessible at the clinical trial website (NCT03845660). The **Central Illustration** shows the study flow. The REVeAL-HF trial is a randomized, single-blind intervention trial that is testing the clinical impact of providing prognostic information to the provider on clinical decisions and patient outcomes. Subjects are automatically recruited when electronically identified. The inclusion criteria are all adults ≥18 years who have an NT-proBNP levels of >500 pg/ml and receive intravenous diuretic agents within 24 h of admission. The 4 participating centers are shown in **Figure 1** and are the teaching hospitals within the integrated Yale New Haven Health System with a shared EHR (Epic Systems, Verona, Wisconsin).

AUTOMATED RANDOMIZATION TO ALERTS USING THE EHR

Patients are randomized to either usual care or the intervention. In the intervention arm, a best practice

FIGURE 1 Locations of the Teaching Hospitals Within the Integrated Yale New Haven Health System



Based on our data, these centers see the majority of hospitalized heart failure patients in Southern Connecticut and almost all post-discharge clinical events occur within the system.

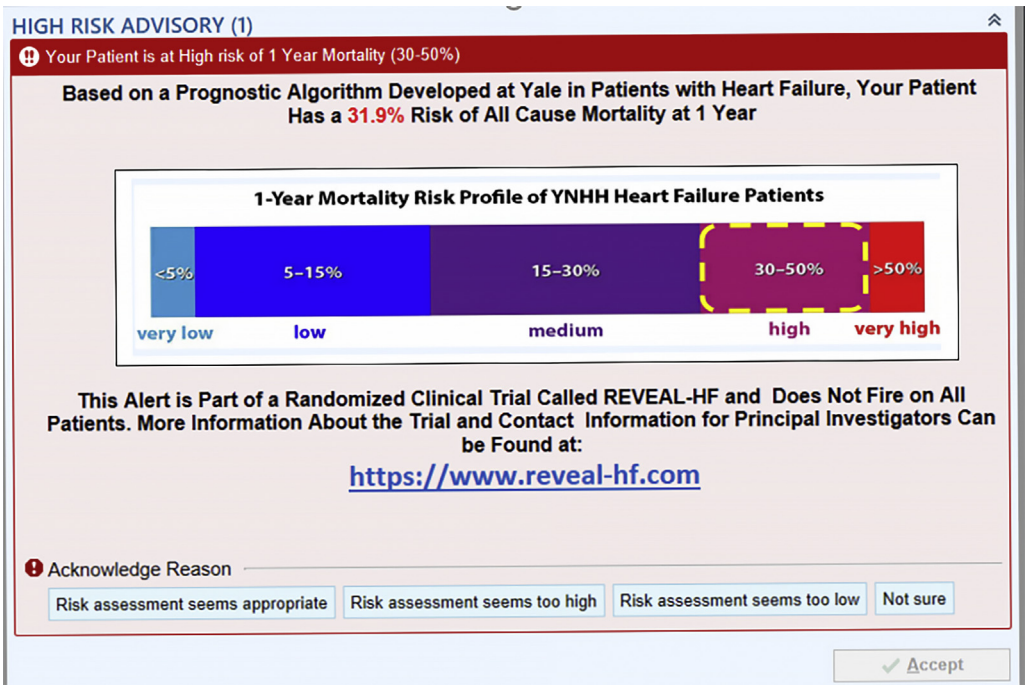
alert (BPA) displays when the provider navigates to the order entry activity within the EHR (**Figure 2**). Randomization is achieved within the Epic EHR system using an internal random number generator (17). Randomization occurs the first time the patient's chart is opened by an eligible provider after they meet study inclusion and exclusion criteria. Once randomized into either arm, the patient remains in this arm for the duration of their hospital stay. Patients randomized to the intervention have an alert of their prognosis based on the Yale New Haven Heart Failure Prognostic Model for 1-year mortality generated with information from their EHR. Providers also have access to a link to most current HF guideline recommendations via the study website. Providers who receive the alert include physicians, physician assistants, nurse practitioners, advanced practice registered nurses, fellows, and residents. The alert is displayed to the relevant provider at order entry. If a provider dismisses the alert, it continues to alert on each subsequent order entry but stops alerting if they ask to no longer see the alert, the patient is transferred to the hospice service, or the patient is discharged from the hospital.

This intervention in this study is the BPA, an embedded clinical decision support platform supported by the Epic EHR. BPAs are constructed within Epic based on a series of rules and have "trigger" conditions (i.e., actions that the user takes within the EHR to launch the BPA). In this trial, we will collect information about BPAs including the user receiving the alert, date and time of alert, as well as the specific variables that flagged the BPA to prompt. Clinician responses, aimed at measuring the perceived accuracy of the model, will also be collected. These data as well as other patient characteristics (e.g., demographics, ward location, comorbidities) will be extracted from Clarity, which is a relational database that contains patient-level data from Epic.

CREATION OF AN EHR-DEPLOYABLE 1-YEAR MORTALITY RISK SCORE

Our derivation and validation datasets were based on patients from our health system to maximize generalizability. We analyzed data on patients with HF who were admitted to Yale New Haven Hospital between January 1, 2014, and April 14, 2018. Using the inclusion and exclusion criteria specified in our study and removing patients who were under comfort measures only or died within 36 h of admission yielded 7,376 unique patients. To ensure ease of integration into the EHR, we set out to find a parsimonious model through data-driven feature selection. Feature selection was performed using population-based incremental learning (18). Population-based incremental

FIGURE 2 The Risk Alert

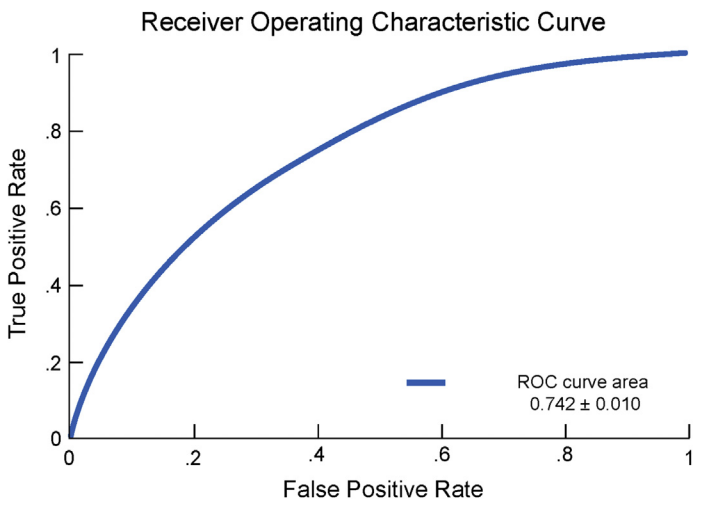


Best practice alert demonstrating risk categories that correspond with calculated risk of 1-year mortality: very low (<5%), low (5% to 15%), medium (15% to 30%), high (30% to 50%), and very high (>50%). It is also color-coded to represent the level of risk.

learning works through successively evaluating "populations" of candidate feature sets and having features with strong performance preferentially represented in successive iterations through increasing their probability of "reproduction." The evaluation of any individual feature set in a population is done in the following way. First, the data are randomly split into a training set and a validation set with balanced outcomes. Second, we preprocess the data by imputing training set medians, center and scale numeric data by training set means and SDs and clip all values at ±10 for numeric stability. Last, we fit a logistic regression model on the training set and evaluate the area under the curve on the validation set to gauge the performance of the feature set (**Figure 3**). We set the number of features considered to 15 for ease of implementation. We choose the 15 features with the highest probabilities after 500 iterations using a population size of 1,000. The final model was a logistic regression fit on the full dataset after performing similar preprocessing as before, except using statistics from the full dataset. The model's coefficients were finally transformed to work with the original feature centers and scales. The variables included in the final risk score were as follows: age, weight, systolic blood pressure, red cell distribution width, blood urea nitrogen, monocyte count, lymphocyte percentage, blood urea nitrogen-to-creatinine ratio, troponin, NT-proBNP, mean corpuscular volume, intensive care unit admission, and measurement of arterial pH. A variable for patients who were on comfort measures was in the initial risk score "codecomfort" and was removed, leaving 14 variables in total. The model achieved an area under the curve of 0.742 ± 0.010 on the full dataset (Supplemental Figure 1).

Our decision to use 15 features rather than a larger feature space was based on several considerations. First, implementation of complex algorithms or models based on large number of variables is not currently feasible in most EHR systems and will require a comprehensive move toward cloud computing approaches. Second, variables in the model must be mapped to the correct variables in the EHR. We have seen that parsimony in model variables is critical both for deployment from a logistical standpoint and for ensuring that the model behaves in a manner similar to the theoretical

FIGURE 3 Performance of the Risk Score



Receiver-operating characteristic (ROC) curve for prediction of 1-year morality with the Yale Heart Failure risk score.

model. Additionally, for any model that is implemented prospectively, variables "break"—this can occur for a variety of reasons (e.g., medications receiving a new code because they are being provided from a new manufacturer)—as such, each variable must be monitored to ensure it is still mapped appropriately over time. Last, complex models with increased variables take increased computing power to run and would slow down computing speeds across the health system preventing such a deployment. We spent several months of a "run in" period ensuring that our algorithm did not have a negative impact on this important parameter across the Yale New Haven Health System. Finally, beyond computing and implementation concerns, we believe that a parsimonious approach is more optimal for such decision support systems. Smaller models tend to be easier to interpret with more commonly seen variables (e.g., common laboratory values, common diagnoses). These are helpful to clinicians receiving the alerts to interpret the model rather than seeing it entirely as a "black box." Using models with large number of features also runs the risk of "overfitting" the data and have excellent performance on training data at the cost of poor performance on test data. We have noticed across our work on several disease processes that there is often very marginal improvement in predictability in models with increasing predictors beyond a point (19).

Our score performed favorably when compared with other published scores, with the caveat that most did not examine 1-year outcomes among hospitalized HF patients (7,20,21). There are several high-profile risk scores that are focused on short-term prediction (in hospital mortality), but our interest was in the longer-term impacts of decision making during the hospitalization. We also note that other well-performing models may perform differently and potentially worse in our patient population. Our model was "validated" in our population in the sense that the data that composed the training of the model were entirely separate from the testing data that ensured model success. Whereas most risk scores include variables cannot be directly extracted from the EHR in a streamlined fashion (e.g., New York Heart Association functional class), making point-of-care prognostication difficult (12–15).

Finally, even in the situation in which other risk models would be implementable and readily available, we believe that deploying a single model for such decision support has many advantages. First, the single model is more interpretable to a clinician, rather than an array of various models with different methodologies and potentially different outputs. Second, none of these models are commonly deployed such that clinicians would be able to readily differentiate between them to make a guided decision; this is unique from, for example, the atrial fibrillation literature in which there are both validated and already-deployed tools such as the CHA_2DS_2-VASc score.

DESIGN OF THE ALERT

The alert was developed using recommended methodologies for clinical decision support: right information, right person, right format, right channel, right workflow (22). Prior to initiation of the clinical trial, we conducted focus groups with providers who care for HF to get feedback on the EHR alert design, user friendliness, and hindrance to workflow. The alert was subsequently modified to reflect the suggestions made by the focus group (**Figure 3**). Specifically, we created risk categories that corresponded with calculated risk of 1-year mortality: very low (<5%), low (5% to 15%), medium (15% to 30%), high (30% to 50%), and very high (>50%). These were also color-coded based on feedback to represent the level of risk based on input from experts in behavioral economics from the Yale Center for Customer Insights. Prior to launch, we underwent successive "field" testing with clinicians who would be at the receiving end of the alert to ensure appropriate use of

content, color, font size, and action items. Finally, we included the option for providers to provide input of their personal assessment of the risk assessment by allowing them to select from 1 of the following options: 1) risk assessment seems appropriate; 2) risk assessment seems too high; 3) risk assessment seems too low; and 4) not sure.

CLINICIAN COMMUNICATION

Although the unit of randomization is the patient, clinicians are also the subject of research. We engaged in extensive pre-trial and periodic outreach to all clinicians who may be exposed to this study, informing them of the nature of the study, the fact that it is a randomized trial, and that alerts do not fire for all patients with HF. We informed them that limited data are being collected regarding provider behavior. This pre-trial education occurred in the form of short education presentations at group and departmental grand rounds. Further, the alert pop-up contains methods to contact the study team. Most notable, if "disagree" is clicked, a free-text box is opened that allows providers to communicate their concern directly to the team. Although piloting the pop-up in pre-trial activities, we used these responses to further tailor the language of the alert.

CLINICAL OUTCOMES OF INTEREST

The primary outcome of the study is a composite of 30-day hospital readmissions and all-cause mortality at 1 year. The secondary endpoints are length of stay, discharge doses of HF therapies, palliative care referral, referral to electrophysiology, and referral for advanced HF therapies. These outcomes were chosen because they can be objectively measured and automatically extracted from the EHR. Also, death is continuously double-checked with the National Death Index, as previously described in our recently completed trial around acute kidney injury (23). Finally, Yale New Haven Health System is an integrated health system that covers all of Southern Connecticut and the vast majority of post-discharge clinical events occur within the system.

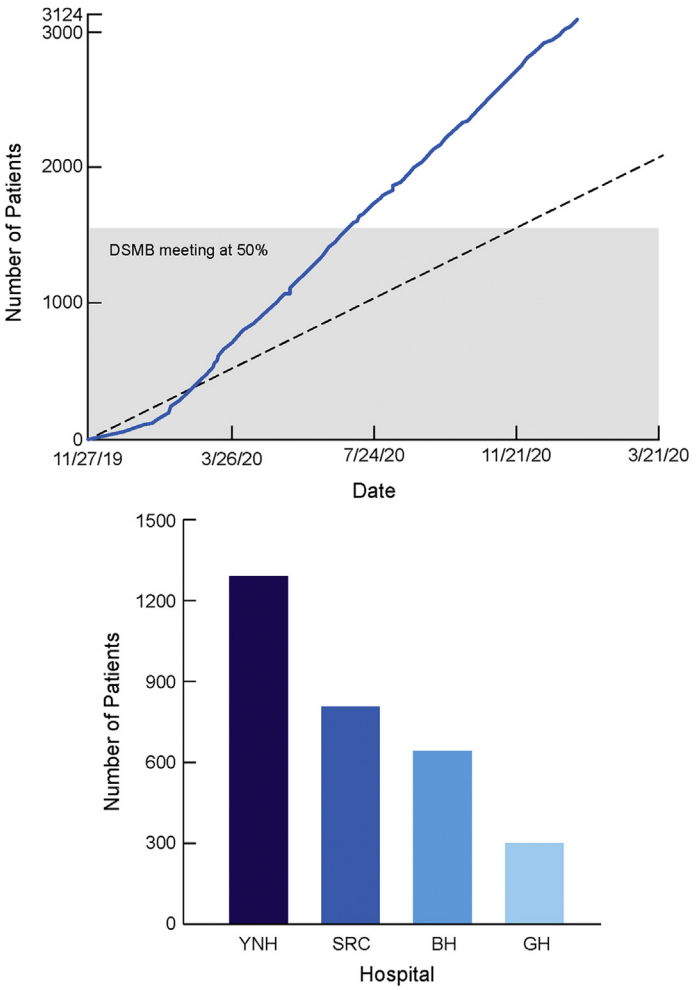
STATISTICAL CONSIDERATIONS

We estimated that the composite outcome of 30-day hospitalization and 1-year mortality occurs in approximately 30% of hospitalized patients with HF. A reduction in this proportion to 25% in the intervention arm would be considered clinically meaningful. To that end, a sample size of 1,562 in each arm achieves 90% power to detect a difference this large at a 2-sided alpha of 0.05 as calculated using the Cochran-Mantel-Haenszel test. This gives a total population of 3,124 individuals hospitalized with HF in order to test our primary hypothesis. The primary analysis will use the intention to treat principle. The proportion of patients experiencing the primary outcome in the intervention and control groups will be compared by the Cochran-Mantel-Haenszel test, accounting for stratification by study hospital. Statistical significance will be based on a p value of <0.05.

ETHICAL ISSUES

This study posed several ethical issues that are worthy of discussion. First, in order to efficiently proceed with the study, we obtained a waiver of informed consent. U.S. federal guidelines require that in order to obtain a waiver of consent that: 1) the research pose no more than minimal risk to the subject; 2) the waiver not adversely affect the rights and welfare of the subject; 3) the research could not be practicably carried out without a waiver; and 4) whenever appropriate, the subjects be provided with additional pertinent information after participation. We felt that our study met all of the criteria noted previously to qualify for a waiver of informed consent. As a result, subjects will not be informed of their randomization status or participation in this trial, as the trial could not be feasibly performed if subjects were told they were enrolled. Also, we do not feel that post facto informing of patients randomized in this trial is appropriate for several reasons. First, there are no guideline-based specific recommendations based on a risk score assessment, or any other prognostic assessment for that matter. Second, patients may not know how to interpret the assessment of their prognosis and this information might engender significant stress or anxiety without offering a tangible benefit. Because the intervention (alert) is a tool to make a provider aware of information already obtainable from the EHR, it is at the discretion of the provider to inform the patient of any relevant information regarding this information. We believe that the determination of the clinical impact and significance of this information rests with the clinical providers and trust that they will act ethically with regard to the disclosure of the relevant medical information. Finally, if we consented subjects, we would need to tell them that they were enrolled in a study about HF prognosis, which might lead them (and their physicians) to

FIGURE 4 Enrollment Rates for the REVeAL-HF Trial



This demonstrates the number of patients per hospital within the integrated Yale New Haven Health System. Enrollment was completed in approximately 1 year, making this the fastest heart failure trial in history. BH = Bridgeport Hospital; DSMB = Data and Safety Monitoring Board; GH = Greenwich Hospital; REVeAL-HF = Risk EValuation And its Impact on ClinicAL Decision Making and Outcomes in Heart Failure; SRC = San Hospital of Saint Raphael; YNH = Yale New Haven Hospital.

discuss or act on prognostic information differently than under the circumstance of usual care.

DATA DISSEMINATION

As we recognize the novel strategies and potential impact of our trial, we are committed to the open and timely dissemination of our data. Our trial has been registered with clinicaltrials.gov (NCT03845660) and will be continually reviewed and updated. We intend to submit the results of our trial no later than 1 year following the completion date and will include aggregate-level primary and secondary outcomes, participant demographics, statistical analyses, and any adverse events.

ENROLLMENT RATES AND THE IMPACT OF COVID-19

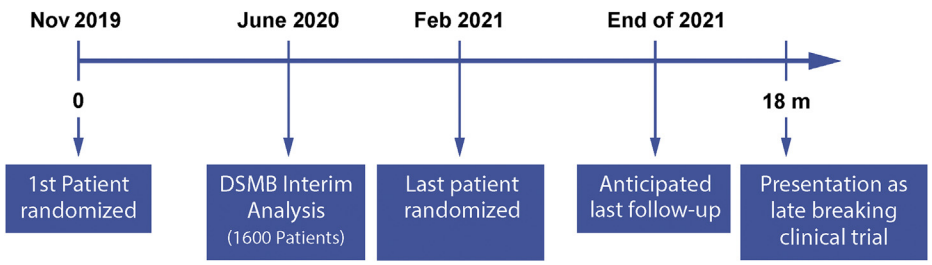
At time of submission, the REVeAL-HF trial has completed enrollment of 3,124 patients in approximately 1 year after initiation of the trial. Figure 4 demonstrates enrollment rate along with the number of patients per center. We prespecified the enrollment goals for each hospital based on their number of HF admissions. Figure 5 shows the study timeline with expected follow-up of the last patient enrolled in February of 2022 and presentation of results either the end of 2021 or early 2022.

As shown, the enrollment into the REVeAL-HF trial was not impacted by the COVID-19 (coronavirus disease-2019) pandemic despite it greatly impacting our health care system, as it has been for others (24). Our enrollment algorithm can be used at any other institution that uses the Epic EHR and we will make it available on the Epic Orchard at time of study publication. Because we made our study fully automated, patients were automatically enrolled in this minimal risk study if they received intravenous loop diuretic and have an NT-proBNP levels of >500 pg/ml within 24 h of admission. With this, we had a minimal number of COVID-19-positive patients enrolled (N = 45), and they were balanced between either arm of the study. Finally, our study was entirely embedded within the health system, with all clinical outcomes including death information, automatically ascertained from the EHR, and double checked with the National Death Index, as previously described in our recently published trial around acute kidney injury (23).

DISCUSSION

Therapeutic interventions in HF do not currently take accurate and precise risk assessments of patients into consideration. This may play an important role in the dismal state of current HF care, which remains the most common causes of hospital admission, death, and disability among adult patients in the United States. By dissociating individual patient risk from treatments, clinicians may underuse or be underaggressive with these interventions. We hypothesized that providing clinicians with a real-time assessment of their HF patient's risk would translate into better clinical decision making and thus improve patient outcomes. For this reason, we designed the REVeAL-HF clinical

FIGURE 5 Study Timeline for the REVeAL-HF Trial



As shown, all patient enrollment was completed at a single health care system in approximately 1 year and all follow-up will be completed within 18 months. Abbreviations as in Figure 4.

trial, a multicenter, randomized, single-blind, entirely electronic, pragmatic clinical trial that is the first ever such study to examine the independent impact of prognostic information on clinician behavior and patient outcomes.

Numerous risk scores have been developed over the years for HF, but none are routinely used by clinicians (7,25). Several reasons have been proposed for this (4). First, and most importantly, risk scores are derived from populations that are dissimilar from those seen in contemporary clinical settings where their predictive performance has not been validated. Second, risk scores are onerous to calculate, and not integrated into the clinical workflow. Third, they do not consider the dynamic nature of HF. Fourth, the majority of risk scores do not provide an output that is understandable to frontline clinicians. Finally, and most importantly, no HF risk score has ever been examined in the randomized controlled fashion; thus, any purported benefits remain entirely theoretical. The REVeAL-HF clinical trial was designed to address all these deficiencies. The score was created and validated from recent patients who met study inclusion and exclusion criteria within the Yale New Haven Health System, allowing for maximal generalizability. Second, the score relies entirely on data fields within the EHR, allowing for instantaneous reporting of results. Third, the score resets with updates in the patient's clinical status. Fourth, the score is outputted in a manner that is understandable to frontline clinicians; indeed, the alert was constructed with extensive input from providers who take care of patients with HF as well as experts in behavioral science. As a result, we were able to design and execute the first ever randomized controlled trial to examine the impact of prognostic information on clinical decision making and outcomes in patients hospitalized for HF.

The REVeAL-HF trial was designed to take place in the inpatient setting for several reasons. On the one hand, patients hospitalized for HF are at particularly high risk for adverse outcomes (26). Providers, on the other hand, have access to a large therapeutic armamentarium, both in terms of pharmaceuticals and devices, that has been shown to reduce adverse outcomes in this patient population (27). Remarkably simple interventions—discharging patients on a beta-blocker and angiotensin receptor antagonist—have significant impact and are now embedded into quality metrics for HF (4). Nonetheless, these are just the "tip of the iceberg," and significant gaps remain in the care of these patients that can be instituted while they are admitted to the hospital. We hypothesized that providers will be nudged to do this when randomized to information about patient prognosis, and that this behavior will lead to better outcomes (28).

Several prior studies have demonstrated that leveraging the EHR to create alerting systems can improve best practices and clinical outcomes. In 2006, a randomized trial found that alerts for "inadequate antimicrobial therapy" led to a doubling of the rate of appropriate antibiotic use in patients and cost reductions for the hospital (28). In 2012, a randomized trial of an automated alert for virological failure in 1,011 individuals with human immunodeficiency virus infection found that the alert significantly improved CD4+ cell counts and clinic follow-ups (4). Alerts have also proven beneficial in the care of patients with diabetes and other comorbid conditions. That these alerts fired in an appropriate, timely manner, and provided links to specifically actionable interventions were central to their success. In the case of HF, prior studies have demonstrated that the mere use of EHRs does not impact quality or outcomes (29). However, no study to date has examined using the EHR data to provide prognostic information

to practitioners. Therefore, there is an unmet need for research that examines whether giving providers the best available prognostic information on HF along with access to guideline-based recommendations will lead to more appropriate treatments and meaningful reductions in adverse clinical outcomes.

Whereas it is common practice to embed best practice alerts within the EHR, it is important that we examine their scientific impact in a rigorous manner. Randomized trials are of utmost importance to prevent implementation of alert systems that not only lack any demonstrable benefits on clinician behavior or patient outcomes, but also may precipitate unforeseen consequences or burdens on the health care system (30,31). The potential utility of an alert system is complicated by a variety of patient- and provider-specific factors that must be considered before its implementation. Positive outcomes on clinical efficacy should be weighed against potential risks. As an example, one frequently documented phenomenon, alert fatigue, is a decreased attention to alerts due to frequent or overabundant alerting (32–34). This may not only lead to lack of efficacy in the studied alert, but also can negatively impact pre-existing alerts once deemed successful. Further, as alert override from physicians is a common problem of current alerting systems, careful thought must be put into design and implementation of the alert so as to create elements that are likely to increase provider adherence and thus improve alert success (35–39). User feedback and positive user perception of the benefits of alerting are critical in creating successful alert systems that are well-received by providers (40,41). We took all these concerns into consideration during the design and implementation of the REVeAL-HF trial.

CONCLUSION

We developed an electronic randomized controlled clinical trial that is entirely embedded with a large integrated health care system and aims to definitively address an important clinical question in HF. The REVeAL-HF trial is designed to examine whether knowledge about prognosis in HF has a meaningful impact on clinical decision making and patient outcomes. It will also examine the relationship between calculated, perceived, and real risk of mortality in this patient population.

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KEY WORDS acute heart failure, electronic health record, randomized controlled trial

APPENDIX For a supplemental figure, please see the online version of this paper.