Data Article

Clinical trial design data for electrocardiogram artificial intelligence-guided screening for low ejection fraction (EAGLE)

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ARTICLE INFO

ABSTRACT

The article details the materials that will be used in a clinical trial - ECG AI-Guided Screening for Low Ejection Fraction (EAGLE): Rationale and design of a pragmatic cluster randomized trial [1]. It includes a clinician-facing action recommendation report that will translate an artificial intelligence algorithm to routine practice and an alert when a positive screening result is found. This report was developed using a user-centered approach via an iterative process with input from multiple physician groups. Such data can be reused and adapted to translate other artificial intelligence algorithms. This article also includes data collection forms we developed for the clinical trial aiming to evaluate the artificial intelligence algorithm. Such materials can be adapted for other clinical trials.

Specifications Table

Subject	Cardiology and Cardiovascular Medicine
Specific subject area	Heart failure
Type of data	Figure
How data were acquired	The data were obtained via the discussion within the investigative team and interviews with clinicians from a variety of specialties. The data were created by the investigators using simple software like Word and pdf.
Data format	Raw
Parameters for data collection	Data were collected via discussion and interviewers with multiple stakeholders including cardiologists, health services researchers, primary care clinicians, emergency room physicians, anesthesiologists, designers, statisticians, study coordinators, etc.
Description of data collection	Data were collected via discussion and interviews.
Data source location	Mayo Clinic Minnesota and Wisconsin United States
Data accessibility	With the article
Related research article	same author list as this paper ECG AI-Guided Screening for Low Ejection Fraction (EAGLE): Rationale and design of a pragmatic cluster randomized trial American Heart Journal 10.1016/j.ahj.2019.10.007

Value of the Data
- These data provide an example of how an artificial intelligence algorithm can be translated to practice and how to design a clinical trial to evaluate the value of the algorithm in routine clinical practice.
- Clinicians and researchers who are working on translating artificial intelligence algorithms to routine practice and who are designing clinical trials.
- Clinicians and researchers can use these materials as a start point and adapt to their own projects.

1. Data

Fig. 1 includes a clinician-facing action recommendation report with two versions – one for a negative result which requires no action, and the other for a positive result, which suggests ordering an echocardiogram. Fig. 2 is a sample email alert to clinicians when a positive screening result is detected. Fig. 3 is the baseline survey that will be administered to clinicians at the time of enrolment. Fig. 4 is the end-of-study survey that will be administered to clinicians in the intervention group at the end of the trial [1].

2. Experimental design, materials, and methods

The clinician-facing action recommendation report was developed over a period of four months (December 2018–March 2019). A multi-disciplinary team developed a prototype of the report using a user-centered iterative approach. The principal investigators of the project (a health services researcher and a cardiologist) drafted an initial prototype. The investigative team then identified major groups of clinicians who frequently order ECG (i.e., those in primary care, cardiology, emergency medicine, and anesthesiology) and introduced the tool to the leadership of these departments during face-to-face meetings. At these stakeholder meetings, the investigative team got a better understanding of their needs and solicited feedback on the new tool and the design of the report. The investigative team also asked the department leaders to suggest 3–5 practicing clinicians in each department to participate in the subsequent testing and refinement of the prototype. Two designers worked with practicing clinicians to conduct interviews and workflow observations. A series of

Test Patient   Age: XX   Sex: X   DOB: X   MC#: XXXXXX

ECG AI Guided Screening for Low Ejection Fraction (EAGLE)

ALGORITHMIC RESULTS

Screening result: NEGATIVE
Recommendation: No further testing unless indicated by other symptoms or conditions

*Results generated from ECG-based AI algorithm

AskMayoExpert: Reduced Ejection Fraction
ECG Lab: 555-555-555

The algorithm is being applied in order to screen for asymptomatic left ventricular systolic dysfunction in patients who have no other indication for echocardiography. Among patients with established heart failure, heart failure symptoms, or other indications for an echocardiogram, this algorithm should not affect your decision to order an echocardiogram.

Risk factors for heart failure, such as hypertension, obesity, diabetes, dyslipidemia, atherosclerotic disease, smoking, and alcohol abuse, should also be evaluated and managed to prevent heart failure.

The prediction algorithm was derived from a sample of Mayo Clinic patients who underwent both ECG and echocardiography. The model demonstrated a c statistic of 0.92, a sensitivity of 82.5%, a specificity of 86.8%, and an accuracy of 86.5% in a prospective validation.

Link to Nature Medicine publication

Test Patient   Age: XX   Sex: X   DOB: X   MC#: XXXXXX

ECG AI Guided Screening for Low Ejection Fraction (EAGLE)

ALGORITHMIC RESULTS

Screening result: POSITIVE
Recommendation: Consider ordering an echocardiogram

*Results generated from ECG-based AI algorithm

AskMayoExpert: Reduced Ejection Fraction
ECG Lab: 555-555-555

RECENT CV HISTORY

Prev Echo	4<=4<=4>
Stress Echo	4<=4<=4>

SCHEDULED CV PROCEDURES & TESTS

Echo	05/05/19

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Fig. 1. Sample clinician-facing report for ECG AI guided screening for low ejection fraction (EAGLE).

Dear XX -

Thank you for participating in the EAGLE trial to test the ECG AI-guided screening for low ejection fraction. This is an automated report to support your use of this new tool.

One of your patients (Patient's Name Clinic Number) had a positive screening result for reduced ejection fraction. Please review the patient's record and consider ordering an echocardiogram unless you feel an echocardiogram would be of low value within the patient's clinical context (e.g., a recent test showing normal EF or finding a low EF would not change management). Information on how to access the screening report and bill for the test can be found here (link to the FAQ hosted on mayo intranet).

If you decide not to order an echocardiogram, please let us know the reason here. This information will greatly help us refine the tool and inform future implementation efforts.

For trial related questions, please contact our study coordinator Emma Behnken (phone: 507-293-0177 Email: Behnken.Emma@mayo.edu). For clinical decision making questions, please contact Dr. Peter Noseworthy (page: 89075. Email: Noseworthy.Peter@mayo.edu).

Thank you very much!

EAGLE Trial Investigators

The content of the Redcap survey will be:

What is the reason for not ordering TTE?

·   This patient is already known to have a low EF

·   This patient had a normal EF on a recent echocardiogram (or other test) and nothing has changed since that time

·   Patient does not wish to pursue echocardiography due to cost, inconvenience, or other reason

·   I think that it is not likely that this patient has a low EF, so the potential cost/inconvenience/risk of echocardiogram is not justified

·   TTE ordered at an outside facility

·   Other, please specify_____

Fig. 2. Sample email alert to clinicians when a positive screening result is detected.

Study ID: _____

Clinician Baseline Survey

ECG AI-Guided Screening for Low Ejection Fraction (EAGLE)

1. Which of the following is your specialty?

☐ Family Medicine

☐ Internal Medicine

☐ Other, please specify: _____

2. What is your position?

☐ Physician   ☐ Physician Assistant   ☐ Nurse Practitioner

☐ Other: _____

3. How many years have you been in practice (post-residency, fellowship, or other training)? _____

4. How many years have you been part of your current care team? _____

5. Over the past 12 months, approximately what percent of your time do you work in direct patient care (include inpatient, outpatient and supervisory roles)?

☐ Less than 25%   ☐ 26-50%   ☐ 51-75%   ☐ 76-100%

6. Do you consider yourself a: ☐ Man ☐ Woman   ☐ Prefer not to say ☐ Other: _____

7. In what year were you born? _____

8. What is your race? (check all that apply)

☐ White

☐ Black or African American

☐ American Indian or Alaska Native

☐ Asian

☐ Native Hawaiian or other Pacific Islander

☐ Other, please specify: _____

☐ Prefer not to say

9. Are you Hispanic or Latino?

☐ Yes   ☐ No   ☐ Prefer not to say

10. How comfortable are you managing patients with LV dysfunction?

Not comfortable at all		Somewhat comfortable		Completely comfortable
☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

11. How often do you consult cardiology for the management of LV dysfunction?

Never		Somewhat often		Always
☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

Fig. 3. Clinician baseline survey.

Survey Instructions

We would like to get a better understanding of your experiences using the AI-enabled ECG-based screening tool for left ventricular systolic dysfunction. This information will be used to further refine the tool and inform implementation strategies. The survey should take about 2-5 minutes to complete.

Last Name: _____   First Name: _____

Location: _____   Care Team Name: _____

:

	Strongly Disagree	Disagree	Neither agree or disagree	Agree	Strongly Agree
1. The screening tool provided valuable information I cannot obtain elsewhere.					
2. I trust the information this new tool provides.					
3. Clinicians in my care team have a shared understanding of the value of this screening tool.					
4. I understand how to use the screening tool.					
5. In the event of a positive screening result, I am well prepared to discuss with my patients.					
6. I have sufficient resources to support the use of the new tool (e.g., education materials, training, and support from the investigative team and clinician champions).					
7. Leadership and management adequately support the new screening tool.					
8. The screening tool improved the care I provided to my patients.					
9. I would like to continue using the tool when the trial ends.					
10. I have no concerns related to costs for patients or the department.					

If you answer "strongly disagree" or "disagree" to any of these questions above, can you provide some more details or explanation?

Is there anything else you want to tell us about your experience or any suggestions for improvement?

Fig. 4. Clinician end-of-study survey.

prototypes were developed, tested, and revised based on these clinicians' feedback. The investigative team met regularly to discuss the iterations of the prototype and the clinicians' feedback. The prototype was also tested with five clinicians using real patient data and was then finalized based on the feedback. Other trial materials were developed by the multi-disciplinary team including physicians from cardiology and primary care, health services researchers, statisticians, and a study coordinator.

Acknowledgments

Conflict of interest

The authors declare the following financial interests: Mayo Clinic holds a patent of this technology and may receive financial benefits from it. P.A.F. and Z.I.A. may also receive financial benefits from this agreement. However, at no point will Mayo Clinic benefit financially from its use for the care of patients at Mayo Clinic.

Reference

[1] X. Yao, R.G. McCoy, P.A. Friedman, N.D. Shah, B.A. Barry, E.M. Behnken, J.W. Inselman, Z.I. Attia, P.A. Noseworthy, ECG AI-Guided Screening for Low Ejection Fraction (EAGLE): Rationale and design of a pragmatic cluster randomized trial, Am. Heart J. 219 (2019) 31–36.