# *Patient Centered Outcomes Research in the Field: Defining Patient Reported Outcomes as a Team*

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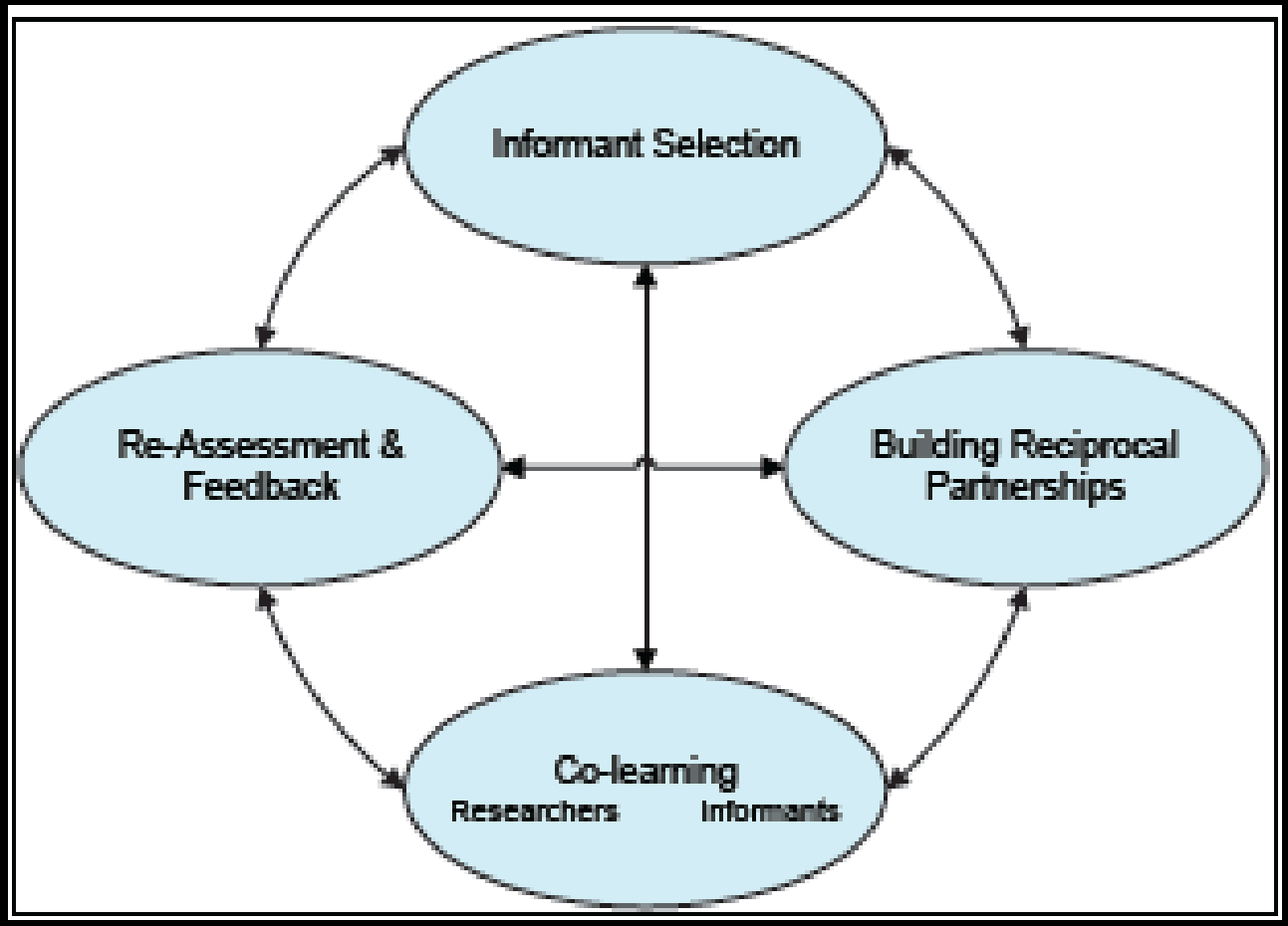
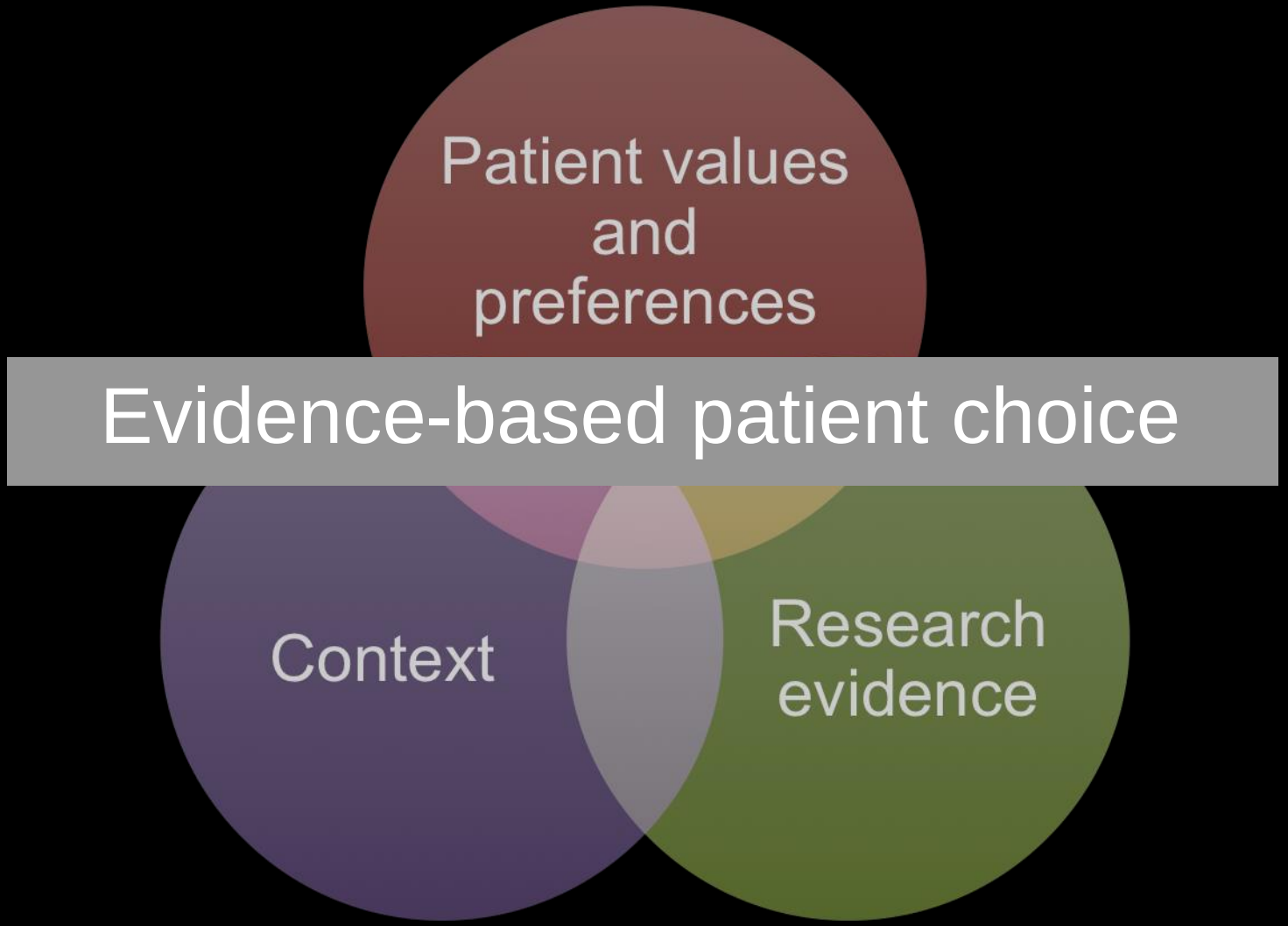
# Objectives

- Describe a paradigm to patient engagement in a clinical trial
- Consider an alternative approach to selecting and engaging patients and stakeholders in Outcome selection

# Approach to Patient and Stakeholder Engagement



# EBM 2.0


Patient values and preferences
Evidence-based patient choice
Context
Research evidence

# I. Preparatory phase

# Background

- Chest pain 2nd most common reason patients visit US EDs
- Low risk patients admitted for cardiac stress testing
- Patient anxiety and life disruption, false positive test results, ↑ procedures and cost

# Effects of Decision Aids

| Variable | Change |
|---|---|
| Patient knowledge | ↑ |
| Accuracy of risk perception | ↑ |
| Uncertainty related to feeling uninformed | ↓ |
| Major elective surgery | ↓ |
| PSA screening | ↓ |

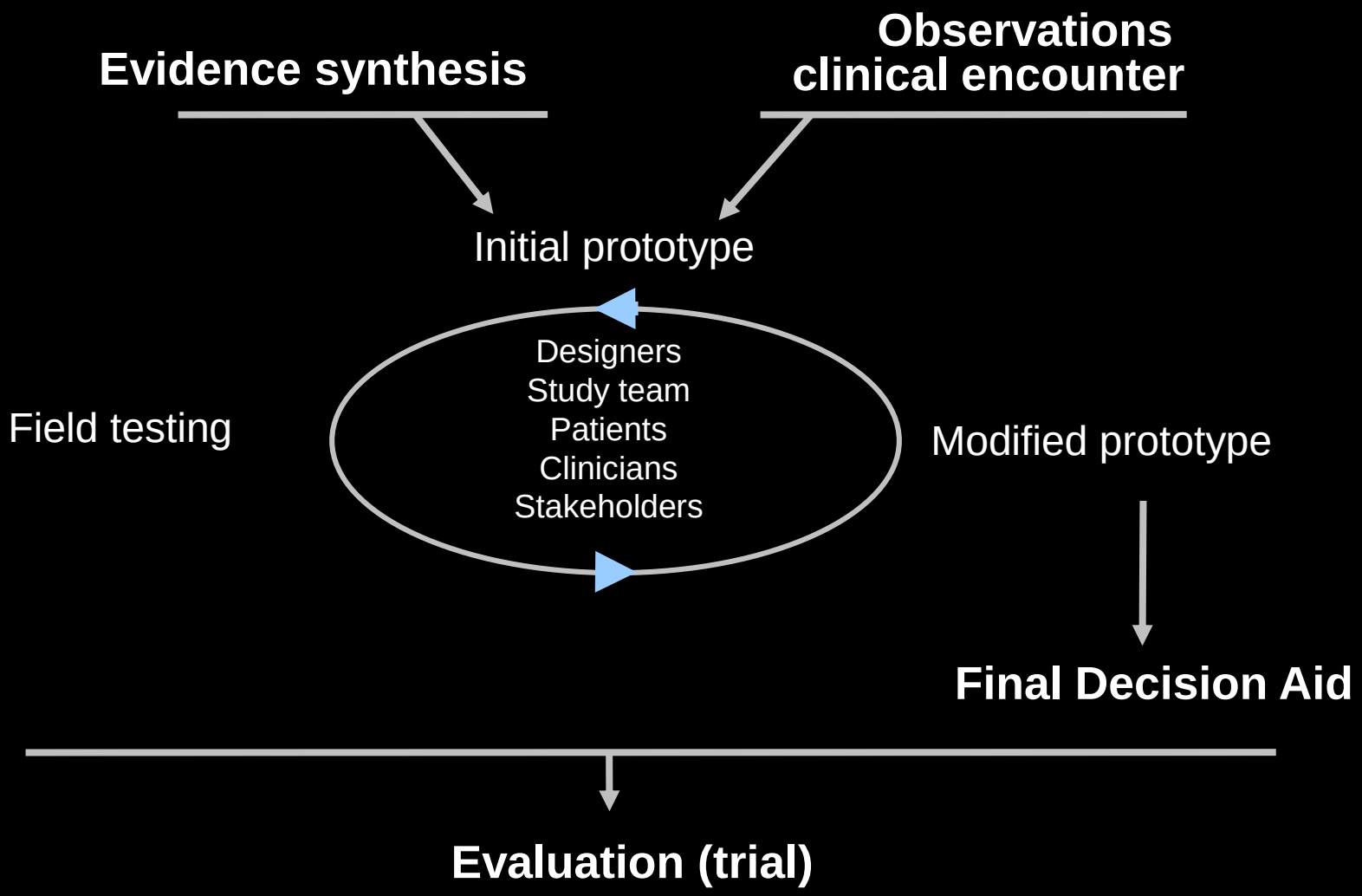
***Stacey et al. Cochrane Collaboration, 2012***

# Hypothesis

*Use of a decision aid in low risk chest pain patients will:*

- ↑ patient knowledge
- ↑ patient engagement
- Safely ↓ resource use

# Design of the Decision Aid




*Breslin, Montori  Patient Educ Counseling 2008*


Valve Shuts Off
East Oxygen

# What's Next?

*Prepared for:* _____

## 1 Your Chest Pain Diagnosis

Your initial test results are **NEGATIVE for a heart attack**. These included:

- **Blood tests** to look for an enzyme called troponin that is released when the heart muscle is damaged. Additional troponin tests may be done to monitor you for heart attack during your emergency visit.
- **An electrocardiogram** to check whether your heart is getting enough oxygen and blood.

However, the chest pain you are experiencing today may be a **warning sign for a future heart attack.**

## 2 What You Can Do

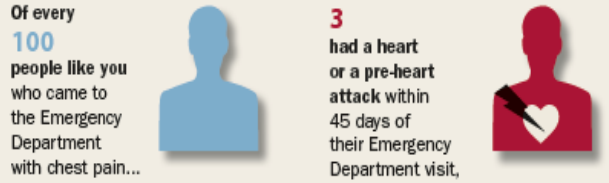
**A STRESS TEST**, which views blood flow to your heart at rest and under stress, may be needed.

Examining your risk will help you and your clinician decide together whether or not you should have additional heart testing.

[1]Stress test options include nuclear stress testing, ultrasound stress testing, or exercise ECG (electrocardiogram) stress testing. Nuclear stress testing involves exposure to radiation which has been shown to be related to increased cancer risk over a lifetime. Your doctor can help you explore which option may be best for you.

## 3 Your Personal Risk Evaluation

Your risk of having a heart or pre-heart attack within the next 45 days can be determined by comparing you to people with similar factors[2] who also came to the Emergency Department with chest pain.




## 4 Would you prefer to have a stress test during this emergency visit or decide later during an outpatient appointment?

- ❑ **I would like to have a stress test during my emergency visit.** I realize that this may increase the cost of my care and/or lengthen my stay.
- ❑ **I would like to be seen by a heart doctor within 24-72 hours** and would like assistance in scheduling this appointment.
- ❑ **I would like to schedule an appointment on my own** to consult with my primary care physician.
- ❑ **I would like my Emergency Department doctor to make this decision for me.**

[2]
- Age
- Gender
- Race
- If chest pain is made worse when manual pressure is applied to the chest area
- If there is a history of coronary artery disease
- If the chest pain causes perspiration
- Findings on electrocardiograms (electronic tracings of the heart)
- Initial cardiac troponin result

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# Summary of Results (n=201)

| Outcome | Change |
|---|---|
| Patient knowledge | ↑ |
| Patient engagement | ↑ |
| Placed in obs | ↓ (19%) |
| Stress testing | ↓ (16%) |
| Outpatient follow up | ↑ |
| Provider experience | ↑ |
| Safety | ↔ |

***Hess, Shah, Pencille, Ting, Sadosty, Nestler, Montori et al. Circulation CQO 2012***

# Prioritization of outcomes

## II. Patient and Stakeholder Engagement Plan

In this study proposal, what are the anticipated central issues at stake for each of the stakeholders?

| | Which Stakeholder? | | | | |
|---|---|---|---|---|---|
| **What is at stake?** | (1) Patients | (2) ED clinicians | (3) Primary care physicians | (4) Health policy decision maker/payers | (5) Cardiologists |
| **Access to outpatient care** | √ | √ | √ | | √ |
| **Quality and safety of care** | √ | √ | | √ | |
| **ED operations (flow, utilization)** | | √ | | √ | |
| **Cardiology procedural services (e.g., stress testing, catheterization)** | | | | √ | √ |
| **Healthcare utilization/costs** | √ | | | √ | |

| Outcome (n = 884) | Usual Care* | Decision Aid* | Difference | Power |
|---|---|---|---|---|
| **Patient knowledge** | 44% (23.3) | 60% (20.9) | 16% | 99% |
| **Patient engagement in the decision making process (n = 221)** | 7.0 (5.5) | 26.3 (8.2) | 19.3 | 99% |
| **Decisional conflict †** | 35.9 (18.9) | 22.3 (21.1) | 13.6 | 99% |
| **Trust in the physician** | 79.3 (19.9) | 83.4 (19.8) | 4.1 | 86% |
| **Patient satisfaction with the decision made (% agree or strongly agree they are satisfied)** | 69.7 (25.6) | 80 (25.6) | 10.3 | 99% |
| **Safety (major adverse cardiovascular events) ‡** | 0% | 0% | 0% | 78% |
| **Proportion of patients admitted for cardiac testing** | 77% | 67% | 10% | 90% |
| **Healthcare utilization** | 8.3 (0.8) | 7.0 (0.7) | 1.3 | 99% |

*Estimates were determined from our completed pilot randomized trial.[24]

†Lower decisional conflict scores indicate less conflict experienced by patients related to feeling uninformed.

‡ Noninferiority, 1-sided test with alpha = 0.05 with a maximum difference of 5%.

# II. Execution phase

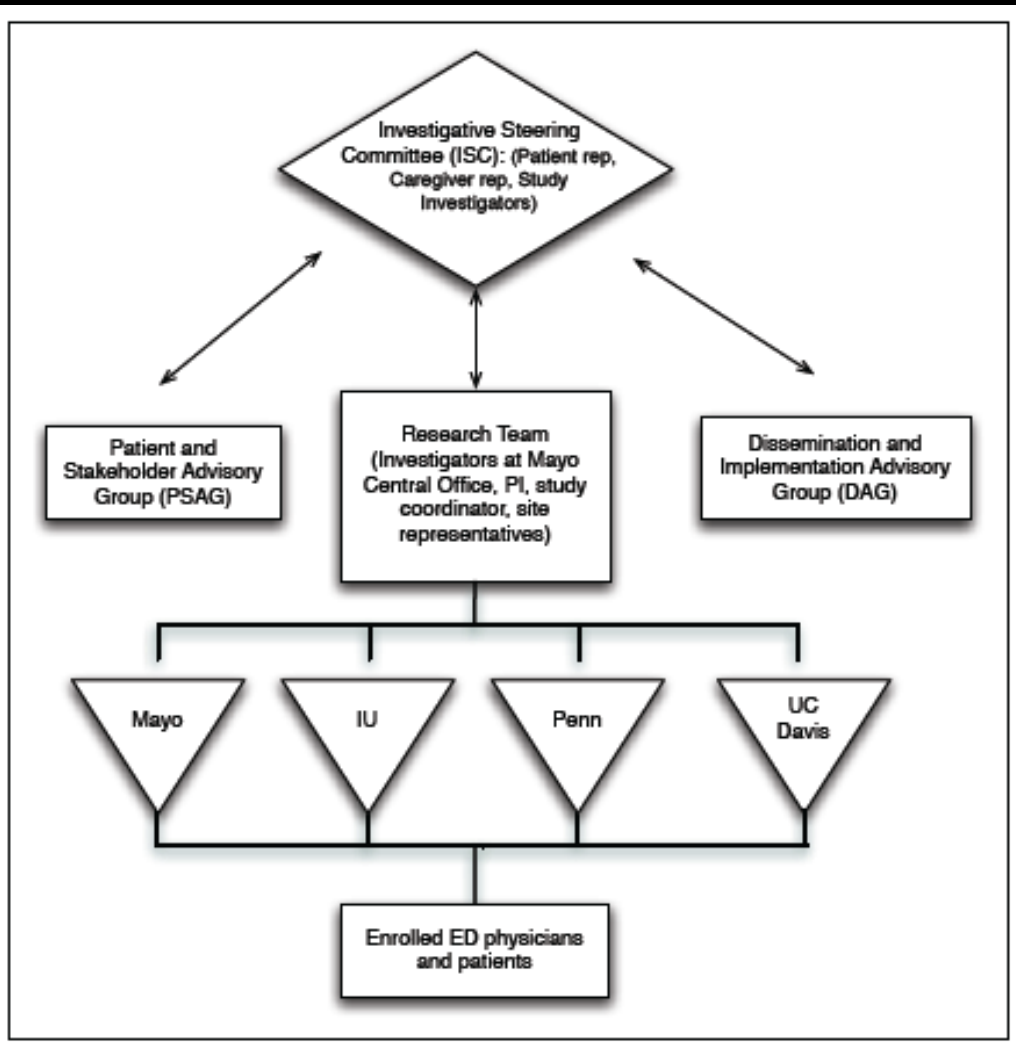
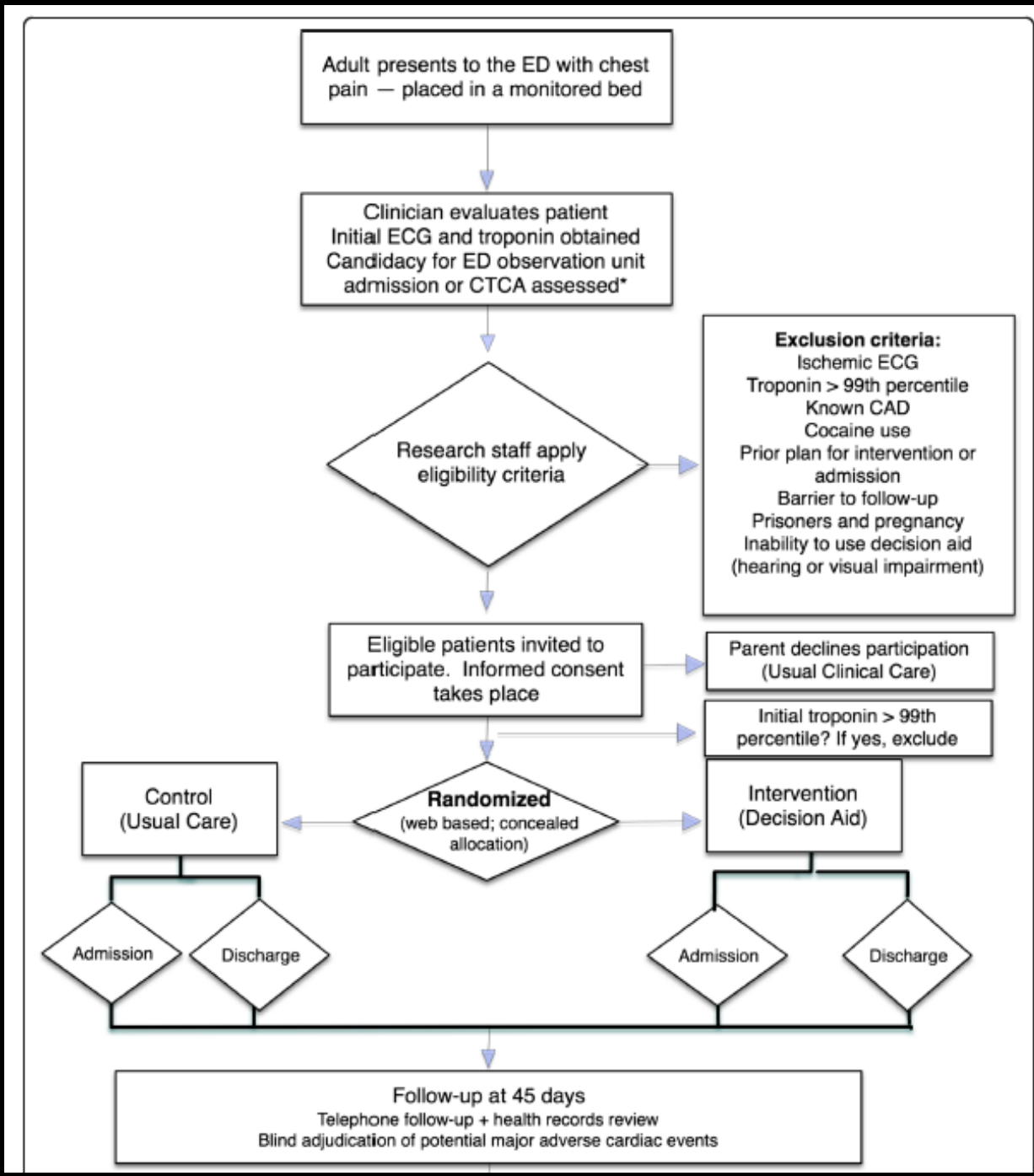



**Figure 1. Overview of Administrative Structure**


Adult presents to the ED with chest pain — placed in a monitored bed
Clinician evaluates patient
Initial ECG and troponin obtained
Candidacy for ED observation unit admission or CTCA assessed*
Research staff apply eligibility criteria
Exclusion criteria:
Ischemic ECG
Troponin > 99th percentile
Known CAD
Cocaine use
Prior plan for intervention or admission
Barrier to follow-up
Prisoners and pregnancy
Inability to use decision aid (hearing or visual impairment)
Eligible patients invited to participate. Informed consent takes place
Parent declines participation (Usual Clinical Care)
Initial troponin > 99th percentile? If yes, exclude
Control (Usual Care)
Randomized
(web based; concealed allocation)
Intervention (Decision Aid)
Admission
Discharge
Admission
Discharge
Follow-up at 45 days
Telephone follow-up + health records review
Blind adjudication of potential major adverse cardiac events

# III. Dissemination phase

Anderson *et al. Trials* 2014, **15**:166
http://www.trialsjournal.com/content/15/1/166

TRIALS

STUDY PROTOCOL Open Access

# Effectiveness of the Chest Pain Choice decision aid in emergency department patients with low-risk chest pain: study protocol for a multicenter randomized trial

Ryan T Anderson[1], Victor M Montori[2,3,4], Nilay D Shah[2,4,5], Henry H Ting[2,6], Laurie J Pencille[2], Michel Demers[7], Jeffrey A Kline[8,9], Deborah B Diercks[10], Judd E Hollander[11], Carlos A Torres[12], Jason T Schaffer[8], Jeph Herrin[13,14], Megan Branda[2,4,5], Annie Leblanc[2,4,5,15] and Erik P Hess[2,4,5,16*]

# Summary

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