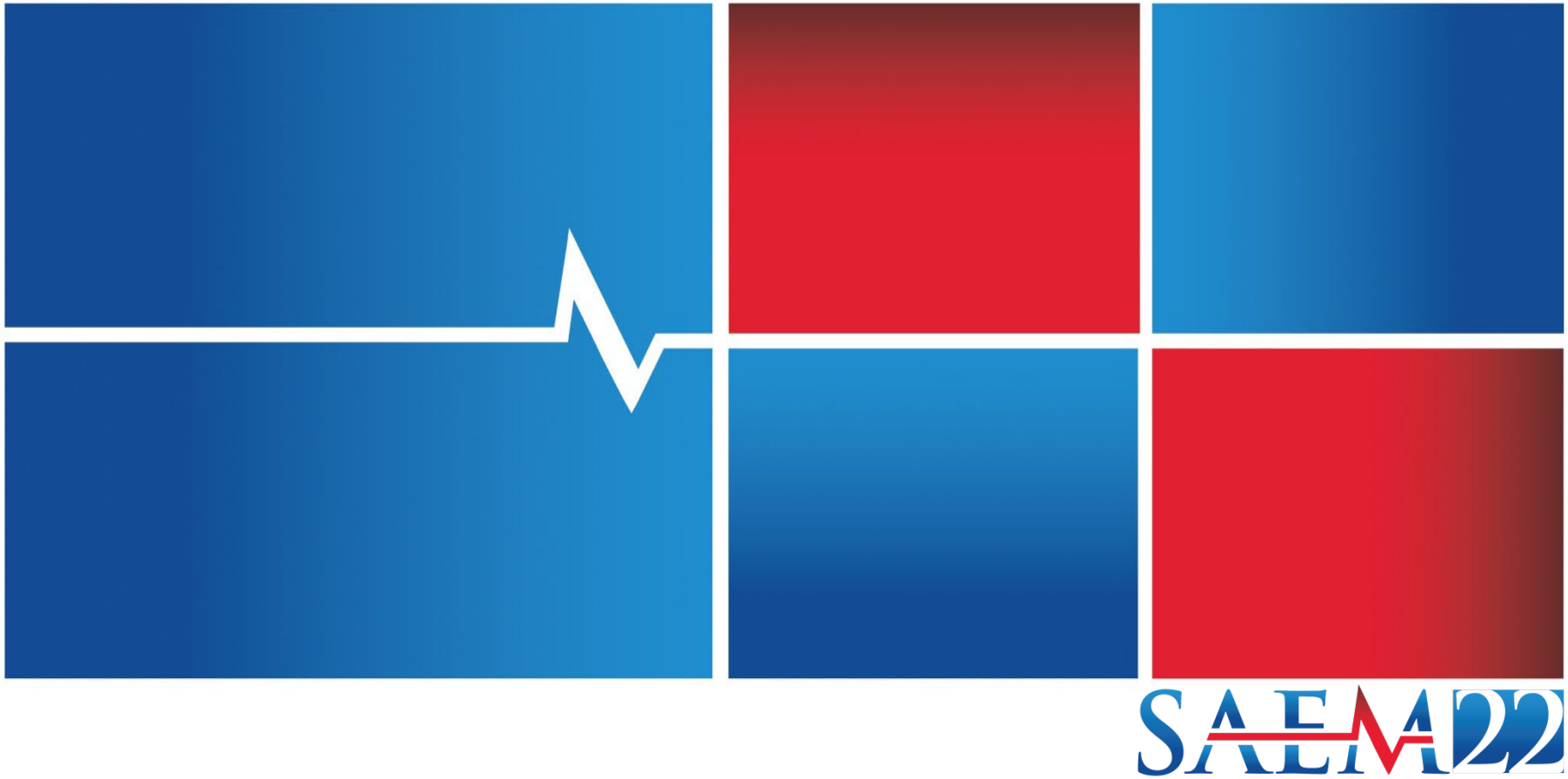

Pragmatic clinical trial design: experience, advice, and key decision points to consider

Cameron Gettel, Maya Yiadom, Henry Wang, Erik Hess, Corita Grudzen, Steven Bernstein, Ted Melnick

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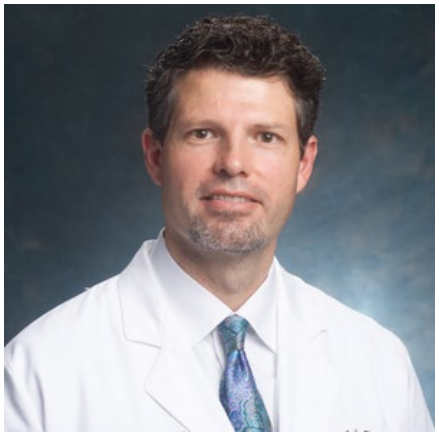
Presenters

Maya Yiadom
Stanford DEM

Henry Wang
Ohio State Univ DEM

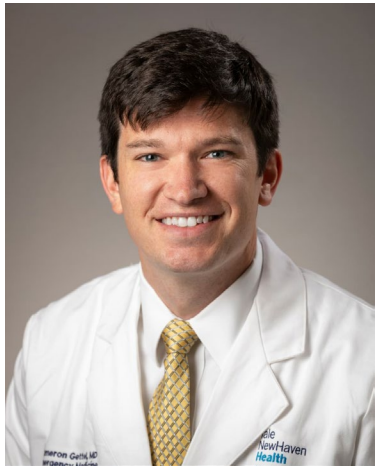


Erik Hess
Vanderbilt DEM

Corita Grudzen
NYU DEM

Steven Bernstein
Geisel SOM at Dartmouth

Ted Melnick
Yale DEM



Cameron Gettel
Yale DEM

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Learning Objectives

1) Summarize key study decisions and considerations when designing pragmatic clinical trials
2) Identify potential study design types
3) Determine the rationale and pros/cons for study design selection in existing ED-based pragmatic clinical trials

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Agenda

- Pragmatic-Explanatory Continuum
  - PRECIS-2 tool
- Additional Study Decisions
  - Randomization
  - Human subjects concerns
- Study Design Types
- Example Pragmatic Components from ED Studies
  - PollEverywhere

Pragmatic – Explanatory Continuum

- Explanatory: Can this intervention work under ideal conditions?

- Pragmatic: Does this intervention work under usual ‘real-world’ conditions?

PRECIS-2

- **PR**agmatic **E**xplanatory **C**ontinuum **I**ndicator **S**ummary tool
  - Developed to help investigators work through study design decisions to avoid designing a trial that did not meet their own intentions
- 2015 – PRECIS-2 Wheel Diagram
  - Eligibility, recruitment, setting, organization, flexibility – delivery, flexibility – adherence, follow-up, primary outcome, and primary analysis

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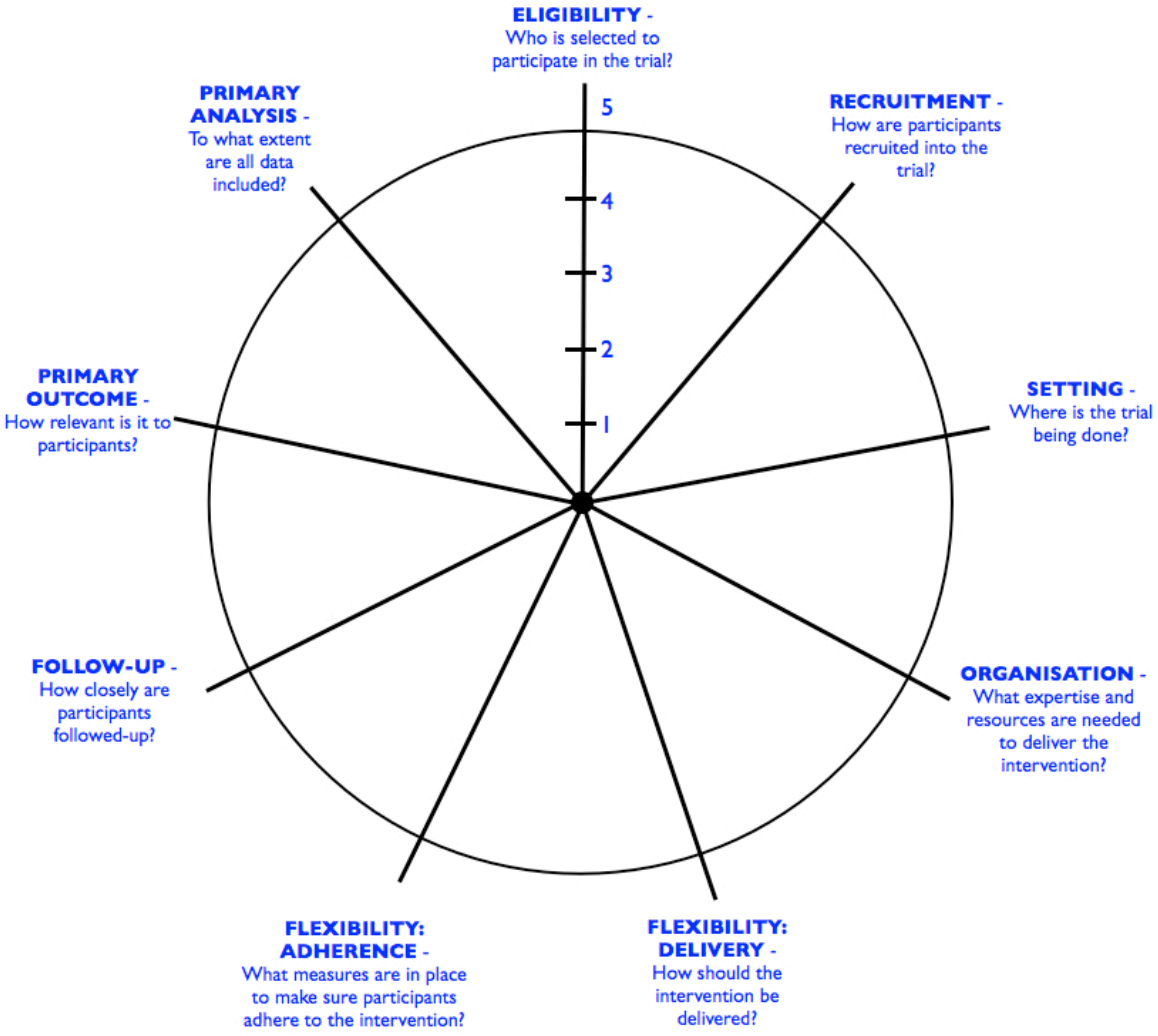
PRECIS-2 Wheel Diagram



Used with permission from the authors of Loudon et al. in BMJ 2015;350:h2147

PRECIS-2 Framework Domains & Study Decisions

- Eligibility criteria
  - Limited exclusion criteria
- Recruitment
  - Minimal overt recruitment effort
- Setting
  - Consider high and low resource EDs
- Organization
  - Minimal reliance on increased staff number or training requirements

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PRECIS-2 Framework Domains & Study Decisions

- Flexibility (delivery)
  - No rigid prescription for intervention implementation
- Flexibility (adherence)
  - Allowance of end user to modify the intervention with certain constraints

PRECIS-2 Framework Domains & Study Decisions

- Follow-up
  - No more follow-up than usual care and no reliance on additional data collection
- Primary outcome
  - Easily measured and salient to stakeholders
- Primary analysis
  - Intention-to-treat analysis

Additional Study Decisions

- Randomization
  - Is the phenomenon of interest something that takes place primarily at the level of the individual participant? Or group?
  - If randomized at individual level, can clinicians avoid contamination?
  - Correlation of participant outcomes within a cluster?
    - Intraclass correlation coefficient (ICC)

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Additional Study Decisions

- Human Subjects Concerns
  - Single, centralized IRB to eliminate redundant reviews across multiple sites
  - Default regulatory board recommendation for written informed consent?
    - Often incompatible with PCT study's nature and intent
  - Additional consent options:
    - Broadcast notification
    - Opt-out consent
    - 'Short form' consent
    - Electronic consent

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Additional Study Decisions

- Human Subjects Concerns (cont'd)
  - Four criteria of the Common Rule must be met to obtain a waiver of informed consent
    - "…research could not practicably be carried out without the waiver or alteration"
  - Language to consider with regulatory board:
    - Counter to the goal of PCTs, non-routine workflow procedures associated with informed consent process can hinder recruitment, introduce selection bias, and impact generalizability.

Choosing the Right Pragmatic Trial Study Design

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Study Design Types

Study Type	Pros/Cons/Rationale
Parallel	Pro – No inadvertent contamination by unplanned interventions or cross-over Con – Often require larger sample sizes due to within- and between-subject variation, which may increase cost and resource utilization Rationale – Most common study type, appropriate if concerns regarding cross-over may be present or if the disease or condition being studies may progress over time.
Cross-over	Pro – Comparison of treatment effect *within* participant Con – Risk of contamination if the intervention cannot be turned 'on' and 'off' without residual practices being carried over from one period to the next; Duration of follow-up generally longer Rationale – Appropriate if concerns exist regarding temporal confounders or significant population variation that may prevent balanced distribution between groups.

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Study Design Types

Time

	1	2	3	4	5	6	7	8
Parallel								
A - Intervention								
B - Control								
Crossover								
A								
B								

Intervention | Control | Wash-out Period | Intervention Component

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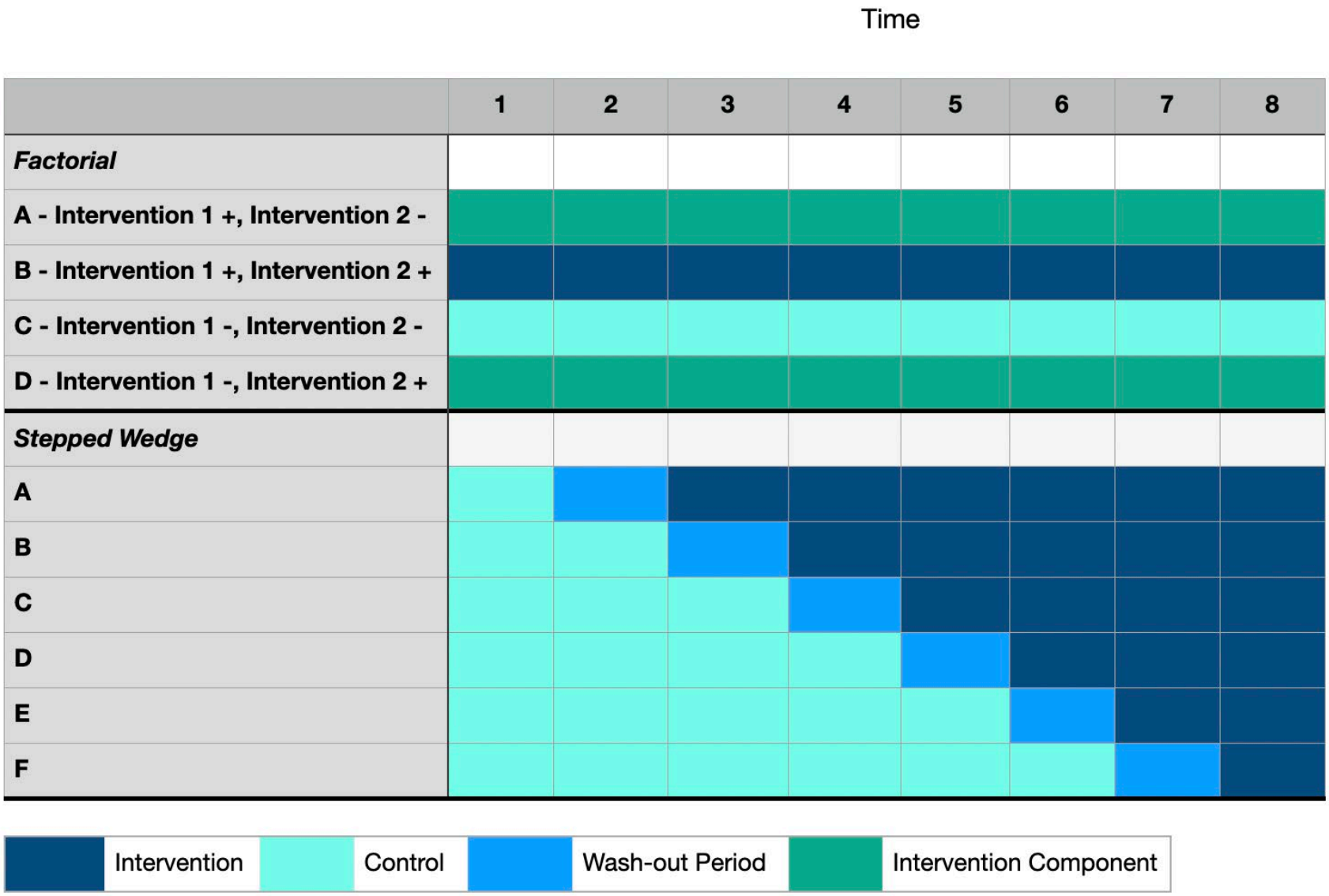
Study Design Types

Study Type	Pros/Cons/Rationale
Factorial	Pro – Efficient, in that multiple research questions may be answered with limited sample sizes Con – Complex in design and statistical analysis; Difficulty meeting inclusion criteria for both intervention(s) or components Rationale – Allows assessment of several intervention(s)/components and even interactions between them, often providing information whether varying levels or doses of an intervention affects different populations in different ways.
Stepped wedge	Pro – All participants receive the intervention; Possible to control for external temporal trends Con – Increased complexity may require additional statistical expertise and resources; May be subject to temporal confounding Rationale – Developed to address feasibility and ethical concerns that all participants should eventually receive the intervention within the study timeframe when the intervention is anticipated to produce a positive outcome.

Study Design Types



Example Pragmatic Study Components

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Example #1

Research

JAMA | Original Investigation

Effect of a Strategy of Initial Laryngeal Tube Insertion vs Endotracheal Intubation on 72-Hour Survival in Adults With Out-of-Hospital Cardiac Arrest

A Randomized Clinical Trial

Henry E. Wang, MD, MS; Robert H. Schmicker, MS; Mohamud R. Daya, MD, MS; Shannon W. Stephens, EMT-P; Ahamed H. Idris, MD; Jestin N. Carlson, MD, MS; M. Riccardo Colella, DO, MPH; Heather Herren, MPH, RN; Matthew Hansen, MD, MCR; Neal J. Richmond, MD; Juan Carlos J. Puyana, BA; Tom P. Aufderheide, MD, MS; Randal E. Gray, MEd, NREMT-P; Pamela C. Gray, NREMT-P; Mike Verkest, AAS, EMT-P; Pamela C. Owens; Ashley M. Brienza, BS; Kenneth J. Sternig, MS-EHS, BSN, NRP; Susanne J. May, PhD; George R. Sopko, MD, MPH; Myron L. Weisfeldt, MD; Graham Nichol, MD, MPH

IMPORTANCE Emergency medical services (EMS) commonly perform endotracheal intubation (ETI) or insertion of supraglottic airways, such as the laryngeal tube (LT), on patients with out-of-hospital cardiac arrest (OHCA). The optimal method for OHCA advanced airway management is unknown.

OBJECTIVE To compare the effectiveness of a strategy of initial LT insertion vs initial ETI in adults with OHCA.

DESIGN, SETTING, AND PARTICIPANTS Multicenter pragmatic cluster-crossover clinical trial involving EMS agencies from the Resuscitation Outcomes Consortium. The trial included 3004 adults with OHCA and anticipated need for advanced airway management who were enrolled from December 1, 2015, to November 4, 2017. The final date of follow-up was November 10, 2017.

INTERVENTIONS Twenty-seven EMS agencies were randomized in 13 clusters to initial airway management strategy with LT (n = 1505 patients) or ETI (n = 1499 patients), with crossover to the alternate strategy at 3- to 5-month intervals.

MAIN OUTCOMES AND MEASURES The primary outcome was 72-hour survival. Secondary outcomes included return of spontaneous circulation, survival to hospital discharge, favorable neurological status at hospital discharge (Modified Rankin Scale score ≤3), and key adverse events.

RESULTS Among 3004 enrolled patients (median [interquartile range] age, 64 [53-76] years, 1829 [60.9%] men), 3000 were included in the primary analysis. Rates of initial airway success were 90.3% with LT and 51.6% with ETI. Seventy-two hour survival was 18.3% in the LT group vs 15.4% in the ETI group (adjusted difference, 2.9% [95% CI, 0.2%-5.6%]; $P = .04$). Secondary outcomes in the LT group vs ETI group were return of spontaneous circulation (27.9% vs 24.3%; adjusted difference, 3.6% [95% CI, 0.3%-6.8%]; $P = .03$); hospital survival (10.8% vs 8.1%; adjusted difference, 2.7% [95% CI, 0.6%-4.8%]; $P = .01$); and favorable neurological status at discharge (7.1% vs 5.0%; adjusted difference, 2.1% [95% CI, 0.3%-3.8%]; $P = .02$). There were no significant differences in oropharyngeal or hypopharyngeal injury (0.2% vs 0.3%), airway swelling (1.1% vs 1.0%), or pneumonia or pneumonitis (26.1% vs 22.3%).

CONCLUSIONS AND RELEVANCE Among adults with OHCA, a strategy of initial LT insertion was associated with significantly greater 72-hour survival compared with a strategy of initial ETI. These findings suggest that LT insertion may be considered as an initial airway management strategy in patients with OHCA, but limitations of the pragmatic design, practice setting, and ETI performance characteristics suggest that further research is warranted.

TRIAL REGISTRATION ClinicalTrials.gov Identifier: NCT02419573

JAMA. 2018;320(8):769-778. doi:10.1001/jama.2018.7044

Visual Abstract

Editorial page 761

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Supplemental content

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Author Affiliations: Author affiliations are listed at the end of this article.

Corresponding Author: Henry E. Wang, MD, MS, Department of Emergency Medicine, The University of Texas Health Science Center at Houston, 6431 Fannin St, JJL 434, Houston, TX 77030 (henry.e.wang@uth.tmc.edu).

- Effectiveness of initial LTI insertion vs ETI in OHCA
- EMS agencies from the ROC
- Multicenter pragmatic cluster-crossover trial
- Initial LTI associated with increased 72-hr survival compared to ETI insertion

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Methods

- The trial included adults (age ≥18 years or per local interpretation) with nontraumatic OHCA treated by participating EMS agencies and requiring anticipated ventilatory support or advanced airway management

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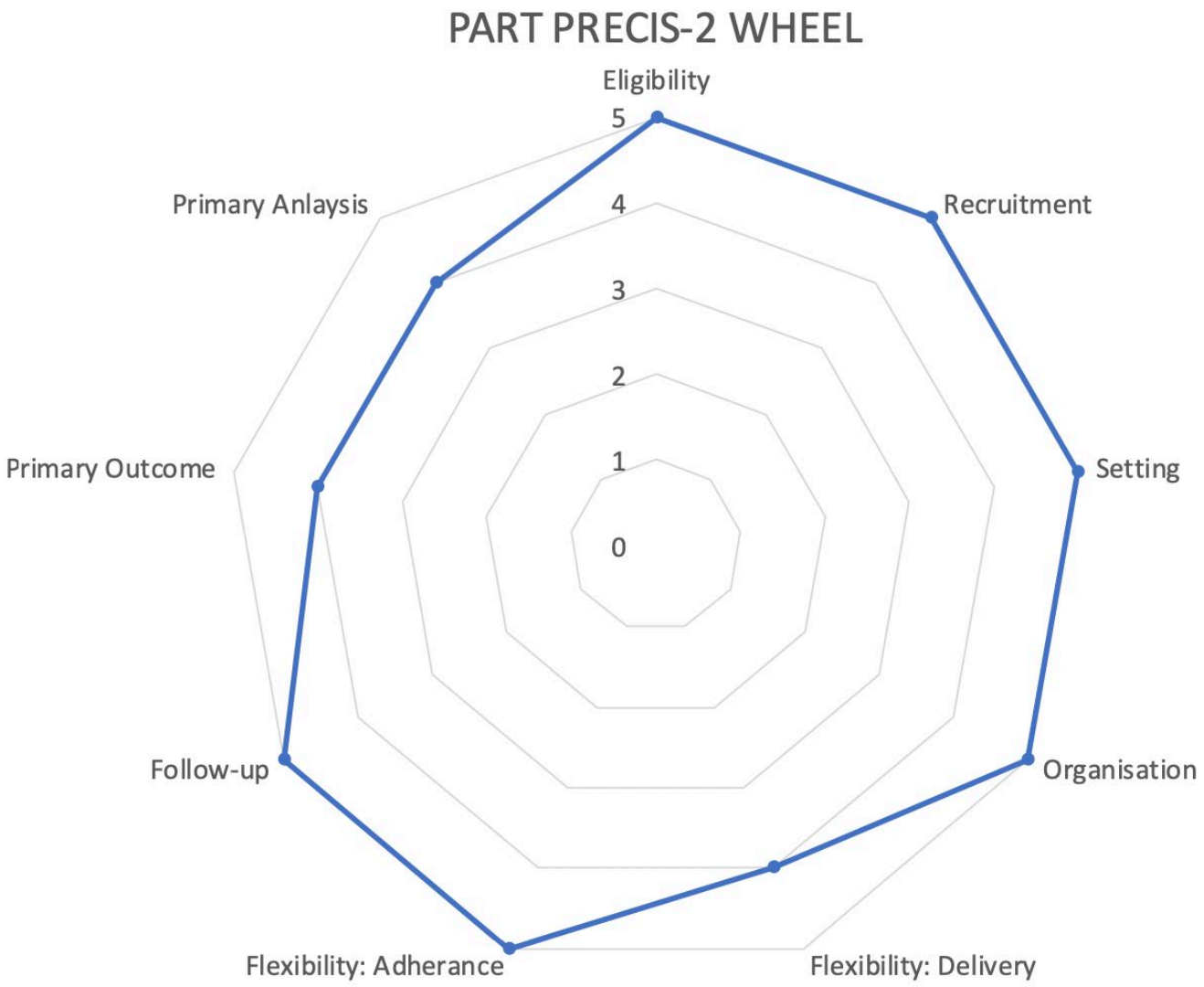
This section of the Methods is a pragmatic example of which PRECIS-2 domain?

- Setting
- Eligibility
- Recruitment
- Organization

Additional pragmatic components

- Leveraged existing research infrastructure of Resuscitation Outcomes Consortium
- Included “all” adult OHCA requiring airway management
  - Few exclusions
- EMS agencies used their own:
  - Airway equipment
  - Clinical protocols
  - Training practices
- Limited data collection
  - Only variables normally collected by ROC OHCA Registry

PRECIS-2


PART PRECIS-2 WHEEL
Eligibility
Recruitment
Setting
Organisation
Flexibility: Delivery
Flexibility: Adherance
Follow-up
Primary Outcome
Primary Anlaysis
5
4
3
2
1
0

Example #2

Open Access Protocol

BMJ Open

Randomised controlled pragmatic clinical trial evaluating the effectiveness of a discharge follow-up phone call on 30-day hospital readmissions: balancing pragmatic and explanatory design considerations

Maame Yaa A B Yiadom,[1] Henry Domenico,[2] Daniel Byrne,[3] Michele Marie Hasselblad,[4] Cheryl L Gatto,[5] Sunil Kripalani,[6] Neesha Choma,[7] Sarah Tucker,[4] Li Wang,[3] Monisha C Bhatia,[8] Johnston Morrison,[9] Frank E Harrell,[3] Tina Hartert,[9] Gordon Bernard[10]

To cite: Yiadom MYAB, Domenico H, Byrne D, *et al*. Randomised controlled pragmatic clinical trial evaluating the effectiveness of a discharge follow-up phone call on 30-day hospital readmissions: balancing pragmatic and explanatory design considerations. *BMJ Open* 2018;**8**:e019600. doi:10.1136/bmjopen-2017-019600

► Prepublication history and additional material for this paper are available online. To view these files, please visit the journal online (http://dx.doi.org/10.1136/bmjopen-2017-019600).

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Revised 9 December 2017
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For numbered affiliations see end of article.

Correspondence to
Dr Maame Yaa A B Yiadom; maya.yiadom@vanderbilt.edu

ABSTRACT

Introduction Hospital readmissions within 30 days are a healthcare quality problem associated with increased costs and poor health outcomes. Identifying interventions to improve patients' successful transition from inpatient to outpatient care is a continued challenge.

Methods and analysis This is a single-centre pragmatic randomised and controlled clinical trial examining the effectiveness of a discharge follow-up phone call to reduce 30-day inpatient readmissions. Our primary endpoint is inpatient readmission within 30 days of hospital discharge censored for death analysed with an intention-to-treat approach. Secondary endpoints included observation status readmission within 30 days, time to readmission, all-cause emergency department revisits within 30 days, patient satisfaction (measured as mean Hospital Consumer Assessment of Healthcare Providers and Systems scores) and 30-day mortality. Exploratory endpoints include the need for assistance with discharge plan implementation among those randomised to the intervention arm and reached by the study nurse, and the number of call attempts to achieve successful intervention delivery. Consistent with the Learning Healthcare System model for clinical research, timeliness is a critical quality for studies to most effectively inform hospital clinical practice. We are challenged to apply pragmatic design elements in order to maintain a high-quality practicable study providing timely results. This type of prospective pragmatic trial empowers the advancement of hospital-wide evidence-based practice directly affecting patients.

Ethics and dissemination Study results will inform the structure, objective and function of future iterations of the hospital's discharge follow-up phone call programme and be submitted for publication in the literature.

Trial registration number NCT03050918; Pre-results.

Strengths and limitations of this study

- ► Single-centre trial conducted at a tertiary care referral centre with inclusion limited to the general medicine population to improve generalisability.
- ► Designed to demonstrate effectiveness with pragmatic concessions (including an anticipated 30% intervention delivery rate) limiting our ability to determine efficacy.
- ► The need to inform a time-sensitive clinical practice decision in the context of clinical equipoise led to the appropriate selection of more pragmatic and less explanatory design elements.
- ► Waiver of consent and use of clinical informatics resources permitted study feasibility.
- ► Potentially obtaining external readmission data from a health information exchange is a data access innovation overcoming a traditional hospital readmission research limitation.

INTRODUCTION

In 2010, the US Affordable Care Act tasked the Centers for Medicare and Medicaid Services to implement financial penalties for hospitals with excessive 30-day inpatient readmission rates.[1] Penalties are withheld reimbursements for select diagnoses designed to incentivise hospital to support higher-quality discharge care transitions.[2] In 2016, penalties amounting to over $500 million were withheld from 2597 (47%) US hospitals.[3] In responses to this national quality improvement challenge Vanderbilt University Medical Center (VUMC) launched a nursing-based discharge follow-up phone call programme to support more successful

- Effectiveness of a discharge follow-up phone call
- Single-center pragmatic RCT
- Outcome: 30-day hospital readmissions

SAEM22

Methods

- …into the operations of daily inpatient care without disturbing the workflow of medical providers.
- We requested a waiver of consent from our IRB given several considerations…The trial examines the effectiveness of a newly established but existing clinical programme calling patients within 7 days of hospital discharge to support successful transition to outpatient care. As a result the intervention is in active use, but its impact is unclear, thus demonstrating equipoise.
- We identify eligible patients via a custom programmed discharged patient report generated from the medical centre's electronic health record admission, discharge and transfer (ADT) system each weekday morning. This auto-generated report…

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This section of the Methods is a pragmatic example of which PRECIS-2 domain?

Recruitment

Primary Outcome

Organization

Setting

Example #3

TBM

ORIGINAL RESEARCH

Design and implementation of decision support for tobacco dependence treatment in an inpatient electronic medical record: a randomized trial

Steven L. Bernstein, MD,[1] June Rosner, MA, MEd,[2] Michelle DeWitt, RN,[3] Jeanette Tetrault, MD,[4] Allen L. Hsiao, MD,[5] James Dziura, PhD,[2] Scott Sussman, MD,[3] Patrick O'Connor, MD, MPH,[4] Benjamin Toll[6]

[1]Emerg. Med., Yale School Med., Health Policy, Public Health, 464 Congress Ave., Suite 260, New Haven, CT 06519, USA
[2]Emerg. Med., Yale School Med., New Haven, CT, USA
[3]Hospital, New Haven, CT, USA
[4]Internal Med., Yale School Med., New Haven, CT, USA
[5]Pediatrics, Emerg. Med., Hospital, New Haven, CT, USA
[6]Psychiatry, Yale School Med., Pop. Health Sciences/MUSC, New Haven, CT, USA
Correspondence to: S Bernstein
steven.bernstein@yale.edu

Cite this as: *TBM* 2017;7:185–195
doi: 10.1007/s13142-017-0470-8

Abstract

Tobacco dependence treatment for hospitalized smokers results in long-term cessation if treatment continues at least 30 days post-discharge. Health information technology may facilitate ongoing tobacco dependence treatment after hospital discharge. To describe the use and impact of a new decision support tool and order set for inpatient physicians, addressing tobacco dependence treatment for hospitalized smokers, embedded in an electronic health record (EHR). In a cluster-randomized trial, 254 physicians were randomized (1:1) to either receive or not receive the decision support tool and order set, which were embedded in the Epic (Madison, WI) EHR used at 2 hospitals in a single city. When an adult patient was admitted to a medical service, an electronic alert appeared if the patient was coded in the EHR as a smoker. For physicians randomized to the intervention, the alert linked to an order set to prescribe tobacco treatment medications and refer the patient to the state tobacco quitline. Additionally, "tobacco use disorder" was added to the patient's problem list, and an e-mail was sent to the patient's primary care provider (PCP). In the control arm, an alert fired with no screen visibility. Generalized estimating equations were used to model the data. Since August 2013, the alert has appeared for 10,939 patients (5391 intervention, 5548 control). Compared to control physicians, intervention physicians were more likely to order tobacco treatment medication (35 vs. 29%, $P < 0.0001$), populate the problem list with tobacco use disorder (41 vs. 2%, $P < 0.0001$), and make a referral to the state smokers' quitline (30 vs. 0%, $P < 0.0001$). In addition, intervention physicians sent an e-mail to the patient's PCP 4152 (99%) times. Designing and implementing an order set and alert for tobacco treatment in an EHR is feasible and helps physicians place more orders for tobacco treatment medication, referrals to the state smokers' quitline, and e-mails to patients' PCPs. Data on cessation outcomes are pending. Trial registration: www.ClinicalTrials.gov (NCT01691105).

Keywords

Smoking cessation, Tobacco dependence treatment, Decision support, Electronic health records

Implications

Practice: Enhancing the treatment of hospitalized smokers with electronic decision support is feasible, and can lead to dramatic improvements in processes of care.

Policy: Because of the near-universality of electronic health records and telephone quitlines in developed countries, and the extensive literature demonstrating the clinical efficacy and cost effectiveness of tobacco dependence treatment, electronic decision support for tobacco is a scalable, cost-effective approach to the population-based management of the leading cause of death in the developed world.

Research: Future work should examine the impact of electronic decision support on quit rates, the incidence of subsequent tobacco-related health events, and how to electronically integrate tobacco dependence treatment across all inpatient and outpatient clinical encounters.

Introduction

Because tobacco dependence remains the leading cause of death and illness in the USA, smoking cessation and tobacco dependence treatment has long been a publicly reported standard of the quality of inpatient care. Screening and treatment for tobacco use is part of the core measure set used by the Center for Medicare and Medicaid Services (CMS) for patients admitted with acute myocardial infarction, pneumonia, or congestive heart failure. It is a core measure of the National Quality Forum and one of the choices in the optional measure set offered by the Joint Commission [1].

- Describe use of new decision support tool and order set for inpatient physicians
- Physicians randomized to the intervention helped physicians place more orders for tobacco treatment medication, referrals to state smokers' quitline, and emails to PCPs.

SAEM22

Methods

- Of note, the alert has three functions that were pre-checked, for the physician, if s/he accepted the alert: (1) a referral to the Connecticut State Smokers' Quitline, (2) opening of the E-STOPS order set, and (3) adding "tobacco use disorder" to the patient's problem list. This saved clinician time while allowing them the autonomy to not order the interventions if they chose.

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This section of the Methods is a pragmatic example of which PRECIS-2 domain?

Flexibility (delivery)

Setting

Recruitment

Follow-up

Example #4

JAMA Network | Open

Original Investigation | Emergency Medicine

Effect of the Head Computed Tomography Choice Decision Aid in Parents of Children With Minor Head Trauma
A Cluster Randomized Trial

Erik P. Hess, MD, MSc; James L. Homme, MD; Anupam B. Kharbanda, MD, MSc; Leah Tzimenatos, MD; Jeffrey P. Louie, MD; Daniel M. Cohen, MD; Lise E. Nigrovic, MD, MPH; Jessica J. Westphal; Nilay D. Shah, PhD; Jonathan Inselman, MS; Michael J. Ferrara; Jeph Herrin, PhD; Victor M. Montori, MD, MSc; Nathan Kuppermann, MD, MPH

Abstract

IMPORTANCE The Pediatric Emergency Care Applied Research Network prediction rules for minor head trauma identify children at very low, intermediate, and high risk of clinically important traumatic brain injuries (ciTBIs) and recommend no computed tomography (CT) for those at very low risk. However, the prediction rules provide little guidance in the choice of home observation or CT in children at intermediate risk for ciTBI.

OBJECTIVE To compare a decision aid with usual care in parents of children at intermediate risk for ciTBI.

DESIGN, SETTINGS, AND PARTICIPANTS This cluster randomized trial was conducted in 7 geographically diverse US emergency departments (EDs) from April 1, 2014, to September 30, 2016. Eligible participants were emergency clinicians, children ages 2 to 18 years with minor head trauma at intermediate risk for ciTBI, and their parents.

INTERVENTIONS Clinicians were randomly assigned (1:1 ratio) to shared decision-making facilitated by the Head CT Choice decision aid or to usual care.

MAIN OUTCOMES AND MEASURES The primary outcome, selected by parent stakeholders, was knowledge of their child's risk for ciTBI and the available diagnostic options. Secondary outcomes included decisional conflict, parental involvement in decision-making, the ED CT rate, 7-day health care utilization, and missed ciTBI.

RESULTS A total of 172 clinicians caring for 971 children (493 decision aid; 478 usual care) with minor head trauma at intermediate risk for ciTBI were enrolled. The patient mean (SD) age was 6.7 (7.1) years, 575 (59%) were male, and 253 (26%) were of nonwhite race. Parents in the decision aid arm compared with the usual care arm had greater knowledge (mean [SD] questions correct: 6.2 [2.0] vs 5.3 [2.0]; mean difference, 0.9; 95% CI, 0.6-1.3), had less decisional conflict (mean [SD] decisional conflict score, 14.8 [15.5] vs 19.2 [16.6]; mean difference, −4.4; 95% CI, −7.3 to −2.4), and were more involved in CT decision-making (observing patient involvement [OPTION] scores: mean [SD], 25.0 [8.5] vs 13.3 [6.5]; mean difference, 11.7; 95% CI, 9.6-13.9). Although the ED CT rate did not significantly differ (decision aid, 22% vs usual care, 24%; odds ratio, 0.81; 95% CI, 0.51-1.27), the mean number of imaging tests was lower in the decision aid arm 7 days after injury. No child had a missed ciTBI.

(continued)

Key Points

Question What is the effect of a decision aid in parents of children with minor head trauma?

Findings In this cluster randomized trial of 172 clinicians caring for 971 children at intermediate risk of traumatic brain injury, the Head Computed Tomography Choice decision aid increased parental knowledge, decreased decisional conflict, and increased engagement. The intervention did not reduce the emergency department computed tomography rate but safely decreased 7-day health care utilization.

Meaning Use of a decision aid in parents of children with minor head trauma had no effect on the emergency department computed tomography rate, but improved decisional quality and safely decreased downstream health care utilization.

+ Invited Commentary

+ Supplemental content

Author affiliations and article information are listed at the end of this article.

- Compare a decision aid with usual care to identify children at high risk of ciTBI
- Decision aid increased parent knowledge, decreased decisional conflict, and increased involvement in decision-making.
- The intervention did not significantly reduce the ED CT rate, but did decrease healthcare utilization within 7 days.

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Methods

- We analyzed all parent-child dyads in the arm to which they were randomized consistent with the principle of intention-to-treat.

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This section of the Methods is a pragmatic example of which PRECIS-2 domain?

Primary Outcome

Primary Analysis

Recruitment

Flexibility (adherence)

Example #5

Schmucker *et al. BMC Emergency Medicine* (2021) 21:83
https://doi.org/10.1186/s12873-021-00478-4

BMC Emergency Medicine

RESEARCH ARTICLE Open Access

Data from emergency medicine palliative care access (EMPallA): a randomized controlled trial comparing the effectiveness of specialty outpatient versus telephonic palliative care of older adults with advanced illness presenting to the emergency department

Abigail M. Schmucker[1], Mara Flannery[2*], Jeanne Cho[2], Keith S. Goldfeld[3], Corita Grudzen[2,3] and The EMPallA Investigators

Abstract

Background: The Emergency Medicine Palliative Care Access (EMPallA) trial is a large, multicenter, parallel, two-arm randomized controlled trial in emergency department (ED) patients comparing two models of palliative care: nurse-led telephonic case management and specialty, outpatient palliative care. This report aims to: 1) report baseline demographic and quality of life (QOL) data for the EMPallA cohort, 2) identify the association between illness type and baseline QOL while controlling for other factors, and 3) explore baseline relationships between illness type, symptom burden, and loneliness.

Methods: Patients aged 50+ years with advanced cancer (metastatic solid tumor) or end-stage organ failure (New York Heart Association Class III or IV heart failure, end stage renal disease with glomerular filtration rate < 15 mL/min/m^2, or Global Initiative for Chronic Obstructive Lung Disease Stage III, IV, or oxygen-dependent chronic obstructive pulmonary disease defined as FEV_1 < 50%) are eligible for enrollment. Baseline data includes self-reported demographics, QOL measured by the Functional Assessment of Cancer Therapy-General (FACT-G), loneliness measured by the Three-Item UCLA Loneliness Scale, and symptom burden measured by the Edmonton Revised Symptom Assessment Scale. Descriptive statistics were used to analyze demographic variables, a linear regression model measured the importance of illness type in predicting QOL, and chi-square tests of independence were used to quantify relationships between illness type, symptom burden, and loneliness.

* Correspondence: Mara.Flannery@nyulangone.org
[2]Ronald O. Perelman Department of Emergency Medicine, NYU School of Medicine, New York University Langone Health, 227 E 30th Street, First Floor, New York, NY 10016, USA
Full list of author information is available at the end of the article

- Compare two models of palliative care
  - Nurse-led telephonic case management
  - Specialty outpatient
- Differences identified in QoL, symptom burden, and loneliness

SAEM22

Methods

- This RCT began recruitment in April 2018 and is currently enrolling at 18 emergency department (ED) sites across the United States (US), with locations representing the geographic diversity of the country.

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This section of the Methods is a pragmatic example of which PRECIS-2 domain?

Eligibility

Recruitment

Organization

Setting

PRECIS-2

Table 1. PRECIS-2 score for PRIM-ER Domains

Domain	Score*	Rationale
Eligibility Criteria	5	Broad eligibility criteria include all older adults 66+ who present to one of the participating EDs with high short-term mortality; very few exclusions (hospice in prior 12 months)
Recruitment Path	5	No individual patient participant consent or recruitment
Setting	5	EDs treat all patients regardless of insurance status or ability to pay
Organization intervention	5	Intervention will be delivered by current emergency provider workforce
Flex of experimental intervention—Delivery	4	Core content (nursing and emergency medicine palliative care content, communications training) is standardized yet the delivery can be tailored to each ED based on their current workforce (*e.g.,* physician assistant or post-graduate trainee involvement) and local EHR
Flex of experimental intervention—Adherence	4	All emergency providers will be invited to participate with varying levels of contact hours depending on their role; monetary incentives ($50-100) and continuing education credits will be provided to encourage adherence
Follow up	5	No additional patient follow up as part of trial
Outcome	4	Acute care admission versus discharge home, healthcare utilization in the 6 months following the index ED visit, and survival are all highly relevant to patient participants
Analysis	5	Intention to treat analysis regardless of compliance with per protocol sensitivity analysis

*1=very explanatory, 2= rather explanatory, 3=equally pragmatic/explanatory, 4=rather pragmatic, 5=very pragmatic

Example #6

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Grant Report

Progress Report on EMBED: A Pragmatic Trial of User-Centered Clinical Decision Support to Implement EMergency Department-Initiated BuprenorphinE for Opioid Use Disorder †

Edward R. Melnick [1], Bidisha Nath [1], Osama M. Ahmed [2], Cynthia Brandt [1,2], David Chartash [3], James D. Dziura [4], Erik P. Hess [5], Wesley C. Holland [2], Jason A. Hoppe [6], Molly M. Jeffery [7], Liliya Katsovich [4], Fangyong Li [4], Charles C. Lu [4], Kaitlin Maciejewski [4], Matthew Maleska [8], Jodi A. Mao [2], Shara Martel [1], Sean Michael [6], Hyung Paek [9], Mehul D. Patel [10], Timothy F. Platts-Mills [10], Haseena Rajeevan [4], Jessica M. Ray [1], Rachel M. Skains [5], William E. Soares III [11], Ashley Deutsch [11], Yauheni Solad [9], Gail D'Onofrio [1]

[1] Department of Emergency Medicine, Yale University School of Medicine, New Haven, CT 06519, USA
[2] Yale University School of Medicine, New Haven, CT 06510, USA
[3] Yale Center for Medical Informatics, Yale University School of Medicine, New Haven, CT 06511, USA
[4] Yale Center for Analytical Sciences, Yale School of Public Health, New Haven, CT 06520, USA
[5] Department of Emergency Medicine, University of Alabama at Birmingham School of Medicine, Birmingham, AL 35233, USA
[6] Department of Emergency Medicine, University of Colorado, Aurora, CO 80045, USA
[7] Department of Emergency Medicine, Mayo Clinic, Rochester, MN 55905, USA
[8] The Patient Revolution, New Haven, CT 06511, USA
[9] Information Technology Services, Yale New-Haven Health, New Haven, CT 06519, USA
[10] Department of Emergency Medicine, University of North Carolina School of Medicine, Chapel Hill, NC 27599, USA
[11] Department of Emergency Medicine, University of Massachusetts Medical School-Baystate, Baystate, MA 01199, USA

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* Correspondence: Edward R. Melnick, Email: edward.melnick@yale.edu; Tel.: +1-203-785-5174; Fax: +1-203-785-4580.

ABSTRACT

Buprenorphine (BUP) can safely and effectively reduce craving, overdose, and mortality rates in people with opioid use disorder (OUD). However, adoption of ED-initiation of BUP has been slow partly due to physician perception this practice is too complex and disruptive. We report progress of the ongoing EMBED (*EMergency department-initiated*

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- Integrate and disseminate Clinical Decision Support to promote ED-initiation of buprenorphine/naloxone
- Parallel group randomized pragmatic trial in 20 EDs

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Methods

- With the exception of some physician-level outcomes (e.g., the proportion of attendings with DATA 2000 waivers), all trial data will be collected from clinical data entered in the EHR…Data collection is underway at all study sites with monthly uploads to the data portal.

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This section of the Methods is a pragmatic example of which PRECIS-2 domain?

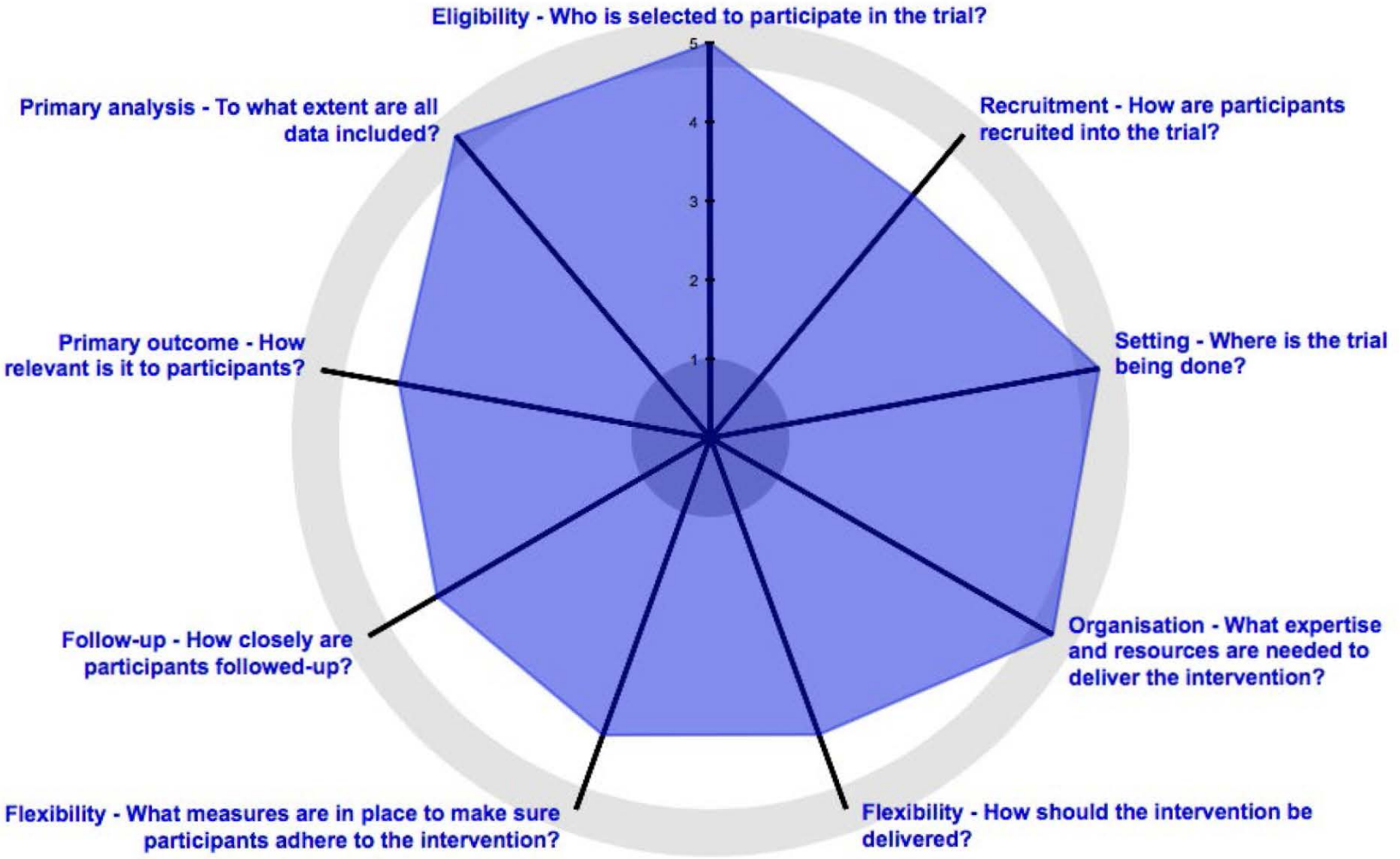
Primary Outcome

Setting

Follow-up

Flexibility (delivery)

PRECIS-2


Eligibility - Who is selected to participate in the trial?
Recruitment - How are participants recruited into the trial?
Setting - Where is the trial being done?
Organisation - What expertise and resources are needed to deliver the intervention?
Flexibility - How should the intervention be delivered?
Flexibility - What measures are in place to make sure participants adhere to the intervention?
Follow-up - How closely are participants followed-up?
Primary outcome - How relevant is it to participants?
Primary analysis - To what extent are all data included?
1
2
3
4
5

Conclusions

- Trial components operate on a continuum of pragmatic -> explanatory
  - Decisions depend on goals of the investigators
  - Findings from pragmatic trials offer benefits of wider translatability and generalizability
- Start with the end in mind
  - Difficult to ‘save’ the trial *post hoc*

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