UT SOUTHWESTERN MEDICAL CENTER

Department of Emergency Medicine
Office of Research

Shannon McNabb, MA, MPH
Clinical Research Manager
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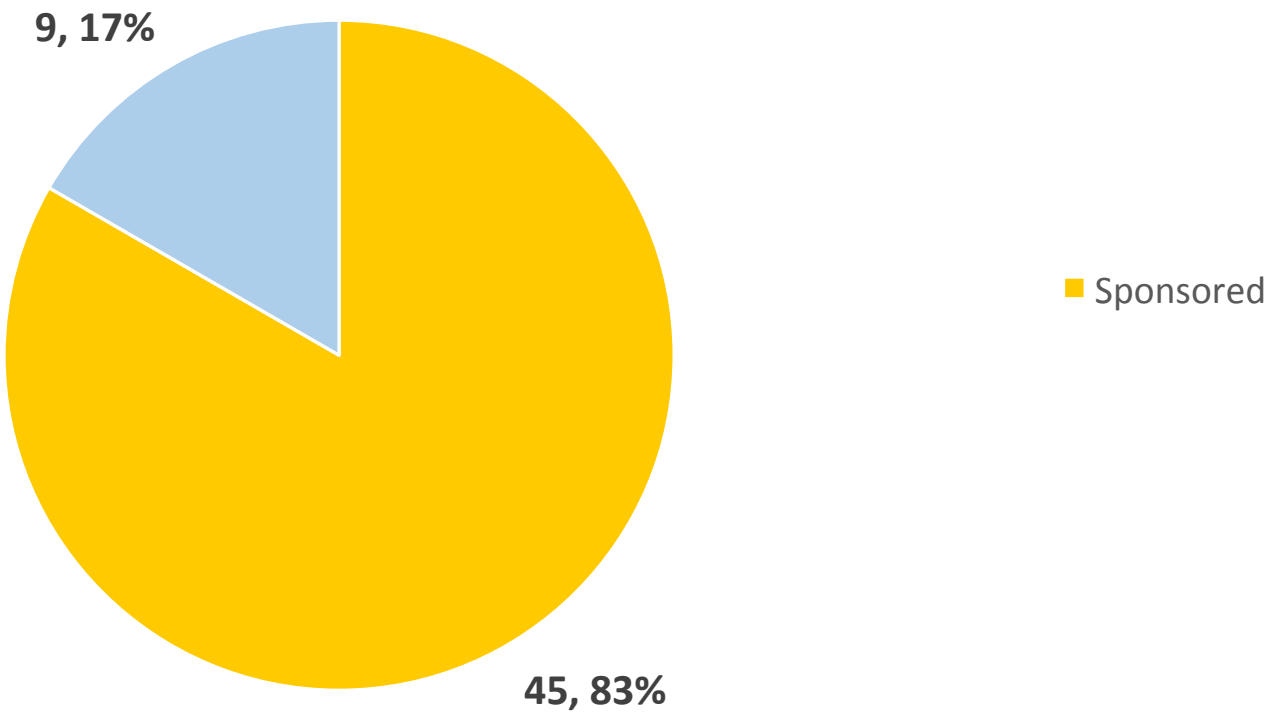
EM Study Tracking System

UPDATED ON:	12/5/2016
TOTAL	**68**
Grants Submitted, Award Pending	6
Industry Sponsor Queries	1
IN DEVELOPMENT	8
ACTIVE	24
Closed to Enrollment, open to FU	5
On Hold/suspended/cancelled	1
Complete	19
Failure to Launch	4
HISTORICAL before my time	*35*

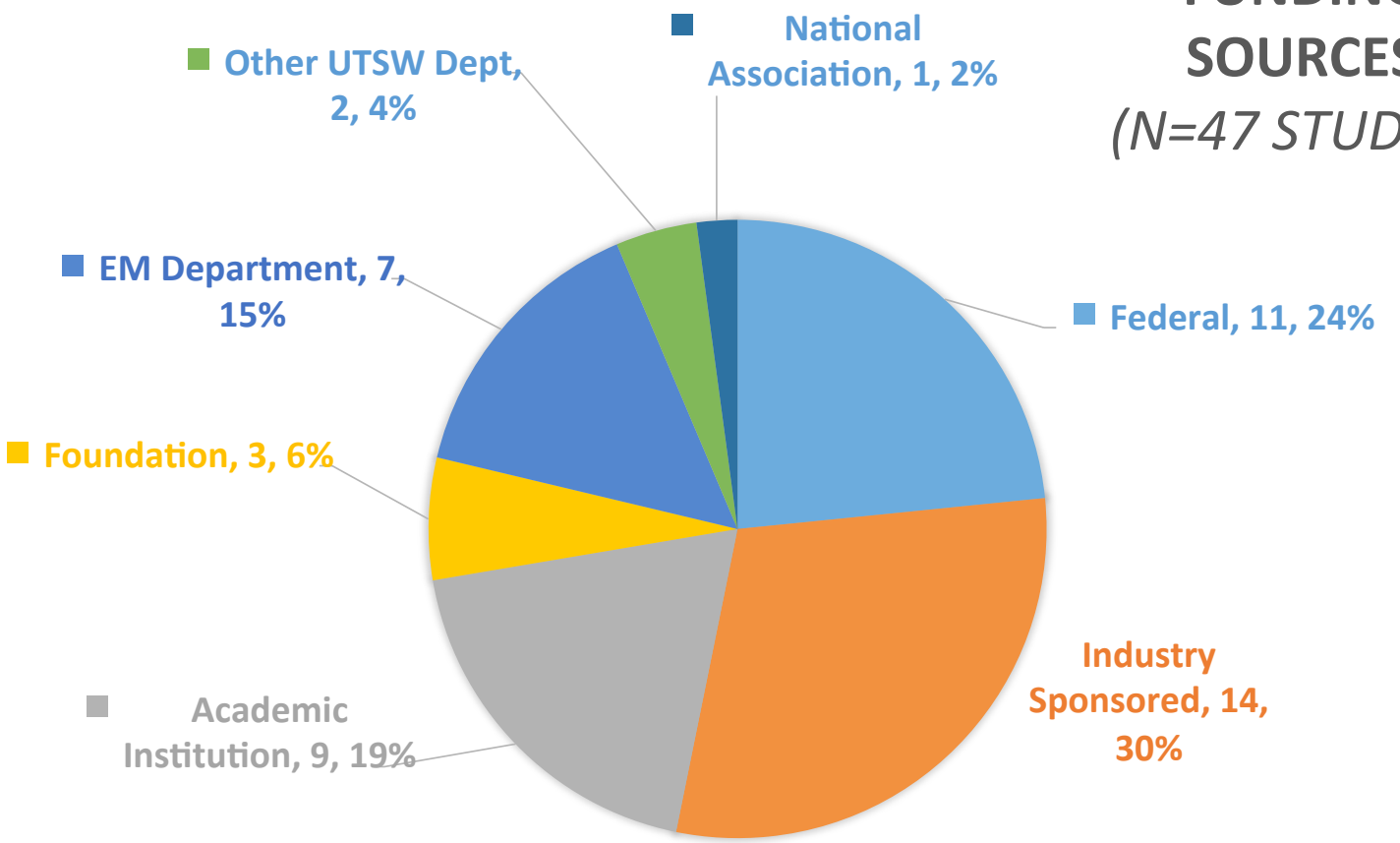
Sponsored vs. Non-Sponsored Studies

(N=54 Studies)

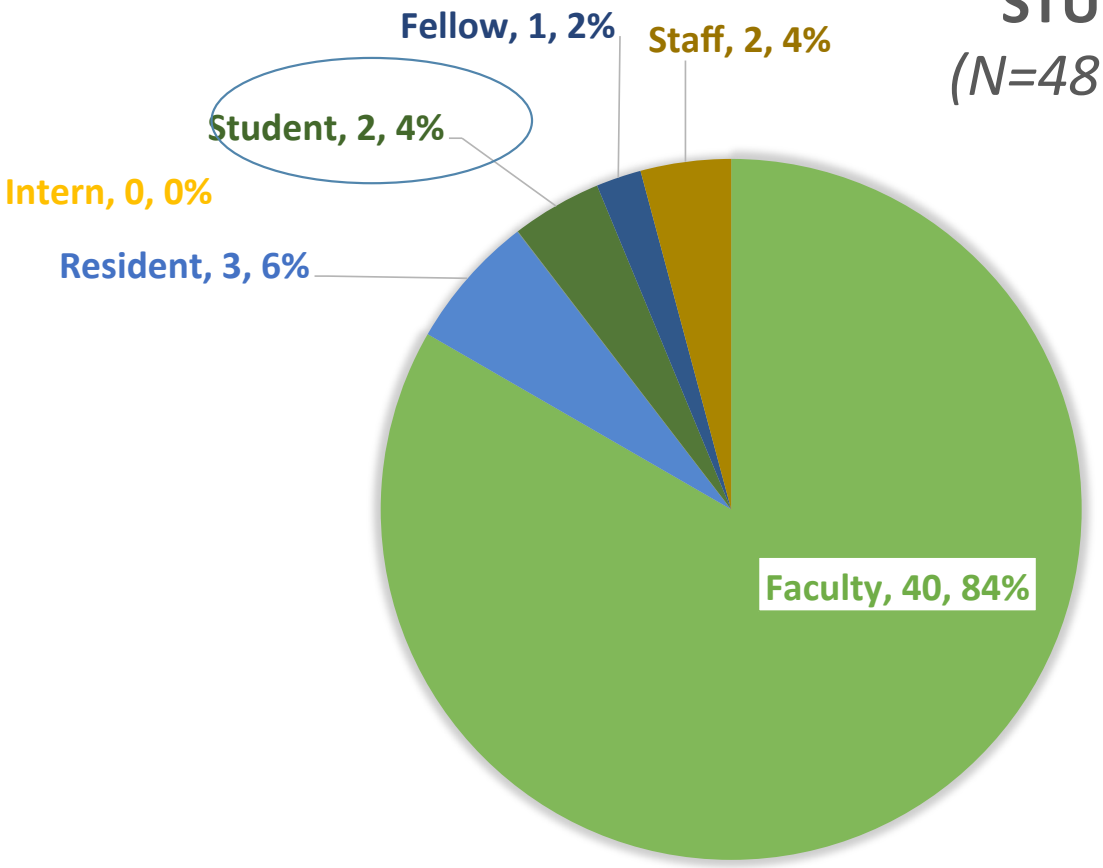


FUNDING SOURCES

(N=47 STUDIES)



STUDY INITIATORS
(N=48 INVESTIGATORS)



PARKLAND EM STUDIES

VAS

This is a prospective anonymous survey study involving a simple pain severity measurement tool, the visual analog scale (VAS). Subjects will be instructed to indicate the intensity of their pain by marking a line anchored with terms describing the extremes of pain intensity from no pain to worst possible pain. Treating physicians and nurses will also be asked to rate their perception of the subject's pain severity.

Purpose:

1. To compare the mean pain severity rating across race and ethnicity to assess potential disparities in patient reporting.
2. To compare the mean perception of pain severity by attending physicians and nurses to assess potential biases among healthcare providers across race and ethnicity.

VAS

Patient Inclusion Criteria:

Potential opportunity for enrollment experience

Aged 18 or above
Presenting to Parkland ED with pain
English speaking
Non prisoner
Not pregnant
Provides verbal consent
Willing to complete the VAS regarding the severity of their pain

Physician/Nurse Inclusion Criteria:

Treating a patient who presented to ED with injury
Willing to complete VAS regarding perception of patient's severity of pain

Patient Preferences

This is a prospective anonymous survey study involving ED patients' preferences for admission with inpatient functional studies vs. discharge with outpatient functional studies when presenting to the ED with chest pain, including preference for non-invasive vs. invasive testing.

Purpose:

1. To compare emergency department (ED) patients' preferences for admission with inpatient functional studies vs. discharge with outpatient functional studies when presenting to the ED with chest pain.
2. To assess whether the ED patient with chest pain would rather a non-invasive vs. an invasive test for risk stratification.
3. To assess whether the Ed patient with chest pain would like to review a chest pain decision tool that shows cardiac risk to help them make a shared decision about having the stress test as an inpatient vs. an outpatients.

Patient Preferences

INCLUSION CRITERIA

Aged 18 or above
Presenting to Parkland ED with chest pain
Non prisoner
Not pregnant
Provides verbal consent

Potential opportunity for enrollment experience

EXCLUSION CRITERIA

ST Elevation Myocardial Infarction on ECG
Positive Cardiac Biomarkers

Morphine and Platelets

The purpose of this study is to determine if there is a difference between morphine and fentanyl effects on platelet aggregation.

Morphine has long been a standard of care in treatment of acute MI, however given the emerging data on morphine's potential ability to lead to increased platelet aggregation we may need to call into question this practice. The few studies that have been conducted have largely examined morphine and platelet aggregation in vitro; there is a paucity of literature examining in vivo effects and changes in clinical outcomes related to morphine administration. Furthermore, to the best of our knowledge, no group has investigated the effects of morphine versus other types of pain medication, opioid or otherwise, on outcome in acute MI.

If the hypothesis is proven true, further studies would investigate clinical outcomes of morphine in MI as well as explore effects of morphine on conditions in which enhanced thrombus formation may be favorable – e.g. trauma, gastrointestinal bleeding.

After consent, blood will be drawn prior to pain medication and 20-60 minutes after IV or IM morphine.

Morphine and Platelets

Inclusion Criteria:

Male or female aged 18-60

Female not pregnant

Patient presents to ED with ortho or abdominal related injury/ pain

Patient is to receive morphine or fentanyl by IV or IM as standard of care

Patient has **not** been given a local anesthetic

Patient has **not** been on any meds that effect platelets for the past 2 weeks

Morphine and Platelets

Exclusion Criteria:

- Pregnant
- Taking platelet altering agent (NSAIDs, Penicillins, Cephalosporins, Macrobid, Hydroxychloroquine
  Amphotericin, Beta-blocker, Nitroprusside, Nitroglycerin, Calcium channel blockers, Anticoagulants [Heparin, Couomadin]
  Tricyclic antidepressants, Phenothiazines, Local anesthesia, Antiplatelet agents [Clopidegrel, aspirin]
- Has known coagulation disorder
- Renal or hepatic dysfunction
  - Cr>1.5
  - AST>100
- Chronic infectious disease
  - HIV
  - Hep B
  - Hep C
- Allergy to morphine or fentanyl

SOAR

Safety of Oral Anticoagulants Registry (SOAR): A National, Hospital-Based, Sentinel Surveillance Study of the Clinical and Economic Impact of Bleeding and Bleeding Concerns due to the Use of Oral Anticoagulants

This is a multicenter observational registry of patients treated with oral anticoagulants who present to the ED or in the hospital with acute illness or injury.

- Data will be recorded on the use of all agents in all indications (and in off-label use). Preprocedural bleeding concerns and frank bleeding complications will be included. Any complications incurred from treatment of OAC safety concerns will similarly be recorded.
- Clinical and economic data from the entire hospital episode of care will be collected. Treatment strategies—protective/anticipatory as well as rescue/resuscitative—will be characterized.
- Throughout the course of hospital care of enrolled subjects, SOAR will collect cost data for diagnostic tests, procedures, lengths of stay (ED and inpatient), and complications related to consideration of the patient's use of OACs upon initial presentation.
- The goal is to enroll 1500 patients in up to 30 centers in the US over a 24-month period.

SOAR

Inclusion Criteria:

- Patients aged 18 years and older will be considered for inclusion in the study. Eligibility will be assessed by the treating clinician based on real-time clinical data. Patients being enrolled in other non-interventional surveillance studies may be enrolled in SOAR.
- Eligible patients will present to the ED or hospital with an acute illness or injury and must, in the opinion of the treating clinician, be experiencing an active anticoagulation effect due to the use of an OAC, **and** have **either:**
- (1) **Bleeding requiring specific intervention** (see below); **or**
- (2) **Bleeding concern** in a non-bleeding patient requiring a specific invasive diagnostic assessment or therapeutic intervention prompting reversal, repletion or decontamination, or a clinically significant delay in

(1) Bleeding requiring intervention – patients must be taking an OAC and meet at least **one** of the following criteria:

- Acute bleeding that is potentially life-threatening at presentation
- Acute bleeding associated with a fall in hemoglobin level by ≥2 g/dL
- Acute bleeding associated with a hemoglobin level of ≤8 g/dL if no baseline hemoglobin is available
- Acute symptomatic bleeding in a critical area or organ
- Any intracranial bleeding
- Bleeding for which more than 8 hours of direct patient monitoring is required prior to ED disposition
- Bleeding for which intravenous (IV) Vitamin K, fresh frozen plasma (FFP), any prothrombin complex concentrates (PCC) or activated PCC (aPCC), any specific factor replacement or reversal agent, or a parenteral hemostatic agent such as tranexamic acid is administered
- Bleeding for which packed red blood cells (PRBCs) or platelets are transfused

(2) Bleeding Concern - patients must be taking an OAC and who, without overt bleeding, meet at least **one** of the following criteria:

- Diagnostic or therapeutic surgical procedure for which hemostasis is desirable (e.g., emergency laparotomy) and which, in the opinion of the treating physician, cannot be postponed at least 8 hours
- Diagnostic or therapeutic percutaneous procedure for which hemostasis is desirable (e.g., lumbar puncture) and which, in the opinion of the treating physician, cannot be postponed at least 8 hours
  - Overdose (deliberate or accidental) of one or more OAC agents that, in the opinion of the treating physician, requires the administration of Vitamin K, FFP, any PCC or aPCC, any specific factor replacement or specific reversal agent, or a parenteral hemostatic agent such as tranexamic acid, with the desire of immediate reversal of anticoagulation
- Bleeding concern for which, in the opinion of the treating physician, more than 8 hours of direct patient monitoring is required prior to ED disposition

SOAR

Exclusion Criteria:

Patients who meet **any** of the following criteria are **not eligible** for inclusion in this registry study:

- Those who have received an investigational reversal agent for an OAC during the index event (data on these patients will be collected as part the pertinent investigational study). If during the course of SOAR enrollment an investigational reversal agent is approved, and that agent is used outside a registration study, that subject is *not* excluded.
- Those who have received treatment for a bleed or bleeding concern at another facility immediately prior to being transferred to Parkland.

REPORT HF

This is an observational registry study looking at heart failure that will document the routine patterns of diagnosis and medical care for heart failure patients as well as treatment type, long-term HF-related clinical events, and re-admission rates following study enrollment.

There is limited information from previous registries on long-term follow-up of heart failure patients. In addition to the long-term data collection, the study will also link treatment plans and clinical outcomes, to identify the best way to treat heart failure, and the extent of healthcare resources use. In addition, data on the patient's quality of life, economic burden and caregiver burden will be collected via questionnaires.

This is a global, multinational, prospective, non-interventional, disease registry with longitudinal data collection. The registry is designed to follow every eligible patient for 3 years. Depending on the rate of recruitment, the registry could be collecting data until this objective is attained or a maximum length of 6 years, 2014 to 2020. There is no treatment or interventions involved with this study.

REPORT HF

Inclusion Criteria:

- Males/females patients 18 year old, or older
- Hospitalized at the registry site with primary diagnosis of acute heart failure

(Diagnoses will be made by the treating physicians according to local practices and their clinical judgment (i.e., History/ examination; Chest X-ray; ECG, Echocardiogram, BNP or NT-proBNP).

REPORT HF

Exclusion Criteria:

- Patients with any condition or prior therapy which, in the opinion of the Investigator, would make the subject unsuitable for this registry
- Concomitant participation in any/a clinical trial with any investigational treatment (for any sponsor).
- Use of investigational drugs within 5 half-lives of enrollment, or until the expected pharmacodynamic effect has returned to baseline, whichever is longer (as guideline, last dose for small molecules should have occurred more than 30 days, and for biologics more than 4 months prior to enrollment).

CONTACT INFORMATION

If you spot a potentially eligible patient for one of the studies currently enrolling in the Emergency Medicine Department at Parkland, please:

- Call our global pager # 214-786-6677
- Email our global page at 214-786-6677@usamobility.net
  - We will receive the text of the entire email on our digital pagers, so feel free to type details.

If you have questions about eligibility, contact Mario Puente at:

- Mario.Puente@utsw.edu
- 214-648-2767