testing for evaluation of possible ACS. Initial structured data collection included demographics, details of current presentation, and medical history. Patients were followed in-house; 30-day and 1-year follow-up was performed by direct telephone contact and medical record review. The main outcome was a composite of death, acute myocardial infarction (AMI), and revascularization. Comparisons between patients with and without stress testing were done using chi-square or t-tests, as appropriate, and 95% confidence intervals (CI).

Results: 2737 patients were enrolled; 586 were less than 40 year old: 7% <30; 42% 30-35; 50% 36-40 years old. Sixty-one percent were female, 71% were Black. 65 had prior stress testing, 1 positive; 23 had prior caths, 3 positive. Within 30 days, 33 patients (5.6%) received testing: 30 stress testing and 5 cardiac catheterization (2 both): none were positive. One year death, AMI, revascularization were not different between patients who did and did not receive stress testing (0% [0-10.3%] v 0.5% [0.1-1.4%]).

Conclusion: Young patients without known heart disease do not appear to benefit from stress testing when they present with potential acute coronary syndrome. This is consistent with Bayesian theory that testing patients at low risk of disease does not frequently change the posterior probability of disease, enough to justify widespread testing.

405 Including Gender in Emergency Medicine Research

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Evidence demonstrates gender variations in health outcomes, disease prognoses and interventions. In contrast to ''women's health'' research, ''gender'' research examines the impact of being male or female on health outcomes. Emergency medicine (EM) physicians, as the clinical specialists for acute care, are at the cusp of a new science, and can directly affect patient care by understanding how outcomes differ for men versus women.

Objective: To determine if EM physicians include gender in their research design.

Methods: The term 'emergency' was used in the OVID Permuted Index to identify all EM-related terms in Medline (EMS, evidence-based EM, emergency medicine, emergency service, hospital and related headings). Inclusion criteria included adults and English language. Case reports, editorials, letters, reviews, concept, guidelines, and non-EM papers were excluded. Abstracts were coded as EM if the first, second, or last author belonged to an EM department. Raters were trained to use a standardized data abstraction form. Inter-coder reliability was measured. Coding ambiguities were clarified and resolved.

Results: Of 38,200 records from 01/06-04/09, 2487 met inclusion criteria; 1737 abstracts met exclusion criteria. Full texts were reviewed for 750 original studies coded as EM. Inter-coder agreement for key gender variables was: outcomes (0.86), composition (0.90), control variable (0.76), and 'independent variable' (0.67). The top four categories were: administration/crowding, cardiovascular, EMS, and trauma. Funding sources were government (16%), institution (12%), foundation (10%), industry (7%), and none listed (65%). While 612 articles (82%) mentioned any gender-related analysis, only 15 (2%) reported a gender-specific outcome; 18% used gender as an independent variable; 11% used it as a control variable; 79% reported it in the demographic composition.

Conclusion: A majority of EM articles report gender in the demographics; however, few studies incorporate gender in their design as predictor or control.

406 Electronic Versus Manual Data Processing in Out-of-Hospital Trauma Research: Validation of an All-electronic Approach

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Objective: Whether electronic data processing for out-of-hospital (OOH) research yields sufficient quality compared to manual record abstraction remains unclear. We compared an all-electronic approach to manual abstraction for OOH trauma patients.

Methods: We analyzed a prospective, population-based cohort of trauma patients collected from 1/2006 through 10/2007 by 16 emergency medical services (EMS) agencies in a dual-advanced life support (ALS) system transporting to 15 hospitals. Inclusion criteria were: SBP <= 90, respirations <10 or >29, GCS <= 12, field intubation, or death in the field. We considered manual chart matching (2+ EMS records per patient) and abstraction by a trained data abstractor as the gold standard for data quality. The comparative approach involved electronic data exports, reformatting, data cleaning, and probabilistic linkage. The two pathways were conducted independent of each other by personnel blinded to patients in the other group. We compared 18 variables (initial and worst physiologic values, field procedures, time intervals, outcomes) using statistical measures of agreement (kappa, wtd kappa, Spearman correlation), Bland-Altman plots, and mismatch rates.

Results: Four hundred and eighteen patients underwent dual data processing. Correlation for physiologic values ranged from 0.97 (highest heart rate) to 0.78 (initial respiratory rate). Weighted kappa for field GCS ranged from 0.88 (lowest GCS) to 0.78 (initial GCS). Kappa values for field procedures ranged from 0.97 (intubation) to 0.76 (IV placement). Correlation for time intervals was highest for transport (0.98) and lowest for response (0.61). Outcome comparison included length of stay (correlation 0.91) and mortality (kappa 0.96). Mismatch rates ranged from 0.9% (intubation) to 4.9% (IV). Processing time per-record was 0.7 min for electronic and 81 min for manual.

Conclusions: Electronic OOH trauma data processing had very good to excellent agreement and low mismatch rates when compared with manual data abstraction for a fraction (<1%) of the average time per record.

407 The Use of Delayed Telephone Informed Consent for Observational Emergency Medicine Research is Ethical and Effective

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Objectives: Emergency medicine research poses unique problems for investigators seeking informed consent. Variability in obtaining consent in the emergency department (ED) introduces bias into study results. The objective of this abstract was to describe the rate of successful informed consent using a delayed telephone consent process in ED patients. We hypothesized that phone consent would be successful in over 90% of patients eligible for a minimal risk, observational study.

Methods: This was an analysis of the consent process for a prospective, multicenter study evaluating elderly patients with head trauma at one university and five community EDs. Informed consent was not obtained during the ED visit. Patients or their surrogates (where consent was not possible due to baseline decreased mental status) were contacted by telephone at least 14 days after

ED discharge and were consented for follow-up after being given all elements of informed consent. The study results are presented with simple descriptive statistics.

Results: Two hundred and ten patients with a mean age of 75.0 ± 13.2 years including 123 (59%; 95% CI 51-65%) female subjects were enrolled. Phone follow-up was successful in 209/210 cases (99.5%, 95% CI 97.3 – 99.9%). Surrogates provided consent in 89 cases (42%, 95% CI 36-49%) All patients and surrogates contacted granted consent for the study (100%; 95% CI 98.6-100%). Median time from ED visit to phone contact was 20 days (interquartile range [IQR] 17, 24). The median number of phone attempts for successful contact was 1 (IQR 1,2).

Conclusions: We achieved a very high rate of successful telephone follow-up in this elderly ED population. Obtaining consent using a delayed, telephone contact process is effective and well-received by both subjects and surrogates. IRBs should strongly consider this method of consent for minimal risk studies requiring telephone follow-up, as opposed to a consent process requiring written informed consent at the time of initial ED visit.

408 Development and Implementation of a Data Collection Instrument to Analyze FDA Adverse Event Reports

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Background: The US Food and Drug Administration (FDA) is responsible for approving medical devices and collecting adverse event reports. The Manufacturer and User Device Experience (MAUDE) Database is available for download from the FDA website. Because the data collected are not device-specific, the particulars of a given adverse event report are described in a free-form narrative, which makes categorization of device failures and trend analysis difficult.

Objectives: To develop and validate a device-specific instrument for rapidly and accurately abstracting MAUDE narratives.

Methods: Key device components and likely models of failure were identified to generate a draft instrument. An iterative process of random sampling of reports, analysis using successive draft instruments by independent observers, and assessment of inter-rater reliability, was performed until overall agreement of 90% on objective questions and 80% on subjective questions was reached. The finalized instrument was used to analyze all available MAUDE narrative reports by two independent reviewers, with disputes resolved by a third, independent reviewer. Disputes that could not be reconciled by the third reviewer were resolved by an arbitration committee.

Results: Four iterations were required before the instrument met the agreement threshold. The final instrument was used to rate 1,284 reports. Agreement for the first two reviewers was 82% (kappa=0.56-0.90) for the objective portion and 70% (kappa =0.06-0.67) for the subjective portion. After dispute resolution by the third reviewer, agreement was reached for 98% of the objective questions and 96% of the subjective questions. The average time for one reviewer to complete abstraction was one to two minutes.

Conclusions: FDA MAUDE narrative reports can be rapidly and accurately abstracted, which facilitates quantitative analysis. Development of device-specific abstraction tools could be used to improve the quality of FDA adverse event reporting.

409 Assessing the Informed Consent Skills of Emergency Medicine Resident Physicians

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Objectives: To assess the ability of emergency medicine (EM) residents to obtain informed consent (IC) for an invasive procedure using a standardized patient (SP).

Methods: This was an observational study in which participants were initially blinded to the objectives of the study. All EM residents from Regions Hospital were invited to participate. Each participant conducted a video-recorded history and physical exam with an SP needing tube thoracostomy due to a 40% spontaneous pneumothorax diagnosed by chest radiograph. Two faculty EM physicians independently reviewed the videos and evaluated the participants' IC skills in two ways: first, they gave an overall impression of whether or not IC was obtained; second, they evaluated the participants using a 30 point score based on the five elements of IC (decision-making capacity, disclosure, voluntariness, understanding, and physician recommendation). Once all participants completed the case, the true objectives of the study were revealed and participants were given the option to withdraw from the study. Descriptive statistics and kappa coefficient were generated from the data collected.

Results: Twenty-two residents completed the study. Twenty residents (91%) obtained IC based on both reviewers' overall impression. One disagreement occurred between reviewers (kappa=0.64). The mean IC score (range 0-30) was 18.5 +/- 0.5.

Conclusions: In a simulated setting, most EM residents at this training program possess the knowledge and skills necessary to obtain IC prior to an invasive procedure.

410 Variations in Local Institutional Review Board (IRB) Responses to a Standard, Multi-center, Emergency Department-based Genetic Research Protocol

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Objective: There are increasing federal regulations concerning the conduct of studies collecting genetic data. Institutional variation in the interpretation and application of these regulations can affect the implementation of multi-center genetic studies. The CRASH study investigates genetic predictors of chronic pain and psychological sequelae after minor motor vehicle collisions. To our knowledge, this study group is the first multi-center genetic research protocol based solely in the emergency department (ED). We sought to assess institutional variability in obtaining approval for this study.

Methods: We performed a survey of the participating CRASH study group (n=7) to investigate the various Institutional Review Board (IRB) approval process using a standardized questionnaire.

Table for Abstract 410

Total number of changes	Changes to methodology	Changes to consent	Changes to eligibility	Changes to statistics	Changes to funding	Changes due to ethical issues	Changes due to genetic testing
4.3 (1.0–7.6)	1.1 (0.31–2.0)	2.3 (0.89–3.7)	0.71(0.10–0.90)	0.29 (-0.30–0.36)	0.29 (-0.49–0.55)	1.71 (-0.29–3.71)	1.4 (-0.08–2.8)