Published in final edited form as:

Resuscitation. 2009 June ; 80(6): 644–649. doi:10.1016/j.resuscitation.2009.03.015.

Is the Enrollment of Racial and Ethnic Minorities in Research in the Emergency Setting Equitable?

Jeremy Sugarman¹, Colleen Sitlani², Dug Andrusiek³, Tom Aufderheide⁴, Eileen M. Bulger⁵, Daniel P. Davis⁶, David B. Hoyt⁷, Ahamed Idris⁸, Jeffrey D. Kerby⁹, Judy Powell², Terri Schmidt¹⁰, Arthur S. Slutsky¹¹, George Sopko¹², Shannon Stephens¹³, Carolyn Williams¹³, and Graham Nichol for the Resuscitation Outcomes Consortium Investigators

¹ *Berman Institute of Bioethics, Department of Medicine, Department of Health Policy and Management, Johns Hopkins University, Baltimore, MD*

² *Department of Biostatistics, Resuscitation Outcomes Consortium Clinical Trial Center, University of Washington, Seattle, WA*

³ *Medical Programs, Emergency and Health Services Commission, and School of Population and Public Health, University of British Columbia, Vancouver, British Columbia*

⁴ *Department of Emergency Medicine, Medical College of Wisconsin, Milwaukee, WI*

⁵ *Department of Surgery, University of Washington, Seattle, WA*

⁶ *Department of Emergency Medicine, University of California San Diego, La Jolla, CA*

⁷ *Department of Surgery, University of California, Irvine, Irvine, CA*

⁸ *Department of Surgery, University of Texas Southwestern Medical Center at Dallas, Dallas, TX*

⁹ *Section of Trauma, Burns and Surgical Critical Care, Department of Surgery, University of Alabama at Birmingham, Birmingham, AL*

Correspondence: Jeremy Sugarman, MD, MPH, MA, Harvey M. Meyerhoff Professor of Bioethics and Medicine, Berman Institute of Bioethics and Department of Medicine, Johns Hopkins University, Hampton House 351, 624 N. Broadway, Baltimore, MD 21205, USA, Phone: 410-955-3119, Fax: 410-614-9567, Email: E-mail: jsugarm1@jhmi.edu.

CONFLICT OF INTEREST STATEMENT.

Jeremy Sugarman has no relevant conflicts of interest.

Colleen Sitlani has no relevant conflicts of interest.

Dug Andrusiek has no relevant conflicts of interest.

Tom Aufderheide is a consultant for Take Heart America, JoLife, and Medtronic.

Eileen Bulger has no relevant conflicts of interest.

Daniel Davis has no relevant conflicts of interest.

Dave Hoyt has no relevant conflicts of interest.

Ahamed Idris has no relevant conflicts of interest.

Jeff Kerby has no relevant conflicts of interest.

Judy Powell has no relevant conflicts of interest.

Terri Schmidt has no relevant conflicts of interest.

Arthur Slutsky has no relevant conflicts of interest.

George Sopko has no relevant conflicts of interest.

Shannon Stephens has no relevant conflicts of interest.

Carolyn Williams has no relevant conflicts of interest.

Graham Nichol serves on the Medic One Foundation Board of Directors; he has received equipment from the Asmund S. Laerdal Foundation for Acute Medicine, Laerdal Inc., and Medtronic Physio-Control Inc.; travel expenses for single trips in 2006 from INNERcool Inc. and Radiant Inc.; and is a consultant to Northfield Laboratories Inc.

Publisher's Disclaimer: This is a PDF file of an unedited manuscript that has been accepted for publication. As a service to our customers we are providing this early version of the manuscript. The manuscript will undergo copyediting, typesetting, and review of the resulting proof before it is published in its final citable form. Please note that during the production process errors may be discovered which could affect the content, and all legal disclaimers that apply to the journal pertain.

10 *Department of Emergency Medicine and Center for Ethics in Health Care, School of Medicine, Oregon Health & Science University, Portland, OR*

11 *Keenan Research Center of the Li Ka Shing Knowledge Institute at St. Michael's Hospital, and University of Toronto, Toronto, CA*

12 *Division of Cardiovascular Diseases, National Heart, Lung and Blood Institute, National Institutes of Health, Bethesda, MD*

13 *Department of Emergency Medicine, Alabama Resuscitation Center, University of Alabama at Birmingham, Birmingham, AL*

14 *University of Washington – Harborview Center for Prehospital Emergency Care, Seattle, WA*

Abstract

Background—Concerns have been raised about the enrollment of racial and ethnic minorities in research in the emergency setting when it is not possible to obtain informed consent. However, there is a paucity of data related to the validity of such claims.

Methods—Retrospective comparison of registry enrollment (4/1/06–3/31/07) and trial enrollment (4/1/07–3/31/08) from 3 sites in the Resuscitation Outcomes Consortium. Subjects compared met the following criteria: 1) Shock, defined by blunt or penetrating force to the body with either systolic blood pressure (SBP) ≤ 70 mmHg or SBP 71–90 mmHg and heart rate ≥ 108 beats/min; and/or 2) Traumatic Brain Injury (TBI), defined by blunt force to the head with out-of-hospital Glasgow Coma Score ≤ 8 .

Results—Overall, compared to a registry there were no differences in the percent of racial or ethnic groups enrolled in the clinical trial [Odds Ratio (OR) for Blacks versus Whites: 0.87, 95% Confidence Interval (CI) 0.65–1.16, $p=.34$; OR for Hispanics versus Whites 1.04; CI 0.72–1.49, $p=.85$]. However, Blacks were less likely than Whites to be enrolled in the TBI cohort [OR 0.58 (0.34–0.97); $p=.04$].

Conclusions—Despite some discordance in subgroups, there was no overall difference in the racial and ethnic distribution of subjects enrolled in a multi-center clinical trial of severe trauma compared to a registry accounting for study entry criteria. These findings help address justice concerns about enrollment of racial and ethnic minorities in trauma research performed using an exception from informed consent under emergency circumstances.

INTRODUCTION

Across a wide spectrum of medical research, concerns have been raised about the appropriate representation of those with a variety of socio-demographic characteristics including gender, age, and race.⁽¹⁾ As a matter of justice, it is essential to ensure that enrollment in research is fair and representative of those who experience a given disease or condition for a variety of reasons. First, if research is not conducted within a particular group, it may be unclear whether a particular intervention is safe and effective in that group. Conversely, members of one group ought not to disproportionately bear the risks of research so that those in another group may benefit.

With respect to race, low participation rates in clinical research trials among African-Americans in the United States are often attributed to a lack of trust in the medical and research communities stemming from historical abuses. ^(2–9) There are also suggestions that low participation rates may be due to the fact that persons of color may be approached for enrollment less frequently. ^(10,11)

In a study of hypothermia treatment in trauma that used prospective informed consent for the first nine months of the study, minorities were under represented by 30% in that time period.

(12) Concerns have also been raised about racial enrollment in research in the emergency setting, where it may not be feasible to obtain informed consent due to the nature of the conditions being studied, such as cardiopulmonary arrest or severe trauma.(13–17) Here, however, the matter relates to possible over-enrollment of racial and ethnic minorities, rather than low participation rates that are decried in other types of clinical research. The underlying issue in this sort of research seems to be the suspicion that the research will be conducted among racial and ethnic minorities without long-term benefits accruing to them for an experimental intervention that proves to be effective. Alternatively, a group might assume the risks of research when the intervention turns out not to be ineffective. Yet, given the prevalence of these conditions and the poor outcomes associated with them among persons of all races and ethnicities(17–20), it is essential to ensure equitable enrollment in ethically sound research in the emergency setting. Only in this way can potentially effective interventions be properly tested and eventually introduced appropriately into clinical practice.

While such concerns about disproportionate enrollment have been raised for research in the emergency setting, the actual extent to which racial and ethnic minorities are enrolled in this research is unclear. In this study, we sought to determine whether racial and ethnic minority enrollment is disproportionate in ongoing research using an exception from informed consent under emergency circumstances.(14) Such data are essential for helping to inform policy and practice for research in the emergency setting.

METHODS

Background

The Resuscitation Outcomes Consortium (ROC) is a research network established to evaluate the treatment of people with life-threatening injury and out-of-hospital cardiac arrest and to conduct clinical trials of promising scientific and clinical advances so as to improve survival. This network consists of 11 sites and one central coordinating center. See <https://roc.uwisc.edu/tiki/tiki-index.php?page=roc-public-home>. (21) ROC created a registry (Epistry) that includes all cases of cardiopulmonary arrest and severe traumatic injuries assessed or treated by emergency medical services (EMS) personnel in participating geographic regions.(22) In addition, a randomized trial (HS) of normal saline versus hypertonic saline versus hypertonic saline with dextran is enrolling patients with shock after traumatic injury or traumatic brain injury (TBI).(23) The Epistry enrolls subjects with a waiver of the requirement to obtain informed consent.(24) The HS trial enrolls subjects using an exception from the requirement to obtain informed consent under emergency circumstances.(14) Use of this exception requires that the research meet a series of provisions which include community consultation and public disclosure.(25) We sought to compare the race and ethnicity of subjects enrolled in the Epistry to the HS trial to assess whether racial and ethnic enrollment is disproportionate. The primary null hypothesis was that the proportion of each race or ethnicity enrolled did not differ when comparing subjects meeting criteria for enrollment in the HS trial who were enrolled in Epistry versus subjects enrolled in the HS trial.

Design

This is a retrospective comparison of observational (Epistry) versus clinical trial (HS) data from EMS agencies and receiving institutions in eight US sites and three Canadian sites that are participants in the ROC. In both Epistry and HS, EMS personnel classify race and ethnicity based on visual assessment, supplemented by additional information such as name or information provided by family members if available. Three sites with sufficient information describing the race and ethnicity of those enrolled in both Epistry and HS were included in the primary analyses.

Population

The study population was all traumatic injury cases that occurred within the catchment area of a participating EMS agency who met HS study entry criteria before the trial began and those patients with traumatic injury who were enrolled in the trial following study implementation. The census tract of the location of each case was identified and recorded in order to assess the catchment population served by each agency.

Inclusion and Exclusion Criteria

The ROC Trauma Epistery is a consortium-wide epidemiologic registry of trauma cases that are assessed or treated by EMS agencies participating in ROC the details of which are described elsewhere. (22)

To be enrolled in the HS trial a person must be at least 15 years of age and must experience: 1) blunt or penetrating force to the body with either out-of-hospital systolic blood pressure (SBP) ≤ 70 mmHg or out-of-hospital SBP 71–90 mmHg and heart rate ≥ 108 beats/min, and/or 2) blunt force to the head with out-of-hospital Glasgow Coma Score ≤ 8 . Patients who experienced both criteria are considered to be part of the first (shock) cohort. Patients are enrolled by the out-of-hospital provider and receive a blinded 250 cc bag of study fluid (either normal saline, hypertonic saline, or hypertonic saline with dextran).

Epistery cases occurring between April 1, 2006 and March 31, 2007 that were assessed by EMS and met the HS physiologic entry criteria, and HS cases entered in the clinical trial (occurring between April 1, 2007 and March 31, 2008) were included in all analyses. These time periods were chosen to permit a comparison of one full year of data from the registry to the subsequent year of data from the trial. Trauma Epistery data were not fully collected after March 31, 2007, and all sites had not yet begun HS at this time, so insufficient data were available to perform concurrent analyses.

Enrollment data from all sites are displayed in Table 1. Sites were assigned a random code to preserve confidentiality. To minimize potential bias, only sites with out-of-hospital race and ethnicity data recorded for $>75\%$ of eligible patients in both Epistery and HS were included in subsequent analyses. Further analyses were limited to subjects who were identified to be White, Black, or Hispanic, representing $>98\%$ of those with available data about race and ethnicity in these three sites. The number of subjects identified as Asian was extremely small, precluding analysis in this regard.

The distribution of these three classifications in the catchment population was estimated via data from the 2000 US census. Analysis was restricted to those 18 years of age and over with only one designated race or ethnicity and who lived in a census tract covered by one or more EMS agencies participating in Epistery. However, incidence of trauma may not reflect this racial and ethnic distribution, so the distribution of race and ethnicity among all trauma cases recorded in Epistery was also provided.

While all ROC sites participated in Epistery, a few ROC EMS agencies within these sites did not. Therefore these analyses are restricted to subjects enrolled by agencies that participated in both Epistery and HS.

Human Subjects

The Epistery and the HS trial were approved by the University of Washington Institutional Review Board, as well as by all participating local institutional review boards or research ethics boards. Epistery was approved with a waiver of the requirement for informed consent. HS was approved with an exemption from the requirement to obtain consent in emergency setting. The

Institutional Review Board at Johns Hopkins Medical Institutions deemed this analysis of previously collected data to be exempt from review.

Data Analysis

The primary analysis involved chi-square tests to assess whether or not there were associations between the races (Black vs. White) or ethnicities (Hispanic vs. White) and enrollment status. Odds ratios and 95% confidence intervals (CI), comparing the odds of being in HS among Blacks (Hispanics) to the odds of being in HS among Whites were also calculated.

RESULTS

From April 1, 2006 to March 31, 2007 there were 8299 subjects enrolled in the Epistry database at 11 sites. Of these 3276 met entry criteria for the HS study. From April 1, 2007 to March 31, 2008 there were 1064 subjects enrolled in the HS study at the 11 sites. The primary analyses were restricted to the three sites with sufficiently complete out-of-hospital data on race and ethnicity (Table 1).

A comparison of matched US Census tract data from 2000 to overall enrollment in Epistry in the sites with sufficient data for analysis is displayed in Table 2. While the catchment population as defined by census data are 63% White, 20% Black, and 17% Hispanic, enrollment in the trauma registry is 39% White, 41% Black, and 20% Hispanic, estimating the prevalence of trauma in this population.

For the three sites with sufficiently complete data on race and ethnicity, there were 855 subjects enrolled in Epistry who met HS enrollment criteria, while 351 subjects were enrolled in HS. These observed differences in enrollment in the registry and the trial are likely related to our data sources. For example, registry data do not include information regarding all the exclusion criteria for the trial (such as having received more than 2 liters of fluids). In addition, data in the registry are less complete than corresponding data in the trial, which represent only those actually enrolled and not those who would simply be eligible. For example, a patient might be eligible, but not enrolled because EMS personnel were too busy to do so. We are unaware of any intervening factors that would account for differential enrollment over time.

Of the Epistry subjects, 782 had available race and ethnicity data and 771 were White, Black, or Hispanic. Of the HS subjects, 317 had available race and ethnicity data and 315 were White, Black, or Hispanic. Subject characteristics are described in Table 3. Consistently, a greater proportion of men were enrolled in HS compared to Epistry.

Overall enrollment in Epistry compared to HS, as well as enrollment by cohort in HS, is shown in Table 4. Blacks were not differentially enrolled compared to Whites (OR for enrollment 0.87; 95% CI, 0.65–1.16, $p=.34$); and Hispanics were not differentially enrolled in the trial compared to Whites (OR for enrollment 1.04; 95% CI 0.72–1.49, $p=.85$).

However, when looking at the cohorts separately, Blacks were less likely to be enrolled in the TBI cohort [OR 0.58 (0.34–0.97); $p=.04$]; there was a non-significant trend for Blacks to be more likely to be enrolled in the shock cohort [OR 1.28 (0.87–1.90); $p=.21$].

DISCUSSION

Some critics of research in the emergency setting have claimed that racial and ethnic minorities are or will be enrolled disproportionately in this research.(13,15) Examining such subjective claims with objective data is essential. We found that the enrollment of racial and ethnic minorities in an ongoing randomized trial was proportionate to the prevalence of the condition

being studied. However, our analyses of census tract data compared to a trauma based registry also confirm that blunt or penetrating trauma and traumatic brain injury occur disproportionately among racial and ethnic minorities in the catchment areas where the research is being conducted. As has been suggested by others, this may be due to the location of many trauma centers and the prevalence of trauma among racial and ethnic minorities.(13,15)

Regardless, while it may be true that more persons in a group may be enrolled in research directed at addressing a particular disease or condition that is more prevalent in that group, *prima facie* it would be incorrect to conclude that this alone is an ethical problem. In fact, one could argue that it is appropriate. From the perspective of justice, such an approach comports with the notion that resources, should be directed at addressing conditions that are highly prevalent and that are associated with considerable morbidity and mortality. On this view, one might expect communities who are disproportionately affected by such conditions, not only to endorse research efforts, but to facilitate them. Of course, one might reasonably contend, at least in the case of traumatic injury, that resources ought to be directed at prevention as well as treatment.

Nonetheless, despite the substantial morbidity and mortality associated with traumatic injury among all people, deliberations about the appropriate enrollment of racial and ethnic minorities for research in the emergency setting are influenced by the disturbing historical legacy of research and medical care among African -Americans.(13,26,27) Such concerns mirror earlier concerns regarding medical research and care in general.(28) Of issue here is the assumption that this legacy is associated with a reluctance to enroll in research and that many racial and ethnic minorities would refuse to consent if it was feasible to obtain consent in this setting. While it is impossible to know for sure whether a particular individual would give consent for a specific trial, this study was not conducted to address this question. Although understanding community attitudes towards research in the emergency setting is of critical importance, deciding not to conduct scientifically and ethically sound research in otherwise appropriate settings simply because of the suspicion that some people in the community would not be likely to give consent if it was possible to do so comes at the price of conducting biased research, which may have profound consequences for public health.(29) Biased research may lead to a further erosion of health disparities by resulting in a failure to apply effective interventions or continuing to apply ineffective ones.

Similarly, our secondary analyses revealed a statistically significant under-enrollment of women compared to men in the trial compared to the registry. While the reasons for this finding are unclear, it warrants subsequent primary examination since it potentially raises similar issues with respect to ensuring appropriate representation in clinical trials. (1) Such issues are recognized in NIH policy. (30)

Limitations

Our findings must be interpreted with some limitations in mind. First, we used historical controls which may not accurately reflect the true incidence of the condition over time. Nevertheless, control data were gathered only one year prior to the time of enrollment and were obtained using the same data collection techniques, thereby minimizing the risk of bias. Furthermore, more accurate comparator data are unavailable.

Second, identification of race and ethnicity was made by EMS personnel and may be inaccurate. However, the same method for classifying race and ethnicity was used for both cases and historical controls, and we have no reason to suspect that these classifications of race and ethnicity would have been made differently for the two datasets or over time, minimizing the likelihood of bias.

Third, our analysis involves three geographic sites within the context of a single clinical trial. Therefore, findings may differ in other geographic regions or in other conditions. Regardless, the multi-center nature of this trial and using sites in the analysis that had sufficient data minimize such concerns.

Fourth, while we did not identify a difference in enrollment according to race and ethnicity, it is conceivable that with a larger sample we may have identified a difference with respect to ethnicity given the width of the confidence intervals associated with these data. Similarly, the sample size precludes further examination of subgroups of those experiencing trauma.

Fifth, while we made every effort to accurately identify those cases in the registry that would have been eligible for the trial, it is possible that some misclassification occurred, as described earlier. Nevertheless, they are unlikely to affect our findings regarding racial and ethnic enrollment.

Sixth, our analysis did not assess whether there were disparities among those enrolled under the exemption from the requirement for informed consent versus those enrolled by a legally authorized representative. While this approach makes the comparison of enrollment in the trial to those in the registry cleaner, it does not provide information about whether there is disparate enrollment in these subgroups.

Finally, information about those not enrolled in the trial was not routinely collected. Nevertheless, such data would likely have enhanced the rigor of our findings.

Concluding Comments

Research in the emergency setting is vital to improving survival after major trauma. While such research raises important ethical issues, especially when it is impossible to conduct it with informed consent, it is essential to bring data into the debate. Such an approach promises to enhance the design and conduct of this research, as well as direct attention to those aspects of the research that most demand it. Moving forward, future research should consider prospectively gathering data about those patients who are not enrolled. Regardless, to meet the broader obligations of the ethical principle of justice, efforts need to be made to ensure that the results of this research be applied in the settings in which it was conducted in hopes of decreasing morbidity and mortality.

Acknowledgments

Many ROC investigators provided useful comments in the design of this project. Alison Boyce assisted with a review of the literature. The authors appreciate the helpful comments of the peer-reviewers on earlier versions of this manuscript.

This study was supported by a series of cooperative agreements to 10 regional centers and one data coordinating center (5U01 HL077863, HL077881, HL077871 HL077872, HL077866, HL077908, HL077867, HL077885, HL077885, HL077863) with the National Heart, Lung and Blood Institute in partnership with the National Institute of Neurological Disorders and Stroke, US Army Research and Materiel Command, The Canadian Institutes of Health Research (CIHR) - Institute of Circulatory and Respiratory Health, Defense Research and Development Canada, American Heart Association, and the Heart and Stroke Foundation of Canada. The study sponsors played no role in the study design, in the collection, analysis and interpretation of data; in the writing of the manuscript; and in the decision to submit the manuscript for publication although one author (GS) is employed by the NIH and the NIH reviewed the manuscript prior to submission.

References

1. Kahn, JP.; Mastroianni, AM.; Sugarman, J., editors. Beyond consent: Seeking justice in research. New York: Oxford University Press; 1998.

2. Corbie-Smith G, Thomas SB, Williams MV, Moody-Ayers S. Attitudes and beliefs of african americans toward participation in medical research. *Journal of General Internal Medicine* 1999;14:537–46. [PubMed: 10491242]
3. Jones, JH. *Bad blood: The tuskegee syphilis experiment*. New York: Free Press; 1993.
4. Harris Y, Gorelick PB, Samuels P, Bempong I. Why african americans may not be participating in clinical trials. *Journal of the National Medical Association* 1996;88:630–4. [PubMed: 8918067]
5. Freimuth VS, Quinn SC, Thomas SB, Cole G, Zook E, Duncan T. African americans' views on research and the tuskegee syphilis study. *Social Science and Medicine* 2001;52:797–808. [PubMed: 11218181]
6. Shavers VL, Lynch CF, Burmeister LF. Factors that influence african-americans' willingness to participate in medical research studies. *Cancer* 2001;91:233–6. [PubMed: 11148585]
7. Shavers VL, Lynch CF, Burmeister LF. Knowledge of the tuskegee study and its impact on the willingness to participate in medical research studies. *Journal of the National Medical Association* 2000;92:563–72. [PubMed: 11202759]
8. Guinan ME. Black communities' belief in "AIDS as genocide". A barrier to overcome for HIV prevention. *Annals of Epidemiology* 1993;3:193–5. [PubMed: 8269075]
9. Pickle K, Quinn SC, Brown JD. HIV/AIDS coverage in black newspapers, 1991–1996: Implications for health communication and health education. *Journal of Health Communication* 2002;7:427–44. [PubMed: 12455762]
10. Biswas MS, Newby LK, Bastian LA, Peterson ED, Sugarman J. Who refuses enrollment in cardiac clinical trials? *Clin Trials* 2007;4:258–63. [PubMed: 17715252]
11. Wendler D, Kington R, Madans J, Van Wye G, Christ-Schmidt H, et al. Are racial and ethnic minorities less willing to participate in health research? *PLoS Medicine* 2006;3(2):e40.
12. Clifton GL, Knudson P, McDonald M. Waiver of consent in studies of acute brain injury. *J Neurotrauma* 2002;19:1121–6. [PubMed: 12427322]
13. Dula A. Bearing the brunt of the new regulations. *Minority populations Hastings Center Report* 1997;27(1):11–2.
14. Exception from Informed Consent Requirements for Emergency Research. Code of Federal Regulations. Title 21, Part 50. Subpart B. Section 24., (2007).
15. Neavling, S. Blood experiment disproportionate: Cities had higher numbers of minorities. *Detroit Free Press*; 2007 December 21.
16. Potter, M. San Diego Reader. *Bad blood*. 2005 July 28:July 20, 2008
17. Arango-Lasprilla JC, Rosenthal M, Deluca J, Komaroff E, Sherer M, Cifu D, et al. Traumatic brain injury and functional outcomes: Does minority status matter? *Brain Inj* 2007 Jun;21(7):701–8. [PubMed: 17653944]
18. Karmali S, Laupland K, Harrop AR, Findlay C, Kirkpatrick AW, Winston B, et al. Epidemiology of severe trauma among status aboriginal canadians: A population-based study. *CMAJ* 2005 Apr 12;172(8):1007–11. [PubMed: 15824405]
19. Lyn-Sue J, Siram S, Williams D, Mezgebe H. Epidemiology of trauma deaths in an urban level-1 trauma center predominantly among african americans--implications for prevention. *J Natl Med Assoc* 2006 Dec;98(12):1940–4. [PubMed: 17225838]
20. NeSmith EG. Racial disparities in acute outcomes of life-threatening injury. *J Nurs Scholarsh* 2006;38(3):241–6. [PubMed: 17044341]
21. Davis DP, Garberson LA, Andrusiek D, Hostler D, Daya M, Pirrallo R, et al. A descriptive analysis of emergency medical service systems participating in the resuscitation outcomes consortium prehospital research network. *Prehosp Emerg Care* 2007;11:369–82. [PubMed: 17907019]
22. Newgard CD, Sears GK, Rea TD, Davis DP, Pirrallo RG, Callaway CW, et al. The resuscitation outcomes consortium epi-stry-trauma: Design, development, and implementation of a north american epidemiologic prehospital trauma registry. *Resuscitation* 2008 Aug;78(2):170–8. [PubMed: 18482792]
23. Brasel KJ, Bulger E, Cook AJ, Morrison LJ, Newgard CD, Tisherman SA, et al. Resuscitation Outcomes Consortium investigators. hypertonic resuscitation: Design and implementation of a prehospital intervention trial. *J Am Coll Surg* 2008;206(2):220–32. [PubMed: 18222373]
24. Protection of Human Subjects. Subtitle A. Part 46. 2003.

25. Dickert N, Sugarman J. Ethical goals of community consultation in research. *Am J Pub Health* 2005;95:1123–7. [PubMed: 15983268]
26. Gamble VN. A legacy of distrust: African americans and medical research. *Am J Prev Med* 1993;9 (6 Suppl):35–8. [PubMed: 8123285]
27. Holloway KFC. Accidental communities: Race, emergency medicine, and the problem of PolyHeme. *American Journal of Bioethics* 6(3):4–16.
28. King, PA. Race, justice, and research. In: Kahn, JP.; Mastroianni, AM.; Sugarman, J., editors. *Beyond Consent: Seeking Justice in Research*. New York: Oxford University Press; 1998.
29. Nichol G, Powell J, van Ottingham L, Maier R, Rea T, Christenson J, et al. Consent in resuscitation trials: Benefit or harm for patients and society? *Resuscitation* 2006;70:360–8. [PubMed: 16908094]
30. NIH policy and guidelines on the inclusion of women and minorities as subjects in clinical research – amended . Oct. 2001 Available from:
http://grants.nih.gov/grants/funding/women_min/guidelines_amended_10_2001.htm

Table 1

Completeness of Data by Site *

Random Site Code	TRAUMA EPISTRY RACE/ETHNICITY DATA (4/2006-3/2007)			HS TRIAL RACE/ETHNICITY DATA (4/2007-3/2008)		
	Missing	Available	% Available	Missing	Available	% Available
216	119	2	2%	127	0	0%
307	306	0	0%	72	0	0%
315	18	254	93%	2	113	98%
389	556	0	0%	105	0	0%
434	67	93	58%	56	50	47%
477	30	56	65%	4	1	20%
663	114	58	34%	0	18	100%
671	309	211	41%	103	129	56%
791	258	0	0%	73	1	1%
864	10	209	95%	3	92	97%
925	45	315	88%	34	112	77%
Total in sites with sufficiently complete race/ethnicity data in both Epistry and HS [315, 864, 925]						
	72	780	92%	39	317	89%

*Note: Agencies not enrolling in HS were excluded from Epistry analysis, and vice versa. Sites in **bold (315, 864, and 925)** had sufficient race and ethnicity data available for analysis.

Table 2

Overall US Census Data and Enrollment in Epistry by Race and Ethnicity *

Race/Ethnicity	US Census 2000 (tracts covered by Epistry)	# enrolled in Epistry (Epistry 4/2006–3/2007)
White	63%	1231 (39%)
Black	20%	1285 (41%)
Hispanic	17%	627 (20%)

* Note: Analyses are restricted to sites with sufficient race/ethnicity data. Census data include those 18 years and older who were designated as being of only one race or ethnicity. Agencies not enrolling in HS were excluded from Epistry analysis.

Table 3

Subject Characteristics by Study and Race/Ethnicity*

Race/Ethnicity	Eligible for HS (Epistry 4/2006–3/2007)	Enrolled in HS (HS 4/2007–3/2008)	p-value
Shock Cohort			
Age – mean (SD)	N	N	
White	175	52	0.25
Black	247	94	0.02
Hispanic	87	27	0.01
Gender - % male			
White	175	52	<0.001
Black	247	94	<0.001
Hispanic	87	27	<0.001
Injury Type - % pen.			
White	175	52	0.28
Black	247	94	<0.001
Hispanic	87	27	0.01
TBI Cohort			
Age – mean (SD)			
White	137	82	0.54
Black	75	26	0.57
Hispanic	50	34	0.61
Gender - % male			
White	137	82	<0.001
Black	75	26	<0.001
Hispanic	50	34	<0.001
Injury Type - % pen.			
White	137	82	-
Black	75	26	-
Hispanic	50	34	-
Entire HS Sample			

Race/Ethnicity	Eligible for HS (Epistery 4/2006-3/2007)	Enrolled in HS (HS 4/2007-3/2008)	p-value
Age – mean (SD)	N	N	
White	312	134	0.24
Black	322	120	0.09
Hispanic	137	61	0.01
Gender - % male			
White	312	134	< 0.001
Black	322	120	< 0.001
Hispanic	137	61	< 0.001
Injury Type - % pen.			
White	312	134	0.92
Black	322	120	< 0.001
Hispanic	137	61	0.14

* Note: Analyses were restricted to those with sufficient race/ethnicity data.

By definition, no injuries were penetrating in HS-TBI-eligible Epistery, whereas some subjects with penetrating injuries were enrolled in HS-TBI. P-values for age were computed using a t-test. P-values for gender and injury type were computed using Pearson's Chi-squared Test. Agencies not enrolling in HS were excluded from Epistery analysis, and vice versa.

Table 4
Enrollment in Epistry versus HS by Race/Ethnicity

Race/Ethnicity	# eligible for HS (Epistry 4/2006–3/2007)	# enrolled in HS (HS 4/2007–3/2008)	Odds Ratio (95% CI)	p-value
Shock Cohort				
White	175	52	-	-
Black	247	94	1.28 (0.87–1.90)	0.21
Hispanic	87	27	1.05 (0.61–1.77)	0.87
TBI Cohort				
White	137	82	-	-
Black	75	26	0.58 (0.34–0.97)	0.04
Hispanic	50	34	1.14 (0.67–1.90)	0.63
Entire HS Cohort				
White	312	134	-	-
Black	322	120	0.87 (0.65–1.16)	0.34
Hispanic	137	61	1.04 (0.72–1.49)	0.85

Note: Analyses restricted to sites with sufficient race/ethnicity data. P-values were computed using Pearson's Chi-squared Test. Agencies not enrolling in HS were excluded from Epistry analysis, and vice versa.