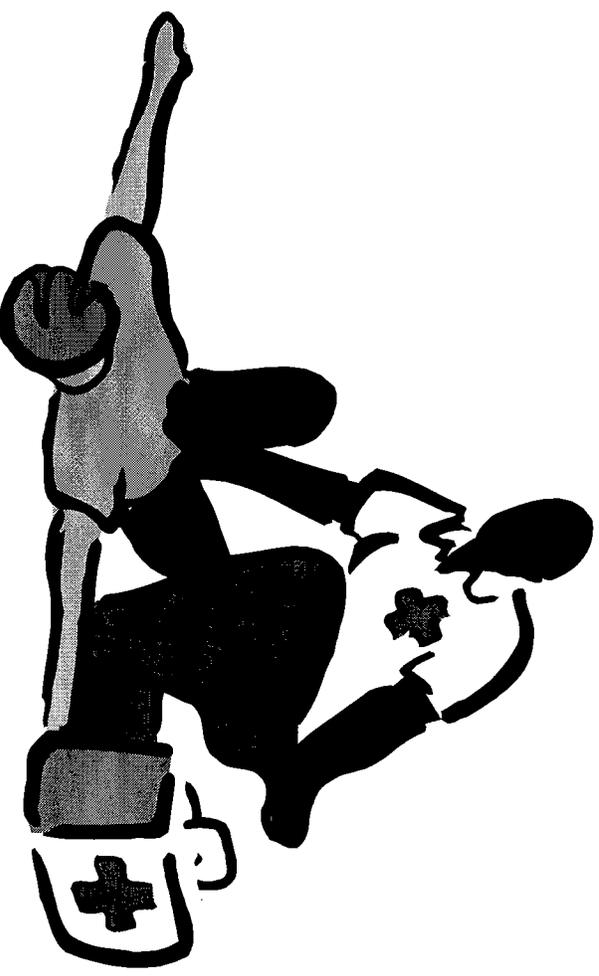


Hypertonic Resuscitation following Traumatic Injury Presentation

Karen J. Brasel, MD

Tom P. Aufderheide, MD

Ronald G. Pirralo, MD

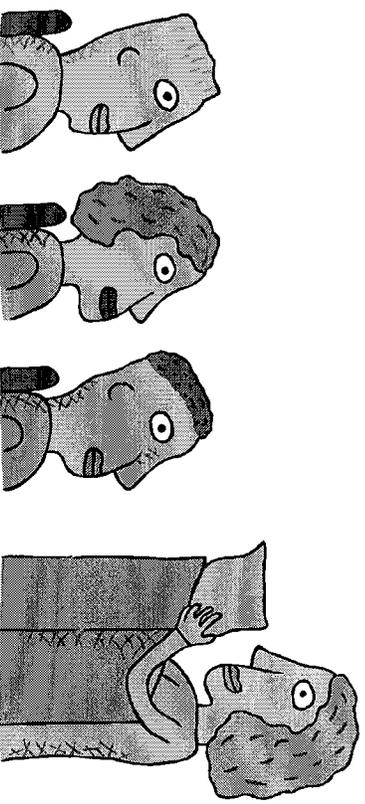


Meeting Purpose

- Consult with the community
- Describe the study that will be conducted
- Explain exception to informed consent
- Opportunity to get feedback and answer questions from:
 - Adults
 - Parents
 - Children aged 15-17 years old

Agenda

- Study overview
- Exception to Informed Consent
- Feedback, Comments, Discussion
- Questions



Extent of the Problem

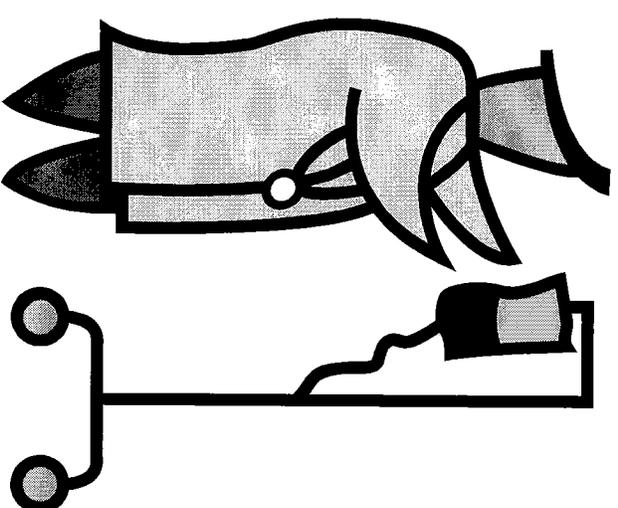
Each year:

- United States:
300,000 victims of traumatic shock
/head injury
150,000 deaths
leading cause of death (1-44 years)
- Milwaukee County area:
about 371 victims of traumatic
shock /head injury



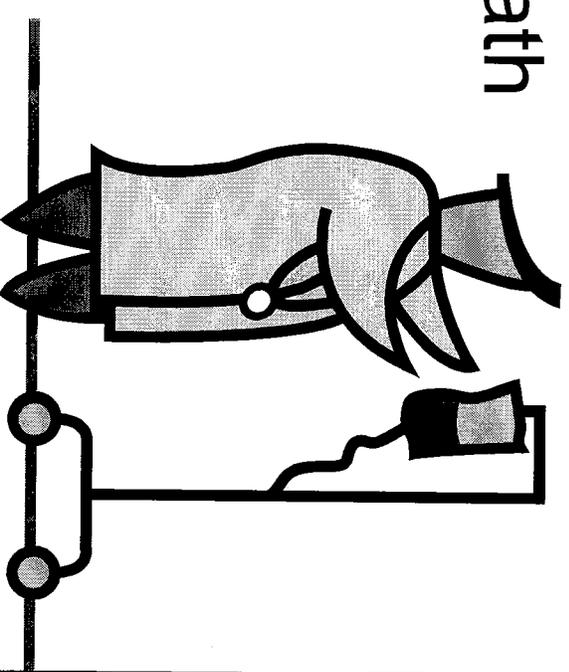
Traumatic Injury Causes Shock

- Definition: life threatening low blood pressure caused by bleeding after severe injury
- Treatment: immediate IV established with fluids
 - Normal Saline (salt water)



Trauma Causes Severe Head Injury

- Definition: Damage to the head and brain caused by severe injury
- Immediate IV established
- Brain swelling can cause death



Hypertonic Fluids

- 0.9% NaCl – Normal Saline solution
 - Salt water
- 7.5% NaCl – Hypertonic Saline (HS) solution
 - Concentrated salt water
- 7.5% NaCl & 6% Dextran – Hypertonic Saline Dextran (HSD) solution
 - Concentrated salt water plus sugar

Previous Hypertonic Saline Research

- Improved heart function
- Improved blood pressure
- Improved survival with severe brain injury
- Most effective when given early (in the ambulance)

Hypertonic Saline Research

Information to date is encouraging

BUT...

Unknown if use of Hypertonic

Saline with or without Dextran
results in:

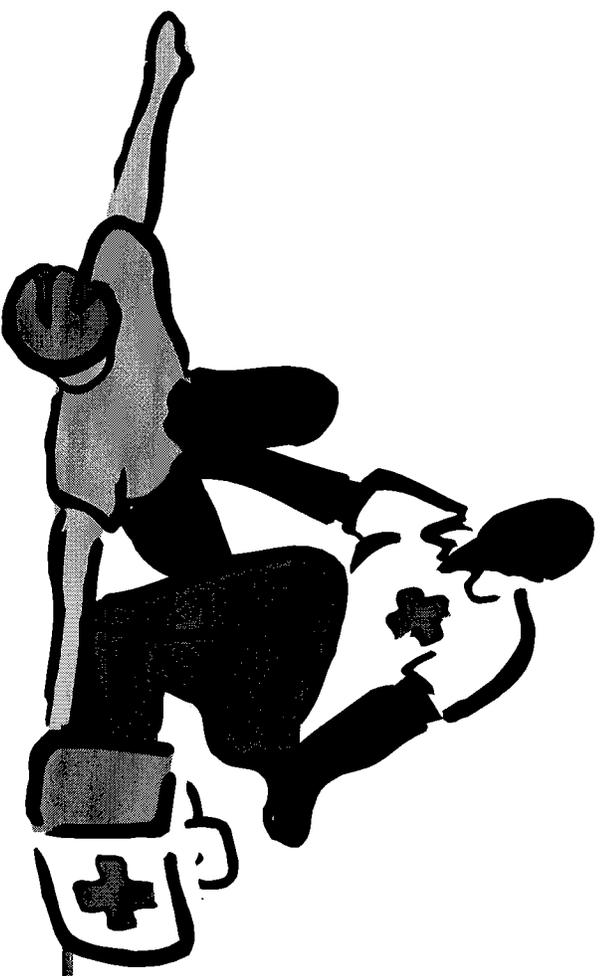
Overall improved survival

Improved quality of life

Improved function

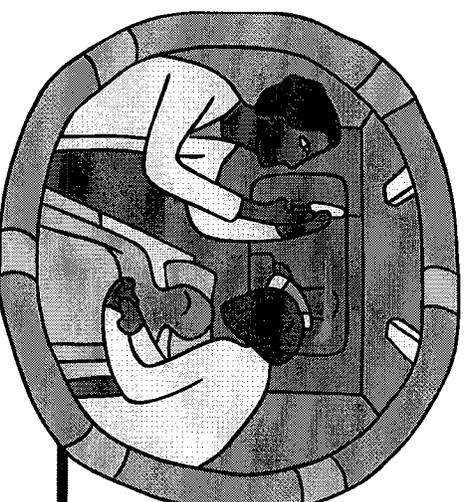
Study

Hypertonic Resuscitation Following Traumatic Injury



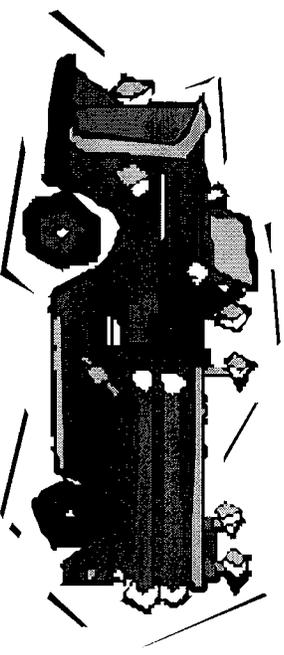
Purpose of the Study

- To determine if Hypertonic Saline with and without Dextran:
 - Improves overall survival
 - Improves outcome in victims of severe brain injury
 - Survival
 - Quality of Life
 - Function



Study Subject Inclusion

- Hypovolemic Shock Cohort
 - Blunt or Penetrating Trauma
 - Blood pressure ≤ 70 or 70-90 with a heart rate > 110
 - Age ≥ 15 yrs or > 50 kg
- Traumatic Brain Injury (TBI) Cohort
 - Blunt trauma/severe head injury
 - Coma and SBP > 70 mmHg
 - Age ≥ 15 yrs or > 50 kg



Study Subject Exclusion

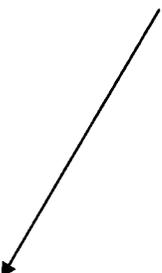
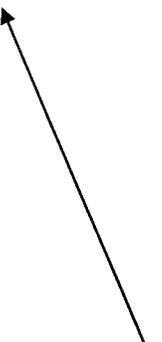
- Known or suspected pregnancy
- Age <15 or <50kg if age unknown
- Getting CPR
- Already go 2 liters of IV fluid
- Very low body temperature
- Drowning or hanging victims
- Burns to more than 10 – 20% of the body
- Penetrating injury to the head (gunshot wounds)
- Paramedics can't start an IV

Study Protocol (1,200 pts)

Traumatic Injury



Randomize



Normal Saline



Hypertonic Saline



Hypertonic Saline Dextran



Standard Treatment
• IV & medications



Outcome

Standard Treatment
• IV & medications



Outcome

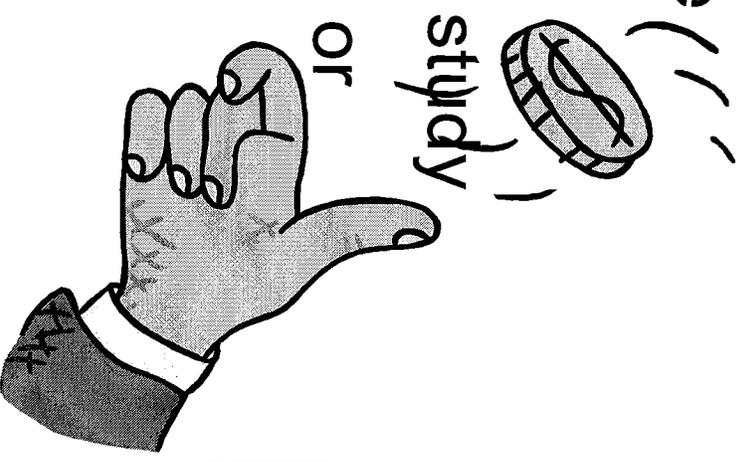
Standard Treatment
• IV & medications



Outcome

Randomization and Blinding

- Randomization: $1/3 - 1/3 - 1/3$ chance
 - Similar to “flipping a coin”
- Randomization assures findings reflect study intervention and do not occur from bias or chance
- Blinding reduces chance of bias



Study Protocol

- **Primary outcome measures:**
 - Low blood pressure due to injury
 - 28 day survival
 - Brain injury
 - Survival
 - Neurologic outcome at six months
- **Secondary outcome measures:**
 - Function
 - Quality of life issues
 - Organ failure
 - Total fluid requirements
 - Infectious complications

Differences Between Treatment and Research

- Treatment
 - Proven to be effective
 - Established as acceptable practice
 - Involves risks and benefits
- Research
 - Attempts to advance knowledge and improve treatment
 - Unproven (experimental) intervention
 - Randomize
 - Involves risks and benefits

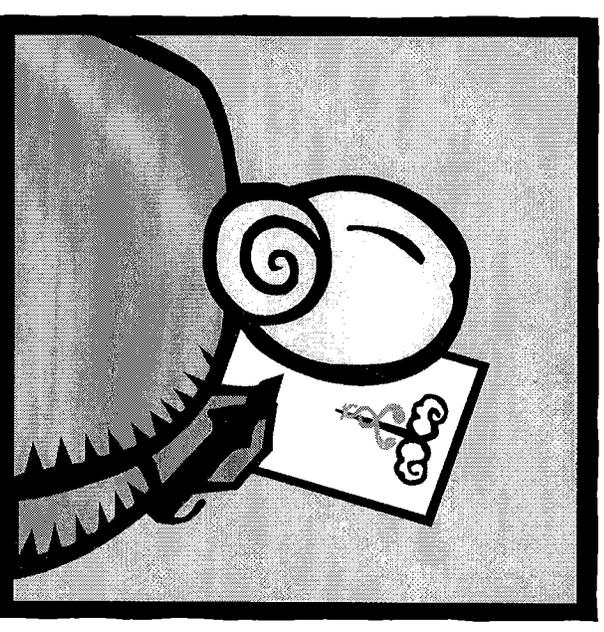
Potential Risks

Associated with Hypertonic Saline

- Abnormal blood chemistry
- Decreased kidney function
- Failure to Provide a Clinical Benefit
- Survival with Neurological Deficits

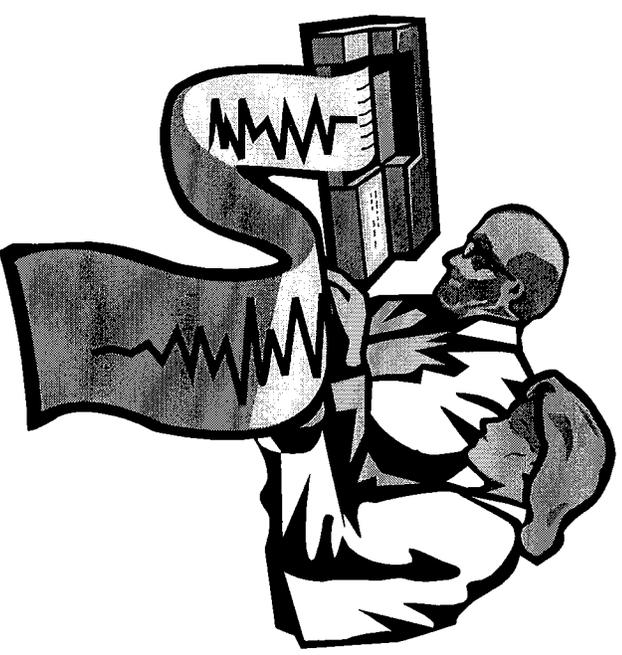
Potential Study Benefits

- Increased chance for survival
- Improved functional outcome
- Improved quality of life
- Helpful to others
- Useful scientifically
- Benefits not guaranteed



Safety Monitoring

- Data and Safety Monitoring Board: Monitor differences in
 - Adverse events
 - Survival rates
 - Neurologic outcome



Study Protocol

- Financial benefits: none
- Alternative procedures: none
- Confidentiality
 - Information will remain confidential
 - Access to medical records
 - Food and Drug Administration (FDA)
 - National Institutes of Health
- Researchers

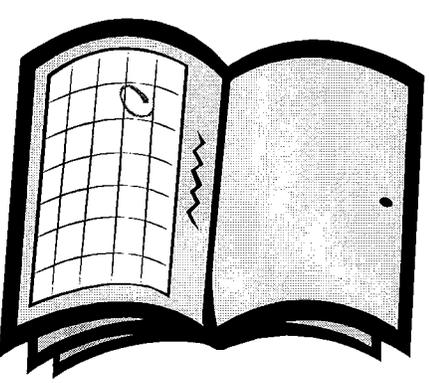
Study Approval

**Study will not proceed without approval
from:**

- **Local Institutional Review Boards**
- **Food and Drug Administration (FDA)**

Study Protocol

- Study Duration
 - Approximately 1,200 patients total (400 each group)
 - 36 months
- Start date: Spring 2006
- Sponsored by: National Institutes of Health (NIH)



~~Exception to Informed Consent Under Emergency Circumstances~~

Informed Consent

- Study involves research
- Study purpose & length
- Risks or discomforts
- Benefits to subject or others
- Alternative treatments
- Compensation
- Treatment for injury
- Voluntary without penalty
- Discontinue at any time

Food and Drug Administration (FDA) Requirements for Exception to Informed Consent

Independent Review Board (IRB) with concurring physician finds and documents

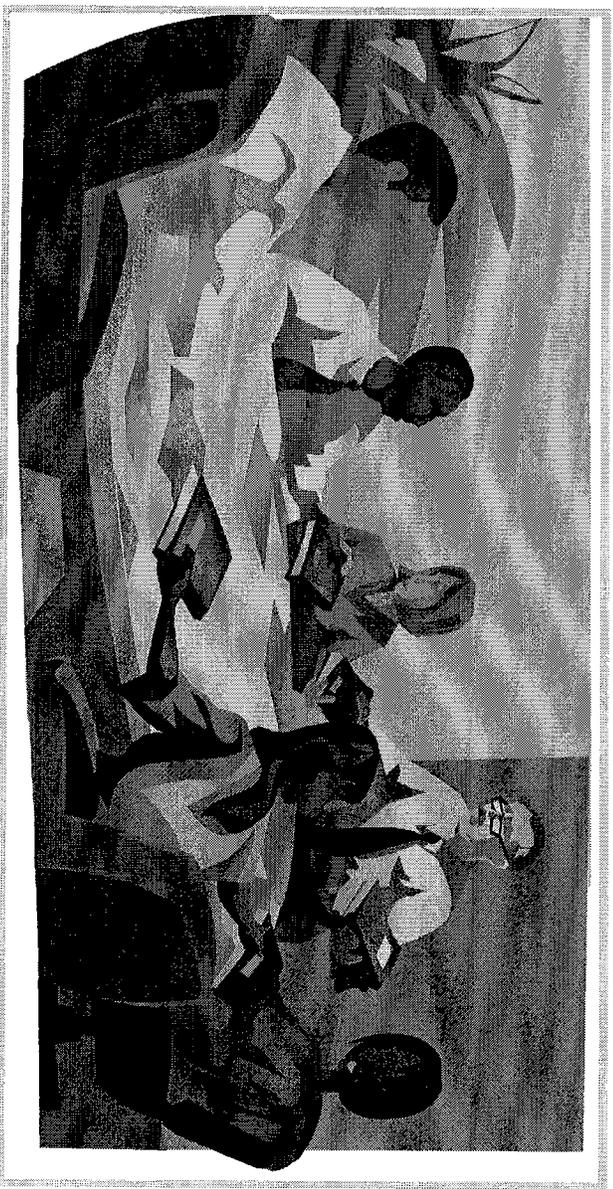
1. Life threatening situation with unproven or unsatisfactory treatment and research is necessary
 2. Obtaining informed consent is not feasible
 3. Participation in research has prospect of direct benefit because
 - i. Situation necessitates intervention
 - ii. Science supports potential of direct benefit
 - iii. Risks are reasonable compared to medical condition
 4. Research could not practicably be done without exception
 5. Potential therapeutic window is short
 6. IRB approves consent document and procedures for subject or legal representative
-

Food and Drug Administration (FDA) Requirements for Exception to Informed Consent

- B. Information provided to subject, legal representative, and/or family as soon as possible
- C. Documentation will be kept on file in accordance with IRB regulations
- D. Separate investigational device exemption (IDE) obtained from FDA for any device
- E. Additional protections
 - i. Public disclosure prior to initiation
 - ii. Public disclosure after completion
 - iii. Independent Data and Safety Monitoring Board
 - iv. Attempt to contact family member when possible
 - v. Community consultation

Community Consultation

- Comments
- Feedback
- Suggestions
- Discussion



**For further questions, comments or
information please contact:**

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Exception to Informed Consent Research

***The Medical College of Wisconsin, Froedtert Memorial Hospital,
and Children's Hospital of Wisconsin***

June 2006

Prepared by

Kenneth Klima, Research Director

Karen Marotz, Research Analyst

Hebert Research

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Bellevue, WA 98005

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As requested by the Children's Hospital of Wisconsin IRB, six focus group presentations were conducted on youth groups in the targeted population that is expected to be enrolled in the Hypertonic Saline (HS) study. A short questionnaire (see attachment 1) was given at the end of each focus group presentation to each youth with three questions about enrollment into the study, their age, gender, and ethnicity. Although investigators requested only youth aged 15-17 attend the presentations, youth aged 13-19 actually did. Results of all focus group presentations are:

59 total responses, which includes all age groups:

1. Would you support a study such as the one described at this meeting being conducted in this community, specifically, a study in which severely injured and bleeding patients would be enrolled without giving their informed consent?

89.8% selected Yes 10.2% selected No

2. If you were severely injured and bleeding and were being treated by the paramedics in your community, would you want to be enrolled in this type of study?

81.4% selected Yes 18.6% selected No

3. If a family member of yours were severely injured and bleeding and were to be treated by the paramedics, would you want him or her to be enrolled in this type of study?

74.6% selected Yes 25.4% selected No

Demographics:

Age: 13 year old – 2 (3.4%)
14 year old – 19 (32.2%)
15 year old – 19 (32.2%)
16 year old – 9 (15.3%)
17 year old – 7 (11.9%)
18 year old – 2 (3.4%)
19 year old – 1 (1.7%)

Ethnicity:

Hispanic or Latino – 5(8.5%)
White – 16(27.1%)
African-American/Black – 28(47.5%)
American-Indian/Alaska Native – 2(3.4%)
Other – 8(13.6%)
Asian – 0
Native Hawaiian/Pacific Islander – 0

When the data was filtered to only give responses for 15-17 year old youth, the results were:

35 total responses, which includes the 15-17 year old age groups:

1. Would you support a study such as the one described at this meeting being conducted in this community, specifically, a study in which severely injured and bleeding patients would be enrolled without giving their informed consent?

97.1% selected Yes 2.9% selected No

2. If you were severely injured and bleeding and were being treated by the paramedics in your community, would you want to be enrolled in this type of study?

85.7% selected Yes 14.3% selected No

3. If a family member of yours were severely injured and bleeding and were to be treated by the paramedics, would you want him or her to be enrolled in this type of study?

82.9% selected Yes 17.1% selected No

Demographics:

Age: 15 year old – 19 (32.2%)
16 year old – 9 (15.3%)
17 year old – 7 (11.9%)

Ethnicity:

Hispanic or Latino – 4(11.4%)
White – 8(22.9%)
African-American/Black – 18(51.4%)
American-Indian/Alaska Native – 1(2.9%)
Other – 4(11.4%)
Asian – 0
Native Hawaiian/Pacific Islander – 0

The name, date, and number of youth that attended from each focus group presentation are:

1. Milwaukee High School of the Arts After School Program
May 24, 1300
Confirmed 10 youth prior, 15 were present

2. Boys and Girls Clubs
May 31, 2006
Confirmed 10 youth prior, 10 were present
3. CHOW Teen Advisory Committee
June 21, 2006
Confirmed 10 youth prior, 7 were present
4. Metro YMCA Black Achievers Group Meeting
July 11, 2006
Confirmed 20 youth prior, 13 were present
5. Project Ujima Camp Focus Group Meeting
July 19, 2006
Confirmed 15 youth prior, 8 were present
6. Health in Practice Camp Focus Group Meeting
August 1, 2006
Confirmed 30 youth prior, 16 were present

Exception to Informed Consent Research

***The Medical College of Wisconsin, Froedtert Memorial Hospital,
and Children's Hospital of Wisconsin***

June 2006

Prepared by

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Exception to Informed Consent Research
June 2006***

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Special Thanks to

David Kitscha and Kimberly Stahl for their support, direction and guidance throughout the conduct of this research.

Hebert Research Team

Kenneth Klima, *Research Director*
Karen Marotz, *Research Analyst*
Tom Fisher, *Director of Operations*

Goal and Objectives

Research Goal:

The goal of this research was to provide unbiased community input regarding the use of an experimental fluid with trauma patients who are not able to provide informed consent.

Research Objectives:

The following objectives were addressed in conducting research for the Medical College of Wisconsin, Froedtert Memorial Hospital, and Children's Hospital of Wisconsin:

1. Assess the proportion of the adults living in the service area who, if severely injured, would want to receive an experimental fluid without providing informed consent.
2. Evaluate the extent of the belief that the exception to informed consent is justified and in the best interests of the patient and community.
3. Assess the concerns of those respondents who do not believe the exception to informed consent is justified.
4. Determine the reasons respondents have for believing the exception to informed consent is justified.
5. Examine whether respondents would prefer an "opt-out" bracelet, which would indicate that they would not want the experimental fluid administered to them without informed consent.
6. Evaluate the level of support among parents for including children, aged 15-18 years, in the study.
7. Determine the level of support for this test fluid among teenagers, aged 15-17 years.
8. Develop a demographic profile of the respondents.

Methodology

A total of 505 surveys were completed with adults living in the households contacted. Respondents were surveyed proportionate to population by zip code throughout the designated population area for the study (see map). The response rate, which represents the proportion of the population who agreed to participate in the research, was 44.9 percent. The overall incidence rate, which represents the proportion of the population qualified to participate in the full survey, was 100 percent. The maximum margin of error at 505 respondents is +/-4.4 percent.

Upon completing each interview, respondents were asked whether there was a teenager between the ages of 15 and 17 years old who would be willing to take the survey. In total, Hebert Research conducted interviews among 5 teenagers. While the results of these interviews are reported and summarized, the results for teenagers should be interpreted with caution given the small sample size.

The data were analyzed using generally accepted univariate measures of central tendency and dispersion. A complete list of responses to open-ended questions will be found in the Appendix.

Hebert Research has made every effort to produce the highest quality research product within the agreed specifications, budget and schedule. The customer understands that Hebert Research uses those statistical techniques, which, in its opinion, are the most accurate possible. However, inherent in any statistical process is a possibility of error, which must be taken into account in evaluating the results. Statistical research can predict consumer reaction and market conditions only as of the time of the sampling, within the parameters of the project, and within the margin of error inherent in the techniques used.

Evaluations and interpretations of statistical research findings and decisions based on them are solely the responsibility of the customer and not Hebert Research. The conclusions, summaries and interpretations provided by Hebert Research are based strictly on the analysis of the data gathered, and are not to be construed as recommendations; therefore, Hebert Research neither warrants their viability nor assumes responsibility for the success or failure of any customer actions subsequently taken.

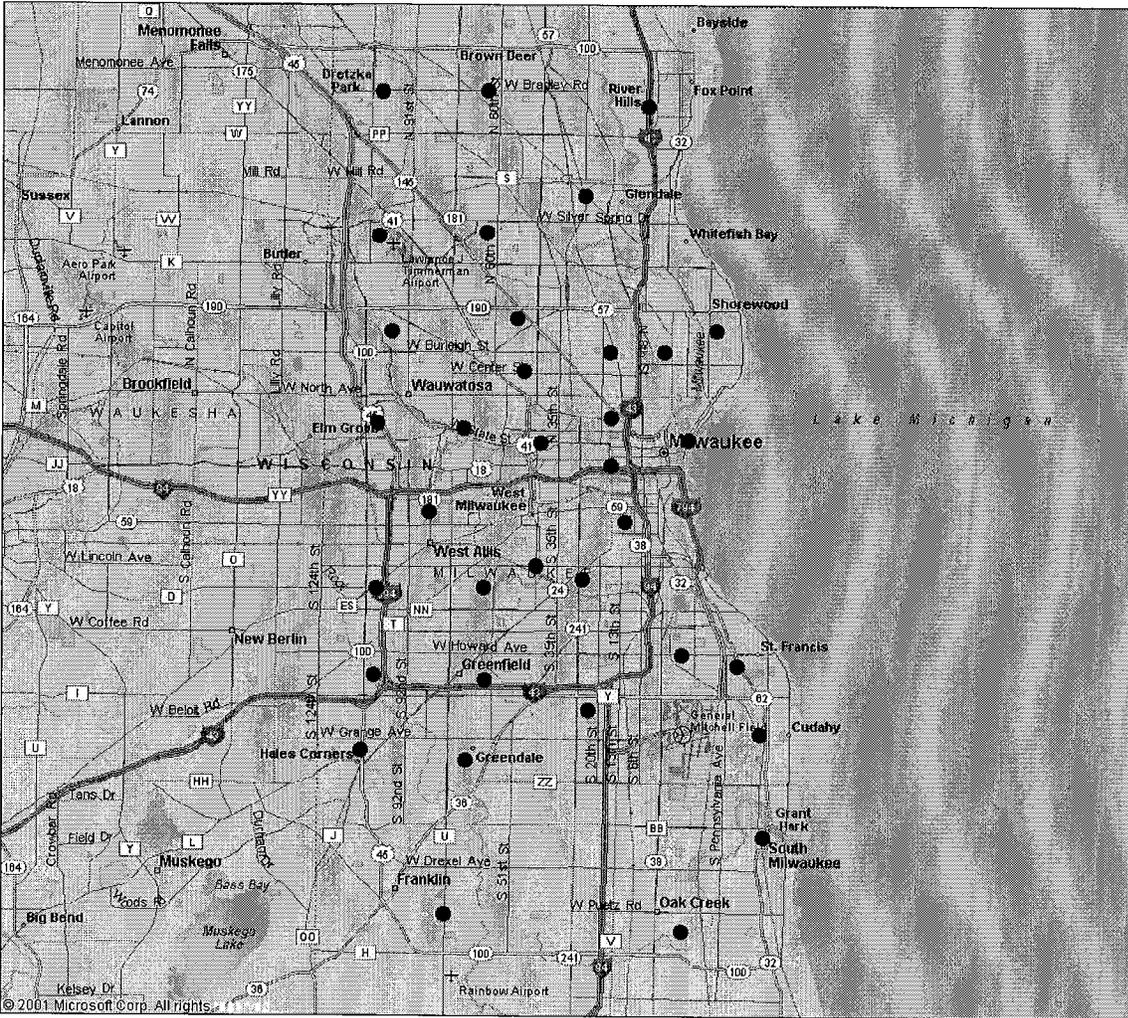
Statistical Weighting

Statistical weighting is a technique that is commonly used in survey research to compensate for sampling and response error. During the process of data collection and immediately after its completion, statistical tests were run to identify demographic factors that cause variance in variables of interest and then these sample parameters were compared with known population parameters to determine if the sample was representative of the population. Demographic data from the U.S. Census was obtained in order to identify population parameters. Demographic sample parameters were compared

with population parameters and adjustments were made to account for response bias. To compensate for potential sampling bias, weights were calculated and applied to the survey sample to ensure that various demographic sub-groups were properly represented. In the final weighting analysis, it was concluded that the sample was representative of the population within the following critical parameters: zip code, gender, and age.

Geographic Area Surveyed

The map below shows geographic distribution of the Milwaukee County zip codes that served as the population area for this survey (the general zip code area is marked by a blue dot). The research sample was drawn from households in these zip codes.



Explanation of Multivariate Analysis

Multivariate analysis was conducted in order to examine differences among respondents according to specific pre- and post-classified segments, or groupings. Multivariates included:

- Age
- Education
- Gender
- Race

Multivariate analysis is an advanced statistical technique used in the testing of hypotheses and measuring the degree of association between variables. It involves Chi Square, analysis of variance and appropriate tests of independence and association.

Interpretations and inferences set forth in the analysis are intended to provide an independent statistical perspective. The statistical procedures utilized were applied with a 0.95 confidence level for estimating values and/or providing significant inferences. This means that if a study were repeated 100 times, 95 times out of 100 the answers would vary by no more than the margin of error. A 0.05 significance level was used as the criterion to test hypotheses. At 0.05, there is no more than a 5 percent likelihood that the answers occurred by chance. The smaller the significance level, the less likely the answers occurred by chance – for example, a 0.001 means it is 1 in 1000 the answers occurred by chance. Multivariate findings, when they are significant and meaningful, are indicated at the end of each section.

In addition to measures of significance in which differences have been determined at the 0.05 level, a measurement of association will also be reported. These measurements vary between 0 and 1. A measurement of 0 indicates the variable in question does not explain (or is not associated with) the dependent variable, and a measurement of 1 indicates that the variable explains all of the dependent variable. This level of association is called Cramer's V, and it is what is reported throughout the report.

Respondent Profile

The following tables describe the demographic profile of the sample. As indicated in the methodology section, the sample was statistically weighted to match the population by gender, age and distribution in the geographic area surveyed. The frequencies in the tables below are the weighted frequencies.

Parent	Percentage
Yes	65.9%
No	33.8%
Refused	0.3%

Age	Percentage
18 – 24	12.8%
25 – 34	20.2%
35 – 44	20.6%
45 – 54	18.1%
55 – 64	11.6%
65 and over	14.3%
Refused	2.4%

Gender	Percentage
Male	47.4%
Female	52.6%

Education	Percentage
Less than high school	3.6%
High school	39.9%
Associate, technical, or vocational degree	22.0%
Bachelor's degree	22.2%
Post-graduate degree	11.5%
Refused	0.9%

Income	Percentage
Less than \$20,000	11.0%
\$20,000 to \$35,000	14.7%
\$35,000 to \$50,000	11.0%
\$50,000 to \$65,000	13.4%
\$65,000 to \$80,000	12.0%
\$80,000 to \$100,000	8.1%
Over \$100,000	8.6%
Don't know	1.0%
Refused	20.2%

Residence - zip code	Percentage
53110	2.8%
53129	3.1%
53130	1.2%
53132	4.4%
53154	4.5%
53172	3.1%
53202	3.5%
53204	1.7%
53205	0.3%
53206	1.3%
53207	5.5%
53208	1.3%
53209	6.0%
53210	2.8%
53211	4.2%
53212	1.4%
53213	4.0%
53214	3.3%
53215	4.4%
53216	4.1%
53217	3.3%
53218	3.1%
53219	4.9%
53220	2.7%
53221	3.7%
53222	3.7%
53223	2.6%
53224	1.3%
53225	3.0%
53226	2.1%
53227	3.1%

Residence – zip code (continued)	Percentage
53228	1.5%
53233	0.3%
53234	0.1%
53235	1.6%

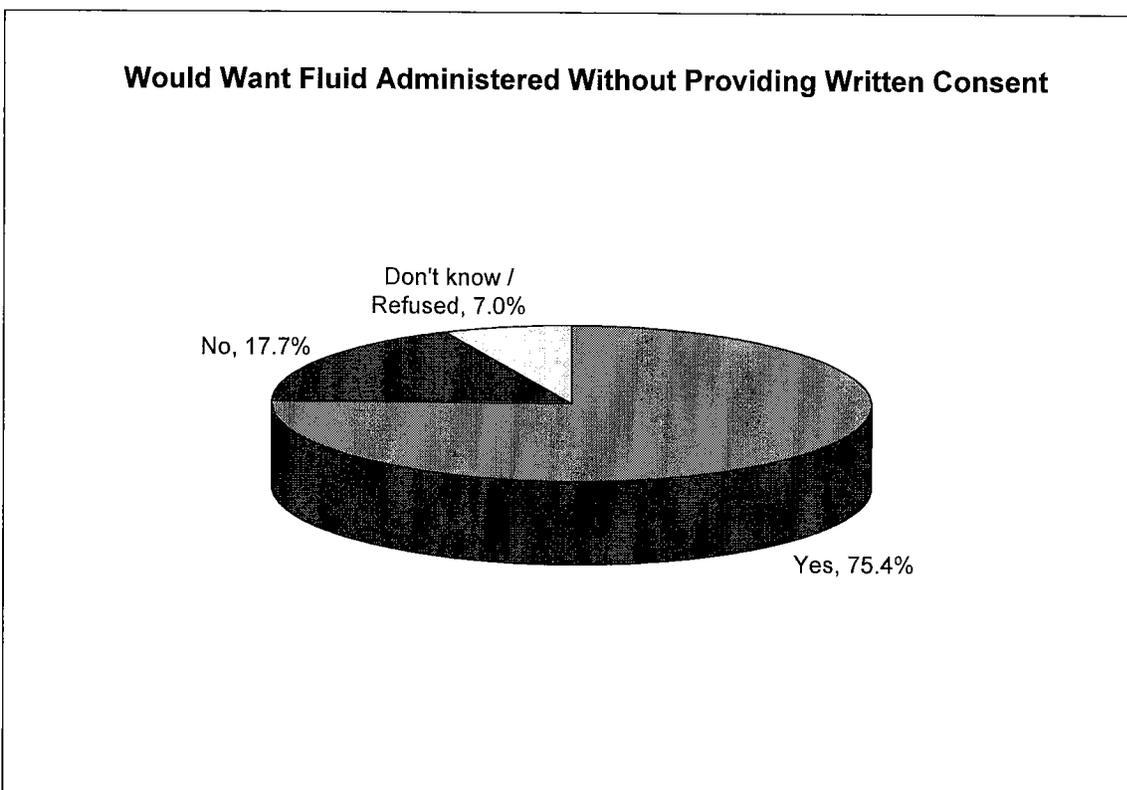
Occupation	Percentage
Retired	16.1%
Housewife/Househusband	7.1%
Student	6.3%
Administrator/Company Officer/Manager/Supervisor	6.2%
Medical Technician/Paramedic/Registered Nurse/Therapist	5.8%
Educator/Lecturer/Teacher/Professor/Coach/Librarian	5.3%
Carpenter/Electrician/Painter/Plumber/Machinist	3.9%
Unable to work	3.7%
Sales - Retail/Florist	3.3%
Refused	3.2%
Unemployed/Temporarily laid off	2.3%
Dentist/Doctor/Optometrlist/Pharmacist/Psychologist/Vet.	2.3%
Receptionist/Secretary/Typist/Admin. Assistant	2.3%
Dental Assistant/Nurses Aide/Medical Assistant	1.9%
Child Care Worker/Housekeeper/Teacher's Aide/Dishwasher	1.6%
Clerk (all except sales)/Data Collector	1.5%
Business, non-Managerial Professional/Business Consultant	1.4%
Construction/Shipping Worker/Warehouseman	1.4%
Factory Machine Operator/Printer	1.4%
Bartender/Cook/Waiter/Waitress/Flight Attendant/Caterer	1.3%
Computer Programmer/Systems Analyst	1.3%
Artist/Entertainer/Writer/Musician/Pro Athlete	1.3%
Architect/Engineer/Draftsman	1.3%
Accountant/CPA	1.2%
Foreman/Inspector/Quality Control	1.1%
Construction or Road Machine Worker/Welder	1.1%
Insurance Adjuster/Real Estate Appraiser/Actuary	1.1%
Barber/Beautician/Aerobics/Yoga Instructor	1.0%
Utility Lineman/Service man	1.0%
Lawyer/Paralegal	0.9%
Economist/Mathematician/Scientist	0.8%
Builder/Contractor/Developer	0.8%
Factory/Railroad Worker/Miner/Blacksmith/Ferrier	0.7%
Sales - Industrial/Wholesale	0.7%
Mechanic/Repairman	0.6%
Technician (except Medical)	0.6%
Delivery/Route Man	0.6%
Computer/Data Entry/Key Punch Operator	0.6%

Occupation (continued)	Percentage
Fisherman/Gardener/Lumberman/Landscaper/Mill Worker	0.5%
Baker/Butcher/Tailor/Seamstress/Book Binder	0.5%
Member of Armed Forces	0.5%
Religious/Social Worker/Counselor	0.5%
Fireman/Guard/Policeman/Fish & Wildlife/Forest Ranger	0.4%
Driver-Bus/Taxi/Truck	0.4%
Owner of business, company or store	0.4%
Sales - Insurance, Real Estate, Services/Travel Agent	0.4%
Pilot/Ship's Captain/Air Traffic Controller	0.3%
Mailroom/Messenger/Postal Worker	0.2%
Bank Teller/Bookkeeper/Cashier	0.2%
Photographer/Interior Designer/Editor/Art Director	0.2%
Janitor/Porter/Car Washer	0.1%
Farmer (Manager, Owner, Worker)/Animal Trainer	0.1%
Banker/Controller/Financial Analyst/Broker	0.1%
Buyer/Purchasing Agent	0.1%

Support for Administration of Fluid without Informed Consent

Respondents were first provided with background information about the nature of the study, the reasons for use of the experimental fluid, the conditions under which it would be administered without the patient providing written consent, and the type of fluid being given. Respondents were then asked if they would personally want the fluid administered to them if they were found in a similar need for emergency care and were unable to provide written consent.

More than three-quarters (75.4%) of respondents said they would want the fluid administered to them without providing written consent if they were unconscious, family was not reachable, and they had a 25 to 50% chance of dying. Only 17.7% of the respondents said they would *not* want the fluid administered. 7.0% of respondents said they did not know. The community is highly in favor of receiving the experimental fluid in a situation where written consent cannot be provided.



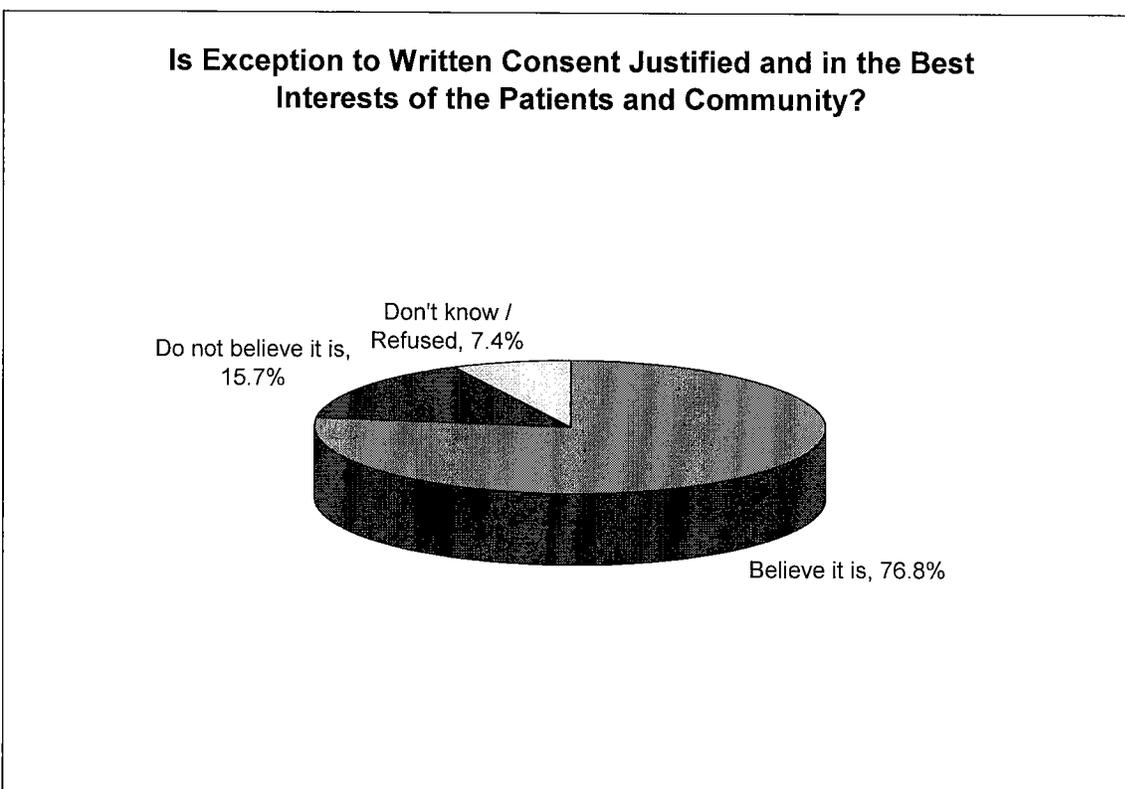
No significant differences in responses were found by gender indicating the desire to receive the experimental fluid was equally strong for both men and women. Likewise, there were no significant differences in responses by education or race/ethnicity, which indicates that all respondents, regardless of educational attainment or race/ethnicity, were

just as likely to want the experimental fluid administered. However, significant differences did arise by age.

Younger respondents were significantly more likely to want the experimental fluid administered without written consent, and as age increased, respondents became less likely to want the fluid administered ($p = .005$, Cramer's $V = .149$). The percentages for each age group in favor of receiving the experimental treatment were: 18 to 24—92.2%, 25 to 34—85.4%, 35 to 44—76.0%, 45 to 54—68.5%, 55 to 64—67.2% and 65 and up—64.4%.

Exception to Written Consent is Justified

76.8% of respondents believed the exception to written consent was justified and in the best interests of the patient and the community. 15.7% of respondents said it was not justified. The community showed a very strong belief that the exception to informed consent is justified.



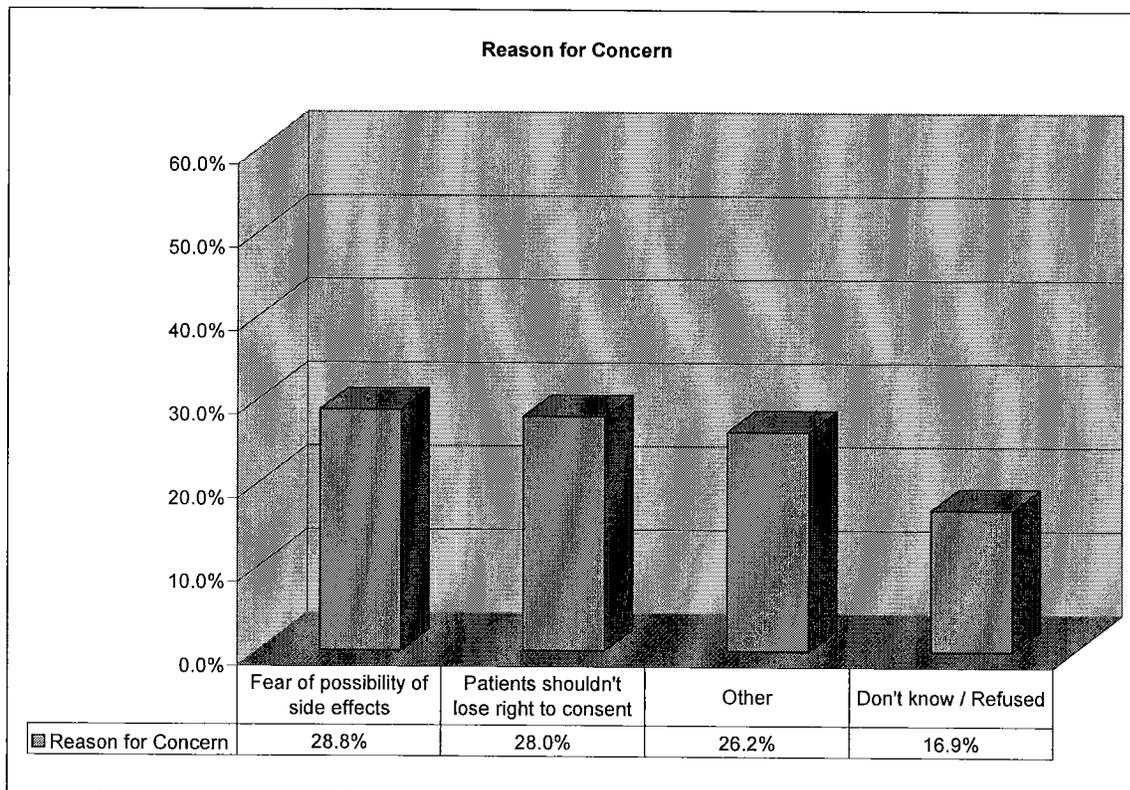
No significant differences in responses were found based on education level, gender, race/ethnicity, or age.

Concerns about Administration Without Informed Consent

Respondents who Did Not Believe or Did Not Know if the Exception was Justified

The respondents who did not believe the exception to informed consent was justified (15.7%) or did not know whether consent was justified (7.7%) were asked the reason for their concern. Of this combined sub-group, 28.8% (6.5 % of total sample) said they feared the possibility of side effects, and 28.0% (6.5% of total sample) said they believed patients should not lose the right to provide consent. Another 26.2% (6.4% of total sample) provided other reasons which included issues about the competence of paramedics in administering the fluid, moral or religious concerns, fears related to the fluid being “experimental”, the desire not to be treated (either because of their age or it might worsen their condition), the lack of knowledge about the experimental fluid, and the possibility of allergic reactions. Examples of these concerns appear on the next page; the full list of responses will be found in the appendix.

Respondents with a high school degree or less were significantly more likely to report that they feared the possibility of side effects compared to respondents with an Associate’s degree, Bachelor’s degree, or Post-Graduate degree (51.1% for respondents with a high school degree or below compared to 21.2% for those with at least a Bachelor’s degree, $p = .003$, Cramer’s $V = .345$).



Other concerns:

Paramedics administering the fluid:

- *A paramedic is making the decisions and determining the 25-50 percent chance of survival. I'd want a second opinion. Also, what about the person's medical history?*
- *Too much autonomy to the paramedics.*
- *If the paramedics are uncertain if it's that grave of a situation then it's questionable.*
- *The written consent is not realistic in many situations and puts trust in the professionals who administer this at the time of trauma.*

Experimental nature of the drug:

- *If it's less than 50 percent go for the experiment.*
- *The fact that this is experimental; there may be some severe side effects.*
- *I don't believe in administering a placebo, give it or don't, there's no experimentation, not to a chosen few.*
- *It's experimental; you're not able to think well enough if you've been in an accident. I think you'd want to go with the known procedures.*
- *I have a real issue with consent; it should be given for any type of experimental treatment.*

Age or Condition:

- *I'm not a young person. I'm 82, and I would not want to be resuscitated.*
- *Because of my age.*
- *I have negative reasons. It would depend on the dying stage. I'm dealing with a heart condition right now.*
- *If I'm dying, let me go on. I don't want to be revived.*

Worsening the situation:

- *If a person had brain injury and inject this fluid, they may survive coming out as a brain vegetable which isn't good.*
- *It could turn bad situation worse; you're tampering with a situation that may be better left to fate. Stimulating resuscitation may have worse repercussions.*
- *Are you going to die from the side affects or are you going to die from the injury?*
- *A patient that has a severe head injury even resuscitated may live to be a vegetable.*

Lack of knowledge:

- *If my family didn't understand it, they shouldn't be taking anything that's not approved without having it explained to them.*
- *Not enough information, too much unknown, could be from other donors/people*
- *I don't know what is in the fluid or how it works.*

Allergic reaction:

- *It's like playing games with someone's life. There are proven techniques that work. I would hate to see someone die because of allergic reaction.*
- *There could be a chance for allergic reaction. Without consent the medical people have no idea to tell if the patient might be allergic to the experimental solution.*
- *Depending on the status of the patient. Life is not sufficient afterwards, if it's still a life. There's too many variables here including a few opposing religious beliefs.*

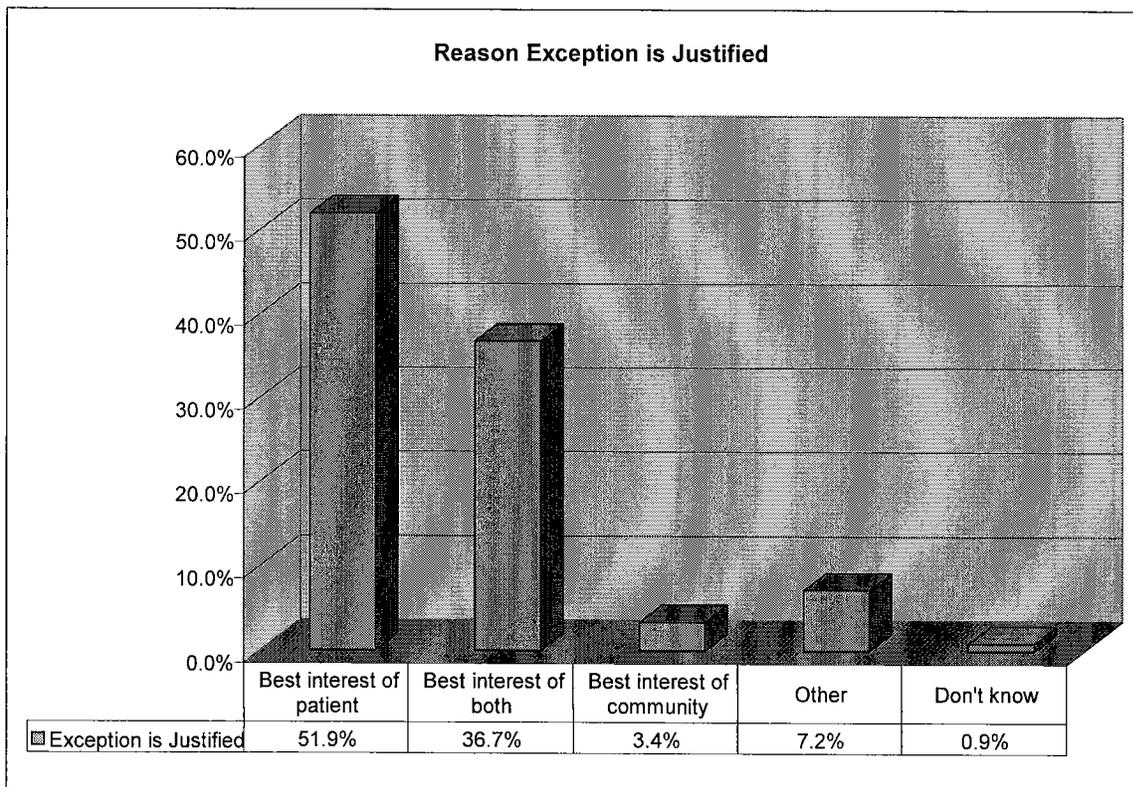
Uncategorized responses:

- *Both [possibility of side effects and patients shouldn't lose right to consent].*
- *You shouldn't do anything to someone without consent. Fear of side effects. I'm thinking of my children and wife in this scenario.*
- *I'm distrustful of drug companies.*
- *Because it's being used in Europe. As far as I'm concerned, our research is better than theirs, so I don't want to have anything to do with their research.*
- *First, it's a learning hospital. I go to Froedtert, I'm a cancer patient. Froedtert's alright, but it's not the best.*
- *It's personal.*
- *I believe an attempt to reach next of kin should be made, before giving anything to the patient.*
- *Immediate emergency care does not change anything depending on the condition of the patients. Any fluid replacement is not good at this point but getting them to emergency is best.*
- *I'm just an ordinary citizen and I don't have a medical background. I don't have the background to speak for the community.*
- *It might happen to me or my children*
- *Maybe it would be the wrong decision; I would rather die. If I have an injury where I'm paralyzed, I would rather die than receive this medication.*

Reasons Exception to Consent is Justified ***Respondents who Believed the Exception was Justified***

Respondents who stated the exception to consent was justified (76.8%) were asked to describe the reasons for this belief. More than half (51.9%) said it was in the best interest of the patient; 36.7% felt it was in the best interest of both the patient and the community. Only 3.4% felt it was in the best interest of the community only. Some respondents (7.2%) said it was justified for some other reason. Reasons in this category dealt with the lack of other options, there are no known side effects, there is a potential to increase the chance of survival, the fluid has been proven safe and successful, and that it would be valuable to both help patients and gain knowledge. Selected responses in the “Other” category appear below; the full listing of “Other” response will be found in the appendix.

Respondents with a high school degree or less were significantly more likely to report that the exception to written consent is justified because it is in the best interest of the patient, compared to respondents with an Associate’s degree, Bachelor’s degree, or Post-Graduate degree (61.6% compared to 51.8%). Furthermore, respondents with an Associate’s degree, Bachelor’s degree, or Post-Graduate degree were significantly more likely to report that exception to informed consent is in the best interest of both the patient and the community compared to those with a high school degree or less (45.6% compared to 33.5%, $p = .050$, Cramer’s $V = .130$).



Other reasons:

No other option:

- *It would be hard to find the family members for consent at that moment of an accident.*
- *If it's a matter of life and death, I wouldn't have any problem with that; if a person is in an accident, I believe that anything possible should be done in saving person's life.*
- *Because no one's on the scene. I would want the paramedics to do whatever possible to save my child or other loved one.*
- *If family can't be contacted, there's no choice but to do whatever can be done to save the person.*
- *If the patient and family can't give consent, there's no other treatment available, effective. They're doing it because it shows promise of helping, it just makes sense.*

Chance of survival:

- *Anytime you can improve someone's chance of survival, it's in their best interest.*
- *To improve the chances of surviving, it's worth trying, but it has to be backed by research, solid research.*
- *If it's better than a regular IV, they have a better chance of survival.*
- *Patient survival and the immediacy of beginning treatment.*
- *It increases the chance of survival.*

No known side effects:

- *No known side effects.*
- *No known side effects, no harm could be done.*
- *It depends on the first few times they tried it out on the patient. If the person did have side effects the first time, then it shouldn't go further.*
- *If it's already in place in Europe and being used then it's a wash. I don't see how it would hurt in a situation like that.*

Sake of knowledge:

- *Without advancements, we would get nowhere.*
- *We have to take chances in order to know what works. If it potentially helps, it'll benefit everyone, you never know.*
- *You have to start somewhere for the greater good to find viable solutions to medical problems, so I am not opposed to experimenting especially considering risk factors involved.*

Seems safe:

- *It's not a toxic solution; it's salt and sugar.*
- *I cannot answer that. It has to be proven safe before I would really consider it.*
- *As long as it's been tested previously, it should be used if it's to save a life.*

Life or death situation:

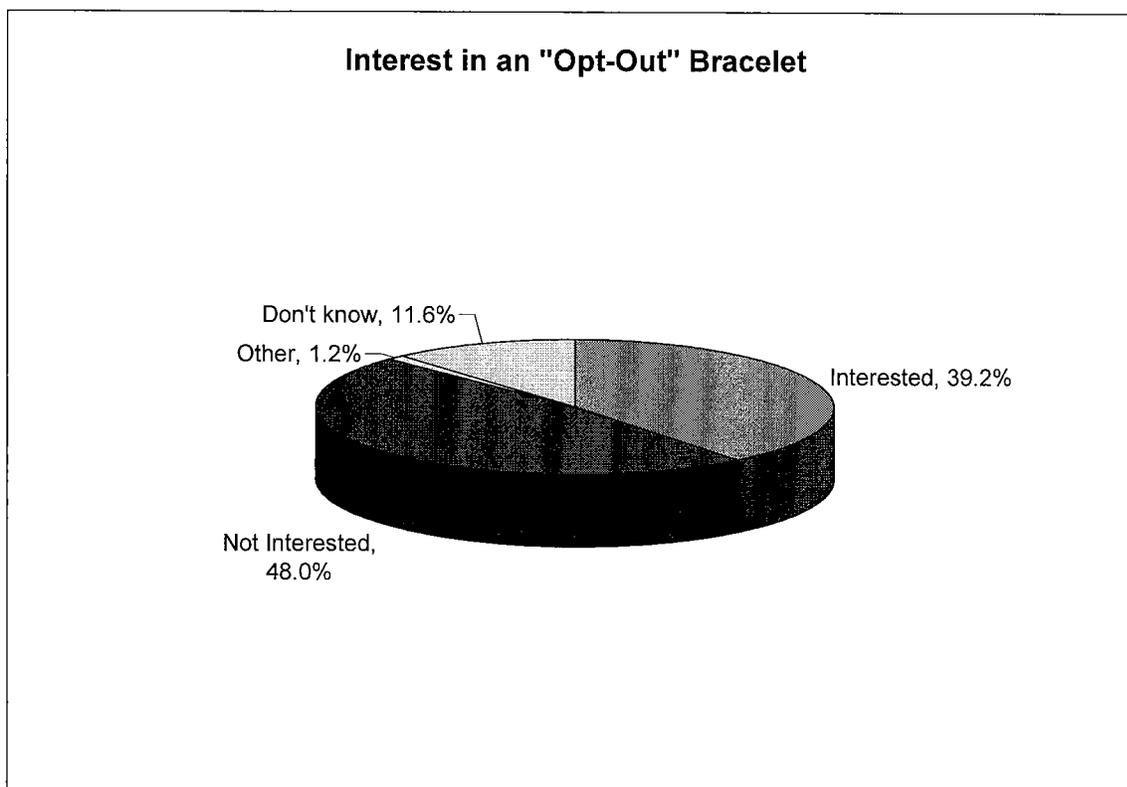
- *If it's a 50/50 chance to live a decent life, why not?*
- *More inclined if higher percent of dying.*
- *It's hard decision, but yes, I don't speak good English, but it's important for life, it's very hard.*

Uncategorized responses:

- *The time element; the sooner they begin treatment, the better.*
- *It's a gamble anyway.*
- *Because it's going to help the person, at least till they can get them to someone better.*

Interest in an "Opt-Out" Bracelet

Most respondents (48.0%) said that if an "opt-out" bracelet were available to those who did not want to participate, they would not be interested in one. 39.2% of respondents said they would be interested on an "opt-out" bracelet, and 11.6% of respondents said they were unsure. A small percentage (1.2%) used this as an opportunity to further express their opinion about the issue. Those responses are included below.



There were no significant differences whether a respondent would be interested in an "opt-out" bracelet based on age, gender, or race. There were, however, significant differences based on education.

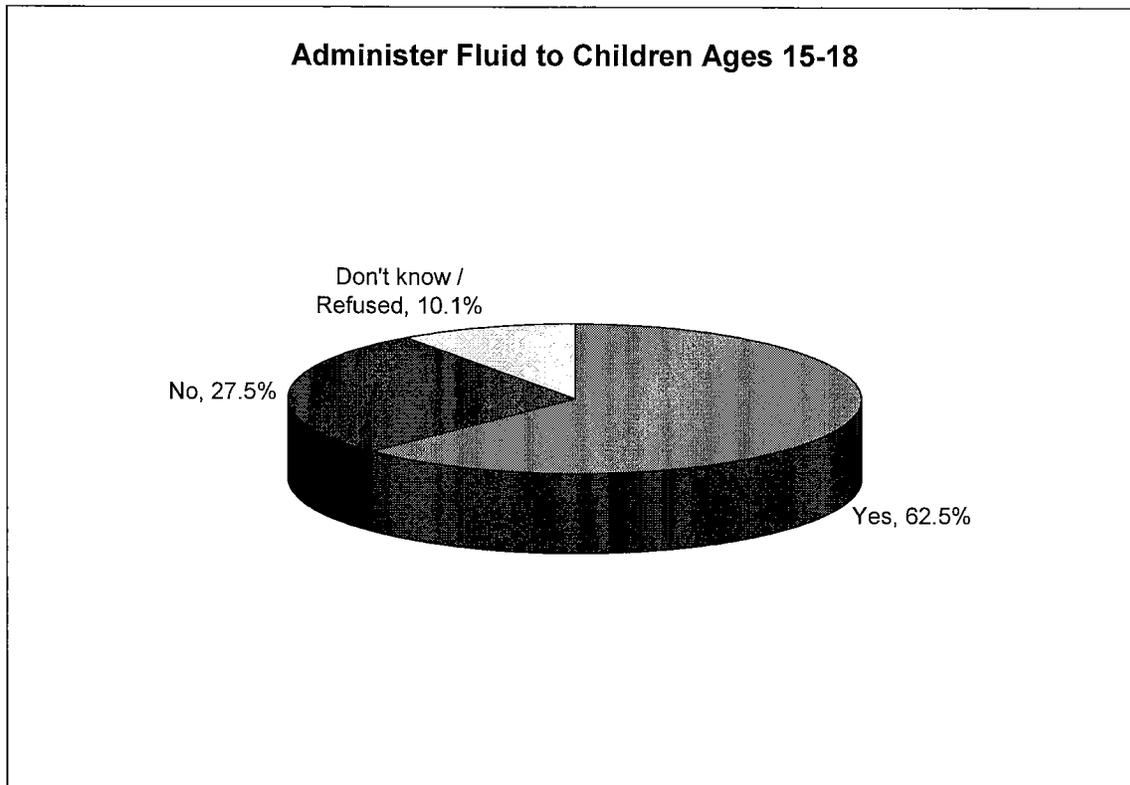
Respondents with a high school degree or less were significantly more likely to show interest in an opt-out bracelet compared to respondents with an Associate's degree, Bachelor's degree, or Post-Graduate degree (54.5% compared to 35.5%, $p < .001$, Cramer's $V = .204$).

Responses regarding the “opt-out bracelet”

- *Not without permission from relatives.*
- *If some body feels that strongly about it, they should have the option to get that bracelet.*
- *You shouldn't have to wear a bracelet.*
- *I would not be interested, but there are those who would be. It should be available to those who are interested.*
- *Why would they give it out to you? If you're in an accident, how do you know if you'll need it? My God, they'd have to give one to everyone in Wisconsin.*
- *I think it would be better to have a bracelet for people to say they do want to have the fluid. What if you lost the bracelet?*

***Support for Administration of Experimental Fluid to Children
Age 15 or Older
Respondents who were Parents***

Respondents who were parents were asked whether they would allow their child or children aged 15 or older to receive this experimental fluid without their written consent. 62.5% of respondents said they would want the fluid administered to their children, while 27.5% said they would not. 10.1% said they did not know or refused to answer the question. Parents in the community show a high level of support for administering the experimental fluid to children ages 15 and older.



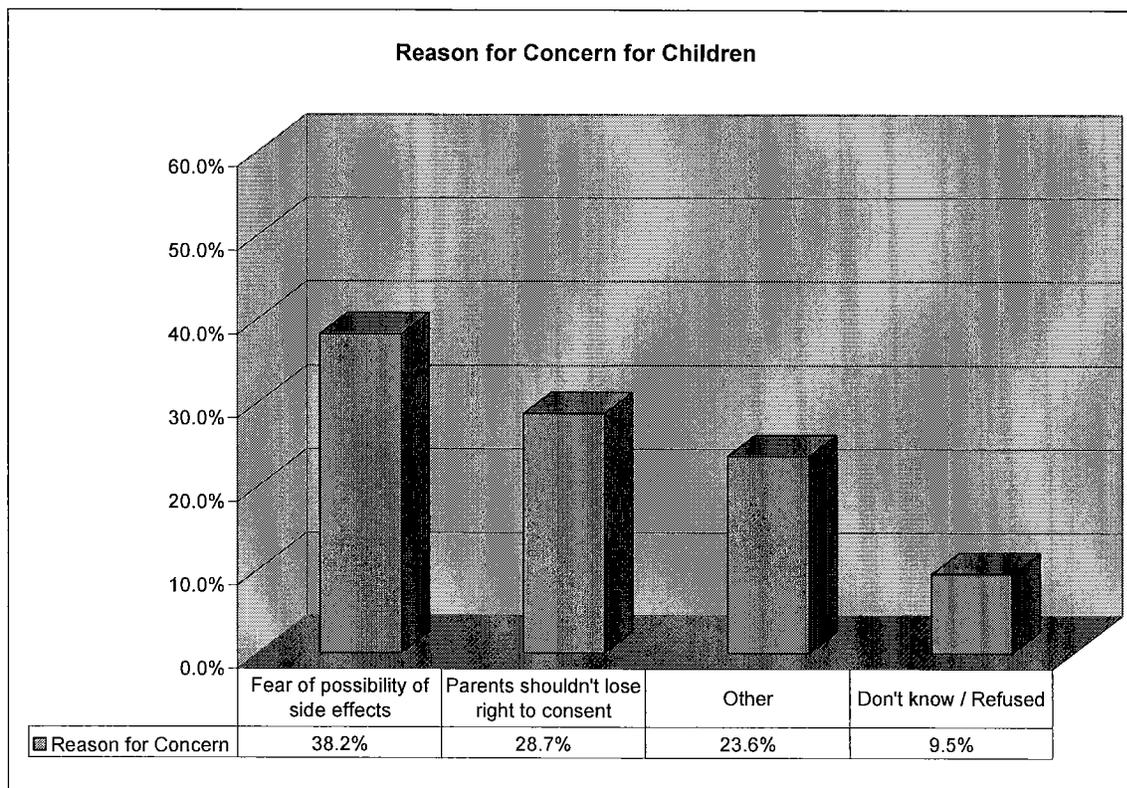
Non-Hispanic Whites showed significantly higher support for their child being administered the fluid compared to all other races/ethnicities (74.2% and 57.1%, respectively; $p = .004$, Cramer's $V = .166$).

Significant differences were also found by age. Respondents between the ages of 25 and 34 were significantly more in favor of their child being administered the fluid compared to respondents between the ages of 18 and 24 (83.7% and 41.7%, respectively; $p = .015$, Cramer's $V = .219$).

Concerns Over Administering the Experimental Fluid to Their Children

Parents Who Did Not Want the Experimental Fluid Administered to Their Children

Of the parents who did not want the experimental fluid administered to their children, most (38.2% of this group, 9.4% of the total sample) said that they are concerned about including their children in the study because they fear the possibility of side effects. Over a quarter of these parents (28.7%) said that they would not want their children included because they do not believe parents should lose the right to consent. 23.6% of respondents provided some other reason for not wanting their child included in the study; however, many of these respondents indicated that they are not responsible for their children, as they are over the age of 18.



Other Responses

Lack of knowledge:

- *I would want to know more about it; how it works. Maybe the concentrated salt or sugar could affect the other organs.*
- *I don't know what's in it.*
- *I'd like to know more about it, including the survival rate.*

- *Would like more information about the fluid; show me the statistics, show me the study, long term effects.*
- *No background or no history of this new saline if it's proven to be effective that we know about.*
- *We don't know enough about this saline and sugar. It might hurt more than do any good.*
- *It has not approved in the United States yet. I'm more willing to take a risk to receive this saline but for my children to have it administered I need more information.*

Experimental nature of the drug:

- *Wouldn't want anything experimental on my kids! I'm not taking a chance on my kids!*
- *First of all it's experimental and there is no background of the patient's medical needs at the site.*
- *I don't believe in experimenting on human life, it's not right.*
- *I do not trust experiments.*
- *Because it's an experiment.*
- *An experimental drug, doesn't know whether you'll come back to a certain quality of life. Side effects are unknown.*

"They're just a child":

- *If he had something on him that was clear not to give him anything but if not, then give it to him.*
- *I'm a risk taker but when it comes to children you just don't know, and there's a finer line to kids when as for myself, I know more about how my body would react to that.*
- *They are only a child.*
- *Would want to talk to my children about it first. I want them to have a say so.*
- *They are minors and I would feel that the decision making should come from the parents. I feel some uncertainty.*

Not a proven drug:

- *I don't know what's in it.*
- *I cannot answer that, as I would want it proven safe for use first.*

Lack of written consent:

- *They don't have the right to give anything without written consent.*

Worsening the situation:

- *The situation could be worse than before the interference.*

Older children:

- *My children are in their 40's and 50's and 60's; I wouldn't have the authority to make that decision anyway. It would be up to their spouse.*

- *I have older children.*
- *It isn't that. They are adults. It would be their choice or their husbands.*
- *My children are all over fifty and they have spouses and children that would make that decision.*
- *I don't have a fifteen year old son or daughter in my household but younger than that.*
- *My children are older, so they would not need my approval.*
- *This is all supposition. There's no 15 year old that lives with me. I'm eighty!*
- *My children don't live at home.*

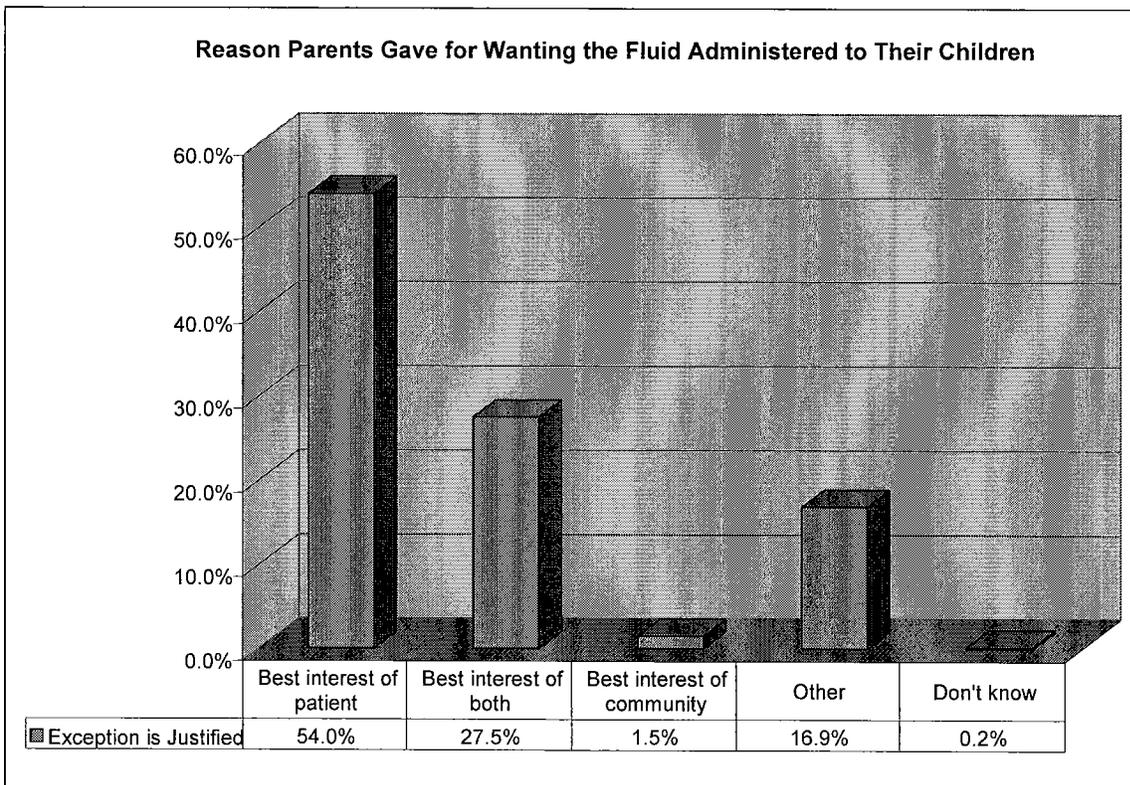
Uncategorized responses:

- *Both; they both fit how I feel.*
- *What would be their recovery? Would they make a full recovery?*
- *What the outcome would be. If the child is saved, what quality of life would they have after a situation like that? I had a 19 yr old friend who suffered a lot after something like this.*
- *Only used as the last option to save the person.*

Reasons for Administering the Experimental Fluid to Their Children

Parents Who Wanted the Experimental Fluid Administered to Their Children

Of the parents who wanted the fluid administered to their children, the majority gave as their reason that it is in the best interest of the patient (54.0%). More than one-quarter of the respondents (27.5%) said that it is in the best interest of both the patient and the community, and 1.5% of respondents said it is in the best interest of the community alone. A small group of respondents (16.9%) provided other reasons why they would approve their children receiving the experimental fluid.



Other Reasons:

Save a Life:

- *If I and my husband weren't there physically at the accident, whatever it takes to save my children's lives.*
- *The medical personnel is just trying to save that person's life and it's worth it.*
- *I would only want it used on my children if it was life or death.*
- *To save their life.*
- *I would want them to do whatever they could to save them.*

- *It's a life saving tool.*
- *Life threatening circumstances.*
- *If it's a spur of the moment decision, a matter of life or death and there's a small window of time, and this effective, then it should be taken advantage of.*
- *If it increased their chance of survival.*
- *The mortality rate without it is very high. I assume they're trying it because it shows promise.*
- *There's chance that somebody's life could be saved.*
- *Because I would want everything done to save my daughter.*
- *If it's going to save my child's life, it's justified.*

Impractical aspect of written consent:

- *We do resuscitation and CPR as a treatment and you don't need written permission for that. And you can put an oxygen mask on someone without their permission.*
- *Their may not be enough time or it wouldn't be practical to wait for written consent during the scene of an accident.*
- *I may not be around or be reached and my child's life is on the brink and is important.*
- *If the child is incapacitated, or I'm not available, I would want anything that would improve my child's chances.*
- *You are not always accessible to get someone else's permission when you are unconscious. It's a small window of opportunity to save someone before they die.*
- *It's a situation where if you couldn't reach a parent quickly enough, it's an emergency, life saving treatment and you need to proceed immediately.*
- *The parent may not be readily available for written consent for the patient at the time so why not go for it.*

Chance of survival:

- *I think it's more beneficial if they have a chance than not having a chance. The odds go up drastically if you take that chance to improve a life.*
- *If the drug will help, 50-50 chance, you've got to take it.*
- *Patient survival.*

Seems safe:

- *A lot of things are done in Europe that are not done here and it's safe. I don't understand why we drag our feet so much here.*

No known side effects:

- *I know what the fluid is.*
- *I know what it is; the risk factor is low.*
- *Low amount side effects.*

Uncategorized responses:

- *Let the medical professionals handle it. They have done enough research on the medicine.*
- *If they think it's going to help, then let it help*
- *It's my child and I would do anything to help them.*
- *My granddaughter- the doctors at Children's used experimental stuff and it worked.*
- *If my loved one died as a result of an accident, I would wonder if the drug would have helped. Allergic reaction, died anyway, would still know did best decision at the time.*
- *If it will help.*

Additional Comments

Respondents were given an additional opportunity to make any further comments. Respondents both in favor of and against administration of the experimental fluid offered additional comments which largely reiterated concerns already expressed. One common issue involved patients losing the right to provide written consent. Respondents also presented issues about the lack of knowledge and awareness regarding the experimental fluid, the potential for side effects and allergic reactions, and the uncertain qualifications of paramedics administering the fluid.

On the positive side, many respondents said that written consent is not always practical in emergency situations. They emphasized that they would want all possible measures taken to help them, and that medical professionals should be trusted to make the right decisions. Additionally, some respondents were reassured that the fluid had been approved in Europe and that it was not an entirely new treatment.

Respondents often mentioned the 25% to 50% likelihood of dying and questioned whether it was a high or low probability of dying. Additionally, respondents used this opportunity to voice their opinions about the “opt-out” bracelet. Respondents either agreed with the bracelet as an option or disagreed and suggested other options.

A selection of responses appears below; the full range can be found in the appendix.

Requirement of written consent:

- *No, like I said, it's kind of a toss-up. I hate the thought of not having written consent, yet if it is something that could save the life of someone, or at least get them to the hospital... This is an iffy... I'm not quite sure...*
- *Anything in experimental stages should not be given without written consent unless the person has no family at all and the doctor thought it was the best treatment.*
- *I believe that the exception to written consent is wrong, you should never give drugs to a person without them knowing, even if it can save their life. What if it kills them? That's a lawsuit waiting to happen. It's unjust to be giving people drugs without them knowing.*

Lack of knowledge and need for public awareness:

- *I want them to make the public aware of this study through the media or websites. We are very impressed with Froedtert and the Medical College. I would be willing to do that.*
- *Well, I would want to know more about it, it sounds like it's made out of what all IV's are made of. I would want to know why it would work as a first line of defense in an accident.*

- *I want to know more about possible side effects from this. I want to know all of the information before going further.*
- *I want to know more about the saline solution. You have to rely on people to know these things so I don't have to worry about it.*

Side effects and allergies:

- *I am DNR and would be very unhappy if it were administered to me.*
- *I don't think I'd want it now. It's too much of a risk. They should go with the stuff they're using right now. I'm a diabetic; I don't want more sugar in me. It might screw me up more than the injuries I would get.*
- *I would assume they would look in their wallet to see if they were allergic to anything.*
- *I would want to know what is the best choice for the patient and look for evidence of diabetes for the patient or allergies.*
- *I would worry about the diabetics and everybody whom have allergies or certain beliefs about what they want to be put in their bodies. I work in a Health food store and I would not want it. I am very careful with my body.*
- *You mentioned that one of the fluids has concentrated sugar in it. I'm worried if the patient you give it to is a diabetic. I don't want something that is administered to me that may have side effects like that.*

Paramedics:

- *I am a fire department head and control a 90 mile radius. The protocol for paramedics should not include experimental drugs.*
- *I would want the Paramedic to check with a doctor prior to giving this drug as a safety catch.*
- *I would want the paramedics trained and tested annually. Some of them have to realize the seriousness of their job. The potential of lawsuits is the bad part.*
- *I'd be really concerned if it were a child. You're making the assumption that the paramedic is experienced out in the field.*
- *If at all possible a physician should make that determination.*

Impractical aspect of written consent:

- *A lot of times you can't get in touch with a proxy to speak for these people. If they can save a life, do it.*
- *Concentrated salt water and/or sugar is not a drug per se, so they shouldn't even need to give consent. I'm in the medical field, and we give different solutions for different conditions. Varying concentrations of salt water are given all the time.*
- *I think it's unrealistic sometimes and when you're the victim of an accident you have to trust the emergency medical technicians to properly handle you. They are not gods but that's their jobs to do that.*
- *If the patient can't get written consent what else is there to do? Sometimes when waiting, the patient dies and that's the end of it. For that reason alone I'd say it would be available.*

Europe:

- *An emergency is an emergency; you have to do what you can do. I approve of stem cell research as well... It's already approved in Europe, so I think it's ok.*
- *As long as it's being used safely in Europe, and it's been studied already, and except for allergic reactions, I think it's okay.*
- *If it is done in Europe and is proved, I think every one should get it. We need to be aware of things that are possible.*
- *If you don't try it, you'll never know how good it is; it's been tried in other countries and you'll never know if you don't try it here. What you're giving them isn't fatal anyway unless they're allergic to it.*

25-50% chance of dying:

- *I have a question. Can they automatically give the solution to someone who is over the 50% chance of dying?*
- *I think when it's life or death the doctors should take over if 50 percent or less.*
- *I would like to see it not used unless there was a higher percentage rate of dying before it was used. 25% to 50% is not very high.*
- *I would say if there is a 25-50 percent chance of dying, then any means necessary should be taken to keep the patient alive.*

"Opt-out":

- *I believe people should volunteer rather than opt-out. They don't know enough about it to make decisions.*
- *I think an alternative of a driver's license donor sticker in the state of Wisconsin which is attached that you can agree to give organ donation or create a pre opt in situation rather than an "opt-out" situation and screen accident victims on their licenses when involved in an accident.*
- *I think the bracelet would work. That would take care of Jahova's Witnesses who don't believe in doing the blood thing.*
- *I would not want to wear the bracelet all the time. It needs a little more research so that we know it's safe. I'd rather have it approved here before it is used even if they are using it in Europe.*
- *No, except like you said, the "opt-out" bracelet could be worn. I think it should be put on the driver's license because the bracelet could be lost.*
- *You are playing God to give this medicine. And who has room for all these bracelets? They have one for Lance Armstrong and everything else. Your wrist is not that big.*

Other favorable comments:

- *I have many allergies. Although I think this study is very important also. The bracelet is a great idea.*
- *I have no problem with it; family members should discuss it ahead. In case an accident happens, should we do this, this and this. My son was 31 when he had the accident, and he was unconscious for a week. You should ask as a family things like, do you want to have special treatment, if they (doctors) feel the*

condition is serious enough for it, if it is not any worse damage to you, and help in the long run, and appoint someone in the family to give it the okay. In a serious accident, I know the rescue squad is well trained and they have a good feel for how the patient is doing.

- *I saw an accident yesterday on the road that I was driving and it looked like it was very severe. So it is wonderful that this fluid might be a helpful option.*

Uncategorized concerns:

- *I believe that the exception to written consent is wrong, you should never give drugs to a person without them knowing, even if it can save their life. What if it kills them? That's a lawsuit waiting to happen. It's unjust to be giving people drugs without them knowing.*
- *I believe that if you could save a life, that's good. If there are severe side effects or risks like brain damage, it would affect their quality of life. I do have concerns about how the hospital is able to protect themselves for lawsuits. A lawsuit bonanza. I am concerned about medical power of attorney.*
- *I'm a no-code and can't receive treatment.*
- *My opinion is colored by the fact that my brother was in the hospital and given the wrong blood. Now I'm skeptical about getting anything.*

Teenagers' Responses

After adult respondents completed the survey, each respondent was asked whether there was a child between the ages of 15 and 17 years old in the house who the adult thought would be willing to answer similar questions. A total of 5 interviews were conducted among teenagers.

Of the 5 respondents, 3 of them stated that they would want the fluid administered to them without written consent. When asked whether exception to written consent is justified, 4 of the 5 respondents said that it is justified. The one respondent who said it is not justified mentioned a concern over the possibility of side effects.

Of the 4 respondents who said that exception to written consent is justified, 3 said it is justified because it is in the best interest of the patient and one did not know why it was justified.

When asked whether they would be interested in an "opt-out" bracelet, 4 of the 5 respondents said they would not be interested in an "opt-out" bracelet, and one respondent expressed an interest in receiving the bracelet.

None of the teenage respondents had any additional comments about the experimental fluid.

Key Findings

- When in the situation of being unconscious due to severe injury, the vast majority of respondents (75.4%) said they would want the experimental fluid given to them knowing that they would be subject to a risk of allergic reaction or other unknown side effects. An even higher percentage of respondents (76.8%) felt the exception to written consent was justified and in the best interests of the patient and the community. The community is clearly in strong favor of receiving the experimental fluid without providing written consent.
- Respondents were reassured regarding the safety of the fluid because it is currently approved for use in Europe. This served to mitigate fears of “experimental” research being conducted on human subjects. Generally, respondents felt that since the effect of this fluid is to preserve and promote life, it should be tried.
- Concerns expressed by respondents over use of the fluid included whether paramedics were able to make the proper judgment of the severity of injuries and the need for administering the fluid, uncertainty because of a lack of information, and the fear of side effects and allergic reactions. Respondents emphasized that every effort should be made to gain the patient’s consent or the consent of the family.
- Respondents who were parents showed strong support for administering the experimental fluid to their children aged 15 to 18 (62.5% were in favor). The primary reasons offered for not supporting administration of the fluid to this age group were the possibility of side effects and the lack of parental consent.
- Three of the five teenage respondents (60.0%) said that they would want the experimental fluid administered to them, and 4 of the 5 (80.0%) said that exception to written consent is justified. However, these results should not be considered representative of the teenage population due to the small sample size.

**THE MEDICAL COLLEGE OF WISCONSIN, FROEDTERT
MEMORIAL HOSPITAL, AND CHILDREN'S HOSPITAL
OF WISCONSIN – EXCEPTION TO INFORMED
CONSENT RESEARCH**

Appendix

Questionnaire – March, 2006

Hello, my name is _____, and I'm calling on behalf of the Medical College of Wisconsin, Froedtert Memorial Hospital, and Children's Hospital of Wisconsin from Hebert Research in Bellevue, Washington.

[IF SPEAKING TO A CHILD] May I speak to someone who is at least 18 years of age? Thank you.

[IF NECESSARY, REINTRODUCE YOURSELF]

We are gathering community opinions about a study involving severely injured patients. The questions take about five minutes. The medical research institutions sponsoring this research will use your opinions to help determine whether the study is acceptable to the community. Your answers will be kept confidential. This call does not involve fund raising or sales of any kind, now or in the future.

Introduction: [READ]

First, I am going to describe the research study to you.

An experimental intravenous fluid is being tested in a study involving patients with severe injuries, such as those in severe auto accidents, who have a 25-50 percent chance of dying from their injuries. Usually, patients in a study must provide written consent for participation after being told about the study, its risks and its potential benefits. In the case of severe injury, it is not always possible for patients to give written consent, because they may be unconscious, and their families may not always be available to speak for them.

The U.S. Food and Drug Administration allows for certain studies to be performed without written consent in emergency settings but only if patients have a high risk of dying without treatment, cannot communicate because of their illness, and don't have family available to speak for them. When there is no known treatment available to improve their chance of survival, patients may be given an experimental agent, but only if it has been approved in advance by an independent University group set up to review

these situations. We would like your opinion on one such study that is proposed involving severely injured patients.

Injury is the leading cause of death in children and younger adults. The usual cause of death in these patients is blood loss or severe head injury. Sometimes a patient will survive the injury but die several days later due to organ failure of their heart, lungs, liver or kidneys. Researchers at the Medical College of Wisconsin, Froedtert Memorial Hospital, and Children's Hospital of Wisconsin are trying an experimental intravenous fluid that may prevent organ failure and improve survival after severe injury. This fluid may also improve outcome after brain injury.

This intravenous fluid has been used in previous clinical studies with no adverse events and is currently approved for use in Europe. As with any medication there is the risk of allergic reaction or other unexpected side effects.

Previous studies suggest that this fluid is most effective if given as the first intravenous fluid after injury. As a result, this study fluid will be given by the paramedics at the scene of the accident and consent to continue enrollment in the study will be obtained in the hospital. Patients in this study will be randomized to receive either the standard fluid (normal saline), or one of two experimental fluids, concentrated salt water or concentrated salt water and sugar. Patients will be randomized (similar to flipping a coin only with a 1/3, 1/3, or 1/3 chance to receive a 250cc dose (about half a pint) of one of three study resuscitation fluids. After receiving the initial fluid, standard treatment will be given for the remainder of medical treatment. We are considering whether to allow the study fluid to be given by the paramedics without written consent.

We would now like to ask you some questions about your opinion on this.

1. At any moment, we are all at risk of serious injury, especially in an automobile. If you were severely injured, such that you had a 25-50 percent chance of dying with standard treatment, would you want this experimental fluid given to you without written consent, knowing that it might improve your chance for survival or recovery from head injury, but that there is a risk of allergic reaction or other unexpected side effects?

1. Yes
2. No
3. Don't know
4. Refused

2. Do you believe or not believe that this exception to written consent is justified and in the best interests of the patients and community?

1. Believe it is [SKIP TO Q4]
2. Do not believe it is
3. Don't know
4. Refused

3. What is your reason for concern?

1. Fear of the possibility of side effects
2. Patients should not lose the right to provide consent for themselves
3. Other **[SPECIFY]**
4. Don't know
5. Refused

[SKIP TO Q5]

4. Why do you feel this exception to consent is justified?

1. It is in the best interest of the patient
2. It is in the best interest of the community
3. It is in the best interest of both the patient and community
4. Other **[SPECIFY]**
5. Don't know
6. Refused

5. If an "Opt-Out" bracelet was made available to those who didn't want to participate, would you be interested in one?

1. Yes, I would
2. No, I would not
3. Other **[SPECIFY]**
4. Don't know

6. Do you have any additional comments about giving this drug without written consent by the patient? **[RECORD VERBATIM]**

7. Are you a parent?

1. Yes
2. No **[GO TO Q11]**
3. Refused **[GO TO Q11]**

8. If you are a parent, would you allow your child or children aged 15 years or older to receive this experimental fluid given to him/her without your written consent?

1. Yes **[GO TO Q10]**
2. No
3. Don't know
4. Refused

9. What is the reason for your concern?

1. Fear of the possibility of side effects.
2. Parents should not give up the right to consent for their children

3. Other **[SPECIFY]**

4. Don't know

5. Refused

[SKIP TO Q11]

10. Why do you feel this exception to consent is justified?

1. It is in the best interest of the patient

2. It is in the best interest of the community

3. It is in the best interest of both the patient and community

4. Other **[SPECIFY]**

5. Don't know

6. Refused

The following questions are only to make sure that we have a representative sampling of the community's opinions. Your answers will be kept anonymous.

11. What is your age? _____

12. What is your race? **[RECORD ONE RESPONSE]**

1. White, non-Hispanic

2. Black, non-Hispanic

3. Alaskan Native or American Indian, non-Hispanic

4. Asian or Pacific Islander, non-Hispanic

5. Spanish or Hispanic, any race

6. Multicultural (parents represent different racial ethnic groups)

7. Other **[SPECIFY]**

8. Refused

9. Don't know

13. What is the highest level of education you have completed?

1. Less than high school

2. High school

3. Associate, Technical or Vocational degree

4. Bachelor's degree

5. Post-graduate degree

6. Refused

14. What is your occupation? **[RECORD]**

15. What is the zip code where you live? **[RECORD]**

16. Into which of the following categories does your approximate annual household income fall?

1. Less than \$20,000
2. \$20,000 to \$35,000
3. \$35,000 to \$50,000
4. \$50,000 to \$65,000
5. \$65,000 to \$80,000
6. \$80,000 to \$100,000
7. Over \$100,000
8. Don't know
9. Refused

17. Is there a child in the house aged 15 – 17 years you would be willing to have me ask similar questions?

- a. Yes
- b. No

[IF YES, RE-INTRODUCE YOURSELF AND REPEAT INTRODUCTION AND ENTIRE DESCRIPTION OF RESEARCH]

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We are gathering community opinions about a study involving severely injured patients. The questions take about five minutes. The medical institutions sponsoring this research will use your opinions to help determine whether their study is acceptable to the community. Your answers will be kept confidential.

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The U.S. Food and Drug Administration allows for certain studies to be performed without written consent in emergency settings but only if patients have a high risk of dying without treatment, cannot communicate because of their illness, and don't have family available to speak for them. When there is no known treatment available to improve their chance of survival, patients may be given an experimental agent, but only if it has been approved in advance by an independent University group set up to review

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We would now like to ask you some questions about your opinion on this.

18. At any moment, we are all at risk of serious injury, especially in an automobile. If you were severely injured, such that you had a 25-50 percent chance of dying with standard treatment, would you want this experimental fluid given to you without written consent, knowing that it might improve your chance for survival or recovery from head injury, but that there is a risk of allergic reaction or other unexpected side effects?

1. Yes
2. No
3. Don't know
4. Refused

19. Do you believe or not believe that this exception to written consent is justified and in the best interests of the patients and community?

1. Believe it is [SKIP TO Q21]
2. Do not believe it is
3. Don't know
4. Refused

20. What is your reason for concern?

1. Fear of the possibility of side effects
2. My parent(s) should not lose the right to provide consent for me
3. I should not lose the right to be involved with the decision
4. Other **[SPECIFY]**
5. Don't know
6. Refused

[SKIP TO Q22]

21. Why do you feel this exception to consent is justified? **[VERBATIM]**

1. It is in the best interest of the patient
2. It is in the best interest of the community
3. It is in the best interest of both the patient and community
4. Other **[SPECIFY]**
5. Don't know
6. Refused

22. If an "Opt-Out" bracelet was made available to those who didn't want to participate, would you be interested in one?

1. Yes, I would
2. No, I would not
3. Other **[SPECIFY]**
4. Don't know

23. Do you have any additional comments about giving this drug without written consent by the patient? **[RECORD VERBATIM]**

THAT CONCLUDES OUR SURVEY. THANK YOU VERY MUCH FOR YOUR TIME AND COOPERATION.

GENDER OF ADULT:

1. MALE
2. FEMALE

GENDER OF CHILD

1. MALE
2. FEMALE
3. NO CHILD INTERVIEWED

DATE: _____

INTERVIEWER: _____

Specified Verbatim Answers

Q3. What is your reason for concern? OTHER:

- *A paramedic is making the decisions and determining the 25-50 percent chance of survival. I'd want a second opinion. Also, what about the person's medical history?*
- *If a person had brain injury and inject this fluid, they may survive coming out as a brain vegetable which isn't good.*
- *The written consent is not realistic in many situations and puts trust in the professionals who administer this at the time of trauma.*
- *I'm not a young person. I'm 82, and I would not want to be resuscitated.*
- *It's like playing games with someone's life. There are proven techniques that work. I would hate to see someone die because of allergic reaction.*
- *It could turn bad situation worse; you're tampering with a situation that may be better left to fate. Stimulating resuscitation may have worse repercussions.*
- *It's experimental; you're not able to think well enough if you've been in an accident. I think you'd want to go with the known procedures.*
- *There could be a chance for allergic reaction. Without consent the medical people have no idea to tell if the patient might be allergic to the experimental solution.*
- *I don't believe in administering a placebo, give it or don't, there's no experimentation, not to a chosen few.*
- *If it's less than 50 percent go for the experiment.*
- *Immediate emergency care does not change anything depending on the condition of the patients. Any fluid replacement is not good at this point but getting them to emergency is best.*
- *The unknown; you don't know side effects.*
- *If the paramedics are uncertain if it's that grave of a situation then it's questionable.*
- *If my family didn't understand it, they shouldn't be taking anything that's not approved without having it explained to them.*
- *Depending on the status of the patient. Life is not sufficient afterwards, if it's still a life. There's too many variables here including a few opposing religious beliefs.*
- *Are you going to die from the side effects or are you going to die from the injury.*
- *The fact that this is experimental; there may be some severe side effects.*
- *Because of my age.*
- *I'm just an ordinary citizen and I don't have a medical background. I don't have the background to speak for the community.*
- *Too much autonomy to the paramedics.*
- *not enough information, too much unknown, could be from other donors/people*
- *I have negative reasons. It would depend on the dying stage. I'm dealing with a heart condition right now.*
- *It might happen to me or my children*

- *It's personal.*
- *A patient that has a severe head injury even resuscitated may live to be a vegetable.*
- *Maybe it would be the wrong decision; I would rather die. If I have an injury where I'm paralyzed, I would rather die than receive this medication.*
- *both*
- *I'm distrustful of drug companies*
- *Because it's being used in Europe. As far as I'm concerned, our research is better than theirs, so I don't want to have anything to do with their research.*
- *First, it's a learning hospital. I go to Froedtert, I'm a cancer patient. Froedtert's alright, but it's not the best. It would take other doctors, it would seem that they should k*
- *I don't know how effective it is.*
- *I have a real issue with consent; it should be given for any type of experimental treatment.*
- *I believe an attempt to reach next of kin should be made, before giving anything to the patient.*
- *I don't know what is in the fluid or how it works.*
- *You shouldn't do anything to someone without consent. Fear of side effects. I'm thinking of my children and wife in this scenario.*
- *If I'm dying, let me go on. I don't want to be revived.*

Q4. Why do you feel consent is justified: OTHER

- *I cannot answer that. It has to be proven safe before I would really consider it.*
- *The time element; the sooner the begin treatment, the better.*
- *It's not a toxic solution; it's salt and sugar.*
- *It depends on the first few times they tried it out on the patient. If the person did have side effects the first time, then it shouldn't go further.*
- *You have to start somewhere for the greater good to find viable solutions to medical problems, so I am not opposed to experimenting especially considering risk factors involved.*
- *If it's already in place in Europe and being used then it's a wash. I don't see how it would hurt in a situation like that.*
- *If it's a matter of life and death, I wouldn't have any problem with that; if a person is in an accident, I believe that anything possible should be done in saving person's life*
- *We have to take chances in order to know what works. If it potentially help, it'll benefit everyone, you never know.*
- *No known side effects*
- *It would be hard to find the family members for consent at that moment of an accident.*
- *It's a gamble anyway.*
- *No known side effects, no harm could be done.*
- *Without advancements we would get nowhere.*
- *As long as it's been tested previously it should be used if its to save a life.*

- *Anytime you can improve someone's chance of survival, it's in their best interest.*
- *Because no one's on the scene. I would want the paramedics to do whatever possible to save my child or other loved one.*
- *If it's a 50/50 chance to live a decent life, why not?*
- *To improve the chances of surviving, it's worth trying, but it has to be backed by research, solid research.*
- *more inclined if higher percent of dying*
- *Patient survival and the immediacy of beginning treatment.*
- *Because it's going to help the person, at least till they can get them to someone better.*
- *It increases the chance of survival.*
- *It's hard decision, but yes, I don't speak good English, but it's important for life, it's very hard.*
- *If the patient and family can't give consent, there's no other treatment available, effective. They're doing it because it shows promise of helping, it just makes sense.*
- *If family can't be contacted, there's no choice but to do whatever can be done to save the person.*
- *If it's better than a regular IV, they have a better chance of survival.*

Q5. Interest in an “opt-out” bracelet: OTHER

- *If some body feels that strongly about it they should have the option to get that bracelet.*
- *You shouldn't have to wear a bracelet.*
- *I would not be interested, but there are those who would be. It should be available to those who are interested.*
- *Why would they give it out to you? If you're in an accident, how do you know if you'll need it? My God, they'd have to give one to everyone in Wisconsin.*
- *I think it would be better to have a bracelet for people to say they do want to have the fluid. What if you lost the bracelet?*

Q6. Do you have any additional comments about giving this drug without written consent by the patient? [258 respondents provided additional comments.]

- *A lot of times you can't get in touch with a proxy to speak for these people. If they can save a life, do it.*
- *Again it needs to be given to mainly adults and not to teens. Their bodies are changing at that age and their systems are not as developed as adults.*
- *An emergency is an emergency; you have to do what you can do. I approve of stem cell research as well... It's already approved in Europe, so I think it's ok.*
- *Any kind of new medication always has its risks. Regardless of age and things, if a person is elderly they should take the medication. It might help in later years. If a person is younger they could help in this study to improve medications.*

- *Anything in experimental stages should not be given without written consent unless the person has no family at all and the doctor thought it was the best treatment.*
- *As an organ donor, I would want it if it preserved my organs, but otherwise, just to save my life, no.*
- *As long as it's being used safely in Europe, and it's been studied already, and except for allergic reactions, I think it's okay.*
- *As long as the paramedics are speaking with the doctor at the time. As long as the paramedics are relaying the vitals to the doctor and the doctor makes the decision.*
- *As long as they would screen for diabetics because of the sugar in the solution, and make sure the EMTs are trained properly.*
- *Concentrated salt water and/or sugar is not a drug per se, so they shouldn't even need to give consent. I'm in the medical field, and we give different solutions for different conditions. Varying concentrations of salt water are given all the time.*
- *Current research needs to be continued with this and let all the public know of it.*
- *depend on the person condition and what would be best for all that was involved*
- *Do they know what the side effects are?*
- *Extreme situations only where consent cannot be obtained.*
- *Feel it's not right, not right*
- *Have to be careful without written consent, and don't know how people will have to live afterwards. Any life is worth carrying on.*
- *I am a fire department head and control a 90 mile radius. The protocol for paramedics should not include experimental drugs.*
- *I am a living witness to experimental drugs having a positive effect. I was in intensive care many times and over came. Do not save a vegetable do not save. If they will have full recovery, go for it.*
- *I am a nurse and have never heard of this.*
- *I am a nurse and I have never used it or heard of it. I would say yes give them a chance.*
- *I am all for transplants. If a person's wishes are known I think this would be an instance where this fluid could be used. As far as I am concerned, I do not want my right of choice sidestepped!*
- *I am confused; how does saline save you from bleeding to death?*
- *I am DNR and would be very unhappy if it were administered to me.*
- *I am going to school to be a first respondent. I need to be able to check vitals and things like that. I think that experimental things are not good. If you are already hurt you could be hurt more.*
- *I am in my 80s now and not sure if I would want that in my body without knowing more than I do now. I am sure there could be a lot of potential benefits from this especially if you are a younger person.*
- *I am not a test animal!*
- *I am not aware of what is going on. I would still support it.*
- *I believe people should volunteer rather than opt-out. They don't know enough about it to make decisions.*

- *I believe that if you could save a life, that's good. If there are severe side effects or risks like brain damage, it would affect their quality of life. I do have concerns about how the hospital is able to protect themselves for lawsuits. A lawsuit bonanza. I am concerned about medical power of attorney.*
- *I believe that the exception to written consent is wrong, you should never give drugs to a person without them knowing, even if it can save their life. What if it kills them? That's a lawsuit waiting to happen. It's unjust to be giving people drugs without them knowing.*
- *I believe that you should do anything possible to save lives.*
- *In case there is head trauma, you would want them to get help immediately.*
- *I do not believe in anything being administered without some sort of permission.*
- *I do not believe in experimental drugs. I do not want it.*
- *I do not believe in saving a life if it is normal recovery.*
- *I do not know.*
- *I do not know enough.*
- *I do not have a comment. It depends on the family and situation.*
- *I don't like the idea of giving an experimental drug without consent.*
- *I don't need any more aches and pains afterwards. We have enough pains at ages 70 to 75.*
- *I don't think a study should be done until it gets to the correct stages of development that is being safe for use. We are not animals to study on. A lot of studies like this fail after they kill someone.*
- *I don't think I have any.*
- *I don't think I'd want it now. It's too much of a risk. They should go with the stuff they're using right now. I'm a diabetic; I don't want more sugar in me. It might screw me up more than the injuries I would get.*
- *I don't think it should be given if the person doesn't want to. You shouldn't be playing God and not give this drug out unless it is totally approved and researched from all over the land.*
- *I don't think it's right to give any; period. We are supposed to have a choice.*
- *I don't think that a patient that they make the decision to take the drug and feels they should be the one who make the choice of weather to have it taken or not*
- *I don't think that paramedics should be the ones to make this decision. At the least, a registered nurse should.*
- *I feel do give any one anything with out consent.*
- *I find amazing that they have come up with something to help the person. I think it's marvelous.*
- *I guess the only comment I can give you is that I can see lawsuits happening all over the place with this sort of experiment.*
- *I have a question. Can they automatically give the solution to someone who is over the 50% chance of dying?*
- *I have little reservations about the study. I think it is fantastic.*
- *I have many allergies. Although I think this study is very important also. The bracelet is a great idea.*
- *I have no idea about this whole thing.*

- *I have no problem administering a drug like that and knowing what the contents are, it makes the risks very low. (I am a doctor. An eye doctor).*
- *I have no problem with it; family members should discuss it ahead. In case an accident happens, should we do this, this and this. My son was 31 when he had the accident, and he was unconscious for a week. You should ask as a family things like, do you want to have special treatment, if they (doctors) feel the condition is serious enough for it, if it is not any worse damage to you, and help in the long run, and appoint someone in the family to give it the okay. In a serious accident, I know the rescue squad is well trained and they have a good feel for how the patient is doing.*
- *I have no qualms about doing it.*
- *I have nothing to say.*
- *I have Parkinson's disease and not sure if I would want to live through anything else.*
- *I have permission on my medical care or a document at St. Joseph hospital to contact my daughter on what should be done or it is also called a legal will.*
- *I have plenty of illnesses and injuries. I think it very important to make sure the doctor is a good doctor and is aware of what you need.*
- *If it is done in Europe and is proved. I think every one should get it. We need to be aware of things that are possible.*
- *I just do not approve it does not sit well with me.*
- *I just think that for some people, it might go against their belief and they don't have a way to communicate that to anyone.*
- *I know a number of people that have died because they didn't have the consent needed.*
- *I presume that the physicians or emergency medical technicians who studied this project think this is effective, and if that's the case, they should just go ahead and do it.*
- *I really do not know. I think to each his own. I have never been one for experimental medicine treatment. I wonder about the concept of practice?*
- *I saw an accident yesterday on the road that I was driving and it looked like it was very severe. So it is wonderful that this fluid might be a helpful option.*
- *I think an alternative of a driver's license donor sticker in the state of Wisconsin which is attached that you can agree to give organ donation or create a pre opt in situation rather than an "opt-out" situation and screen accident victims on their licenses when involved in an accident.*
- *I think anything that would help save lives should be used.*
- *I think as long as this has been medically studied that it should be used.*
- *I think if it can help save a life, they should go along and do so. If it's not proven to be harmful, go ahead and do so.*
- *I think if you give them and they do not know they might be affected.*
- *I think when it's life or death the doctors should take over if 50 percent or less.*
- *I think it should be used if there is a chance on saving a life.*
- *I think it a wonderful idea.*
- *I think it might be a good thing.*

- *I think it should be given.*
- *I think it should be the other way around, a bracelet to opt-in.*
- *I think it's an interesting idea, but I need a lot more information to understand it better. I can't give an informed answer without more information.*
- *I think it's an interesting concept, with so many other drugs given as standard procedure, I don't see why this would be any different. It's just that everybody is always afraid of something new!*
- *I think it's extremely tricky that they use something that people might still have reactions to.*
- *I think it's unrealistic sometimes and when you're the victim of an accident you have to trust the emergency medical technicians to properly handle you. They are not gods but that's their jobs to do that.*
- *I think it's very controversial. Given my life's experience, having clinical trials is important but still controversial. It's a test and I have experience with clinical trials in decreasing the health of a patient and shortening the life span and it's only brave and courageous people who go through this.*
- *I think people should at least be notified about the study if that does happen.*
- *I think that any that can help a person to live is good*
- *I think that because there is no data it is really hard to give any real thought> I did not know that the medical profession was considering this. I believe under structure it would be ok.*
- *I think that if something like this could save your life, you would want to try it.*
- *I think that if there is chance to save someone it should be done*
- *I think that like that stroke drug that they give people to prevent all of the bad effects of the stroke. I think whatever they have to do, they can do is the way to go... I'm all for that.*
- *I think that most of the time when experiments get to this level, it's not going to kill you. You will probably die of your injuries or something else. Doing this will find better ways of doing this, so I would probably do this. I believe the outcome of experimental research is positive. I worked for a University for a long time, and I know how long it takes to get approval. Especially, with humans.*
- *I think that people are not able to consent to that help*
- *I think that the doctors can prove what they are doing then I think I might give it a change. It must have more doctors' approval on it*
- *I think that's what science and the medical field is all about, coming up with new things. In emergency situations where there is bleeding, I wouldn't want not to have that chance.*
- *I think the bracelet would work. That would take care of Jehovah's Witnesses who don't believe in doing the blood thing.*
- *I think the plusses are better than the minuses.*
- *I think there might be a problem if someone had a religion that this might interfere with.*
- *I think they already have a Good Samaritan act in place. Isn't that correct?*

- *I think to be giving a medication to a person whom you don't know their health background is not going to work. They may have congestive heart failure in the past of be diabetic which is dangerous to inject this ivy fluid into them.*
- *I think we need to try new things like other countries do.*
- *I think we should preserve life.*
- *I think that advancement is important so let's try it.*
- *I think you have to try thing on people. If they are going to die anyway why not try something?*
- *I think you're opening a can of worms for lawsuits; if something terrible happened to a loved one, people want someone to blame. A better way to do it, in my opinion is have people wear a volunteer bracelet if they what to participate. I suppose if it's done on people that are just severely injured, then they can't really volunteer.*
- *I trust medical personnel will do what they have to do on my behalf to save my life.*
- *I trust the doctors; if they feel it is necessary to save the person's life at the time of an accident.*
- *I want to know more about possible side effects from this. I want to know all of the information before going further.*
- *I want to know more about the saline solution. You have to rely on people to know these things so I don't have to worry about it.*
- *I was not given enough information to decide and am distrustful of the drug industry.*
- *I would think if the person had a better chance of dying like over 50 percent then give them the experimental, if they were going to be paralyzed or brain damaged. Only use it in the extreme circumstances.*
- *I would assume they would look in their wallet to see if they were allergic to anything.*
- *I would be curious to know the legal implications of it if the next of kin was contacted later and said no way.*
- *I would be especially worried if they administer this to a child; that it may survive as a vegetable. It would be similar to experimenting this on rats where they are seeing if it really works or not but on humans instead which I don't agree.*
- *I would have a problem even with the written consent. Usually people don't understand what they are signing. They don't have enough medical knowledge to make an intelligent decision.*
- *I would hope that if there is any way to communicate at all with the patient, you would try to find out about allergies. I would worry about lawsuits.*
- *I would just be concerned about potential allergies.*
- *I would like to know if it really works. If some ones life is at stake I would want the thing to work. I am a diabetic and thing get sickening.*
- *I would like to see it not used unless there was a higher percentage rate of dying before it was used. 25% to 50% is not very high.*
- *I would need to know more about the possible side effects. If half the patients die from a heart attack, it's not a good idea to give it, but if they get hives, something*

minor, then I feel it should be administered. What sounds good about it is that it is approved for use in Europe. Once I know what those adverse episodes are I could say yea or nay.

- *I would not be without family on the road. I am a widow; I'm dependent on my children. My children would always be with me on the road.*
- *I would not to be part of a blind study. I would want the best treatment. I am not in favor of no consent.*
- *I would not want to wear the bracelet all the time. It needs a little more research so that we know it's safe. I'd rather have it approved here before it is used even if they are using it in Europe.*
- *I would say if there is a 25-50 percent chance of dying, then any means necessary should be taken to keep the patient alive.*
- *I would them to make the public aware of this study through the media or websites. We are very impressed with Froedtert and the Medical College. I would be willing to do that.*
- *I would think even if ask the person, even if the person can't sign, they can say yes or no, or even have a bracelet, then they know. I would say to make it more known and public the studies done on this; what are the benefits, side effects and long term effects.*
- *I would think it would not be used unless it was a really bad accident.*
- *I would try it once, but after that I wouldn't do it again. Once I try it and I survive, and I didn't have any disabilities then I would continue with it in the hospital.*
- *I would want the Paramedic to check with a doctor prior to giving this drug as a safety catch.*
- *I would want the paramedics trained and tested annually. Some of them have to realize the seriousness of their job. The potential of lawsuits is the bad part.*
- *I would want them to do anything they could so that I could live.*
- *I would want to know more about for sure. It worries me about the sugar additive. I am a diabetic.*
- *I would want to know more about the benefits. I do not want experiments.*
- *I would want to know what is the best choice for the patient and look for evidence of diabetes for the patient or allergies.*
- *I would worry about the diabetics and everybody whom have allergies or certain beliefs about what they want to be put in their bodies. I work in a Health food store and I would not want it. I am very careful with my body.*
- *I wouldn't mind, but other people would be thinking about the side effects. I would take the risk of side effects, to survive.*
- *I wouldn't want it, my family would have to give consent*
- *I wouldn't want to lose my rights to have permission.*
- *I'd be really concerned if it were a child. You're making the assumption that the paramedic is experienced out in the field.*
- *If at all possible a physician should make that determination.*
- *If it keeps you alive we should use it.*
- *If it saves your life why ask questions. Just save the life*

- *If it was a smaller child who couldn't make it, it would be good to introduce this fluid to save his life, but I'm old; it don't matter if I live or die. I do love the concept though.*
- *If it were an experiment, I would prefer having consent myself or for a family member.*
- *If it's a possibility that it's going to save a life and nobody is there to sign! I'd prefer to give my consent, but if you can't reach me, and it can save a child's or an adult's life!*
- *If it's given without written consent or an agreement with the drug manufacturers and if something goes wrong with it, there's going to be a lot of lawyers that will be on those cases.*
- *If it's going to help them, and you say studies have been done in Europe, then yeah.*
- *If it's just a supped-up saline solution, and the chemistry is not made by certain by-products and not a real drug which might be against some peoples' religious beliefs, I can't see what the fuss is all about. After all, paramedics are already giving saline.*
- *If patient had no other chance and he needs fluids, but it's still experimental, I'm wondering are there allergies? I suppose any drug has side effects and I think I'd take a chance on it.*
- *If the patient can't get written consent what else is there to do? Sometimes when waiting, the patient dies and that's the end of it. For that reason alone I'd say it would be available.*
- *If the patient's unconscious, they should go ahead and do it.*
- *If there's no relative, or anyone that has power attorney, it should be given! I'm an old nurse, and they should pull out all of the stops and just do what they can!*
- *If they are food and drug say its ok Then approve*
- *If they are young persons go ahead and give the medication but if they are old i feel that they should have written consent*
- *If this is something that has been approved by certain groups that do regulate the medical industry. Then I would be in favor*
- *If this prolongs someone's life why not go for it. The lawsuits in people's mind is so horrible but saving someone's life is worth it.*
- *If you can not speak for your self someone else should be able to speak.*
- *If you don't try it, you'll never know how good it is; it's been tried in other countries and you'll never know if you don't try it here. What you're giving them isn't fatal anyway unless they're allergic to it.*
- *I'm 88. Suppose I was in an accident, and something was available, and no one was around, then give it a try! If I had a seven year old grandchild and no one is around, then go for it! As far as allergies, what would be the chance if someone didn't have allergies and didn't get the fluid? You might lose someone!*
- *I'm a diabetic and is afraid of the medication and the effects of them clashing with each other*
- *I'm a no code and can't receive treatment*

- *I'm concerned about the paramedics making that determination. If there were a doctor in the emergency room saying that there is no better treatment and if the patient were to die either way then they should give it to him. I think they should try and get people to give their consent. The paramedics may not know; there may be something else that would stabilize them so another treatment can be performed.*
- *I'm eighty, and if people who are eighty through eighty five have it and if they became crippled, then they wouldn't want it. If it were my daughter, a younger person, then it should be given.*
- *I'm for anything that would be a potential for help, even if there were a risk of side effects. I'd be happy if it were done on someone I loved if it would help them.*
- *I'm just wondering if it can be given to children. It might have more adverse effects on children.*
- *I'm more concerned about it containing chemicals but if it's just natural sugar and salt and if they're careful not to increase the salt to a high level then okay. It might wind up hurting the organs instead of helping them. They should look at all the studies done in Europe and elsewhere. Patients should be number one. Doctors should make sure to study all the studies done in the world. They should also bring in people who started this as speakers to address all the people interested in the intravenous fluid study.*
- *I'm sure that all the legal ramifications have been looked at. I think that people want to blame somebody for the death of the loved one and they're always looking for a reason.*
- *In a very severe accident, I'd probably go for it. It should be placed on your license plate, and it should say that if you're messed up and if you were in an accident, then give it to me. No one expects to be in an accident. I was just informed that I have leukemia and I'm being asked to do these experimental things. It's just me; I don't like that medication going through me.*
- *In an emergency, they do all they can to save life. Being a paramedic is a tough enough job without worrying about getting permission. I know, because we have a policeman in the family.*
- *In this state the doctors do what they feel what they can to keep someone alive. Only if no one is there to speak for this person is where they do what they can.*
- *Instead of an opt-out bracelet, put it on the driver's license back where the donor sticker is.*
- *Is there some other way to be questioned?*
- *Is this a part of their routine in Europe? It's approved for use, but is it met with success? Is it just a drug company here pushing it? Is it part of the European protocol for emergency situations? I want more information on the background of these solutions. I would want the paramedics to do the appropriate triage, and not randomize for the purpose of the test. I assume that the paramedics are acting in my best interests already without written consent. How do you quantify high risk of dying?*
- *Isn't that against the law for them to do that without your consent? I'd be afraid that they'd get a lot of lawsuits against them if they do that. Who's to say that the drug didn't kill your daughter or loved one. I think they're looking for a lawsuit.*

- *It doesn't appear to be a drug if it a solution is sugar and salt it would not hurt and it would save a life then it should be used.*
- *It improves your chances, and you might not have any other options...*
- *It is debatable. I really do not know. I need more knowledge.*
- *It provides a short window of time to help save someone's life. The crime rate is up there where you see so much shootings going on.*
- *It seems like a very interesting experiment based on how it sounds. You want to choose life and it's interesting that an accident or taking a motorcycle training class where they mention an impact of a motorcycle person who collides into something resulting in a heart attack.*
- *It sounds like a common thing.*
- *It sounds like a good thing to try. This might be a good thing also to try for saving organs for donations.*
- *It would not be something that I would encourage because it is experimental. If I can not make my decision ahead forget it.*
- *It would be good to hear the other side to have a balanced opinion. Sometimes I feel the drug companies are pushing things, getting people in their weaker moments to take medication, and then later on find that its not good for the people. If it's the drug companies that are pushing it, I would be suspicious of it.*
- *It would be great to use for a child or young adult but if it was an adult like myself, I have epilepsy and I don't know how that drug would interact with the current drugs I'm using for that disorder.*
- *It would have to be given with discretion. The problem I have with this is if it's given without consent, where does it stop. If something goes through the door where does it stop? But, if it would save the life of children, then yes. My 14 year old grandson was in an accident, he's 28 now, and at that time we would have said, yes, whatever it takes. I'm for it as long as it doesn't include other medications. If it was a dire emergency and it was a qualified decision maker, then definitely, yes.*
- *It's a risky thing without being fully tested. To be given without consent, no. It should be the consent with the use of an organ donor card or the actual victim or that person's family should make the decision.*
- *It's fine if the patient is injured and unconscious. It is better to give the experimental fluid but it's a good idea to have the bracelet if you don't want the fluid.*
- *It's great, but I don't know the certainty of receiving side effects from this. In other words, I don't know how safe I would feel from being ill if this drug was inserted into me or my kids.*
- *It's obviously a tough situation and the treatment sounds like it's only suitable for severe injury. It's a situation where it should be given right away. I'm sure that there are people who are going to object, but I think we should be doing everything we can to find a new method of treatment.*
- *It's too iffy, paramedics don't have as much training as doctors who should be the ones to decide what treatments you get.*

- *It's totally unconstitutional in this country to perform that. We have a right to make our own decisions. I don't think it is acceptable without written consent first.*
- *I've seen other experiments at Children's. If it's their only chance go for it. If the risk is they are more likely to die. From what I've seen at Children's for the 18 years I've been there, I'd say, "go for it".*
- *Just so long that it was tested the would approved by the people doing the test and that it would benefit the patients*
- *Just that if the procedure was able to be done, that they could contact the family and relatives as soon as possible, there might be someone from the family that could give consent. That would have to be a law, or passed into a law. I can't really think of any more*
- *Just the fact if you're a marginal diabetic and don't wear a bracelet what would happen, then. I don't know if the sugar might hurt something. A friend of mine is borderline diabetic; I'm wondering how that would affect them.*
- *leave it up to the doctors*
- *More the after part with the random flip of a coin that would bother me, wouldn't want to be an object of that.*
- *Most family members know what patients really want.*
- *My mother died recently. I am allergic to a lot of different drugs and would not want drug administered to me.*
- *My only comment is, if it's in the best interest of the patient and it's a judgment call, I don't see why it shouldn't be given.*
- *My only concern is about FDA approval. Although I am using an experimental medicine for my arthritis.*
- *My only concern is, I would just like to know the success ratio*
- *My opinion is colored by the fact that my brother was in the hospital and given the wrong blood. Now I'm skeptical about getting anything.*
- *New drugs could be tricky. I would only want them used on me or my children if it proven to be totally safe for use.*
- *No like I said, it's kind of a toss-up. I hate the thought of not having written consent, yet if it is something that could save the life of someone, or at least get them to the hospital... This is an iffy... I'm not quite sure...*
- *No, but it'll be interesting to see though what the study shows.*
- *No, except like you said, the "opt-out" bracelet could be worn. I think it should be put on the driver's license because the bracelet could be lost.*
- *No, I guess the only thing is... it just concerns me that the paramedics to do it, instead of at the hospital.*
- *No, I really don't. It's a situation you don't know. You can't write on a paper whether you want it or not because you don't even know you're there, if you're unconscious.*
- *No, just that this is a hard question because I am a nurse. As long as there is an "opt-out" option for say, senior citizens who don't want extra measures introduced.*
- *No, I do think it is a good thing.*

- *No. If it was my child and it would save her, I would want her to have a chance.*
- *No. Now that I think about it, if the solutions are only salt water and sugar, maybe it's ok.*
- *Not at all, really. It's a judgment call and if you need it right away, you can't wait till it's too late.*
- *Not if it's been drug approved. That's what you are trying to find out, isn't it?*
- *Nothing should be given to anyone without their right to consent.*
- *Only that it's not an equal opportunity thing; one out of three will be given this opportunity to recover, then what about the other two. My biggest objection is that they'll be charging an arm and a leg for a simple solution. Water's been here forever! I've worked in hospitals and I've seen bill padding. Wisconsin has the highest medical costs. I don't know why. It's the same treatment; it's not any better than anyplace else.*
- *Only the guidelines where use and made clear to the patient and kept it that way.*
- *People who are in their older years may not want to survive a severe type injury. We do not heal the same way anymore.*
- *Probably there are some people who don't want medical assistance at all. They don't want anything that interferes with what nature does. For example, for religious reasons some people may not want any medications.*
- *Really tough; I want it for myself, but not a policy for everyone.*
- *Tell the next of kin first.*
- *That if at the scene they should wait and give it to the hospital.*
- *The bracelet should be an opt-in bracelet since people come here from all over. I would need to know more about the effects of the sodium.*
- *The family should have an option whether to judge when the victim is unable to decide for him or herself (a close family member).*
- *The Federal Drug Agency has approved drugs before, like Vioxx, and later found them not to be safe. I think that drugs are okayed way too fast. That's just an example.*
- *The malpractice suits that could ensue. To arbitrarily infuse it into patients only opens the door to suits wider, causing insurance rates to go up, so that I will have to pay more when I go to the doctor.*
- *The medical field should do everything they can to help people.*
- *The only thing I could say that if there was someone that is around and knows them, hopefully they could give the permission.*
- *The range given in the survey, 25-50% does not seem great enough to justify the use of an experimental drug. What would the side effects be? Would they kill you?*
- *There might be a lawsuit.*
- *There needs to be more research.*
- *They should come up with a fluid that transmits oxygen; artificial blood. That's what people die from anyway. As far as this fluid, if you're going to die, then who cares?*

- *I think if it's going to be beneficial to the patient, a family member would have to give permission and would then expect treatment. If unable to contact the family, the patient should expect to be treated if unconscious.*
- *Think that I don't trust the medical option and that it is up to the patient*
- *Think that it is a worthy study but need percentage of effectiveness of fluid.*
- *It's always scary when you get something without written consent, no matter what care you're receiving...*
- *Unless you get the written consent at the scene, it won't be effective. I think this could be considered an extension of the Good Samaritan law where a trained paramedic or a passerby could not be held liable for trying to save the victim.*
- *was not given enough information*
- *We should not have someone else assume what we need for medical treatment.*
- *We went through this with my granddaughter, so, this is hitting home to me. If something is believed to help a person and there is a feeling it would help the patient, then it would be good. In other words, it's an option they should use.*
- *Well If it is experimental then I would like to have the bracelet if i could since the fluid has already been introduced in Europe and it saves lives over there I think it would be good if this fluid of water and sugar Could be useful over here.*
- *Well, I would want to know more about it. It sounds like it's made out of what all IV's are made of. I would want to know why it would work as a first line of defense in an accident.*
- *Well, if there isn't any one to speak for them, the hospital, I believe, looks out for the best interest of the patient.*
- *What happens if a family says yes and patient says no. How it is going to be obtained or not. Who should really make it for them? There can be religious reasons why patients might not want this. There can be lawsuits. People do not have health insurance would they have the same treatment.*
- *What if someone was diabetic? It might still be beneficial; I know it increases insulin in body. But, it might be a risk factor for someone who is a diabetic. They should have an opt-in bracelet as well.*
- *What is the science behind this? I cannot make any comment unless I know how much salt is in the fluid. I don't give my opinion because it is not worth much, science is science; truth is truth. I am an engineer and I need facts. It is basically playing Russian roulette with a patient because they don't have the facts. Don't give me a feel good theory, or conjecture. I need facts; give me science. The body can only take so much saline, how much is in this fluid? You are not giving me the truth.*
- *When it comes to children, I think you need some kind of consent; with adults, most people are more apt to say yes if saves their life. In most cases, especially with children, there's always somebody that can be reached.*
- *Why do things like this get the okay to be used in other countries but not here? It all turns into a money thing.*
- *With people my age, what about the "DNR" folks?*
- *Would not be something that should be legislated, it would be something that families would be able to make a choice.*

- *Would the sugar hurt diabetics? You're not supposed to have sugar when you're a diabetic.*
- *Would you also do this treatment on children?*
- *Yes, I think everything should be done to save a life or even save the organs. If the injured had a very bad head injury, and not be able to survive, it might be helpful if they were an organ donor.*
- *You are playing God to give this medicine. And who has room for all these bracelets? They have one for Lance Armstrong and everything else. Your wrist is not that big.*
- *You just have to take your chances and hope for the best.*
- *You mentioned that one of the fluids has concentrated sugar in it. I'm worried if the patient you give it to is a diabetic. I don't want something that is administered to me that may have side effects like that.*
- *You wouldn't ask for consent for anything else to save a life. People do whatever is necessary to save a life.*

Q9. What is your reason for concern: OTHER (For children)

- *I would want to know more about it; how it works. Maybe the concentrated salt or sugar could affect the other organs.*
- *Wouldn't want anything experimental on my kids! I'm not taking a chance on my kids!*
- *My children are in their 40's and 50's and 60's; I wouldn't have the authority to make that decision anyway. It would be up to their spouse.*
- *The situation could be worse than before the interference.*
- *First of all it's experimental and there is no background of the patient's medical needs at the site.*
- *I cannot answer that as I would want it proven safe for use first.*
- *I have older children.*
- *If he had something on him that was clear the not to give him any thing but if not, then give it to him.*
- *They don't have the right to give anything without written consent.*
- *My children are older, so they would not need my approval.*
- *I don't know what's in it.*
- *I'm a risk taker but when it comes to children you just don't know, and there's a finer line to kids when as for myself, I know more about how my body would react to that.*
- *This is all supposition. There's no 15 year old that lives with me. I'm eighty!*
- *I'd like to know more about it, including the survival rate.*
- *What would be their recovery? Would they make a full recovery?*
- *They are minors and I would feel that the decision making should come from the parents. I feel some uncertainty.*
- *Children don't live at home.*
- *Would like more information about the fluid; show me the statistics, show me the study, long term effects.*
- *I don't believe in experimenting on human life, it's not right.*

- *Would want to talk to my children about it first. I want them to have a say so.*
- *It has not approved in the United States yet. I'm more willing to take a risk to receive this saline but for my children to have it administered I need more information.*
- *Both; they both fit how I feel.*
- *No background or no history of this new saline if it's proven to be effective that we know about.*
- *Only a child.*
- *I do not trust experiments.*
- *What the outcome would be. If the child is saved, what quality of life would they have after a situation like that? I had a 19 yr old friend who suffered a lot after like this.*
- *We don't know enough about this saline and sugar. It might hurt more than do any good.*
- *I don't have a fifteen yr old son or daughter in my household but younger than that.*
- *My children are all over fifty and they have spouses and children that would make that decision.*
- *Because it's an experiment.*
- *An experimental drug, doesn't know whether you'll come back to a certain quality of life. Side effects unknown.*
- *Only used as the last option to save the person.*
- *It isn't that. They are adults. It would be their choice or their husbands.*

Q10. Why do you feel consent is justified: OTHER (For children)

- *I think it's more beneficial if they have a chance than not having a chance. The odds go up drastically if you take that chance to improve a life.*
- *If I and my husband weren't there physically at the accident, whatever it takes to save my children's lives.*
- *A lot of things are done in Europe that are not done here and it's safe. I don't understand why we drag our feet so much here.*
- *The medical personnel is just trying to save that person's life and it's worth it.*
- *Their may not be enough time or it wouldn't be practical to wait for written consent during the scene of an accident.*
- *Let the medical professionals handle it. They have done enough research on the medicine.*
- *I may not be around or be reached and my child's life in on the brink and is important.*
- *We do resuscitation and CPR as a treatment and you don't need written permission for that. And you can put an oxygen mask on someone without their permission.*
- *You are not always accessible to get someone else's permission when you are unconscious. It's a small window of opportunity to save someone before they die.*
- *Life threatening circumstances.*

- *It's a situation where if you couldn't reach a parent quickly enough, it's an emergency life saving treatment and you need to proceed immediately.*
- *I know what the fluid is.*
- *I would only want it used on my children if it was life or death.*
- *I know what it is; the risk factor is low.*
- *To save their life.*
- *The parent may not be readily available for written consent for the patient at the time so why not go for it.*
- *If they think it's going to help, then let it help*
- *It's my child and I would do anything to help them.*
- *My granddaughter— the doctors at Children's used experimental stuff and it worked.*
- *If my loved one died as a result of an accident, I would wonder if the drug would have helped. Allergic reaction, died anyway, would still know did best decision at the time.*
- *Low amount of side effects.*
- *If it will help.*
- *I would want them to do whatever they could to save them.*
- *It's a life saving tool.*
- *If it's a spur of the moment decision, a matter of life or death and there's a small window of time, and this effective, then it should be taken advantage of.*
- *If the child is incapacitated, or I'm not available, I would want anything that would improve my child's chances.*
- *There's chance that somebody's life could be saved.*
- *Because I would want everything done to save my daughter.*
- *Patient survival.*
- *If it's going to save my child's life, it's justified.*
- *If it increased their chance of survival.*
- *The mortality rate without it is very high. I assume they're trying it because it shows promise.*
- *If the drug will help, 50-50 chance, you've got to take it.*

Appendix A

Summary Report for Community Consultation and Notification for the Hypertonic Resuscitation Following Traumatic Injury, ROC, Milwaukee, WI

This document summarizes the activities completed in order to fulfill the regulatory requirements for conducting research under the 'exception to informed consent under emergency circumstances' regulations. {21 CRF 50.24} The involved Institutional Review Boards approved all of the content presented at the Community Consultation and used for Community Notification, prior to its dissemination.

Community Consultation

To perform community consultation and elicit feedback from the community, we conducted a random digit dialing survey, performed as a structured telephone interview by a company experienced in this process (Hebert Research, Inc. in Bellevue, Washington).

The random digit dialing survey model used a proportionate population survey of the medical treatment area by zip code through a random, structured telephone survey to elicit feedback from the potential study community.

The final report from Hebert Research, Inc indicated that the vast majority of respondents (75.4%) said that they would want the experimental fluid administered to them and that 76.8% felt that exception to informed consent is justified and in the best interests of the individual patient and the community.

Children's Hospital of Wisconsin

Additional questions targeting parents and adolescents were added to the Hebert Research random digit dialing survey. 62.5% of parent respondents stated that they would want the fluid administered to their children. Hebert was able to interview 5 teenagers between 15 and 17 years old. 3 of the 5 respondents stated that they would want the fluid administered to them.

Focus Groups

Investigators also elicited feedback from focus group sessions targeting adolescents and minorities.

Meeting Logistics

Meetings were scheduled at 7 youth-related organizations in the Milwaukee area. Attendees were given feedback forms (*Attachment 1*) so as to document age, gender, and ethnic background, and to elicit feedback from their age group.

Invitees

The youth centers agreed to distribute Parent Opt-Out forms (*Attachment 2*) that only needed to be returned if the youths' parents did not want them to attend the focus group meeting. No opt-out forms were returned. There were 66 youths aged 13 to 19 years old that have attended these focus groups. Out of the 66, there were 42 youths that fell into the 15-17 year age range. Responses from these youths to the question: "Would you support a study such as the one described at this meeting being conducted in this community, specifically, a study in which severely injured and bleeding patients would be enrolled without giving their informed consent?", 95.2% said yes. (*Attachment 3*)

Public Notification

The process of Public Notification uses multiple media outlets to inform the citizens of Milwaukee County.

1. A news release will be distributed to all metro media (*Attachment 3*) as soon as community consultation is approved by the Children's Hospital IRB. Public Relations will work with individual reporters to do follow-up stories. The telephone and email address for contacting Dr. Brasel and the research team, as well as the WEB site address will be included.

2. Newspaper

The *Milwaukee Journal Sentinel* will run a Risk/Benefit Public Announcement (*Attachment 4*) in the Sunday circulation. The Sunday circulation is 461,000 individuals in all ethnic groups of all ages.

50 Plus will run an Intermediate Public Announcement (*Attachment 5*) that has a circulation of 150,000 people (monthly) in the elderly population.

In order to better include minority populations in the print media public notification process, the *Milwaukee Community Journal* will run a Risk/Benefit Public Announcement for two Wednesday additions. The *Milwaukee Courier* and *Milwaukee Times* will run an Intermediate Public announcement, and the *Spanish Journal* will run a Risk/Benefit Public Announcement.

The total circulation for print media will be 741,000.

3. Television

4 local television channels (Channels 4, 6, 12 and 58) will be running the Brief Public Announcement (*Attachment 6*) during the 5:00 p.m. weekday news.

4. MCW Website

The research team developed and is maintaining a website specific to this trial. The address is www.mcw.edu/roc. Contact information for Dr. Brasel is listed on the website.

The community consultation and public disclosure plan for this site was completed to the satisfaction of the reviewing institutional review boards for this site.

Site Principal Investigator

Date

Attachment 1

Feedback from participants

_____, 2006

Please circle your answers

1. Would you support a study such as the one described at this meeting being conducted in this community, specifically, a study in which severely injured and bleeding patients would be enrolled without giving their informed consent?

Yes No

2. If you were severely injured and bleeding and were being treated by the paramedics in your community, would you want to be enrolled in this type of study?

Yes No

3. If a family member of yours were severely injured and bleeding and were to be treated by the paramedics, would you want him or her to be enrolled in this type of study?

Yes No

4. Do you have any comments or concerns you wish to share with the investigators?

Age: _____ Ethnic background: _____

Gender: Male _____ Female _____

Thank you for your participation today.

*Attachment 3***News Release**

For more information, contact:
Toranj Marphetia
toranj@mcw.edu
Associate Director of Public Affairs
Director of Media Relations
Phone: 414-456-4700
Home: 262-784-8430
FOR IMMEDIATE RELEASE
DRAFT

**Medical College of Wisconsin
Researchers To Study Effectiveness
Of New Drug for
Traumatic Injury Victims**

Research to study the effectiveness of a new resuscitation fluid used during the care of patients suffering from traumatic injury in Milwaukee County, underwent successful community consultation in May 2006.

Members of the public responded to a phone survey of Milwaukee County, Wisconsin residents who were explained the design of the study and expressed support to proceed with the study. The Food and Drug Administration requires this community consultation because informed consent cannot be obtained from a patient suffering a traumatic injury.

"This is very important research, which has the potential to save lives and improve delivery of healthcare nationally" said Dr. Brasel, who is a trauma surgeon at the Froedtert & Medical College Emergency Trauma Center.

The goal of the study is to compare the effectiveness of standard crystalloid IV solution to hypertonic saline with and without dextran IV solution.

Attachment 3

The functional and quality of life outcomes, and survivors of severe brain injury will be attained.

For more information on exception to informed consent under emergency circumstances, risks and benefits, Opt-Out Bracelets and details of the study please call Dr. Karen Brasel at (414) 805-8624 or email kbrasel@mcw.edu, or visit the web site at (www.mcw.edu/roc).

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*Attachment 4***Risk/Benefit Public Announcement****PUBLIC NOTIFICATION OF AN EXCEPTION TO
THE REQUIREMENTS FOR INFORMED CONSENT FOR A TRAUMATIC INJURY RESEARCH
STUDY IN MILWAUKEE COUNTY, WI**

This announcement serves as public notification of a research study in patients with severe injury that will begin August 7, 2006 and will be performed in Milwaukee County, Wisconsin using the Food and Drug Administration's (FDA) regulations allowing exception to informed consent under emergency circumstances. The study will include victims of traumatic injury aged 15 years or older who are in shock due to blood loss or have a severe head injury and are treated by the Milwaukee County Emergency Medical Services (EMS) System. All patients will receive standard care. The only difference for this study will be that patients will be randomized to either receive initial intravenous fluid treatment with standard fluid (normal saline), hypertonic saline (concentrated salt water), or hypertonic saline (concentrated salt water) with dextran (sugar). There is a 1/3, 1/3, or 1/3 chance to receive one of these three treatments.

Shock occurs when the body has experienced a severe loss of blood, usually from a blunt or penetrating injury. The purpose of the study is to compare the effectiveness of the three fluids as an initial treatment for patients with shock or head injury. Preliminary studies indicate that concentrated salt water increases blood flow, heart function, and survival in patients with shock or head injury. The experimental aspect of this study is to compare functional and quality of life outcomes for patients with severe injury or head trauma receiving one of the three treatments.

It is currently unknown whether these treatments will improve functional and quality of life outcomes. Regardless of which group patients are randomized, every patient will receive either the standard of care or the standard of care plus the experimental treatment.

All research contains risks. The risks of this study include: abnormal blood chemistry, (the use of concentrated salt water may cause blood chemistry to become out of balance), decreased kidney function, (to minimize any potential risk, kidney function will be closely monitored), lack of benefit from the concentrated salt water, (the use of this solution may not improve functional and quality of life outcome), and survival with brain damage. Surviving a severe injury with damage to the brain is a potential risk for any patient with shock or head injury, whether they are entered in the study or not. It is possible that survivors in one group may have more damage to the brain. This will be monitored on an ongoing basis and the study stopped if it occurs.

Attachment 4

Females known to be pregnant will not be entered in the study. However, it is possible that rescuers will not know that a severely injured patient is pregnant. If a pregnant female is entered in the study, the risks include going into labor early (preterm labor), delivering the child early (preterm delivery), delivering a child whose lungs are not developed (fetal distress syndrome), or needing emergency surgery to deliver the unborn child. These risks could occur for pregnant women who receive treatment for an injury with or without participating in the study.

There may also be some unknown or unanticipated risks because the treatments used in this study are attempts to advance medical knowledge. Every precaution will be taken to assure personal safety.

The information that is obtained from this study may be useful scientifically and possibly helpful to others. The benefit that may reasonably be expected from participating in this study is improved functional and quality of life outcomes or an increased chance for survival for patients with shock or head injuries, but these potential benefits are not guaranteed. There are no financial risks or benefits for study participation. For this study, there are no appropriate alternative procedures that are known to be advantageous. All information obtained from this study that can be identified to an individual person will remain absolutely confidential. The scientific or medical information not identifiable with a patient resulting from the study will be presented at meetings and published so that the information can be useful to others.

The Food and Drug Administration (FDA) has issued regulations allowing exception to informed consent under emergency circumstances where acquiring written informed consent is impossible and there is reasonable scientific evidence to suggest a possible benefit from a new treatment. FDA regulations require public notification to inform the community that a research project will be done that may impact members of the local population. This notification must be made prior to the initiation of the study, which will begin on [DATE], and continue through [DATE] (anticipated). Public notification will also occur after the study is completed.

For those who do not want to be entered into the study, an "Opt-Out" bracelet will be made available. Paramedics have trained to look for these bracelets and will not enter those patients who are wearing one.

This study meets the FDA guidelines for exception to informed consent under emergency circumstances because informed consent cannot be obtained from a victim of shock or head injury. Members of the community with questions or concerns are encouraged to contact the principal investigator, Dr. Karen J. Brasel, either by phone (414-805-8624), mail (Department of Surgery, 9200 W. Wisconsin Ave., Froedtert West Clinics, Milwaukee, Wisconsin 53226 or email (kbrasel@mcw.edu), or visit the WEB site at (www.mcw.edu/roc). Feedback from the community may be used to further modify the design of the study.

Attachment 5**Intermediate Public Announcement****Public Notification:**

Research to study the effectiveness of a new resuscitation fluid used during the care of patients suffering from severe injury in Milwaukee County, will begin August 7, 2006 in Milwaukee County. Initial studies indicate that Hypertonic Saline (concentrated salt water) with or without Dextran (sugar) increases blood flow, cardiac output, and survival in patients with severe brain injury.

Researchers at the Medical College of Wisconsin will compare functional and quality of life outcomes for severe injury patients receiving intravenous Hypertonic Saline with and without Dextran solution versus the standard fluid (normal saline).

This study meets the Food and Drug Administration (FDA) guidelines for exception to informed consent under emergency circumstances because informed consent cannot be obtained from a victim of traumatic injury. For details, on the risks and benefits, exception to informed consent, opt-out bracelets and other aspects of the study please call Dr. Karen Brasel at (414) 805-8635, email at kbrasel@mcw.edu, or visit the WEB site at (www.mcw.edu/roc).