ROC PRIMED
COMMUNITY NOTIFICATION
2006

0627 7 SEP 20 A11 :20

Telephone Survey – Hebert Research, Inc.

- Conducted September, 2006
- Random survey of 210 households in King County
- 73.9% favorable response for receiving experimental CPR treatment

Website: www.uwheartroc.org

- Online October, 2006
- Accessed 55 times by 46 unique visitors. There were 8 hits on 11/2/06.
- Average time spent on website was 2.5 minutes. 75% of visitors left the site without accessing other links. According to the webmaster, this signifies that visitors found all of the information they were looking for on the webpage.
- No direct response to website

Metro Bus Ad

- Posted in 200 metro buses throughout King County 10/25/06 thru 11/23/06
- No direct response (e-mail or phone) from the ad

Press release: November 1, 2006

- Recipients:
  - Seattle Times
  - Seattle P-I
  - KOMO TV
  - King 5 TV
  - KIRO TV
  - KCPQ FOX TV
  - KUOW Radio
  - KOMO Radio
  - NPR radio
  - AP wire services
  - Reuters News Service
  - Bloomberg News Service
  - LA Times
  - NY Times
  - San Francisco Chronicle
  - Washington Post
- One telephone inquiry (11/6/06) from NPR followed by radio report below

NPR radio report: Ken Seinfeld – KPLU Health & Science editor

- Objective but favorable report
- Aired 11/7/06 four times (2 morning & 2 afternoon times)
- No direct response from radio story

Targeted Minority Advertising

- Real Change – Homeless newspaper – Circulation approx. 40,000
  - 10/25/06, 11/1/06, 11/8/06 - quarter page ad
  - 2 direct responses to e-mail address from one individual wanting to eliminate the use of sirens on cardiac calls
- NW Asian Weekly– Targets Asian community – Circulation approximately 10,000
  - 10/28, 11/10 – quarter page ad
  - No direct response to ad.

If you have an out-of-hospital cardiac arrest in King County, you can be enrolled in a research study without your consent.

Getting consent for special treatments isn't possible when you are unconscious from cardiac arrest, because life-saving therapies must be given immediately.

If you would like more information, call or click:

800-607-2926

www.uwheartroc.org

February, 2007	Visits	Views	January, 2007
HOME PAGE LINKS			**HOME PAGE LINKS**
Harborview Home Page	22121	30012	Harborview Home Page
RESEARCH			**RESEARCH**
Research/index.htm	99	123	Overview/Research/index.htm
Research/Hypothermia/FAQ.htm	97	151	Overview/Research/HypertonicSaline/
Research/HypertonicSaline/	56	61	Overview/Research/Hypothermia/FAQ.htm
Research/esdfaqs.htm	30	36	Overview/Research/esdfaqs.htm
Research/Hypothermia/	16	24	Overview/Research/Hypothermia/index.htm
Research/HypertonicSaline/Press+Release.htm	12	14	Overview/Research/Hypothermia/PublishedStudies.htm
Research/Hypothermia/Research.htm	11	20	Overview/Research/Prehospital+interventions.htm
Research/Hypothermia/Community+Consultation.htm	10	12	Overview/Research/HypertonicSaline/Press+Release.htm
Research/Hypothermia/PublishedStudies.htm	8	10	Overview/Research/Arrest+FAQ.htm
Research/Prehospital+interventions.htm	7	7	Overview/Research/Hypothermia/Research.htm
Research/Arrest+FAQ.htm	5	5	Overview/Research/Hypothermia/Community+Consultation.h

Visits	Views	December, 2006	Visits	Views
		HOME PAGE LINKS		
23566	31997	Harborview Home Page	17063	23440
		RESEARCH		
116	146	Overview/Research/index.htm	62	76
60	67	Overview/Research/Hypothermia/FAQ.htm	60	88
54	91	Overview/Research/HypertonicSaline/	49	52
38	49	Overview/Research/esdfaqs.htm	32	34
16	21	Overview/Research/Hypothermia/PublishedStudies.htm	14	19
10	16	Overview/Research/Hypothermia/index.htm	13	17
10	12	Overview/Research/Arrest+FAQ.htm	9	11
9	10	Overview/Research/Hypothermia/Research.htm	8	9
7	10	Overview/Research/Prehospital+interventions.htm	7	8
7	8	Overview/Research/HypertonicSaline/Press+Release.htm	5	6
3	3	Overview/Research/Hypothermia/Community+Consultation.h	4	4

November, 2006	Visits	Views	October, 2006
HOME PAGE LINKS			**HOME PAGE LINKS**
Harborview Home Page	20304	27806	Harborview Home Page
RESEARCH			**RESEARCH**
Overview/Research/index.htm	88	104	Overview/Research/HypertonicSaline/
Overview/Research/esdfaqs.htm	78	98	Overview/Research/esdfaqs.htm
Overview/Research/HypertonicSaline/	73	78	Overview/Research/Hypothermia/FAQ.htm
Overview/Research/Hypothermia/FAQ.htm	42	65	Overview/Research/
Overview/Research/HypertonicSaline/index.htm	24	27	Overview/Research/Prehospital interventions.htm
Overview/Research/Arrest+FAQ.htm	12	19	Overview/Research/Hypothermia/
Overview/Research/HypertonicSaline/Press+Release.htm	12	14	Overview/Research/Prehospital+interventions.htm
Overview/Research/Hypothermia/index.htm	12	19	Overview/Research/Arrest+FAQ.htm
Overview/Research/Hypothermia/Community+Consultation.h	7	9	Overview/Research/Hypothermia/PublishedStudies.htm
Overview/Research/Hypothermia/PublishedStudies.htm	7	7	Overview/Research/Hypothermia/Research.htm
Overview/Research/Hypothermia/Research.htm	4	7	Overview/Research/HypertonicSaline/Press+Release.htm
			Overview/Research/Hypothermia/Community+Consultation.h

Visits	Views	September, 2006	Visits	Views
		HOME PAGE LINKS		
22443	30695	Harborview Home Page	19931	27860
		RESEARCH		
94	99	Research/	36	45
93	107	Research/Arrest+FAQ.htm	12	14
79	126	Research/ASPIRE/	32	40
46	58	Research/ASPIRE/ASPIRE+Introduction.htm	4	6
15	18	Research/ASPIRE/AutoPulse.htm	24	38
14	18	Research/ASPIRE/Contact+Us.htm	1	1
13	18	Research/ASPIRE/FAQs.htm	15	19
9	9	Research/ASPIRE/Public+Disclosure.htm	4	4
9	17	Research/ASPIRE/Research.htm	2	4
7	11	Research/esdfaqs.htm	108	127
6	9	Research/HypertonicSaline/	94	95
5	8	Research/Hypothermia/FAQ.htm	64	89

August, 2006	Visits	Views	July, 2006	Visits
HOME PAGE LINKS			**HOME PAGE LINKS**	
Harborview's Home Page	21347	29697	Harborview's Home Page	19673
RESEARCH			**RESEARCH**	
Research/	57	90	Research/	30
Research/Arrest+FAQ.htm	5	7	Research/ASPIRE/	22
Research/ASPIRE/	24	29	Research/ASPIRE/ASPIRE+Introduction.htm	3
Research/ASPIRE/ASPIRE+Introduction.htm	2	3	Research/ASPIRE/AutoPulse.htm	31
Research/ASPIRE/AutoPulse.htm	22	36	Research/ASPIRE/FAQs.htm	25
Research/ASPIRE/FAQs.htm	11	12	Research/ASPIRE/Public+Disclosure.htm	3
Research/ASPIRE/Public+Disclosure.htm	4	5	Research/ASPIRE/Research.htm	3
Research/ASPIRE/Research.htm	4	9	Research/ASPIRE/Slide+Presentation.htm	12
Research/ASPIRE/Slide+Presentation.htm	12	18	Research/ASPIRE/Study+Methods.htm	9
Research/ASPIRE/Study+Methods.htm	9	19	Research/esdfaqs.htm	122
Research/esdfaqs.htm	83	92	Research/HypertonicSaline/index.htm	176
Research/HypertonicSaline/	68	74	Research/HypertonicSaline/Press+Release.htm	35

Views	June, 2006	Visits	Views
	HOME PAGE LINKS		
27762	Harborview's Home Page	19622	27600
	RESEARCH		
41	Research/ASPIRE/	33	46
26	Research/ASPIRE/AutoPulse.htm	32	46
3	Research/ASPIRE/FAQs.htm	22	25
48	Research/ASPIRE/Slide+Presentation.htm	11	17
32	Research/ASPIRE/Study+Methods.htm	11	14
3	Research/ASPIRE/Research.htm	10	22
7	Research/ASPIRE/Public+Disclosure.htm	9	9
22	Research/ASPIRE/ASPIRE+Introduction.htm	5	5
10	Research/HypertonicSaline/index.htm	103	138
146	Research/HypertonicSaline/	89	94
221	Research/esdfaqs.htm	78	87
38	Research/HypertonicSaline/Press+Release.htm	24	27

May, 2006	Visits	Views
HOME PAGE LINKS		
Harborview's Home Page	20571	29369
RESEARCH		
Research/	52	60
Research/ASPIRE/	31	41
Research/ASPIRE/AutoPulse.htm	36	64
Research/ASPIRE/FAQs.htm	32	39
Research/ASPIRE/Study+Methods.htm	13	21
Research/ASPIRE/Research.htm	12	31
Research/ASPIRE/Slide+Presentation.htm	12	15
Research/ASPIRE/Public+Disclosure.htm	8	12
Research/ASPIRE/Contact+Us.htm	5	6
Research/ASPIRE/ASPIRE+Introduction.htm	2	3
Research/esdfaqs.htm	117	147
Research/HypertonicSaline/	128	140

April, 2006	Visits
HOME PAGE LINKS	
Harborview's Home Page	18575
RESEARCH	
Overview/Research/	35
Overview/Research/ASPIRE/	37
Overview/Research/ASPIRE/AutoPulse.htm	36
Overview/Research/ASPIRE/FAQs.htm	17
Overview/Research/esdfaqs.htm	128
Overview/Research/HypertonicSaline/	129
Overview/Research/HypertonicSaline/index.htm	20
Overview/Research/Hypothermia/	19
Overview/Research/Hypothermia/FAQ.htm	72

Views	March, 2006	Visits	Views	February, 2006
	HOME PAGE LINKS			HOME PAGE LINKS
26432	Harborview's Home Page	19803	28279	Harborview's Home Page
	RESEARCH			RESEARCH
46	Overview/Research/	62	96	Overview/Research/
47	Overview/Research/ASPIRE/FAQs.htm	43	51	Overview/Research/ASPIRE/
53	Overview/Research/ASPIRE/AutoPulse.htm	37	68	Overview/Research/ASPIRE/AutoPulse.htm
24	Overview/Research/ASPIRE/	29	39	Overview/Research/ASPIRE/FAQs.htm
156	Overview/Research/ASPIRE/Study+Methods.htm	19	30	Overview/Research/ASPIRE/Research.htm
139	Overview/Research/ASPIRE/ASPIRE+Introduction.h	10	11	Overview/Research/ASPIRE/Slide+Presentation.htm
28	Overview/Research/HypertonicSaline/	157	184	Overview/Research/ASPIRE/Study+Methods.htm
32	Overview/Research/esdfaqs.htm	117	142	Overview/Research/Birth+Control+Pill+Study.htm
101	Overview/Research/Hypothermia/	25	32	Overview/Research/esdfaqs.htm
	Overview/Research/Hypothermia/FAQ.htm	83	131	Overview/Research/Fibromyalgia.htm
				Overview/Research/HypertonicSaline/
				Overview/Research/Hypothermia/

Visits	Views	January, 2006	Visits	Views
		HOME PAGE LINKS		
15080	21842	Harborview's Home Page	12145	17452
		RESEARCH		
28	34	Overview/Research/	31	40
24	39	Overview/Research/ASPIRE/	16	21
30	49	Overview/Research/ASPIRE/AutoPulse.htm	21	28
44	50	Overview/Research/ASPIRE/FAQs.htm	35	39
6	11	Overview/Research/ASPIRE/Slide+Presentation.htm	10	17
14	23	Overview/Research/ASPIRE/Study+Methods.htm	9	15
15	22	Overview/Research/Birth+Control+Pill+Study.htm	14	19
15	17	Overview/Research/esdfaqs.htm	106	127
91	108	Overview/Research/Fibromyalgia.htm	28	40
16	21	Overview/Research/HypertonicSaline/	102	124
124	141	Overview/Research/Hypothermia/FAQ.htm	45	65
16	20	Overview/Research/Hypothermia/	10	12

University of Washington and Medic One

Exception to Informed Consent Research (Experimental CPR) Research Report

September 2006

Prepared by

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University of Washington and Medic One
Exception to Informed Consent Research
September 2006

V1.2

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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 CPR treatment with individuals who experience an out-of-hospital cardiac arrest.

Research Objectives:
The following objectives were addressed in conducting this research for the University of Washington and Medic One.

1. Assess the proportion of the adults living in King County who would want to receive or want a relative to receive an experimental treatment if they experienced cardiac arrest without knowing if the treatment will be better than current practice.
2. Determine the proportion of respondents who would want the experimental treatment knowing they did not provide consent.
3. Assess the concerns of those respondents who would not want to be included in the study.
4. Examine the reasons community members have for wanting to receive the experimental treatment.
5. Determine respondents' attitudes toward allowing investigators to review their medical record arising from the experimental treatment without their prior consent.
6. Develop a demographic profile of the respondents.

Methodology

A total of 210 surveys were completed with adults living in households within King County. The response rate, which represents the proportion of the population who agreed to participate in the research, was 48.5 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 210 respondents is +/- 6.8 percent.

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: gender and age.

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
- Gender
- Race
- Education

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 independent variable explains all of the variation in 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 present the demographic profile of the sample. As indicated in the methodology section, the sample was statistically weighted to match the population in King County by gender and age. The table frequencies are the weighted percents.

Age	Percentage
18 – 24	10.5%
25 – 34	18.4%
35 – 44	21.7%
45 – 54	20.4%
55 – 64	13.9%
65 and over	12.6%
Refused	2.4%

Gender	Percentage
Male	48.9%
Female	51.1%

Race	Percentage
Caucasian/White	86.0%
African American/Black	3.5%
Asian	5.6%
Latino	2.8%
American Indian/Native American	0.7%
Mixed Race	0.3%
Other	1.2%

Education	Percentage
Less than high school	2.5%
High School Diploma	27.1%
Associate or Technical Degree	18.9%
Bachelor's Degree	31.4%
Post - Graduate Degree	18.4%
Refused	1.8%

Residence – zip code	Percentage
98103	4.0%
98052	3.6%

Residence – zip code (continued)	Percentage
98023	3.3%
98155	3.2%
98007	3.1%
98038	3.0%
98146	2.7%
98001	2.6%
98105	2.5%
98040	2.5%
98029	2.5%
98198	2.5%
98003	2.4%
98115	2.3%
98042	2.3%
98058	2.3%
98059	2.3%
98092	2.2%
98004	2.2%
98125	2.1%
98075	2.0%
98008	2.0%
98056	1.9%
98117	1.8%
98108	1.8%
98168	1.8%
98011	1.7%
98006	1.7%
98177	1.7%
98106	1.6%
98112	1.6%
98119	1.5%
98118	1.4%
98102	1.4%
98166	1.4%
98031	1.3%
98019	1.3%
98033	1.3%
98188	1.2%
98199	1.0%
98074	0.9%
98027	0.9%
98065	0.9%
98133	0.9%
98122	0.8%

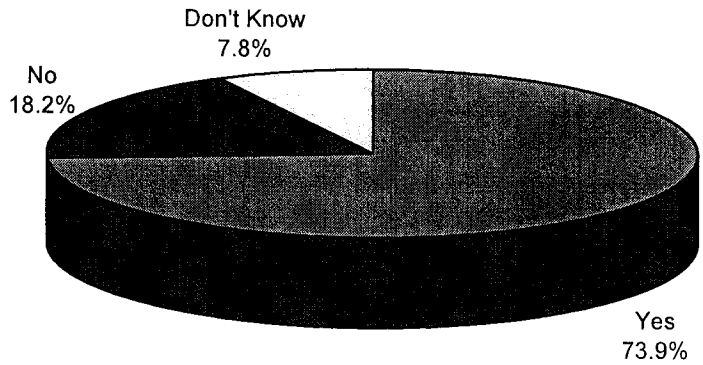
Residence – zip code (continued)	Percentage
98014	0.8%
98030	0.8%
98034	0.8%
98148	0.7%
98072	0.6%
98116	0.6%
98022	0.6%
98121	0.6%
98028	0.6%
98055	0.6%
98010	0.5%
98047	0.5%
98057	0.5%
98136	0.5%
98032	0.5%
98107	0.3%
98178	0.3%
98002	0.3%
98053	0.2%
98063	0.2%
98045	0.2%

Support for Receiving the Experimental CPR Treatment

Respondents were first provided with background information about the nature of the study, the reasons for use of the experimental treatment, and the conditions under which it would be administered. Respondents were then asked if they would want themselves or a relative to be administered the treatment if they experienced cardiac arrest.

Nearly three-quarters (73.9%) of respondents said they would want the experimental treatment administered to themselves or a family member if they experienced an out-of-hospital cardiac arrest and had a very high chance of dying. Only 18.2% of the respondents said they would *not* want the experimental treatment administered. 7.8% of respondents said they did not know. The community is highly in favor of receiving the experimental CPR treatment.

Would want the experimental CPR treatment, not knowing whether the treatment is better or worse than the treatment already being done

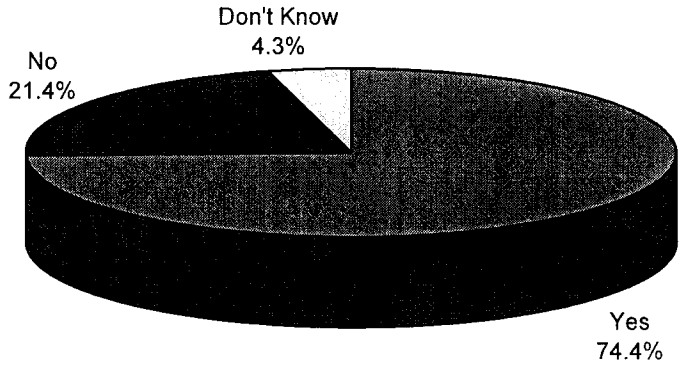


Would Want the Treatment Even though it would be Done Without Consent

The vast majority of respondents (74.4%) said that they would want the treatment, knowing that it would be done without consent. 21.4% of respondents said they would not want the treatment administered without consent, and 4.3% of respondents were unsure whether or not they would want the treatment.

Of the respondents who originally said that they would want the treatment (73.9% of total sample), 3.2% (2.4% of total sample) said that they would not want the treatment if it would be done without consent, and 1.9% (1.4% of total sample) said they were unsure whether they would still want the treatment if they were unable to provide consent.

Would want the treatment knowing that it would be done without consent

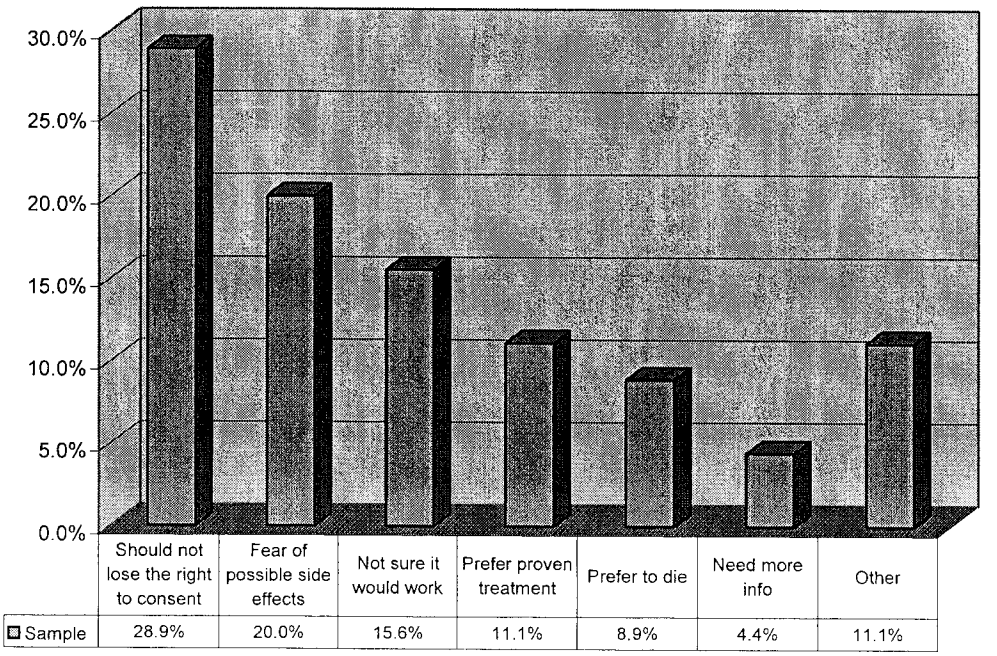


Concerns about Receiving the Experimental CPR Treatment Without Giving Consent

Respondents Who Would Not Want to Receive the Experimental CPR Treatment

The respondents who did not want to receive the experimental CPR treatment (21.4% of total sample) were asked the reason for their concern. Of this sub-group, 28.9% (6.2% of total sample) said they believed patients should not lose the right to provide consent, and 20.0% (4.3% of total sample) said they feared the possibility of side effects. Another 15.6% (3.3% of total sample) said that they are not sure that the experimental CPR treatment would work, and 11.1% (2.4% of total sample) said that they would prefer a treatment that has already been tested and proven. Other groups of respondents stated that they would prefer to die than receive treatment (8.9%) and they would need more information before making a decision (4.4%).

Reason for not wanting the treatment knowing that it would be done without consent



Respondents' "Other" reasons for not wanting to receive the treatment without consent were:

- *I do not have trust in the people administering the study.*
- *I understand it works well if they can get to you in time. That's why I'm not sure that I would want to be in that test.*

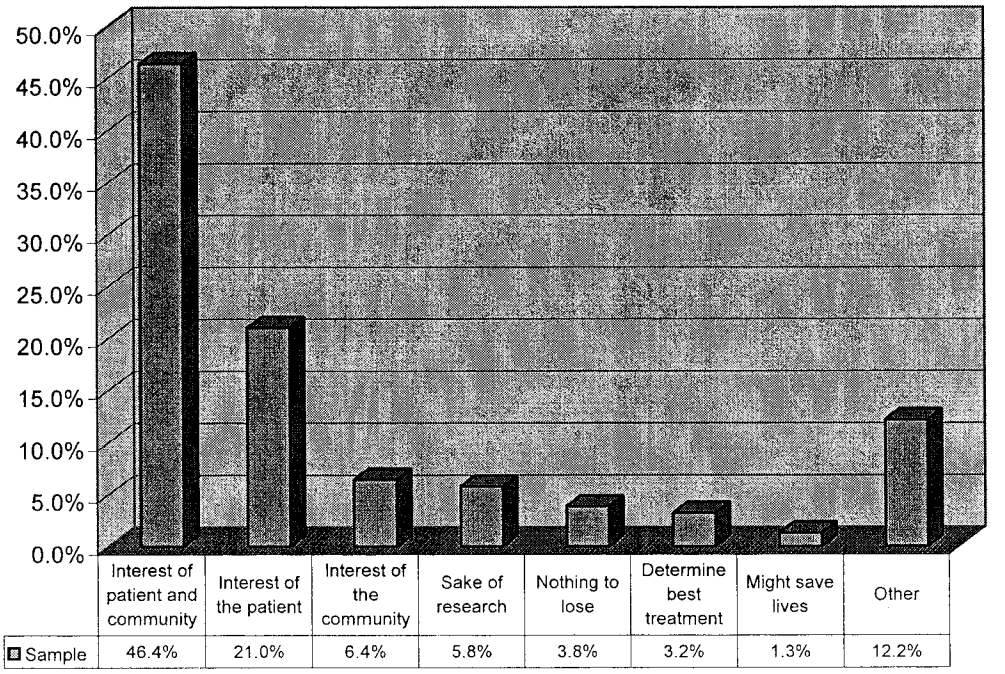
- *I watch myself carefully because I am diabetic. Wouldn't want to take the chance especially because of the diabetes.*
- *I would have it tested on somebody else rather then myself first. You have a small chance of living.*
- *I'm already dead.*

Reasons for Feeling that it is All Right to Conduct this Experimental Study

Respondents who Would Want the Experimental Treatment without Giving Consent

About half of the respondents in favor of receiving the experimental treatment without giving consent (46.4%; 34.5% of total sample) said that it is all right to do this study without patient consent because it is in the best interest of the patient and community. 21.0% of respondents (15.6% of total sample) said that it is in the best interest of the patient, and 6.4% of respondents (4.8% of total sample) said it is in the best interest of the community. Respondents also explained that it is all right to do the study for the sake of research and gaining knowledge, because there is nothing to lose by conducting the study, the study is necessary in order for the medical profession to determine the best treatment, and the study might ultimately save people's lives.

Reason it is all right to do this study without patient consent



	Interest of patient and community	Interest of the patient	Interest of the community	Sake of research	Nothing to lose	Determine best treatment	Might save lives	Other
Sample	46.4%	21.0%	6.4%	5.8%	3.8%	3.2%	1.3%	12.2%

The reasons that respondents provided differed significantly by race ($p = .004$). Specifically, all of the non-white respondents (100%) said that it was all right to conduct the study because it was in the best interest of the patient, the best interest of the community, or the best interest of both. Only 69.9% of white respondents provided one of these reasons, with 30.1% providing other reasons.

Reasons also varied by educational attainment (p = .038), with 53.6% of respondents with a bachelor's degree or higher saying that it is in the best interest of both the patient and the community; 45.7% of respondents with a high school degree or less provided the same reasons, and only 23.1% of respondents with an associates or technical degree providing those reasons.

Respondents' "Other" reasons for feeling it is all right to do this study without patient consent were the following:

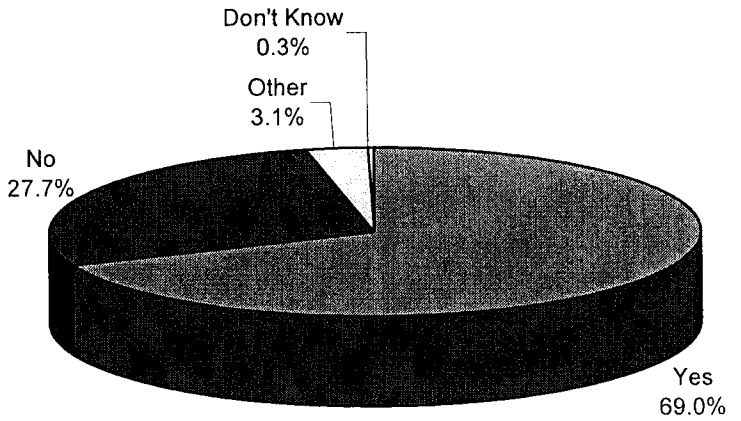
- *All the info came based on the studies they did previously.*
- *Anything that might improve the chance of survival is good.*
- *As long as they are doing effective CPR.*
- *Assuming they have good standards and not educated guesses.*
- *Because I am not in well enough health as it is, so, I would be more than willing to help others out.*
- *CPR sucks.*
- *I had a bypass and I know if something happens close to that I think it would be the same or better. Along with the controversy or the shot coming first.*
- *I have had loved ones and relatives suffer from this type of heart attack.*
- *It's a study that has not been used. We want to see if the procedure is working or failing and it is okay to do it.*
- *It's the UW. It's the best hospital for a heart attack.*
- *So, if they can improve it, it would be way better in the long run.*
- *That's the only way we'll know how to do something.*
- *The circumstances as you explained are conducive or reasonable to give consent.*
- *The main objective is to get the heart back beating.*
- *The paramedics would have my best interest at heart. If I die, they failed, but they do everything they can to help the patient so they won't fail.*
- *There's not enough time to do research or there's no time on that deal.*
- *The work must be done to come up with new procedure.*

Allow Investigators to Look at Medical Records without Consent

Respondents who Would Want the Experimental Treatment without Giving Consent

Respondents who said that they would want the experimental CPR treatment administered without providing consent were asked whether they would allow investigators to look at their medical records without having received consent. A majority of respondents (69.0%; 51.3% of total sample) said that they would allow the investigators access to their medical records even if they or a family member did not provide consent. Slightly over one-quarter of the respondents (27.7%; 20.6% of total sample) said that they would not want the investigators to look at their medical records. Those who would want the experimental treatment are clearly in favor of allowing access to medical records without first providing consent.

Allow investigators to look at medical records without consent



Older respondents were significantly more likely to agree to allowing investigators to look at the medical records without consent compared to younger respondents ($p = .001$). Only 27.8% of respondents ages 18 to 24 said "yes" while the percents for other age groups who said "yes" ranged from 65% to nearly 90% (71.0% aged 25-34 said yes, 65.6% aged 35-44, 75.8% aged 45-54, 70.8% aged 55-64, and 88.9%over the age of 65).

Respondents who provided a response classified as "Other" (3.1%) said the following:

- *Limited access only.*
- *I would want the records...I think they should try to ask for consent. If no one was around, then I would say yes.*
- *It depends on how in-depth the record would be.*

Reason for Denying Access to Medical Records

Of the 30.8% of respondents who said they would not want the investigators to look at the medical records or provided an "Other" reason for denying access, most (68.7%) said that patients should not lose the right to provide consent for themselves. Additional reasons provided by respondents (26.9%) included the need for privacy and confidentiality, a desire to be able to make the decision, and the need to stay informed about what was taking place regarding their case.

Here are the comments provided by respondents:

- *Make sure confidentiality is maintained; make sure the people are part of the initial team and not a secondary team.*
- *It has to do with confidentiality... I wouldn't be concerned... but there would need to be consent given to look at these private medical records...*
- *There is no way of confirming who is looking at your records. I would feel more comfortable if the hospital sent the information with basic demographic information.*
- *Privacy, constitutional rights, my rights to make choices for myself, there needs to be controls.*
- *Into the study, someone should give options, whoever is there, or the patient should be allowed to at that point.*
- *I want the family to know what is going on.*
- *It depends. Is it how many times a day you go to the bathroom?*
- *I don't want anyone to look at my medical treatments without telling me. The treatment is secondary.*
- *I'd have to know a little about who it was.*
- *I don't know what would happen between the medical treatment and the records review. There may be things that occur in that time that I only want my Doctor knowing about.*
- *Medical Records are very private.*

Additional Comments

Slightly more than half of all respondents provided additional comments on the issue of receiving the experimental CPR treatment without providing consent. Many respondents provided positive comments regarding the experimental treatment, mentioning that it is not practical to obtain informed consent in this situation, that the new treatment has the possibility of saving lives and was likely better than the standard treatment. Respondents also explained that research of this type is necessary in order to better the medical field.

Respondents also voiced some concerns over the procedure, explaining that they would prefer the standard treatment because it has been proven, that they would not want to lose their right to consent to the treatment, and they do not believe it is appropriate for investigators to look at medical records without consent.

Positive Comments

Possibility of Saving Lives

- *It's alright, especially if the process and results are widely disseminated.*
- *Anything they can learn from me, dead or alive, is better for everybody.*
- *Anytime you are trying to save a life and they have a heart attack and you hear the sirens of the ambulance, so be it rather then letting them die.*
- *No, just that it's good we are trying new methods for helping people. We need to save more lives if we can.*
- *Oh, it seems like an okay thing to do, to save someone. We won't know if it will work better if we don't try it.*

Impractical Situation for Informed Consent

- *I wouldn't want paramedics overruling the family, but in the absence of yes or no, just do it. The standard wave is a crapshoot; defibrillation stresses the family; the convulsion.*
- *I believe in informed consent but, in this case, do it without consent.*
- *I think they wouldn't be in a position to give consent.*
- *They have to do the study and it's hard to get consent.*
- *They should do it without consent.*
- *If something might work it's worth a shot. You can't get consent; it's a situation where they can try a different option.*
- *No, I think we need to do the consent, but in an emergency time...*
- *No, I understand that in this case there is no way to give consent in advance, it has to be done.*
- *No, in this situation I understand why you can't always get consent and that this means the study won't always work.*
- *No. I don't think they should have to have consent.*

- *You know the thing is, is that if you're totally out, there is no way you can consent...you want them to do whatever... there is nothing you can say.*

It's a Good Idea, but I Wouldn't Want it Done on Me

- *I think and I understand that would be a good thing to do I just wouldn't want it done on me.*
- *As long as it's not on me but it should be done on other people so we know along the road if it actually works or not.*

It's Necessary to Conduct This Type of Research

- *You've got to try something new to try to help people.*
- *What is being used is not working, would be in everyone's interest to try something better.*
- *We are trying our best for mankind and we are trying to find the answers. My son's father in law died recently with a massive heart attack and tomorrow is his funeral. My son went to the UW.*
- *The experimental thing is the only way to find about these treatments. It is kind of a touchy situation.*
- *In order for medicine to improve you have to experiment somehow.*
- *No, I think it's good to go ahead and try new things.*
- *No, I think it's good we're trying new treatments.*
- *It would help a lot of people. If you don't know whether it would work or not, you have to experiment on people to find out if it would work or not. They can't get any worse. I do think prevention is the best treatment, preventing a cardiac arrest.*
- *I hope they are able to do it or else how will they ever know. Without trying it, how can they even do it?*
- *No, I'm always into something that can be improved and I think it's great. New experiments arise each and every day.*
- *I think it's an important study to do, I understand the concerns do make the world a safer democracy.*

Experimental Treatment Might be More Successful than the Standard Treatment

- *It appears it would not reduce the effectiveness of CPR, but it could. I assume the study is being pursued due to the promise of enhanced treatment. If so, I'd agree to it.*
- *If it's getting positive results, it's ok.*
- *I would hope that they would find something that worked more effectively.*
- *Yes. Being certified in CPR, and knowing the risks, they are more likely to die; you should do whatever you can.*

Other Positive Comments

- *If having such a small opportunity to do anything, no matter what you do, if it's doing it in good faith is acceptable.*
- *If you don't know, I think it's fine.*

- *I wouldn't personally have a problem but I would guess there would be some people that would.*
- *I just think that more people should get involved in research like this.*
- *No I have no comments on that, I think its all going in the right direction.*
- *No, I mean obviously they feel there is some validity to it. It's a free market.*
- *The study is fine. But I have "do not resuscitate." I had a big fight with the fire dept and doctors about my dad; he'll die. I wanted to take him home to die. He died 9 months later. A bitter experience. It doesn't have to happen.*
- *There's no other way to do it.*
- *No, I'm glad you're doing it.*
- *Umm, I think if it's an experimental treatment, it would be okay. The Medics are going to do everything they can to stabilize you anyway. As long as it's not some sort of experimental drug, that very little is known about. It sounds like it's a good idea.*
- *Ok in the case of life or death.*
- *Well this is progress isn't it?*
- *What ever helps to advance treatment.*
- *Seems reasonably benign.*
- *For something with cardiac arrest I don't see any other way to test treatments so I agree.*
- *I have heard about such studies and have considered it to be a reasonable idea.*
- *I have no problem with it.*
- *Good luck.*
- *I am an electronic engineer and a bio-medical engineer. There are special circumstances and I have some information about when the people out here in Seattle built that first unit--heart start--in a UW engineering class. It made so much sense when I was reading Popular Science, and I think to myself: Why didn't I ever think of that?*
- *I wouldn't personally have a problem but I would guess there would be some people that would.*
- *When someone is near death use the best possible treatment available*
- *One thing: If I should have a heart attack I want everything possible to save me.*
- *Only thing is medicine is a science. We should do it scientifically.*

Concerns

Medical Records Issue

- *There are a lot of ignorant people in a situation like this; it can save their lives. A look into my medical records is something that I would refuse, unless I give consent.*
- *As I already stated, I feel randomized access to people's records should be allowed. A patient should be asked for consent before their information is used by other patients.*
- *As long as the information isn't used under my name, the data will be anonymous; I don't want my info used for anything else.*

- *Just that medical records shouldn't be given out without consent.*
- *They can't look at my records with consent.*
- *No I just don't believe the right to consent for medical records should be given up...*

Patient Should Provide Informed Consent

- *Anyone that goes to a regular Doctor should be able to fill out some sort of a form to give permission.*
- *People should have consent.*
- *Anyway, if any treatment is going to be happening to me or my family, I have to know. They have to tell me before they do anything, so I can know what is going on.*
- *I don't like the idea of doing without patient consent even if you are unconscious and/or dying. A family member should be the one to make that decision.*
- *I don't think the study should not be done without consent. I would be reluctant to give consent. I'd be giving consent to possibly dying faster than current treatments allow. It's a tough question.*
- *I don't think they have the right to do that without consent, it infringes on a persons rights. It takes away their civil rights where they should be able to choose.*
- *Sounds like a terrible idea. People should be able to choose.*
- *If I'm conscious I would like to give consent!*
- *I think its very interesting; I don't have any comments one way or the other. Then again, if you have a family member, who is directly related to you, and they're in the house, and you're wherever, and you have a cardiac arrest, you definitely need permission for that family member.*
- *If the person is unable to give consent, I approve this for the life of my family member. But if the doctor could receive consent from the patient, I would prefer that.*
- *If you throw it wide open, it's like giving a blank check to someone. There needs to be a control of some sort, like consent from immediate family, quality of life afterwards would be a consideration.*
- *The thing that would concern me most is how they would pick people to do the study without consent.*
- *There should be consent given first or there's going to be trouble later on like the person's frame of mind and all of the legal loopholes because it changes and some people are going for this and others are not.*

Concerns About Side Effects and Quality of Life

- *I was in an experimental drug trial in 1976; suffering from chronic back pain. The drug could damage my liver, Tylenol 3.*
- *Agree that quality of life is a paramount concern but studies need to be done.*

Experimental Treatment Compared to the Standard treatment

- *I'd be concerned giving the new procedure to my 9-year-old daughter. If she dies I would want to know they tried standard treatment, not experimental procedure.*
- *If there is a possibility it might be worse than the standard treatment, I might change my answers.*
- *It doesn't have the research behind it yet. I'd rather select a potentially less effective treatment with research behind it than an experimental treatment with no research.*

Legal Concerns

- *From a legal standpoint, if somebody initially approves this thing in advance there's no legal recourse to the medical association, otherwise don't do the deal. Medical and attorneys costs too much and there's a certain gamble that you take to the extreme then you wind up with not doing anything and the guy dies. I have no patience with the attorney's with the damage which is a sensitive issue. I have heart disease currently and I take all kind of pills. Most attorneys take advantage of the situation and someday it may turn but the costs are way up there currently.*
- *Get rid of HEPA*
- *I think it would be difficult. Someone might sue you.*
- *Most people don't want anyone doing anything without their permission; most people would want to know what's going on, to give authorization. Sometimes people sue someone who has done something to save their lives. People are in a blame mode; they want to blame someone. You could run into lawsuits with this study; some people would want to go back and say if a person dies, if it weren't for the experiment, maybe they could have lived. It's the lawsuits that concern me regarding this study.*
- *My only thought would be the liability of the city employees (i.e. paramedics) after administering procedure without consent. Some people will do anything for money.*
- *Just that the study should fall with the governing bodies, like the AMA or whatever research group. It should meet all the protocol and government regulations that need to be done.*

Other Concerns

- *Do not do it.*
- *Nightmares about this.*
- *It may do some sort of harm.*
- *How do they decide on jurisdictions, and are their opinions on research reaction? I don't want them to work on me because I've had that kind of incident and I'm concerned with people who are responding who will be trained and what methods they would use.*

Other Comments

Have the Ability to Opt Out.

- *Maybe if there's bracelets that they could wear to show if they give consent, or a card in their wallet, like on the back of your drivers license if you don't want to be resuscitated. But maybe there's not time to look for the card or bracelet, so I don't know.*
- *Would rather have an opt-out bracelet.*

Need more information

- *I would have to learn more about it - I don't know what the procedure would be or be about.*
- *Who would be doing this study? Who would be conducting this study? Who would be monitoring it? Would the public be told about the results? How long would the study go on for? Where would the study be going on at?*
- *What was the basis for thinking it might be better if they don't know? I think there needs to be some explanation that is more commonly out there if they are talking about this, so that it is clear that there is a possibility of a benefit. It may be that they don't understand. Whatever they can give to the general public in explaining this would be useful.*
- *It would be nice to know a little bit more about the study, but if you have the arrest, there is no time to ask you.*
- *That's a tough question. This isn't like does this taste better or does that taste better. This is a situation where a person's life is on the line; you can increase or decrease their chances to live. I think if people would really need to know, information should be sent out and given to people so they can look at this type of situation and have their mind made up, get their reaction that way. That's a tough call. If you could convince a person that regardless of what we do, it's better than what you normally get or no worse than what you normally get, there's no much an issue. If it's as efficient as what is being done, I wouldn't have a problem with that.*
- *I want to know more about the treatment before I could give a good opinion.*
- *I would rather have known something about it ahead of time.*
- *If it's shown to be safe then yes, otherwise I don't know. I need to do more research.*
- *Well I don't know anything about the way it's currently done.*
- *Is it invasive or not? If it is, what exactly is it doing? If it would have to be put in the body to absorb oxygen it may be too invasive.*

Prefer Other Methods of Testing the Treatment

- *I would think you could try it at a hospital first.*
- *Would like to see tested on animals if possible.*
- *I think we should be able to test these treatment methods in another way other than random. What if these methods are worse and people lose their lives because of it?*

- *It's too bad people can't give consent beforehand. How do they have an apparatus like that? I wouldn't want to be a guinea pig, but I don't know if they can try it on animals first. Why risk a human life.*

Additional Thoughts

- *Later, after the experiment, they should have the option to participate in the study, because of medical ethics.*
- *I just don't think it's a good idea, but I guess it has to be done.*
- *No, because as we go through life everyone tries different things anyway, what will work on one person won't on another.*
- *No, I find it very interesting that Medic One is involved in this...*
- *No, I think that right now that the way they are going about it they want opinions, there is probably more research to be done.*
- *No, it's sort of self-explanatory.*
- *Only that if you do that kind of study it will be done without consent.*
- *Well no, as long as they had nothing to do with blood transfusions as far as non-consensual treatment is concerned.*
- *As far as I'm concerned all medical people, the medical practice, sometimes, it's trial and error. They say that they're not sure and to try this. Sometimes, they just don't know and are just guessing. They call it a practice for a reason and they're not always right. After you die, they can tell better what the problem was. They can dig deeper and do an autopsy and find out more.*

Conclusions

- If suffering from cardiac arrest, a very high majority of the respondents (73.9%) would want the experimental treatment not knowing whether it is better or worse than the way CPR is already done. Even more respondents (74.4%) said that they would want the treatment knowing that it would be done without consent. The community shows very strong support for receiving the experimental treatment.

- The primary reasons respondents would not want to receive the experimental CPR treatment involved a belief that patients should not lose their right to consent, a fear of the possibility of side effects, uncertainty as to whether the experimental treatment would work, and preference for a treatment that has already been tested and proven.

- Respondents who said that they would want to receive the experimental treatment explained that it is all right to do the study because it is in the best interest of the patient and/or community. Respondents also said it is all right to do the study for the sake of research and new knowledge, because there is nothing to lose by conducting the study, the study is necessary in order for the medical profession to determine the best treatment, and the study might save people's lives.

- Of the respondents who would want to receive the experimental treatment without providing consent, most (69.0%) would allow investigators to look at their medical records without consent. The community is in favor of allowing medical personnel to have access to their medical records without giving them consent.

- The primary reason respondents would not want the investigators to look at their medical records was that patients should not lose the right to provide consent.

Appendix: Questionnaire
UNIVERISTY OF WASHINGTON and MEDIC ONE
WAIVER OF CONSENT RESEARCH

V1.2

May I speak to someone who is at least 18 years of age? Thank you.

Hello, I'm calling on behalf of the University of Washington and Medic One. This call does not involve fund raising of any kind. My name is _____.

I am calling from the Hebert Research Firm. I represent researchers at the University of Washington as well as Medic One. We are planning a study of persons who have a serious kind of "heart attack" called a cardiac arrest. Your phone number was picked by chance (at random) for this call. This call does not involve sales of any kind. We're calling only to get your opinion about this study. This should take 5-10 minutes. This study is voluntary. We will ask questions like "If you had a cardiac arrest and had a very high chance of dying, would you want to receive a new experimental treatment?" You don't have to answer any questions that you don't want to and you may stop the survey at any time. Your answers will be kept anonymous. If you are over 18, would you be willing to answer some questions?

First may I give you a little background information –
A cardiac arrest is a medical emergency. During a cardiac arrest, the heart stops beating, leaving the body without blood flow or oxygen. When this happens, a person "passes out" (becomes unconscious). Death usually occurs within minutes without CPR and electrical shock treatment. Even with such treatment, few persons survive a cardiac arrest. Because survival is so poor, doctors are working on ways to improve these outcomes from cardiac arrest, such as this study.

Emergency treatments for cardiac arrest are not always successful. Many people with cardiac arrest die at the scene or before they reach a hospital. So emergency medical teams want to test new ways to treat cardiac arrest. They hope the new ways of treatment will be better than the treatments currently being used. But because no one knows if the new treatments are better or worse, they have to be tested on people having cardiac arrests. The United States Food and Drug Administration sets the rules for testing new medical treatments and the rules for how patients are asked to participate in studies on experimental medical treatments.

Usually persons in a study must be given an explanation of the study and an opportunity to agree to participate in it. This is called "informed consent". It is not possible to ask a person having a cardiac arrest if they would like to participate in a study for an experimental treatment. The person is unconscious. A family member may or may not

be with the person having the cardiac arrest. If a family member is at the scene there is not time to ask the family member for consent on behalf of the person with the cardiac arrest. The emergency medical team must treat the person with cardiac arrest immediately or that person will die within minutes.

In situations like this, the Food and Drug Administration will allow the medical team to use the experimental treatment without getting consent from anyone. The study we are going to talk about will be done without getting consent from anyone at the scene of the cardiac arrest.

STUDY

The purpose of this study is find ways to improve CPR. CPR means pumping the chest and giving breaths to produce some circulation until the heart can be restarted. Some experts believe that the most important step to restart the heart is to immediately give an electrical shock. Others believe that providing a few minutes of CPR before a shock treatment helps the heart to regain its own natural heart beat better than if shocked right away. Whether shocking the heart first, or delaying shock by a few minutes in order to give more CPR is better is not known. We hope to test this by treating some persons with cardiac arrest with electrical shock first, and others with a few minutes of CPR before the shock.

We also want to test whether the way we do CPR can be improved by using something called an impedance threshold device (ITD). This device is smaller than your fist and attaches to the end of the breathing bag that is used by Medic One to give breaths during CPR. It works to increase the amount of blood that is pumped in and out of the chest during CPR. Whether it will improve survival from cardiac arrest is not known. We hope to test this by treating some persons with cardiac arrest with the ITD, and others without it.

Whether treated by shocking the heart first, or after a few minutes of CPR; and with or without the ITD, patients will otherwise receive all standard treatments for cardiac arrest. This type of study, called a randomized trial, is the truest way to find the best treatment for cardiac arrest.

QUESTIONS

1. If you or a relative had an out-of-hospital cardiac arrest and had a very high chance of dying, would you want this experimental CPR treatment, even if no one yet knows if the treatment is better or worse than the way CPR is already being done?

   a. Yes
   b. No
   c. Don' t know
   d. Refused to answer

2. Would you want to have this treatment knowing that it would be done without your consent?

   a. Yes. **[GO TO Q4]**
   b. No
   c. Don't' know **[SKIP TO Q7]**
   d. Refused to answer **[SKIP TO Q7]**

3. **[ASK IF Q2=b]** Why not?

   a. Fear of possible side effects
   b. Patients should not lose the right to provide consent for themselves
   c. Don't know
   d. Refused to answer
   e. Other **[SPECIFY]**

[GO TO Question #7]

4. Why do you feel that it is all right to do this study?

   a. It is in the best interest of the patient
   b. It is in the best interest of the community
   c. It is in the best interest of both -- the patient and community
   d. Don't know
   e. Refused to answer
   f. Other [SPECIFY]

Assume you had a cardiac arrest and were later told you had received this experimental treatment. You are in the hospital. Medical records have been created that tell about your health since your cardiac arrest. You may or may not feel able to talk to anyone. Relatives have visited you and talked to members of your health care team. The investigators who are studying the experimental treatment you received want to look at your medical records for the time you are in the hospital, or possibly at several months after you leave the hospital, to see if the treatment has been safe and effective.

5. Would you allow them to do this if they did not ask you or a relative for consent before they started to look at your records?

   a. Yes. If treated, I would want to know if someone was helped or harmed by it. **[GO TO Q7]**
   b. No. I would want to have the chance to give or refuse consent
   c. Don't know **[SKIP TO Q7]**
   d. Refused to answer **[SKIP TO Q7]**
   e. Other **[SPECIFY]**

6. **[ASK IF Q5=b]** Why not?

a. Patients should not lose the right to provide consent for themselves
b, Don't know
c. Refused to answer
d. Other **[SPECIFY]**

7. Do you have any additional comments about doing such a study without consent? **[VERBATIM]**

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

8. What is your age? **[RECORD NUMBER]**

9. What is your race?

a. Caucasian/White
b. African American/Black
c. Asian
d. Latino
e. American Indian/Native American
f. Mixed Race
g. Other_____(specify)
h. Don't know
i. Refused

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

a. Less than high school
b. High School
c. Associate, Technical or Vocational degree
d. Bachelor's Degree
e. Post-graduate degree
f. Refused

11. What is your occupation? **[VERBATIM]**

12. What is your zip code?

That concludes the survey. If you have any questions or comments about either of these studies I can give you a contact person. Would you like that information?
Sally Ragsdale or Debi Solberg
206-447-5671; or 1-800 607 2926

THANK YOU VERY MUCH FOR YOUR TIME AND COOPERATION.

POSTCODE GENDER:
1. MALE
2. FEMALE

DATE: _____

INTERVIEWER: _____

Appendix: Occupations

Listed below are the occupations reported by respondents.

Accountant (3)
Analyst
Architect
Attorney
Baby sitter
Banker
Beautician
Business Analyst (Medical)
Business Manager (2)
Business Owner (5)
Cabinetmaker
Caregiver
Carpenter, foreman construction
Catalogue coordinator
Childcare provider.
Child welfare administrator
Commercial Diver
Company manager
Computer Programmer
Computer scientist
Construction worker
Consulting.
Counselor
Customer service representative
Customer Service.
Data operations supervisor
Dental Assistant (2)
Dental Hygiene
Designer
Dietician
Disabled.
Doctor (2)
Editor
Educator (12)
Employment Coordinator.
Engineer (10)
Facilities coordinator
Fashion Model-Retired
Finance director
Financial Adviser
Hairdresser (2)
Health care giver
Homemaker (10)
Hospital
Hospitality
Human Services Administrator
International Travel Agent and Demonstrator
Ironworker
Janitor
Kitchen Designer
Lab technician
Library assistant at a school
Maid.
Maintenance Manager
Maintenance electrician
Manager
Marketing
Mechanic (2)
Medical Assistant
Medical Courier
NAC
Nurse (3)
Nursing Assistant
Office assistant
Office worker
Owner/operator trucker
Para educator (2)
Personal Trainer
Physician (2)
Plumber
Pre-school teacher
Professor
Program Director
Project Manager (2)
Realtor (4)
Registered Nurse (4)
Research Assistant / Post Graduate Student
Retail sales clerk

Retail/Student
Retired (50)
Sales
Sales Person
Sales-Insurance
Scientist
Self-employed (3)
Social worker.
Software Developer (2)
Student (4)
Sustainable project development
System analyst.
Technical Writer
Truck driver (2)
Unemployed
Waitress/Student - 2 years so far
Warehouse Manager
Warehouseman
Woodworking
Workers compensation coordinator
Writing instructor, and pre-school aid
Yard work

HEALTH SCIENCES / UW MEDICINE
NEWS AND COMMUNITY RELATIONS

UNIVERSITY OF WASHINGTON

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FOR IMMEDIATE RELEASE: UW Researchers Focus on Improving CPR

Researchers at the University of Washington (UW) and Harborview Medical Center, in cooperation with King County Emergency Medical Services and Seattle Medic One, are evaluating new ways to help save lives after out-of-hospital cardiac arrest. Cardiac arrest is the sudden, abrupt loss of heart function that kills about 180,000 persons each year in the United States, or nearly 500 people every day. It strikes without warning, and within an instant can turn a healthy, productive person into a victim only minutes away from death. Even with life-saving treatments such as CPR and defibrillation shock, nationwide only about one person in 20 survives a cardiac arrest.

University of Washington researchers are keen on improving those odds. Their planned study, called PRIMED (Prehospital Resuscitation using an Impedance Threshold Device and Early versus Delayed Rhythm Analysis) will be the largest evaluation of out-of-hospital cardiac arrest in history. It will evaluate and compare the benefits associated with the length of time CPR is given before the heart is shocked, as well as the benefits from using a device designed to enhance

(more)

C301 Health Sciences Center Box 356345 Seattle, Washington 98195
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blood flow during CPR. Supported by a grant from the National Institutes of Health, researchers expect to enroll approximately 15,000 people in 11 communities across the United States and Canada, including Seattle, during the next two years.

Cardiopulmonary resuscitation, better known as CPR, is a proven medical intervention for improving survival after cardiac arrest. Some experts believe that achieving good blood flow with a longer period of CPR before giving other treatments, such as a defibrillation shock, may be especially important, and will be evaluated by this study. In addition, some people may be treated with a fist-sized device called an ITD or impedance threshold device. The ITD is attached to the mask or breathing tube used to provide breaths during CPR and acts to increase the amount of blood pumped each time the chest is compressed and released. Investigators hope to prove whether such a device can improve outcome after cardiac arrest by treating some persons in cardiac arrest with the ITD, and others without it.

Emergency treatments like these for cardiac arrest must be administered immediately to patients who are unconscious as a consequence of their condition. This makes it impossible for emergency-care providers to obtain informed consent from patients or their families before enrolling them in the study. U.S. Food and Drug Administration (FDA) regulations stipulate that the medical team is allowed to use the experimental treatment and enroll patients in the study without first getting consent due to the emergency nature of their illness. All participants (or family members) will be completely informed of their participation in the study as soon as it is possible to do so. The study is currently under review by the University of Washington's Institutional Review Board (IRB), which, along with the FDA and independent experts at the National Institutes of Health will have oversight of the trial.

"We know that CPR is a life-saving treatment for cardiac arrest," said Dr. Peter Kudenchuk, UW professor of medicine and principal investigator for the study. "But countless thousands of lives might be saved by doing CPR better. The results from PRIMED may change the manner in which patients with cardiac arrest are resuscitated and the ultimate success of such efforts throughout the world."

"The Seattle community has a long history of supporting research related to emergency medical treatment," Kudenchuk said. "Our goal is to keep the community informed of our project, and our hope is that they will, in turn, let us know their thoughts and any concerns they may have."

The University of Washington and Seattle Medic One-King County EMS welcome public comment on the study and on enrollment without consent. More information can be found on the study's web site: www.uwheartroc.org or by calling the study coordinators, nurses Sally Ragsdale, Debi Solberg, or Michele Olfuska, at 206-447 5671.

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New Research Studies May Improve Outcomes after Cardiac Arrest

If you have a cardiac arrest in Seattle or King County you can be enrolled in this research study without your prior consent. Researchers in Seattle-King County and 10 other communities across North America are investigating methods to improve survival after out-of-hospital cardiac arrest. Getting consent for these treatments is not possible when you are unconscious from cardiac arrest, because life-saving therapies must be given immediately. In this study, you could be treated with either a short (30 seconds) or longer (3 minute) period of CPR before your heart rhythm is evaluated and shocked. In addition, you may be treated with a fist-sized device (called an ITD), which is attached to the face mask or breathing tube used to provide breaths during CPR, and acts to increase blood flow. The University of Washington welcomes your feedback on this study. For more information, please visit our website at www.uwheartroc.org , e-mail kcroc@u.washington.edu or call our cardiac arrest hotline at 206 447 5671 or 1-800 607 2926.

ROC Web Site Document

Approaches to improve blood flow during CPR may improve survival following cardiac arrest (The PRIMED Study)

Overview

THIS IS A STUDY IN WHICH YOU CAN BE ENROLLED WITHOUT YOUR CONSENT. [Link to section: What about consent for the study?]

Cardiac arrest is the sudden, abrupt loss of heart function. Death usually occurs within minutes unless cardiopulmonary resuscitation (CPR), rapid defibrillation, and paramedic interventions are available. CPR consists of pumping on the patient's chest and delivering breaths to produce some circulation until the heart can be restarted. When the chest is compressed, oxygen-rich blood is pumped forward. When the chest is released, oxygen-poor blood is brought back to the heart and lungs where it can be restored with oxygen before being pushed out to the body with another compression. Both actions – pushing oxygen-rich blood forward and bringing oxygen-poor blood back to the heart and lungs - are important. CPR however produces only about 30% of normal circulation. Methods to improve the circulation produced by CPR may lead to better survival.

One experimental device, called an impedance threshold device or ITD, is being studied in this clinical trial. The ITD is a device smaller than your fist that attaches to the end of the breathing bag used by EMTs and paramedics. The ITD works to bring more oxygen-poor blood back to the heart so that ultimately more oxygen-rich blood is available to be pushed forward.

The timing of the CPR compressions is also being studied in this trial. Some evidence indicates that the period right before the heart is shocked may be especially important for the heart to have the best chance to regain its own natural heart beat. Experts have long believed that the first priority when trying to restart the heart was to shock the abnormal heart rhythm. More recently however some evidence has indicated that CPR should be the priority before delivering the shock. The research indicates that delaying the shock a few minutes to provide CPR may actually help the heart. The CPR seems to prime the heart pump so that after a few minutes of CPR the shock is more likely to produce a natural heartbeat than if the heart was shocked right away.

A study is planned involving the Emergency Medical Services of Seattle and King County to evaluate whether either of these strategies – the ITD or priming the heart with CPR before the shock – will improve survival following cardiac arrest. The study is entitled ROC-PRIMED (Resuscitation Outcomes Consortium Prehospital Resuscitation using an Impedance threshold device and Early versus Delayed rhythm analysis), is supported by the National Institutes of Health and will involve 10 communities from across the United States and Canada. Seattle and greater King County are one of the 10 communities. Although these approaches appear promising and safe, they are yet to be proven to save lives.

If you still have questions after reviewing the website, please contact us via e-mail at (insert email address) (Note that the confidentiality of email communications cannot be guaranteed) or at 206- 447 5671 where you will be able to leave a voice message. The email and voicemails are checked regularly and you can expect to receive a reply within 3 days.

Research

Information Sheet

Consent Form

HIPAA Form

Community Consultation

Press Release

Random Digit Dialing Survey

Community Meetings

FAQs

- What is cardiac arrest?
- What is an out-of-hospital cardiac arrest?
- What is the incidence of out-of-hospital cardiac arrest?
- What causes a cardiac arrest?
- What is the treatment for out-of-hospital cardiac arrest?
- How does CPR help?
- How does the Impedance Threshold Device increase blood flow during CPR?
- What is the effect of CPR before shocking the heart?
- Who will be eligible to be enrolled in the study?
- How will the study decide which treatment is provided?
- How will the study affect care after admission to the hospital?
- Will the study affect care after discharge from the hospital?
- Who is supporting the study?
- Are other communities participating?
- How long will the study take?
- Who are the investigators for the study?
- How is the study being supervised?

- δ **What about consent for the study?**
- δ **How will I know if my relative or I was enrolled in the study?**
- δ **How will enrolled subjects' medical information be kept confidential?**
- δ **How can I get more information about the study?**

δ **What is cardiac arrest?**
Cardiac arrest is a serious medical condition. During a cardiac arrest the heart stops beating effectively and is unable to pump blood to the organs of the body. It usually occurs suddenly and unexpectedly. Death can occur within minutes unless treatment is started.

δ **What is an out-of-hospital cardiac arrest?**
Cardiac arrest can happen any place. If the cardiac arrest occurs outside of the hospital, it is referred to as an out-of-hospital cardiac arrest.

δ **What is the incidence of out-of-hospital cardiac arrest?**
Cardiac arrest is one of the most common killers of Americans each year. Statistics indicate that cardiac arrest may kill anywhere from 180,000 up to 450,000 people annually in the US.

δ **What causes a cardiac arrest?**
The most common underlying reason for patients to die suddenly from cardiac arrest is coronary heart disease. These people are at varying risks for cardiac arrest. In general, those with damaged hearts are at greater risk. Specific risk factors include a previous episode of cardiac arrest, a history of heart failure and a family history of sudden cardiac arrest. Other factors besides heart disease can cause cardiac arrest. They include respiratory arrest, electrocution, drowning, choking and drug overdoses. Cardiac arrest can also occur without any identifiable cause.

δ **What is the treatment for out-of-hospital cardiac arrest?**
The first step in the treatment of an out-of-hospital cardiac arrest is quick identification of the problem. This can be done by checking for signs of life (consciousness, movement, normal breathing). Once a cardiac arrest is confirmed, quick access to the 911 system is essential. The standard treatment for cardiac arrest is immediate CPR, which can be started by citizens before emergency medical services providers are on the scene. Once the emergency medical providers are on scene they continue CPR. Many times an electrical shock or shocks are given to the heart to try and restore a normal heartbeat. This electrical shock is called defibrillation. Other procedures to treat patients in cardiac arrest are the placement of electrodes to monitor the heart's electrical rhythm, the placement of an intravenous line (needle into the vein) to give fluids and medications, and the placement of an endotracheal tube (tube into the lungs) to provide air for breathing.

δ **How does CPR help?**
During a cardiac arrest the heart no longer pumps blood and the organs of the body no longer receive oxygen and so begin to die. CPR consists of pumping on the patient's chest and delivering breaths to produce some circulation until the heart can be restarted. When the chest is compressed, oxygen-rich blood is pumped forward. When the chest is released, oxygen-poor blood is brought back to the heart where it can be restored with oxygen before being pushed out to the body with another compression. Both actions – pushing oxygen-rich blood forward and bringing oxygen-poor blood back to the heart - are important. CPR produces some blood flow – but only about 30% of normal circulation. Methods to improve the circulation produced by CPR may lead to better survival.

δ **How does the Impedance Threshold Device increase blood flow during CPR?**
The Impedance Threshold Device or "ITD" is a device smaller than your fist that attaches to the end of the breathing bag or breathing tube used by emergency medical technicians (EMTs) and paramedics. The ITD works to increase the vacuum effect when the chest is released during CPR. We believe that by increasing the vacuum effect, chest release, also called decompression, during CPR brings more oxygen-poor blood back to the heart so that ultimately more oxygen-rich blood is available to be pushed forward. In one study, the ITD produced better circulation and more patients were able to regain their own natural heartbeat.

But we don't know for sure that using the ITD will be beneficial.

δ **What is the effect of CPR before shocking the heart?**
Evidence indicates that an electrical shock applied early after cardiac arrest helps restart the heart so that common practice has set the shock as the first priority when trying to restart the heart. When a shock is given to the heart during cardiac arrest, it resets the abnormal heart rhythm but does not necessarily start blood circulating again. Some more recent evidence indicates that delaying the shock to provide CPR first may provide a better chance for the heart to regain its own natural heart beat. CPR seems to fill the heart with oxygen-rich blood so that when the heart rhythm is reset with the shock, normal circulation can be restored. This circumstance may be especially the case if the patient has been collapsed for more than 5 minutes. But we don't know for sure which way of doing CPR is better.

δ **Who will be eligible to be enrolled in the study?**
All adult subjects (over age 18 years) treated by Seattle or King County Emergency Medical Services (EMS) for a cardiac arrest during the study period may be eligible. The cardiac arrest cannot be due to trauma such as a gunshot wound, stabbing, or severe motor vehicle accident.

δ **How will the study decide which treatment is provided?**
As part of the study, a person suffering cardiac arrest in King County may be treated by Emergency Medical Services providers with a short (30 seconds) or longer (3 minutes) period of CPR before the first shock, an impedance threshold valve, both or neither (regular care). In Seattle, 2 minutes of CPR will be given before the first shock, but otherwise the study will be conducted identically. There is a chance of receiving any of these treatment approaches. We believe that this type of study, called a randomized trial, will give us the clearest answer about the best approach for the treatment of cardiac arrest.

δ **How will the study affect care after admission to the hospital?**
All study treatments will have been given before hospitalization. After admission to the hospital, no study treatments will be given. All persons will receive standard care by their health care providers in the hospital regardless of whether they were a part of this study or not.

δ **How will the study affect care after discharge from the hospital?**
All study treatments will have been given before hospitalization. No study treatments will be given thereafter. At hospital discharge subjects will be asked to consent to take part in a telephone interview that will evaluate their recovery from cardiac arrest at 1, 3 and 6 months. Participation in this telephone follow-up is strictly voluntary.

δ **Who is supporting the study?**
The study is supported by the National Institutes of Health

δ **Are other communities participating?**
Yes, a total of 11 communities from the US and Canada are participating. More information about the collaboration of communities to help learn more about treatment of cardiac arrest is available at (CTC Website).

δ **How long will the study take?**
Once underway, the study will take about 2 years to complete.

δ **Who are the investigators for the study?**
Investigators from the University of Washington and Harborview Medical Center in collaboration with the Emergency Medical Services agencies of Seattle and King County will conduct the study.

δ **How is the study being supervised?**

We take the responsibility of conducting this kind of research very seriously.

- Seattle-King County and all other participating sites were selected for this study based on their prior success at conducting high-quality out-of-hospital emergency care research. An experienced team of physician investigators and nurse coordinators will be supervising highly trained emergency medical responders (emergency medical technicians and paramedics) throughout the trial.
- Prior evaluation of the treatments being provided in this study holds out the promise of their success over current standard treatments.
- This study was reviewed for its merit and safety, and approved by an independent committee appointed by the National Institutes of Health.
- This study was reviewed and approved by the U. S. Food and Drug Administration (FDA) and will continue to be monitored by the agency throughout the study
- Specific regulations developed by the FDA must be followed in this study. These regulations require that the community where the research is being conducted be notified and consulted before the research is started, and later notified of the results of the study. All enrolled subjects must also be notified of their participation and have the study explained to them as soon as it is feasible to do so.
- Another independent group, including experts in medicine, ethics, statistics and clinical trial methods, called a Data Safety Monitoring Board (DSMB) has been appointed by the government to monitor the safety of the patients throughout the course of the study. This group has access to the study outcome information and can recommend changes, including stopping the study at any time if there is any indication of safety issues, if the study is not progressing as planned, or if results from one particular treatment are extremely favorable.
- An independent Human Subjects Review Committee at the University of Washington, comprised of scientists and lay representatives from our community, is evaluating the procedures in this study to insure that all appropriate conditions have been met and the safety and confidentiality of all enrolled subjects insured. The study will not begin until this group has given their final approval.
- Any adverse events during the study must be immediately reported to the Human Subjects Review Committee, the DSMB and FDA.

δ **What about consent for the study?**

The CPR study is being done under "waiver of consent". This means subjects are enrolled in the study without their prior consent. Federal regulations usually do not allow subjects to be enrolled in a study without their informed consent or without the consent of their next of kin. However, in certain limited situations, such as emergency medicine research, the U. S. Food and Drug Administration (FDA) does allow some studies to be conducted without prior consent. In order to be able to do a study using "waiver of consent" the following requirements established by the FDA must be met.

- The study involves a life-threatening situation with unproven or unsatisfactory treatment where research is necessary to improve outcome.
- Obtaining informed consent is not feasible because the patient is unresponsive and treatment must begin immediately.
- Participation in research has the prospect of direct benefit because the situation necessitates an intervention, science supports the potential of direct benefit and the risks of the research are reasonable compared to the medical condition.
- The research could not practicably be done without waiver of informed consent.
- The potential therapeutic window is short (in the case of cardiac arrest, treatment needs to be given within minutes)
- The researchers must develop informed consent procedures they will implement when it is possible to obtain consent.
- An Institutional Review Board (IRB) must approve the study.

- A Data Safety Monitoring Board must regularly evaluate the study for safety.
- Consultation and public disclosure with the community about the research has been conducted

After treatment, the medical record of subjects pertaining to their cardiac arrest will be reviewed by investigators to evaluate the safety and effectiveness of the study treatments received. The review involves little or no risk to the privacy of the subject

- Does not adversely affects the rights and welfare of the subjects
- Will not affect the care of the subject nor deprive them or normal clinical care
- The research could not be carried out without review of records or without waiver of consent
- The benefit of evaluating the safety and effectiveness of the treatment outweighs any risks to subjects
- The privacy of health information of subjects is protected
- All subjects are notified and informed about their participation in the research

Community consultation is also required before any study can be done using a waiver of consent. The purpose of this consultation is to make sure the community wishes to participate in the study and that any concerns about that participation are addressed. Researchers are required to disclose to the public the nature, risks, and benefits of the study. This is being done through a variety of means:

- This website
- Press releases
- Consultation with community organizations
- Community survey (using random digit telephone dialing)
- Written brochures explaining the research, available upon request

In addition, we plan to provide information to the community regarding progress of the trial and its results, once those are available. This will be done through this website and press releases.

The investigators, with oversight by an independent Human Subjects Review Committee at the University of Washington, will take steps to insure that all of these conditions have been satisfied for this research.

δ **How will I know if my relative or I was enrolled in the study?**
You or your legally authorized representative will be notified soon after enrollment into the study and provided information about it. In addition, we plan to provide information to the community regarding progress of the trial and its results, once those are available. This will be done through this website and press releases.

δ **How will enrolled subjects' medical information be kept confidential?**
By law, researchers must protect the privacy of health information about subjects. We make every effort to keep the information confidential. All subjects enrolled in the trial will be assigned a code number. This code number is used on any data we collect. A key linking the subject to the code number is kept locked in a secure location and will be available only to the investigators. Once this study is completed this key will be destroyed. In addition, all investigators have signed a Confidentiality Agreement to protect the privacy of health information about subjects.

δ **Who are the investigators for the study?**

Principal Investigator:

Peter J. Kudenchuk, MD
Professor of Medicine
Division of Cardiology
University of Washington

Co-investigators:

Tom Rea, MD
Associate Professor Of Medicine
Division of General Medicine
Harborview Medical Center
Medical Director: King County Medic One
Public Health – Seattle & King County

Mickey Eisenberg, MD
Professor of Medicine
Division of Emergency Medicine
University of Washington
Medical Director: King County Emergency Medical Services
Public Health – Seattle & King County

δ **How can I get more information about the study?**
We are very interested in your comments.

Please call Sally Ragsdale MN, ARNP, Deb Solberg RN, MN, or Michele Olsufka RN, Research Coordinators, with any questions or comments regarding the CPR study.

Phone: 206-447-5671; 1 800 607 2926
E-mail: kcrod@u.washington.edu
PLEASE NOTE THAT WE CANNOT GUARANTEE THE CONFIDENTIALITY OF EMAIL CORRESPONDENCE
Address: Resuscitation Outcomes Consortium (ROC)
600 9th Avenue, #103
Seattle, WA 98104

Published Studies

1. Aufderheide TP, Pirrallo RG, Provo TA, Lurie KG. Clinical evaluation of an inspiratory impedance threshold device during standard cardiopulmonary resuscitation in patients with out-of-hospital cardiac arrest. Crit Care Med. 2005 Apr;33(4):734-40.

2. Cobb LA, Fahrenbruch CE, Walsh TR, Copass MK, Olsufka M, Breskin M, Hallstrom AP. Influence of cardiopulmonary resuscitation prior to defibrillation in patients with out-of-hospital ventricular fibrillation. JAMA. 1999 Apr 7;281(13):1182-8.

3. Wik L, Hansen TB, Fylling F, Steen T, Vaagenes P, Auestad BH, Steen PA. Delaying defibrillation to give basic cardiopulmonary resuscitation to patients with out-of-hospital ventricular fibrillation: a randomized trial. JAMA. 2003 Mar 19;289(11):1389-95.

4. Jacobs IG, Finn JC, Oxer HF, Jelinek GA. CPR before defibrillation in out-of-hospital cardiac arrest: a randomized trial. Emerg Med Australas. 2005 Feb;17(1):39-45.

ROC PRIMED Seattle-King County
Media Coverage 2007

- Washington Post Article 5-27-2007
- Seattle Times article June 3, 2007
- Seattle Times article June 5, 2007
- Seattle Times editorials June 10, 2007
- Seattle Times editorials, June 11, 2007
  Copies of articles included
- KIRO Radio interview June 22, 2007
  Link: http://www.uwmedicine.org
- Fox News video June 2007
  Link: http://www.foxnews.com/video2/launchPage
- IRB Modification Approval for Opt-out Process
  Approval included
- # of opt-out bracelets requested in June 2007:
  253 for both waiver of consent studies in Seattle-King County