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# The Random Dialing Survey as a Tool for Community Consultation for Research Involving the Emergency Medicine Exception From Informed Consent

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## Abstract

**Study objective—**In 1996, the Food and Drug Administration and the Department of Health and Human Services enacted rules allowing a narrow exception from informed consent for critically ill patients enrolled in emergency research. These include requirements for community consultation prior to trial implementation. Previous studies have noted difficulty in engaging the community. We seek to describe the experience with random dialing surveys as a tool for community consultation across 5 metropolitan regions in the United States.

**Methods—**Random dialing surveys were used as part of the community consultation for an out-of-hospital clinical trial sponsored by the Resuscitation Outcomes Consortium. The survey method was designed to obtain a representative sample of the community according to population demographics and geography. Logistics of survey administration, role of the survey in community consultation, and survey results by population demographics are discussed.

**Results—**Random dialing surveys were conducted in 5 of 8 US Resuscitation Outcomes Consortium sites. Overall, 70% to 79% of respondents indicated they would be willing to be enrolled in this study. Support for the inclusion of children (aged 15 to 18 years) ranged from 52% to 71%. Respondents aged 18 to 34 years were more willing to participate in the trial than older age groups. Women and racial minorities were less likely to favor the inclusion of minors.

**Conclusion—**Random dialing surveys provide an additional tool to engage the community and obtain a sample of the opinion of the population about research conducted under the emergency exception from informed consent regulations. Similar results were obtained across 5 diverse communities in the United States.



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# INTRODUCTION

## Background

In 1996, the Food and Drug Administration (FDA) and Department of Health and Human Services issued regulations allowing resuscitation research to take place without informed consent, providing specific criteria were met.[1,2] These regulations are commonly referred to as the Emergency Medicine Exception From Informed Consent. Specifically, this approach can be implemented only when the condition being studied is acute and life threatening, current therapies are inadequate, the window of opportunity for intervention is brief, it is not possible to obtain informed consent from the patient or legally authorized representative, there is the potential of direct benefit to the participant, and the risks of participation are reasonable in proportion to the potential benefit. Furthermore, these regulations stipulate that before initiation of the study, a process of community consultation and public disclosure must be undertaken. Community consultation is a process of direct consultation with the community from which potential research subjects will be drawn, after which the opinion of the community must be considered by institutional review boards when a determination is made about whether an exception from informed consent will be granted.3 In addition, the public must be notified of the trial, including the risks and potential benefits. Subsequent draft guidance from the FDA about implementation of the regulations suggests that the community in which the research will take place be defined geographically and the community from which the research subjects will be drawn be based on demographic characteristics of patients previously treated for the condition being studied.3

The explicit procedures used to implement community consultation are not specified but are left to investigators and local institutional review boards to define according to the particular needs of the local community. As a result, there has been variability in the practical application of these procedures in the studies conducted since these regulations were implemented.[4–6] There are no standard criteria by which to gauge community involvement or support. Several reports have noted significant difficulty in engaging the community in the process of community consultation, and it has been observed that the process can be resource intensive.[4,7–9] The most common approach to community consultation has been the conduct of public meetings and forums, but the majority of these have been poorly attended and there is concern that those in attendance may not be representative of the community as a whole. We present an alternative or additional approach, which involves a more formal polling of community opinion by using a random dialing telephone survey. This approach was used in 5 diverse geographic communities in the United States in preparation for an out-of-hospital clinical trial of hypertonic resuscitation sponsored by the Resuscitation Outcomes Consortium.

## Importance

This is the first detailed description of the use of the random dialing survey for community consultation and thus provides valuable information for researchers and institutional review boards seeking to implement trials under these regulations. In addition, the opportunity to compare data from similar surveys according to demographics in diverse communities across the United States provides insight about survey design and target populations.

## Goals of This Investigation

The purpose of this project is to describe the methodology of using a random dialing survey as part of the community consultation process. In addition, we sought to compare the survey results across these 5 metropolitan regions in the United States and describe different responses according to population demographics. Recognition of differential responses

according to demographics may guide investigators in defining target populations for additional consultation methods.

## MATERIALS AND METHODS

### Study Design and Setting

The Resuscitation Outcomes Consortium is a clinical trials network funded by the National Institutes of Health and the Canadian Institute for Health Research (available at https://roc.uwctc.org/tiki/tiki-index.php). The mission of this network is to conduct phase 3 multicenter, clinical trials of promising therapeutic options for the management of out-of-hospital cardiac arrest and life-threatening traumatic injury. The network consists of 8 sites in the United States and 2 in Canada. The first trial to be implemented by this network involves the out-of-hospital administration of hypertonic fluids as the initial resuscitation fluid for patients with evidence of either severe traumatic brain injury or hemorrhagic shock.[10] The predicted mortality for these cohorts is 30% to 50%. Patients are randomized to receive 250 mL of either 7.5% saline/6% dextran70 (HSD), 7.5% saline without dextran, or normal saline solution (0.9%) as the initial resuscitation fluid administered by out-of-hospital providers. All subsequent care is unchanged. Previous studies of hypertonic fluids in this patient population suggest minimal risks, with the potential for direct benefit to the individual. There is a potential risk of allergic reaction to dextran, estimated to occur in 1 in 100,000 patients. However, this has never been observed in a trauma patient receiving HSD.[11] Investigational drug approval was obtained from the FDA. The local institutional review boards in each community were responsible for oversight of the community consultation and notification process. As part of the community consultation process, 5 of the 8 US sites elected to include a random dialing survey. The other 3 sites chose not to use a random dialing survey because of financial concerns. This report outlines the experience with a random dialing survey at these 5 sites. All sites have institutional review board approval for publication of these data.

The 5 sites using a random dialing survey included Dallas, TX; Milwaukee, WI; Portland, OR; San Diego, CA; and Seattle, WA. Each of these cities housed the Level I trauma centers participating in the trial and defined the community for consultation according to the geographic catchment area of the participating ground and aeromedical out-of-hospital services. As a result, the community of potentially eligible patients in most sites extended into several counties surrounding the primary city. For the Dallas site, this included residents of 9 counties; 1 county for Milwaukee and for San Diego, 4 at the Portland site, and 7 counties at the Seattle site. Table 1 depicts the population demographics for each survey community according to US census bureau data. Because this study is focused on patients with severe injury, the entire population older than 15 years is at risk and thus represents the community of potentially eligible patients for the study. Inclusion in the survey required the respondent to be 18 years of age or older and able to interact with the interviewer in English or Spanish in the Dallas and San Diego surveys. Four of the 5 sites used the same research firm, Hebert Research Inc, Bellevue, WA, to conduct the survey. The Portland site conducted 2 local surveys with an independent university survey research laboratory.

### Methods of Measurement

The initial design of the random dialing survey text was based on experience with a previous phase 2 trial of hypertonic resuscitation and a previous trial of early administration of a monoclonal antibody after injury, both conducted at the Seattle site.[12,13] The survey text was modified by the local site investigators and institutional review board to meet the needs of each community (see site variations below). Because this study planned to enroll minors between the ages of 15 and 18 years, in addition to adults, specific questions were added to

the survey to assess community opinion about the inclusion of this age group. Each survey consisted of a description of the proposed research project in lay language, with a description of the risk of dying from the injury, the risks and potential benefits of being included in the study, and the regulations surrounding the Emergency Medicine Exception From Informed Consent. Respondents were then asked their opinions about inclusion in the study and the justification of the exception from informed consent for this study. Specific questions about their reasons for supporting or objecting to the study were also included. Categories of questions included personal willingness to be enrolled in the trial, willingness for family members to be enrolled in the trial, willingness to be enrolled according to the risk of allergic reaction, opinion about the justification of the waiver of informed consent, and opinions about the inclusion of teenagers in this study (aged 15 to 18 years). These questions were asked in a yes/no/or don't know format. Additional open-ended questions were asked about the reasons for the responses to the primary questions. All comments made during this process were recorded verbatim and included in a final report to the institutional review boards. Demographic data were collected from respondents, including age, sex, race/ethnicity, occupation, level of education, and household income. The Portland site conducted 2 surveys, with 186 respondents included in the first survey and 86 respondents included in the second survey. A representative sample of the survey design is included as Appendix E1 (available online at http://www.annemergmed.com). The survey text was written at a 12th-grade reading level, with the questions at an 11th-grade level.

The only significant difference in the primary survey questions between the sites was that for the Seattle and Milwaukee surveys, the primary risk of allergic reaction was described before the initial query about willingness to enroll, whereas the remaining sites asked this as a separate question later in the survey (Appendix E1; available online at http://www.annemergmed.com). This difference was at the request of the institutional review boards involved. One site asked an additional question about community interest in an opt-out mechanism for the trial, and 2 sites asked about the use of media options for public notification. In 2 sites, questions were also added about an additional proposed study involving resuscitation after cardiac arrest; these questions were not considered in this analysis.

Because one of the local institutional review boards requested modification of the survey questions, the Portland site conducted 2 surveys. The first was in March 2006, with 186 respondents; the second, in June 2006, with 86 respondents. The first survey referred to the intervention as an experimental treatment, whereas the second survey used the term "study fluid." In addition, the order of questions was changed between surveys such that the second survey asked all questions relevant to individuals' enrollment before asking their opinions about the enrollment of family members.

The Dallas and San Diego surveys did not collect data on education, income level, and race. In addition, because of the high proportion of Hispanics in the Dallas and San Diego sites, surveys there were conducted in either English or Spanish.

All surveys conducted by the Hebert Research firm included a minimum of 500 respondents and were geographically distributed by zip code to be representative of the geographic catchment area. A list of telephone numbers was purchased from a list company. The list company maintains a list of all telephone numbers appearing in all telephone books in the United States, which are cross-referenced by zip code. The list company is given the zip codes covering the study area and then draws a random sample of telephone numbers from this comprehensive list. This approach ensures the proper proportionate sampling of high- versus low-density areas because high-density areas will have more numbers. The randomly drawn telephone numbers are then loaded into a Computer-Aided Telephone Interviewing

system (Ci3; Sawtooth Software, Sequim, WA), which randomly draws numbers from this list as required during the interviewing process. Each telephone number was called at least 5 times before being replaced by a new number, which helps to ensure that the survey is not administered only to easy-to-reach people. Potential respondents were called at various times from 9 AM to 9 PM during weekdays and from 11 AM to 6 PM on weekends. An appointment and callback procedure was used when necessary to minimize refusals and allow respondents to complete the survey at a more convenient time.

All interviews were conducted by staff experienced with medical issues. Staff underwent special training specific to this study, including the objectives of the study, screening questions, purpose of questions, probes for open-ended questions, special instructions within the survey, skip patterns, and techniques for handling anticipated problems. After the questionnaire was programmed, it was rigorously tested to ensure that skip patterns function properly and that data are accurately recorded. Hebert Research pretested the survey among a small sample of respondents to validate the programming and evaluate any issues about the questions asked. Interviews were regularly monitored by supervisors to ensure consistency in their conduct.

Demographic data for the target population were obtained from the US Census Bureau (available at http://www.census.gov) (Table 1) for comparison with the study cohort. To compensate for potential response bias, sampling weights were calculated and applied to the survey sample to ensure that various demographic subgroups were properly represented. Weights were inversely proportional to the probability of selection and response. Those respondents with demographics that were underrepresented had weights greater than 1, whereas those that were overrepresented had weights less than 1, with the average sampling weight equal to 1. In the final weighted analysis, it was concluded that the sample was representative of the population within the following critical variables: zip code, sex, and age. The data from the Portland surveys were not weighted, and therefore all sampling weights were set to 1.

The margin of error for these surveys was defined based on a confidence level of 95%. Thus, if the survey was conducted 100 times, 95% of the margin of error confidence intervals (CIs) would encompass the true response rate for each question. The formula used to calculate the margin of error was where $n$ is

$$1.96\sqrt{0.5(1-0.5)/n}=0.98/\sqrt{n}$$

the sample size and we are assuming a binary outcome response of 0.5, which maximizes the variance and width of the sample size.[14]

## Primary Data Analysis

Raw survey data were obtained for each survey conducted, and the data sets were merged for analysis of the response to the primary survey questions. Weighted frequencies for the responses yes, no, and don't know were calculated for each survey question by site and survey date, using the response bias correction weights. For all other analyses, the data from the 2 surveys performed in Portland were combined.

Analysis of the relationship between demographic factors including age, sex, education level, income, and race on response to survey questions Would want study fluid administered to them without written consent? (yes compared with no/don't know) and Do you believe it is appropriate to include 15- to 17-year-old children in this study? (yes compared with no/don't know) was conducted on the entire survey cohort (n=2418: Dallas

n=639, Milwaukee n=505, Portland n=272, San Diego n=502, and Seattle n=500). Weighted relative risk regression models were run separately for both survey response outcomes.[15] Relative risk regression models are a type of generalized linear model where the distribution is the binomial/Bernoulli and the link is the log. Weighted logistic regression was not used because the survey response outcomes were not rare and therefore the logistic link was replaced by log link to estimate relative risks instead of odds ratios. All analyses adjust for site effects by including an indicator variable for each site in the model. The first set of analyses evaluated the existence of bivariate associations between each demographic variable on each of the survey response outcomes. The second set of models tested for interactions between site and each demographic variable. This was done for each of the survey response outcomes. Tests were conducted using likelihood ratio tests comparing the model with all site and the demographic variable interaction terms to a model without the interaction terms. All analyses only included a single demographic variable in a given model. All 95% CIs are 2-sided, using a relative risk test statistic. All analyses were performed using the statistical software package R, version 2.6.1.16

## RESULTS

The surveys were all conducted in 2006. Each of the surveys conducted by the Hebert Research firm involved full responses from more than 500 households. Telephone response rates ranged from 32.6% to 44.9%, requiring more than 1,000 calls at each site to obtain 500 responses. The maximum margin of error for these surveys was ±4.4%. Sampling weights of the survey were calculated for those that completed all survey questions, except for demographic variables, so we have complete outcome follow-up. Some site-specific procedural variations were required, as noted above. Because of the high proportion of Hispanics in the Dallas and San Diego sites, surveys there were conducted in either English or Spanish. In Dallas, 20.9% of surveys were administered in Spanish, and in San Diego, 12% were administered in Spanish.

The cost of the surveys administered by the Hebert Research firm averaged $15,000 per site. The cost of both surveys administered by the Survey Research Lab in Portland was $8,800.

All surveys included a brief description of the study and an initial question about whether individuals would want to be given this study fluid if they were severely injured. Support for being personally enrolled in the study ranged from 64% to 79%. Table 2 illustrates the results for each category of question asked. Not all sites asked questions in each category. More respondents indicated a willingness to be enrolled once the primary risk of allergic reaction was discussed (70.9% to 85.7%).

Among respondents who indicated they would not want to be enrolled in the study or did not believe the exception from informed consent was justified, the primary reasons stated were fear of the possibility of adverse effects (23.4% to 28.8%) and feeling that the patient should not lose the right to consent (15.4% to 28.0%). Additional concerns expressed included preference for standard treatment, therapy has not been proven effective, need more information to decide, would rather die than be saved, and concern about paramedics administering the fluid. Among those who believed the exception from consent was justified, the primary reasons given were best interest of the patient (52%), best interest of both the patient and community (34% to 37%), and best interest of the community alone (2% to 3%).

The responses to the 2 questions, which were common to all surveys, are illustrated in Table 3 according to site and demographic data. Data represent the percentage of respondents in each category who answered yes to the question as opposed to no or don’t know. Analysis of

the entire survey population adjusted for site revealed that as age increased, the desire to enroll in the study tended to decrease (relative risk [95% CI] compared to aged 18 to 34 years: aged 35 to 44 years 0.95 [95% CI 0.90 to 1.02], aged 45 to 54 years 0.89 [95% CI 0.83 to 0.95], aged 55 to 64 years 0.88 [95% CI 0.82 to 0.95], and aged ≥65 years 0.89 [95% CI 0.82 to 0.96]). There were no differences between site and age responses. There was no relationship between sex, income, and race on the willingness to enroll in the trial. The proportion of blacks indicating willingness to be enrolled was lowest at the Seattle site (33%), but this represented only 9 survey respondents, 4 of whom responded yes, 3 no, and 2 don't know. However, this group was much more supportive of the inclusion of minors (89%), and thus there may be an effect of the order in which the questions were asked because this was much later in the survey. In regard to education level, although there was no effect overall, respondents from Milwaukee suggested an increasing willingness to be enrolled as education level increased, whereas the reverse trend was present in the Portland and Seattle sites. Respondents from the Milwaukee site with high school or less education (N=219) were less willing to be enrolled compared with those of the same education level in Seattle (N=125) (1.24 [95% CI 1.09 to 1.45]) and Portland (N=59) (1.24 [95% CI 1.06 to 1.45]).

Because this study was designed to include children aged 15 to 17 years, specific questions were included concerning this age group. As noted in Table 2, support for including this age group ranged from 42.7% to 71.0%. This question was asked of all respondents in Dallas, Portland, San Diego, and Seattle. However, in Milwaukee, this question was restricted to respondents with children. In Seattle, parents or legal guardians of children in this age group were more in favor of including them compared with respondents without children in this age group (78.9% versus 70.0%). Analysis of the total survey cohort suggested that women are less likely than men to support the enrollment of minors (0.92 [0.86 to 0.97]), with no interaction by site. There was no effect of age or income level in response to this question. In regard to education level, those with a bachelor's degree or higher were more likely to support the inclusion of minors (1.11 [1.00 to 1.23]). Overall, white non-Hispanics were more likely to support enrollment of minors compared with all other races (black non-Hispanics 0.81 [0.70 to 0.99]; other 0.81 [0.70 to 0.95]). In Dallas, those completing the survey in English were more likely to favor inclusion of this age group than those completing it in Spanish (70.3% versus 58.1%).

Among those opposed to the inclusion of children in the study, the primary reasons given were fear of the possibility of adverse effects and the belief that parents should not lose the right to consent. At the conclusion of the survey in Milwaukee, respondents were asked whether there was a minor aged 15 to 17 years available to speak to them. Five interviews were conducted with teenagers by using this approach. Among the 5, 3 stated they would want the fluid administered to them without their consent, and 4 of the 5 thought that the waiver of informed consent was justified. Given the difficulty in achieving an adequate response rate from this age group by a random dialing survey, the Milwaukee site elected to pursue additional focus group meetings to target this population.

To guide additional media efforts for community notification, respondents in Dallas, San Diego, and Portland were asked about the various sources they used to obtain information. Table 4 illustrates the most common sources noted. The majority of respondents at all 3 sites preferred television, radio, Internet, and newspaper as primary sources of information.

The random dialing survey was only one component of a comprehensive effort to involve the community at each site. In addition to the surveys, information about the study was provided through media campaigns, which included, depending on the site, television, radio, local newspapers, and advertisements on metro buses. Many sites established a Web site

with additional information on the study and contact information to provide feedback to the investigators. In some sites, mass e-mail announcements were sent to groups at increased risk of injury, such as cycling clubs. Several sites held open community meetings and focus groups and attended meetings of neighborhood associations, churches, rotary clubs, union groups, and other community groups to provide information on the study and solicit feedback from the community.

## LIMITATIONS

The primary limitation of this study is that the survey questions and order in which the questions were asked varied among the sites, according to local institutional review board guidance. Although there were no substantial differences in the text of the questions, response may vary according to the order in which the questions were posed. In addition, 2 sites did not collect data for education, income, and race, which limits this analysis. The data from the Portland site were not weighted, and this limits the ability to compare them to the data from the other sites. Another limitation to the multiple demographic comparisons is that a statistical difference may have been observed as a result of chance alone. However, to our knowledge, this remains the first report to describe in detail the use of a random dialing survey as a means of community consultation and to compare findings across the United States.

## DISCUSSION

Since their inception, the regulations surrounding the emergency exception from informed consent in resuscitation research have generated discussion and debate, including a consensus conference on the topic held in 2005 and an FDA public meeting in 2007.[17,18] Investigators and regulatory boards (institutional review boards) have struggled with the appropriate processes for community involvement. The 2 primary components of community involvement include community consultation and public disclosure. Public disclosure is a 1-way process designed to inform the community about a study and can be conducted by traditional media campaigns, with specific interventions targeted to notify high-risk groups. Community consultation, on the other hand, requires feedback from the community and thus requires a 2-way interaction. The first step is to define the community at risk. In some studies, the target population can be narrowed to focus on specific populations. For example, studies investigating treatment of cardiac arrest or acute myocardial infarction can focus on the elderly or those with preexisting cardiac disease. In the case of traumatic injury, however, all ages, both sexes, and all ethnicities are at risk, and thus a broad spectrum of community involvement must be targeted. For our study, we defined the community according to the entire geographic region from which patients may be drawn, which resulted in communities ranging from 900,000 to 3.3 million residents. Because no community consultation process can involve the entire population, this highlights the challenge of ensuring that a representative sample of the opinion of the population is obtained.

Previous studies involving community consultation have relied largely on community meetings. Shah and Sugarman4 reported a review of 4 studies reported to the FDA docket before November 1999. They report that the use of 2-way communication did not occur at all sites and participation was limited. One study reported 10 meetings with community groups, 8 open public meetings, and 2 talk radio programs, which totaled 264 participants. Another study reported 7 meetings with community groups, 2 open public meetings, and 2 telephone polls, for a total of 182 participants. The authors observed that the average number of participants was fewer than 20 for all studies when telephone polls were excluded and that the use of telephone polls increased participation substantially. Another report about

a community consultation for a study involving the state of Mississippi observed that 7 meetings were held during a 1-year period, with an average of 19 participants per meeting.7 In 2001, McClure et al[8] conducted surveys of patients presenting to the emergency department (ED) of 2 Level I trauma centers in Oregon and Minnesota. The majority of respondents reported that they would prefer to be informed about a study using emergency exception from informed consent by radio and television media, and less than half indicated that they would attend a community meeting. Another recent ED survey of patients in a community conducting a blood substitute study using the exception from informed consent observed very low rates of awareness of this study in this population.[19]

It seems evident that community meetings alone are insufficient to gauge the opinion of the larger community. Furthermore, those who do attend such meetings may do so to express strong opinions that are not representative of the larger community. A random dialing survey provides the advantage of reaching a wide geographic region and distributing calls by zip code to be representative of the entire region. Furthermore, the results can be adjusted according to population demographics to provide a reasonable representation of the study community. This survey approach is commonly used for marketing research and political polling. Determination of the sample size is dependent on the acceptable margin of error for the survey. The typical sample size for marketing research is 385 respondents, which provides a margin of error of ±5.0% (K. Klima, written communication, February 2008, Hebert Research). Provided that the sampling is truly random, population size does not affect sample size. In this case, we selected a sample size of 500 respondents, which provided a margin of error of 4.4%. Further increase in the sample size increases the expense of the survey, and to reach a margin of error of 2.0% would require 2,401 respondents. An additional advantage of a random dialing survey is that the average survey can be completed within 2 weeks.

Disadvantages to a random dialing survey include that there may still be some selection bias among those whose choose to complete the survey, responses may be affected by the language used in the script describing the study, the opportunity for direct interaction with the investigators is limited, and the cost may be significantly greater than what is required to conduct town hall meetings. The 2 main areas of bias in telephone surveys include sampling error and nonresponse bias.[20,21] Sampling error occurs when too many of one kind of respondent are surveyed. For example, women and older adults tend to be more likely to participate in these surveys, as was true in our case. To account for this bias, the final sample must be weighted to the population demographics so the opinions of these participants are not given undue emphasis. The second concern involves nonresponse bias, which is the concern that those who chose not to participate in the survey would hold different opinions about the research than those who chose to participate. Unfortunately, individuals who do not want to participate are usually not amenable to discussing why they do not wish to do so, and attempts to gather these data can be costly. Previous studies have shown that there is no consistent relationship between response rates and nonresponse bias.[22] Rather, nonresponse bias is a function of the correlation between response propensity and the attributes the survey is assessing. We have no reason to believe that nonresponders would be more in favor of or opposed to the waiver of informed consent or participation in this trial, because most did not know the topic of the survey at the point of refusal. Regardless of these concerns, it remains likely that this approach provides a far more representative opinion of the community than conduct of community meetings, which are poorly attended.

Another concern with the random dialing survey approach is that certain segments of the population may not be well represented, including non–English-speaking minorities, those without access to a telephone, and those whose telephone numbers are unlisted. Our data

suggest that minority populations tended to be less in favor of involvement in the trial, especially about the inclusion of minors. We conducted surveys in Spanish at the 2 sites with a high proportion of Hispanics, but additional efforts for community notification are required to reach minority communities and the homeless.

It also appears that negative press coverage of unrelated studies using the emergency exception from informed consent can also influence results. The Portland site conducted 2 surveys because of a requested language change by the institutional review board. Between the 2 surveys, there was considerable negative media attention placed on the emergency medicine waiver of informed consent for an out-of-hospital study involving a blood substitute. This may demonstrate the influence of the recency effect of memory on public opinion and thus affected the results of the second survey conducted in Portland.[23] Although the majority of respondents in the Portland area still supported the trial, the number wanting to receive the study fluid decreased from 77% in April 2006 to 64% in June 2006.

Another limitation of random dialing survey tools is the limited feedback that can be obtained from these short surveys. Although the researchers can gauge overall support for a study and answer simple questions such as the community's willingness to enroll children, it is more difficult to explore in depth the attitudes and beliefs that underlie those responses. Other methods such as focus groups and meetings targeted to particular groups, such as minorities or religious communities, may also be important aspects of engaging the community. Finally, because there are no standard accepted criteria by which to judge what level of support represents approval of the community for a study to go forward, these decisions must be made at the local institutional review board level, which introduces variation into the process. As experience with this approach improves, development of national standards for interpretation of results will be valuable to standardize this process.

We believe that a random dialing survey provides important feedback about the opinion of the community as a whole for emergency research in the area of traumatic injury. Larger samples of the community can be surveyed, with less apparent bias than poorly attended community meetings. Support for this out-of-hospital study was similar in diverse sites across the United States. Future studies should focus on comparing a random dialing survey to other means of assessing community opinion in this area, such as ED-based surveys. We believe that standard metrics for random dialing surveys, such as components of survey content, number of responses, and appropriate levels of support required to conduct a trial, should be developed. This will greatly assist local institutional review boards struggling with this challenging aspect of emergency research, as well as the investigators designing and conducting these trials.

**Editor's Capsule Summary**

### What is already known on this topic

Resuscitation-related research without subjects' informed consent is permitted if certain conditions are met, one of which is community consultation and public disclosure before initiation of the study.

### What question this study addressed

Investigators describe their experiences conducting random dialing surveys in 5 urban centers before initiating a multicenter resuscitation research project.

### What this study adds to our knowledge

Roughly 40% of randomly selected telephone numbers produced a complete interview. Opinions were similar across cities. A majority of respondents indicated their willingness to be study subjects should they become eligible.

### How might this change clinical practice

Random dialing surveys appear to be a useful means of fulfilling regulatory requirements to consult the community before initiation of resuscitation-related research without obtaining informed consent.

## Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

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**Table 1**

Demographics of survey populations: US Census Bureau 2005.

| Site | Dallas County (Portion of 8 Surrounding Counties) | Milwaukee County | Portland/Vancouver, WA (4 Counties) | San Diego County | Seattle/King County (Portion of 6 Surrounding Counties) |
|---|---|---|---|---|---|
| Population | 3,315,320 | 897,972 | 1,918,188 | 2,824,259 | 2,734,019 |
| **Age,y,** % | | | | | |
| <5 | 9.2 | 7.9 | 6.8 | 7.8 | 6.1 |
| ≥18 | 71.1 | 74.6 | 75.1 | 73.2 | 78.3 |
| ≤65 | 8 | 12.1 | 9.9 | 11 | 12.1 |
| **Sex,** % | | | | | |
| Male | 50.3 | 48 | 49 | 49.6 | 49 |
| Female | 49.7 | 52 | 51 | 50.4 | 51 |
| **Race/ethnicity,** % | | | | | |
| White | 60.3 | 62 | 79.5 | 68.2 | 73.1 |
| Black | 20.3 | 25.9 | 6.1 | 5 | 5.7 |
| American Indian/Alaska native | 0.6 | 0.7 | 0.7 | 0.7 | 0.8 |
| Asian | 4.4 | 3 | 5 | 10.5 | 13.3 |
| Native Hawaiian/Pacific Islander | 0 | 0 | 0.3 | 0.4 | 0.6 |
| Other race | 12.7 | 6.3 | 5.5 | 11.9 | 3.1 |
| Hispanic/Latino (any race) | 36.8 | 11 | 16 | 29.9 | 6.8 |
| **Education,** % | | | | | |
| High school or higher | 74.7 | 84.8 | 86.8 | 84.7 | 91.6 |
| Bachelor's degree or higher | 27.1 | 26.4 | 30 | 34 | 43.6 |
| Median household income, $ | 42,598 | 37,808 | 52,681 | 56,335 | 58,370 |

Sites identified by primary city, but population estimates include surrounding counties within the emergency medical services agency catchment areas for transport of major trauma (available at http.www.census.gov).

## Table 2

Survey results.

| Survey question | Yes, % | No, % | Don't Know, % |
|---|---|---|---|
| **Would want study fluid administered to them without written consent** | | | |
| Dallas | 77.4 | 13.7 | 8.9 |
| Milwaukee | 71.5 | 21.0 | 7.5 |
| Portland, April 2006 | 76.9 | 19.4 | 3.8 |
| Portland, June 2006 | 64.0 | 32.5 | 3.5 |
| Seattle | 78.8 | 15.9 | 5.3 |
| San Diego | 74.3 | 19.7 | 6.0 |
| **Would want study fluid administered to a family member without written consent** | | | |
| Dallas | 78.1 | 16.0 | 5.9 |
| Portland, April 2006 | 73.1 | 24.7 | 2.2 |
| Portland, June 2006 | 68.3 | 29.3 | 2.4 |
| San Diego | 67.2 | 24.9 | 8.0 |
| **Would want the study fluid administered if there were a <1:100,000 risk of allergic reaction** | | | |
| Dallas | 85.7 | 9.2 | 5.1 |
| Portland, April 2006 | 83.3 | 12.4 | 4.3 |
| Portland, June 2006 | 70.9 | 26.7 | 2.3 |
| San Diego | 81.5 | 14.8 | 3.7 |
| **Believe that the exception to written consent is justified and in the best interests of the patients and community** | | | |
| Seattle | 80.5 | 14.1 | 5.4 |
| Milwaukee | 74.6 | 17.1 | 8.2 |
| Believe it is appropriate to include 15- to 17-year-old children in this study | | | |
| Dallas | 66.4 | 27.0 | 6.6 |
| Milwaukee | 63.1 | 26.3 | 10.6 |
| Portland, April 2006 | 61.5 | 31.9 | 6.6 |
| Portland, June 2006 | 42.7 | 53.7 | 3.7 |
| Seattle | 71.0 | 22.0 | 7.0 |
| San Diego | 64.7 | 29/0 | 6.3 |
| **Would be upset if later learned that they were enrolled in this study** | | | |
| Dallas | 13.8 | 82.0 | 4.2 |
| Portland, April 2006 | 16.7 | 81.2 | 2.1 |
| Portland, June 2006 | 17.4 | 77.9 | 4.7 |
| San Diego | 11.7 | 84.5 | 3.8 |
| **Would be interested in an opt-out bracelet** | | | |
| Milwaukee | 39.0 | 48.4 | 12.6 |

## Table 3

Response rates based on demographics.

| | | | Willing to Enroll in Study | | | | | | | | Believe Minors Should Be Included | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | Total | | All | | | DAL | MIL | POR | SAN | SEA | All | | | DAL | MIL | POR | SAN | SEA |
| | N = 2,418 | | 2,416 | | | 639 | 503 | 272 | 502 | 500 | 2,216 | | | 638 | 366 | 264 | 499 | 499 |
| **Demographics** | **No.** | **(%)** | **%** | **Relative risk*** | **(95% CI)** | **%** | | | | | **%** | **Relative risk*** | **(95% CI)** | **%** | | | | |
| Total | | | 74.1 | | | 77.4 | 71.5 | 72.8 | 74.3 | 78.8 | 65.7 | | | 66.4 | 63.1 | 55.7 | 64.7 | 71.0 |
| **Age, y** | | | | | | | | | | | | | | | | | | |
| 18–34 | 371 | (15.7) | 81.1 | 1 | | 79.4 | 86.9 | 73.9 | 78.7 | 85.4 | 66.9 | 1 | | 65.5 | 66.8 | 57.8 | 68.4 | 70.0 |
| 35–44 | 359 | (15.1) | 77.7 | 0.95 | (0.90–1.02) | 77.1 | 77.4 | 70.5 | 78.8 | 80.5 | 65.0 | 0.98 | (0.90–1.07) | 61.6 | 69.0 | 54.5 | 62.7 | 73.2 |
| 45–54 | 492 | (20.8) | 72.2 | 0.89 | (0.83–0.95) | 78.0 | 69.0 | 72.5 | 72.2 | 68.4 | 64.6 | 0.98 | (0.90–1.07) | 63.9 | 67.5 | 52.9 | 62.5 | 70.8 |
| 55–64 | 492 | (20.8) | 70.8 | 0.88 | (0.82–0.95) | 78.4 | 67.2 | 70.0 | 61.7 | 76.6 | 64.8 | 1.01 | (0.91–1.11) | 75.4 | 57.8 | 51.7 | 63.9 | 73.7 |
| ≥65 | 656 | (27.7) | 71.6 | 0.89 | (0.82–0.96) | 68.1 | 64.6 | 79.4 | 74.1 | 77.7 | 66.0 | 1.01 | (0.92–1.11) | 75.3 | 61.0 | 61.9 | 65.5 | 68.5 |
| Missing | 48 | | | | | | | | | | | | | | | | | |
| **Sex** | | | | | | | | | | | | | | | | | | |
| Male | 883 | (36.6) | 76.4 | 1 | | 77.1 | 72.9 | 78.9 | 72.9 | 81.6 | 68.7 | 1 | | 71.2 | 62.0 | 57.8 | 70.5 | 72.1 |
| Female | 1527 | (63.4) | 74.5 | 0.98 | (0.93–1.02) | 77.7 | 70.3 | 70.7 | 75.8 | 76.1 | 62.4 | 0.92 | (0.86–0.97) | 61.8 | 64.0 | 54.9 | 59.2 | 69.9 |
| Missing | 8 | | | | | | | | | | | | | | | | | |
| **Education** | | | | | | | | | | | | | | | | | | |
| High school or less | 403 | (32.1) | 72.4 | 1 | | — | 65.5 | 81.4 | — | 81.2 | 62.6 | 1 | | — | 57.8 | 55.9 | — | 73.2 |
| Assoc., tech, voc., some college | 339 | (27.0) | 76.0 | 1.03 | (0.95–1.12) | — | 74.1 | 69.0 | — | 81.6 | 61.0 | 0.96 | (0.85–1.08) | — | 62.2 | 55.2 | — | 63.7 |
| Bachelor's or higher | 514 | (40.9) | 76.7 | 1.03 | (0.95–1.11) | — | 77.8 | 73.5 | — | 77.5 | 70.4 | 1.11 | (1.00–1.23) | — | 72.1 | 56.9 | — | 76.3 |
| Missing† | 1,162 | | | | | | | | | | | | | | | | | |
| **Income, $** | | | | | | | | | | | | | | | | | | |
| ≤35,000 | 280 | (27.1) | 80.0 | 1 | | — | 78.8 | 79.6 | — | 81.9 | 65.6 | 1 | | — | 65.4 | 59.3 | — | 69.4 |
| 35,000–65,000 | 332 | (32.1) | 76.3 | 0.95 | (0.88–1.04) | — | 73.5 | 75.0 | — | 79.9 | 66.8 | 1.07 | (0.74–1.53) | — | 61.4 | 56.6 | — | 77.0 |
| >65,000 | 423 | (40.9) | 79.0 | 0.98 | (0.91–1.06) | — | 79.1 | 75.5 | — | 80.6 | 68.9 | 1.14 | (0.81–1.62) | — | 75.3 | 56.1 | — | 72.0 |
| Missing† | 1,383 | | | | | | | | | | | | | | | | | |

| | | | Willing to Enroll in Study | | | | | | | | | Believe Minors Should Be Included | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | Total | | All | | | DAL | MIL | POR | SAN | SEA | All | | | DAL | MIL | POR | SAN | SEA |
| | N = 2,418 | | 2,416 | | | 639 | 503 | 272 | 502 | 500 | 2,216 | | | 638 | 366 | 264 | 499 | 499 |
| **Demographics** | **No.** | **(%)** | **%** | **Relative risk*** | **(95% CI)** | **%** | | | | | **%** | **Relative risk*** | **(95% CI)** | **%** | | | | |
| **Race** | | | | | | | | | | | | | | | | | | |
| White, non-Hispanic | 866 | (72.7) | 76.3 | 1 | | — | 71.8 | 78.3 | — | 80.5 | 70.5 | 1 | | — | 66.7 | 65.2 | — | 73.4 |
| Black, non-Hispanic | 111 | (9.3) | 71.5 | 0.94 | (0.84–1.09) | — | 71.2 | 80.6 | — | 33.0 | 54.5 | 0.81 | (0.70–0.99) | — | 50.3 | 54.8 | — | 89.3 |
| Other | 250 | (21.0) | 75.5 | 0.96 | (0.87–1.07) | — | 69.4 | 74.9 | — | 79.4 | 56.9 | 0.81 | (0.70–0.95) | — | 44.4 | 57.0 | — | 59.4 |
| Missing† | 1,227 | | | | | | | | | | | | | | | | | |

*All*, Entire cohort; *DAL*, Dallas; *MIL*, Milwaukee; *POR*, combined Portland data; *SAN*, San Diego; *SEA*, Seattle.

*Relative risk and 95% CI from a bivariate generalized linear model with log link adjusted for site.

†Dallas and San Diego did not ask for education, race, or income on their surveys.

## Table 4

Popular sources of information.

| Sources of Information | Dallas, % | San Diego, % | Portland, % |
|---|---|---|---|
| Television | 89.3 | 87.0 | 87.9 |
| Radio | 78.8 | 81.0 | 82.3 |
| Internet | 78.3 | 72.5 | 71.6 |
| Newspaper | 70.5 | 71.2 | 83.0 |
| Newsletters | 54.0 | 52.5 | 62.5 |
| Churches | 53.5 | 39.1 | 47.2 |
| Schools | 49.9 | 41.3 | 45.7 |
| Neighborhood associations | 25.3 | 26.2 | 30.9 |