Sodium Nitrite Community Consultation Survey Report

University of Washington and Harborview Medical Center
Seattle, Washington


Klima Research
DISCOVERIES THAT MATTER

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A Special Thank You to

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Purpose and Objectives of the Survey

Purpose
The University of Washington and Harborview Medical Center are planning to carry out a research study testing the therapeutic effect of sodium nitrite in improving the outcomes for patients experiencing a cardiac arrest. This study involves patients in emergency situations where it may not be possible to acquire the patient's or a family member's informed consent prior to administering the experimental treatment. Consequently, the research will be conducted under the conditions of an exception from informed consent (EFIC, under regulation 21 CFR 50.24). One of the requirements for EFIC research is that community consultation be carried out in the geographic community where the research will take place and that the resulting information be presented to the Institutional Review Board (IRB) overseeing implementation of the research. Taking public comment into account is particularly important since all adults living in the research area may potentially become a research subject. For public comment to provide insight into community-wide attitudes toward the research, information needs to be gathered in a way that allows the results to be representative of the geographic region where the research will be conducted. A random digit dialing (RDD) telephone methodology is the only economically feasible research approach that allows generalization of findings from the sample to the relevant community. Consequently, a RDD telephone survey of adults was carried out in Seattle, Washington.

Research Objectives

- Determine the percent of respondents who would be willing to be part of the study without first providing consent.
- Identify the reasons respondents would not be willing to be part of the study.
- Identify the reasons respondents would be willing to be part of the study.
- Determine the percent of respondents who are in favor of the having the study conducted in their community.
- Assess the statistical significance of differences between selected demographic segments in their responses to key questions.
Geographic Area Covered in the Survey

The geographic area targeted by the survey was Seattle, WA, as shown in Figure 1. The survey methodology included contacting respondents using both landlines and cell phones. The process of generating random phone numbers for landlines relies on zip codes. A few zip codes for Seattle bleed over to neighboring communities outside the city limits. The process of generating random phone numbers for cell phones relies on banks of phone numbers which are associated with a specific geographic rate centers. Individuals with wireless phones may purchase their phone in Seattle but live outside of the city or move out of the city after acquiring their cell phone. Consequently, it is likely that a small number of respondents were contacted who live outside of the targeted area. Including respondents outside of Seattle is considered to be acceptable due to the possibility that these individuals may be traveling through the targeted area and be subject to study enrollment.

Figure 1. Geographic Area Targeted in the Survey: Seattle, Washington
Demographic Profile of Respondents

The sample was statistically weighted by age and gender to match the demographics of Seattle. The standard demographic figures used for weighting were derived from population demographics from the 2010 Census. The demographic data reported in the tables below is unweighted except for Table 1 which also shows both the unweighted and weighted frequencies for gender and age. Weighted data is presented in the report for the two key questions, Q3 and Q6. Both raw and weighted data are presented in Appendix A.

<table>
<thead>
<tr>
<th>Table 1. Gender and Age</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Raw Data</strong></td>
</tr>
<tr>
<td>Sample Size</td>
</tr>
<tr>
<td>% of Total</td>
</tr>
</tbody>
</table>

| **Weighted Data** | **Total** | Gender | Age | Refuse |
| Sample Size | 400 | Male | 199 | 49.8% | 56 | 98 | 77 | 63 | 55 | 51 | 0 |
| % of Total | 50.2% | Female | 201 | 49.8% | 14.0% | 24.5% | 19.3% | 15.8% | 13.8% | 12.8% | 0.0% |

| Area Surveyed | 515,147 | Male | 49.8% | 14.0% | 24.6% | 19.4% | 15.6% | 13.7% | 12.7% |

<table>
<thead>
<tr>
<th>Table 2. Ethnicity</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Ethnicity</strong></td>
</tr>
<tr>
<td>Hispanic/Latino</td>
</tr>
<tr>
<td>Non-Hispanic/Latino</td>
</tr>
<tr>
<td>Don't Know</td>
</tr>
<tr>
<td>Refused</td>
</tr>
</tbody>
</table>
Table 3. Race

<table>
<thead>
<tr>
<th>Race</th>
<th>Survey Respondents</th>
<th>Geographic Area Surveyed</th>
</tr>
</thead>
<tbody>
<tr>
<td>White</td>
<td>74.5%</td>
<td>69.5%</td>
</tr>
<tr>
<td>Black or African American</td>
<td>6.5%</td>
<td>7.9%</td>
</tr>
<tr>
<td>Alaskan Native or American Indian</td>
<td>1.7%</td>
<td>0.8%</td>
</tr>
<tr>
<td>Asian</td>
<td>7.0%</td>
<td>13.8%</td>
</tr>
<tr>
<td>Native Hawaiian or other Pacific</td>
<td>2.3%</td>
<td>0.4%</td>
</tr>
<tr>
<td>Some other race</td>
<td>2.0%</td>
<td>2.4%</td>
</tr>
<tr>
<td>Two or more races</td>
<td>3.3%</td>
<td>5.1%</td>
</tr>
<tr>
<td>Not sure/Don't Know</td>
<td>1.0%</td>
<td></td>
</tr>
<tr>
<td>Refused</td>
<td>1.7%</td>
<td></td>
</tr>
</tbody>
</table>

Responses for "Some other race":
- Hispanic (2)
- Latino (2)
- Arabic
- European American
- Jamaican
- Mexican
- Samoan

Table 4. Highest Educational Level Completed

<table>
<thead>
<tr>
<th>Education – Highest Grade Completed</th>
<th>Survey Respondents</th>
<th>Survey Respondents</th>
<th>Geographic Area Surveyed*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Less than 9th grade</td>
<td>0.5%</td>
<td>4.0%</td>
<td>6.8%</td>
</tr>
<tr>
<td>9th to 12th grade, no diploma</td>
<td>3.5%</td>
<td>11.5%</td>
<td>11.7%</td>
</tr>
<tr>
<td>High school graduate/equivalency (GED)</td>
<td>11.5%</td>
<td>29.0%</td>
<td>27.8%</td>
</tr>
<tr>
<td>Some college credit up to one or more years of college, no degree</td>
<td>19.0%</td>
<td>54.8%</td>
<td>53.7%</td>
</tr>
<tr>
<td>Associate, Technical or Vocational degree</td>
<td>10.0%</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Bachelor's degree</td>
<td>31.0%</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Graduate or professional degree</td>
<td>23.8%</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Don't Know/Refused</td>
<td>0.7%</td>
<td>0.7%</td>
<td></td>
</tr>
</tbody>
</table>

*Data aggregated by US Census Bureau.
Respondent Understanding of the Research Study

At the beginning of the survey, respondents were read a disclosure statement which informed them of the purpose and essential details of the research (the complete text of the disclosure statement appears in the survey questionnaire in Appendix A). The information in the disclosure statement was intended to provide respondents with a sufficient level of detail about the research to enable them to provide reasonably informed answers to survey questions. The disclosure statement covered the purpose of the research, key aspects of the research design, issues related to carrying out the research under an exception from informed consent research design, information about the study meeting strict requirements, research approval being received from the FDA and project oversight being provided by physicians on a medical Review Board.

After hearing the disclosure statement, respondents were asked if they understood what the study was about. The vast majority of respondents numbering 388 or 97.0% of the total sample of 400 respondents reported they understood what the study was about. The remaining twelve respondents who did not understand (3.0% of the total sample) were read the following information:

The important points are these. In cardiac arrest, the heart stops beating. Death can occur in minutes without treatment. Current treatments are inadequate and unacceptable. Fewer than one in five survive. Better treatments are needed. This research will test the use of sodium nitrite, one the most promising new treatments. This drug has been proven to be safe and has the potential to improve oxygen delivery to the heart and brain, helping to save lives. The study will be done in two phases. In Phase 1 of the study, paramedics will give patients sodium nitrite at the scene of an out-of-hospital cardiac arrest. This phase will determine how much sodium nitrite must be administered to reach the desired level in the blood and how safe the drug is. If it is found to be less safe, the study will be immediately stopped. This second phase will determine if giving sodium nitrite saves more lives over and beyond the current success rate. Cardiac arrest patients will be randomly assigned to receive either sodium nitrite or a placebo. The placebo is simply water with the same salt level as the human body. In all other ways, every patient will receive the best life-saving care available in medical practice. Since patients in cardiac arrest are unconscious and close to death, treatment must be started immediately. The study will need to begin without the patient’s informed consent or the consent of a family member who may not be present. Regulations in the United States allow and support medical studies without the patient’s consent. The study must meet strict conditions. This study meets these conditions. The study has been approved by the Food and Drug Administration and by a board of physicians who are responsible for protecting patient safety. The board will continue to monitor and approve the study until it ends.

After hearing this additional information, respondents were again asked if they understood what the study was about. All twelve of the respondents reported understanding what the study was about.

One hundred percent of respondents said they understood what the study was about.
Respondent Willingness to be Part of the Study Without Providing Consent

After respondents confirmed they understood what the study was about, they were asked if they experienced a cardiac arrest, would they be willing to be part of the study without first providing consent. The answer to this question provides a general indication of the overall acceptance of the research by the community as well as an estimate of what the actual enrollment rate may be. Results from a separate EFIC study suggest that the actual enrollment rate will be higher than survey data indicates. Two out of three respondents (65.9%, n=264) said they would be willing to be part of the study without first providing consent. Less than three in ten (27.1%, n=109) said they would not.

Q3. If you experienced a cardiac arrest, would you be willing to be part of this study without first providing consent?

- Yes 65.9%
- No 27.1%
- Don’t Know, Refused 7.0%

Statistical Differences in Demographic Subgroups
No meaningful significant differences in participation were found based on gender, age, ethnicity or educational attainment. A similar percent of respondents in the subgroups of each demographic would be willing to be in the study without giving prior consent.

A significant difference was found based on race. White respondents were significantly more willing to be a part of the study compared to the group of Other-than-White respondents (78.8% vs. 52.9%, Chi square = 22.1 p < .01, Cramer’s V = .24).

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1 Beshansky, Sheehan, Klima, Hadar, Vickery and Selker, A Community Consultation Survey to Evaluate Support for and Success of the IMMEDIATE Trial, Clinical Trials 2014; 11: 178-186.
<table>
<thead>
<tr>
<th>Race</th>
<th>Q3 Willing to Participate</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>n</td>
</tr>
<tr>
<td>White</td>
<td>265</td>
</tr>
<tr>
<td>Other-than-White</td>
<td>99</td>
</tr>
</tbody>
</table>

**Reasons Respondents Would Not Be Willing to Be Part of the Study**

The reasons given by respondents for not wanting to be a part of the study are presented in the chart below. The three top reasons were a fear over possible side effects, the feeling that the patient should provide consent, and a need for more information. Other respondents said they were not interested in the study or did not want to participate, did not want to receive the placebo, or thought the study involved too much risk. “Other” reasons given by individual respondents included already using sodium nitrite, not trusting UW or hospitals to do what was right, not believing in or trusting the study, a need to discuss participation with the family cardiologist, a desire to carry out a personal evaluation, not feeling comfortable with participating or with giving consent, and the possibility of not wanting to be resuscitated.

**Q4. Reasons Respondents Would NOT be Willing to be Part of the Study**

\[ n = 107 \]

- Fear about possible side effects: 25.2%
- Patients should provide consent: 19.6%
- Need more information: 16.8%
- Not interested/Does not want to participate: 11.2%
- Does not want placebo: 5.6%
- Not safe/Too risky: 2.8%
- Other: 18.7%
Selected Quotes from "Other" Responses

Two response categories were listed in the questionnaire for this question: "Patients should not lose the right to provide consent" and "Fear over possible side effects." A third response alternative recorded "Other" reasons respondents offered which were coded and are shown in the bar chart above. Selected examples of these "Other" reasons are presented below by coded subject. The full list of quotes will be found in Appendix C.

Need more information
- I need more information about it.
- I want to read it first before agreeing.
- I would like to research and know more about it.
- I'd like to know the considerations in using it.
- I'm not familiar and have to think about it.
- I need more information on who can get this treatment.
- Need to do personal first research with my doctor.
- Need to know more about the advantages and results.

Not interested/Does not want to participate
- I am not interested in being part of the trial.
- I don't care to be part of the study.
- I don't want to risk my life for some research.
- I just don't participate in the studies.
- I just wish to be at home in bed.

Does not want placebo
- I don't want a placebo. I want to be treated.
- I don't want placebo content in the medicine.
- Prefer they save me rather than be part of placebo study.

Not safe/Too risky
- It doesn't sound safe.
- I won't take the risk. It may cause more problems.

Other
- Already had an attack and carry my nitrite with me.
- Don't trust UW or hospitals to do what is right.
- I don't believe in it.
- I don't trust it.
- I need to talk to my cardiologist.
- I would want to do my own individual evaluation.
- I'm not comfortable doing it.
- I'm not comfortable in giving consent.
- I may not want the situation of being resuscitated.
**Reasons Respondents Would Be Willing to Be Part of the Study**

The reasons given by respondents for being willing to be a part of the study are presented in the chart below. The three top reasons were the respondent's expectation that participation may help them, the desire to save lives and help others, and the belief that the trial drug was safe to try. Others said the research is needed to advance medical science, that they approved of the research or thought it was a good idea, important or necessary. Other reasons included wanting to help the research, believing in or supporting it, thinking it may help in the future, that medical treatment should be improved or that there was no reason to say "No." Several respondents couldn’t give a reason.

**Q5. Reasons Respondents Would be Willing to be Part of the Study**

\[ n = 267 \]

- It could help me: 33.0%
- It may save lives/help others: 14.6%
- It is safe to try: 7.9%
- Needed to advance medical science: 4.5%
- It is a good idea/i approve: 4.1%
- It is important/necessary: 3.4%
- I want to help the research: 3.0%
- I believe in/support research: 3.0%
- It may help in the future: 2.2%
- We should improve medical treatment: 2.2%
- No reason to say "No": 1.9%
- Can't give a reason: 1.5%
- Other: 18.7%

Individual respondents gave a variety of "Other" answers. Respondents in this group wanted to try the treatment and see if it worked, expressed curiosity about what the results might turn out to be, expressed the understanding that drugs are needed for emergency situations, believed it is reasonable to use sodium nitrite for cardiac arrest, wanted to help, believed in and trusted the researchers, and felt comfortable with the procedure. Others expressed trust in the University of
Washington and the review board, considered the research to be more efficient without consent and already appropriate to do given FDA involvement. Also, there is no other way to learn about it. One respondent said, “The medical personnel do not always get to try new medical procedures without prior consent.” Another said, “When you are in the situation, it’s about saving the life whether you have the consent or not.”

Selected Quotes from Those Who Would Be Willing to be Part of the Study

Selected quotes are presented below from all the reasons respondents gave for being willing to be in the study. The full list of quotes will be found in Appendix C.

It could help me

- Anything that increases survival and security that has no side effects, or any chemical probability with minimal side effects or that causes no harm is acceptable with me.
- Based on how you explained it, it sounds like there would be a potential benefit. It could help, and it won’t hurt.
- First, it has a higher rate of success. Second, I am also a type 1 diabetic and participated in a study like that. I have gained from the benefits of the study today.
- I already had a heart attack. It would be worth the shot.
- I believe my life will be saved.
- I don’t particularly want to die. Isn’t that about saving lives? The study is supposed to save lives.
- I just trust the medical researchers. I think I would get the benefit of it.
- I like anything that would help me to survive to be done.
- I like science. It is a really weird answer. There is a lot of pushback when you get into things, like life threatening situations and the lack of consent when you are unconscious. At the same time though, there is this higher success story potentially and less long-term effect, so yes, why not?
- I want sodium nitrite. I would want a better chance of surviving.
- I want to be alive and reduce the risks of cardiac arrest.
- I would like to survive and still live with my family.
- I would rather appreciate to live my life because I do not want to die.
- I would say yes if it is going to save my life. That is what the emergency people are trying to do. There is a chance that you can expire with or without it.
- I would say yes, hoping that I will be receiving the experimental drugs rather than having no chance, but not the placebo.
- If I was going to die, then, this might save me. It is just worth it.
- If it can improve my chances of living, that will be a good thing. I will be willing to try it.
- If it will save somebody’s life and it may save mine, then I will be in favor of it.
- If sodium nitrite increases the ability of my survival in a cardiac arrest, then I would like to have it.
- If we lay unconscious, who would know what may happen? Right now, all you get is the regular IV, but sodium nitrite may help.
- I’m enjoying life and I want to live long.
• It is a chance to survive a cardiac arrest. It would help the statistics and study on what the relevant procedure is and on whether this would help people who are having a cardiac arrest.
• It is a research that will help me save my life.
• It is based on the information you just told me, and that is that the drug is safe and helpful. If it will save my life, then yes.
• It is for protecting my life.
• It might save my life. My dad has had a heart attack three times. I know how it feels. It is really scary.
• It sounds like there are more positive outcomes than negative outcomes and that there are chances of life. I’d rather choose that.
• It would help save my life. It will improve our technology.
• The reason is that it sounds like an important study. It could save my life.
• There is a better chance of survival.
• There is a small likelihood of surviving anyway. If it would not cause any damage, then it could help.
• When you’re close to death, anything that can be used to survive will be worth the risk.
• It would be helpful.
• It’s an appropriate treatment plan and worth the opportunity to test it.
• It’s worth a shot.
• I’ve heard about sodium nitrate before. It helps increase survival.
• Study shows that it increases cancer survival. If I’m conscious in any way and you can ask me, then, of course, I would say yes.
• There is not much that can be done so having an option for treatment seems to be desirable.
• We should take the risk for its potential benefits.
• You guys are supposed to be the professional. If it’s something that’s going to work and not cause more harm, might as well go for it.
• I would like to receive all the assistance available in case of a cardiac arrest.
• I would want the best care possible no matter what.
• I would want them to do everything they could.
• If there is another way you can improve to increase the chances of survival, do it.

It may save lives/help others
• I am willing to help the community. I will do what I can to help those people who are in need.
• I think saving a life is good. CPR is not helping that much, but sodium nitrite is.
• I was a first responder for a fire department. The study would have a big benefit for everybody. I know how it is to not have a first treatment in an emergency.
• If it can help save lives, I’d be willing to.
• If it helps somebody live who might not be ready to die, then that would be a positive thing. It is also if it helps the patient and decreases cardiac arrest.
• I’m a caregiver for my mother and father, who are both in their 90’s. My mom has a pacemaker. It worked well for her when she had a heart problem. If there is anything that can offer a change, then it’s good. I think it’s wonderful.
• I’m saying yes because I believe that the potential to save lives is greater than the ethical issue of not asking for consent.
• It can help to decrease the number of deaths caused by cardiac arrest.
• It can save lives. Anything should be tried to save lives.
  • It gives the person a better chance of survival. It is worth using.
  • It is a new treatment and is helpful for the patients.
  • It is for the benefit of the others.
  • It is to help people.
  • It sounds like it would be helpful to older people my age who are at risk.
  • It sounds very beneficial for persons who have that illness. There is a better chance of survival.
  • It will help others, and I will be more likely to help.
  • It will increase people’s chances of survival.
  • It will make people better. It will help them get better and be alive.
  • It would be nice to have something that will help out if my dad has something like that. My father is approaching 80. This will help him out.
  • It would help people, and I am not doing anything better with my time right now. I have free time to do things, so I should make it worthwhile. I have free time on my end that I would like to do something productive with.
  • More people have a higher chance of living.
  • My dad had a heart attack. I want him to have the best care. If sodium nitrate is approved, it could be life-changing.
  • My husband had a heart attack. I would be up for anything that would possibly save his life.
  • The result of the study will help every patient.
  • This can help my dad. My dad has heart problems.
  • This might save lives.
  • This will help the patient.
  • Based on the information given, it would not decrease my chances of survival and would offer valuable information to save people’s lives.
  • It sounds like important research that will save lives.

It is safe to try

• I am not able to speak for myself. It has been reviewed by the FDA and other bodies, so maybe it is safe to try.
• I cannot see any harm in the procedure.
• I don’t see any downside to it.
• I don’t think that it will hurt me in any way. Sodium nitrite is not new, but it is something new to use in an emergency. I will be willing to try something new.
• I don’t think that there is more danger in receiving this kind of drug. Why not use it? It is going to give you a chance of survival. It will not make you worse. Why not try this to save other lives?
• I feel it is safe.
• It seems like a safe study and a valuable research.
• It seems like it is something that is supported by reputable studies and has been safely used in hospitals.
• It seems that there are adequate safeguards and little or no added risks.
• It sounds like the method has already been tried and there is not likely to be any harm from trying it.
• It's just minimal risk versus reward. I do believe in research studies.
• It's not the standard treatment at this point. I would be forgoing a nonstandard treatment if I would refuse to. The treatment is not dangerous. If I'm forgoing, there wouldn't be a substantial difference one way or the other, other than something good that might come out from it.
• The risk of the study is really low in that situation. I would not have a hard time with it. It would be acceptable but I want to know more about sodium nitrate. As you've said though, there is low risk.
• There is no harm in what the study could do. It seems worthwhile to find out if it will work.
• Theoretically, considering that the FDA and all other medical bodies say that it would be sound and valid, then I would be willing to take part in the study.

Needed to advance medical science
• I understand that this kind of study is necessary to advance in medical science.
• I'm going to die anyway, so it is not going to hurt. This is for the greater good of science.
• It is to further research and see what is the best practice to use.
• It makes sense. It seems to me that it has a high chance of doing some good. It has a very low probability of doing bad. Even if it doesn't result into saving life, we would learn something.
• Medical progress is based on experimentation. The study sounds like it was well-thought-out. It presented a good argument.
• Science moves forward through clinical trials. I like the long-term benefits.
• The importance of the study is for the greater good. Its benefits for the society outweigh the costs of the individuals.
• The study will help advance the state-of-the-art medical capabilities.
• We need to try new things. If they think that it can increase the level of survival in cardiac patients, then we should try applying the study to prove or disprove the hypothesis.

It is a good idea/I approve
• Having a trial for research purposes to see if they are effective is a good idea.
• I approve, but I can't express it because I don't speak English very well.
• I understand the process of the study and I favor it.
• I'm a nurse and I support the research.
• It sounds good. I would be willing to undergo the experiment.
• It sounds promising.

It is important/necessary
• That is a very reasonable thing. This would be an important improvement.
• I work in public health, so I understand how this study is conducted. I know how important it is.
• I work in the health care industry, and I recognize how well this study works, and how logical and necessary it is.
• It sounds like it’s a good study because it focuses on improving the survivorship of the person during a cardiac arrest. It is an important study. It’s okay that you can do it without consent.
• I have to because it is necessary.

I want to help the research
• I want to help the research.
• I would be willing to help for the survival rate of patients having cardiac arrest.
• It sounds like it is dangerous, but I want to be a part of it.
• I don’t have a specific reason. I just want to be a part of the research.

I believe in/support research
• I am a toxicologist. I am very familiar with the study methods and reviews about what you told me, the human testing and all of the qualifications. I am willing to be part of the study.
• I am in the emergency medical field. I’m happy to advance cardiac science.
• I believe in research to improve medical care, so I want to take part in it. If there is a chance that I can help, then I would do it. If the sodium nitrite could be helpful, then I would want to have the chance to have it.
• I support research.
• I used to be a paramedic, and I know what cardiac arrest is. If it can help, then it would be great.

It may help in the future
• Anything can help the future.
• It could be used to help people in the future. Sodium nitrate is safe to take. I wouldn’t mind participating.
• Science is great. I Would like to have a better future for the world.
• The chances of me dying are high anyway. If future people would be saved because of this study, then, I am willing to do that.

We should improve medical treatment
• I don’t think it will happen to me. I don’t have heart issues, but life-saving measures need to be improved. You can’t improve life-saving measures without studying.
• It is just to get the best care possible. It will improve the previous process.
• You’ve got to try to do whatever you can do to help somebody, right? If only 8 out of 10 don’t survive, you’ve got to try to increase those odds, right?
• The reason for the response is that I know the medical community is looking for different ways to do things. That is exactly what they should be doing.

No reason to say “No”
• I don’t have any good reason to say no.
• I don’t see any reason to say no.
• I think it’s valid research. I see that I’ve got nothing to lose by taking part in it. If it advances the research, then I’ll be happy to take part.
Can't Give a Reason

- I can't really give any reasons.
- I don't have a specific reason.
- I just don't know the science behind it in order to give an explicit reason.

Other

- I am familiar with sodium nitrite. It is reasonable to use it for cardiac arrest.
- I am just curious on what the results would be, especially for African American women. Heart attacks and heart diseases are the number one illness for African American women. I am curious to see what the results might be.
- I am not an idiot. We need to have drugs for emergency situations. Sodium nitrite improves survival and has been proven to be safe.
- I am old. I am obese and I am curious.
- I am part of the community. Information gathered about the situation or study would help the government.
- I believe in the scientists and physicians. I trust their judgment.
- I feel comfortable with that procedure.
- I know the scientific method and what the study is doing. It is determining the validity of this process.
- I trust the University of Washington to have a human subject review board that is looking into this research to determine that the benefits outweigh the risks of this study.
- I want to see if it really works.
- I would just want to try the options based on your information.
- If it will be approved, it will be beneficial for the study. It could potentially help benefit those who are doing this study.
- It is more efficient. It is quicker to do it without consent.
- It is the only way to test the effectiveness of the drug.
- It sounds like a potential solution to a serious problem.
- It sounds like it is already legal to do such treatment for cardiac arrest patients. That part of it is already decided by the FDA and American physicians.
- I've taken part in a study before. I had brain injury. I tend to trust them. I trust the study.
- Since the study doesn't involve the absence of any existing treatment but only the opportunity for additional treatment, that is why I would support it.
- The medical personnel do not always get to try new medical procedures without prior consent.
- There is no other way of learning about it.
- When you are in the situation, it's about saving the life whether you have the consent or not.
In Favor of the Study Being Conducted in the Respondent’s Community

Respondents were very highly in favor of the study being conducted in their community with 82.3% (n=329) being in favor and only 11.2% (n=45) saying they were not in favor.

Q7. Are you in favor or not in favor of this study being conducted in your community?

- In Favor 82.3%
- Not in Favor 11.2%
- Don't Know 5.8%
- Refused 0.7%

No Statistical Differences in Demographic Subgroups

No meaningful significant differences in responses were found based on the demographics tested. A similar proportion of women and men are in favor of the study being conducted in their community. A similar percent of respondents by age, ethnicity, race, and educational attainment also are in favor of the study taking place in their community.
Requests for Contact Information and Additional Comments

Requests for Contact Information
At the end of the survey, respondents were told if they would like more information about the study, the contact information for the study coordinator is available. Eighty-one respondents (20.3%) requested the contact information.

Additional Comments
Respondents were also invited to provide the researchers with any additional comments they wished to offer. The vast majority of the respondents (71.7%, n=287) had no comment. One hundred and thirteen respondents (28.3%) offered a final comment. As shown in the chart below, the highest number of respondents (n=46, 11.5% of the full sample) offered their good wishes, hopes and other comments in support of the research. The study was described as “very cool,” “a very good idea,” “a very good study,” “a pretty cool idea,” “worthwhile,” and “great.” Respondents hoped the researchers would be “very successful,” “find positive results” and “move towards wider administration to help save people’s lives.” One respondent said, “This will really benefit our community.” Others said, “We live and learn. That’s a good thing. It is discovery,” and “It could change the way we do medicine.”

Q7. Do you have any additional comments you would like to tell the researchers about this study?
Percentages are based on the total sample size, n=400
n = 113

<table>
<thead>
<tr>
<th>Comment</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Good wishes/Support the research</td>
<td>11.3%</td>
</tr>
<tr>
<td>Advice to the researchers</td>
<td>4.0%</td>
</tr>
<tr>
<td>Wants/needs more information</td>
<td>2.5%</td>
</tr>
<tr>
<td>Question about the research</td>
<td>2.3%</td>
</tr>
<tr>
<td>Concerns about the placebo</td>
<td>1.8%</td>
</tr>
<tr>
<td>Comments on the survey</td>
<td>1.0%</td>
</tr>
<tr>
<td>Opposed to the research</td>
<td>0.8%</td>
</tr>
<tr>
<td>Consent is needed</td>
<td>0.8%</td>
</tr>
<tr>
<td>Other</td>
<td>4.3%</td>
</tr>
</tbody>
</table>
A group of 16 respondents offered their advice to the researchers. The researchers should consider the age of the patient given that a 20-year-old faces a longer future compared to a 65-year-old. People should be told the pros and cons associated with using sodium nitrite including the negative effects and risks. The researchers should be cautious and 100% sure the science is right and make sure “to diagnose properly to know when to use the sodium nitrite.” Everything should be done to help patients survive even when they receive the placebo. If sodium nitrite is shown to be effective early on, it should be adopted immediately to save lives “even if it means spoiling the study and the data.”

Ten respondents said they needed more information, perhaps being able to read it on the web. They wanted to know the name of the study and who the researchers are, more details about sodium nitrite, how the researchers would know if it is effective and what is the available evidence associated with the research.

Nine respondents raised questions about the research including how the researchers determine if sodium nitrite will work well for a certain patient; whether there will be side effects/interactions between sodium nitrite and other drugs the patient is taking; will the EMT’s training or willingness to use sodium nitrite be affected by participating in the research; if sodium nitrite is found to increase survival, why would the researchers continue to give some patients the placebo; how safe is sodium nitrite; and what are the side effects of sodium nitrite after treatment?

A small group of respondents (n=7) reiterated concerns about the placebo primarily saying the placebo its use is not fair, it should be dispensed with, that everyone should receive sodium nitrite “because we want the people to live.”

Four respondents commented on the survey saying it should be shortened to take less time and it was a waste of time. One respondent said it presented a very good argument that “was presented very clearly.”

Three respondents expressed their opposition to the research saying it is unethical, the risk is too great, and it is unacceptable for a paramedic to enroll the respondent in the research when a placebo is involved and the effect of the treatment is uncertain. One respondent said the research probably can add value but, “I just don’t want it tried in my community.”

Three respondents reiterated that consent was needed.

Finally, 17 respondents offered a diverse array of comments involving the research, tangential subjects, personal attitudes, and general ideas. One respondent said some people do not fear death and that was something to consider, but that this research, if effective, “will save an individual’s life.” Another expressed concern over whether sodium nitrite was safe. One respondent believed in testing the treatment in other ways before using it with humans to avoid putting people at risk. One expressed worries that sodium nitrite was painful, gave “terrible headaches and stomach disorders,” and may not work. Another said she wished this would have been available at the time her father had a cardiac arrest and passed away.
Selected Comments
Selected comments appear below. The full list of comments will be found in Appendix C.

No comment: 287 respondents

Good wishes/Support the research

• It is a very cool study. I would just like to tell them that I want to have a consent from my physician before I make any decisions.
• I just pray that it will be successful.
• I hope it goes well. I hope it will save many people's lives.
• No, I hope it works.
• If it is going to help, please do it.
• This will really benefit our community. We can really learn something from it.
• There are none, just, good luck.
• I know they have to do this in order to find out if it's workable. The only way they can do that is to do this study. I'm in favor of it.
• It is a very good idea. I would like to see it approved.
• I know most of the important emergency lifesaving techniques in this area. I am in favor of continuing the kind of research we have been doing here.
• They will do their best for the community.
• I think this is a good idea.
• Good luck.
• I hope it will go through.
• Keep up the good work.
• I'm all in favor of research. I have a neighbor who had a walnut allergy. They came here and gave him medication. He's now fine. If we can find things like that, then I think it's good. We live and learn. That's a good thing. It is discovery.
• I hope it would be very successful.
• I hope it would be successful that they can treat cardiac arrest and save lives.
• It is good to have tools. We never know. People may collapse in the road. We need to give a person a chance to be rescued.
• It is a very good study.
• I would like to be part of the research.
• I strongly feel that it should be administered, like the sodium nitrite in addition to all of the other available treatment.
• We need to keep finding and exploring ideas.
• It is a pretty cool idea.
• It is worthwhile. My cousin died last year from cardiac arrest, and so anything that helps is great.
• It sounds like a good idea. I wish them all loads of success.
• Keep going forward. Keep it in position. They have to excel with their plan.
• I think this will help other people.
• Our area is known for cardiac arrest study. I am happy to be a part of this survey.
• It could change the way we do medicine. It is great.
• I'm just happy to know that there are more things going on out there, like medicines and technology, to fight for survival.
• I would just hope that if they find positive results, they're going to move towards wider administration to help save people's lives.
• If there is no research, there is no progress. I trust them so they should do a good job and improve it.
• It is good but people should be aware of the side effects of sodium nitrite.
• As much as the community is concerned about this, they are not the doctors. I trust the physicians who will do the study, not the average community. The physicians should be the one to decide on the study.

Advice to the researchers
• They should probably consider the age of the patient, like a 20-year-old or a 65-year-old dying of a heart attack. The 20-year-old has to live a long way still. There is still a chance of survival compared to the 65-year-old.
• What could be the negative effects of ingesting this particular sodium nitrite chemical? They should give the people the pros and cons, too, about the possible risks of this.
• Just don't overprice it.
• Just be 100% sure that the science is right. It could potentially cost lives but just be careful on that end. Be cautious.
• For the sake of public safety, they should include the geographical area where the study will take place and the duration of the study, like when it is going to get started and be done.
• Their research should be more completely defined so we will know what are the positive and negative effects of it.
• It should be conducted in a hospital setting.
• If this sodium nitrite is shown to be effective in the early rounds of it, I hope that they would adopt it immediately for people whose lives are at risk. I hope that they won't keep giving people placebos just to find more information. If it looks like it is going to work, then they should do it, even if it means spoiling the study and the data. If it saves lives, they should do it immediately.
• I hope that even with the placebo, everything is being done to help the patient survive.

Wants/needs more information
• I would like to be able to read about this more on the web.
• I want to know who they (the researchers) are.
• I do not know about the drugs. I do not know enough about what is going on.
• I just want to understand how they would know this is effective. I would like to know more about what they are trying to do with it.
• I need more information about this. I did get information from your side, but I just need more information for this.
• Give us more information. We need more evidence to internalize.

Question About the Research
• There is just one thing. How do they figure out if sodium nitrite or placebo will work well for a certain patient? How well does it work?
• I just want to know if there are reactions on certain medications that the patients have taken. If they have known patients who have heart issues or are diabetic and they have medications, when they take sodium nitrite, would they have any side effects?
• Will the EMT’s training or willingness to use sodium nitrite be affected by the study or is the study merely for data collection purposes and the EMTs training or willingness to use sodium nitrite will not be affected? That is my question.
• If your study shows that sodium nitrite increases survival in patients with cardiac arrest and you give some patients placebo, that would concern me. Why not give all patients sodium nitrite? My concern is that what would be the criteria for giving some patients sodium nitrite and what would be the criteria for giving some patients placebo? Would there be an age range for that? I really don’t know if this works in the study. That is my only concern.
• There is nothing. I’m just curious about how they decide who gets the experimental drugs and who gets the placebo.
• How safe is it and what are the side effects after the treatment?

Concerns about the placebo
• It seems that some will get the placebo material and some may not, which is not fair for some.
• I want this study to have the best possible outcome. They should get rid of the placebo and only use sodium nitrite in helping other people.
• I understand the need for a control group for scientific studies, but there is a question on the idea of administering a lifesaving substance to one group of people and denying another group and giving the placebo.
• Everybody should be given medicine.
• Forget about the placebo because we want the people to live.

Comments on the survey
• You can shorten the study to make it clearer in a shorter amount of time.
• It seems to me that conducting a phone survey for this study is a waste of time.
• It was presented with very good argument. It was presented very clearly.
• I would tell them to reconstruct the questionnaire in a way that the respondents will not be offended. No one wants to have a cardiac arrest.

Opposed to the research
• It can probably add value. I just don’t want it tried in my community.
• It is unethical.
• The risk is too great for this particular study. The patient is not very much informed. No one is there to speak to them of the possible effects because they are unconscious. I have been a heart patient for a number of years. I am highly against a paramedic who will go to my house and conduct a study with me, especially with the placebo. Its effect is uncertain.

Consent is needed
• They must get consent before they put the patients into the study group.
• They should have a patient sign a consent about it.
• During emergency cases, there should be no placebo given to patients when at home. When you are in the hospital, there should be a patient consent.

Other
• There are some people who don't have the feeling of fear of death. That's something to be realized or considered, but the goal is to save lives. If this is effective, it will save an individual's life.
• My primary concern is whether it is possibly safe.
• I still believe in the older ways to test the product before putting it on humans. It's still a hypothesis. I don't feel comfortable putting ourselves at risk on this.
• They should show people how to eat with nutrients for themselves.
• It is really painful. It would give terrible headaches and stomach disorders. Maybe, it won't work.
• I just want to live long.
• My dad passed away because of cardiac arrest. I wish this was available at the time he had a cardiac arrest.
Key Findings

If respondents experienced a cardiac arrest, 65.9% would be willing to be a part of the study without first providing consent and 27.1% would not.

The primary reasons respondents would not be willing to be in the study involved a fear of possible side effects and a belief that patients should provide consent followed by a need for more information and a lack of interest in the study or not wanting to participate, a desire not to be given the placebo and a feeling the study is too risky.

The primary reasons respondents would be willing to be in the study involved the belief that it could help them, it may help or save others, and it is safe to try. Other reasons included the idea that research is needed to advance medical science, the study is a good idea which the respondent approves of, the research is important or necessary, and the respondent believes in and supports the research and wants to help.

Respondents were very highly in favor of the study being conducted in their community with 82.3% being in favor and only 11.2% being not in favor.
Appendix A: Questionnaire with Raw and Weighted Data

THE UNIVERSITY OF WASHINGTON AND HARBORVIEW MEDICAL CENTER
SODIUM NITRITE COMMUNITY CONSULTATION SURVEY QUESTIONNAIRE

If speaking to a child] May I speak to someone in your household who is at least 18 years of age? Thank you.

Hello, my name is _______________________. I am calling on behalf of the University of Washington about a medical research study that will take place in your community. This study may involve you or someone in your family. We are contacting members of the community to understand your views about this study. The study will test a new method for saving the lives of patients in an emergency situation.

**CELL**

S1. First, for safety reasons, I need to ask, is this a cell phone?

   1. Yes
   2. No [SKIP TO S3]
   3. Refused [THANK AND POLITELY DISCONTINUE]

   Unweighted
   132 33.0%

S2. To ensure your safety and the safety of others can you please tell me if you are currently driving a motor vehicle?

   1. Yes [SCHEDULE CALLBACK]
   2. No
   3. Refused [THANK AND POLITELY DISCONTINUE]

   Unweighted
   132 33.0%

S3. In your household, do you only have a telephone that is not a cell phone (meaning a wired landline), a cell phone only or both?

   1. Telephone landline only
   2. Cell phone only
   3. Both telephone landline and cell phone
   4. Refused

   Unweighted
   31 7.8%
   100 25.0%
   267 66.7%
   2 0.5%

[READ THE FOLLOWING PRIOR TO ASKING SURVEY QUESTIONS]

   First, I will tell you about the research and then ask you a few questions.
A cardiac arrest is a medical emergency. When a cardiac arrest takes place, the heart stops beating. Then the person becomes unconscious. Without treatment, death usually occurs within minutes. Even with emergency treatment, about 8 out of 10 will not survive. More than 326,000 individuals died of cardiac arrest in the US in 2015.

Research suggests that sodium nitrite may increase survival by improving the delivery of oxygen to the heart and brain. Animal studies have shown the greatest benefit occurs if sodium nitrite is given when a cardiac arrest is taking place.

The study will be conducted in two phases. In Phase 1, paramedics will give patients sodium nitrite at the scene of an out-of-hospital cardiac arrest. The amount being given should raise the blood level to the proper amount. The right blood level will provide the greatest benefit. When patients arrive at the hospital, their blood will be tested. In this way, we can determine the exact amount of sodium nitrite needed to reach the blood level required.

In hospital testing, sodium nitrite has been proven to be safe. It is currently in use to treat other medical conditions. It is fully expected that sodium nitrite will be just as safe in this study. If it is found to be less safe, the study will be stopped immediately.

The purpose of the second phase of the study is to find out if sodium nitrite improves survival. Patients will be randomly split into two groups. Paramedics will give the first group sodium nitrite. The second will receive a placebo. The placebo will be the normal saline solution. It is made up of water with the same low salt level as found in the human body. A placebo has no effect on the patient. In all other ways, every patient will receive the best care available in medical practice.

All cardiac arrest patients are close to death and most will not survive. Their heart may not restart; if their heart does restart, the heart rate or blood pressure may go down. Their heart may stop beating again. There may also be unexpected problems. These risks will be present with or without sodium nitrite. However, sodium nitrite offers something new. It offers the possibility of increasing the number of lives saved over and beyond the current success rate.

Usually, researchers ask patients for their informed consent before including them in a medical study. In the case of life-threatening cardiac arrest, however, patients are unconscious and close to death. Family members may not be available to speak for them. Treatment must begin immediately to save the patient’s life. For these reasons, this study must be started without first receiving the patient’s consent.

Government regulations allow and support research studies without prior consent. Strict conditions must be met. This study meets these conditions. The study has also been examined and approved by the United States Food and Drug Administration and by a board of physicians responsible for protecting patient safety. They have all agreed the science is accurate and the study is safe to perform. The board of physicians will continue to monitor and approve the study until it ends. Part of the board’s responsibility is to understand how community members view this study. Answers in this survey will help the board to make decisions regarding the study.
Now I would like to ask you a few questions.

Q1. Based on the information I just read to you, do you understand what this study is about?

<table>
<thead>
<tr>
<th></th>
<th>Weighted/Unweighted</th>
<th>Unweighted – Reported</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Yes [SKIP TO Q3]</td>
<td></td>
<td>388 97.0%</td>
</tr>
<tr>
<td>2. No</td>
<td></td>
<td>9 2.3%</td>
</tr>
<tr>
<td>3. Don’t know</td>
<td></td>
<td>3 0.7%</td>
</tr>
<tr>
<td>4. Refused</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

The important points are these. In cardiac arrest, the heart stops beating. Death can occur in minutes without treatment. Current treatments are inadequate and unacceptable. Fewer than one in five survive. Better treatments are needed. This research will test the use of sodium nitrite, one the most promising new treatments. This drug has been proven to be safe and has the potential to improve oxygen delivery to the heart and brain, helping to save lives. The study will be done in two phases. In Phase 1 of the study, paramedics will give patients sodium nitrite at the scene of an out-of-hospital cardiac arrest. This phase will determine how much sodium nitrite must be administered to reach the desired level in the blood and how safe the drug is. If it is found to be less safe, the study will be immediately stopped. This second phase will determine if giving sodium nitrite saves more lives over and beyond the current success rate. Cardiac arrest patients will be randomly assigned to receive either sodium nitrite or a placebo. The placebo is simply water with the same salt level as the human body. In all other ways, every patient will receive the best life-saving care available in medical practice. Since patients in cardiac arrest are unconscious and close to death, treatment must be started immediately. The study will need to begin without the patient’s informed consent or the consent of a family member who may not be present. Regulations in the United States allow and support medical studies without the patient’s consent. The study must meet strict conditions. This study meets these conditions. The study has been approved by the Food and Drug Administration and by a board of physicians who are responsible for protecting patient safety. The board will continue to monitor and approve the study until it ends.

Q2. Based on this information, do you understand what this study is about?

<table>
<thead>
<tr>
<th></th>
<th>Weighted/Unweighted</th>
<th>Unweighted – Reported</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Yes</td>
<td></td>
<td>12 100%</td>
</tr>
<tr>
<td>2. No [FIND OUT WHAT THEY DON’T UNDERSTAND AND CLARIFY BASED ON ABOVE DESCRIPTIONS]</td>
<td></td>
<td></td>
</tr>
<tr>
<td>3. Not sure [FIND OUT WHAT THEY DON’T UNDERSTAND AND CLARIFY BASED ON ABOVE DESCRIPTIONS]</td>
<td></td>
<td></td>
</tr>
<tr>
<td>4. Refused to answer [THANK AND POLITELY DISCONTINUE]</td>
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</tbody>
</table>

[RESPONDENT MUST ANSWER YES TO Q2 TO CONTINUE, OTHERWISE THANK AND POLITELY DISCONTINUE]
Q3. If you experienced a cardiac arrest, would you be willing to be part of this study without first providing consent?

<table>
<thead>
<tr>
<th></th>
<th>Weighted - Reported</th>
<th>Unweighted - Reported</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Yes</td>
<td>264</td>
<td>267</td>
</tr>
<tr>
<td>2. No</td>
<td>109</td>
<td>106</td>
</tr>
<tr>
<td>3. Don't know, Refused</td>
<td>28</td>
<td>27</td>
</tr>
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</table>

Q4. What is the reason for your response? [DO NOT READ]

<table>
<thead>
<tr>
<th>Reason</th>
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<tbody>
<tr>
<td>1. Fear about possible side effects</td>
<td>27</td>
</tr>
<tr>
<td>2. Patients should not lose the right to provide consent</td>
<td>21</td>
</tr>
<tr>
<td>3. Don't know</td>
<td>20</td>
</tr>
<tr>
<td>4. Refused</td>
<td>6</td>
</tr>
<tr>
<td>5. Other [SPECIFY]</td>
<td>60</td>
</tr>
</tbody>
</table>

Q5. [ASK IF Q3=1] [INFO: THIS QUESTION CAPTURES THE REASONS RESPONDENTS ARE IN FAVOR OF THE RESEARCH] What is the reason for your response? [VERBATIM]

Q6. Are you in favor or not in favor of this study being conducted in your community?

<table>
<thead>
<tr>
<th>View</th>
<th>Weighted - Reported</th>
<th>Unweighted - Reported</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. In favor</td>
<td>329</td>
<td>336</td>
</tr>
<tr>
<td>2. Not in favor</td>
<td>45</td>
<td>39</td>
</tr>
<tr>
<td>3. Don't know, Uncertain</td>
<td>23</td>
<td>22</td>
</tr>
<tr>
<td>4. Refused</td>
<td>3</td>
<td>3</td>
</tr>
</tbody>
</table>

Q7. Do you have any additional comments you would like to tell the researchers about this study? [VERBATIM]

Comment Provided

I just have a few more questions to ask to make sure we have a good cross-section of the community.

DEMOGRAPHICS

Q8. What is your age?

<table>
<thead>
<tr>
<th>Age Group</th>
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<td>77</td>
</tr>
<tr>
<td>65+</td>
<td>51</td>
<td>71</td>
</tr>
</tbody>
</table>

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Q9. Are you of Hispanic, Latino or Spanish origin? [RECORD ONE RESPONSE]  
1. Yes  
2. No  
3. Don’t Know/Uncertain  
4. Refused to Answer  

Q10. What is your race? [ACCEPT ONE RESPONSE]  
1. White  
2. Black or African American  
3. Alaskan Native or American Indian  
4. Asian  
5. Native Hawaiian or Other Pacific Islander  
6. Some other Race  
7. Not Sure/Don’t know  
8. Refused  
9. Two or more races  

Q11. What is the highest level of education you have completed?  
1. Less than Grade 8, No Diploma  
2. Grade 8, Elementary School Diploma  
3. Grade 12, High School Diploma  
4. Associate’s Degree (2-year college)  
5. Bachelor’s Degree  
6. Master’s Degree  
7. Doctorate or Professional Degree  
8. Refused  

Q12. What is your primary occupation? [VERBATIM]  

Q13. [CODE BASED ON PERCEPTION; ASK IF NECESSARY] What is your gender?  
1. Male  
2. Female  
3. Refused  

Q14. If you would like more information about this study, I can give you the name and phone number of a contact person. Would you like this information?  
1. Yes, information given  
2. No, information not given  

Information to give out:
THAT CONCLUDES OUR SURVEY. THANK YOU VERY MUCH FOR YOUR TIME AND COOPERATION. YOU HAVE BEEN VERY HELPFUL.
Appendix B: Research Design, Methodology and Statistical Analysis

Time and Geographic Area of the Survey
The survey was fielded during the period from June 28 to July 10, 2016. Residents living in Seattle, Washington, were targeted.

Questionnaire
The questionnaire was written by Dr. Francis Kim, revised by Klima Research and approved by the presiding University of Washington IRB.

RDD Sampling
Recent years have seen a substantial change in telephone surveys that involve live interviewers. These surveys are now termed "interactive voice" surveys to differentiate them from robocalls which are automatically dialed telephone calls with a recorded voice asking survey questions. A recent report from the CDC shows that nearly one-half of American households (48.3%) are now wireless-only (Wireless Substitution: Early Release of Estimates From the National Health Interview Survey, July-December 2015, by Stephen J. Blumberg, Ph.D., and Julian V. Luke Division of Health Interview Statistics, National Center for Health Statistics, released 5/11/2016). This shift to cell phones is especially characteristic of adults aged 25-34 where more than two-thirds live in a wireless household and for adults 18-24, where the prevalence was 61.1%. To effectively include the under-35 age group, wireless interviews must be included in the sampling design. It is worth noting that Klima Research has compared the data from landline interviews with data gathered via cell phones in surveys involving two different EFIC studies. These surveys employed a split-sample design where half of the interviews were conducted using landlines and half using cell phones. The resulting findings were identical regarding the willingness to participate in the study. The modality used to conduct the interview (landline vs. cell phone) had no impact on the data.

Telephoning was based on RDD sampling of both landlines and wireless phones. For landlines, the RDD methodology used special algorithms to generate random phone numbers within Seattle for the study. The RDD methodology gives a more complete representation of households in the survey area since it includes both listed and unlisted landline phone numbers. The RDD cell phone sample was developed using a list of all possible wireless telephone numbers in the research area which was built using industry databases. The sample telephone numbers were entered into a Computer-Assisted Telephone Interviewing System (CATI) which managed the random process of selecting numbers to be called. The CATI system presents interviewers with survey questions on a monitor and records respondent answers as entered by the interviewer. Each telephone number was called up to eight times before being removed from the call list thereby helping to assure that interviews are completed by individuals who are less readily available as well as those who are easy to reach.

Interviews were conducted in English with a random sample of adults (18 and older). A total of 400 interviews were completed which gives a maximum margin of error of ±4.9% at the 95% Confidence Level. The margin of error indicates that if the same survey was repeated 100 times in the same region and in the same way, in 95 of the 100 repetitions, the resulting percentages for each response
would be within ±4.9% (the margin of error) of the result that would be obtained if all adults in the targeted area were interviewed.

**Interviewer Training**
Interviewers underwent training regarding the objectives of the research study, questionnaire administration and all aspects of the survey. Training enabled interviewers to successfully administer the survey and produce quality data.

**Survey Pre-testing**
The programming of the survey was tested by Klima Research prior to fielding. The survey was also pre-tested with a small sample of respondents and the data reviewed to verify that the data was properly recorded. All recording was found to be correct.

**Interview Completion**
Respondents were called weekdays at various times and evenings until 9:00 pm and on weekends. When necessary, appointments were scheduled with respondents who were unable to complete an interview until a later time.

**Monitoring**
Telephone interviews were monitored by data collection supervisors to assure proper administration and data entry. Interviews were recorded solely for quality control purposes.

**Weighting the Data**
The raw data were weighted by age and gender to align the sample characteristics to the demographics of the area being called. Quotas were set up by age based on US Census Bureau statistics in 2010 for Seattle. The number of interviews completed were within ±40% of the quota for each age category. This allowed variance from the quota produced data sufficiently close to the census demographics to eliminate the need for large weight factors. The weights employed by age and gender appear in the following table.

<table>
<thead>
<tr>
<th>Age Range</th>
<th>Male</th>
<th>Female</th>
</tr>
</thead>
<tbody>
<tr>
<td>18-24</td>
<td>1.04</td>
<td>1.70</td>
</tr>
<tr>
<td>25-34</td>
<td>1.25</td>
<td>2.54</td>
</tr>
<tr>
<td>35-44</td>
<td>1.28</td>
<td>0.96</td>
</tr>
<tr>
<td>45-54</td>
<td>0.88</td>
<td>0.70</td>
</tr>
<tr>
<td>55-64</td>
<td>0.75</td>
<td>0.68</td>
</tr>
<tr>
<td>Over 65</td>
<td>0.72</td>
<td>0.72</td>
</tr>
</tbody>
</table>

By assuring proper proportional representation by age and gender, the results increase the accuracy of the estimates of the public’s attitudes across the geographic community where the research will be conducted. Following weighting, the percent of actual responses for each question alternative in the key questions (Q3 and Q6) changed by 1.7% or less from the raw data.

**Number of Phone Calls Made, Survey Length, Incidence Rate and Cooperation Rate**
A total of 151,867 phone calls were made to secure 400 interviews. The vast majority of calls placed were not answered or involved a language barrier, individuals who were ineligible to be interviewed or individuals who were not available for an interview at the time of the call: 149,155. The average time it took to complete a survey was 10 minutes and 41 seconds. The
Incidence Rate for the survey was 48.0%. The incidence rate represents the percent of individuals contacted who were qualified to complete the survey. The Cooperation Rate was 13.2%. The cooperation rate is the percent of qualified respondents who completed an interview among all eligible individuals who were contacted. A high cooperation rate is more desirable because it theoretically reduces the potential for non-response bias (the error introduced when those who do not complete an interview possess different views from those who do). However, a low cooperation rate does not necessarily equate to the presence of non-response bias. Fundamentally, the presence of nonresponse bias is a function of the correlation between an individual's willingness to be a respondent and the specific issues addressed in a survey. For non-response bias to be introduced, the reasons individuals decline to be interviewed would need to be directly related to the questions in a way where their answers to survey questions would be substantially at variance from the responses given by respondents who did agree to be interviewed. In essence, the group of nonrespondents would have to hold opinions or attitudes that were substantially different from respondents. If this were the case, the result of not including them would be to cause the data to be nonrepresentative of the population of interest. Despite a cooperation rate being low, there is no minimum rate below which survey results are necessarily affected by nonresponse bias. Since potential subjects who declined to complete an interview for this survey did not know the subject of the survey when they declined, there is little possibility that their attitudes toward EFIC research played any role in their declining to participate. As a group, their attitudes toward this research were likely as randomly distributed as the attitudes of those who did respond and it is assumed that if the non-responders were included, the survey results would not be substantially affected.

Statistical Analysis
Univariate and bivariate statistical analyses were conducted. Univariate analysis summarizes and examines individual variables such as the number of respondents who answered "Yes" or "No" to a question. This information is graphically presented in the report in the form of pie charts and bar charts and in tables. Bivariate analysis involves examining the relationship between two variables such as demographic subgroups and the answers to a specific question. Bivariate analysis uses a statistical test to determine if, for example, one age group answered a question in a way that is significantly different from the way other age groups answered the question. Bivariate analysis using the Chi square statistic was conducted to examine differences in responses by age, gender, race and educational attainment.

Meaningful results that reached the .05 level of significance (indicated as a p-value, meaning the probability of observing the result) are reported for questions where significance was found along with an explanation of the finding in practical terms. A significant finding or p-value equal to or smaller than .05 means there is a small chance, 5 out of 100 or less, of finding the result and, consequently, the difference seen is likely occurring as a consequence of an actual pattern rather than occurring simply as a chance happening. Chi square results reaching statistical significance also include a measure of association which indicates the degree to which the two variables being tested vary in parallel. The measure of association reported is Cramer's V which varies between 0.0 and 1.0 and is similar to a correlation coefficient. A value of 0.0 indicates no relationship between the two variables tested (they vary independently) and casts doubt on the

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meaningfulness of a related finding of statistical significance using Chi square. A value of 1.0 suggests that variations in one variable completely predict variations in the second variable. A higher value for Cramer’s V supports the meaningfulness of a statistically significant Chi square result.
Appendix C: All Answers to Open-ended Questions, “Other” Responses and Respondent Additional Comments

Question number 3 included two follow-up question which asked respondents to explain the reason for their response. Appendix C contains all answers to these questions provided by respondents as well as responses to the final survey question asking for any additional comments about the study.

Respondents who would not be willing to be part of this study (answered “No” to Q3) were asked to explain the reason for their answer in Q4. Two response categories were listed under Q4. A third response, “Other,” captured all other answers. The full list of these “Other” responses categorized by reason appears below.

The reasons given by respondents who would be willing to be part of the study will be found beginning on page 39.

Q3. Reasons respondents would not be willing to be part of the study

Q3. If you experienced a cardiac arrest, would you be willing to be part of this study without first providing consent?
   1. Yes [SKIP TO Q5]
   2. No
   3. Don’t know, Refused

Q4. What is the reason for your response?
   1. Fear about possible side effects
   2. Patients should not lose the right to provide consent
   3. Don’t know
   4. Refused
   5. Other [SPECIFY]

“Other” responses to Q4 categorized by subject.

Need more information
   • Don’t know enough, don’t go to the hospital much.
   • I need more information about it.
   • I need more information.
• I need to do more research about it.
• I need to know more about the study.
• I still need more information about it.
• I want more information about it.
• I want to know more about the study.
• I want to read it first before agreeing.
• I would like to research and know more about it.
• I'd like to know the considerations in using it.
• I'll do my own research first.
• I'm not familiar and have to think about it.
• I need more information on who can get this treatment.
• Need to do personal first research with my doctor.
• Need to know more about the advantages and results.
• Need to know more information.
• Not enough information.

Not interested/Does not want to participate
• I am not interested.
• I am not interested in being part of the trial.
• I am not interested in the study.
• I don’t care to be part of the study.
• I don’t want to be a subject.
• I don’t want to be included in the study.
• I don’t want to risk my life for some research.
• I don’t want to.
• I just don’t participate in the studies.
• I just don’t think I would be able to participate.
• I just wish to be at home in bed.
• I’m not interested.

Does not want placebo
• I don’t like the possibility of the placebo.
• I don’t want a placebo. I want to be treated.
• I don’t want placebo content in the medicine.
• I don’t want to be part of the placebo group.
• I would not like to receive a placebo.
• Prefer they save me rather than be part of placebo study.

Not safe/Too risky
• I don’t have security. I don’t feel safe.
• It doesn’t sound safe.
• I won’t take the risk. It may cause more problems.
Other

- Already had an attack and carry my nitrite with me.
- Don't trust UW or hospitals to do what is right.
- Don't want to think about having a cardiac arrest.
- Have to talk about it with my wife if she agrees.
- I am old and it is hard for my part.
- I am on a mission. I am a missionary in a church.
- I don't believe in it.
- I don't trust it.
- I live alone. There is no one to help.
- I need to talk to my cardiologist.
- I want the physicians to take care of it
- I would ask permission from my cardiologists.
- I would want to do my own individual evaluation.
- I'm going back to my home country.
- I'm not comfortable doing it.
- I'm not comfortable in giving consent.
- I may not want the situation of being resuscitated.
- Not sure if it works like it did with my husband.
- There is more advanced research, like in Texas.
- Will sodium nitrate work?
Q5. **Reasons respondents would be willing to be part of the study**

Q3. If you experienced a cardiac arrest, would you be willing to be part of this study without first providing consent?
   1. Yes [SKIP TO Q5]
   2. No
   3. Don’t know, Refused

Q5. [ASK IF Q3=1] What is the reason for your response?

Respondents who answered "Yes" to Q3 were asked to explain the reason for their answer in Q5. The following is the full list of responses categorized by reason.

*It could help me*

- Anything that increases survival and security that has no side effects, or any chemical probability with minimal side effects or that causes no harm is acceptable with me.
- Anything that will preserve your life is always worth taking.
- Based on how you explained it, it sounds like there would be a potential benefit. It could help, and it won’t hurt.
- First, it has a higher rate of success. Second, I am also a type 1 diabetic and participated in a study like that. I have gained from the benefits of the study today.
- I already had a heart attack. It would be worth the shot.
- I am 90 years old. What do I have to lose on that?
- I believe my life will be saved.
- I don’t particularly want to die. Isn’t that about saving lives? The study is supposed to save lives.
- I don’t think that I’ll be having a cardiac arrest, so it is not applicable to me. If I will have a cardiac arrest, it might save me.
- I guess if I would be dying, I want them to do anything they could to help me survive. That is if they could actually do that.
- I just trust the medical researchers. I think I would get the benefit of it.
- I like anything that would help me to survive to be done.
- I like science. It is a really weird answer. There is a lot of pushback when you get into things, like life threatening situations and the lack of consent when you are unconscious. At the same time though, there is this higher success story potentially and less long-term effect, so yes, why not?
- I think the study is worthwhile. It provides a possibility of survival.
- I want sodium nitrite. I would want a better chance of surviving.
- I want to be alive and reduce the risks of cardiac arrest.
- I want to have every chance to survive.
- I want to try anything that works.
- I would like to survive and still live with my family.
- I would rather appreciate to live my life because I do not want to die.
• I would say yes if it is going to save my life. That is what the emergency people are trying to do. There is a chance that you can expire with or without it.
• I would say yes, hoping that I will be receiving the experimental drugs rather than having no chance, but not the placebo.
• If I was going to die, then, this might save me. It is just worth it.
• If I will have cardiac arrest, I will not survive.
• If it can improve my chances of living, that will be a good thing. I will be willing to try it.
• If it increases the chance of survival, I would gladly be part of it.
• If it is improving the chances, why not try?
• If it is proven to work and is safe, then why not? If it could save my life, then I am surely for it.
• If it will save my life and help me out, I'll give it a try.
• If it will save somebody's life and it may save mine, then I will be in favor of it.
• If it would save my life, then I'd rather put on the lifesaver.
• If sodium nitrite increases the ability of my survival in a cardiac arrest, then I would like to have it.
• If we lay unconscious, who would know what may happen? Right now, all you get is the regular IV, but sodium nitrite may help.
• I'm enjoying life and I want to live long.
• It could save my life.
• It doesn't make things get worse. It could make things better.
• It improves the odds of my survival.
• It is a chance to survive a cardiac arrest. It would help the statistics and study on what the relevant procedure is and on whether this would help people who are having a cardiac arrest.
• It is a research that will help me save my life.
• It is based on the information you just told me, and that is that the drug is safe and helpful. If it will save my life, then yes.
• it is for protecting my life.
• It is for survival. It will help out in certain cases.
• It is going to give the best chance for me to survive.
• It might lengthen my life. It might keep me from dying.
• It might save my life. My dad has had a heart attack three times. I know how it feels. It is really scary.
• It might work.
• It sounds like it is something likely to be helpful.
• It sounds like it would probably save my life.
• It sounds like there are more positive outcomes than negative outcomes and that there are chances of life. I'd rather choose that.
• It will help me add more knowledge about sodium nitrite and its future uses.
• It will improve my chance of survival.
• It will not only help me but also others who have experienced a cardiac arrest.
• It will save my life.
• It would help others and raise my chance of survival.
• It would help save my life. It will improve our technology.
• It’s another way for survival. It said that there is an eight out of 10 chance of surviving. I am at that point. Why not try it.
• It's beneficial in my life. It would save my life when I'm having a cardiac arrest.
• That could save my life.
• That would be helpful.
• The reason for my response is to survive.
• The reason is because if I'm already having a cardiac arrest, the chance of survival is minimal.
  I would definitely be taking any means possible or be testing any drug.
• The reason is that it sounds like an important study. It could save my life.
• There is a better chance of survival.
• There is a small likelihood of surviving anyway. If it would not cause any damage, then it could help.
• There is an increased chance of survival.
• This can save me.
• We still want to live.
• What you have told me sounds like my success rate of survival could go up.
• When you're close to death, anything that can be used to survive will be worth the risk.
• You convinced me. It increases the chances of survival according to what you told me.
• You said that it will give you a bigger possibility to come back from cardiac arrest and a bigger possiblity of a longer life.
• It could be a benefit.
• It has an improved success rate. That is based on what you told me.
• It will make a difference.
• It would be helpful.
• It's an appropriate treatment plan and worth the opportunity to test it.
• It's worth a shot.
• I've heard about sodium nitrate before. It helps increase survival.
• Something should be done if I'm having a cardiac arrest.
• Study shows that it increases cancer survival. If I'm conscious in any way and you can ask me, then, of course, I would say yes.
• There is not much that can be done so having an option for treatment seems to be desirable.
• They are proven helpful. Their study is proven to work.
• We should take the risk for its potential benefits.
• You guys are supposed to be the professional. If it's something that's going to work and not cause more harm, might as well go for it.
• I would like to receive all the assistance available in case of a cardiac arrest.
• I would want the best care possible no matter what.
• I would want them to do everything they could.
• If there is another way you can improve to increase the chances of survival, do it.

It may save lives/help others
• The person would not get it otherwise. Eight out of 10 will die anyway. The benefit outweighs the risk. Let's just put it that way.
• As what I understand, it's pretty much useful for folks who have experienced stroke. I like the idea. I think it will work that way and they will be able to cope up from having a heart attack.
  I think using sodium nitrite is more okay than doing CPR.
• I am willing if it could help save someone's life.
• I am willing to help the community. I will do what I can to help those people who are in need.
• I think saving a life is good. CPR is not helping that much, but sodium nitrite is.
• I was a first responder for a fire department. The study would have a big benefit for everybody. I know how it is to not have a first treatment in an emergency.
• If it can help save lives, I'd be willing to.
• If it helps somebody live who might not be ready to die, then that would be a positive thing. It is also if it helps the patient and decreases cardiac arrest.
• I'm a caregiver for my mother and father, who are both in their 90's. My mom has a pacemaker. It worked well for her when she had a heart problem. If there is anything that can offer a change, then it's good. I think it's wonderful.
• I'm saying yes because I believe that the potential to save lives is greater than the ethical issue of not asking for consent.
• It can help to decrease the number of deaths caused by cardiac arrest.
• It can save lives. Anything should be tried to save lives.
• It gives the person a better chance of survival. It is worth using.
• It is a new treatment and is helpful for the patients.
• It is for the benefit of the others.
• It is to help people.
• It is to save the life of the patient. If it is necessary, then do it.
• It might help other people. It might work.
• It sounds like it would be helpful to older people my age who are at risk.
• It sounds very beneficial for persons who have that illness. There is a better chance of survival.
• It will help others, and I will be more likely to help.
• It will help the patient to have a better chance to survive.
• It will increase people's chances of survival.
• It will make people better. It will help them get better and be alive.
• It would be nice to have something that will help out if my dad has something like that. My father is approaching 80. This will help him out.
• It would help people, and I am not doing anything better with my time right now. I have free time to do things, so I should make it worthwhile. I have free time on my end that I would like to do something productive with.
• I've actually seen the defibrillator that's been used in schools to save lives. If this one saves lives, too, then I am for it.
• More people have a higher chance of living.
• My dad had a heart attack. I want him to have the best care. If sodium nitrate is approved, it could be life-changing.
• My husband had a heart attack. I would be up for anything that would possibly save his life.
• Other people might benefit from if it works out.
• The result of the study will help every patient.
• This can help my dad. My dad has heart problems.
• This might save lives.
• This will help the patient.
• You are trying to improve the survival rate of people with cardiac arrest.
• Maybe, it will do some good to people.
Based on the information given, it would not decrease my chances of survival and would offer valuable information to save people's lives.

It sounds like important research that will save lives.

It is safe to try

- I am not able to speak for myself. It has been reviewed by the FDA and other bodies, so maybe it is safe to try.
- I cannot see any harm in the procedure.
- I don't see any downside to it.
- I don't think that it will hurt me in any way. Sodium nitrite is not new, but it is something new to use in an emergency. I will be willing to try something new.
- I don't think that there is more danger in receiving this kind of drug. Why not use it? It is going to give you a chance of survival. It will not make you worse. Why not try this to save other lives?
- I feel it is safe.
- It has already been used by some medical staff without any consequences.
- It is fairly harmless.
- It seems like a safe study and a valuable research.
- It seems like it is something that is supported by reputable studies and has been safely used in hospitals.
- It seems that there are adequate safeguards and little or no added risks.
- It sounds like the method has already been tried and there is not likely to be any harm from trying it.
- It's just minimal risk versus reward. I do believe in research studies.
- It's not the standard treatment at this point. I would be forgoing a nonstandard treatment if I would refuse to. The treatment is not dangerous. If I'm forgoing, there wouldn't be a substantial difference one way or the other, other than something good that might come out from it.
- My husband has a heart disease. The study seems to be positive and not risky compared to a heart attack.
- No harm can be done.
- Primarily, it has no significant risk in helping individuals.
- The risk of the study is really low in that situation. I would not have a hard time with it. It would be acceptable but I want to know more about sodium nitrate. As you've said though, there is low risk.
- The science is back, and the actions are taken, so it is safe and appropriate.
- There is no harm in what the study could do. It seems worthwhile to find out if it will work.
- Theoretically, considering that the FDA and all other medical bodies say that it would be sound and valid, then I would be willing to take part in the study.

Needed to advance medical science

- I understand that this kind of study is necessary to advance in medical science.
- I'm going to die anyway, so it is not going to hurt. This is for the greater good of science.
- It is for the potential benefit of medical science.
- It is to advance in medical research and to improve patient outcome.
• It is to further research and see what is the best practice to use.
• It makes sense. It seems to me that it has a high chance of doing some good. It has a very low probability of doing bad. Even if it doesn’t result into saving life, we would learn something.
• It may provide a benefit. Overall, it may improve medical science.
• Medical progress is based on experimentation. The study sounds like it was well-thought-out. It presented a good argument.
• Science moves forward through clinical trials. I like the long-term benefits.
• The importance of the study is for the greater good. Its benefits for the society outweigh the costs of the individuals.
• The study will help advance the state-of-the-art medical capabilities.
• We need to try new things. If they think that it can increase the level of survival in cardiac patients, then we should try applying the study to prove or disprove the hypothesis.

**It is a good idea/approve**
• Having a trial for research purposes to see if they are effective is a good idea.
• I approve, but I can’t express it because I don’t speak English very well.
• I understand the process of the study and I favor it.
• I’m a nurse and I support the research.
• It sounds like a good idea.
• It sounds like a good idea.
• It sounds like a good idea. It is somewhat better than not getting the treatment.
• It sounds like a good idea. It will increase survival.
• It sounds good. I would be willing to undergo the experiment.
• It sounds promising.
• It sounds reasonable.

**It is important/necessary**
• That is a very reasonable thing. This would be an important improvement.
• I work in public health, so I understand how this study is conducted. I know how important it is.
• I work in the health care industry, and I recognize how well this study works, and how logical and necessary it is.
• It is important to do medical studies. It sounds like this can be only confirmed through this.
• It is important to further the cause of scientific research. The downside risk is relatively low.
• It is important to scientifically test the medical intervention.
• It is very important to study that. It seems it has a low risk for patients.
• It sounds like it’s a good study because it focuses on improving the survivorship of the person during a cardiac arrest. It is an important study. It’s okay that you can do it without consent.
• I have to because it is necessary.
I want to help the research

- I want to help the research.
- I would be willing to help for the survival rate of patients having cardiac arrest.
- It helped the medical researchers.
- It is a good idea to find out if it will increase the survival rate.
- It is to help the research study.
- It sounds like it is dangerous, but I want to be a part of it.
- I don’t have a specific reason. I just want to be a part of the research.
- I like to be a part of it. I like to know more about cardiac arrest and how it works.

I believe in/support research

- I am a nurse. I realize how important it is to have accurate data to support research.
- I am a toxicologist. I am very familiar with the study methods and reviews about what you told me, the human testing and all of the qualifications. I am willing to be part of the study.
- I am in the emergency medical field. I’m happy to advance cardiac science.
- I believe in medical research and studies.
- I believe in research to improve medical care, so I want to take part in it. If there is a chance that I can help, then I would do it. If the sodium nitrite could be helpful, then I would want to have the chance to have it.
- I believe in research. It’s the only way to find a cure for things.
- I support research.
- I used to be a paramedic, and I know what cardiac arrest is. If it can help, then it would be great.

It may help in the future

- Anything can help the future.
- It could be used to help people in the future. Sodium nitrate is safe to take. I wouldn’t mind participating.
- It is to help future patients.
- It may help other people in the future.
- Science is great. I would like to have a better future for the world.
- The chances of me dying are high anyway. If future people would be saved because of this study, then, I am willing to do that.

We should improve medical treatment

- I don’t think it will happen to me. I don’t have heart issues, but life-saving measures need to be improved. You can’t improve life-saving measures without studying.
- I think we should strive to be better and be more efficient. This method of advancing and keeping patients alive is worth a shot. It’s the main reason.
- It is just to get the best care possible. It will improve the previous process.
- It is so that we can learn how to treat cardiac arrest.
- You’ve got to try to do whatever you can do to help somebody, right? If only 8 out of 10 don’t survive, you’ve got to try to increase those odds, right?
• The reason for the response is that I know the medical community is looking for different ways to do things. That is exactly what they should be doing.

No reason to say “No”
• I don't have any good reason to say no.
• I don't see any reason to say no.
• I don't see any reason to say no.
• I have no reason not to do it. I don't see myself having a cardiac arrest in the next 10 years.
• I think it's valid research. I see that I've got nothing to lose by taking part in it. If it advances the research, then I'll be happy to take part.

Can't Give a Reason
• I can't really give any reasons.
• I don't have a specific reason.
• I don't know what to say.
• I just don't know the science behind it in order to give an explicit reason.

Other
• Based on the statement, the individual probably would not survive. All of the normal treatments would also be provided.
• I am 60 years old and I live alone.
• I am familiar with sodium nitrite. It is reasonable to use it for cardiac arrest.
• I am just curious on what the results would be, especially for African American women. Heart attacks and heart diseases are the number one illness for African American women. I am curious to see what the results might be.
• I am not an idiot. We need to have drugs for emergency situations. Sodium nitrite improves survival and has been proven to be safe.
• I am old. I am obese and I am curious.
• I am part of the community. Information gathered about the situation or study would help the government.
• I believe in the scientists and physicians. I trust their judgment.
• I feel comfortable with that procedure.
• I had an aneurysm in my brain 25 years ago.
• I have a weak heart. I don't know if I'm going to die of a heart attack.
• I have been in a clinical study.
• I have experienced cardiac arrest last November.
• I have had high blood pressure since I was about 18 and was put on medication somewhere in my mid-twenties. I currently take four medications for the condition, not including aspirin.
• I know how to do CPR and I'm a nurse.
• I know the scientific method and what the study is doing. It is determining the validity of this process.
• I like sodium nitrite.
• I may have a heart attack.
• I trust the University of Washington to have a human subject review board that is looking into this research to determine that the benefits outweigh the risks of this study.
• I want to see if it really works.
• I work as a researcher and I know what the research is all about.
• I would just want to try the options based on your information.
• I would like to do it. It is not a good thing or a bad thing.
• If it will be approved, it will be beneficial for the study. It could potentially help benefit those who are doing this study.
• If the first respondent came to me and was a professional and I am unconscious, then I would have to go with their opinion as a professional, and their best judgment would be what I would want for me as a patient.
• I'm interested in it.
• It is already a life-threatening situation.
• It is an informative call to inform me about the study. It is important for people to know about this thing.
• It is because of what I have heard. I know all about it already.
• It is because there are family members who care about me whether I am around or not.
• It is important to be ready.
• It is more efficient. It is quicker to do it without consent.
• It is the only way to test the effectiveness of the drug.
• It sounds like a potential solution to a serious problem.
• It sounds like it is already legal to do such treatment for cardiac arrest patients. That part of it is already decided by the FDA and American physicians.
• It sounds like it is better than doing nothing.
• It's good to know stuff like this, just in case something like this happens.
• I've been having chest pains a month ago, and so I don't mind.
• I've taken part in a study before. I had brain injury. I tend to trust them. I trust the study.
• My grandfather had a massive heart attack. They have done a lot of research on him. They've learned so much about him in the University of Washington. They have given an additional 10 years to his life.
• My husband died from heart attack.
• People need to try new things.
• Since the study doesn't involve the absence of any existing treatment but only the opportunity for additional treatment, that is why I would support it.
• The concern for it being an emergency is important.
• The medical personnel do not always get to try new medical procedures without prior consent.
• The medical professional knows better than I do.
• The risk of death is very high without it, but the risk of taking the survey is low.
• There is no other way of learning about it.
• We have a history of heart attacks in our family.
• When you are in the situation, it's about saving the life whether you have the consent or not.
Q7. Do you have any additional comments you would like to tell the researchers about this study?

This open-ended question was asked of all respondents at the end of the survey. One hundred and thirteen respondents provided a final comment. All comments appear below, categorized by subject matter.

**No comment:** 287 respondents

**Good wishes/Support the research**
- It is a very cool study. I would just like to tell them that I want to have a consent from my physician before I make any decisions.
- It was okay.
- I just pray that it will be successful.
- I hope it goes well. I hope it will save many people’s lives.
- It is good.
- I trust that their research is to help people and not harm them.
- The biggest thing is that I don’t trust the FDA. I see them approve things that I believe they shouldn’t. As a result, I see a little bit later on that people are dying or having terrible reactions to things that give them a lifelong problem. I trust though the local paramedics, but not the FDA.
- No, I hope it works.
- If it is going to help, please do it.
- This will really benefit our community. We can really learn something from it.
- There are none, just, good luck.
- I know they have to do this in order to find out if it's workable. The only way they can do that is to do this study. I'm in favor of it.
- There is nothing, but good luck.
- It is a very good idea. I would like to see it approved.
- I know most of the important emergency lifesaving techniques in this area. I am in favor of continuing the kind of research we have been doing here.
- They will do their best for the community.
- I think this is a good idea.
- Good luck.
- I hope it will go through.
- Keep up the good work.
- I'm all in favor of research. I have a neighbor who had a walnut allergy. They came here and gave him medication. He's now fine. If we can find things like that, then I think it's good. We live and learn. That's a good thing. It is discovery.
- I hope it would be very successful.
- I hope it would be successful that they can treat cardiac arrest and save lives.
- It is good to have tools. We never know. People may collapse in the road. We need to give a person a chance to be rescued.
- It is a very good study.
• I would like to be part of the research.
• I strongly feel that it should be administered, like the sodium nitrite, in addition to all of the other available treatment.
• It sounds like a good idea to me.
• We need to keep finding and exploring ideas.
• It is a pretty cool idea.
• It is worthwhile. My cousin died last year from cardiac arrest, and so anything that helps is great.
• It sounds like a good idea. I wish them all loads of success.
• Keep going forward. Keep it in position. They have to excel with their plan.
• I hope it goes well.
• It is okay.
• I think this will help other people.
• Our area is known for cardiac arrest study. I am happy to be a part of this survey.
• It is a good idea.
• It could change the way we do medicine. It is great.
• I would like to say, good luck. I wish them success.
• I think it’s a good study.
• I’m just happy to know that there are more things going on out there, like medicines and technology, to fight for survival.
• I would just hope that if they find positive results, they’re going to move towards wider administration to help save people’s lives.
• If there is no research, there is no progress. I trust them so they should do a good job and improve it.
• It is good but people should be aware of the side effects of sodium nitrite.
• As much as the community is concerned about this, they are not the doctors. I trust the physicians who will do the study, not the average community. The physicians should be the one to decide on the study.

Advice to the researchers
• They should be careful of the admitted leverage of the Republicans. Somebody rich and powerful can say this is what I want. The public should know their reason for the approval of a new drug or procedure. They could just want funding for a new medical center or funding for this and that.
• They should probably consider the age of the patient, like a 20-year-old or a 65-year-old dying of a heart attack. The 20-year-old has to live a long way still. There is still a chance of survival compared to the 65-year-old.
• Maybe, they should have it educated in hospitals and not just through telephone calls.
• What could be the negative effects of ingesting this particular sodium nitrite chemical? They should give the people the pros and cons, too, about the possible risks of this.
• Help the people how to find the recipe of the formula to help people who are dying.
• Just don’t overprice it.
• Try a different method. Placebo and sodium nitrate would drive your nervous system up the wall. Some people don’t react to sodium nitrate. It would only save some people. It would be unfair to others.
• Just be 100% sure that the science is right. It could potentially cost lives but just be careful on that end. Be cautious.

• Maybe you should ask about a person's medical condition before you give them information about the study just to make sure they are qualified.

• For the sake of public safety, they should include the geographical area where the study will take place and the duration of the study, like when it is going to get started and be done.

• Their research should be more completely defined so we will know what are the positive and negative effects of it.

• It should be conducted in a hospital setting.

• If this sodium nitrite is shown to be effective in the early rounds of it, I hope that they would adopt it immediately for people whose lives are at risk. I hope that they won't keep giving people placebos just to find more information. If it looks like it is going to work, then they should do it, even if it means spoiling the study and the data. If it saves lives, they should do it immediately.

• They need to do more research. There could be side effects. What happens if they misdiagnose? The key there is they have to diagnose properly to know when to use the sodium nitrite.

• Just from the legitimacy viewpoint, they could send an email or provide us with some website that would provide information. I just don't think phone calls are the best means to make you believe about the study.

• I hope that even with the placebo, everything is being done to help the patient survive.

Wants/needs more information

• I would like to be able to read about this more on the web.

• They could provide written information about the study.

• I want to know who they (the researchers) are.

• I do not know about the drugs. I do not know enough about what is going on.

• I need more information about the study.

• I just want to understand how they would know this is effective. I would like to know more about what they are trying to do with it.

• It does not provide adequate information. The study lacks information. What you have just read doesn't make any sense. I want to know more about it.

• I would want to know the name of the study.

• I need more information about this. I did get information from your side, but I just need more information for this.

• Give us more information. We need more evidence to internalize.

Question About the Research

• There isn't anything really other than I would be interested in knowing if there is another name of sodium nitrite and if it has a common name that it is known by.

• There is just one thing. How do they figure out if sodium nitrite or placebo will work well for a certain patient? How well does it work?

• I don't understand this medication that increases the chance of curing cardiac arrest. Why does half of the people get the medication and half of the people don't? Half of the
people survive and half of the people don't. Is this drug owned by a pharmaceutical company? How much does this cost?

- I just want to know if there are reactions on certain medications that the patients have taken. If they have known patients who have heart issues or are diabetic and they have medications, when they take sodium nitrite, would they have any side effects?
- Will the EMT's training or willingness to use sodium nitrite be affected by the study or is the study merely for data collection purposes and the EMT's training or willingness to use sodium nitrite will not be affected? That is my question.
- If your study shows that sodium nitrite increases survival in patients with cardiac arrest and you give some patients placebo, that would concern me. Why not give all patients sodium nitrite? My concern is that what would be the criteria for giving some patients sodium nitrite and what would be the criteria for giving some patients placebo? Would there be an age range for that? I really don't know if this works in the study. That is my only concern.
- There is nothing. I'm just curious about how they decide who gets the experimental drugs and who gets the placebo.
- If somebody is having a cardiac arrest and needs a shot to help them survive, can the EMT give that shot immediately upon arrival at the person's house? Do they have to wait until they get to the hospital? If the ambulance or EMT person arrives at an emergency situation where a person is having a cardiac arrest, can they give the shot right away, or do they have to wait until they get to the hospital to receive it?
- How safe is it and what are the side effects after the treatment?

Concerns about the placebo

- During emergency cases, there should be no placebo given to patients when at home. When you are in the hospital, there should be a patient consent.
- The risk is too great for this particular study. The patient is not very much informed. No one is there to speak to them of the possible effects because they are unconscious. I have been a heart patient for a number of years. I am highly against a paramedic who will go to my house and conduct a study with me, especially with the placebo. Its effect is uncertain.
- It seems that some will get the placebo material and some may not, which is not fair for some.
- I want this study to have the best possible outcome. They should get rid of the placebo and only use sodium nitrite in helping other people.
- I understand the need for a control group for scientific studies, but there is a question on the idea of administering a lifesaving substance to one group of people and denying another group and giving the placebo.
- Everybody should be given medicine.
- Forget about the placebo because we want the people to live.

Comments on the survey

- You can shorten the study to make it clearer in a shorter amount of time.
- It seems to me that conducting a phone survey for this study is a waste of time.
- It was presented with very good argument. It was presented very clearly.
• I would tell them to reconstruct the questionnaire in a way that the respondents will not be offended. No one wants to have a cardiac arrest.

Opposed to the research
• It can probably add value. I just don't want it tried in my community.
• It is unethical.
• The risk is too great for this particular study. The patient is not very much informed. No one is there to speak to them of the possible effects because they are unconscious. I have been a heart patient for a number of years. I am highly against a paramedic who will go to my house and conduct a study with me, especially with the placebo. Its effect is uncertain.

Consent is needed
• They must get consent before they put the patients into the study group.
• They should have a patient sign a consent about it.
• During emergency cases, there should be no placebo given to patients when at home. When you are in the hospital, there should be a patient consent.

Other
• I do not want to be in a nursing home.
• We were planning to move. Maybe, it is not convenient for them to include me in this study.
• It is funny because sodium nitrite is used to preserve meat and has been listed as a serious carcinogen. However, who cares when you are in an emergency situation? It would be a one shot, one-time thing. You would not be taking it long term, and so it would not be an issue.
• Technically, it sounds very complicated. Researchers are unrealistic.
• There are some people who don’t have the feeling of fear of death. That’s something to be realized or considered, but the goal is to save lives. If this is effective, it will save an individual’s life.
• We have a really good emergency system that has a defibrillator.
• If the professionals say so. Their opinion is what I should be after.
• I don’t know about the study, so, I just go with them on what comes up with the study.
• They could do a few more research studies on it.
• My primary concern is whether it is possibly safe.
• I was wondering where we could buy sodium nitrite and if you could sell it.
• I still believe in the older ways to test the product before putting it on humans. It’s still a hypothesis. I don’t feel comfortable putting ourselves at risk on this.
• They should show people how to eat with nutrients for themselves.
• It is really painful. It would give terrible headaches and stomach disorders. Maybe, it won’t work.
• They can give sodium nitrate or placebo. That is a very interesting approach. The patient might be alert.
• I just want to live long.
• My dad passed away because of cardiac arrest. I wish this was available at the time he had a cardiac arrest.
Appendix D: Respondent’s Primary Occupation

Below is the complete list of respondent answers to Q12. The number in parenthesis following a response indicates the number of respondents who gave the same answer.

Q12: What is your primary occupation?

Accountant (3)
Accounting bookkeeper
Acupuncturist
Administrative assistant (2)
Administrator, nonprofit organization
Admission nurse
Aerospace engineer
Agency
Airport ramp agent
Announcer
Archaeologist
Architect (2)
Associate director, nonprofit organization
Attorney
Auditor (2)
Auto body technician
Banking
Biomedical researcher
Biotechnology consultant
Book seller
Bookkeeper
Business
Business analyst
Business consultant
Business manager
Business Owner (2)
Business owner of a web development company
Caregiver (2)
Cashier (2)
Certified nurse midwife
Certified nursing assistant
Chef (2)
Chemist
Chemistry laboratory assistant
Church organist
Clerk
Client manager
Community volunteer
Computer programmer (2)
Computer repair
Computer scientist
Computer software developer
Computers
Construction supervisor
Construction worker
Construction worker (3)
Consultant (3)
Contractor
Cook
Corporate assistance
Counselor (2)
Data administrator
Data analyst
Delivery driver
Dental assistant
Dental hygienist
Dietary aide
Dietitian
Director in insurance management
Disabled (12)
Dishwasher
Doctor
Educational researcher
Educator (4)
Electrical engineer
Electrician (2)
Engineer (12)
Engineering
Environmental planner (2)
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<th>Occupation</th>
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<td>Research scientist</td>
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<tr>
<td>Research technologist</td>
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<tr>
<td>Researcher (2)</td>
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<tr>
<td>Restaurant manager (2)</td>
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<td>Statistician</td>
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<td>Vice-president of a not-for-profit organization</td>
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<td>Wine sales</td>
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