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Protecting study participants in emergency research: is community consultation before trial commencement enough?

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ABSTRACT

Background This article presents the results of a community consultation (CC) process completed in Toronto, Ontario, using a random digit dialling technique, on the attitudes and perceptions of the public toward the use of exception from informed consent when conducting emergency research involving the use of massive blood transfusions.

Methods In 2012, our hospital conducted a CC, using a random digit dialling technique, to elicit the attitudes and perceptions of the public toward the use of an exemption from informed consent for an upcoming clinical trial. A total of 500 participants from high violent crime areas were interviewed as part of this consultation.

Results The response rate for the telephone survey was 54%. Participants indicated a personal acceptance rate of 76%, acceptance of the justification for the exception to consent at 81%, thatthe study would meet the best interest of patients and the community at 81% and that youth (between 15 and 18 years) could be enrolled at 71%. When offered, no participant requested an opt-out wrist band to avoid being enrolled in this study.

Discussion The use of violent crime neighborhoods to locate at risk communities was not effective in identifying the appropriate community of interest for this study. Though only representing a small subpopulation from a large Canadian city, the attitudes noted here is suggestive that Canadians may have a similar level of acceptance as the US based on published studies. However, given the resources needed to undertake this process and that in the end it did not elicit any useful feedback or recommendations for enhancing the safety of participants, the future use of phone surveys as a means of engaging communities should be reconsidered.

Level of evidence (Level V) This is a retrospective subanalysis of a CC using a randomized phone dialling technique from a site prior to the start of the Pragmatic Randomized Optimal Platelet and Plasma Ratios Trial. The CC was not designed specifically for research purposes and as such reflect only a case study from a single center.

Trial registration number Pre-result, NCT01545232.

INTRODUCTION

Emergency research is needed to advance clinical knowledge and evidence in support of providing new therapies and treatments for patients requiring emergent care.[1 2] However, research conducted in an emergency context is challenged when it involves patients unable to provide consent due to the following factors: the inherent and often traumatic circumstances resulting in a loss of decisional capacity for the potential research subject, the time-sensitive requirement for actually initiating many emergency therapies and the lack of access to a legally recognized substitute decision maker to provide timely consent.[3] The confluence of the above circumstances necessitates the considered use of study protocols that enable research to proceed with exception from the usual written first person or surrogate consent.

Since 1996, the US regulations (Rule 21 CFR 50.24)[4] have stipulated that approval to conduct emergency research requires that a two-part formal community engagement process be undertaken prior to a start of the study where exception from informed consent (EFIC) research is being planned. One form of engagement involves a public disclosure process of the planned research activities in a community; the second involves a community consultation (CC) process to ensure the affected (by disease group or geographical catchment area) community is provided with an opportunity to make known their comments and concerns prospectively. A CC is meant to be a two-way process designed to take into account community attitudes and cultural beliefs regarding the specific research project being considered.[5 6] It was envisioned that the CC process could provide study investigators and the research ethic board/institutional review board with potentially meaningful input into its deliberation concerning the appropriateness of conducting the study within that particular community.

Canadian-initiated emergency research, approved by Health Canada, relies on the Canadian Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans[7] for guidance on the requirements and appropriate use of a waiver or deferral of consent model to enroll research subjects into clinical trials. The Canadian guidelines do not include a stipulation that a CC be required for emergency research studies using EFIC. Studies originating in the USA and regulated by the Federal Drug Administration (FDA), but open to enrollment in Canada, will often request that Canadian sites undertake a CC as part of the ethics approval process;however, the decision is left to the discretion of the local ethics board as to whether a CC is required for local approval. A comparison of the US and Canadian regulations pertaining to the studies involving EFIC is presented in table 1.

Though CCs for emergency research protocols have taken place in Canada, there is lack of studies addressing its effectiveness in capturing

Table 1 Regulations governing EFIC Studies

Criteria	United States 21 CFR 50.24 (1996)[4]	Canada TCPS2 (2014)[7] Chapter 3
Terminology	► Exception from informed consent (EFIC)	► Exception from consent
Medical condition	► Life threatening	► Serious compromise to health
Capacity	► Lacking	► Lacking
Risk	► Reasonable to what is known about the underlying medical condition of the class of subjects, the risks and benefits of standard therapy and what is known of the intervention itself	► Not greater than standard care or clearly justified by the benefit
Standard of care	► Available treatment unproven or unsatisfactory ► In need of evidence to determine safety and efficacy	► No standard efficacious care exists
Intervention	► Hold prospect of direct benefit to subject ► Study cannot be carried out without waiver	► Must address needs of the patient ► Must offer realistic potential for direct benefit over standard of care
Surrogate decision maker	► Timing prevents surrogate consent ► Must indicate therapeutic window for intervention ► Outline plan to contact SDM	► Document all attempts to contact SDM
Pre-clinical trial data	► Animal and other pre clinical data has been considered and completed	
Advance Directives		► No prior directives
Prospective consent	► Cannot be determined ahead of time	► Cannot be determined ahead of time
Public Disclosure	► Required dissemination of information to communities, and the public prior to initiation of the study	
Community Consultation	► Consultation with representatives from community where the research is conducted and from the population of potential subjects	► If feasible and appropriate, consultation with former or prospective patients and additional expert review
Misc. Requirements	► Public disclosure prior to and after trial ► Provide IRB details at each continuing review ► Show requirements for informing participants and SDM ► Keeping related records for 3 years ► Allowance of refusal from any family member	

potential Canadian study participants and their attitudes and perceptions toward this issue. Our study has two main goals: (1) to evaluate the representativeness of a CC method undertaken for a US-led multicenter clinical trial involving Canadian bleeding trauma patients; and (2) to describe the attitudes and perceptions of a community in Toronto toward this EFIC research protocol

METHODS

This is a retrospective subanalysis of the CC results from the Canadian site of the Pragmatic Randomized Optimal Platelet and Plasma Ratios (PROPPR) Trial.[8] The PROPPR study was a Phase III trial designed to evaluate the difference in 24-hour and 30-day mortality among subjects predicted to receive massive transfusions. The goal of the PROPPR study was to analyze the effectiveness and safety of transfusing patients with severe trauma and major bleeding using plasma, platelets and red blood cells in a 1:1:1 ratio compared with a 1:1:2 ratio. The study sponsor stipulated that Canadian participation in this study would require our site to use the same CC process outlined in the FDA regulations to involve potential at-risk citizens from our trauma catchment area prior to the initiation of the study. A private research company (Hebert Research) was contracted to conduct phone surveys using a randomized digit dialling (RDD) technique based on a set of postal codes provided by our center. The design of the RDD process utilizes a technique that makes random calls to various homes within the prescribed catchment area for the consultation—based on a rotating sequence of daytime, evening and weekend timeframes and a prescribed number of repeat calls to homes where no response to the calls were initially recorded.

Survey development and implementation

The RDD CC process involved the use of a phone survey script (which was provided by the US study sponsor) that consisted of a detailed initial preamble explaining the reason for and nature of the PROPPR study and how EFIC may be initially needed to enlist participants. The survey consisted of 15 questions in total. Seven questions solicited the participant's input on their level of understanding, and theoretical support for the research per se and the use of a waiver of consent specifically, and eight descriptive questions to elicit the demographics of the survey participants (survey as online supplementary file). In addition to the above series of questions, those who completed the survey were informed of and offered a means to 'opt out' of the proposed study by the use of a special wrist band,which was created specifically for this study. The participants were informed that during the trial recruitment period, any individual wearing this wrist band would be considered to have declined (refused consent) participation in the study.

CC population

The actual catchment area used to identify participants for the CC was analyzed in collaboration with the Toronto Police Services using their census data on most violent neighborhoods (defined by number of shootings and stabbings) as the target population for this study. The Toronto Police Services provided our research team with the postal codes of 'risk areas' and based on a closer review of this data, using our hospital's trauma registry, it was analyzed that these areas represented a 54.74% incidence rate, defined as the number of actual trauma cases per total number of people at risk during a specified time.

Study outcomes

The main study outcomes are: (1) the proportions of CC and trial participants by age group, gender, ethnicity, educational level, type of trauma and matching postal codes; and (2) the acceptability and beliefs of CC participants toward the proposed EFIC research protocol.

Statistical analysis

The sample size calculation, used to analyze the number of participants needing to be included in the RDD was based on achieving a margin of error based on a confidence level of 95%. The formula, used by Herbert Research, to calculate the margin of error where n is the sample size, is: $1.96\sqrt{0.5(1-.05)}/n = 0.98/\sqrt{n}$.

A series of multivariate analysis was conducted to examine differences among respondents according to groupings defined by age, gender, education level, ethnicity and income. The significant differences were reported, tested using the 0.05 level of significance as the criterion value for the χ^2 analysis. A finding of no significance was also reported; however, a statistical test to examine differences was not performed. Among the statistical significant results, Cramér's V values were calculated to describe the strength of the association between the variables.

Canadian trial enrollment data

During the Canadian enrollment phase of this study, a log was maintained of all participants, documenting the actual age, ethnicity and postal code information of all enrolled subjects to compare with the CC demographics.

RESULTS

The CC data from the Toronto phone surveys were collected in August of 2012. To obtain a targeted sample of 500 participant surveys, a total of 933 calls were required to individuals living in the selected catchment areas (overall response rated 54%). Only individuals over the age of 18 were asked to complete the phone survey.

Table 2 provides the demographic information for both the individuals who participated in the CC phone surveys and the

Table 2 Demographic Data of Community Consultation participants and actual

Characteristics	CC Group N=500 %	Actual Participants N=26 %	P value*
Age			
Less than 18	NA	15	NA
18-24	11	27	<0.01
25-34	19	15	0.80
35-44	18	4	0.06
45-54	19	8	0.45
55-64	14	12	1.00
Over 65	18	19	0.79
Gender			
Male	47	73	0.01
Respondent Ethnicity			
Caucasian/ White	76	35	<0.01
Black	4	23	<0.01
Asian	9	23	0.03
Latin American	1	8	<0.01
Mixed Race	2	NA	NA
Other	4	NA	NA
Respondent Educational Level			
Less than 9th Grade	1	NA	NA
9th to 12th Grade	5	NA	NA
High School Graduate	19	NA	NA
Associate's/ Technical/Vocational	17	NA	NA
Bachelor's Degree	34	NA	NA
Post-graduate Degree	20	NA	NA
Refused to Respond	4	NA	NA
Mechanism of Trauma			
Gunshot/ Stabbing	NA	46	NA
Motor Vehicle	NA	23	NA
Pedestrian	NA	8	NA
Fall	NA	12	NA
Other	NA	11	NA
Within Prescribed Postal Code			
Participants by postal codes	100	27	<0.01

*Chi square or Fisher's exact test used when appropriate; p<0.05 considered statistically significant

Table 3 Summary results of the CC process

	Yes (%)	No (%)	Don't Know/ Refused(5)
Would you find it acceptable to be enrolled with delayed consent?	76	12	11
Do you feel this exception to consent is justified?	81	9	10
Do you believe the research is in the best interest of the patients and community?	86	7	6
Do you think it is appropriate to include children 15-18 in the study?	71	20	9

actual trial participants. As indicated in the methodology section, the CC sample was statistically weighted by age and gender to ensure the sample's statistics more accurately represent known population parameters based on a near perfect reflection of the 2010 Canadian Census data.[9] The reported frequencies for education, ethnicity and income are unweighted.

Outlined in table 2, our analysis revealed significant differences between our CC population and actual trial participants with respect to trauma mechanism, age, gender and ethnicity. The trial cohort had higher proportions of penetrating traumas, males, of participants younger than 24 years of age and higher percentages of Black, Asian, Latin American and mixed race participant. Of note, approximately 27% of the trial population met the prescribed postal code used in the CC.

As part of the CC RDD process, a script of the basic study intent and design was read out, and each respondent was asked if, based on the information provided, they understood what the study was about, and 100% self-reported that they understood the purpose of the study. However, it should be noted that their actual level of understanding was not test verified by the interviewer.

The overall summary of the CC results are presented in table 3. Seventy-six percent of the respondents stated that they would find it acceptable to be personally enrolled in the described study involving the use of an independent physician authorization (IPA) process and a delayed consent (EFIC) study design. Eighty-one percent think EFIC would be justified given the type and nature of the study parameters, and 86% stated they thought the research would be in the best interest of the patient and community. Seventy-one percent of respondents stated they approved the enrollment of youth between 15 and 18 years old into the study.

Table 4 outlines the results of the multivariate analyses completed on question 1: acceptability to be enrolled in this study, and question 4: approval of youth (15–18 years old) to be enrolled in this study. On the question of acceptability to be enrolled in this study, the largest divergences were men responding 'yes' 9% more than women, and women responding 'don't know' 8% more than men. Based on a Cramer's V of 0.154, it would suggest 15% of the variances in response to this question can be explained by gender. The multivariate analysis on question 4 also revealed differences between how men and women answered this question. Notable differences are that men answered 'yes' 9% more than women, and women answered 'no' 7% more than men on the issue of approval of youth (15–18 years of age) to be enrolled in this study. A Cramer's V of 0.127 suggests that gender can explain 13% of the response to this question. Multivariate analyses were conducted on the results from question 2: belief in the justification to use EFIC, and question 3: that the research is in the best interest of the patient and community. No statistically significant findings emerged, suggesting that these demographic variables are not related to respondents' feelings on the justifiability of persons being enrolled with delayed consent or that the research is in the patient and community's best interest.

DISCUSSION

Based on the demographic profile used to initially analyze the community of interest versus the patients actually enrolled into this study (at the level of gender, ethnicity and source/type of traumatic event), reliance on the use of police data on reported neighborhoods with high rates of violent crimes proved to be a poor community representation for soliciting CC input in this case. A paucity of research is available to support strategies for identifying a truly representational sample of a community for the purposes of CC.[10] These findings might be explained by several factors. First, the PROPPR trial was designed to enrol patients with significant haemorrhage, which is most frequently associated with penetrating trauma (gunshot/stabbing). Accordingly, the most violent neighborhoods in our community where

Table 4 Multivariate Analysis on the impact of Gender on (1) Participant Acceptability to be Enrolled in this Study and (2) Approval of children 15-18 to be enrolled in this study

Multivariate Analysis (1)- Acceptability of enrollment in this study		
Response	**Male %**	**Female%**
Yes	80.5	71.6
No	12.3	11.7
Don't Know	7.2	15.2
Refused	0	1.5
p 0.008		
Cramér's V 0.154		
Multivariate Analysis (2) - Approval of children 15-18 enrolled in this study		
Yes	75.4	66.7
No	16.1	22.7
Don't Know	6.8	10.2
Refused	1.7	0.4
p 0.046		
Cramér's V 0.127		

penetrating trauma would most likely occur were identified. However, although targeted violent neighborhoods would potentially identify the desirable population, the association of land phone utilization and willingness to participate in surveys among this population were difficult to predict in advance. Second, due to the random nature of the telephone survey and skewed distribution of Caucasians based on Canadian census data, one could expect to find fewer representation from other ethnicities. Finally, current societal trends in rising cell phone utilization only versus land lines among young people might have also affected the demographics of our CC population.

The Toronto, Ontario CC indicated a 76% personal acceptance rate for considered enrollment into this study. This is comparable with results reported in a 2014 systematic review of studies undertaken in the USA, where personal acceptance rates for emergency research using EFIC clustered in the 64% to 80% ranges.[11] However, simply comparing reported CC results between sites is challenging, given the various types of CC processes actually used, as well as the different types of populations that were engaged (ie, a general community response vs responses from specific and highly affected communities). CCs can be undertaken using a variety of methods: researchers attending standing committee meetings, presentation at special public meeting, the use of social media and interactive websites, face-to-face interviews, focus groups, as well as the RDD surveys used in our study.[12] Each method offers specific strengths and advantages as well as limitations. RDD surveys, though more cost effective than the other methods listed above, are limited as a technique to only being able to reach participants with land lines and, in general, is not conducive to deeper levels of engagement to ensure the more nuanced understanding that comes from the resource intensive face-to-face sessions.[13 14] RDD surveys can provide notification and opportunities for a community to provide input into these studies; however, given the inherent epistemological restraints previously noted this method may only be able to elicit an emotional or 'gut feeling' response to the more generic concepts of using EFIC in emergency research situations.

A unique feature of Canadian emergency research studies using EFIC for enrollment is the use of an independent physician authorization (IPA) model as a final screen prior to enrollment of a patient into a study. The IPA's role is to simply confirm the patient's eligibility for enrollment and to verify that appropriate attempts have been made to contact the substitute decision maker. The IPA is usually a physician, knowledgeable in emergency medicine and not personally involved in the study under consideration. The effect of adding the IPA components on the attitudes of Canadians participating in this CC, and in attempting direct comparison of results between a Canadian and US site, is difficult to quantify.

In addition to the CC process eliciting personal attitudes and acceptance level toward participating in the study, the participants were also asked to weigh in on the general acceptability of the study design and the appropriateness of using EFIC. In this study, 84% of participants stated that EFIC design was appropriate for the study in question. A review of the literature noted a large range of responses to this question, 30% to 84%, indicative of either potential methodological concerns (framing and language used in the questions themselves) or as a result of contextual variations based on the actual communities consulted or the types of research being considered.[15–18] Interestingly, a multisite study using a single RDD questionnaire across five US cities reported an overall acceptance rate that ranged only between 70% and 79% for a US Resuscitation Outcomes Consortium study, indicating a tighter response can be expected when identical tools are used.[19] Participants were also asked if they thought this study was appropriate for conduct in the proposed community and in the best interest of the patient—86% responded affirmatively. In the literature, the range of responses for a similar question ranged in the 74%–96%.[16 20–22] These results further substantiate that Canadian attitudes and acceptance rates are in line with data published from similar US studies. The Canadian study also asked about the acceptability of enrolling younger participants (15–18 years old) and found that 71% of participants found this acceptable, suggesting a supportive but more conservative level of acceptance when considering younger patients.

A multivariate analysis was conducted on the survey results to analyze what correlations gender, ethnicity and location might have on the reported attitudes and acceptance rates. A gender correlation (only) was noted in two of the CC questions: personal acceptance for enrollment and approval of younger children into the study. In both case, males were more likely to agree to acceptance for enrollment into the study than their female counterparts.

The CC survey also provided participants with an opportunity for qualitative data to be collected to better understand the reasoning for their responses to the primary questions outlined in table 3. Of the 9% of respondents who indicated that EFIC was unjustified, 27% thought only family should analyze if a person is to be enrolled in a study; 17% thought the medical risks of this study to be too high; 14% worry that the pursuits of science will override a patient's safety in this type of study; and 12% stated that they would need more information about the study before changing their opinion. Though limited data is published on this, Nelson and colleagues published an interesting study in 2013 exploring the various reasons individuals cited for wanting to opt out of a hospital cardiac arrest study, and unlike the results reported in our study most of the respondents felt strongly that individual autonomy needed to be exercised when it comes to medical research as a predominant reason for not wanting to be enrolled in a study using EFIC.[23]

All participants of this CC (as well as the general public who may have encountered the community notifications about this study) were offered an opportunity to 'Opt-out', and yet the local trial center reported that no opt-out wrist bands were requested. Similarly after the study closure, the adverse event reports were reviewed, and no complaints were logged from either family members of or trial participants indicating they felt EFIC constituted harm. By comparison, published CC data on EFIC studies conducted in the USA, a small but notable percentage (2%–14%) of respondents actually requested a wrist band to ensure they were not enrolled into the study.[24 25]

LIMITATIONS

The generalizability of the results for this CC process are limited by consideration that it is representative of only a discreet and small subsection of a large metropolitan Canadian city. In addition the authors acknowledge that the content of several survey questions and the inappropriate language used in the script to communicate important aspects of the study will undoubtedly affect the actual level of a participant's understanding and ultimately their response to the questions asked; however, this is a known concern and critique of RDD-based methodologies in general.[26]

CONCLUSION

This study presents Canadian data on the results of a CC process involving the use of an RDD technique. Results

indicate an overall affirming attitude toward the use of EFIC for emergency studies in Canada. However, generalizability of these data is restricted due to study methodological issues. Namely, reliance on 'at risk' geographical areas, based on reports of violent crimes, and the use of national census data for subject selection was found to have poor concordance for CC engagement when compared with the demographics of actual study participants.

The results obtained from the Toronto, Ontario CC process confirmed that in general the targeted community supports emergency research. They also think that it is an endeavour that promotes the best interest of both the patient and the community and that the use of EFIC is justified in these cases. Though inconclusive, and based only on a very cursory review of the literature, Canadian attitudes appear closely aligned with the US when it comes to acceptance data on CC for Emergency Research requiring EFIC to proceed. Though the results of this study were affirming of the research itself at a general level, the CC process itself did not elicit any specific concerns or issues that provided substantive data for either the researchers or the local research ethics board to specifically act on to potentially enhance the ethical conduct of the research.

Contributors All authors contributed equally to this project. BH was the primary author, and all others were involved equally in the review and editing process. All authors have reviewed and agree on the final version being submitted.

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