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Local Media Influence on Opting-Out from an Exception from Informed Consent Trial

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Abstract

Objectives—News media are used for community education and notification in exception from informed consent clinical trials, yet their effectiveness as an added safeguard in such research remains unknown. We assessed the number of callers requesting opt-out bracelets following each local media report and described the errors and content within each media report.

Methods—We undertook a descriptive analysis of local media trial coverage (newspaper, television, radio, and weblog) and opt-out requests over a 41-month period at a single site participating in an exception from informed consent out-of-hospital trial. Two non-trial investigators independently assessed forty-one content-based media variables (including background, trial information, graphics, errors, publication information, assessment) using a standardized, semi-qualitative data collection tool. Major errors were considered serious misrepresentation of the trial purpose or protocol, whereas minor errors included misinformation unlikely to mislead the lay reader about the trial. We plotted the temporal relationship between opt-out bracelet requests and media reports. Descriptive information about the news sources and the trial coverage are presented.

Results—We collected 39 trial-related media reports (33 newspaper, 1 television, 1 radio, and 4 blogs). There were thirteen errors in 9 (23%) publications, 7 of which were major and 6 minor. Of 384 requests for 710 bracelets, 310 requests (80%) occurred within 4 days after trial media coverage. Graphical timeline representation of the data suggested a close association between media reports about the trial and requests for opt-out bracelets.

Conclusions—Based on results from a single site, local media coverage for an exception from informed consent clinical trial had a substantial portion of errors and appeared closely associated with opt-out requests.

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Introduction

Background

Media has been shown to influence public opinion about medical research (1-6). Several case reports indicate that news media can sway public opinion about health-related controversies (7,8) and media coverage increased public interest about a phase 1 pharmaceutical trial (9). For emergency care research conducted under exception from informed consent regulations, investigators utilize media to educate the community and to facilitate required public notification (10,11). However, prior studies have found that only 5-8% of the population was aware of an exception from informed consent project on-going in their community (12,13).

Because research subjects cannot consent prior to enrollment in exception from informed consent trials, many institutional review boards (IRBs) require investigators to offer a mechanism for individuals to prospectively opt out (though this is not required by federal regulations). The opportunity to opt out is dependant upon awareness that the trial is ongoing, which, at our site, was primarily accomplished through local media coverage. For a member of the community, the decision to opt-out hinges on knowing that the trial is on-going, fearing enrollment in the trial, and having the contact information to reach investigators. It is possible that some element of what people read or hear in media reports triggers a reaction strong enough to drive requests to opt out of the trial, though it is also possible that simply knowing about the trial (regardless of the language used) prompts community objection.

Importance

Investigators designing exception from informed consent trials frequently use the media to educate and notify the community about such trials, yet there is little objective data about how such media may influence public behavior. It is possible that the timing, content, and accuracy of trial information conveyed through news media influence public perception about these trials, plus individual behavior (e.g., the desire to opt out). Data about whether the media may influence public behavior and the accuracy of media reports regarding exception from informed consent trials may help guide investigators in communicating with the media.

Goals of this Investigation

In this study, we evaluate local media coverage of an exception from informed consent trial and seek to characterize the media reporting of the study and its temporal relation to requests to opt out of the trial.

Methods

Study Design

This was a qualitative analysis of all local media coverage for an exception from informed consent out-of-hospital trial at one clinical research site over a 41-month period (September 1, 2004 through January 31, 2008). This period covered the creation of the multisite research consortium (described below), clinical trial design, community consultation and public notification phases, as well as the first 12 months of trial enrollment. Data collection for this study was stopped after the first 12 months of the trial because the majority of media coverage and opt-out bracelet requests occurred during the pre-trial period and the first 6 months following initiation of the study (i.e. fewer than 2 bracelet requests per month after the first 6 months of enrollment). All local media coverage about the clinical trial and research consortium was included. National media coverage was included in a secondary

analysis, but only as it related to local bracelet requests at the single study site. The IRB at Oregon Health & Science University (OHSU) approved this study.

Setting

The Resuscitation Outcomes Consortium (ROC) is a research network formed to conduct out-of-hospital controlled clinical trials on patients presenting with life threatening trauma or cardiac arrest (14). ROC clinical trials function under exception from informed consent regulations (21 CFR 50.24). The first ROC study involves the use of hypertonic saline (with and without dextran) versus normal saline as an early, field-based resuscitation fluid in patients with severe traumatic brain injury or hemorrhagic shock (15). The media analysis was conducted at one of the 10 ROC study sites (Portland, Oregon/Vancouver, Washington) during the ROC hypertonic saline and dextran clinical trial. This study site includes all communities served by emergency medical service providers in a four-county region containing urban, suburban, rural, and frontier areas, with a total population of approximately 1.75 million people (14).

At the request of local IRBs, the public could request opt-out bracelets for the trial beginning at the public notification phase (i.e., after final IRB approval of the study), several months before the trial was initiated. The intent of the bracelet is to prevent enrollment in the trial, should the wearer become eligible. Bracelet availability was mentioned in all press releases following final IRB approval of the study, letters to the community (e.g. neighborhood associations, city and government officials, community leaders), and the local Portland ROC website. Any community member age 15 or older (the minimum age for enrollment) within the 4-county study region (i.e. Clackamas, Clark, Multnomah and Washington counties) could request an opt-out bracelet by calling the study coordinator and providing a United States Postal Service mailing address. Callers could request bracelets for themselves and for immediate family members (i.e. spouse, or children at least 15 years old). Callers were not permitted to request bracelets for general distribution (e.g. to co-workers, neighbors or other groups).

The opt-out bracelets are adjustable and made of stainless steel, resembling “medical alert” tags. The bracelets are inscribed with the words “NO STUDY”, indicating that the wearer does not wish to be enrolled in any out-of-hospital exception from informed consent trial. Although there was only one trial being initiated during this time period, investigators anticipated future exception from informed consent trials for which the same bracelet could be used. As part of the emergency responder training for the trial, EMS providers were instructed to look specifically for a bracelet before enrolling a patient.

Selection of Media Reports

The OHSU News and Publications Department circulated news releases about the research consortium and hypertonic saline and dextran trial. All news releases were reviewed for accuracy and were distributed to a commonly used list of 100 reporters and editors in the metropolitan region. Recipients included a broad range of large distribution newspapers, minority papers, community newspapers and newsletters, as well as radio and television stations. All five news releases were also available to the public at the university's website. Reporters were invited to contact investigators through the OHSU News and Publications Department for further inquiry. A press conference was held immediately before initiation of the trial.

All pertinent local newspaper, radio, television and internet coverage was collected by the investigators and by OHSU's News and Publications Department over the 41-month period. To ensure that they had found every mention of the trial in the news media, this information

was corroborated by tracking OHSU's clipping services (private companies that contract with the media department to monitor all audited media publications statewide), web-based news sites, statewide television service, and radio coverage in the metropolitan region. The single non-English language article was translated by an independent translator. Media releases were gathered through an exhaustive search using the on-line archives of news outlets with the highest nationwide distribution (top 15 news sources), local distribution, and a general internet search engine. Search terms used included "hypertonic saline study," "trauma trial," "resuscitation outcomes consortium," "ROC trial," "ROC hypertonic saline," "research without consent," and "exception from informed consent trial."

Data Collection

Investigators developed a standardized media assessment and data abstraction tool for media coverage related to the trial. Coding of media content (described in detail below) was based on a gestalt of phrases and ideas, rather than specific code words (8). The data collection tool was pilot tested by two reviewers using newspaper articles that had been published at another ROC site (San Diego, CA), allowing adjustments to ensure appropriate definitions for each variable, consistency between reviewers, and clarity in the data collection instrument. Each media piece was transcribed and then independently graded by reviewers, both of whom were not directly involved in the ROC network. Following comparison of the reviewer assessments and data abstraction, reviewers met to discuss and resolve discrepancies before compiling a final database. A third reviewer mediated final resolutions for discrepancies that could not otherwise be resolved. Mediation was required only in two categories: "author's bias/tone" (12 articles mediated) and "degree to which presentation of information was scientific vs. editorialized (3 articles mediated)."

Measurement

Six categories of media content were used, including: background, clinical trial, graphics, errors, publication details, and assessment of writing style. Contained within these media content categories were 41 detailed variables (Table 1). Of note, the term "author bias" as used in this context is distinct from "statistical bias." "Author bias" is used to describe the tone or editorial angle used by the reporter, which may be used either to promote or decry the study topic. Because the written word is subject to interpretation, reviewers were deliberately conservative in assessing author bias; only articles perceived to be unequivocally "biased" either in favor or in opposition of the research were categorized as other than "neutral."

Errors were categorized as "logistical" (e.g., a wrong contact phone number or incorrect trial start date), "ethical" (e.g., error in approval process, legality, or rationale behind exception from informed consent research), "content" (e.g. error in the clinical trial study objective, purpose of the study, description of fluid), or "protocol" (e.g., error in timing of study, who participates, opt-in vs. opt-out). Each type of error was further classified as either "major" (a serious misrepresentation of information, misleading the recipient) or "minor" (error in semantics or wording, leaving recipient unlikely to misinterpret the main intent or mechanics of the study based on the error).

Outcome Measures

The primary outcome was the total number of callers requesting opt-out bracelets over the time period. Calls were grouped into weeks (rather than considered daily) for clarity of graphical representation, however the timing of calls (by day) following the date of specific media coverage was also tracked. We also calculated the total number of opt-out requests (plus total bracelets) occurring up to four calendar days after each media report. Four days was chosen *a priori* to provide a reasonable time window during which individuals exposed

to a specific media report may call to request a bracelet based on information contained in the report (e.g., for calls placed on a Friday, the resulting discussion about opt-out bracelets may not have occurred until the following Monday). This time window was supported by 15 months (public notification and initial trial enrollment period) of tracking prospective local media coverage, monitoring the timing and volume of subsequent opt-out calls, and through informal interviews with opt-out bracelet requesters. The date recorded for bracelet requests represented the date bracelets were mailed to the caller. A secondary outcome for the study was the number of bracelets requested (each caller may have requested more than one bracelet, potentially representing people who would otherwise have been individual callers).

Data Analysis

To describe media content, errors, and timing, all media reports over the 41-month period were included and assessed using descriptive statistics (median, interquartile range, and proportions). The database was maintained using Microsoft Access 2000 and statistical analyses were performed using SAS (version 9.1; SAS Institute, Inc., Cary, NC).

Results

A total of 39 local media reports were collected during the 41 month period, including 33 (85%) newspapers or newsletters, 4 (10%) weblogs, one (3%) television broadcast that aired twice on local news, and one (3%) radio announcement that aired five times. One additional television report was aired, but excluded because no copy was available. Length of media reports ranged from 183 to 2,197 words (median 498).

Most (90%) of the articles mentioned that an exception from informed consent would be used in the study and noted the federal rule allowing for such research (82%), while only 64% explained the background information behind these regulations. The ethical considerations involved in doing this type of research were cited in 13% of media reports. The effects of trauma on the individual were discussed more often than the public health implications of the trial (23% vs. 5%). Fifteen percent quoted experts in support or in opposition to the research. Descriptive characteristics of media reports are summarized in Table 2.

Thirteen errors were found in 9 (23%) publications, including 7 major and 6 minor errors (4 content, 3 ethical, 1 logistical, and 5 protocol). Errors were primarily found in mainstream news sources (i.e. major newspapers and a television news broadcast). No errors were found in alternative internet news sources, smaller distribution papers, or newsletters. Articles with large author bias against the research tended to have more errors. Sample text of errors found in media reports is listed in Table 3.

During the 16 months that bracelets were available, there were 28 (72% of total) media reports and 384 requests for 710 opt-out bracelets. Three hundred ten (80%) requests for 578 (81%) bracelets were made within four days of local media coverage about the trial (although only 16% of the days were within four days of a media event). No duplicate names or addresses were given by bracelet requesters. A median of 47 (IQR 38 – 106) bracelets were requested up to four days after media coverage. Figure 1 demonstrates media coverage of the trial and bracelet requests over time. Letters to community leaders and neighborhood associations were mailed once during community consultation and once during the public notification phase. Inclusion of the additional national media reports (n = 6) did not suggest a relationship between opt-out bracelet requests and national media coverage (data not shown).

Limitations

These findings are limited to a single site participating in a multisite research consortium. Consequently, results are based on a modest sample size of local media articles and bracelet requests. In addition, media coverage is frequently triggered by sentinel articles that are picked up by other media outlets, suggesting correlation (clustering) between certain media reports. Such clustering of articles may have also affected opt-out bracelet requests, a possibility that is suggested by the figure.

Secondly, because we did not ask callers to identify how they had heard about the trial or what prompted the call, it is possible that some of the apparent associations between the media content and opt-out requests represent surrogate measures of other factors influencing such requests (e.g., penetration of trial information through the news media and other sources). We have previously demonstrated associations between socioeconomic factors (e.g., individual beliefs, sociodemographic and cultural factors), geospatial location in the study region, and opt-out requests (16). As this study was not designed to investigate individual views about the trial or exception from informed consent studies in general, prospectively collected data from individuals requesting to opt-out of such trials would add substantially to our findings.

Discussion

Our results suggest that the content and timing of media reports for an exception from informed consent trial are associated with requests to opt-out of the trial. The findings also demonstrate inaccuracies in such media coverage. Prior research examining health and medicine, as reported in the popular press, has documented a tension between science and news media (1,7,17-21). Specific to research, one author noted the presence of negative media statements and attitudes towards clinical trials (22). The same study found that people who reported unwillingness to participate in medical research cited media “stories” as a common source of concern (22). Others have commented that media reports of new biomedical developments often exaggerate findings and have the potential to mislead the reader (23,24). To our knowledge, the link between media content, public behavior, and the decision to participate in emergency care research has not been previously demonstrated. These findings should be considered when developing press releases for future exception from informed consent trials.

We noted that several media reports referenced a recent controversial exception from informed consent study assessing a blood substitute in hemorrhagic shock. A trial of the blood substitute PolyHeme® (Northfield Laboratories, Inc., Evanston, IL) was proposed (but not conducted) two years earlier in the same region with negative press and public opposition. Several of the errors in the media coverage for this trial either directly confused the hypertonic saline study with PolyHeme® (25) or could have easily caused the lay reader to recall the PolyHeme® trial and opposition to it (26). Media coverage may have intentionally heightened confusion between the controversial blood substitute trial and the current “salt water solution” trial for dramatic effect, to the detriment of public opinion about the actual proposed trial.

The close timing between media coverage for the trial and opt-out requests could be interpreted as an indication that the public was effectively notified of the research, a portion of whom acted on the opportunity to opt out. *If* some subset of the population will always want to opt out of exception from informed consent trials, then effective community notification (e.g., media coverage) *should* lead to increased opt-out requests. Opt-out requests during community notification processes might be considered one marker of

successful community notification (provided the contact information to opt out is included in such notification), with the caveats that some communities may have inherent propensity (or lack thereof) for declining participating in such research, and some research projects may invite more or less public controversy and opposition.

Based on the proportion of errors in the media coverage for this trial and selective inclusion of media content, one might also consider media coverage as an inadequate mechanism to notify the community about such research. If this is the case, then reasonable alternatives should be considered, including the development of clear goals for community consultation and public notification processes in these trials (11,27,28). Further clarification and development of tangible goals for community consultation and notification in emergency care research may better guide the delivery of trial information to the public. Our findings suggest that current media coverage is not standardized and contains substantial errors, the impact of which is unknown. Alternatives are equally challenging, yet deserve consideration. For example, direct communication (e.g., via mail or phone) with each household prior to enrollment in the trial may be cost prohibitive and may further restrict the ability to conduct such research, yet creative use of other public media such as advertising or public service announcements may hold possibility.

It is crucial that investigators and reporters strive to present reliable and accurate information about exception from informed consent trials. The public has a right to know about research conducted in their communities, yet it is important to recognize that the content of such media coverage may directly influence public behavior and decision-making regarding participation in emergency care research. As has been previously suggested, the responsibility for good reporting lies not only with journalists but also with the scientific community in communicating with news media (24,29,30). Exception from informed consent researchers and funding agencies might consider budgeting for media training as a means of educating investigators interacting with news media and local reporters covering such research about how to effectively and accurately represent these challenging topics to the public (31).

Conclusion

Local media reports appeared closely associated with requests to opt out of an exception from informed consent trial in one study region. Media coverage for the trial contained a substantial amount of misinformation, errors, and inaccuracies, although the impact of these factors on opt-out decisions made by community members remains unknown.

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Figure 1.
Local media reports and opt-out bracelet requests for the hypertonic saline and dextran clinical trial, by week *

* Plot for total opt-out bracelet requests (rather than phone calls for bracelets) is qualitatively similar to the plot for bracelets (data omitted for clarity).

Table 1**Media content variables.***

<u>Background Information</u> (8):	
EIC background	The federal rule allowing exception from informed consent research
ROC	The structures or goals of the Resuscitation Outcomes Consortium (ROC)
Federal	Federal regulatory bodies, NIH funding, any federal support
Ethics	The ethical considerations or unique ethical nature of exception from informed consent research
Trauma outcomes	General outcomes of patients suffering from hemorrhagic shock or traumatic brain injury (patients who would be eligible for enrollment in the study)
Public health	Use of the words “public health”
Trauma information	Trauma as an important public concern (i.e. number of trauma deaths per year)
PolyHeme® trial	The PolyHeme® (Northfield Laboratories, Inc., Evanston, IL) trial that was considered in Portland and enrolled patients in other US cities [†]
<u>Trial Information</u> (13):	
EIC in this study	The use of the exception from informed consent in this study
FDA/federal approval	The FDA or other federal regulatory body approved the study
Protocol, objective	Objective description of the study protocol
Protocol, editorial	Editorialized description of the study protocol
Trial rationale	How the study will contribute to current medical knowledge or advance science
Blood substitute	Saline solution would be used in this trial to replace lost blood
Experts, opposed	Experts quoted to say they oppose the research
Experts, in support	Experts quoted to say they support the research
Non-experts, opposed	Non-experts (lay persons) quoted to say they oppose the research
Non-experts, in support	Non-experts (lay persons) quoted to say they support the research
Opt-out bracelet	Availability of a bracelet to wear to signify opt-out of the study
Opt-out number	Contact information for how to obtain a bracelet
Opt-out location	Place in the article the opt-out option was first mentioned
<u>Graphical Content</u> (6):	
Graphics	Presence of any graphic associated with a newspaper article
Bracelet	Picture of an opt-out bracelet
Investigator	Picture of a trial investigator
Community member	Picture of a community member
Paramedic	Picture of a paramedic (who would enroll patients)
Study fluid	Picture of a bag of study fluid
<u>Errors</u> (9):	
Content error, major	Major error in the content of the study
Content error, minor	Minor error in the content of the study
Ethics error, major	Major error in the ethics or legality of study
Ethics error, minor	Minor error in the ethics of the study
Logistic error, major	Major error in the logistics of how study is conducted
Logistic error, minor	Minor error in the logistics of how study is conducted
Protocol error, major	Major error in the description of the study protocol
Protocol error, minor	Minor error in the description of the study protocol

Error location	Location of each of above error types within a media report
<u>Publication Information</u> (3):	
Day	Day of the week media report was published or first aired
Forum	Type of media report (newspaper, radio, TV, web, unknown)
Length	Length in words of article or transcribed TV or radio script
<u>Assessment</u> (2):	
Author bias	Author's bias or tone in description of study (strongly opposed, moderately opposed, neutral, moderately in favor, strongly in favor)
Editorialization	Degree to which media report gave facts versus editorialization about the research study (mostly facts, both factual and editorialized content, mostly editorialized)

* Abbreviations include: exception from informed consent (EIC), Resuscitation Outcomes Consortium (ROC), Food and Drug Administration (FDA)

[†] Safety and efficacy of PolyHeme® in hemorrhagic shock following traumatic injuries beginning in the pre-hospital setting [homepage on the Internet]. Northfield-Laboratories July 31st, 2006 [cited June 18, 2008]. Available from: <http://clinicaltrials.gov/ct2/show/NCT00076648>

Table 2

Content in media reports for the hypertonic saline and dextran out-of-hospital clinical trial.

Variable*	Media Reports (n = 39)	
Background information		
EIC background	25	64.1%
ROC	20	51.3%
Federal	32	82.1%
Ethics	13	33.3%
Trauma outcomes	9	23.1%
Public health	2	5.1%
Trauma information	24	61.5%
PolyHeme® trial	4	10.3%
Trial information		
EIC in this study	35	89.7%
FDA/federal approval	27	69.2%
Protocol, objective	33	84.6%
Protocol, editorial	2	5.1%
Trial rationale	17	43.6%
Blood substitute	11	28.2%
Experts, opposed	2	5.1%
Experts, in support	4	10.3%
Non-experts, opposed	1	2.6%
Non-experts, in support	0	0%
Opt-out bracelet	23	59.0%
Opt-out number	20	51.3%
Graphics	4	10.3%
Errors		
Content error, major	3	7.7%
Content error, minor	1	2.6%
Ethics error, major	1	2.6%
Ethics error, minor	2	5.1%
Logistic error, major	0	0%
Logistic error, minor	1	2.6%
Protocol error, major	3	7.7%
Protocol error, minor	2	5.1%

* Exception from informed consent (EIC), Resuscitation Outcomes Consortium (ROC), Food and Drug Administration (FDA)

Table 3

Text or description of media errors, categorized by error type.

Text or Description of Error	Error type
"Now with the experiment of hypertonic saline, survival rates would be improved for those patients with severe trauma."	Content, Major
"So this is a wonderful opportunity for a blood substitute."	Content, Major
"The trial research will replace the use of traditional blood."	Content, Major
"[The] test will evaluate a new type of saline solution that paramedics give intravenously to badly injured patients in place of highly perishable blood."	Content, Minor
"[The university] is about to ... pull off yet another public fraud."	Ethical, Major
"... waived consent ..." (four times in article)	Ethical, Minor
"... waived consent saline study ..."	Ethical, Minor
"... paramedics will chart how trauma patients fare when given a saline solution of a higher concentration than in normal treatments."	Logistic, Minor
"You need to get a free medical alert-type bracelet that paramedics are trained to recognize [in order to participate]."	Protocol, Major
[graphic of the principle investigator hanging a bag of study fluid in the hospital Emergency Department]	Protocol, Major
"... testing unapproved solutions ..."	Protocol, Major
"The study ... will test one of two intravenously administered solutions ..."	Protocol, Minor