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Subjects' views of obligations to ensure post-trial access to drugs, care, and information: Qualitative results from the Experiences of Participants in Clinical Trials (EPIC) Study

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Abstract

Objectives—To report the attitudes and opinions of subjects in US clinical trials about whether or not, and why, they should receive post-trial access (PTA) to the trial drug, care, and information.

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COMPETING INTERESTS
None declared

ETHICS APPROVAL
The following institutional review boards reviewed the EPIC Study: Partners Human Research Committee, Harvard School of Medicine Human Subjects Committee, IRBMED at the University of Michigan Medical School, Public/Private Ventures IRB, New England IRB, and National Institutes of Health IRB.

Design—Focus groups, short self-administered questionnaires.

Setting—Boston, Dallas, Detroit, Oklahoma City.

Participants—Current and recent subjects in clinical trials, primarily for chronic diseases.

Results—Ninety-three individuals participated in ten focus groups. Many thought researchers, sponsors, health insurers, and others share obligations to facilitate PTA to the trial drug, if it benefited the subject, or to a therapeutic equivalent. Some thought PTA obligations include providing transition care (referrals to non-trial physicians or other trials, limited follow-up, short-term drug supply) or care for long-term adverse events. Others held, in contrast, that there are no PTA obligations regarding drugs or care. However, there was agreement that former subjects should receive information (drug name, dosage received, market approval date, long-term adverse effects, trial results). Participants frequently appealed to health need, cost, relationships, reciprocity, free choice, and sponsor self-interest to support their views. Many of their reasons overlapped with those commonly discussed by bioethicists.

Conclusion—Many participants in US trials for chronic conditions thought there are obligations to facilitate PTA to the trial drug at a "fair" price; these views were less demanding than those of non-US subjects in other studies. However, our participants' views about informational obligations were broader than those of other subjects and many bioethicists. Our results suggest that the PTA debate should expand beyond the trial drug and aggregate results.

Keywords

Ethics, Research; Clinical Trials; Human Experimentation; Health Services Accessibility; Disclosure, ethics

INTRODUCTION

There is increasing interest in the question of what, if anything, research subjects are owed after their participation in a clinical trial ends. Bioethicists' reasons for and against ensuring post-trial access (PTA) include avoidance of exploitation, distributive justice, feasibility, and stakeholder costs and/or benefits.[1–13] While initial discussion addressed research in resource-poor countries, PTA may be equally important for former subjects in high-income nations.[6,8,14,15]

US research regulations do not mention PTA, but other guidelines recommend discussion of PTA to the trial drug before the trial commences and provision of PTA in some cases.[1,2,16–19] Increasing attention is being paid to researchers' obligations to share individual and aggregate trial results with subjects and their communities.[1,2,11,20,21] However, important questions remain regarding what – if anything – should be provided, who should receive it and for how long, who should fund it, and who should distribute it.

There are some data about researchers' and institutional review board members' views on PTA obligations, but little is known about the opinions of current or potential subjects in trials for conditions other than HIV.[22–25] Among Kenyans receiving non-trial care for HIV (n=38) or for unspecified conditions (n=35), nearly all agreed that researchers should provide PTA to HIV trial drugs for as long as necessary if they benefited the subject.[26] A commonly cited reason was health need. US subjects in an international HIV trial (n=38) were less likely than European and Latin American subjects (n=299) to state that the trial drug, if proven safe and effective, should be free.[25]

Our study aimed to understand the views of subjects with common chronic illnesses in US clinical trials concerning the content and justification of PTA obligations. Subjects' opinions

and expectations have implications for subject recruitment, research regulations and guidelines, and debates about PTA obligations.

METHODS

We conducted focus groups to identify clinical trial subjects' opinions about the extent of and reasons for or against obligations to provide PTA. Focus group methodology allows researchers to explore complex views in depth and probe for additional information.[27] For clarity, we refer to individuals in clinical trials as 'subjects' and attendees in our study's focus groups as 'participants'.

participants

During 2006, we convened ten focus groups in Boston (4), Detroit (2), Dallas (2), and Oklahoma City (2), locations selected to ensure a racially and socio-economically diverse sample. We included English-speaking adults who participated in a clinical trial for depression, arthritis, or diabetes within the last twelve months. Subjects in trials for chronic conditions were selected because PTA could be important for their continued well-being. Participants were recruited through newspapers, posters at trial sites, and the Center for Information and Study on Clinical Research Participants database of former subjects. Interested individuals were pre-screened to ensure adequate representation of uninsured individuals, the three health conditions, and a range of clinical trial sites (contract research organizations, academic medical centers, and community-based physician practices). Subjects received reimbursement for transportation costs and $50 for their time.

data collection

We developed a semi-structured interview guide, to explore motives for trial participation, experiences of adverse events, health status, and health care and pilot-tested it in four groups. Based on these sessions, we added one neutrally-worded, non-directive question soliciting opinions about PTA obligations, probes about PTA to the trial drug and health care, and a probe regarding the bearer of PTA obligations (Appendix 1). Since participants in the pilot-test groups made unsolicited comments about PTA obligations, we included that data in our analysis.

A trained, experienced facilitator led each group, usually with a co-facilitator (JW, JB, SG, GK). A team member (CT, NS) observed and noted speakers' identities and non-verbal cues. Each 60 to 90-minute focus group was audio-recorded and transcribed. Prior to the discussion, participants gave written consent and completed a brief self-administered questionnaire about their demographics, insurance status, regular source of care, and previous trial experience. Participants were told they could decline to answer questions or discontinue participation at any time, and were assured their comments were confidential. All relevant IRBs approved this study.

coding and analysis

Two team members (NS, CT) conducted the analysis in multiple steps. At least one team member checked each transcript against the audio-recording and field notes, then linked each comment to its speaker. Quotations from the transcripts were grouped by study objective. Next, the transcripts were reviewed multiple times to identify major themes within each study objective.[28] When no new themes emerged (thematic saturation), the list was refined; team members developed inclusion and exclusion criteria for each theme, independently assigned thematic category codes, and resolved discrepancies. This process was repeated for subcategories (minor themes) within each theme. Transcript passages were assigned more than one thematic category or sub-category when appropriate. Analysis

distinguished between statements about what subjects *should* receive (obligations) versus what subjects *would appreciate* receiving (not obligations). Each comment was grouped by code and linked to the speaker's self-administered questionnaire data (CT).

In the results section, we report the views of "one" or "two" participants as such, those of 3–5 as "several", 6–10 as "some", and more than 10 as "many". Insurance status is reported in the results to provide context about a speaker: the views of uninsured and insured participants did not differ systematically.

data quality

We employed various measures to ensure data consistency and verifiability. Both transcripts and detailed field notes were used during analysis. Each team member summarized the main points and reviewed transcripts of sessions attended to verify their completeness and accuracy. Two team members independently coded data to ensure reliability. Discrepant, unclear, or unusual data were reviewed to ensure clarity and consistency. All data were rechecked (CT) using the proofed transcripts.

RESULTS

participants

The characteristics of our 93 focus group participants are described in Table 1. Slightly more than half were women, 20% were uninsured, and most had participated in more than one trial.

obligations

Participants' comments about PTA obligations, detailed in the following paragraphs, focused on 1) access to the trial drug, 2) short-term transition care, 3) treatment for adverse events, and 4) information.

Access to the Trial Drug—Many participants thought that former subjects should receive PTA to the trial drug or a therapeutic equivalent if such access would be beneficial. One woman participating in her first diabetes trial said:

> They should be working with the drug companies to say, OK, we've got 12 patients who are having good response. We need to work with you guys, if the system's not already in place, to help provide them open-label drug. To provide them prescriptions….I think there are mechanisms in place that could be either tapped into or tweaked a bit to find other ways to get the medication, whether it is FDA-approved or not.

Participants alluded to shared responsibility among sponsors, researchers, the FDA, and others to ensure PTA to the trial drug. They mentioned a variety of means of access, including later phases of the same trial, follow-up studies, different trials, and the conventional health care system. Many participants thought they should be offered the trial drug or alternative at a "fair" price: "I think they should charge you for it…but not an arm and a leg!...You know? A *fair* price." Other participants suggested a "reduced price" or patient assistance programs. Several thought insurance co-payments for PTA to the trial drug were fair.

However, some participants endorsed more demanding views: that sponsors or researchers should directly provide the trial drug to former subjects for several years, until marketed, or for the rest of the former subjects' lives. Many participants, in contrast, held that there are no obligations to provide PTA to the trial drug. Unexpectedly, the latter view was expressed by

several uninsured individuals who attributed their post-trial health decline to their inability to continue taking the trial drug.

Short-term Transition Care—Some participants said that sponsors or researchers should "bridge" the gap between trial and post-trial care to ensure that subjects "don't fall off", that is, experience a post-trial deterioration in health. Some thought researchers have ethical obligations to conduct limited post-trial surveillance of former subjects:

> They should check to see if you're still living. Perhaps, at least to check and make sure everything is okay with you…if it makes you sick, you can get hospitalized; if it makes you die…At least they could know if you're dead.

Several participants said that, after the trial, personnel should refer the subject to a non-trial healthcare provider or other trials. According to one, researchers have a "duty to at least give you some direction or to make you aware of all your options and the things you might do." Other transition obligations included providing a short-term supply of the trial drug and transferring trial-related medical records to subjects' non-trial physicians.

Treatment for Adverse Events—Participants held conflicting views about obligations to provide care for adverse events that persisted or arose after the trial. Two claimed that researchers should pay the full cost of care: "I'd sue their butts off….What if it had some long-term effect and it was found out in ten or twenty years that that caused cancer?" In contrast, several participants – including one uninsured individual who believed the trial drug caused her serious post-trial health problems – thought researchers have no post-trial obligations for adverse event care.

Information—There was widespread agreement that sponsors and researchers should notify former subjects about the trial drug's adverse effects, even if these were discovered years after the subject's participation. "Our cars get recalled," noted one participant with experience in five trials. Several participants who had been in Vioxx™ trials or knew people who had, and complained that they heard about the problems only from the media. Another participant, a subject in many asthma trials, said:

> Celebrex and Vioxx, when those were in the research stage, they knew about all that, and they didn't contact anybody and tell them. And I think that a drug company should say "Money is not the bottom line here, health care is. And these people took our drugs for us to see what was going on, and a year down the road we found out, oh, by the way, these might kill you. Hey, maybe we ought to call them and let them know!"

One participant stated that PTA to information was as important as to the trial drug.

There was also agreement that subjects should be told whether they received a drug or placebo, the name and dosage of any drug taken, the date the trial drug would be marketed, and aggregate trial results. Many knew that this information could not be provided immediately after the trial and might never become available for early phase trials. Nevertheless, several asserted that this information should be provided sooner to enable former subjects more quickly to resume beneficial treatment.

reasons

Participants articulated a variety of reasons for their opinions that PTA ought to or need not be provided. Some reasons justifying PTA obligations included subjects' health need, sponsors' self-interest, and respect for subjects; reasons denying PTA obligations included the nature of clinical trials, subjects' choices to enroll, and interpretation of the consent form

as a contract. Three reasons, reciprocity for assumption of risk, sponsors' or researchers' burden, and researcher-subject relationships, were used by some participants to support but by others to deny PTA obligations. These and less frequently expressed reasons are presented in Table 2.

Reasons why PTA obligations may exist—The most frequent reason for PTA obligations was concern about post-trial deterioration in health (health need). Some participants emphasized former subjects' financial constraints. One uninsured participant in a long-term diabetes trial summarized these concerns: "all of a sudden [they] just cut the cord, and you're off on your own, you know. You come up with the three or four hundred dollars a month to keep this thing going or just go ahead and die."

In contrast, several participants suggested that PTA provision would not impose an excessive burden on sponsors. One stated that sponsors "can afford to pay for a small group" to continue receiving the trial drug because "they're making billions and billions." One participant thought that researchers had special access to information about potential post-trial sources of care or other trials. Sharing this information was seen as a minimal burden for researchers relative to the difficulties former subjects might face seeking this information on their own.

Several subjects in trials longer than a year viewed their special relationships with researchers as reasons for PTA obligations. Ongoing interaction with and disclosures to researchers led some participants to think of them as care-takers who had "taken me under their wing" and "taken care of my health." Two individuals who thought researchers had no or limited PTA obligations perceived the absence of post-trial care as betrayal of this relationship; they reported feeling "abandoned" or "left in the lurch" after their trial. A woman in a rheumatoid arthritis trial said:

> I knew it was a study, and I knew I had signed papers, and I knew all that. But, at the end…I've developed a relationship with the doctor and coordinator and all, and I liked the doctor. And I want to continue to go there, and I want to get the medication that I was given, but I couldn't.

Some argued that subjects' exposure to risk generated reciprocal obligations to provide PTA. One said, "If I'm going through the study, and I'm putting *my* butt on the line…they should take care of me, on down the line."

Others, including some who rejected PTA obligations nonetheless thought it might be in researchers' and sponsors' self-interest to offer PTA to the drug or care. Some suggested PTA would enable researchers to collect data on former subjects, "assets" in which they had "invested all this medication, all the time, all this note taking." Two others noted that PTA offers might enhance subject recruitment and retention.

Reasons why PTA obligations may not exist—Other participants, including several uninsured individuals who experienced adverse events that persisted after the trial, stated that researchers have no obligations to provide PTA to the trial drug. Some regarded the trial drug's risks as a fair trade-off for possible health benefits, or noted that non-trial drugs also pose risks. Some thought PTA was beyond the scope of research: "I thought that was the nature of a trial. That there's a beginning and an ending point." Some participants asserted that subjects' informed, voluntary choices to enroll absolve researchers of post-trial obligations: "You did it of your own free will…And they didn't guarantee you anything when you went in…so they're not obligated after it's over." Several participants considered the consent form a "contractual arrangement" that establishes and limits obligations; researchers are responsible merely for ensuring the participants understand the agreement's

terms and for abiding by them. Two thought PTA would be too costly for sponsors; one asserted that mandating PTA would have the undesirable effect of decreasing research.

DISCUSSION

We conducted focus groups with current and former subjects in US clinical trials to explore what, if anything, they think they should receive post-trial, and why.

Our results suggest that US subjects endorse less demanding PTA obligations to care and drugs than subjects in other countries, although data are extremely limited. Many participants felt that it is fair for former subjects to pay co-payments for the trial drug after the trial; this view implies they think that health insurers should pay the balance. Their opinions mirror Grady's proposal that insurers, governments, sponsors, and researchers should collaborate to provide PTA to the trial drug.[4] In contrast, in a small study in Kenya, nearly all potential HIV trial subjects stated that former subjects should have PTA to care for all conditions, and that the trial drug should be provided free for as long as needed.[26] Our results are consistent with Pace's finding that US subjects are less likely than European or Latin American subjects to think they should receive the trial drug free.[25] This difference may be due to Americans' emphasis on personal responsibility for health, lack of a socialized or nationalized health care system, or greater awareness of the distinction between therapy and research.[29] Additionally, our respondents' views may differ from those previously reported because they were in trials for conditions other than HIV/AIDS.

Participants thought PTA to information was important: all groups mentioned informational obligations in the absence of prompts from focus group facilitators. While new US regulations require that sponsors report aggregate trial results to an online trial registry within 90 days of approval, our results provide further evidence that many subjects think they should receive aggregate results *even if the drug is not FDA-approved*.[30,31] Moreover, many participants stated they should receive *individual* results – findings relevant to specific participants – and information such as their trial arm, trial drug dose, and medical test results. The obligation to disclose individual results has been discussed only recently.[21]

While some bioethicists invoke reciprocity to justify PTA obligations, others argue that reciprocity does not always require PTA when there are conflicting claims.[5,32] For our participants**,** reciprocity was a less important justification for PTA than health need. Notably, participants did not mention three reasons for PTA that dominate bioethicists' discussions about PTA in resource-poor countries: concerns that PTA offers might unduly induce potential subjects to enroll in a clinical trial, the use of PTA to address global distributive injustices, and the degree to which PTA may prevent exploitation of subjects.[2,3,5,12,13,33] Our results emphasize that participants did not question the validity of their consent and, in general, thought they were treated fairly and respectfully.

Our results also suggest that subjects with chronic diseases may gradually come to regard researchers as caretakers. Participants' views were not based on therapeutic misconceptions: indeed they understood that randomization, placebo-controls, double-blinding, or protocol adherence would determine researchers' assignment and restriction of their treatment options.[34] Instead, as evidence of researchers' care-giving roles and responsibilities, participants appealed to researchers' long-term relationships with, health education of, and medical record keeping for subjects. Hence, this study validates previous empirical claims underlying arguments that researcher-subject relationships generate obligations to provide care during the trial unrelated to the research purpose or PTA.[9,33,35] Relationships are commonly thought to ground duties and obligations; the employer-employee and doctor-patient relationships are frequently analogized to the researcher-subject interaction.[36,37]

Further empirical work should examine the effect of factors such as trial length or investigator type (e.g. community-based physician versus contract research organization employee) on subjects' experiences of these relationships. Additional philosophical analyses should explore if such experiences generate role-related or fiduciary obligations to provide PTA.

strengths and limitations

To our knowledge, this is the first report of US subjects' views of obligations following trials for conditions other than HIV/AIDS. Our qualitative methodology enabled participants to express a variety of views and modify them during the discussion. The focus group dynamic simulated – to a limited extent – deliberative processes proposed as a means of generating informed and reflective policies.[38] However, group discussions may stifle unpopular opinions. Focus group participants did not always know their trial's phase. Our participants may over-represent minorities, individuals with experience in multiple trials, and subjects in trials of FDA-approved drugs.[39] Results may not be generalizable to subjects in trials for other conditions. Reciprocity, for instance, may have greater weight in healthy volunteers' assessments of PTA obligations. Questions did not probe views on PTA obligations to subjects who withdrew, took the placebo, or participated in unsuccessful or early-phase trials. Finally, while subjects' opinions can and should inform ethical arguments, caution must be taken when drawing normative conclusions about PTA obligations from their views.

conclusion

Subjects in US trials for chronic conditions, for the most part, thought there are obligations to facilitate PTA to the trial drug or therapeutic equivalent at a "fair" price, offer transition care, and provide care for long-term adverse events. While our participants expressed less demanding views about PTA obligations to the trial drug than subjects in other countries, they thought PTA obligations to information extend beyond bioethicists' current focus on dissemination of aggregate trial results. The reasons participants provided for PTA obligations – health need, affordability, relationships with researchers, sponsor self-interest, and reciprocity – overlapped with those most commonly advanced in the bioethics literature. However, other participants offered various reasons against PTA obligations, including: voluntary enrollment, the nature of research, and concerns about decreasing future research.

Subjects' views should be relevant to sponsors, researchers, bioethicists, and society. Our participants' experiences enable them to identify issues that policymakers have largely overlooked and to suggest practical interventions. Their comments indicate that subjects would, at a minimum, welcome systematic and consistent discussion of PTA during the informed consent process, and post-trial information about adverse events and aggregate study results. Such disclosure may increase recruitment rates, improve researcher-subject relationships, mitigate subjects' anxieties about post-trial abandonment, and help restore trust in research, particularly after recent drug recalls and reports of FDA regulatory failures.[14, 40] Furthermore, participants' concerns suggest that the US should improve its adverse event reporting system, consider establishing a research injury fund, and re-evaluate regulations that permit sponsors to waive responsibility for adverse event care.[40–42] Bioethicists, policy makers, and sponsors should consider if there are obligations to provide former subjects with a broader range of information and care.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

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Table 1

Focus group participant characteristics

	Overall (n=93)	Boston (n=33)	Detroit (n=19)	Dallas (n=20)	Oklahoma City (n=21)
Mean age (n=91)	54 (sd=11.2)	50 (sd=11.5)	59 (sd=10.2)	56 (sd=10.7)	54 (sd=10.5)
Male	38 (41%)	16 (49%)	8 (42%)	7 (25%)	7 (33%)
Race					
White	61 (66%)	23 (70%)	10 (53%)	13 (65%)	15 (71%)
African American	21 (23%)	5 (15%)	9 (47%)	6 (30%)	1 (5%)
Other	7 (8%)	3 (9%)	0	1 (5%)	3 (14%)
Unknown	4 (4%)	2 (6%)	0	0	2 (10%)
Hispanic/Latino	5 (5%)	2 (6%)	0	2 (10%)	1 (5%)
Uninsured during the 12 months prior to the FG	19 (20%)	5 (15%)	6 (32%)	3 (15%)	5 (24%)
Condition					
Arthritis	32 (34%)	5 (15%)	0	12 (60%)	15 (71%)
Depression	17 (18%)	12 (36%)	1 (5%)	4 (20%)	0
Diabetes	26 (28%)	5 (15%)	18 (95%)	0	3 (14%)
Other chronic condition	13 (14%)	6 (18%)	0	4 (20%)	3 (14%)
Healthy control or survey	5 (5%)	5 (15%)	0	0	0
Number of trials (including current one)					
1	22 (24%)	1 (3%)	12 (63%)	3 (15%)	6 (29%)
2	9 (10%)	2 (6%)	4 (21%)	1 (5%)	2 (10%)
3 or more	34 (37%)	17 (52%)	2 (11%)	6 (30%)	9 (43%)
Unknown	28 (30%)	13 (39%)	1 (5%)	10 (50%)	4 (19%)

Table 2

EPIC participants' reasons why PTA obligations to former subjects may or may not exist

Reason	Do PTA obligations exist? (frequency of view)
Subject need	
Health need	Yes (Many, more than 10)
Financial need	Yes (Many, more than 10)
Sponsor or researcher burden	
Sponsor affordability	Yes (Several, 3–5) No (Two)
Researchers' access to information	No (One)
Logistical considerations	Yes (One) No (One)
Researcher-subject relationship	Yes (Several, 3–5) No (Several, 3–5)
Reciprocity for subject risk assumption	Yes (Some, 6–10) No (Several, 3–5)
Sponsor or researcher self-interest	
Value of additional data	Yes (Some, 6–10)
Enhance subject recruitment & retention	Yes (Two)
Nature of a trial	
Subject choice	No (Some, 6–10)
Contract	No (Several, 3–5)
Research disincentive	No (One)
Respect for subject	Yes (One)
Legal	Yes (Two) No (Several, 3–5)