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Qualitative differences among cancer clinical trial explanations

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Abstract

This paper examines how medical oncologists present to breast cancer patients the option of participating in experimental treatment trials. The investigation takes a case study approach, comparing two contrasting presentations of the clinical trial option. One presentation constructs the experimental trial as a locally organized, joint physician–patient effort to determine "best" treatments, and minimizes uncertainty by oversimplification of the randomization process; the second presentation situates the clinical trial within the larger national research effort, underscores the uncertainty created by randomization, and casts non-enrollment as a reasonable option. These observations provide initial evidence that physician presentation of the clinical trial varies substantially and provides the first detailed look at actual discourse practices used in the United States to recruit patients to experimental protocols.

Keywords: Clinical trials; Recruitment; Breast cancer trials; United States

Introduction

Overall, enrollment in clinical trials for cancer treatment is astonishingly low; estimates range from 2% to 5% of eligible patients. (Gotay, 1991; Lawrence et al., 1991; Winn, 1994). These estimates are similar for accrual to trials for breast cancer treatment (Fisher, 1991; Johansen, Mayer, & Hoover, 1991) the subject of this investigation. Since experimental trials are the primary mechanism for testing new treatment regimens, accounting for low enrollments is seen as consequential for the advance of medical science. Without sufficiently large samples, progress is slow, and without sufficiently representative samples, issues of treatment bias may be exacerbated.

Because of the far reaching consequences of low enrollment, the problem has been studied from numerous vantage points (see Foster, 1994; Gotay, 1991; Grant, Cissna, & Rosenfeld, 2000 for recent overviews). Physician-related concerns include disinclination to expose their patients to side effects (Winn, Miransky, & Kerner, 1984), their doubts about the efficacy of experimental treatments (Mackillop, Ward, & O'Sullivan, 1986; Moore, O'Sullivan, & Tannack, 1988), and concern about tainting the doctor–patient relationship (Taylor & Klener, 1987). Additionally, organizational and health care system factors may present obstacles (Winn, 1994), including type of insurance (Klabunde, Springer, Butler, White, & Atkins, 1999); although Gotay (1991) concludes that Medicaid coverage is not a factor in non-participation.

From the patient's perspective, declining to participate in clinical trials is related to a number of issues, among them are concerns about possible additional costs (Hunter, Frelick, & Feldman, 1987) uncertainty about toxicity of treatments, or the fact that they find human experimentation objectionable (Barofsky & Sugarbaker 1979). Lack of social support such as available child care, lack of transportation, and work-related concerns can also be barriers to participation (Richardson, Post-White, Singletary, & Justice, 1998). One recent retrospective study (Grant et al., 2000) reports physician communicative style (e.g. whether the physician is affiliative or dominating) as potentially affecting patient's willingness to enroll and also locates relevant patient characteristics (e.g. whether the patient prefers doing decision-making, desires information, etc).

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Studies which examine patient demographics are somewhat equivocal. Robertson (1994) reports under representation of minority groups in cancer trials (Robertson, 1994; Swanson & Ward, 1995); however, Klabunde et al. (1999) find no evidence that race predicted enrollment (among 2300 potential enrollees) nor does Simon, Brown, Du, LoRusso, and Kellogg (1999) among 136 female breast cancer patients in Detroit. Gotay (1991) concludes that race and other demographic variables (sex, marital status, religion) do not affect enrollment while the evidence on age is presented as equivocal.

Even this brief review indicates a complex situation in which patients, doctors, availability of appropriate experimental therapies, and macro-social constraints all impinge heavily on enrollment in cancer clinical trials. Despite fairly extensive surveys, retrospection studies, and forensic study of medical records, completely absent from this literature on accrual to trials is a close examination of the way that physicians actually present this option to patients. So the question remains open as to what transpires in physician offices during explanation of the cancer clinical trial treatment option.

This paper addresses that question by investigating how oncologists organize their talk for recruiting patients to clinical trials. It appears that physicians vary considerably in their presentation of this particular treatment option. The inherent uncertainty about efficacy may render it impossible for physicians to confidently recruit to trials, yet to move the science along and to potentially allow patients a more promising treatment than is standardly available, physicians do open the door to enrollment. How that door gets opened and to what extent the physician encourages enrollment, is what is being examined here. What will be detailed is a contrast between two oncologists' presentations of the clinical trial option for breast cancer patients. One presentation is hearably more persuasive, verbally constructed as the physician's and patient's shared project of finding the "best" treatment for the patient. The second, more equivocal recommendation, constructs a "physician's only" project of institutional duty or responsibility, and leaves the patient room to not choose the trial. The ethics of these two contrasting approaches is not under consideration here, nor is their efficacy for achieving enrollment. What is under consideration is the sharp qualitative difference between these presentations, a finding which demands continued study of actual interactions for clarifying one potentially crucial element in the puzzle of low enrollments.

Data

The current analysis is part of an ongoing project to better understand how medical recommendations are interactively achieved within, and as part of, larger processes of identity management (Roberts, 1999; Roberts, 2000; Costello & Roberts, 2001). These qualitative analyses are based on 21 audiotaped interactions which had been collected as part of a larger study concerning the correlates of breast cancer adjuvant treatment decisions (Siminoff, 1987; Siminoff & Fetting, 1989, 1991; Siminoff, Fetting, & Abeloff, 1989). All recordings were made in the United States at a prestigious teaching hospital associated with a comprehensive cancer centre; the clinic visit recorded was the meeting between each study patient and her oncologist at which they discuss options for adjuvant therapy.

For the current study two audiotapes were selected that best illustrate how oncologists differ markedly in their presentation of clinical trial information; insights gained from prior work with the data informed the choice. However, these cases are not meant as exemplars of particular approaches used by oncologists; such an oversimplification would be unproductive and misleading. Rather, these contrasting cases are detailed as illustrative of the substantive qualitative differences that are manifestly apparent across oncologists' explanations of experimental treatments. An additional consideration in choosing these two cases to contrast was also an intent to minimize any potentially distracting factors in an already complex interpersonal and medical event. Thus, both the contrasting cases involve senior, male oncologists and female patients. The women are similar in terms of age and stage of disease.[1] Both physicians and patients are white.

Because of their menopausal status, the women are eligible for different randomized controlled trials. The fact that these are different trials opens the possibility that they have unequal merit from a medical standpoint and that this may impinge on the oncologist's enthusiasm for the particular one he has to offer in a particular patient's case. However, the stance taken in this analysis is that each oncologist has, in fact, opened the door for recruitment and, whether lukewarm or enthusiastic in their presentation, they nonetheless pursue a presentation of the clinical trial option. Once they have chosen to open that door, it becomes relevant for patients how the oncologist presents the option, regardless of what their reasons may be for crafting it in a particular way. Patients will likely never know all of the factors contributing to a physician's recommendation for a particular trial, or the oncologist's stance towards trials in general, all they have in front of them is how the option is presented. As analysts, that is all we can reliably have access to as well.

[1] Patient A is 43, postmenopausal, and stage 2 (defined at the time as 1 positive lymph node with a tumor ranging in size from 2 to 5 cm). Patient B is 41, premenopausal, and also stage 2 (1 positive lymph node with a tumor <2 cm).

Enrollment Pitch A: Finding the "Best" Treatment

Prior to the talk transcribed here, oncologist A has finished his argument in favor of chemotherapy as a treatment for this patient. He uses that term generically, not explaining that it comprises a wide range of pharmacological agents that are injected or ingested. The term is used in a taken-for-granted way, an unspecified agent for reducing the risk of cancer recurrence. The physician's formulation would be akin to a recommendation to "eat more fruit" to increase Vitamin C intake without specifying which fruits were the richest sources of it. With the oncologist's generic recommendation for "chemotherapy" on the table, we pick up his talk at line 373 of the transcript where he moves from the most general characterization of treatment to a more and more specified version. At line 381, the physician then says: "An:d there's a big question as to which one a those is best = They're probably pretty close". (Transcription conventions appear in the Appendix A.)

Excerpt 1 ("which is best")

373 DR A: So:: (1.8) our recommendation would be that you get chemotherapy *of some kind*.
374 (0.6)
375 Now the other question is whether or not (2.0) there are differences in the *kinds of
376 Chemotherapy* AND THERE probably are.
377 (1.4)
378 A LOT of different chemotherapies have been shown to help in this- in breast
379 Cancer.
380 (1.0)
381 → An:d there's a big question as to which one a those is the best. = They're probably
382 Pretty close.
383 (1.0)

The trajectory of the talk in Excerpt 1 is, if we go back to the Vitamin C parallel, something like the doctor saying: "I think you should eat fruit... of some kind... there probably are differences in fruits... a lot of them are good for getting Vitamin C... but the question is, which is the best". And it is this labeling as "best" that is worth particular note. At line 381, the physician is not pointing to a question of which treatment is cheapest or least toxic or most convenient or most current, but which is the best at helping reduce risk of recurrence in breast cancer. Thinking in terms of how speakers formulate descriptions that index a possible shared universe and each participant's relationship to that (see, for example, Sacks, 1972a, b; Schegloff, 1988), then it seems the oncologist is moving to construct the co-understanding and shared goal that the patient wants the "best" treatment, whatever that will mean. Now this may seem a vacuous analysis on the face of it if one assumes that, of course, the doctor is going to point towards the best treatment, but such a stance should not be taken for granted. It seems that how the oncologist formulates what the patient wants is important, not at all a trivial move. By choosing the term "best" the doctor has not only reflected a positive formulation, but has dually deflected the dire opposite (worst) and brought into focus that "worst" (or other negative alternatives) is a potentiality which is pointedly not being engaged (see Burke, 1966, on terminology as simultaneously reflective, selective, and deflective). If the physician successfully constructs their shared concern as finding the best treatment for this patient, then he lays the groundwork for what is to come, namely the clinical research effort aimed at determining that.

Note that in lines 381–382 there is no gap (transcribed by the equal sign) at the possible completion after the word "best" and the beginning of the following assessment ("They're probably pretty close"). This "rush through" (Schegloff, 1987) to the assessment of the rough equivalency of the treatments potentially forestalls any patient upshot that the oncologist does not really know which is best or perhaps that the patient wants something other than the best. The commentary "they're probably pretty close" foregrounds that patients are not at excessive risk for getting bad treatments. In fact, this is part of the ongoing work that the oncologist does throughout this phase of the visit in which he reassures the patient that he is minimizing her risk, not deliberately giving bad treatments, and not actually experimenting on her.

In sum, the first notable feature of this physician's presentation is how he verbally constructs a project in which he and the patient are embarking together on finding the best treatment among some very good ones. This point will later be contrasted with Enrollment Pitch B.

A second point of contrast concerns the way in which the enterprise of the clinical trial is presented as a local event. Note in lines 383–390, below, that the doctor in referring to the question of which treatments are best talks about investigating that "right here" (line 383) "with some of our studies" (line 383) and how they try

to get "all our patients" (line 386) to enroll in "our study that we have here" (line 388); there's no mention of the larger national research group (Eastern Cooperative Oncology Group (ECOG)) that coordinated and administered these trials. (ECOG is, however, mentioned in Pitch B).

Excerpt 2 ("we're looking at that question right here")

383 DR A We're looking at that question right here. With some of our studies too. We're trying
384 to determine (.) which eh which (.) treatments might be the best in *trying to prevent
385 breast cancer from coming back.* A::nd- so one thing that we try ta do is we try ta
386 get all our patients- > since we don't know which of these drugs is better, we have a
387 pretty- we know that they all work to some degree in breast cancer,< (1.0) the:n uh
388 (1.0) what we try to do is try ta (.) enroll patients in our study that we have here. To
389 try to answer that question.

On this second point of contrast, local versus national scope of investigation, it is clear that the oncologist works to present a clinical trial that is relevant to the immediate needs of current patients at that particular hospital. In this way, he provides a sense of local physicians working with local concerns in a locally controlled way. Note once again how at 386–387 he parenthetically inserts the goal of finding better treatments among those that are known to work.

The third point of contrast between the two pitches is the way in which randomization is described by the two physicians. In line 504 of Excerpt 3, DR A mentions that patients are randomly assigned to treatment groups, but he does not explain the process of randomization; he simply notes that patients are "randomly" assigned to one of "two arms". The term "arm" is then replaced by the perhaps more accessible term "group" while the term "randomly" is left unexplicated. The patient does not move to have it clarified. Thus, the interaction continues with the concept of "random" as understood, whether or not it actually is.

Excerpt 3 ("we would ask you to enroll")

498 DR A We don't know which of these drugs are better yet *so we compare.* And: we would
504 ask you ta (.) to enro:ll in the study to help us find out? (We would) (.) RANdomly
505 assign one of the two arms, (.) a the study. One of the arms- all thee- this one
506 group a patients all would get (.) one certain group of drugs. The other arm will get
507 the other certain group a drugs. = BOTH a those groups a drugs have been shown to
508 work in breast cancer, but we're trying to compare which one's better. = If we knew
509 we wouldn't be doing the study. As far as we can tell right now, they're equal and
510 that's why we're putting em into the study,
511 PT A Yeh. =
512 DR A = but one may turn out ta be better than the other. In terms of (.) r:isk fer (.) the
513 breast cancer *coming back.*
514 PT A I (al)most feel lucky years ago they didn't know nothin.

The information about the treatment arms is presented as two alternative treatments, both of which work and, according to this oncologist, they are "equal". Again, a rush through at possible completion in line 507 works to possibly forestall any incursion by the patient of a concern that one treatment arm is less efficacious than the other. The oncologist indeed highlights the uncertainty of which is the better treatment (lines 509–510), but asserts that they are at least equal. As others have discussed, uncertainty permeates the illness experience (Atkinson, 1995; Babrow, Kasch, & Ford, 1998; Katz, 1984) and, de facto, the randomization procedure opens up a multitude of uncertainties. However, that mulitiplicity is simply glossed with the adverbial "randomly" and, unchallenged by the patient, they collaboratively construct an assumption that the procedure and its entailments are understood. Thus, the uncertainty crystallized by the randomization procedure is bypassed in favor of the uncertainty about which of two treatments that "work" is the "better" one. This kind of uncertainty is, in a sense, more positive—it is the uncertainty associated with a possible pay-off. In Enrollment Pitch B, as discussed below, the description of randomization is constructed in such a way that it highlights the uncertainty of the procedure itself and focuses on the patient's lack of control.

Although we are bereft of much evidence of patient A's response to the doctor's pitch thus far, she does display an understanding of what has been presented to her by offering a positive assessment when she says, in line 514: "I (al)most feel lucky, years ago they didn't know nothin". From this it seems that the patient has been encouraged that the level of knowledge about breast cancer treatment is beyond what it once was and

displays a positive orientation to the information that has been presented to her so far.

From a rhetorical standpoint, in terms of classical elements of persuasion, the physician has provided the logical warrant for doing the study ("they don't know what treatment is best"); he bolsters his credibility (ethos) as one member of an institution that is working on the question of "best" treatments; and he has tried to put the patient in the right frame of mind ("pathos") in that they (the doctors at this particular hospital) are trying to work on the problem along with "all" their patients whose help they require.

Overall, this physician's presentation is hearable as persuasive in that he establishes that the effort they are engaged in is to find the best treatment from among those that are already known to work. He establishes the undertaking as locally organized and in that sense more personal, something that doctors and patients are working on together. The physician allows for the uncertainty of getting one of two good treatments, but does not explain the randomization process, nor does the patient press him to. The patient displays a positive orientation to the pitch in that she assesses her situation in terms of being "almost lucky". At the end of this visit, the patient apparently signs a consent form. After the oncologist has explained the study in more detail, he provides the telephone number of the physician monitoring this particular clinical trial and then says: "So you know what I gotta do? I gotta ask you to sign here for the study". There is no verbal indication that the patient resists signing.[2]

Enrollment Pitch B: Institutional Responsibility

In the second case examined, the oncologist provides more detail about the scope of the clinical trial (as situated under the umbrella of ECOG) and provides more detail about the process of randomization. His pitch is less about the effort to find best treatments and is more directed to explicating the mechanics of the experimental protocols within the study. In this case, the patient is not presented with a consent form to sign.

Just prior to the talk transcribed as Enrollment Pitch B, the oncologist has been describing the duration and delivery of standard therapy. At line 651, he says "AnOTHER approach one that (.) uh is peculiar to this institution... would be to participate in a clinical trial." In this way, the oncologist delays the announcement of this additional treatment option until he has characterized it ahead of time as something "peculiar" to the "institution".

Excerpt 4 ("an approach peculiar to this institution")

```
648 DR B  Uhm? (1.0) So THAT would be:: (0.8) uh I think one approach (here.)
649 PT B:  Mm-hm?
650        (0.8)
651 DR B:  AnOTHER approach one that(.)uh is peculiar to this institution and would be for (.)
652        Loamer and Bulli[ns[3]
653 PT B:                  [hm?
654 DR B:  as well, would be to participate in a clinical trial.
655 PT B:  Mm-hm.
656 DR B:  We talked about (.) earlier about thee: way in which we've lear::ned
657 PT B:  [( ) adjuvant therapy
658 DR B:  [that adjuvant therapy is helpful in, (.) patients like yourself participated in trials.
659 PT B:  Mm-hm?
660 DR B:  We are (.) currently (.) doing a trial here, uh Bullins and Loamer are also
661        participating .hh along with the Eastern Cooperative Oncology Group
662 P30:   hm? =
663 D4:    =which is a lar:ge (.) na:tional
664 P30:   Right. I [(know) hm
665 D4:              [cooperative oncology group. ComPARING (.) a C M F based regimen...
```

Of the terms available to the oncolgist for describing the clinical trial approach, "peculiar" is a rather ambiguous one in that it has a wide range of possible meanings. It could mean anything from "distinctive" to the somewhat

[2] Signing the consent form does not entail participation; indeed, the oncologist's formulation here may even seem coercive (usually patients leave the office with some time to think over their options, see Roberts, 1999, pp. 99–103). Thus, the fact of signing does not necessarily indicate that the physician has been persuasive, nor that the patient will pursue the clinical trial option.

[3] Loamer and Bullins are pseudonyms for oncologists associated with an institution closer to the patient's home. She has been considering getting her treatment at that institution rather than traveling to the teaching hospital. The oncologist is thus making it clear that what he is about to propose is available to her nearer her home as well.

less neutral meaning of "bizarre". In whatever way the patient may understand the word, it seems that at the very least the oncologist has made a choice that is particularly polysemous, and probably more open to a negative shading than the choice of a superlative like "best" as we saw in Pitch A. What emerges more clearly through DR. B's discourse is a universe in which the trial is primarily an institutional endeavor, not necessarily related to finding best treatments, as characterized by DR. A, but contextualized rather prosaically in terms of discovering things that are "helpful". He alludes, in lines 656–658, to their prior discussion of how adjuvant therapy was discovered to be "helpful" in reducing recurrence of breast cancer and this is the context in which he now introduces the clinical trial option.

Excerpt 5 ("randomization")

682		DR B: So th- thee eastern cooperative group study ee see o gee study then, would
683		be a see em eff based regimen,
684		PT B: Mm right.
685		DR B: compared to a see em eff regimen one month, next month the adria,
686		PT B: Mm yeah right.
687		DR B: next the see em [eff,
688		PT B: [mm
689		DR B: next the adria,
690		PT B: hm?
691	→	DR B: hhh and hh that study is a randomized ssstudy. =
692		PT B: = Mm-hm?
693	→	DR B: By that I mea:n if- if you were to agree to participate in that study, you would
694		say, I will allow::, >essentially I will< allow: uh:: *>some sort of<* random (.)
695		number selection to determine which treatment I'm going t[o get
696		PT B: [Mm. Right. Mm-hm?
697		DR B: hhh uh::m (.) now, (.) there are some differences and now >we mays well<
698		(2.0) AS A as a (.) member of a research institution I will recomme:nd to you,
699		PT B: Mm-hm.
700		DR B: the trial.
701		PT B: ↑Sure. ↓
702		DR B: Uhm (3.0) either either option is (.) reasonable.
703		PT B: Yeah. =
704		DR B: = Uh::m, And if you wanted ta >get treated here and you didn't want to
705		participate in the trial an ya just wanted to get this (here), tha(d) be fine.<
706		PT B: ↑Sure↓.
707		DR B: >Tha- that's fine.<

As the talk continues, he presents the trial in its full breadth as a national and institutional endeavor. Because this patient may choose to get her treatment closer to home, he mentions the oncologists who are also cooperating in the study and then further enlarges the scope of the undertaking by situating it within the larger national study. Recall from Enrollment Pitch A that the clinical trial was presented solely as a local event, no mention is made of the larger consortium. Although mention of Loamer and Bullins may well entail enlarging the institutional context in which the clinical trial is situated, it does not necessarily require, at this point, mention of the ECOG. Once it has been mentioned, and the description of it is out on the table, the patient moves (line 664) to display a recognition of the term. Rather than orient to her recognition and abandon his explanation, the oncologist pursues the trajectory of his turn, completing the definition of ECOG and specifying for all present the organizational universe within which they are operating.

After a brief description of the treatment regimens to be tested in the experimental trial, DR B mentions that it is a randomized study (line 691, below), and describes what that would mean (lines 693–695).

In lines 691–695, through a "footing shift" (Goffman, 1981), the oncologist characterizes what randomization is by animating the patient's voice, using the "I" pronoun. Rather than explaining the concept as an externally designed procedure, the oncologist derives an explanation from what the patient's personal choice would be should she agree to go on study. He highlights not only the lack of choice, but the occult way in which the selection is done: the phrase "some sort of random number selection" (line 694) picks out that there are perhaps multiple methods of randomization and that the

patient would not even know which of those methods was to be used. In this formulation, the patient's lack of control is highlighted as well as the uncertainty of which treatment the patient would be receiving.

Just as the physician is launching the specific differences among the treatment arms, he alters that trajectory to further underscore the institutional nature of his stance toward this recommendation of the study protocol. At line 699, he prefaces a personal recommendation with the invocation of his role as an institutional representative, explicitly framing the recommendation as rooted in his persona within an institution. The fact that he draws the connection in this way (as opposed, for example, to drawing on his medical expertise or experience) indicates some privileging of the institutional affiliation. Speakers have available a variety of ways of contextualizing some bit of advice or some opinion that they may have. One can say "as your mother..." or "as someone who has been married for 49 years..." and these prefaces will have different resonances in terms of logical and emotional appeal. By the same token, this physician could have prefaced this recommendation "as a medical oncologist" or "as someone who has been seeing patients for over 10 years" or some other formulation to highlight any aspect of his identity that he might wish to make relevant, each with its own valence. However what he chooses to foreground as context for his recommendation is his membership in an institution, not his membership in a profession which is precisely in the business of treating cancer with pharmacological agents (as opposed to radiation or surgical treatments).[4]

Finally, towards the end of this pitch, the physician makes it clear that either option, standard therapy or going into the study, "is reasonable". Indeed, as discussed elsewhere (Roberts, 1999) both patients and oncologists work within these recommendation visits to coopertively construct the patient as knowledgeable, educable, and reasonable. By appealing here to the "reasonableness" of either enrollment or not enrollment, the oncologist clearly sanctions the choice of not participating in the trial (lines 702–707) and leaves the patient a safe and respectable exit; given his formulation of the reasonable choices, there is neither loss of face nor, apparently, any loss of medical advantage, regardless of the treatment path chosen.

[4]In one instance this same physician, with a different patient, does foreground his specific membership in the category medical oncologist. After referring to an unspecificed set of persons with an "institutional we" pronoun, he cuts off the utterance and reformulates it in the following way: "... so I mean we- people in oncology do think that timing is important". In this way, he specifies the professional realm of expertise from which his opinion is derived.

Discussion

Initially, in listening to these instances in which physicians present the clinical trial option, it sounded as though one was more persuasive than the other. This initial hearing then invited some grounding in the particulars of the discourse. As it turns out, it seems that DR A provides the patient with the immensely attractive goal of finding the "best" treatment. The sense of a local effort created by the oncologist toward reaching that goal may also have been attractive to this patient (she was, in fact, a long-term resident of the city in which the hospital is located), but that supposition may be too far reaching. Suffice it to say that at the initial stages of his explanation, the oncologist does not explain the national consortium of hospitals participating in the research (something which he does towards the end of the visit). He also couches randomization in terms of getting one or the other of two good treatments, not as a procedure in which the patient has no control over which treatment she will get. Whichever aspects of the presentation were attractive to the patient, it is clear that she responds positively to what she has heard and, at the end of this visit, after receiving further details on the scope of the study and the drugs and side effects, she does appear to sign the consent form.

In contrast, DR B does not go so far as to say that the clinical trial effort is in search of best treatments; he situates his discussion as part of the evolution of "better" treatments. His presentation of the trial is in terms of its national scope and he quite pointedly animates the uncertainty and lack of control introduced by the randomization process. This patient does not, by the end of the visit, seem positively disposed to the trial option.

But this is not to say that the purpose of the current analysis is to advocate one of these pitches over the other, particularly in that one may even appear coercive for the manner in which the patient is asked to sign the consent form. However, pointing out these differences serves to alert scholars and other interested parties that physicians have extremely disparate approaches to explaining clinical trials and that such differences may be not only consequential for enrollments, but more importantly for individual patients as well. In the United States, where these data were collected, Institutional Review Boards are responsible, at the local level, for ensuring compliance with federal regulations (Title 45, Part 46, as overseen by the US Department of Health and Human Services, Office of Human Research Protections). They review proposed procedures and consent forms, but whether or not information provided by a physician constitutes "informed consent" is ultimately a question decided in the courts, and cannot be settled here. What is clear is that what each physician tells their patients can vary enormously within the limits

of informed consent. Only further examination of similar materials can yield a strong basis on which to illuminate contributing factors to low enrollment; moreover, analysis of actual interactions allows more realistic assessment of consent procedures in terms of ethics and information, and their relationship to, from the medical communities vantage point, successful enrollment.

Siminoff and Fetting (1989) note that, based on discriminant function analysis of the larger data set from which these current two cases are drawn, in visits where there is greater "specificity of information" (in terms of benefits and side effects) patients tend to be non-acceptors of the physician recommendation. Furthermore, those patients perceived such recommendations as "less strong". That quantitative analysis is supported and enriched here with the specific focus on clinical trial explanations: Pitch B could be viewed as offering more concrete detail about the study while Pitch A does not go into specifics until a positive framing of participation has been accomplished.

Despite the clear contrasts between these two physicians' explanations, how might one abstract these differences so they are properly reflected in an outcome code of some kind? An initial methodological implication to be drawn from this question is that the qualitative difference between Pitch A and B can be too easily lost in a coding procedure. Thus for those interested in the process of recruitment to clinical trials, these qualitative differences may well be important and merit further careful descriptive study.

A related implication of this work is for clinical practice: perhaps physicians and those responsible for overseeing informed consent procedures can gain some insight into presentation strategies by reflecting on these sorts of descriptive empirical data and considering the ethical implications of when and how much information to present. Furthermore, before institutions embark on educating physicians about how to present clinical trial options to patients, there must be some base line research into what current actual practices are (not self-reports or interview data to get at what one may perceive oneself to be doing).

Finally, for those scholars interested in persuasion, this analysis launches a challenge to think about situated, naturally occurring occasions of hearably persuasive discourse and to investigate further what some of the mechanisms may be that provide for that persuasive tone. Clearly, the decision to enroll in a clinical trial is affected by myriad social constraints, information from a variety of professional and lay sources, and a matrix of personal preferences and disposition to risk (Siminoff & Fetting, 1989); however, the input from the physician is a key aspect in patient decision-making (Siminoff & Fetting, 1989; Siminoff & Fetting, 1991) and the detail of that input should not be overlooked given the interactional complexity of the physician–patient encounter.

Appendix A. Transcription symbols

.	falling, "final" intonation
,	continuing, "comma" intonation
?	rising intonation
:	sound stretch
CAPS	louder than surrounding talk
* *	reduced volume between these signs
> <	faster speech between these signs
—	(underline) stressed element
↑ ↓	speech between these is hearable as higher in pitch
(.)	untimed "micropause"
(1.0)	timed pause, represented in seconds
=	talk that is latched
[	marks onset of overlap
]	marks end of overlap
-	(hyphen) speaker cuts own speech
( )	transcriber doubt,
((sniff))	untranscribed sound

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