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A Disparity of Words: Racial Differences in Oncologist-Patient Communication About Clinical Trials

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Abstract

Background—African-Americans are consistently underrepresented in cancer clinical trials. Minority under-enrollment may be, in part, due to differences in the way clinical trials are discussed in oncology visits with African-American versus White patients.

Objective—To investigate differences in oncologist-patient communication during offers to participate in clinical trials in oncology visits with African-American and White patients.

Methods—From an archive of video recorded oncology visits, we selected all visits with African-American patients that included a trial offer (n=11) and a matched sample of visits with demographically/medically comparable White patients (n=11). Using mixed qualitativequantitative methods, we assessed differences by patient race in (1) word count of entire visits and (2) frequency of mentions and word count of discussions of clinical trials and key elements of consent.

Results—Visits with African-American patients, compared to visits with White patients, were shorter overall and included fewer mentions of and less discussion of clinical trials. Also, visits with African-Americans included less discussion of the purpose and risks of trials offered, but more discussion of voluntary participation.

Discussion and Conclusions—African-American patients may make decisions about clinical trial participation based on less discussion with oncologists than do White patients, as shown by a discourse analysis of two interactions. Possible explanations include a less active communication style of African-Americans in medical visits, oncologists' concerns about patient mistrust, and/or oncologist racial bias. Findings suggest oncologists should pay more conscious attention to developing the topic of clinical trials with African-American patients, particularly purpose and risks.

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Keywords

patient-physician communication; cancer; health care disparities; minorities; discourse analysis

Introduction

Health disparities are differences in health or health risks in which disadvantaged social groups, such as racial/ethnic minorities, women, or the poor, systematically experience worse health or greater health risks than more advantaged groups for reasons that could be addressed by social policies.[1] In the United States, racial disparities exist in cancer outcomes: African-Americans with cancer have lower five-year survival rates and higher mortality rates compared to White patients.[2] One very likely cause of these differences is racial disparities in health care.[3, 4] In cancer research, African-Americans are consistently underrepresented in clinical trial recruitment and enrollment. Underrepresentation may contribute to health disparities in two ways: first, clinical trials are considered state-of-the-art cancer management for all patients, and thus all patients should have access to clinical trials; second, findings from research conducted without adequate minority representation may not be generalizable to minority populations.[5-8]

Studies have shown that the communication between oncologists and patients influences decision-making about participation in clinical trials.[9-11] Prior studies using patient self-reported perceptions of clinical interactions and observations of audio and/or video recorded interactions have also demonstrated consistently that the quality of communication between physicians and African-American patients, as compared to White patients, is of lower quality.[4, 12-18] For example, systematic observational analyses of video and/or audio recorded clinical interactions have shown that physicians use more patient-centered communication with and provide more information to White patients than African-American patients, and that African American patients participate less actively in clinical interactions, such as by asking questions or stating concerns.[14, 15, 19-21] However, we found no studies using real-time interactional data from actual oncology visits to investigate whether there are differences by patient race in physician-patient communication about clinical trials. These communication differences, if they exist, would suggest that African-Americans may make less informed decisions about clinical trial participation or may be less likely to agree to participate. These differences would, therefore, contribute to underrepresentation in clinical trials and to racial health disparities in cancer care.

Thus the purpose of this study was to compare physician-patient communication during offers to participate in clinical trials in oncology visits with African-American and with White patients. Using word count as an objective measure of the amount of actual face-to-face discussion between oncologists and patients, we first compared the length of the entire visits in which clinical trials were offered for African-American vs. White patients. Second, we analyzed differences in offers to participate in clinical trials as a topic of discussion during the visits. Finally, we analyzed differences in an important type of information within the topic of clinical trials, the five key elements of consent, as subtopics – the purpose of the study, its potential risks and benefits, alternatives to participation, and the voluntary nature

of participation. These elements of consent are identified by federal regulations as necessary to obtaining informed consent.[22]

Patients and Methods

Data for this secondary analysis were taken from an archive of transcripts of oncology visits video-recorded between April 2002 and March 2006 in multidisciplinary outpatient clinics at two comprehensive cancer centers.[10, 11] All patients and physicians provided informed consent as required by the Institutional Review Boards at both institutions. Patients were recruited for the study on their first visit to a participating oncologist if clinic staff indicated they were potentially eligible for any clinical trial. The parent study included 235 video recorded visits with patients who were potentially eligible for clinical trials, but only 47 of these visits included explicit offers of clinical trials to patients. Of these, 11 patients were African-American.

Sample

From the parent study, transcripts of all visits that included the explicit offer of a clinical trial to an African American patient (n=11) were selected. Rather than analyzing transcripts of all visits with White patients for comparison, we selected a sample of White patients (n=11), matched to the African-American patients to the extent possible by factors in the following order: SEER[23] diagnostic codes for type of cancer, education, income, gender, and age (Table 1). Eleven different oncologists saw the patients in the 22 visits. For African-American patients, ten of the 11 visits (91%) were with White oncologists; the remaining visit was with an African-American physician. For White patients, ten of the 11 visits (91%) were with White oncologists; the remaining visit was with an Asian physician.

Procedures

We used mixed qualitative-quantitative methods for coding and analysis in this study. To extract the data we used discourse analysis, a qualitative method for analyzing transcripts of talk by topics and subtopics. We chose to use discourse analysis because it takes an interactional perspective, which allows us to analyze how oncologists organize offers to participate in clinical trials and how patients respond as part of the ongoing interaction.[24] We adopted definitions of topic and subtopic following Chafe.[25] Specifically, we defined a *topic* as a coherent set of utterances about a main idea; a topic can be as short as an utterance or two or as long as a lengthy discussion. We similarly defined a *subtopic* as a set of utterances about a subsidiary idea within the main idea of the topic. Topics and subtopics are identifiable by multiple linguistic criteria: pauses; shifts in content; discourse topic markers such as *so*, *now*, and *OK*; and items in lists (for subtopics). To create the database for this study, one author (EB) extracted all mentions of clinical trials in the transcripts of the 22 visits, by oncologists, patients, and patients' companions. Mentions are defined as the sets of utterances related to a topic or subtopic. Within the extracted mentions of the *topic* of clinical trials, two authors (EB and AW) then independently extracted mentions of any of the five key elements of consent noted earlier – purpose, risks, benefits, alternatives, and voluntary participation—as *subtopics*. Elements of consent were defined following the 45 CFR 46 (2005/1999) federal regulations and guidance.[22] Overall percent agreement between

authors on identification of subtopics was 87.4%; discrepancies were resolved through discussion. Table 2 provides definitions and examples of elements of consent.

In the quantitative analysis, we calculated the amount of time spent discussing these aspects of clinical trials. To do this, we calculated the word count during each topic and subtopic mention using Microsoft Word Count. The study sample (22 visits) was quite small, making tests of the statistical significance of differences between average word counts inadvisable. Therefore, we assessed the size of the effect of patient race on the discussion of clinical trials using Cohen's d,[26] which is the difference between two means divided by the pooled standard deviation for the two samples. It is, thus, the size of a difference expressed in units of standard deviations. Cohen's d is not dependent on sample size and is often used to describe the magnitude of the difference between two means. Cohen proposed the following guidelines for the interpretation of effect sizes: small (≥ .2), medium (≥ .5), and large (≥ .8).

Results

Table 3 presents the mean word count of the entire visits, the frequency (i.e., number of times a topic or subtopic was mentioned during a visit) and mean word count of mentions of clinical trials as a topic, and the frequency and mean word count of mentions of elements of consent as subtopics in offers to participate in clinical trials with African-American and with White patients.

Mean word count of entire visits

Mean word count of the entire visit was less for African-American than White patients ($4877.73_{\text{African-Americans}}$ vs. 7247.18_{Whites}, d=.8740).

Frequency and mean word count of mentions of clinical trials as a topic

The topic of clinical trials was mentioned less frequently during visits with African-American than White patients ($M=2.73_{\text{African-Americans}}$ vs. 4.27_{Whites}, d=1.2099). When the topic of clinical trials was mentioned, mean word count during mentions was also less for African-American patients ($M=1089.64_{\text{African-Americans}}$ vs. 1867.09_{Whites}, d=1.0618).

Frequency and mean word count of mentions of elements of consent as subtopics

The patterns of effect size were mixed for the subtopics of elements of consent. For purpose, the effect of race on the frequency of mentions was minimal ($M=2.36_{\text{African-Americans}}$ vs. 2.55_{Whites}, d=.1209); however, when purpose was mentioned, the mean word count during mentions was substantially less for African-American patients (M=90.91 African-Americans vs. 181.22 Whites, d=.9272). For benefits, the effect of race was minimal for both frequency of mentions ($M=2.64_{\text{African-Americans}}$ vs. 2.73_{Whites}, d=.0505) and mean word count ($M = 181.27_{\text{African-Americans}}$ vs. 200.10_{Whites}, d=.1230). Risks, however, were mentioned less frequently for African-American patients ($M=1.91_{\text{African-Americans}}$ vs. 3.18_{Whites}, d=.5782) and the mean word count when risks were mentioned was also less for African-American patients ($M=211.900_{\text{African-Americans}}$ vs. 390.27_{Whites}, d=.6477). For alternatives, the effect of race was minimal for frequency of mentions ($M=2.00_{\text{African-Americans}}$ vs. 1.91_{Whites}, d=.0564) and small for mean word count ($M=136.20_{\text{African-Americans}}$ vs 172.33_{Whites}, d=.2084).

There were more frequent mentions of voluntary participation for African-American patients ($M=2.18_{\text{African-Americans}}$ vs. 1.55_{Whites}, d=.4139) and the mean word count for voluntary participation with African-American patients was also marginally greater ($M=123.00_{\text{African-Americans}}$ vs. 107.25_{Whites}, d=.1831).

In a different way to summarize the findings of this study, we converted mean word count to mean time of discussion, using an estimate of 150 words per minute of talk adapted from Yuan et al (2006).[27] This estimate takes into account individual variation in rate of speech. Figures 1 and 2 illustrate the same findings in a different way: visits with African-American patients include less time spent overall (32 minutes, 30 $\text{seconds}_{\text{African-Americans}}$ vs. 48 minutes 19 $\text{seconds}_{\text{Whites,}}$), less time spent discussing clinical trials (7 minutes, 16 $\text{seconds}_{\text{African-Americans}}$ vs. 12 minutes, 27$\text{seconds}_{\text{Whites}}$), and half as much time spent discussing risks (85 $\text{seconds}_{\text{African-Americans}}$ vs. 155 $\text{seconds}_{\text{Whites}}$), but visits with African-American and White patients include almost the same amount of time discussing benefits (73 $\text{seconds}_{\text{African-Americans}}$ vs. 80 $\text{seconds}_{\text{Whites}}$).

Discussion and Conclusions

This is the first study to use a linguistic analysis to compare offers to participate in cancer clinical trials by patient race, and the findings indicate a disparity of words. Oncology visits in which clinical trials are offered to African-American patients, as compared to White patients, included less discussion overall, fewer mentions of and discussion of clinical trials, and less discussion of the purpose of a clinical trial and the risks of participation. The only aspect of clinical trials and elements of consent that received more discussion during visits with African-American patients was voluntary participation.

Findings raise concerns that African-American patients may make decisions about clinical trial participation based on less discussion with oncologists than White patients. More specifically, there is a worrisome disparity in the pattern of information about the risks and benefits of trial participation in discussions with African-American and with White patients: African-American patients engage in the same amount of discussion about the benefits of trial participation as White patients, but notably less discussion about the risks. Providing information about the benefits of trial participation is a powerfully persuasive strategy for oncologists to use with patients in discussing a trial,[9, 28] and our study shows that oncologists appear to use this strategy similarly with African-American and with White patients. But the ethics of clinical trial recruitment require that patients also receive adequate information about the risks of the trial, and here African-American patients experience notably less discussion.

The following examples from *the same oncologist* in visits with an African-American patient and with a White patient illustrate differences in the discussion of risks by race: Example One [African-American patient]:

> Oncologist: [A]t any time if you say ‘It’s making me too sick, I’ve had this side effect, it’s too bad’ [Patient: Right.] we’ll pull you off and try one of the other possible regimens. [Patient: Right.]

Example Two [White patient]:

> Patient: So on this, would you say fatigue will [stop me] from doing anything?
> Oncologist: It varies. There's some people that the fatigue certainly does. There are other people that say they notice it and that they feel better the weeks off. That it doesn't stop—
>
> Patient: Will I be able to [golf] without a problem?
>
> Family: You don't [golf] anyway.
>
> Oncologist: I can't predict how it would be for you but … I mean if the fatigue is such for you that you can't get out of bed, we can certainly adjust the dose, if— And you can always withdraw from the trial, too. If you say at some point, hey this isn't worth it, I'm just lying here because I'm so tired. I don't expect that, that'll happen and we certainly haven't seen that much of it. Some people do complain of the fatigue.

The contrasts here are not solely in amount of discussion, but also in interactional form, elaboration, and reassurance. Both examples include references to side effects and withdrawal from the trial. In Example Two, however, the discussion of fatigue as a specific side effect takes place within a substantive dialogue between the patient and the oncologist, not as part of a short monologue mentioning side effects in general, as in Example One. The discussion of fatigue is also elaborated, personalized by the patient and family member with its joking talk of golf and reassurance about managing side effects. In Example One, the burden of discussing side effects and any subsequent decision to withdraw seems to be solely the patient's. In Example Two, the burden seems more shared between the patient and the oncologist as part of a therapeutic alliance related not only to treatment on the trial but also to quality of life during treatment.

Why is there a disparity of words in discussing clinical trials with African-American patients? One possible explanation has been suggested by prior researchers, and is illustrated in the examples above--that African-American patients may have a less active interactive style in oncology visits, asking fewer questions, providing low uptake responses to physician contributions that do not generate more topic development (e.g., "*right*"), and providing fewer high uptake responses that keep topics developing (e.g., personalizing information).[14, 15, 19] This study suggests that something similar may occur for discussions of clinical trials with African-American patients, particularly with respect to risks.

Another possible explanation is that oncologists may be less willing to fully discuss clinical trial participation with African-American patients due to concerns about African-Americans' mistrust. Mistrust in physicians and medical institutions has been shown to be greater among African Americans than among whites, in great part due to the legacy of racism and poorer health care for minorities in the U.S.[3, 29-33] In this study, voluntary participation was the only element of consent discussed more with African-American patients than with White patients, suggesting that oncologists are sensitive to the issue of mistrust when discussing clinical trials with African-American patients. It may be that oncologists do not persist in offering clinical trials to African-American patients – not mentioning the topic multiple

times and/or not developing the topic if African-American patients seem less responsive -- out of concerns about harming the clinical relationship.

Yet another explanation is that oncologists' racial attitudes and beliefs lead to differences in communication. Recent research in cognitive and social psychology suggests certain stereotypes about African-American patients (e.g., that African-Americans are non-compliant), even among physicians who genuinely and explicitly claim egalitarian attitudes, can make clinical communication less patient-centered.[34-37]

The literature on minority recruitment in clinical trials has repeatedly identified patient, provider, and system barriers to minority enrollment in clinical trials, two decades after the NIH Revitalization Act of 1993.[38-41] In their review of provider barriers to enrollment in clinical trials, Howerton and colleagues[42] identified communication practices as a barrier, along with provider attitudes about adherence and minority patient mistrust of medical research; however, these studies were based on retrospective survey and focus group methodologies, not prospective methodologies investigating face-to-face interactions between oncologists and patients. By measuring the amount of actual discussion about clinical trials, the present study identified specific disparities in communication: perhaps because oncologists are sensitive to the issues of racism and the importance of emphasizing that participation in clinical trials is voluntary for African-American patients, mentions of clinical trials occur less often and with less discussion in visits with African-American patients particularly about the risks of participation.

This study had several limitations that suggest directions for future research. First, the sample size was small; however, as far as we know, this is the first study of clinical trial recruitment to directly compare offers to African-American versus White patients using real-time interactional data, and the results generally showed substantial effect sizes. Future comparative studies should include larger numbers of oncology visits with African-American patients. Second, visits with African-American patients were almost all race-discordant in this study, reflecting not only the race of the participating oncologists, but also the demographics of oncology as a sub-specialty in medicine.[43] Third, this study looked at just one type of information within offers to participate in clinical trials, the discussion of key elements in informed consent. Future studies should look at other informational dimensions of offers to participate in clinical trials, such as descriptions of the procedures of the trial and discussions of the trial regimen in comparison to standard treatment. Similarly, some information was not available from the parent study, such as patients' cancer stage and prognosis, the type of trial discussed (e.g., whether it included a randomized controlled trial), and what patients understood about trials offered. Future studies should assess relationships between the quality of communication and these variables. Fourth, the small sample size did not allow a meaningful analysis of outcomes, such as patient decisions about participation. Finally, this study looked at just one minority population, African-American Americans in the United States. The NIH Revitalization Act[41] identified multiple populations of underrepresented patients, including Latinos/Hispanics, women, older adults, rural residents, and economically disadvantaged groups. Ideally, research using real-time interactional data from oncology visits should be conducted on other underrepresented

populations to discover whether there are other disparities of communication in offers to participate in cancer clinical trials.

This research suggests that deliberative discussions about pros and cons of decisions may help overcome the effects of implicit attitudes.[44] In communication about medical research, already fraught with racial issues in the United States, oncologists may need to pay more conscious attention to achieving the goals of patient-centered communication and shared decision-making in offers to participate in clinical trials in general and in discussions of the risks of trial participation in particular. Thus, to improve the quality of shared decision-making about trials, oncologists could be more conscious of mentioning and developing the topic of clinical trials in oncology visits with African-American patients, and provide more information about the risks of trial participation. More mentions and development of the topic of clinical trials may lead to greater enrollment, improving the representation of African-American Americans in clinical trials; more discussion of purpose and risks may help to achieve shared decision-making.

Clinical trials remain the gold standard of progress in cancer research and patient care, but low enrollment, particularly among minorities, threatens that progress and may contribute to disparities in cancer care and outcomes. Studies of real-time recruitment such as this one can identify racial disparities in communication that may lead to minority underrepresentation in clinical trials and suggest communication strategies that may lead to greater minority enrollment in clinical trials.

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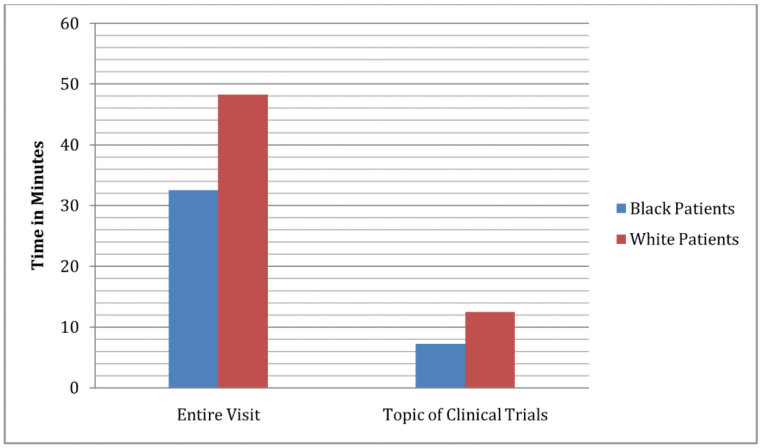

Figure 1.
Time of Entire Visit and Time on Topic of Clinical Trials

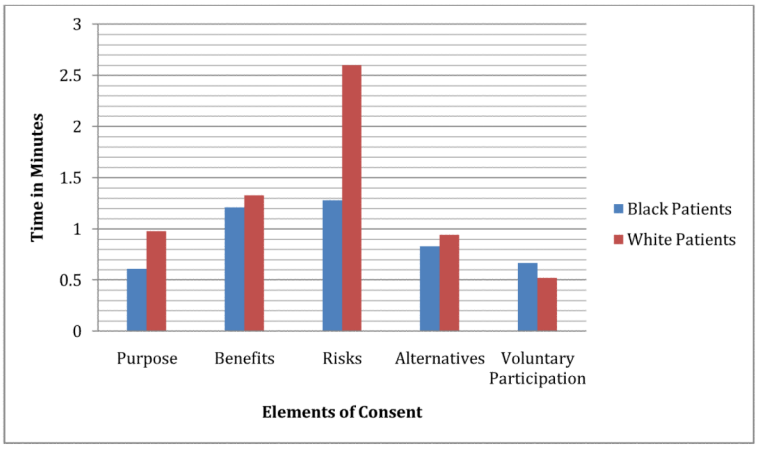

Figure 2.
Time on Subtopics of Elements of Consent

Table 1

Patient Characteristics

	African-American	White	
Total			
Race	11 (50%)	11 (50%)	22 (100%)
Type of Cancer (SEER[4] diagnostic codes)			
Digestive	3 (27%)	3 (27%)	6 (27%)
Genital	3 (27%)	2 (18%)	5 (23%)
Breast	3 (27%)	1 (9%)	4 (18%)
Oral	1 (4%)	1 (4%)	2 (9%)
Myeloma	1 (4%)	1 (4%)	2 (9%)
Respiratory	0 (0%)	3 (27%)	3 (14%)
Education			
High school, trade school or less	5 (45%)	5 (45%)	10 (45%)
Some college or greater	6 (55%)	6 (55%)	12 (55%)
Income			
≤ $39,999	6 (55%)	3 (27%)	9 (41%)
≥ $40,000	3 (27%)	6 (55%)	9 (41%)
Mean/SD	37,700/19.4	57,200/34.6	47,700/28.7
Independent t-test			p=.1702
Gender			
Male	7 (64%)	6 (55%)	13 (59%)
Female	4 (36%)	5 (45%)	9 (41%)
Age			
≤ 59	6 (55%)	1 (4%)	7 (32%)
≥ 60	5 (45%)	10 (96%)	15 (68%)
Mean/SD	60.5/12.8	65.8/6.9	63.2/10.4
Independent t-test			p=.2444

Table 2

Coding for Elements of Consent

Element of Consent	n=	% agree	Definition	Example
Purpose	54	92.6	A statement of the scientific question of the research (NIH, 2008).	And I'll go through one of the research studies we're doing here, trying to figure out some new ways to mix and match.
Risks	56	80.4	A statement of the probability and magnitude of harm or discomfort that may arise from participating in research (45 CFR 46, 2005/1999), including both side effects and negative outcomes (NIH, 2008).	The consent form has all the information that is about the trial, what the drug is, why we are using it, and what its potential side effects are. Or if it's [the tumor] against the blood vessel and the blood vessel can rupture, so that's always a small risk. It's a small risk with Gleevec, it's been a small risk with this [experimental drug].
Benefits	59	88.1	A statement of the direct benefits to the patient, including access to the treatment, care, and education patients receive on the trial, as well as their feelings of autonomy and altruism derived from participating in the research; a statement of indirect benefits to others or society, including the likely importance of the scientific knowledge resulting from the clinical trial (NIH, 2008).	And, um, it's one pill a day and … the … early information that we have is that the combination-- th-this combination might be one and a half or two times more effective than the older one that I was telling you about. OK. PH: But the information that's derived will go on to further help medical research -- PT: And other people. PH: -- may be able to help others in the future know if there's a difference or not.
Alternatives	43	83.7	Disclosure of appropriate alternative treatments, if any, that might be advantageous to the patient (45 CFR 46, 2005/1999).	So among the drugs that we can give to you there are three options. Either the standard chemotherapy drugs, which have a ten to fifteen percent chance of working. And they are—they could have some potential side effects. The second option is to try one of the newer, more selective drugs … which has the same probability of working, same chance it works but [is] easier to take.
Vol. Part.	42	92.8	A statement that participation is voluntary (45 CFR 46, 2005/1999).	This is also voluntary. And if you decide either now or later that you don't wanna participate we'll still take care of you, we're not gonna chase you away for it.
Total	254	87.4		

Table 3

Word Count of Entire Visits, Frequency and Word Count of Mentions of Clinical Trials as a Topic, Frequency and Word Count of Mentions of Elements of Consent as Subtopics

	African-American		White		
	Mean	**SD**	**Mean**	**SD**	**d=**
Entire Visit					
Mean word count	4877.73	2519.06	7247.18	2890.36	d=.8740
Topic of Clinical Trials					
Mean times trial mentioned	2.73	1.01	4.27	1.49	d=1.2099
Mean word count	1089.64	330.62	1867.09	980.48	d=1.0618
Subtopics of Elements of Consent					
Purpose					
Mean times Purpose ment.	2.36	1.29	2.55	1.81	d=.1209
Mean word count	90.91	58.36	181.22	124.77	d=.9272
Benefits					
Mean times Benefits ment.	2.64	1.80	2.73	1.76	d=.0505
Mean word count	181.27	144.41	200.10	161.23	d=.1230
Risks					
Mean times Risks ment.	1.91	1.87	3.18	2.48	d=.5782
Mean word count	211.90	192.73	390.27	338.46	d=.6477
Alternatives					
Mean times Alt. ment.	2.00	1.61	1.91	1.58	d=.0564
Mean word count	136.20	165.48	172.33	180.99	d=.2084
Voluntary Participation					
Mean times Vol. Part. ment.	2.18	1.60	1.55	1.44	d=.4139
Mean word count	123.00	59.70	107.25	105.97	d=.1831