Why Does Informed Consent Fail?
A Discourse Analytic Approach

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Informed consent often fails to meet the intended goals that a prospective subject should understand fully and choose autonomously to participate in research. The current study is an attempt to understand such failures by applying linguistic methods of discourse analysis to the transcripts of informed consent interviews. Elements of conversation and of the frame of discourse were analyzed to understand how the participants shaped their spoken interaction during the interview. We looked at the degree to which the subject appeared to be fully informed, at the problem of therapeutic misconception, and at the degree to which the subject was helped to explore concerns relevant to the choice at hand. We found that lapses or miscommunications could be understood specifically in terms of conversational elements and framing. This kind of detailed, language-based analysis is an alternative to approaches that are more abstract and inferential, such as those that are based upon the attitudes or the cognitive performance of speakers. We discuss possible educational and research implications of this approach.


Why is the performance of informed consent (IC) so often found to be lacking, when its basic requirements and protocol have been established and discussed for decades?

The essential procedure is straightforward enough: information is given about a proposed medical treatment or research study and the patient or the prospective subject is asked for his consent. The clinician or researcher who requests consent is required to provide the information that a reasonable person would want to know to make his decision; to tell the risks and benefits of the proposed intervention; to describe the alternative courses (of treatment, for example); and to determine that the decision-maker is competent and can express a choice. While medical law does not specify a particular format, IC is not to be treated merely as “information transfer.”

The puzzle is that a large amount of the information in the informed consent process seems to be misunderstood or not understood and we do not know why. Why does this happen despite the efforts by institutional review boards (IRBs) to craft carefully worded consent forms? Likewise, why is therapeutic misconception so pervasive?

In this article, we will analyze some selected examples of IC interviews that were performed for participation in research studies. Our focus will be on examining in detail the raw data of spoken language between interviewer and interviewee. This emphasis is different from the usual focus of studies on IC, which explains the problems with IC interviews based on the viewpoints and motivations of the speakers. Typical of the latter approach are formulations such as differences in clinicians’ and patients’ perspectives, different desires for information, and “lack of concordance between the content of the consultations, and the women’s expressed perception of benefits and risks” (Ref. 4, p 352). Our approach, by contrast, emphasizes how speakers communicate, how meaning emerges based on the dynamics of the discourse, and how language is used to negotiate what is discussed and what is agreed on.

We use an approach that is based on the methods of discourse analysis (DA), which we will explain later in the article. The central idea is that the content and the meaning of IC are not merely expressed through spoken ideas but are dependent on the form of the discourse.
Methods

We studied videotapes of IC interviews in which consent was being sought from psychiatric patients for participation in different research studies. The interviews were recorded in the 1980s with subjects who were either inpatients or psychiatric day hospital patients and were being recruited for research projects. Excerpts were selected for analysis based on how well they illustrated the relevant aspects of the IC process. The use of IC interviews that had been performed for research purposes, as opposed to clinical purposes, was dictated by their availability; but we believe that much of this material would also apply, with some modification, to clinical IC interviews. Both the initial studies and our secondary analysis were approved by the University of Pittsburgh IRB.

We utilized methods from the linguistic discipline of discourse analysis to examine how miscommunications or lapses came to occur in selected IC interviews. The basic approach here is to examine the discourse as a text. One looks for patterns of word usage, cues, topic shift, underlying expectations, and other features, to understand how the interview dialogue works.5

In our transcriptions of discourses, we used standard methods to indicate not only the words that were spoken but some features of timing and prosody. Segments of speech are punctuated according to the apparent sense of the utterance rather than grammatically. Table 1 explains the symbols used in transcription of the dialogues.

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<thead>
<tr>
<th>Table 1. Transcription Symbols</th>
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<tbody>
<tr>
<td>Symbol</td>
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<tr>
<td>Comma</td>
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<tr>
<td>Question mark</td>
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<tr>
<td>Colon(s): “lo-ng”</td>
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<tr>
<td>Period</td>
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<tr>
<td>Group of two to three periods:</td>
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<tr>
<td>“he said...”</td>
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<tr>
<td>Number in parentheses: (0.5)</td>
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<td>Paired equal signs: last time=</td>
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<td>=no</td>
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<td>Paired brackets, e.g. [so he said it]</td>
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Theoretical Background

In his classic book on IC, The Silent World of Doctor and Patient, Jay Katz6 explored the integral relationship among information sharing, the psychology of authority and trust between doctor and patient, patient autonomy, and the negotiation of a treatment contract. An essential element, Katz wrote, is “the obligation for conversation” (Ref. 6, p 130).

What makes conversation meaningful? Essentially it is the sense of alignment between the speakers (being on the same page) and coherence in the dialogue. One sociolinguist noted, “both speaker and hearer must actively respond to what transpires by signaling involvement . . . The response, moreover, should relate to what we think the speaker intends, rather than to the literal meanings of the words used” (Ref. 7, p 1). As this carefully worded description suggests, conversation is far from being a matter of simple information transfer. It includes features such as involvement, signaling, intention, active response, and other features of verbal exchange. These features, in turn, depend on formal elements that are in each speaker’s practiced repertoire and that cue the other speaker about what is intended and expected.

We will focus on two elements that create form in discourse: adjacency-pair organization (also known as turn-taking), and frame. To understand failures in IC, we need to look at how these form-creating elements operate, or how they fail, during conversations that interviewers conduct with their patients or prospective subjects.

Adjacency Pair Organization, or Turn-Taking

Researchers on conversation have codified patterns of interaction between speakers that tend to promote order and coherence in dialogue.8 Chief among these is the allocation of the floor to one speaker at a time, with specific cues as to when one person’s speaking turn is finished. These turn-taking cues include pauses, gaze, gestures, syntax, and transitional phrasing, among others. Order and meaning are created also by sequential features such as how a given lexical form shapes the next speaker’s response (e.g., a question or an implicit demand obligates a reply).

Although we unconsciously tend to follow such rules, we also notice the violations of expectable turn-taking and the repairs that speakers provide. Such violations might include interruptions or excessive pauses, repetitions or non sequiturs, premature closure, and many other features. These violations can indicate different things: sometimes lapses or miscommunications, but sometimes emphasis or disagreement. Thus, discourse is shaped largely by turn-
taking, turn-taking violations, and speakers’ choices about how to handle these events. Here is an example from a medical interview, reported by the sociolinguist Richard Frankel, of how a violation of the expectable pattern in turn-taking is analyzed in DA and what significance might be attached to it:

Dr: What brings you to the office today
Pt: (3.0)
Dr: Mr. Allen?
Pt: Yes
Dr: What brings you to the clinic today?
Pt: My back’s been acting up again

The doctor’s question would have been expected to generate a timely answer, not a three-second pause. Frankel comments that “In situations in which the context itself cannot be relied upon to have produced any clear indications that both parties have heard and understood a particular utterance . . . silence is ‘readable’ as a failure to establish minimal sequential evidence for conversational attention” (Ref. 9, p 34). Hence, we see the doctor’s repair of pointedly stating the patient’s name (to establish conversational attention) and then of repeating the initial question (to return to the initial conversational task).

The reader may notice that Frankel uses the terms “understood” and “attention” not primarily in a psychological sense but in relation to conversational alignment. This use of the concept of “attention” may seem to be parochial and tangential to our IC concerns. In fact the contrary is true: all that we know of the subject’s attentiveness, engagement, and understanding is what we infer from the features of his conversation with us as we discuss IC.

Frame

Frame may be defined as the set of expectations that governs how one will interpret what is being said. It is a basic determinant of whether people are on the same page. So, for example, the question “How are you?” in casual conversation is a friendly social greeting. However, if it is asked by a doctor at the beginning of a medical interview, we expect that it is more likely an inquiry about our health.

Cues to the frame may be established by the setting itself, by the social and cultural context, or by signals within the dialogue itself.10,11 Consider the following hypothetical dialogue, which is an example of a doctor-patient exchange at the end of the history-taking portion of the visit:

Dr: So you’ve had this pain in your lower abdomen for a week now?
Pt: Yes, about that long.
Dr: Okay, why don’t you lie down here (pointing) on the table.
Pt: This okay?
Dr: Scoot up just a little bit.
(Patient moves up on the table)
Pt: (pointing) It’s right here.
Dr: (washing his hands) Okay.
Say, how’s Annette?
Pt: Oh she’s fine. She’s out with Robbie at his hockey game this afternoon.
Dr: Well that should be a treat. Relax your stomach.

In this dialogue there are actually four frames: the overarching frame of a medical visit; the stage-specific frame of history-taking to elicit details about the pain; the frame of the physical examination; and the social frame of inquiry about the patient’s wife. The shift to a frame of physical examination is cued by a direct order from the doctor, together with his pointing gesture. Its acceptance is cued by the patient’s obedient “This okay?” and his gesture to indicate where the pain is. The shift to an adjacent frame of social (not medical) inquiry is accomplished by the doctor’s direct and informal-sounding question (“How’s . . . ?”). This shift is validated by the patient’s immediate response of offering a social detail. The doctor then makes a quick shift back to the physical examination frame, using a direct order.

This train of frame settings and shiftings is discernable, and the patient’s collaboration is plausible, because it is set within the overall social context of a medical visit. As usual in medical interviews, the doctor is in charge. The patient expects to be examined and mostly to follow the doctor’s lead. If the same comments were spoken by someone else and in a different context (i.e., a different frame), then they would be interpreted very differently.

Another point is that frames in discourse may be multiple, nested, or suspended. The shifting, as well
as the suspension and subordination, of frames may be accomplished either semantically or through cues such as pauses, gestures, or facial expressions; directions of gaze; prosody; and voice register. DA studies have shown how conversational and framing elements contribute to alignment and organization in doctor-patient interviews. In contrast to ordinary conversation, the medical interview tends to progress through familiar stages (elicitation of chief complaint, history of present illness, and so on). It also follows a pattern in which the doctor asks most of the questions and the patient gives answers. Consequently, what constitutes a variation or a violation differs from usual conversation. For example, a patient’s interrupting or contradicting a doctor would be more notable than in casual conversation with a friend.

The overall frame of medical interviews is one of clinical caregiving. Advocacy and persuasion about treatment options fit within this frame, since giving one’s best medical opinion is considered an appropriate use of the doctor’s power in the relationship. DA has also been applied to analyzing the shortcomings of medical interviews. Problems such as doctors’ use of jargon, inattention to cultural variations, dominating speech, avoidance of the patient’s psychosocial concerns, premature closure, and other behaviors have been well characterized. Mismatching of frames may also interfere with good communication, as when terms that are used by the doctor, such as “complaint” or “sensitive” are incorrectly expected by a patient to carry a moral valence equivalent, respectively, to “whining” and “touchy.”

Applications to the Research IC Interview

The research IC interview differs from a medical interview in specific ways. Instead of going through the usual stages that characterize a medical interview, and instead of using questions and answers to elicit the patient’s symptoms and history, the research IC interview is aimed at presenting information about the study and requesting consent. Prospective subjects may not only be unfamiliar with this mode of interviewing, they may actually find it confusing and may have to be oriented away from the usual set of expectations about talking with a medical professional. This task is doubly difficult if the researcher who is conducting the interview happens to be the same doctor who is also providing clinical care. There may be a fine line between advocacy or persuasion, on the one hand, and peremptoriness or coercion on the other.

The primary difference is in the frame. In a clinical interview, including its IC component, the frame is one of providing care. In a research IC interview, however, the frame is one of requesting consent to be included in a study. The following example from our database illustrates a clear frame of request to participate in research:

Dr: What I want to do now is to make sure you understood everything on the tape and to find out if you’re willing to participate with us.

The following example, also from an actual research IC interview though a different source, illustrates the contrary—a frame of demand rather than request:

Dr: I need to get you to sign a couple of consent forms just to say that I talked to you about it and the fact we’re not going to use it for anything except our own uses.

Application to Interviews for Informed Consent for Research

We will use DA methods to look at three types of problems in research IC interviews: limited informedness, therapeutic misconception, and possible coercion.

Limited Informedness

“The informed” refers in large part to the subject’s state of mind. It refers both to the interviewer’s conveying a sufficiency of information and to the prospective subject’s level of understanding. “Understanding” includes that the frame of the interview is to provide information and make a request, not to elicit symptoms or prescribe treatment.

To begin with a positive example, the following excerpt shows how a research interviewer conveys information about a drug’s side effects, and how this information appears to be understood by the prospective subject. We will look at how this mutuality is created.

Before this excerpt, the interviewer has oriented the subject to the IC and request nature of this interview and has begun explaining the purpose of the study. The subject has already mentioned a side effect that he has experienced with medication.
Example 1

Dr: At our low dose, the effects are usually if people do get side effects they’re kind of mild. We have the flexibility in our protocol to lower the dose or to add Akineton.

Pt: Yeh uh uh uh uss ss I’msay I’m a very leery about that d-dose because I was taking fo:ur..

Dr: mm hm=

Pt: I=milligrams a day and I count’nt walk uh uh get yeah I wasn’t able to walk

(2.0)

Dr: Well [ as I said]

Pt: [aaahhh]

Dr: we have the we can use the akineton, you’re here in the hospital, and that’s a major advantage... uh so we can adjust the dosage.

We have one other advantage, which your doctors before or your doctors in the community don’t have, and that’s once a week we take a blood sample and we analyze it for the amount of Haldol in your blood.

We have a target dose range that we want in your blood and we know approximately where side effects appear in that range, we’ll try to keep it, we can adjust the amount you take by mouth to be down below that range.

Pt: (nods)

Dr: Now there’s only a one-third chance that you’ll be on Haldol.

Pt: Yeah

Dr: Um...the other drug amitriptyline is the antidepressant which is used in normal strength

By the end of this vignette, the subject has heard several details about how the researchers could address haloperidol-induced parkinsonian stiffness. These include monitoring of the blood haloperidol level to help assess the likely appearance of side effects, using the blood level to determine the dose and adjusting the dosage of haloperidol, and using the anticholinergic agent Akineton. However, it was not preordained that this amount of detail would emerge during this vignette. Initially, all that the interviewer provided was the brief reassuring comment that “side effects [are] kind of mild. And we have the flexibility . . . to lower the dose or to add Akineton.”

The richer information appears to have emerged in association with a sense of mutual attentiveness, give and take, and willingness to explain and persuade in the dialogue. These create an atmosphere of alignment and of sharing information.

We can see how these qualities are created by analyzing turn-taking and frame. The turn-taking pattern is not question-and-answer, but a more equally shared pattern, with each speaker leaving room for the next to initiate talk. So, after “Akineton” there is a “turn-relevant place,” meaning that the first speaker gives enough of a pause that the next speaker’s utterance will not sound like an interruption.

Furthermore, in the midst of the subject’s comment, during the pause after “fo:ur...” the interviewer utters “mm-hm” which is a nonverbal acknowledgment or at least a sign of active listening. After the subject finishes with, “I wasn’t able to walk,” the interviewer does not promptly jump in, but waits a full two seconds before replying. (On the videotape he maintains eye contact and appears attentive.) This gives the subject time, if he had so wished, to continue his turn without feeling pressured. When the interviewer does speak, the subject does not interrupt. He gives a nod, and then he utters “Yeah” toward the end, indicating conversational attention (and probably, in this case, agreement). All of these speaking and listening behaviors convey active attention and responsiveness.

The interviewer establishes from the beginning, and maintains consistently, a frame of request and persuasion. He presents the researchers’ options: “We have the flexibility,” “we can use,” “we can adjust.” These phrases inform the listening subject without presuming his approval or consent. A skeptical reader might note how the interviewer plays up his advantages (“you’re here in the hospital, and that’s a major advantage,” and “Now there’s only a one-third chance that you’ll be on Haldol”). This reader might ask why such comments are not considered coercive. It is a fair question. We would reply, first, that persuasion is the appropriate mode within a frame of request and, second, that the interviewer’s comments are informational answers to the patient’s objection, not exhortations or assurances.

Reciprocating this stance of persuasion, the subject presents his negative response in the manner of a reservation rather than a direct objection or refusal:
Failure of Informed Consent

“I’m a very leery,” he says. He follows this with an explanation (“because . . .”) and this explanation notably contains a personal narrative (“I was taking four milligrams a day and I couldn’t walk”). Given that the subject does not appear overall to be refusing consent, the effect of giving the brief narrative is to engage the interviewer and to invite a response. This is exactly what occurs, beginning with “Well as I said . . . .”

In summary, several discourse features in this dialogue show the speakers working toward alignment. These include the shared pattern of turn-taking, cues of invitation to continue or to respond, and mutual adherence to the frame of request. This sets a collaborative tone that encourages the sharing of important information: the subject shares his specific concerns based on prior experience, and the interviewer shares details of the study protocol that may well not have been mentioned otherwise. In these ways, we see that the content of this IC discussion is embedded in the form of the discourse.

The next example shows a problematic dialogue, where both information and understanding appear to be much less complete. The prospective subject is a patient in a psychiatric day hospital.

Example 2

Superficially the interviewer sounds as though she is providing substantial information, but actually her language is quite vague. For example, she mentions “a series of tests,” “find out . . . how you feel,” and “sort of like . . . .” When it comes to knowing how much the subject comprehends, again it sounds superficially as though the interviewer is probing his understanding, because she uses repeated checks. However these checks leave no pauses to allow for a response. These checks, furthermore, are spoken in a manner that is almost that of a parent with a child (“okay? . . . okay? . . . okay?”). If our first example exhibited a richness of material in the exchange, here we find a paucity of actual information being conveyed and no clarity about how it is being understood. What qualities in the form of the discourse account for this outcome?

The turn-taking pattern shows almost no pauses by the interviewer. She does pause after her first “okay?” but this follows a statement, not a question or any other utterance that would invite a reply. At the end of her first turn, where the patient overspeaks with “yeah,” she proceeds without making any pause to acknowledge his utterance. Even when she introduces her first question, on the new topic of role-playing, she does not pause: “we like to do some role-playing with you did you ever do role-playing before?” It is only where she needs to elicit his past experience about role-playing that she offers a turn-relevant place, with a pause and with a break point in her topic.

The patient, for his part, does signal attention and alignment, by means such as “yeah,” nodding, and answering questions when he is asked. However, his signals are tags on to what the interviewer...
has said, and he does not initiate any questions or statements of his own. The interviewer’s speech gives him no cues or invitations to formulate a question or to indicate his consent, and the subject provides no information about his level of understanding.

Her comments reveal a frame not of requesting, but of telling him what the researchers will do: “We’re trying to,” “what we do is,” “we like to give,” “we like to do,” and so on. There is no linguistic signal of shifting to a request frame; and, concomitantly, there is no evidence that the subject understands—i.e., “informed”—that the frame is one of request. Where she does ask for a response, it is about what she presumes he will be doing. “Were you ever in a play at school...?” she asks; but rather than eliciting what this experience was like, she informs him “this is sort of like being in a play”; and she goes on to provide the reassurance that “it’s real easy... .” This is different from Example 1, in which the frame of request is more in accord with conveying possibilities rather than conclusions: “we can use the Akineton” and “we can adjust the amount.”

In summary, this is a circumscribed and one-sided discourse. The formal elements of discourse, a turn-taking pattern of uninterrupted dominance and a frame of presumption and advice, combine to create the sense of a guardian speaking with her ward, rather than that of a requester speaking with a decider. The lack of richer information is consistent with this constricted quality and this unfitting frame.

In both this negative example and the preceding positive one, we see that the content and meaning of IC are dependent on the form of the discourse.

Therapeutic Misconception

Therapeutic misconception is the term given to the tendency of research subjects to “carry strong expectations that research, like the therapy they have received previously, is designed and will be executed in a manner of direct benefit to them” (Ref. 28, pp 327–328). This problem essentially involves the frame of the informed consent discourse—that is, whether the discussion is about a research proposal or a clinical intervention. Of course, one can never expect that individuals will come together without biases or wishes. Nor can one expect the interviewer to abstain from efforts at persuasion (as in Example 1). The concern here is how the frame of the IC discourse is established and maintained by the interviewer. Is the discussion about a clinical intervention, or is it about a research proposal?

We said earlier that analyses of problems with IC tend to rely excessively on the motivations and viewpoints of the speakers. This reliance may be particularly true in therapeutic misconception.29,30 To illustrate this tendency and to provide some background for the discussion that follows, let us examine a vignette from the literature. In a study by Benson et al.31 the following excerpt from a dialogue for informed consent for research is reported by the authors. In the article, it is intended to illustrate problems around the ideas and attitudes that underlie an informed consent interview:

Nurse: What this study is about is we want to get you on a dose (of medication) that is going to make you feel good mentally with the least amount of side effects. That’s why we are going to watch you so closely.

Subject: I feel like you are doing me a great favor.

Nurse: That’s what we’re doing, we’re trying to eliminate side effects and get the dose that is best for you individually [Ref. 31, p 1338].

We present the vignette as spoken, though admittedly it is confusing to read because of several subordinate clauses whose referents are unclear. Indeed, it is not clear that the nurse actually understands either the proper use of an IC interview or even what the study is specifically intended to accomplish. Apparently, the nurse is trying to tell the subject “what this study is about” and that she thinks it will be good for him.

The authors present this vignette for the purpose of illustrating how “researchers... often emphasized the therapeutic and personalistic elements of the study” with the result that “general long-term research goals were not clearly distinguished from short-term clinical benefits for the individual subject.” Possible reasons for this, they suggest, include the difficulty for both researchers and subjects of disentangling treatment from research; the attitude on the part of researchers that “compared with their usual level of care... research subjects were getting superior treatment”; and the tendency of subjects to be “generally passive and acquiescent to medical authority” (Ref. 31, p 1335).
A frame analysis, however, rather than attributing this mistaken emphasis to attitudes or passivity, would focus on the expectations that appear to underlie the conversation. Here the nurse’s frame (notwithstanding her use of the term “study”) is one of explaining clinical care to be delivered (“we want to get you on...” and “That’s why we are going to...”).11 The therapeutic frame is also cued by mention of a therapeutic outcome: “make you feel good.”

The subject calls the nurse’s gesture a “great favor.” His comment could well be interpreted as irony. (After all, it is his consent that would be, in effect, the favor.) Whether ironic or not, his response is actually in alignment with the nurse’s frame. He is telling her that her description sounds not only like clinical care, but like an offer that goes above and beyond the usual level of care. The nurse, however, just takes “great favor” at face value and reconfirms her frame: “That’s what we’re doing...”

The advantage of using a frame analysis on this dialogue is that it keeps us closer to the actual data, suggesting more clearly what is known and what remains uncertain. We know that the nurse is conveying an expectation that the subject will participate and that she is using the promise of clinical care to convince him. We do not know how much she herself can differentiate research from clinical goals, or whether her failure to do so is a matter of attitude. We also do not know the meaning of the subject’s reply: it could be a statement of understanding, a feeling, a question, a hope, a puzzled comment, a note of irony, or something else. Frame analysis thus encourages the specific identification of underlying expectations and of the evidence to support these.

But frame analysis may be of even greater help in showing how a therapeutic misconception may emerge from the dynamics of the developing discourse.

Consider the framing problems in this excerpt in which an interviewer is describing a study protocol that involves ratings of mental status. The interviewer has already discussed the research design and confidentiality for subjects and has asked the subject to sign the consent form. This interviewer-researcher is also the patient’s hospital psychiatrist. We will be paying particular attention to the dynamics of frame shift during the dialogue.

**Example 3**

Dr: And that all the things we learn about you will be kept totally confidential. You’re...You’ll be assigned a research number=

Pt: =mm-hm=

Dr: =and all of our reports will just talk about the numbers=

Pt: =Mm, mm-kay=

Dr: =not about you as a person. So let me just ask you to sign this if you agree to participate. Since we each have a copy you can, you initial the first page (she signs) ...Actually you don’t have to initial your own copy...

Pt: (laughs) It helps

....

Dr: Now I have to talk to Dr. Stanley who’s my (1.0) partner in this and um (1.0) when doctor we’ll find a time either t’ probably tomorrow to get together with you and do the first assessment that we do together, we review your progress of the previous week and how things stand for you now with y’know [how much do you]

Pt: [prog:ress hehe]

Dr: well how much depression you’ve had

Pt: Uh huh

Dr: Uh how much y[ou

Pt: [han’t had too many depression I just have these weird moods

Dr: [Well

Pt: [these spacing out feelings

Dr: That’s what we’lll

Pt: [and the impulse

(1.2)

I can’t that impulse is really hard to control.

Dr: Okay well we’re going to have to work out ways of helping you control that on the sur- on the inpatient unit here so you don’t get in trouble with nurses.

Pt: Yeah...

Dr: Um

Pt: I’ve been able to control it but at times it gets really hard.
The interviewer begins by orienting his prospective subject very clearly to the research IC frame. The therapeutic misconception involves the shift later on to “we’re going to have to work out ways of helping you control that....” While this shift of frame is temporary, it is unmistakably clinical, and it creates some ambiguity about the task. How does this occur?

Both speakers work at achieving and maintaining alignment. This is evident in their repetitions of key words (“progress,” “depression,” “control”). It is also seen in the interviewer’s restraint when the subject interrupts. He allows her to finish her turns without doing interrupting of his own, and he allows the pause of over a full second before she finishes a turn. Another facilitator is the interviewer’s repeated use of “well,” which in a small but significant way acknowledges her disappointment. Toward the end of the vignette the subject insures alignment as well, by relaxing the exchange: that is, after emphasizing her difficulty with self-control, she volunteers that “I’ve been able to control it....” This in effect permits the interviewer to return to his agenda.

The interviewer’s response is actually to try to repair her first turn-taking—her interruption at “progress.” This is remarkable in itself, because in the clinical interview setting it is the patient who invariably does the repairing. He does this by clarifying what it might mean to review “progress,” saying that it might mean “how much depression you’ve had.” His effort at repair serves to confirm the doubt or irony inherent in her repetition of the word “progress.”

The result of the subject’s insistent symptomatic complaints (“depression,” “spacing out feelings,” and “impulse... hard to control”) is to push the discourse away from the interviewer’s frame of describing the research protocol into a clinical frame of caring for her emotional problems: “Okay well” he says, “we’re going to have to work out ways of helping you....”

The reader may think it pedantic to assert that this shift to a clinical frame comprises a therapeutic misconception. After all, we have already noted that the subject herself ends by providing an opening for the interviewer to return to his agenda, and the entire vignette concludes with her receiving the consent document that she had signed. Also, it is easy for us to think of factors that lend impetus to this shift, such as the interviewer’s supportiveness as an incentive for the subject to complete her giving of consent, their contemporaneous relationship as caregiver and patient, and their mutual purpose of maintaining conversational alignment in the discourse, among other possible reasons.

The fact remains that, however transiently, the patient pushed the doctor from a research frame into a clinical frame. That shift is the essence of therapeutic misconception. The focus on frame enables us to understand how the research frame came to be transmuted. The analytic value is to adjust our focus away from a critique of the attitudes or role behavior of the speakers toward understanding how this shift develops in the interview. We see that it develops under the pressure of specific moves in the dialogue and as part of the effort to maintain alignment.

That kind of understanding is a step toward conceptualizing solutions. For example, if one is alert to the frame, one might consider that after the patient protests “that impulse is really hard to control,” the doctor could attempt to return to the IC frame by saying something like, “Well, I understand your concern, but we need to finish our talk about doing the...
ratings for the study.” If this seems too abrupt, then awareness of frame could guide a slightly more compromising, but still IC-focused, comment such as, “Well, I understand your concern. How do you think you might be able to handle your impulses and these disturbing, weird feelings to do the reviews of progress that we need?” Neither comment would suggest that the interviewer is adopting a clinical role, and both would clarify for the patient that the frame remains one of IC.

**Possible Coercion**

Up to now we have been considering mainly the “informed” part of IC. In our last example we will address “consent.”

It is axiomatic that coercion would invalidate informed consent. But Berg et al. note that “the term informed consent itself suggests that patients are expected to agree to be treated rather than to decline treatment” (Ref. 33, p 227). They also aver that “the line between persuasion and coercion is exceedingly fine” (Ref. 33, p 238). Concerns about coercion are greater in the case of informed consent for research than for clinical care. Because the purpose of research is not primarily to benefit the subject, medical authoritarianism is less justifiable.

Some key studies of coercion come from the arena of psychiatric treatment and particularly of commitment to psychiatric hospitals. A key determinant of whether a patient feels coerced is whether and how much he feels a sense of agency and inclusion in the process.34

Such patient perceptions have often been measured by questionnaires and post hoc interviews. However, the assessment by analysis of the IC interview itself, of how freely consent is being given, is complicated not only by the methodological challenges of DA but also by two other considerations. One is that expressions of disagreement to a doctor, at least in the clinical setting, tend to be indirect rather than overt.35 The second is that an absence of coercion is not equivalent to autonomy (there being no such thing as complete freedom of choice). These considerations suggest that the degree to which a prospective research subject exhibits freedom of choice has some relation to how adequately his reservations or uncertainties are elicited and addressed in the IC interview.

There are no guidelines on how far the interviewer should go with eliciting the subject’s concerns to assure his autonomy in decision-making. Several questions could be asked. How deeply must the interviewer probe a subject’s motivation or his sense of being pressured by family and caregivers? How unconflicted must the subject feel about consent for it to be considered freely given? At what point should the interviewer’s own interest in obtaining research subjects legitimately counterbalance any further, and possibly discouraging, exploration of a subject’s feelings?36

It is not our purpose to suggest where such boundaries should lie. What a DA approach can usefully show is how an interviewee may express a wish to discuss conflicted feelings, and how such cues may be missed.

In the following example, the subject has seen a tape describing the research.

**Example 4**

I: You saw the tape?

Pt: Yeah

I: Um, do you have any questions...about what you saw?

(2.0)

Pt: Uh, no

I: No? Okay

Pt: I don’t think so.

I: What I have here is the consent form...

At the beginning of this excerpt, the interviewer clearly establishes the frame as one of inquiring about the subject’s understanding of the research. After asking whether he has any questions, she waits a considerable time (two seconds) for the answer. The interviewer makes another offer to answer questions (“No?”), followed by a request for signature on the consent form. This sounds like a natural pattern of turn-taking.

But the subject tosses in one, albeit tentative, hint of ambivalence: after denying that he has any questions, he adds “I don’t think so.” It is unclear what he means. At the least he is expressing some sense of doubt: he has no questions to ask, but he is unsure that he actually has none in his mind, or else he doesn’t know how to formulate one.

The interviewer proceeds with her presentation of the consent form as though this interruption had not occurred. And indeed, the subject goes along, volunteering “Okay.” In terms of alignment, there is no obvious disjunction. However, the subject’s doubt is left hanging. It is evident that the frame is one of
asking for questions but not one of probing the subject’s thoughts or understanding. One might conclude that although there was no mandate to pursue the subject’s doubt, an opportunity was lost.

To return to the interview, the subject reads the informed consent documents for about three minutes, he asks how often he will be required to come for assessments, and he is given brief answers which appear to satisfy him. He then expands upon his initially tentative expression of doubt, but he articulates it much more strongly as follows:

Pt: Oh, ss, hm, no problem –
(1.5)
I: Aw, okay
(1.6)
Pt: I think...my biggest reason for doing though would be to visit my parents
I: Your parents?
Pt: Yeah, they’re concerned for me and they want me ta=
I: =mm=
Pt: =get as much help as possible
I: Well, I’m thinking it will be good for you a-and that there’s probably some things we can teach you and the:::n
Pt: [Okay
I: I need your signature
Pt: And it says
that I can withdraw at any time=
I: =mm,mm hm=
Pt: =no
prob[lem.
I: [right

Again, there is no obvious disjunction in the pattern of turn-taking or alignment between speakers. Ample time is given for each response; both speakers voice signals of agreement (“okays” and “mm’s”); and the interviewer repeats the subject’s word to indicate alignment with his topic (“my parents” . . . “Your parents?”). However, if we look at frame, we see the subject cueing a major shift. The interviewer has set the frame of obtaining a signature for consent. The subject’s interjection about “my biggest reason . . . would be to visit my parents” is unprompted: he has not been asked his reason for participating, and although he was earlier invited to ask questions, this is not a question. His intent is not much clarified when he adds “they want me to get as much help as possible.” In effect, his comment carries special force both because it is unprompted and because it contains an abrupt shift of frame.

What does he mean by “visit my parents”? Have they made his participation in the day hospital, or in the research study itself, a condition of his being allowed to visit them? By bringing this up, is he appealing to the interviewer to discuss his reason for participating, or to discuss his relationship with his parents? Is he expressing a reservation about being in the study? Likewise, it is unclear what he means when he refers to “doing” (in the uncompleted “my biggest reason for doing”) : the referent could be participation in either the day hospital or the research study. More likely it is the former, but we cannot be sure. All of this remains up in the air.

The interviewer’s immediate reply “Your parents?” and her attentive “mm” suggests that she might move to explore his idea in more detail. However, this is not what she does. Instead, she uses his “get . . . help” as an opening to shift the frame in another direction so that further exploration is blocked. She shifts it to one of clinical caregiving: “it will be good for you . . . there’s probably things we can teach you . . . .” Whatever the interviewer is referring to by “it” (in “it will be good for you”) remains ambiguous. In any event this comment, along with this frame, is a classic example of encouraging a therapeutic misconception.

A lack of alignment occurs not just because of the therapeutic misconception, but because the interviewer for the second time avoids an opportunity to probe the subject’s thoughts. Just as we would reasonably expect signals of agreement to be dependent on the form of the discourse, we see that some sense of coercion is dependent on the form of the discourse. This dependency is evident in the emphatic way in which the subject conveys his perception of pressure from his parents and in the definitive way in which the interviewer blocks exploration of the topic.

As it happens, following this informed consent interview, there was a second interview for a separate research study about the informed consent process itself. This second interview was aimed at determining the subject’s level of understanding in the first interview. In
The subject feels that he is being compelled to cooperate with the program by his parents rather than being allowed to pursue his real preference of individual outpatient counseling and, collaterally, that the need to cooperate with the study as requested by Joanne is part of the deal. His answers to this second interview highlight the dilemma of deciding whether this subject’s consent is really being given freely.

This second interviewer demonstrates impressive technical skills for eliciting hidden or suppressed material, including open-ended questioning (“Can you tell me why...?”),37 noticing and probing discourse anomalies (“You jumped in quickly...”), picking up quickly upon expressed affect (“as though you’d been thinking about it”),38 and following up on the subject’s expressed thoughts (“Can you explain that to me?”). Although these are skills possessed by any astute psychiatrist, a discourse analysis helps us to appreciate the linguistic ability that underlies them: consistency of maintaining an exploratory framework; and patience about turn-taking, without the premature use of closing markers, so that the subject has a chance to develop his thoughts.

In summary, this follow-up interview confirms the existence of conflicted thoughts and feelings to which the subject had alluded in the IC interview proper. In our introduction to this example, we stated that the question of how deeply to explore a subject’s motivation is not within the province of DA. This is true, but in our example, the interviewer did not simply miss an opportunity to explore, she actively avoided and diverted from it. Analysis of the discourse clarifies how the subject used the elements of conversational alignment to emphasize his concerns and how the interviewer handled these elements, especially frame, to block exploration.

Conclusions

We have tried to show how an analysis of the form of interview discourse may help in understanding lapses or miscommunications in IC. These include such problems as paucity of information being conveyed or of comprehension being elicited, therapeutic misconception, and ambiguity about whether a subject’s decision to consent is being given freely and autonomously.

The use of the DA method has the advantages of being grounded in the specific language of the in-
interview and of uncovering the discourse dynamics that lead to these problems with communication. Our study is qualitative, and it is limited by a very small and selected sample of interviews, but it yields suggestive hypotheses. One of these is the centrality of frame in the outcome of the IC discourse. This hypothesis remains to be established, along with the overall matter of how effective DA might be as a method for assessing the outcomes of IC interviews. Qualitative methods\(^\text{39}\) as well as quantitative ones\(^\text{20,32}\) or a combination of the two\(^\text{35}\) have been used in DA generally as well as in the analysis of medical interviews.

How does this kind of analysis help? Or is it only an interesting theoretical aside to the main thrust of concerns about IC?

We suggest that a DA approach conveys specific research and educational implications. From the research point of view, the field is wide open to apply to IC the same techniques that have been used extensively for studying features of the medical interview in general. Those studies have addressed such topics as how medical information is conveyed\(^\text{40}\) and how treatment decisions are negotiated.\(^\text{41,42}\) But despite the direct connection of IC to these kinds of interview concerns, DA has been used very little for the purpose of analyzing IC encounters. Another potential of DA is to help look in an integrated, interview-based way at concerns that are too often seen separately as belonging to clinical interviewing, medical ethics, decision analysis, and law. An important first question for such research would be how the discourse features of the clinical and the research IC interview may relate to those of the clinical interview.

Regarding educational implications, Maynard and Heritage\(^\text{43}\) report that medical educators who have learned conversation analysis (in workshops, for example) teach by encouraging students to record their interviews with patients so that “critical junctures” can be reviewed on a turn-by-turn basis to see what went well or badly in the interview. Although there do not yet appear to be outcome studies of the effectiveness of such techniques, or of techniques similar to those applied to IC interviews, this is a fertile field for investigation.

Educationally, we think that the essential subject to be used is frame: Is the discussion or is it not about a request for consent? While this task of clarifying frame can be simply stated, it is not necessarily easy to learn and to do. For example, it is related to the kind of self-discipline that psychotherapists must learn about how to establish and maintain technical neutrality.\(^\text{44}\) The difficulty is heightened, as we saw in Example 3, by the need to find ways to maintain frame and “return to base” under the pressure of exigencies in the dialogue as one negotiates consent. We have previously sketched an approach to teaching how concerns regarding frame might be handled\(^\text{45}\); but here too, the application of DA ideas to IC remains a challenge and an opportunity.

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