Developing ethical strategies to assist oncologists in seeking informed consent to cancer clinical trials

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Abstract

Randomised clinical trials have come to be regarded as the gold standard in treatment evaluation. However, many doctors see the discussion of a clinical trial as an intrusion into the doctor–patient relationship and find these discussions difficult to initiate. Detailed informed consent is now a requirement of patient participation in trials; however, it is known that patients commonly fail to understand and recall the information conveyed. These difficulties for doctors and patients raise questions about the ethical integrity of the informed consent process. In this study, we have developed a set of communication strategies underpinned by ethical, linguistic and psychological theory, designed to assist doctors in this difficult task. Initially, audiotape transcripts of 26 consultations in which 10 medical oncologists invited patients to participate in clinical trials were analysed by expert ethicists, linguists, oncologists and psychologists, using rigorous qualitative methodology. A subset of seven of these was subjected to detailed linguistic analysis. A strategies document was developed to address themes which emerged from these analyses. This document was presented to relevant expert stakeholders. Their feedback was incorporated into the final document. Four themes emerged from the analysis; (a) shared decision-making, (b) the sequence of moves in the consultation, (c) the type and clarity of the information provided and (d) disclosure of controversial information and coercion. Detailed strategies were developed to assist doctors to communicate in these areas. We have developed a set of ethical strategies which may assist health professionals in this difficult area. A training package based on these strategies is currently being evaluated in a multi-centre randomised controlled trial.

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Introduction

For more than a century, doctors have been grappling with the question “Have we the right to perform experiments...on man...and within what limits?” (Bernard, 1865). On the one hand, randomised clinical trials (RCTs) have come to be regarded by many as the gold standard for treatment evaluation underpinning evidence-based medicine (Oxman, 1995; Sackett, Rosenberg, & Muir, 1996; Fisher, 1991), despite their operational drawbacks (slow trial accrual delays the assessment and introduction of effective new treatments and the abandonment of less effective or dangerous ones, and selective refusal and rigid eligibility criteria can also raise concerns about generalisability of the trial findings to the broader population).

On the other hand, discussion of clinical trial participation is seen by many as an intrusion into the doctor/patient relationship, which may compromise the duty of care (Cancer Research Campaign Work Party, 1983). The acknowledgement of medical uncertainty, the stringency of the trial design, and the relocation of the treatment decision from human transaction to computerised randomisation (for RCTs) are believed to...
undermine the patient’s need, at a time of great vulnerability, to place their faith in a caring doctor to navigate the route to an optimal treatment/outcome. Others have argued that patients do not understand the methodology and rationale for clinical trials and should not be required to, particularly when grappling with a life threatening disease.

Central to these divergent views are the competing interests of protecting research participants from potential harm versus the advancement of medical knowledge and the ensuing benefit of this knowledge to the community as a whole. Following World War 2, the ethics of human experimentation were codified in documents such as the Declaration of Helsinki and the Nuremberg Code. Well-publicised breaches of these codes led to stronger legislation protecting participants in research. More recently, in the United States for instance, there has been a new wave of legislation and Congressional review targeting patient protection. What is apparent in the implementation of these procedures is a shift away from paternalistic decision-making and an erosion of the researcher’s self-regulation in the conduct of experiments.

As part of the shift towards stronger patient protection, independent ethics review committees require detailed informed consent procedures and information provision as an integral part of clinical trial recruitment. Morally valid consent requires that patients understand the information provided, and be competent to reason about possible courses of action. However, the complex language and excessive detail of some information statements and consent forms may confuse rather than enhance patient understanding (Grossman, Piantadosi, & Cohavey, 1994). Furthermore, while information sheets and consent forms are vetted by institutional ethics committees, the type and amount of information provided by doctors in the process of seeking informed consent is not monitored, and the impact of that information provision on patient accrual to clinical trials and other outcomes is not clear.

Clinicians often report that they experience difficulty with explaining trials, and audiotape audits have shown that in many consent interviews critical information is omitted or poorly presented. Jenkins, Fallowfield, Souhami, and Sawtell (1999) analysed 82 audio-taped discussions in the UK in which consent was being sought for participation in an RCT. In most, the concept of the trial was introduced by describing uncertainty about treatment decisions, and all clinicians used the word trial; however, the word “randomisation” was used in only 62% of cases. Information leaflets were not given to 28% of the patients, and patient understanding was never checked in 83%. The median duration of ‘consent’ interviews was less than 15 min, and most patients signed the consent document at the first consultation in which the clinical trial was discussed.

Tomamichel et al. (1995) analysed the content of informed consent interviews and concluded that while doctors’ information provision and emotional supportive skills were adequate, the negotiative quality of interactions, characterised by doctors’ capacity and willingness to perceive and discuss the emotional needs, complaints or objections of patients, needed to be improved. Thus, the participation of the patient in decision-making was not encouraged, divergent views were not always examined and negotiation was partially avoided.

Doctors’ and patient perceptions of informed consent also cast some doubt on the validity of this process. Verheggen, Jonkers, and Kok (1996) interviewed 32 trial clinicians who had approached 198 patients for clinical trials at the University Hospital in Maastricht. These clinicians were quite skeptical of the patients’ ability to comprehend 15 of 20 medico-legal aspects of informed consent. Of the 32, only six felt that the consent procedure ensured that patients understood the nature and course of the trial; 22 felt that understanding was incomplete, four were uncertain about levels of understanding. Edwards, Lilford, and Hewison (1998a) reported that for many doctors “Informed consent seemed little more than a ritual”. For a more extensive review of this literature see Edwards, Lilford, Jackson, Thornton, and Braundholtz (1999b)

Patient experiences and perceptions of being recruited to Phase I and II clinical trials have been analysed in a qualitative study by Cox (2002). A small majority (56%) of patients reported being invited to defer their decision-making about the trial to a subsequent consultation: however, over 80% of the entire sample were ready to make a decision immediately, preferring the doctor to take the lead. According to Cox the major factors influencing trial participation were (a) a positively framed description of the trial by doctors and research staff, reinforced by the patient’s perception that the doctor was acting in their best interest by offering the trial and (b) the utility of the written information sheet as a reference.

Such research has usefully described the nature of the information contained within informed consent discussions and patient/doctor perceptions of this difficult process. However, little research has been conducted which (a) explores interventions designed to assist in the communication process or (b) systematically attempts to define optimal communication content and process to ensure ethical informed consent. Fleissig, Jenkins, and Fallowfield (2000) conducted an intervention study in which trial patients completed questionnaires detailing their information preferences and attitudes to RCTs prior to seeing their doctor. Doctors were shown the questionnaire results of half of these patients prior to the consultation and were expected to tailor their information provision in accordance with the reported
preferences and attitudes. A high proportion (77.4%) of the sample agreed to trial participation; neither accrual, nor consultation length nor patient satisfaction were influenced by the intervention. However, the impact of this intervention may have been limited by (a) the non-participation of the doctors in the process of negotiating information preferences and seeking attitudes of patients to participating in treatment decisions and (b) the lack of doctor training.

Simes, Tattersall, and Coates (1986) compared the impact of full versus individualised disclosure of information about clinical trials on patient accrual and psychological adjustment. This study found that full disclosure increased patient understanding of trial issues, but also increased anxiety and reduced accrual. However, differences in anxiety levels had disappeared within 3–4 weeks and were mediated by the perceived adequacy of doctor–patient communication.

In the current study we aimed firstly to develop a typology to describe doctor–patient interactions which occur when participation in phase 2 and 3 clinical trials are discussed. Secondly, we aimed to develop ethical strategies for discussing participation of eligible patients in phase 2 and 3 clinical trials. These are currently being used in a randomised trial of training doctors in ethical informed consent procedures to determine if doctor behaviour can be changed and whether such changes influence patient and oncologist outcomes.

Method

Institutional ethics committee approval to conduct the project was obtained from the University of Sydney, Central Sydney Area Health Service Human Research and Peter McCallum Cancer Institute ethics committees.

Development of strategies document

Phase 1

To gather information about the range of communication styles oncologists used to discuss clinical trials with their patients, a qualitative analysis of 16 transcripts of audio-taped consultations containing discussions of phase 2 and 3 clinical trials, between nine medical and radiation oncologists (five male and four female) working at two university teaching hospitals, and their patients, was conducted. These 16 audiotape transcripts were part of an existing library of transcripts of over 300 initial consecutive oncology consultations collected as part of a previous randomised controlled trial of a question prompt sheet (Brown, Butow, Dunn, & Tattersall, 2001) and were selected at random from the control arm of this data set. The transcripts were analysed by a panel including experts in Ethics, Cancer Medicine and Psycho-oncology. The analysis was initially limited to an exploration of the language used to seek informed consent to clinical trials. The transcripts were analysed using the constant comparative method (Glaser & Strauss, 1967) and continued until no new themes emerged.

Phase 2

In order to ensure that an exhaustive analysis had been conducted and that theoretical saturation or redundancy (Miles & Huberman, 1984) had been reached, written consent was obtained from a further sample of 10 consecutive patients who were approached to participate in a clinical trial by one of four medical oncologists. These consultations were audio-taped, transcribed in full and analysed. It was apparent from the phase 1 analysis that there were difficulties in exploring the clinical trial discussion in isolation from other aspects of the consultation discourse. Therefore, the aim of phase 2 was to conduct an expanded analysis allowing an exploration of the structure of the whole consultation: in particular, (a) the framework within which doctor–patient communication had been established at the beginning of the consultation, (b) the types of strategies employed by the oncologist to introduce and encourage a positive approach to clinical trials and ensure understanding prior to the specific trial discussion, and (c) the implications of gaining prior informed consent to standard treatment on the subsequent clinical trial discussion. An identical procedure to that utilised in phase 1 was used to analyse the transcripts of the audiotapes of this patient sample. Demographic and disease information for patients participating in both phases 1 and 2 are presented in Table 1.

Phase 3

Expert linguists (authors 4 and 5) analysed seven of the 26 transcripts (the sample were selected at random using random number lists generated by SPSS) to explore the type of language used in offering clinical trials as treatment options, in particular coercive and non-coercive elements. A Systemic Functional Linguistics approach was taken (Eggs, 1994; Halliday, 1994). This model theorises the relation between a text and its context as one of mutual realisation between different strata (levels of organisation) of language, building on the work of Malinowski (1923) among others. To demonstrate this approach, the strata are listed below.

Context of culture: Patterning at this level distinguishes societies and groups at the broadest level. For instance in western culture, the medical context is seen as a predominantly scientific context rather than a religious one.

Context of situation: By being systematic about the relevant dimensions of this specific context of situation—how it is both like and unlike other forms of social process and interaction, we can establish why it is that
wording that in one place might seem quite suitable can be anathema (or even illegal) at another point in the same interaction, or in a similar consultation (Butt & Moore, 2002). The context of situation studied here is that of consultations between oncologists and their patients in which trials are offered as a treatment option. Any context of situation can be modelled dynamically in terms of the moves or phases by which it typically unfolds (its Generic Structure Potential—see Halliday and Hasan, 1985).

Semantic level (system of meanings): In the context of oncology consultations, critical areas of meaning include risk, choice, agency, actual/potential, inclination/obligation, along with concepts particular to medicine such as equipoise which are usually highly technical and often contentious (see Lilford, 2001 for an example of recent debate). Each of these concepts can be seen as a dimension of the “meaning potential” which may or may not be actualised in any given instance of the context, and, where actualised, may take various forms in terms of words and grammar. Sometimes these wording differences put a crucial spin on semantics. For example, oncologists often take options in the semantics of spatial proximity, which tend to indicate that the oncologist is the owner of, or possesses control of, the clinical trial in which the patient has been invited to participate, and this tends to foreground the doctor’s agency. Clusters of semantic choices like these can construe the context of situation as one with quite a hierarchical relation between doctor and patient, which may influence the treatment decision.

Lexico-grammar (systems of wording): To continue the example above, wording such as “You can join us on the trial”, or “If you come onto the trial” realises the semantics of positioning the trial in close spatial proximity to the doctor, which indicates to patients that the physician is the owner of the trial, or is some kind of agent of the trial.

The audiotape analyses in phases 1–3 resulted in the identification of a range of issues and the development of a strategies document designed to assist oncologists in the difficult task of presenting clinical trial information as a treatment option.

Phase 4
This document was presented for feedback at a consensus workshop auspiced by the New South Wales Cancer Council. In order to ensure rigorous qualitative methodology, the Delphi technique was used to guide the conduct of the workshop. (Bowles, 1999). Twenty-seven experts including; surgeons, medical and radiation oncologists, linguists, ethicists, psychologists, research nurses, data managers, consumers, lawyers specialising in medico-legal litigation and pharmaceutical company representatives, participated in the workshop. All workshop sessions were audio-taped and transcribed in full. The workshop transcripts were content-analysed and suggested amendments to the strategies document were listed. As a result of this process a revised document was produced which incorporated changes suggested during the workshop. All participants agreed with the revised version.

Results
As a result of the analysis in phases 1–3, four themes emerged which formed the basis of the strategies document. These were (a) shared decision-making strategies, (b) the sequence of moves in the consultation, (c) the type and clarity of the information provided, and (d) disclosure of controversial information and coercion. These themes reflect the clinical judgment and theoretical perspectives of the linguists, psycho-oncologists, ethicists and oncologists involved in the analysis. Each theme represents an overlap of these views rather than a discrete set of items based on only one area of expertise.

Shared decision-making strategies

Participation in treatment decision-making, at the patient’s preferred level of involvement, was identified as an essential component of seeking informed consent to the clinical trial. Shared decision-making promotes (a)
autonomy in making treatment choices and (b) positive psychological outcomes for the patient once a decision has been reached (Gattellari, Butow, & Tattersall, 2001). Fourteen strategies contributing to a collaborative decision-making framework were identified. They are summarised in Box 1. Below that selected strategies are described and illustrated with interpolations from transcript data.

Unless the patient is explicitly offered joint decision-making he or she may be unaware that this option is available to them. It is important that the rationale for joint decision-making is provided; otherwise the patient may feel that s/he is being abandoned and that the doctor’s expertise is being withdrawn.

**Box 1**

Strategies for doctors to encourage collaborative decision-making

- Introduce joint decision-making process
- Use language which realises and reflects patient autonomy
- Check preferred decision-making style (involved or not)
- Check information preferences of patient
- Invite questions and comments
- Check medical knowledge of patient
- Check patient understanding
- Explicitly offer choice of treatment
- Acknowledge uncertainty of treatment benefits
- Declare professional recommendation
- Provide opportunity for amplification of patient voice
- Provide time and opportunity to discuss patient concerns in detail
- Offer decision delay
- Offer ongoing decision support/answers to future questions

Language which portrays the patient as an active agent in the process of deciding about and enacting their own health care encourages the sense of an autonomous self among patients. Grades of agency occur; the most active participant is portrayed as the doer, decider. The least active participant is portrayed as the person or object “done to” (the one who is treated, told, organised). Another way a person may be portrayed in the least active role is to use wording in which they do not appear as a participant at all (Van Leeuwen, 1996). For example, Doctor: “I’ll begin the chemotherapy next week” implies that the patient is passive and the doctor is active and controls the therapy and its timing. Thus, in order to promote a collaborative decision it would be important for the doctor to avoid making statements such as:

Doctor: We will develop a treatment plan for you by the end of this session. I’ll let your surgeon know what I’ve decided, and I can organise treatment to begin next week. For the chemotherapy, we will be putting a cannula into your arm for about an hour, and then you can go home.

Another subtle example occurs where treatment recommendations are couched in ways that imply a degree of obligation for the patient to choose a particular treatment option which can discourage patient autonomy. For example, Doctor: “You should consider chemotherapy. Most of my patients choose chemotherapy”, implies an obligation on the part of the patient to have chemotherapy. On the other hand, Doctor: “I would recommend the chemotherapy; what are your thoughts on this?” implies that there is no obligation, and that both parties have a valid point of view.

**Sequence of moves in the consultation**

The consultation data were categorised into a series of phases and an ideal sequence of these phases was identified. This model was developed to promote patient understanding of information, to ensure equal weight was given to the discussion of standard and experimental treatments, and to avoid potential coercion (see Fig. 1).

**Bearings:** The first phase, “Bearings” ensures that the doctor and patient have a shared understanding of the patient’s illness. If this is not established, further discussion can be at cross-purposes. For example, if the patient believes that their disease is curable, while the doctor does not, negotiation of the values by which they will choose the most appropriate treatment will not be possible. This is also an opportunity for the doctor to...
introduce the importance of patient question asking and to elicit the patient’s information preferences.

**Pathway 1:** The next phase, “Pathway 1” (the discussion of standard treatment) should be discussed before the trial is introduced, in enough detail for the patient to be clear about the standard treatment available off the trial. This may also involve a discussion of the option of having no treatment. This sequence is important to establish the treatment decision as a choice amongst options, rather than as consent to a pre-selected plan, and ensures a balance between standard treatment and clinical trial discussion. This phase also provides an opportunity for the doctor to introduce the notion of evidence-based treatment which can be invaluable when later introducing the trial option.

Doctor: We know from studies done over the last twenty years internationally, that using extra treatments, and we're talking about hormonal or chemotherapy treatment here, can reduce the risk of the cancer coming back by about a third. We are very confident that these treatments can improve the situation.

**Amplification 1:** Under both Pathways 1 and 2 there are three components which occur after an explanation has been provided. Firstly, “Amplification 1” involves giving the patient an opportunity to express their reactions to the treatment options presented if they have not already done so, what it will mean for them in their own individual circumstances, and to begin to weigh up the benefits and costs of each of these. It is important that the doctor provide a rationale for such a discussion, i.e. that the treatment choice may be influenced by apparently unrelated factors such as the patient’s daily schedules or future plans. Misconceptions and concerns about treatment which are uppermost in the patient’s mind can be identified at this point. Until these concerns are addressed the patient may not be able to consider further possibilities. Of note, we have found that Amplification is the component least likely to be incorporated in current practice.

Doctor: I would like to hear about your lifestyle and what is important to you because these things might influence what the best treatment is for you. So if you can’t stand the thought of your hair falling out or feeling nauseous that might influence the treatment that you have.

**Declaration 1:** Secondly, within this model the doctor should make their treatment recommendation (from the range of available treatment options, including the clinical trial) explicit because if it is implicit then it is more likely to be coercive. Within Declaration 1 it is important for the doctor to point out that a treatment choice needs to be made and that there is time to make that choice, that the doctor will help to make the decision and will make a treatment recommendation. Unlike previous moves it is crucial that this move is not “process shared”—it is made by the doctor.

Doctor: This is really your decision to make...you have to be happy with what happens...you may need some time to weigh up the various side effects and benefits of the treatment options we have discussed in light of what is important for your life and you might want to talk to some other people about this. I would recommend the chemotherapy because I think it will give us the best chance to get rid of the disease.

**Enunciation 1** is a move in which the patient articulates their decision, not merely accedes to/agrees to the doctor’s framing of a decision. It is important that the decision is actually voiced, firstly to enhance patient autonomy and secondly to provide an opportunity for the doctor to assess whether or not to move on to a discussion of a clinical trial. If the patient is not happy to receive standard chemotherapy it is usually pointless to move on to a discussion of a chemotherapy clinical trial. The decision voiced may be to defer the treatment decision for a period of time, or to delegate the decision to someone else (possibly the doctor or a relative).

Example of Enunciation 1:

Doctor: You don’t have to decide now, it’s a matter of weighing up the pros and cons.

Patient: Oh no, I know I should have it. I don’t really want to but I’ll never be able to live with myself if I didn’t and the cancer came back.

Segue: It is also important before moving to Pathway 2 (the discussion of a clinical trial) to acknowledge that the trial is another treatment option which will add a further level of complexity to the discussion and gain the patient’s agreement to move on to that phase. This phase is called the “Segue”. If this phase is not included, the patient can become overwhelmed and confused about the standard and clinical trial options.

Doctor: Ok, so you’re happy with the idea of chemotherapy. In that case I’d like to raise another issue, which is going to add more complexity. There is another possible choice that we could make about your treatment. That would be to have treatment in a clinical trial which looks at different ways of giving chemotherapy. I know that you have had a lot to take in and think about to-day. Would you like to discuss the clinical trial option now or leave it for another time?

**Pathway 2:** During “Pathway 2” the clinical trial is presented as another treatment option. It is important to clearly delineate that the treatment choice is between receiving standard treatment and treatment on trial. A
Regarding the general explanation of trials, including a description of the rationale for clinical trials, usefully precedes a detailed explanation of the current trial on offer. This explanation can include a description of the ethical rationale for the trial, including equipoise, beneficence, non-maleficence and issues of justice and autonomy. The patient then has a framework which may make it easier to subsequently consider the advantages and disadvantages of the specific trial.

Amplification 2 provides an opportunity for patients to talk about their attitudes towards and understanding of clinical trials, based on their own or others’ experience. A patient’s concerns and fears about issues such as randomisation, medical uncertainty, being an experimental subject, and lifestyle factors which may influence the decision to participate or not in the clinical trial might be discussed here. As with Amplification 1 it is important to provide a rationale for such a discussion.

Declaration 2: During “Declaration 2” the doctor can emphasise that the patient’s choice will not influence his or her relationship with the doctor and other staff or their medical care, and also that the patient can withdraw from the trial at any time. As in Declaration 1 it is important that the doctor make a treatment recommendation. This may state the doctor’s view that either the standard treatment or the clinical trial would be an acceptable decision for him/her but that the trial is the doctor’s preferred option. This is an important step, in order to make explicit, rather than leave covert, the doctor’s view.

Enunciation 2: Finally, in “Enunciation 2” the patient is given an opportunity to declare their decision about participation in a clinical trial. Again this may involve a choice to defer the decision to a subsequent consultation.

Enactment: After all that has been achieved, the doctor needs to implement the decision or describe the next steps; this is called “Enactment”. The logistics of the decision are then set out and the implementation is begun. It is crucial that logistic institutional arrangements (for example, timing of treatment, availability of beds) are not made before a full opportunity to discuss and reflect on the options has been provided, and the patient has reached a clear decision.

Doctor: Of course—there are a lot of things to think about, and read. Let’s make a time to meet up again. Perhaps your husband could come with you that day—no doubt he’ll have questions too. Then once we have come to a decision I’ll introduce you to the nurses and other staff who will be treating you and we’ll get things underway.

In what we present here of the linguistic characterisation of offering clinical trials as treatment, we have focussed on the generic shell, as a representation of the interactional contours of this social process. In some respects this is similar to early phase analyses of medical consultations such as Byrne and Long (1976) and more recent ones such as Elwyn et al. (2001). The chief way our model differs is that the inclusion of a systematic account of semantic and grammatical strategies allows us to bridge the gap between consultation ‘phases’ and ‘behaviours’, and show that they mutually condition each other. Ultimately, the findings depend on adequate detail—in particular concerning the systematic relationship between specific dimensions of the context, the orientation to meaning in the dialogue, and the precise grammar and wordings by which treatment options are explored. In other presentations, e.g. Butt and Moore (2002), socio-semantic networks have been used to model these systematic relationships in a way that can compare any instance of an actual or hypothetical consultation with the ‘typical actual’ consultation, as well as with what our interpretation of the literature suggests is ideal. These networks can be used, for instance, to set out the different pathways that subgroups of practitioners or patients take in traversing the chains of choice that are available to them, both as participants in this social process, and as speakers of English.

Type and clarity of information

Within Pathways 1 and 2 a number of facts need to be communicated in order for the patients to give ethical informed consent. These are listed in Table 2.

However, merely including these facts will not necessarily ensure understanding. The fullness and clarity of the explanation needs also to be considered. This is so important that it may be useful to develop a standard script to explain particularly difficult concepts such as equipoise and randomisation. Intervention studies designed to facilitate understanding of complex information in medical consultations (underpinned by cognitive and social psychological models) have identified a number of useful strategies to ensure clarity. These include: avoiding jargon, using simple language, using analogies, repeating and summarising, explicitly categorising information into manageable chunks and paying close attention to the order of presentation of information (Kupst, Dresser, Schulman, & Paul, 1975; Ley, 1972).

Explaining randomisation has been identified in the literature as being a primary area of difficulty for doctors inviting patients to participate in RCTs (Fleissig et al., 2000). The example below depicts a clear description of randomisation which exemplifies some of the factors described above.

Doctor: OK, let me tell you how a trial works. When you are trying to work out whether two treatments
are different, it’s important that the patients getting the two treatments are as similar as possible. Then if we see a difference in outcome, we know that it is due to the treatment. For example I could say, well, you look like a fit person who could cope with longer treatment, I’ll give you that. And then the next person who comes and sees me might be a bit fragile, so I could think—better put her on a shorter treatment. Then, any difference we see might be due to fitness, rather than the length of the treatment.

So to avoid that problem, the people planning the study make sure that no-one has a chance to pick and choose particular people for particular treatments. Rather, treatment is decided by chance so that similar people are in each of the two groups. They do that using a process called randomisation. That means there’s a 50/50 chance of you getting either of the treatments. The final treatment choice is not going to be decided by me, or by you—it has to be organised by one of the people running the trial. They’ll work out with a computer which treatment you’ll have, similar to pulling names out of a hat—so it is by chance.

Disclosure and coercion

The final themes which emerged from the analysis included: (a) disclosure of information which may influence patient decision-making not commonly revealed and (b) communication styles which may be subtly coercive.

Various items of information that were not reported to patients included: (a) that drug companies often make sizeable per patient payments to hospitals which participate in clinical trials sponsored by these companies; (b) that in a small percentage of cases in Australia individual doctors may receive personal remuneration for the additional time needed to participate in trials; (c) that in many instances the participating doctors may be investigators on the trial and thus have a potential conflict or duality of interest; (d) the accessibility of trial treatments after the trial has ceased; (e) the availability of other potentially suitable trials. It is not known whether disclosure of such information is ethically required or rather would needlessly complicate the consent interview and overwhelm the patient.

The linguistic analysis, in particular, revealed subtle communication techniques which could avoid coercing patients into participating in clinical trials. These are outlined below.

1. Preferences may be covertly suggested in many ways, for example by spending more time talking over the trial treatment versus standard treatment, by minimising versus maximising side effects and/or benefits of one or other treatment, or by differential use of

| Explain the general rationale for clinical trials | Aim is to improve the current situation and to test new treatments before they are made readily available |
| Equipose | Trials are conducted only when it is believed that the experimental treatment will be at least as effective as the standard arm |
| Beneficence | The trial is conducted to determine whether there is a significant additional benefit from the experimental treatment |
| Non-maleficence | There is evidence to suggest that being involved in a clinical trial will in no way worsen your chances |
| “NB research evidence suggests that participation in clinical trial improves outcomes in some patients. Presenting this evidence to patients may be coercive thus it was decided to avoid phrases such as…being involved in a clinical trial may improve your chances” |
| Ethics committees | All trials have to receive approval from ethics committees |
| Inform the patient about the trial being offered | Explain the rationale for the randomised or non-randomised clinical trial |
| Equipoise | State how important the question is, and how the results may change practice |
| Beneficence | State that the experimental treatment is only available on the trial if this is true |
| Non-maleficence | Explain how randomisation works in the context of this trial |
| Ethics committees | Discuss access to the treatment after the trial |
| Describe the treatment arms available on the trial | Standard treatment has been already introduced, greater detail is likely to be required at this point, in order that the differences between arms can be highlighted |
| Inform the patient about other possible clinical trials | If other suitable trials are known then doctors should refer patients to an appropriate information source |
| Refer to the information sheet | Patients should know the relevance of this document and how to use it |
| Highlight any additional inconveniences associated with being on the trial. | These may include extra questionnaires, additional blood tests and scans, more frequent visits, additional expenses |
agency (patient active in one treatment, passive in the other), proximity (patient will be part of the team if they join the trial, or offered standard treatment) and framing (chances of survival presented for one option and chances of dying for the other). Another subtle example of this is where probabilities are presented as group statistics in one treatment and as personalised in another. For example, “most patients will lose their hair on this treatment” (group) versus “it is most likely that you will lose your hair” (personalised). Subtle differences such as these may influence patient decisions.

2. Doctors commonly use the term “you are eligible for this trial”. This phrase, however, can imply that the patient is “lucky” to have been selected, or should be hopeful that their disease status allows them to participate in the trial. We suggest using the phrase “the trial is suitable for you”. This is a subtle yet powerful delineation. Making it clear that a trial is “suitable” for the patient objectifies the trial and does not imply the patient should aim to meet a set of criteria. Further research could explore the meanings that patients actually extract from such statements.

3. A common motivation for patients to enter clinical trials is a sense of making a contribution to medical knowledge which will benefit others or altruism. Finding the balance between recognising and appreciating patient altruism and using it in a coercive fashion can be difficult. Once again, the terms used can make a difference. Thus, “You can benefit future generations” is perhaps more coercive than “this will help us find the answer to this question”.

Discussion

The results of this analysis led to the development of a set of strategies designed to assist doctors to communicate with their patients in four key areas outlined above and considered essential to seeking informed consent to clinical trials in an ethical, non-coercive manner.

Shared decision-making

The traditional paternalistic role of the doctor has become increasingly incongruous and perhaps unacceptable in the light of changes in patient attitudes towards medical practice in the late 20th century. Individuals no longer presume that the doctor knows best and many prefer an approach which involves greater patient involvement in decision-making and respect for individual autonomy. However, the dimensions of the shared decision-making model are as yet unclear. Emmanuel and Emmanuel (1992), Gafni, Charles, and Whelan (1998) and Thomasma (1983) have outlined three models. The informative model defines the doctor’s role solely as the provider of information which patient’s use in selecting a treatment option. However, this model has been criticised for reducing the physician–patient relationship to educator and student and ignoring the importance of a caring approach which incorporates respect for patient values. Furthermore, recent evidence suggests that patients do not benefit from this approach. Gattellari et al. (2001) have demonstrated that patients who perceive that either they or the doctor were primarily responsible for a cancer treatment decision regardless of their initial preference, were less satisfied than those who perceived that the decision had been shared.

Charles, Gafni, and Whelan (1999) and Emmanuel and Emmanuel (1992) describe two further models within a shared decision-making tradition. In the interpretive model, the doctor’s role is to elicit and help clarify the patient’s values about treatment and to help the patient translate these into a treatment preference that best corresponds with these values. The deliberative model is similar. Here the doctor aims not only to elicit but possibly to influence health related values and expresses his or her opinion about the most appropriate treatment choice. Charles, Gafni, and Wheelan (1997) prefer the interpretive model and caution against the doctor conveying his or her own values as this may, albeit unintentionally, influence the patient’s treatment choice.

In the model proposed in this paper an open discussion of the doctor’s treatment recommendation is supported to avoid covert influence. It is argued that if the doctor tries to hide his/her own values and opinion, patients may second guess them, may guess wrongly and be more strongly influenced by this covert process than by an open discussion. However, to avoid the concerns of Charles et al. (1997) we recommend that the doctor clearly flags in the Declaration phase that it is a personal recommendation and explains/discloses the values (evidence-based medicine) by which it is underpinned. This process can also empower the patient to participate more fully and confidently in decision-making. This model assumes that the doctor does have expert information which will be valued by the patient (Little, 1995). Furthermore, equal weight is then given to the patient’s views about the best treatment in the Enunciation phase, allowing open negotiation between doctor and patient.

The other helpful contribution of our approach is elucidating specific strategies to encourage shared decision-making. This has been rarely done before and primarily within a research context where attempts have been made to describe the process rather than assist doctors to facilitate shared decision-making. The inclusion of linguists in our research team proved invaluable as they suggested novel approaches to shared decision-
understand the information they are given. It is known that patients may not understand enough information to give truly informed consent (Montgomery, Lydon, & Lloyd, 1997). Thus, we have suggested a number of techniques drawn from the psychological and linguistic literature which can be usefully employed to assist doctors to convey information in ways which will be clear to patients and maximise the potential for patients to understand and recall what they have been told. In addition, we suggest the use of pre-determined and rehearsed stories, for example, a randomisation story, as aids in clarifying difficult concepts which patients need to understand in order for them to make informed treatment choices.

Limitations

This model, although positively reviewed by a sample of relevant experts representing a broad range of perspectives regarding clinical trials, is untested in clinical practice. However, this body of work has now been included in a training programme designed to provide doctors with communication skills to assist them in seeking informed consent in an ethical manner. This training programme has been evaluated in a pilot study. Feedback indicates that doctors find this model a useful way of structuring and sequencing the social process of offering a clinical trial as a treatment option. Of note, communication skills training has now been demonstrated by Fallowfield to be (a) highly acceptable to oncologists and (b) successful in facilitating stable changes in doctors communication styles. The doctors in Fallowfield’s study identified a need for specific skills training in communicating about clinical trials and gaining informed consent (Fallowfield et al., 2002).

A second limitation is that the model is based exclusively on a sample of Australian oncologists and thus may have limited application to clinical trial discussion in other settings. It would be of interest to compare the current data with that derived from audio-taped consultations in which informed consent are sought, from other cultures. On the basis of our pilot study we are currently conducting an international randomised controlled trial to further evaluate the acceptability of the concepts, and the impact on doctor behaviour and patient outcomes of training doctors in gaining informed consent using this model. The doctor sample will include oncologists from Australia, New Zealand and some European countries.

A third limitation is that our study focused only on phase 2 and 3 trials. It is possible that different issues and concerns arise in the setting of phase 1 trials.

Finally, only doctor–patient interactions were explored, whereas other health professionals such as research nurses and data managers deliver much information about trials. These interactions require
separate exploration to determine whether different processes and issues occur, requiring alternative models.

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