ELECTRONIC WORKSHOPS IN COMPUTING

Series edited by Professor C.J. van Rijsbergen

Frank Dignum, Jan Dietz, Egon Verharen and Hans Weigand, (Eds)

Communication Modeling - The Language/Action Perspective

Proceedings of the First International Workshop on Communication Modeling, Tilburg, The Netherlands, 1-2 July 1996

Informed Consent: Implementing Shared Decision-Making in Health Care

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British Computer Society

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Informed consent: implementing shared decision-making in health care

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Abstract

Informed consent has been proposed to encourage patient participation in medical decision-making. Informed consent is commonly operationalized as a two phase process of receiving information and making a decision by the patient. Currently, computers are introduced to sustain informed consent. The programmes used, so-called Shared Decision-making Programmes (SDP's), are based upon the standard model of informed consent, focussing on information disclosure and patient decision-making. We argue that this view of informed consent is too narrow to do justice to actual processes of negotiation in health care. We propose a more refined model of informed consent, in which processes of communication play a pivotal role. On the base of Habermas' theory of communicative action, we propose that decision aids should not only support information disclosure, but also processes of communication and joint decision-making.

1. The doctrine of informed consent

Modern medicine has made room for the informed consent doctrine and has recognized the right of patients to consent to and refuse certain kinds of treatment. Professional workers in health care are increasingly under an obligation to provide adequate information disclosure and to obtain informed consent from patients prior to involving them in treatment protocols or in clinical trials. In the youngest decennia, informed consent has also been specified in more detail in health care legislation. In the Dutch law informed consent has been exemplified in (draft) legal rules to emphasize patient rights in medical treatment (Medical Contract Act) and protect human test subjects when participating in clinical trials (Medical Research with Human Beings Bill). The aim of these regulations is to give patients an active role in medical decision-making.

Appeals to patient rights and legal visions of informed consent alone do not adequately enable patient involvement in medical decision-making. Legal requirements, if regarded as mere obligations, may constitute an obstacle to doctor-patient communication [3]. If they are applied when the subject is uneducated, they only function as an ideology [8]. Empirical studies suggest that as a result of illness, patients tend to feel they have to do whatever the doctor suggests, to become less aggressive in seeking alternatives, and to become inert out of a sense of powerlessness in the face of massive technical information [14]. Information overload diminishes rather than enhances comprehension [21]. The effectiveness of communication is diminished by the provision of too much information. Studies have shown that relevant information disclosure may not be remembered by a sick, anxious and sometimes frightened patients. Illness has physical, cognitive and emotional consequences, and decision-making abilities can be undermined by emotional distress and diminished capacities.

One of us recently conducted a PhD-research into the myth and reality of informed consent [19]. The study focussed upon the interaction between patients and trial-clinicians in the daily practice of the informed consent process. The study showed that decision-making in health care is not adequately conceptualized if it is seen in terms of information-gathering, followed by a decision of the patient. Information disclosure is only one of the many

factors which appear to be relevant in the patient's decision-making process of entering the trial. Many aspects of a trial which are thought to be relevant by authors on informed consent, don't seem to influence patient's willingness to participate in a trial. Legal requirements of informed consent are not regarded as reasons to take part in a trial. Trial-characteristics such as randomisation do not influence participation either. One of the major factors influencing patient's willingness to participate in a trial appears to be the patient's perception of his or her health. Some general attitudes towards medical care, research and institutions appear to have indirect effects upon trial participation. Patients' prior experiences regarding their health condition and more general attitudes towards medical care, research and institutions also may contribute importantly to their perception of the information given and the evaluation of the decision-making process.

The study shows that a patient's participation in a trial is not the outcome of a process of receiving information about risks and benefits, comparing options and rational decision-making. It is the result of a patient's intricate way of making sense of the situation, in interaction with the physician. Past experiences seem to be more decisive than current information. Decisions are guided by diffuse and general ideas rather than by concrete and objective information. From the standard view of informed consent, the obvious reaction to these facts is twofold. In the first place, it will be noted that the ideal of informed consent is not met. In the second place, the solution will be to provide more and better information, and to secure that the patient makes an independent and deliberate choice. However difficult this may be, the ideal of rendering objective information and giving freedom of choice should not be given up. One of the ways to enhance informed consent is to design computer programmes which enable patients to actively acquire information and balance options. Many of the programmes currently used result from an urge to improve the practice of decision-making by making the key factors of informed consent - information and conscious decision-making - more readily accessible to the patient.

2. Interactive shared decision-making programs (SDP's)

The importance of patient's participation in the decision-making process has been the focus of increasing interest. Innovative communication tools like interactive shared decision-making programs (SDP's) are being developed through which patients can learn about their medical conditions and the treatment options available to them [9]. SDP's have been developed with regard to surgery in early stage breast cancer and need of adjuvant therapy, benign prostatic hyperplasia, mild hypertension and low back pain [1,17,20]. A considerable amount of work is on its way to evaluate the use of such programs to help patients with treatment decision-making [15].

In the clinical context, efforts have been made to sustain patient involvement in medical decision-making [11]. Patient decision supports describe choices and outcomes, using probabilities tailored to the patient's particular clinical profile. They aim to assist in clarifying values, augment decision implementation skills, identify patient's information needs and provide information relevant to choices so that patients can participate in treatment selection. Decision aids may also reduce emotional distress by enhancing patient's personal control over difficult situations. The use of decision aids is to foster effective decision making in which patients make informed choices. An important issue is the selection of information to be presented in a decision aid. There are differing points of view about the relative importance of items of information about treatment protocols, side effects and anticipated treatment outcomes [12]. What types of benefits should be described? Should probabilities be described in numerical, verbal or graphic form? And also: what is the preferred mode of presentation? Many formats are used. These include decision boards, interactive videodiscs, personal computer programs and audiotape-booklets [1]. Each of those decision aids has associated tradeoffs regarding costs, time, portability, the ease of updating with new information and the ease of constructing an individualized value-clarification component for a particular patient's clinical profile. Value clarification can help patients who are unclear about the relative degrees of importance of the attributes in a decision and the implicit tradeoffs they will be making in selecting an alternative [12].

Supplementary decision aids roughly fall into two groups. One group includes those decision aids in which the patient rather passively receives a 'bolus' of information in a standardized sequence [5]. This might include tape-recorded material, brochures and consent forms. In the second group of decision aids, the patient actively acquires the information in an individualized sequence. These include interactive video discs [17] and personal computer programs [13]. Interactive video discs have been primarily developed for treatment decisions rather than clinical trial entry [2]. The incorporation of a value-clarification component seems easier in such a second type of individualized interactive format, than in a more standardized linear format of a decision aid [16]. Vivid information presented on a computer screen may attract the respondents' attention to a greater extent than the same information presented in an oral or written form [10]. Regarding the process whereby the respondents gain the information, they also can control the pace, sequencing, and periodic review of the detailed 'bits' as they are fitted into the overall outline of the problem [13].

All these aids and programmes have in common that they are designed to support a process of decision-making which is seen as a rational balancing of options by an individual patient. This is in line with the standard view of

informed consent, discussed above. In the next paragraph we will criticize this view of decision-making. We will present a more refined view of decision-making. On the base of this view, we suggest an alternative model of informed consent, which can be used as a base for the design of alternative decision-supporting programmes.

3. Two models of informed consent

The most simple model of informed consent consists of two aspects: information and decision-making. These are ordered in two stages: the phase of disclosure of information and the phase of decision-making. The doctor is supposed to provide information and to give opportunity to the patient to make a decision; the patient is supposed to be able to comprehend information and to make a decision. This can be depicted as follows (see figure 1):

Stages of informed consent:	Doctor's involvement:	Patient's involvement:
Disclosure of information	Give information	Comprehend information
Decision-making	Give opportunity of choice	Make decision

Figure 1: Simple model of informed consent

In the literature on informed consent, we find several suggestions to extend this model. One such proposal is developed by Wear [21]. He distinguishes three stages.

The stages are: a comprehensive disclosure stage, emphasizing an overall, global provision of information; a core disclosure stage, presenting the essentials of the choice at hand in a more concrete way; and the stage of assessment, clarification and making a choice. We will describe each of the three stages in more detail (see also [19]).

The *comprehensive disclosure* stage emphasizes the integrated provision of information. The goals of this stage are to give a patient the opportunity to gain a full understanding of the situation as well as to rule himself in or out regarding hesitancy, ambivalence, misconceptions or a desire for more information or discussion. Patients should be informed about the problem or diagnosis, the recommended intervention as well as alternate modalities, with their significant benefits and risks and the prognosis if no intervention is attempted.

The *core disclosure* stage attempts to counter the information overload tendency of the first stage. The basic goal of the core disclosure stage is to present the essentials of the choice at hand to the patient in an approachable and palatable fashion. The core disclosure should center around whatever choice that patient is being asked to make, either authorizing the intervention that a physician feels is clearly indicated, or asking a patient to engage in a personal assessment of alternative modalities. A core disclosure of the choice at hand should enable the patient more readily to recognize the essential character of his authorization.

Assessment, clarification and making a choice will be the next, more interactive part of the informed consent process, eventually aiming to enable a patient to make an informed choice. Getting the relevant information across is only the first step. The physician must not only provide the patient with sufficient information but should also make sure that the patient understands the situation well enough to decide whether or not to provide a consent. Consideration must be given whether the disclosure of information is sufficient in quantity, if it is comprehended, if the consent is voluntary and if the patient is clear about his or her values. This interactive part of the informed consent even could assist in identifying contradictory aspects in a patient's values, respond to any significant misconceptions, false hopes or fears that the patient may have and stimulate the patient to be more forthcoming with information, leading a patient to a realistic appreciation of his or her situation and prospect.

This extended model of informed consent implies a more elaborate view on doctor's and patient's involvement. Besides providing information, the doctor should actively discuss the options with the patient. Besides comprehending information and making a decision, the patient should make the options part of an intersubjective deliberation process. Thus the patient should have the ability to understand the relevant information necessary to reach a decision, to deliberate about the disclosed information and to formulate and express the final decision at hand. In this process, the patient's values are not seen as given, but as issues which should be explored. The extended model can be visualized as follows (figure 2):

	Doctor's involvement:	Patient's involvement:
Stages of informed consent:	Present information	Interpret information
Core Disclosure	Discuss options	Deliberate about options
Assessment, clarification and making a choice	Check comprehension and quality of decision	Express final decision: agreement or disagreement

Figure 2: Extended model of informed consent

The extended model of informed consent does more justice to the intricate process of making decisions about treatment or about participation in clinical trials than the simple model does. By stressing the role of communication in decision-making, the extended model acknowledges that informed consent requires more than offering information by the doctor and making a decision by the patient. Information and decision have to be discussed and deliberated about. Such a discursive deliberation process has to be open, in order to ensure that both doctor and patient know what the decision enhances, so that a mutual commitment to cooperate in the project (treatment or research) is created. The extended model is in line with the deliberative model of doctor-patient interaction, described by the Emanuels [6].

The extended model of informed consent can help to explain why the practice of decision-making is not in line with the standard legal requirements. The practice of decision-making is not only and not primarily focussed upon an exchange of information and a drawing of logical conclusions from the information at hand. It contains joint work which aims to create understanding about the essence of the decision and commitment with the decision. Communication and deliberation are essential elements in creating mutual understanding and agreement. In order to sustain informed consent, we should not emphasize the content of information and the freedom of decision-making, but we should improve the process of communication between doctor and patient.

4. Habermas' theory of communicative action

The extended model of informed consent shows that decision-making requires communication. Thus, to improve decision-making, we should develop aids which can support communication between doctor and patient. In this respect, Habermas' theory of action can be relevant for two reasons (see [4]). In the first place, Habermas' approach to communication explicitly starts from the presupposition that communication is not an exchange of information, but a means to coordinate action. In the second place, Habermas' theory entails a model of communication which can be used for system design (see also [18]). In this paragraph we will discuss Habermas' theory, and show that it can help us to design programmes which support shared decision-making.

According to Habermas [7], the aim of communication is not exchange of information but coordination of actions. In communicative action, coordination is based upon an orientation towards mutual understanding. This orientation is fundamental for the kind of negotiations which take place within communicative action. Negotiations take the form of an exchange of validity-claims. According to Habermas, every communicative action entails three validity-claims: a claim to truth, to justice and to sincerity. The speaker claims that his utterance is true, that it is right in relation to the normative context, and that he expresses his intentions sincerely. If the hearer agrees (he says "yes"), he agrees to all three claims. If he disagrees (he says "no"), he disagrees with at least one of the claims. The hearer also has the option to ask for further specification (he says "why"). In that case he will need an explanation about (at least) one of the three claims. To give an example from medical practice: if a doctor proposes to do a test, the patient may disagree. If he does so, he will say "no" to the test, either because he does not see the use of it (he takes the position that the test is not appropriate, given his physical or social condition - in that case, the claim to truth is contested), or because he thinks the doctor is not in a position to do the proposal in the way it is expressed (he does not want to be ordered or bullied, for instance - now the claim of justice is involved), or, finally, because he is not convinced of the sincerity of the proposal (he may see it as a deliberate attempt of the doctor to acquire information for other purposes, for instance for research - the sincerity-claim is doubted).

It is important to notice that communicative action is always about something that has to be done (a diagnostic test to be performed, a medication to be given, a decision about participation in a trial, etc.). In communicating about what should be done, both partners make suggestions containing validity-claims. These claims

can be the subject of negotiations. Thus, the doctor can question the validity of the patient's claims to truth, justice and sincerity, and vice versa. Communication aims at mutual decision-making about the further course of action.

From this it follows that we should regard the three phases of informed consent as an ongoing process of communication about what should be done. In every phase, both doctor and patient raise claims to truth, to justice and to sincerity, and negotiate about them. If we want to sustain the process of decision-making, we should distinguish between the claims involved, and make clear that every claim might become an issue of disagreement at any time.

If a disagreement turns up, the process can be continued in three ways. In the first place, the opposed claim can be sustained by giving further specifications. Typically, after a "No, why should I" from the addressee, the speaker will try to make more clear what he meant, and why he raised his claim. If this does not work, two options remain. Either communication is ended, or the participants can enter into a dialogue (discourse), in which they critically examine the presuppositions they both started from. In a discourse, communicative action is put into brackets. It aims at finding a common ground, which makes new communicative action possible.

If we compare Habermas' model to the model of decision-making which lies behind the Shared Decision-making Programs discussed above, we can conclude that Habermas' approach introduces a radically different perspective. In the first place it sees decision-making as a process of coordination of action, based upon negotiations about validity-claims. In the second place, it distinguishes between three dimensions of such negotiations: the dimension of truth (the objective world); the dimension of justice (the intersubjective world) and the dimension of sincerity (the subjective world). In the third place, it contains a way out of a possible conflict: the level of discourse.

5. A communicative approach to informed consent

As an example, we want to apply Habermas' model to decision-making about entering a clinical trial. We will use the extended model of informed consent, described above. We will first describe communicative action in direct doctor-patient interaction for each of the three stages. Next we will discuss how such interaction might be structured into a model which can be used to develop a computer program.

The *comprehensive disclosure* stage aims to provide general information about the trial. It has to be clear that the doctor wants to ask the patient to cooperate in a study, and that for this purpose the study has to be explained first. The aim of this stage is not to elicit a decision from the patient, but to secure enough background for a discussion about the various options which will follow in the next stage. Thus, communication will have to start with a request from the doctor towards the patient to devote some time and attention to get to know the study in order to discuss possible participation afterwards.

D: "I am doing scientific research which needs the participation of patients. I would like you to consider taking part. May I explain the aim of the research to you, so that we can discuss whether you want to participate?"

If the patient agrees, general information about the trial can be provided. It should be clear, however, that the aim is to ensure that the patient has sufficient information to enter into the next stage, the deliberation about consequences of possible participation.

If the patient does not agree, this may be for various reasons. The most obvious one is that the patient does not accept the claim to justice which is involved. In that case, the patient doubts whether the doctor is entitled to ask for his time and attention. If the claim to justice is disputed, the doctor will have to argue why he thinks to be justified to put forward his proposal. He may have to specify that scientific research is an essential part of medicine, and that it is therefore justified to take some time from the patient to talk about it. If the claim to justice is problematic, it may be helpful to make clear that the decision whether or not the patient is going to participate is not at stake in this stage, but will be discussed extensively in the next two stages.

Apart from disagreement about the claim to justice, there may also be problems with the claim to truth or the claim to sincerity. The patient may not need the information, because he already knows about the trial. Or he may doubt whether the doctor is sincere about his motives. Will the information be impartial, or will it be biased? Is this request for attention a cheap way to gain cooperation? If the patient does not agree, it is necessary to find out which validity-claim is at stake. In a concrete interaction between doctor and patient, this is done by asking for the reason for refusal. In this, the doctor has to be careful to pay attention to the slightest doubt, since patients may find it hard to express disagreement in a direct way.

Usually, a negotiation about validity-claims in this stage will entail further explanation of the reasons for the claim; if this is not sufficient, it might be necessary to consider entering a discourse about the presuppositions behind the claims involved, for instance about the norms guiding the doctor-patient relationship.

The next step after providing general information is to enter the *core disclosure* stage. The doctor proposes the patient to consider participation in the trial. The emphasis is not on general information about the aim and usefulness of the trial, but upon the consequences of a possible entering of the trial for the patient. This could be stated in the following way:

D: "I have explained the research in general to you; now I would like you to consider participation. Therefore I suggest that we discuss the procedure and the consequences of participation for you."

The answer to the doctor's proposal can be either positive or negative. In the first case, the doctor can proceed to give specific information about the trial which is relevant to the patient's decision, and thereby prepare the patient to make a decision. In the second case, the patient evidently has no intent to consider participation, knowing what the trial is about. The answer should be regarded as final, since any further discussion might become entangled with aspects of power and persuasion which would break down communicative action. Thus the negotiation should end by acceptance of the refusal by the doctor.

In case of a positive answer, the consequences for the patient of entering the trial should be explored. The discussion should entail possible physical or psychological effects (aspects of truth). What will be the physical and emotional burden of taking part in the trial? This question can only be answered by discussing the risks and side-effects, and how they will be dealt with. In the second place, mutual rights and obligations (aspects of justice) should be explored. Why is the doctor entitled to ask the patient's participation? In what way does this request fit into the doctor-patient-relationship? Things to be discussed here might include the twofold responsibility of the doctor - to take care of his patients and to perform scientific research -, as well the way in which these two roles are combined. Attention should also be paid to the patient's perception of his condition and his expectations about treatment and care, since these factors may influence the patient's view of taking part in a trial (see section 1). These factors center around values, which can be related to the issue of sincerity, since they are about personal motives for action. Thus, all factors which might be relevant for the decision should be considered as possible objects of discussion and deliberation.

The stage of *assessment, clarification and making a choice* focusses upon the patient giving a motivated response to the request for participation. Given that the patient understands the cognitive, normative and evaluative aspects of the request (this understanding should be the result of stage 2), what is his answer going to be? This may be put forward by the doctor in the following way:

D: "Now that we have discussed various issues that are relevant, I would like to request you to participate in the trial. Can you tell me what the answer will be?"

It should be clear that it is the commitment of the patient that is at stake here. If he says "yes", this means he commits himself to cooperate in a project. If he says "no", this means he refuses to do so. Given the delicate nature of the situation, a negative answer has, again, to be accepted without further ado. If the patient refuses, the negotiation has to stop. The doctor should respect the patient's refusal, and only discuss how further treatment will be organized given this refusal.

If the answer is positive, however, the doctor should not be satisfied straight away. It is important to check whether the nature of the commitment is fully understood, and whether it is truly motivated. Thus, the doctor should be aware of possible doubts and hesitations, or, on the other side, excessive cooperation or dedication on the part of the patient. Further discussion of the consequences and motives of participation may therefore be necessary.

The process of communication described above shows the following structure (fig 3):

Figure 3: Model of Informed Consent Procedure for entering a Clinical Trial

This model can be used to build a program. Such a program differs from existing SDP's in that it models an intersubjective decision-making process. It also differs from existing programs in that it not only conveys information about the facts, but also focusses on the normative aspects of the relation between doctor and patient and on the values which may be relevant to the patient.

5. Conclusion

Informed consent is more than a two stage process of giving information by the doctor and making a decision by the patient. It should be seen as a communicative process of deliberation about a proposal for treatment or a request to participate in a trial. The outcome should be a motivated answer to such a proposition or request, and a mutual agreement about the result of the negotiation process. The communication process should be structured in such a way that motivation and agreement are enhanced. This means that all relevant aspects should be explored. Emphasis should be both on facts and on norms and values.

In this paper we presented a model of informed consent which contains three stages. For each of the stages, we made explicit the communicative structure. This structured model can be used as a base for shared decision making programs which make explicit mutual expectations and obligations. It can help us to do justice to the intricacy of the doctor-patient relationship. It can give us new opportunities to handle relevant issues in informed consent, such as patient's experiences with medical care and patient's expectations of the doctor, issues which are relevant to actual processes of decision-making in health care. It can help us to operationalize informed consent as intersubjectively shared decision-making.

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