# Ethical Issues in Family Practice

## "Consent for Medical research - Is the patient capable of autonomy?"

**Case study:** Dr. Dogma – a surgeon is involved in a clinical trial of a new drug for the treatment of breast cancer. One of his patients, Mrs. M who has terminal breast cancer is being recruited for the trial. The drug offers her the chance for a cure. Is she capable of autonomy to decide whether to take part in the trial or not?

Dr. A: **"Autonomy"** what a wonderful concept: 'self-rule'; the capacity to make deliberated or reasoned decisions for oneself and to freely act on the basis of such decisions. Autonomy involves two major elements:

- The examination of alternatives and the ability to distinguish between them
- The resources to put a conceived plan into action.

*Dr. B: Why don't we look at "**Respect for Autonomy**", one of the four recognised* prima facie *principles associated particularly with health care ethics. It grounds such ethical concerns as the* prima facie *obligations to obtain **informed consent** from patients before performing any action on them; to **keep promises; not to deceive** patients and (at least in part) the obligation to maintain **confidentiality**.*

Dr. A: But there are many debates raging concerning the concept of autonomy. Is the concept of autonomy the same in South Africa as in the highly 'individualised' Western World?

*Dr. B: I am not too sure on how to answer your question, but in America, for example, autonomy celebrates a hearty individualism emphasising creativity and productivity. Even in Western societies, those who are 'free' are never entirely 'free': While autonomous, we still live within a complex social network that influences our actions, just as our actions influence it.*

Dr. A: What I heard you say is that, we are never entirely "free" in the sense that our actions are, at the very least, influenced by competing claims and interests such as the demands and expectations of society. While I may be responsible for myself and my actions, the community can also be involved in my learning, what my responsibilities are and can also set obligations that I need to respect as I make my decisions.

*Dr. B: Yes, you are right. If we admit that we as non-patients, from whatever our countries of origin, are not entirely free, then what about patients? Are patients or can patients be regarded as 'free' autonomous persons? What about consent for medical research, is a patient capable of autonomy?*

*My understanding is that, in the case of our patient, by virtue of simply being a person who is ill, may infer a limit on her autonomy. In fact, at the far end of the continuum, some patients involved in research projects may be considered as being in **anti-autonomous, coercive situations**.*

Dr. A: But, we have all heard about coercion. Action control at its ultimate - a threat of great harm given by one person to another so that the latter is unable to refrain from acting to avoid it. But how can a research situation be anti-autonomous, coercive?

*Dr. B: Okay, consider the scenario under discussion: As part of the research project, the terminal cancer patient is given the opportunity to take the experimental but possibly toxic drug. But this drug also holds a chance for cure. The prospect that without this drug she will die appears to coerce a choice, no less than if a real person was standing in front of her forcing, with threat of harm or action. We could make a similar analogy in cases of economic deprivation. If starving patients are offered free food as part of a research project, their situation (hunger) coerces them into an action, that is to participate in the research project.*

Dr. A: So in both cases, the situation itself may be coercive; a coercive situation sways the patient's judgement of the risk-benefit ratio involved in the research project and thus becomes anti - autonomy. Their physical situation forces a negation of 'self-rule'.

*Dr. B: I think it is a correct claim that "losses of options" caused by grave circumstances and coercive situations in the extreme continuum do influence autonomy. However, I'm not certain that autonomy can be entirely negated. This is because even under 'normal' circumstances there are limits placed on the ability of patients (and non-patients) to make autonomous choices. But at this juncture is where the practical difficulty arises. How do you know or how can you know what a patient feels?*

Dr. A: It is very difficult. Often as doctors, we think that we know what a patient feels about his or her illness. We may know much, however we don't know everything about our patients. Perhaps he or she is in a state of denial that

we interpret wrongly, or appears to make rational choices. Most of our decisions are based on our 'rationality', not theirs. In fact, to carry it further, as family practitioners, we must remember that the focus should not only be on our patients, but with them in a 'systems model'; considering them in relationship to and interaction with other family members as well as the society at large.

*Dr. B: Yes, you have reminded me about an article that I read on "autonomy". It was stated that the extent to which a patient may lose or have autonomous choice diminished is dependent on at least three major factors:*

- ***The actual severity of the illness,***
- ***The patient's perception of the illness,***
- ***The perception of the illness by the family or society.***

Dr. A: You are saying that in general, patients and those involved in research are not really "free" and are not completely autonomous. Hence, in the research situation, we have an obligation to recognise these limitations and consider the question of how "free" is the consent to participate in such a research project?

*Dr. B: Correct, if we consider that one of the duties of family practitioners is to restore the patient's capacity for psychological autonomy, as opposed to making the patient make illusory moral choices. Then a balance must be found within the 'systems model' of returning to the patient, control over his or her life. This would, by extension, infer that the decisions to participate, or not to participate, in the research are as freely made as circumstances will allow.*

*In addition, you should not forget that within this 'systems model' many other questions arise. We know that whenever informed consent is given under threat of harm, it is invalid. What about anti-autonomy / coercive situations, does this also create invalid contracts and invalid consents? Because, if we follow this reasoning, it seems to me that patients in such situations can't act autonomously, and autonomy is necessary for informed consent.*

Dr. A: But, what we are obliged to look for is an answer to how a particular situation in which the patient finds herself relates to the possibility of the subjugation of her emotions to such an extent that her capacity for autonomous choice ( informed consent) is or might be impaired.

*B: So, what you are suggesting is that we hunt for a balance. The way to achieve the balance would be to consider both our patient's physical and psychological conditions and the circumstances under which she lives, then judge if she will be better or worse off by her involvement in the research. In this way, we emphasise both autonomy and maintain our prime directive – "respect for patient autonomy".*

Dr. A: But, make no mistake, the hunt for this balance is fraught with difficulties. Researchers may want to see their research projects completed at any cost and misuse the patient's trust. The psychological reactions of patients to their illnesses may be hidden from the researcher or ill defined and, the level and extent of information provided by the researcher may be too little or too much to meet the needs of the patient. Too much interference may undermine the rights and responsibilities of an autonomous person, and too little is irresponsible...and so on!

**"... a balance must be found within the 'symptoms model' of returning to the patient control over his or her life."**

*Dr. B: So all in all, the question seems to revolve around the tension between respecting our patient's autonomy and providing for her best interests. Konrad puts forth the argument that in the context of the Doctor-Patient (or researcher / subject) relationship, because illness necessarily diminishes autonomy, soft medical paternalism, aimed at restoring her health (and her linked autonomy) is justifiable.* [1]

Dr. A: Food for thought.

*Dr. B: That's the idea.*

**Reference:**

1. Konrad, MS. 1983. A defense of medical paternalism: maximising patients' autonomy. J Med Ethics. 9: 38-44.

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