CHAPTER 2

AUTONOMY IN MEDICAL ETHICS: ISSUES OF INFORMED CONSENT

Following the previous general discussion of autonomy in philosophical and ethical theory, I will now turn to medical ethics, and set out how the principle of respect for autonomy has been interpreted and elaborated in that field. In standard works and textbooks on medical ethics, 'autonomy' is generally understood as the patient's right to self-determination within the context of medical and research practices. As mentioned earlier, this right to self-determination is primarily a *negative right to non-interference*: the right to make decisions concerning one's own life for oneself without being controlled by others. The principle of respect for autonomy thus functions as a moral rule that protects patients from unwelcome interference by physicians and other health care professionals and has become a principle that guides interactions between patients and care givers. Assuming this interpretation, the medical ethical literature discusses various aspects of and problems related to patient autonomy. Who has this right to self-determination? How can we make sure patients' rights are respected? Can anything justify interference with these rights, and if so, what? What constitutes a free or autonomous choice? When is a person incapable of making such a choice, and how can his rights be respected when he is unable to exercise them?

For the most part, these questions echo the questions and problems discussed previously from the perspective of autonomy and paternalism as more general philosophical and ethical issues. The development of the leading contemporary theories about autonomy and paternalism in ethics and legal and political philosophy took place simultaneously with the development of contemporary medical ethics. Though influencing each other, these simultaneous developments in the fields of philosophy and medical ethics have remained to some extent independent. As a result, many similarities and interfaces have emerged between theories of autonomy and paternalism in general and theories of patient autonomy, informed consent and medical paternalism in medical ethics, while at the same time the authors in the respective fields often use different definitions and interpretations of major concepts. One example is the concept of voluntariness. As used by Feinberg, it is somewhat different from the concept of voluntariness as used in the theory of informed consent.

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22 The report of the President's Commission on health care decisions and informed consent was published in 1982, the same year in which Childress' *Who should decide, paternalism in health care* was published. A year later Sartorius published a collection of essays on paternalism. Faden and Beauchamp's *History and theory of informed consent* was published in 1986, the same year as VanDeVeer's *Paternalistic intervention* and Feinberg's *Harm to Self*. 
consent. Another example is the concept of valid consent as used by VanDeVeer in his discussion of paternalism, which is not exactly the same as the concept of informed consent used in medical ethics. Discussions and theories about autonomy, paternalism, and informed consent all focus on the same set of problems and intuitions but approach them from different angles or perspectives. For this reason, the discussions in this chapter will exhibit a certain amount of overlap with those in Chapter 1. At the same time, however, some central concepts and problems will receive their own specific meaning and interpretation or will be elaborated in greater detail.

In medical ethics, the issue of patient autonomy is most frequently discussed in terms of informed consent, a concept that refers both to a patient's free and voluntary consent to treatment as well as to the procedures to be followed and the criteria to be satisfied to ensure this consent. After placing the concept of informed consent into a social and historical perspective, the following sections go into greater detail to explain and discuss the concept itself. This is followed by a discussion of the manifestations of informed consent in practice as well as the exceptions to the requirement of informed consent. Section 5 will discuss the concept of competence that plays an important part as a prerequisite for informed consent. This chapter ends with an overview of the medical ethical literature on decision-making for patients who are found to be incompetent.

1. MEDICAL ETHICS, AUTONOMY AND INFORMED CONSENT

Historically, the doctrine of informed consent was developed within the context of medical experiments with human subjects, but it has become equally important within the context of medical decision-making in a therapeutic setting. The doctrine of informed consent, however, is not only (and perhaps not even primarily) a product of medical ethics. It developed within the framework of law and medical practice as well as in medical ethics, and its development was stimulated by historical events and social changes and directed by legal and practical considerations and by social movements (such as the civil rights movement and the patients' rights movement) as well as by ethical and philosophical theory. Since informed consent is simultaneously a legal doctrine, an ethical concept and a clinical practice, it is not surprising that a review of the literature on informed consent and associated issues reveals a recurring tension between what is morally desirable, what is legally required and what is feasible in clinical practice. Often, these aspects are so intertwined that it is difficult to separate them.

Within the framework of medical ethics, informed consent is usually considered to be primarily an important means [according to de Beaufort and Dupuis (1988), the only means] to achieve the goal of patient autonomy or self-determination. According to another viewpoint, the very attempt to secure consent is an expression of respect for the autonomy of the patient (Dworkin 1982, Brock 1987). The doctrine of informed consent is commonly believed to find its most important justification in patient autonomy or self-determination, although some authors consider beneficence or patient well-being to be equally important principles in
justifying informed consent (Brock 1987, Wear 1993). These authors claim that informed consent promotes patients' well-being because it enables patients to make their own choices and because people's own choices will, in general, promote their well-being. Besides protecting patient autonomy and promoting patients' well-being, some other functions or effects of informed consent such as the promoting of rational decision-making, stimulating self-criticism among physicians, protecting research subjects and reducing medicalisation are frequently mentioned as well (Brock 1987, Kimsma 1993, Wear 1993). For now, I will adopt the viewpoint that self-determination is the basic value behind the doctrine of informed consent. I will not go into its possible other functions at this point but will instead limit myself to a discussion of informed consent as an ethical requirement that protects and promotes the self-determination of patients.

2. THE THEORY OF INFORMED CONSENT

This section addresses the theory of informed consent assuming the interpretation of informed consent as being the autonomous authorisation of a medical intervention. The basic elements of informed consent - intentionality, understanding, and voluntariness - will be discussed in succession.

2.1 Informed consent as autonomous authorisation

In their standard work entitled *A History and Theory of Informed Consent*, Faden and Beauchamp not only give a historical overview of the development of the doctrine in terms of both legal and ethical theory but also present a systematic conceptual analysis of informed consent. Their conceptual approach will be used here to clarify the basic ethical requirements for informed consent.

Faden and Beauchamp distinguish between two common but starkly different meanings of informed consent that they label 'sense-1' and 'sense-2'. Sense-1 (or 'true') informed consent is a specific kind of action taken by individual patients and subjects; it is an autonomous authorisation. Sense-2 informed consent refers to a legally or institutionally 'effective' authorisation from a patient or subject. In this sense, informed consent is not necessarily an autonomous act or a meaningful authorisation; here, a consent is called informed if it is obtained through procedures that satisfy the legal and institutional rules and requirements. From a moral point of view, the criteria for sense-1 informed consent ought to be the benchmark or model for sense-2 informed consent. The rules and regulations for sense-2 informed consent should maximally conform to the conditions of sense-1, within the limits of what is fair and reasonable to require of health care professionals. Sense-1 informed consent thus serves as an evaluative standard for informed consent in sense-2. In their study, Faden and Beauchamp discuss only this sense-1 informed consent and

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23 As we have seen, this is one of the arguments used to explain the value of the right to autonomy in general.
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