PART II

MORAL PRINCIPLES

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Respect for Autonomy

The principle of respect for the autonomous choices of persons runs as deep in the common morality as any principle, but determining its nature, scope, or strength requires careful analysis. We employ the concept of autonomy and the principle of respect for autonomy in this chapter largely to examine individuals' decision making in health care and research, both as patients and as subjects (or "participants"[1]).

Although we begin our analysis of a framework of principles of biomedical ethics with the principle of respect for autonomy, the order of our chapters does not imply that this principle has moral priority over other principles. We do not hold, as some of our critics have suggested, that the principle of respect for autonomy always has priority over all other moral considerations. We also argue, in contrast to some of our commentators, that respect for autonomy is not excessively individualistic (to the neglect of the social nature of individuals and the impact of individual choices and actions on others), is not excessively focused on reason (to the neglect of the emotions), and is not unduly legalistic (highlighting legal rights while downplaying social practices and responsibilities).

THE CONCEPT OF AUTONOMY AND THE PRINCIPLE OF RESPECT FOR AUTONOMY

The word *autonomy,* derived from the Greek *autos* ("self") and *nomos* ("rule," "governance," or "law"), originally referred to the self-rule or self-governance of independent city-states. Autonomy has since been extended to individuals, but the precise meaning of the term is disputed. At a minimum, personal autonomy encompasses self-rule that is free from both controlling interference by others and limitations that prevent meaningful choice, such as inadequate understanding. The autonomous individual acts freely in accordance with a self-chosen plan, analogous to the way an independent government manages its territories and sets its policies. In contrast, a person of diminished autonomy is in some material respect controlled by others or incapable of deliberating or acting on the basis of his or her desires and plans. For example, cognitively challenged individuals and prisoners often have diminished autonomy. Mental incapacitation limits the autonomy of a person with a severe mental handicap, whereas coercive institutionalization constrains a prisoner's autonomy.

Virtually all theories of autonomy view two conditions as essential for autonomy: *liberty* (independence from controlling influences) and *agency* (capacity for intentional action). However, disagreement exists over the meaning of these two conditions and over whether additional conditions are required.[2] How a theory can be constructed from these basic conditions is the first subject we will consider.

Theories of Autonomy

Some theories of autonomy feature the abilities, skills, or traits of the *autonomous person,* which include capacities of self-governance such as understanding, reasoning, deliberating, managing, and independent choosing.[3] However, our focus in this chapter on decision making leads us to concentrate on *autonomous choice* rather than on general capacities for governance and self-management. Even autonomous persons who have self-governing capacities and are, on the whole, good managers of their health sometimes fail to govern themselves in particular choices because of temporary constraints caused by illness, depression, ignorance, coercion, or other conditions that limit their judgment or their options.

An autonomous person who signs a consent form for a procedure without reading or understanding the form has the capacity to act autonomously, but fails to so act in this circumstance. Depending on the context, we might be able to correctly describe the act as one of placing trust in one's physician and therefore as an act that autonomously authorizes the physician to proceed. However, even if this claim were accurate, the act is not an autonomous authorization *of the procedure* because this person lacks material information about it. Similarly, some persons who are generally incapable of autonomous decision making can at times make autonomous choices. For example, some patients in mental institutions who cannot care for themselves and have been declared legally incompetent may still make some autonomous choices, such as stating preferences for meals, refusing medications, and making phone calls to acquaintances.

Split-level theories of autonomy. An influential group of philosophers has presented a theory of autonomy that requires having the capacity to reflectively control and identify with or oppose one's basic (first-order) desires or preferences through higher level (second-order) desires or preferences.[4] Gerald Dworkin offers a "content-free" definition of autonomy as a "second-order capacity of persons to reflect critically upon their first-order preferences, desires, wishes, and so forth and the capacity to accept or attempt to change these in the light of higher-order preferences and values."[5] An example is an alcoholic who has a desire to drink, but also a higher order desire to stop drinking. In a second example, a dedicated physician may have a first-order desire to work exceptionally long hours in the hospital, while also having a higher order commitment to spend all of her evening hours with her family. Whenever she wants to work late in the evening and does so, she wants what she does not autonomously want, and therefore acts nonautonomously. Action from a first-order desire that is not endorsed by a second-order volition is not autonomous and represents animal behavior. Accordingly, in this theory an autonomous person has the capacity to reflectively accept, identify with, or repudiate a lower order desire independent of others' manipulations of that desire. This higher order capacity to accept or repudiate first-order preferences *constitutes* autonomy, and no person is autonomous without this capacity.

This theory is problematic, however, because nothing prevents a reflective acceptance, preference, or volition at the second level from being caused by and assured by a strong first-order desire. The individual's second-level acceptance of, or identification with, the first-order desire would then be the causal result of an already formed structure of preferences. Potent first-order desires from a condition such as alcohol addiction are antithetical to autonomy and can cause second-order desires. If second-order desires (decisions, volitions, etc.) are generated by prior desires or commitments, then the process of identifying with one desire rather than another does not distinguish autonomy from nonautonomy.

This theory needs more than a convincing account of second-order preferences and acceptable influences. It needs a way for ordinary persons to qualify as deserving respect for their autonomy even when they have not reflected on their preferences at a higher level. This theory also risks running afoul of the criterion of coherence with the principle of respect for autonomy discussed throughout this chapter. If reflective identification with one's desires or second-order volitions is a necessary condition of autonomous action, then many ordinary actions that are almost universally considered autonomous, such as cheating on one's spouse (when one truly wishes not to be such a person) or selecting tasty snack foods when grocery shopping (when one has never reflected on one's desires for snack foods), would be rendered *non*autonomous in this theory. Requiring reflective identification and stable volitional patterns deeply narrows the scope of actions protected by a principle of respect for autonomy.

Agnieszka Jaworska insightfully argues that choosing contrary to one's stable or accepted values need not constitute an abandonment of autonomy even if a choice contradicts the person's own professed, fixed set of values. For example, a patient might request a highly invasive treatment at the end of life against his previous judgment about his best interests because he has come to a conclusion that surprises him: He cares more about living a few extra days than he had thought he would. Despite his long-standing and firm view that he would reject such invasive treatments, he now accepts them. Jaworska's case is not uncommon in medical contexts.[6]

Few decision makers and few choices would be autonomous if held to the standards of higher order reflection in this split-level theory, which seems to present an aspirational ideal of autonomy rather than a suitable theory of autonomy for decision making of the sort under study in this chapter. A theory should not be inconsistent with pretheoretical assumptions implicit in the principle of respect for autonomy, and no theory of autonomy is acceptable if it presents an ideal beyond the reach of ordinary, competent agents and choosers.

Our three-condition theory. Instead of depicting such an ideal theory of autonomy, our analysis focuses on nonideal conditions. We analyze autonomous action in terms of normal choosers who act (1) intentionally, (2) with understanding, and (3) without controlling influences that determine their action. This account of autonomy is specifically designed to be coherent with the premise that the everyday choices of generally competent persons are autonomous.

1. *Intentionality.* Intentional actions require plans in the form of representations of the series of events proposed for the execution of an action. For an act to be intentional, as opposed to accidental, it must correspond to the actor's conception of the act in question, although a planned outcome might not materialize as projected.[7] Nothing about intentional acts rules out actions that one wishes one did not have to perform. Our motivation often reflects *conflicting* wants and desires, but this fact does not render an action less than intentional or autonomous. Foreseen but undesired outcomes are often part of a plan of intentional action.

2. *Understanding.* Understanding is the second condition of autonomous action. An action is not autonomous if the actor does not adequately understand it. Conditions that limit understanding include illness, irrationality, and immaturity. Deficiencies in the communication process also can hamper understanding. In our account, an autonomous action needs only a substantial degree of understanding and freedom from constraint, not a full understanding or a complete absence of influence. To restrict adequate decision making by patients and research subjects to the ideal of fully or completely autonomous decision making strips their acts of any meaningful place in the practical world, where people's actions are rarely, if ever, fully autonomous.

3. *Noncontrol.* The third of the three conditions of autonomous action is that a person be free of controls exerted either by external sources or by internal states that rob the person of self-directedness. Influence and resistance to influence are basic concepts for this analysis. Not all influences exerted on another person are controlling. Our analysis of noncontrol and voluntariness later in this chapter focuses on coercion and manipulation as key categories of influence. We

there concentrate on *external* controlling influences—usually influences of one person on another—but no less important to autonomy are *internal* influences on the person, such as those caused by mental illness. All of these conditions can limit voluntariness.

The first of the three conditions of autonomy—intentionality—is not a matter of degree: Acts are either intentional or nonintentional. However, acts can satisfy both the conditions of understanding and absence of controlling influence to a greater or lesser extent. For example, threats can be more or less severe; understanding can be more or less complete; and mental illness can be more or less controlling. Children provide a good example of the continuum running from being in control to not being in control. In the early months of life children are heavily controlled and display only limited ability to be in control: They exhibit different degrees of resistance to influence as they mature, and their capacity to take control and perform intentional actions, as well as to understand, gradually increases as they develop.

Acts therefore can be autonomous by degrees, as a function of satisfying these two conditions of understanding and voluntariness to different degrees. A continuum of both understanding and noncontrol runs from full understanding and being entirely noncontrolled to absence of relevant understanding and being fully controlled. Cutoff points on these continua are required for the classification of an action as either autonomous or nonautonomous. The lines between adequate and inadequate degrees of understanding and degrees of control must be determined in light of specific objectives of decision making such as deciding about surgery, choosing a university to attend, and hiring a new employee.

The line between what is substantial and what is insubstantial may appear arbitrary. However, thresholds marking substantially autonomous decisions can be carefully fixed in light of specific objectives such as meaningful decision making. Patients and research subjects can achieve substantial autonomy in their decisions, just as substantially autonomous choice occurs in other areas of life such as choice of diet. The appropriate criteria for substantial autonomy are best addressed in a particular context.

Autonomy, Authority, Community, and Relationships

Some theorists argue that autonomous action is incompatible with the authority of governments, religious organizations, and other communities that prescribe behavior. They maintain that autonomous persons must act on their own reasons and can never submit to an authority or choose to be ruled by others without losing their autonomy.[8] However, no fundamental inconsistency exists between autonomy and authority if individuals exercise their autonomy in choosing to accept an institution, tradition, or community that they view as a legitimate source of direction.

Choosing to follow medical authority is a prime example. Other examples are a Jehovah's Witness who accepts the authority of that tradition and who therefore refuses a recommended blood transfusion and a Roman Catholic who accepts the authority of the church and chooses against an abortion. That persons share moral norms with authoritative institutions does not prevent these norms from being autonomously accepted, even if these principles derive from traditions or from institutional authority. If a Jehovah's Witness who insists on adhering to the doctrines of his faith in refusing a blood transfusion is deemed nonautonomous on the basis of his religious upbringing and convictions, many of our choices based on our confidence in institutional authority will be likewise deemed unworthy of respect. In our account, a theory of autonomy that takes this course is morally unacceptable.

We encounter many limitations of autonomous choice in medical contexts because of the patient's dependent condition and the medical professional's authoritative position. On some occasions authority and autonomy are incompatible, but not because the two *concepts* are incompatible. Conflict arises because authority has not been properly presented or accepted. For example, an undue influence may have been exerted. Some critics of autonomy's prominent role in biomedical ethics question what they deem to be a model of an independent, rational will that is inattentive to emotions, communal life, social context, interdependence, reciprocity, and the development of persons over time. They charge that such an account of autonomy focuses too narrowly on the self as independent and rationally controlling. For instance, some writers have sought to affirm autonomy while interpreting it through relationships.[9] This conception of "relational autonomy" is motivated by the conviction that persons' identities are shaped through social interactions and complex intersecting social determinants, such as race, class, gender, ethnicity, and authority structures. Persons are both interdependent and in danger of oppressive socialization and oppressive social relationships that impair their autonomy by conditions that unduly form their desires, beliefs, emotions, and attitudes and improperly thwart the development of the capacities and competencies essential for autonomy.[10]

We will largely address the challenges of relational autonomy through the ethical principles analyzed in Chapters 5 through 7. For instance, principles of justice provide a basis for condemning oppressive relationships and for determining which constraints on autonomous choice are and which are not ethically justified. In our view, relational conceptions of autonomy are defensible as long as they do not neglect or obscure the principal features of autonomy, as we analyze the concept in this chapter.

The Principle of Respect for Autonomy

To respect autonomous agents is to acknowledge their right to hold views, to make choices, and to take actions based on their values and beliefs. Such respect involves respectful *action,* not merely a respectful *attitude.* It also requires more than noninterference in others' personal affairs. It includes, in some contexts, building up or maintaining others' capacities for autonomous choice while helping to allay fears and other conditions that destroy or disrupt autonomous action. Respect, so understood, involves acknowledging the value and decision-making rights of autonomous persons and enabling them to act autonomously, whereas disrespect for autonomy involves attitudes and actions that ignore, insult, demean, or are inattentive to others' rights of autonomous action.

The principle of respect for autonomy can be stated as both a negative obligation and a positive obligation. As a *negative* obligation, the principle requires that autonomous actions not be subjected to controlling constraints by others. It asserts a broad obligation that is free of exceptive clauses such as "We must respect individuals' views and rights so long as their thoughts and actions do not seriously harm other persons." Of course, the principle of respect for autonomy needs specification in particular contexts to function as a practical guide to conduct, and appropriate specification will incorporate valid exceptions. This process of specification will affect rights and obligations of liberty, privacy, confidentiality, truthfulness, and informed consent—all of which receive attention in this and subsequent chapters.

As a *positive* obligation, the principle requires both respectful treatment in disclosing information and actions that foster autonomous decision making. Many autonomous actions could not occur without others' material cooperation in making options available. Respect for autonomy obligates professionals in health care and research involving human subjects to disclose information, to probe for and ensure understanding and voluntariness, and to foster adequate decision making. As some contemporary Kantians have argued, the demand that we treat others as ends requires that we assist them in achieving their ends and foster their capacities as agents, not merely that we avoid treating them solely as means to our ends.[11]

These negative and positive sides of respect for autonomy are capable of supporting many more specific moral rules, some of which may also be justified, in whole or in part, by other moral principles discussed in this book. Examples of such rules include the following:

1. Tell the truth.
2. Respect the privacy of others.
3. Protect confidential information.
4. Obtain consent for interventions with patients.
5. When asked, help others make important decisions.

Respect for autonomy has only prima facie standing, and competing moral considerations sometimes override this principle. Examples include the following: If our autonomous choices endanger the public health, potentially harm innocent others, or require a scarce resource for which no funds are available, others can justifiably restrict our exercises of autonomy. The principle of respect for autonomy often does not determine what, on balance, a person ought to be free to know or do or what counts as a valid justification for constraining autonomy. For example, a patient with an inoperable, incurable carcinoma once asked specifically, "I don't have cancer, do I?" The physician lied, saying, "You're as good as you were ten years ago." This lie infringed the principle of respect for autonomy by denying the patient information he may have needed to determine his future courses of action. Although the matter is controversial, such a lie might be justified by a principle of beneficence if certain major benefits will flow to the patient. (For the justification, see our discussions of paternalism in Chapter 6 and veracity in Chapter 8.)

Obligations to respect autonomy do not extend to persons who cannot act in a sufficiently autonomous manner—and who cannot be rendered autonomous—because, for instance, they are immature, incapacitated, ignorant, coerced, or exploited. Infants, irrationally suicidal individuals, and drug-dependent patients are examples. This standpoint does not presume that these individuals are not owed moral respect.[12] In our framework, they have a significant moral status (see Chapter 3) that obligates us to protect them from harm-causing conditions and to supply medical benefits (see Chapters 5–7).

The Triumph or Failure of Respect for Autonomy?

Some writers lament the "triumph of autonomy" in American bioethics. They charge that autonomy's proponents sometimes disrespect patients by forcing them to make choices, even though many patients do not want to receive information about their condition or to make decisions. Carl Schneider, for example, claims that stout proponents of autonomy, whom he labels "autonomists," concern themselves less with what patients *do want* than with what they *should want.* He concludes that "while patients largely wish to be informed about their medical circumstances, a substantial number of them [especially the elderly and the very sick] do not want to make their own medical decisions, or perhaps even to participate in those decisions in any very significant way."[13]

The duty of respect for autonomy has a correlative *right* to choose, but there is no correlative *duty* to choose. Several empirical studies of the sort cited by Schneider seem to misunderstand, as he does, how autonomous choice functions in a theory such as ours and how it should function in clinical medicine. In one study, UCLA researchers examined the differences in the attitudes of elderly subjects (sixty-five years or older) from different ethnic backgrounds toward (a) disclosure of the diagnosis and prognosis of a terminal illness, and (b) decision making at the end of life. The researchers summarize their main findings, based on 800 subjects (200 from each ethnic group): "Korean Americans (47%)

and Mexican Americans (65%) were significantly less likely than European Americans (87%) and African Americans (88%) to believe that a patient should be told the diagnosis of metastatic cancer. Korean Americans (35%) and Mexican Americans (48%) were less likely than African Americans (63%) and European Americans (69%) to believe that a patient should be told of a terminal prognosis and less likely to believe that the patient should make decisions about the use of life-supporting technology (28% and 41% vs. 60% and 65%). Korean Americans and Mexican Americans tended to believe that the family should make decisions about the use of life support." Investigators in this study stress that "belief in the *ideal* of patient autonomy is far from universal" (italics added), and they contrast this ideal with a "family-centered model" focused on an individual's web of relationships and "the harmonious functioning of the family."[14]

Nevertheless, the investigators themselves conclude that "physicians should ask their patients if they wish to receive information and make decisions or if they prefer that their families handle such matters." Far from abandoning or supplanting the moral demand that we respect individual autonomy, their recommendation accepts the normative position that the choice is rightly the patient's. Even if the patient delegates that right to someone else, the choice to delegate can itself be autonomous.

In a second study, this time of Navajo values and the disclosure of risk and medical prognoses, two researchers sought to determine how health care providers "should approach the discussion of negative information with Navajo patients" to provide "more culturally appropriate medical care." Frequent conflicts emerge, these researchers report, between autonomy and the traditional Navajo conception that "thought and language have the power to shape reality and to control events." According to the traditional conception, telling a Navajo patient recently diagnosed with a disease the potential complications of that disease may actually produce those complications, because "language does not merely describe reality, language shapes reality." Traditional Navajo patients may process various forms of negative information as dangerous to them. They expect instead a "positive ritual language" that promotes or restores health.

One middle-aged Navajo nurse reported that a surgeon explained the risks of bypass surgery to her father in such a way that he refused to undergo the procedure: "The surgeon told him that he may not wake up, that this is the risk of every surgery. For the surgeon it was very routine, but the way that my Dad received it, it was almost like a death sentence, and he never consented to the surgery." The researchers therefore found ethically troublesome those policies that, in compliance with the Patient Self-Determination Act, attempt to "expose all hospitalized Navajo patients to the idea, if not the practice, of advance care planning."[15]

These two studies enrich our understanding of diverse cultural beliefs and values. However, several studies misrepresent what the principle of respect for autonomy and many related laws and policies require. They view their results as opposing rather than enriching the principle of respect for autonomy. A fundamental obligation exists to ensure that patients have the right to choose, as well as the right to accept or to decline information. Forced information and forced choice are usually inconsistent with this obligation. From this perspective, a tension exists between the two studies just discussed. One study recommends inquiring in advance to ascertain patients' preferences about information and decision making, whereas the other suggests, tenuously, that even informing certain patients of a right to decide may cause harm. The practical question is whether it is possible to inform patients of their rights to know and to decide without compromising their systems of belief and values or otherwise disrespecting them.

Health professionals should almost always inquire about their patients' wishes to receive information and to make decisions, and they should not assume that because a patient belongs to a particular community or culture, he or she affirms that community's worldview and values. The fundamental requirement is to respect a particular person's autonomous choices, whatever they may be. Respect for autonomy is not a mere ideal in health care; it is a professional obligation.

Complexities in Respecting Autonomy

Varieties of autonomous consent. Consent sometimes grants permission for others to act in ways that normally would be unjustifiable—for instance, engaging in sexual relations or performing surgery. However, when examining autonomy and consent in this chapter, we do not presume that consent is either necessary or sufficient for certain interventions to be justified. It is not always necessary in emergencies, in public health interventions, in research involving anonymized data, and so forth; and it is not always sufficient because other ethical principles too must be satisfied—for example, research involving human subjects must pass a benefit–risk test and a fairness test in the recruitment of participants.[16]

The basic paradigm of the exercise of autonomy in health care and in research is *express* or *explicit* consent (or refusal), usually informed consent (or refusal).[17] However, the informed consent paradigm captures only one form of consent. Consent may also be implied, tacit, or presumed; and it may be general or specific.

Implicit (or *implied*) consent is inferable from actions. Consent to a medical procedure may be implicit in a specific consent to another procedure, and providing general consent to treatment in a teaching hospital may imply consent to various roles for physicians, nurses, and others in training. Another form is *tacit* consent, which occurs silently or passively through omissions. For example, if the staff of a long-term care facility asks residents whether they object to having the time of dinner changed by one hour, a uniform lack of objection constitutes consent.

Presumed consent is subject to a variety of interpretations. It is a form of implied consent if consent is presumed on the basis of what is known about a particular person's choices; in certain contexts, presumed consent is tacit consent that gives good grounds for accepting the consent as valid. By contrast, presuming consent on the basis of human goods that are desirable or what a rational will would accept is morally perilous. Consent should refer to an individual's actual choices or known preferences, not to presumptions about the choices the individual would or should make.

Different conceptions of consent have appeared in debates about teaching medical students how to perform intimate examinations, especially pelvic and rectal examinations.[18] Often medical students have learned and practiced on anesthetized patients, some of whom have not given an explicit informed consent. For instance, many teaching hospitals have allowed one or two medical students to participate in the examination of women who are under anesthesia in preparation for surgery. Anesthetized patients have been considered ideal for teaching medical students how to perform a pelvic examination because the patients are relaxed and would not feel any mistakes. When questioned about this practice, some directors of obstetrics and gynecology programs have appealed to the patient's general consent upon entering a teaching hospital. Such consent typically authorizes medical students and residents to participate in patients' care for teaching and learning purposes. However, it is not specific as to which procedures might involve participation by medical students.

It is debatable whether general consent is sufficient or whether specific informed consent is necessary in these circumstances. We often seek specific informed consent when a procedure is invasive, as in the case of surgery, or when it is risky. Although pelvic examinations are not invasive or particularly risky by comparison to surgery, patients may object to the intrusion into their bodies, especially for education and training. Some women readily consent to the participation of medical students in such examinations, but others view the practice as a violation of their dignity and privacy. One commentator appropriately states that "the patient must be treated as the student's teacher, not as a training tool."[19]

Using anesthetized women who have given only a general consent may be highly efficient in clinical training, but in view of the importance of respect for autonomy, there are ethically preferable alternatives such as using anesthetized patients who have given specific informed consent or using healthy volunteers who are willing to serve as trainers or models. Either of these alternatives respects personal autonomy and avoids negative medical education. A study of medical students in the Philadelphia area found that the practice of conducting pelvic exams on anesthetized patients without specific informed consent desensitized physicians to the need for patients to give their consent before such procedures. For students who had finished an obstetrics/gynecology clerkship, consent was significantly less important (51%) than for students who had not completed a clerkship (70%). The authors conclude that "to avoid this decline in attitudes toward seeking consent, clerkship directors should ensure that students perform examinations only after patients have given consent explicitly."[20]

Nonexpress forms of consent have been considered and sometimes adopted. In late 2006, the U.S. Centers for Disease Control and Prevention (CDC) changed its recommendations about HIV screening for patients in health care settings where various other diagnostic and screening tests are regularly performed. The recommendations moved away from specific, explicit informed consent, usually in written form, to general, implicit consent as part of the acceptance of medical care. Previous policies required specific disclosure of information and a decision to accept or refuse testing.[21] For many commentators, this shift indicated that conventional public health measures were now being applied to HIV infection and AIDS, rather than being excluded on grounds of respect for the autonomy of patients and associated principles such as privacy and confidentiality.[22]

The CDC justified its new recommendations on two main grounds. First, because HIV and AIDS are chronic conditions that can be effectively treated, although not cured, the new screening approach would enable more people who are infected to take advantage of available therapies that could extend their lives at a higher quality. Second, the information gained from screening could enable persons who are infected with HIV to take steps to protect their sex partners or drug-use partners from infection. The CDC estimated that in 2008, over 1,175,000 people in the United States were HIV-infected, but that over 236,000 infected individuals were not aware of their infection. More recently it has become evident that treating individuals to reduce their viral load is very effective in reducing the spread of HIV infection to their sexual partners.[23]

The CDC's new approach did not eliminate patient autonomy in health care settings—patients could still refuse testing—but, by shifting the default from "opt in" to "opt out," the CDC expected that more people previously unaware of their HIV infection would be tested and would gain knowledge that could benefit themselves and others. Despite its potential benefits, some critics of the "opt-out" policy warned that in the absence of a requirement for explicit, written informed consent, compromises of autonomy are inevitable and "compulsory" screening would occur in some contexts. According to one AIDS activist, "This is not informed consent, and it is not even consent, [but rather an attempt] to ram HIV testing down people's throats without their permission."[24] Although an "opt-out" approach can be justified in such circumstances, this strategy can be ethically improved by the use of *notification* while retaining the possibility of "opting out."

Another context in which an opt-out approach, in the form of presumed or tacit consent, could, in principle, be justified is organ donation from deceased individuals. In the opt-in system in the United States, deceased organ donation requires express, explicit consent, whether by an individual while alive or by the next of kin after his or her death. Even though the information disclosed for the individual's consent is usually quite limited—for instance, in a cursory exchange when obtaining a license to operate an automobile—it is arguably adequate for purposes of postmortem organ donation. In view of the tremendous gap between the number of organs donated each year and the number of patients awaiting a transplant, many propose that the United States adopt an opt-out model for organ removal from deceased persons, as several European countries have done. This model shifts the default so that an individual's silence, or nonregistration of dissent, counts as consent. Two questions arise: Is such a policy of presumed consent ethically acceptable? Could it be adopted and would it be effective in the United States?

To be ethically justifiable, such a policy would require vigorous efforts to ensure the public's understanding of the options they face as individuals, as well as a reliable, easy, and nonburdensome mechanism to use to opt out. Such a policy will not likely be adopted in the United States because of historical and legal commitments to individual choice. Even if it were adopted, it probably would not increase the number of organs for transplantation overall because, according to survey data, too many citizens would opt out; and opting out would prevent postmortem familial donations, which now provide a large number of transplantable organs.[25]

The varieties of consent we have now examined point to a fundamental question in this chapter: Who should seek what kind of consent from whom and for what?

Consents and refusals over time. Beliefs and choices shift over time. Ethical and interpretive problems arise when a person's present choices contradict his or her previous choices, which, in some cases, he or she explicitly designed to prevent possible future changes of mind from affecting an outcome. In one case, a twenty-eight-year-old man decided to terminate chronic renal dialysis because of his restricted lifestyle and the burdens his medical conditions imposed on his family. He had diabetes, was legally blind, and could not walk because of progressive neuropathy. His wife and physician agreed to provide medication to relieve his pain and further agreed not to put him back on dialysis even if he requested this action under the influence of pain or other bodily changes. (Increased amounts of urea in the blood, which result from kidney failure, can sometimes lead to altered mental states, for example.) While dying in the hospital, the patient awoke complaining of pain and asked to be put back on dialysis. The patient's wife and physician decided to act on the patient's earlier request not to intervene, and he died four hours later.[26] Although their decision was understandable, respect for autonomy suggests that the spouse and physician should have put the patient back on dialysis to flush the urea out of his bloodstream and then to determine if he had autonomously revoked his prior choice. If the patient later indicated that he had not revoked his prior choice, he could have refused again, thereby providing the caregivers with increased assurance about his settled preferences.

In shifts over time the key question is whether people are autonomously revoking their prior decisions. Discerning whether current decisions are autonomous may depend, in part, on whether they are in character or out of character. Out-of-character actions can raise caution flags that warn others to seek explanations and to probe more deeply into whether the actions are autonomous, but they may turn out to be autonomous. Actions are more likely to be substantially autonomous if they are in character (e.g., when a committed Jehovah's Witness refuses a blood transfusion), but acting in character does not necessarily indicate an autonomous choice. How, then, are we to determine whether actions are autonomous?

THE CAPACITY FOR AUTONOMOUS CHOICE

Many patients and potential research subjects are not competent to give a valid consent or refusal. Inquiries about competence focus on whether such persons are capable, cognitively, psychologically, and legally, of adequate decision making. Competence in decision making is closely connected to autonomous decision making, as well as to the validity of consent. Several commentators distinguish judgments of capacity from judgments of competence on the grounds that health professionals assess capacity and incapacity, whereas courts determine competence and incompetence. However, this distinction breaks down in practice, and we will not use it. When clinicians judge that patients lack decision-making capacity, the practical effects of these judgments may not differ from those of a legal determination of incompetence.[27]

The Gatekeeping Function of Competence Judgments

Competence or capacity judgments in health care serve a gatekeeping role by distinguishing persons whose decisions should be solicited or accepted from persons whose decisions need not or should not be solicited or accepted. Health professionals' judgments of a person's incompetence may lead them to override that person's decisions, to turn to informal surrogates for decision making, to ask the court to appoint a guardian to protect his or her interests, or to seek that person's involuntary institutionalization. When a court establishes legal incompetence, it appoints a surrogate decision maker with either partial or plenary (full) authority over the incompetent individual. Physicians and other health professionals do not have the authority to declare patients incompetent as a matter of law, but, within limits, they often have the de facto power to override or constrain patients' decisions about care based on assessments of limited capacity or incapacity.

Competence judgments have the distinctive *normative* function of qualifying or disqualifying persons for certain decisions or actions, but those in control sometimes incorrectly present these judgments as *empirical.* For example, a person who appears irrational or unreasonable to others might fail a psychiatric test, and therefore be declared incompetent. The test is an empirical measuring device, but normative judgments establish how the test is to be used to sort persons into the two classes of competent and incompetent, which determines how persons ought to be, or may permissibly be, treated.

The Concept of Competence[28]

Some commentators hold that we lack both a single acceptable *definition* of competence and a single acceptable *standard* of competence. They also contend that no nonarbitrary *test* exists to distinguish between competent and incompetent persons. We will engage these issues by distinguishing between definitions, standards, and tests—focusing first on problems of definition.

A single core meaning of the word *competence* applies in all contexts. That meaning is "the ability to perform a task."[29] By contrast to this core meaning, the *criteria* of particular competencies vary from context to context because the criteria are relative to specific tasks. The criteria for someone's competence to stand trial, to raise dachshunds, to answer a physician's questions, and to lecture to medical students are radically different. The competence to decide is therefore relative to the particular decision to be made. Rarely should we judge a person incompetent with respect to every sphere of life. We usually need to consider only some type of competence, such as the competence to decide about treatment or about participation in research. These judgments of competence and incompetence affect only a limited range of decision making. For example, a person who is incompetent to decide about financial affairs may be competent to decide to participate in medical research, or able to handle simple tasks easily while faltering before complex ones.

Competence may vary over time and may be intermittent. Many persons are incompetent to do something at one point in time but competent to perform the same task at another point in time. Judgments of competence about such persons can be complicated by the need to distinguish categories of illness that result in *chronic* changes of intellect, language, or memory from those characterized by *rapid reversibility* of these functions, as in the case of transient ischemic attack or transient global amnesia. In some of the latter cases competence varies from hour to hour. Here a determination of specific incompetence may prevent vague generalizations that exclude these persons from all forms of decision making.

These conceptual distinctions have practical significance. The law has traditionally presumed that a person who is incompetent to manage his or her estate is also incompetent to vote, make medical decisions, get married, and the like. The global sweep of these laws, based on a total judgment of the person, at times has extended too far. In one classic case, a physician argued that a patient was incompetent to make decisions because of epilepsy,[30] although many persons who suffer from epilepsy are competent to decide in most contexts. Such judgments defy much that we now know about the etiology of various forms of incompetence, even in hard cases involving persons with mental retardation, with psychosis, or with uncontrollably painful afflictions. In addition, persons who are incompetent by virtue of dementia, alcoholism, immaturity, and mental retardation present radically different types and problems of incompetence.

Sometimes a competent person who can usually select appropriate means to reach his or her goals will act incompetently in some circumstances. Consider the following actual case of a hospitalized patient who has an acute disc problem and whose goal is to control back pain. The patient decided to manage the problem by wearing a brace, a method she had used successfully in the past. She believes strongly that she should return to this treatment modality. This approach conflicts, however, with her physician's unwavering and near-insistent advocacy of surgery. When the physician, an eminent surgeon who alone in her city is suited to treat the patient, asks her to sign the surgical permit, she is psychologically unable to refuse. Her illness increases both her hopes and her fears, and, in addition, she has a deferential personality. In these circumstances, it is psychologically too risky for her to act as she desires. Even though she is competent to choose in general, she is not competent to choose on this occasion.

This case indicates how close the concept of competence in decision making is to the concept of autonomy. Patients or prospective subjects are competent to make a decision if they have the capacity to understand the material information, to make a judgment about this information in light of their values, to intend a certain outcome, and to communicate freely their wishes to caregivers or investigators. Law, medicine, and, to some extent, philosophy presume a context in which the characteristics of the competent person are also the properties possessed by the autonomous person. Although *autonomy* and *competence* differ in meaning (*autonomy* meaning self-governance; *competence* meaning the ability to perform a task or range of tasks), the criteria of the autonomous person and of the competent person are strikingly similar.

Persons are more and less able to perform a specific task to the extent that they possess a certain level or range of abilities, just as persons are more and less intelligent and athletic. For example, in the emergency room an experienced and knowledgeable patient is likely to be more qualified to consent to or refuse a procedure than a frightened, inexperienced patient. It would be confusing to view this continuum of abilities in terms of degrees of *competency*. For practical and policy reasons, we need *threshold levels* below which a person with a certain level of abilities for a particular task is incompetent. Not all competent persons are equally able, and not all incompetent persons are equally unable, but competence determinations sort persons into these two basic classes, and thus treat persons as either competent or incompetent for specific purposes. Above the threshold, we treat persons as equally competent; below the threshold we treat them as equally incompetent. Gatekeepers test to determine who is above and who is below the threshold. Where we draw the line depends on the particular tasks involved.[31]

Standards of Competence

Questions about competence often center on the standards for its determination, that is, the conditions a competence judgment must satisfy. Standards of competence feature mental skills or capacities closely connected to the attributes of autonomous persons, such as cognitive skills and independent judgment. In criminal law, civil law, and clinical medicine, standards for competence cluster around various abilities to comprehend and process information and to reason about the consequences of one's actions. In medical contexts, physicians usually consider a person competent if he or she can understand a procedure, deliberate with regard to its major risks and benefits, and make a decision in light of this deliberation.

The following case illustrates some difficulties encountered in attempts to judge competence. A man who generally exhibits normal behavior patterns is involuntarily committed to a mental institution as the result of bizarre self-destructive behavior (pulling out an eye and cutting off a hand). This behavior results from his unusual religious beliefs. The institution judges him incompetent, despite his generally competent behavior and despite the fact that his peculiar actions coherently follow from his religious beliefs.[32] This troublesome case is not one of intermittent competence. Analysis in terms of limited competence at first appears plausible, but this analysis perilously suggests that persons with unorthodox or bizarre religious beliefs are less than competent, even if they reason coherently in light of their beliefs. This policy would not be ethically acceptable unless specific and careful statements spelled out the reasons under which a finding of incompetence is justified.

Rival standards of incompetence. We focus on standards of *incompetence,* rather than *competence,* because of the legal, medical, and practical presumption that an adult is competent and should be treated as such in the absence of a determination of incompetence or incapacity. In the clinical context, an inquiry into a patient's competence to make decisions usually occurs only when the medical decision at stake is complex and involves significant risks or when the patient does not accept the physician's recommendation.[33] The following schema expresses the range of inabilities currently required under competing standards of incompetence presented in literature on the subject.[34]

1. Inability to express or communicate a preference or choice
2. Inability to understand one's situation and its consequences
3. Inability to understand relevant information
4. Inability to give a reason
5. Inability to give a rational reason (although some supporting reasons may be given)
6. Inability to give risk/benefit-related reasons (although some rational supporting reasons may be given)
7. Inability to reach a reasonable decision (as judged, for example, by a reasonable person standard)

These standards cluster around three kinds of abilities or skills. Standard 1 looks for the simple ability to formulate a preference, an elementary standard. Standards 2 and 3 probe for abilities to understand information and to appreciate one's situation. Standards 4 through 7 concentrate on the ability to reason through a consequential life decision. These standards have been and still are used, either alone or in combination, to determine incompetence.

Testing for incompetence. A clinical need exists to turn one or more of these general standards into an operational test of incompetence that establishes passing and failing evaluations. Dementia rating scales, mental status exams, and similar devices test for factors such as time-and-place orientation, memory, understanding, and coherence. Although these clinical assessments are empirical tests, normative judgments underlie each test. The following ingredients incorporate normative judgments:[35]

1. Choosing the relevant abilities for competence
2. Choosing a threshold level of the abilities in item 1
3. Choosing an empirical test for item 2

For any test already accepted under item 3, it is an empirical question whether someone possesses the requisite level of abilities, but this empirical question can only be addressed if normative criteria have already been fixed under items 1 and 2. Institutional rules or traditions usually establish these criteria, but the standards should be open to periodic review and modification.

It is beyond the scope of our discussion to analyze and evaluate the numerous tests and instruments that have been developed to assess decisional capacity for clinical treatment or research. Several reviews[36] of these instruments—one review examined twenty-three such instruments—have found that, even though these instruments can aid clinicians' and researchers' assessment of decision-making competence, they produce variable results. Accordingly, it is premature to conclude that any one of them provides a satisfactory and reliable way to assess decision-making capacity. In the final analysis, the assessment of decisional capacity remains heavily a matter of clinical judgment, although some studies indicate that these clinical judgments too are often not reliable.[37]

The sliding-scale strategy. Properties of autonomy and of mental and psychological capacity are not the only criteria used in delineating competence standards. Many policies use pragmatic criteria such as efficiency, feasibility, and social acceptability to determine whether a person is competent to make decisions about medical care. For example, age has conventionally been used as an operational criterion of valid authorization or refusal of medical procedures. Established thresholds of age vary in accordance with a community's standards, with the degree of risk involved, and with the importance of the prospective benefits. From this perspective, standards of competence are connected to levels of experience, maturity, responsibility, and welfare.

Some writers offer a sliding-scale strategy for how to realize this goal. They argue that, as the risks of a medical intervention increase for patients, so should the level of ability required for a judgment of competence to elect or refuse the intervention. As the consequences for well-being become less substantial, we should lower the level of capacity required for competence. For example, Grisso and Appelbaum present a "competence balance scale." An autonomy cup is suspended from the end of one arm of a measuring scale, and a protection cup is suspended from the other; the fulcrum is set initially to give more weight to the autonomy cup. The balancing judgment depends "on the balance of (1) the patient's mental abilities in the face of the decisional demands, weighed against (2) the probable gain-risk status of the patient's treatment choice."[38] If a serious risk such as death is present, then a correspondingly stringent standard of competence should be used; if a low or insignificant risk is present, then a relaxed or lower standard of competence is permissible. Thus, the same person—a child, for example—might be competent to decide whether to take a tranquilizer but incompetent to decide whether to authorize surgery.[39]

This sliding-scale strategy is attractive. A decision about which standard to use to determine competence depends on several factors that are risk-related. The sliding-scale strategy rightly recognizes that our interests in ensuring good outcomes legitimately contribute to the way we create standards. If the consequences for welfare are grave, the need to certify that the patient possesses the requisite capacities increases; but if little in the way of welfare is at stake, we can lower the level of capacity required for decision making. For example, if a patient with reversible dementia needs enteral nutrition to recover, a powerful reason exists for protecting that patient against rash or imprudent decision making and, accordingly, for adopting a more stringent standard of decision-making capacity.

Although the sliding-scale strategy may function as a valuable protective device, it creates confusion regarding the nature of both competence judgments and competence itself because of certain conceptual and moral difficulties. This strategy suggests that a person's *competence* to decide is contingent on the decision's importance or on some harm that might follow from the decision. This thesis is dubious: A person's competence to decide whether, for example, to participate in cancer research does not depend on the decision's consequences. As risks increase or decrease, we can legitimately increase or reduce the rules, procedures, or measures we use to *ascertain* whether someone is competent; but in formulating what we are doing, we need to distinguish between a person's *competence* and the *modes of ascertaining* that person's competence. Leading proponents of the sliding-scale strategy hold the reverse view that *competence itself* varies with risk. For example, according to Allen Buchanan and Dan Brock, "Because the appropriate level of competence properly required for a particular decision must be adjusted to the consequences of acting on that decision, no single standard of decision-making competence is adequate. Instead, the level of competence appropriately required for decision making varies along a full range from low/minimum to high/maximal."[40]

This account is conceptually and morally perilous. It is correct to say that the level of a person's capacity to decide will rise as the *complexity* or *difficulty* of a task increases (deciding about spinal fusion, say, as contrasted with deciding whether to take a minor tranquilizer), but the level of competence to decide does not rise as the *risk* of an outcome increases. It is confusing to blend a decision's complexity or difficulty with the risk at stake. No basis exists for believing that risky decisions require more ability at decision making than less risky decisions.

We can sidestep these problems by recognizing that the level of *evidence* for determining competence should vary according to risk. As examples, some statutes have required a higher standard of evidence for competence in making than in revoking advance directives, and the National Bioethics Advisory Commission recommended a higher standard of evidence of competence to consent to participate in most research than to object to participation.[41] These are counsels of prudence that protect patient-subjects. Whereas Brock and Buchanan propose that the level of decision-making *competence itself* belongs on a sliding scale from low to high in accordance with risk, we recommend placing only the required *standards of evidence* for determining decision-making competence on a sliding scale.

THE MEANING AND JUSTIFICATION OF INFORMED CONSENT

At least since the Nuremberg trials, which exposed the Nazis' horrific medical experiments, biomedical ethics has placed consent at the forefront of its