Informed Consent and the Capacity for Voluntarism

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Objective: Informed consent is built upon the elements of information, decisional capacity, and voluntarism. Of these elements, voluntarism in clinical and research consent is the least well understood. This has interfered with the ability to resolve key ethical problems faced by the field of psychiatry.

Method: The author suggests that voluntarism encompasses an individual's ability to act in accordance with one's authentic sense of what is good, right, and best in light of one's situation, values, and prior history. Voluntarism further entails the capacity to make this choice freely and in the absence of coercion. Deliberateness, purposefulness of intent, clarity, genuineness, and coherence with prior life decisions are implicitly emphasized in this construction.

Results: The author offers and illustrates a framework for voluntarism in clinical and research consent decisions, focusing on four domains of potential influence: 1) developmental factors, 2) illness-related considerations, 3) psychological issues and cultural and religious values, and 4) external features and pressures.

Conclusions: It is hoped that improved understanding of voluntarism will help in our efforts to fulfill the principle of respect for persons in clinical care and research.

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Informed consent is built upon the elements of information, decisional capacity, and voluntarism. Information in the consent process generally encompasses issues such as the nature of the illness, the anticipated risks and benefits of the proposed procedure, and possible alternatives, including nonintervention (1, 2). Decisional capacity, in turn, comprises the ability to communicate, understand, and logically work with information and to appreciate the meaning of a decision within the context of one's life (3, 4). Our understanding of voluntarism in this country is more intuitive and involves philosophical ideals of freedom, independence, personhood, and separateness (5, 6).

The application of the concept of voluntarism has been very unclear in both research and clinical contexts (7–18). This ambiguity, furthermore, has prevented the resolution of several serious controversies in the field of psychiatry (7, 19, 20). The question of whether people suffering from chronic psychotic illnesses who are involuntarily hospitalized can freely choose to participate in research, for example, is a key controversy, and it is a different issue than questions as to whether they have the capacity to understand and make an informed decision (20–22). Whether people with depression complicated by suicidality are too vulnerable to make a voluntary choice regarding treatment preferences or research enrollment, separate from their level of understanding, is another important ethical dilemma that is increasingly gaining attention in the study of mental illness (23–25). Similarly, current practices of obtaining consent for nonapproved uses of prescription medications among elders with dementia or children pose serious ethical problems. These are not simply because of the issues of decisional capacity of ill elders and children but also because of the expectation in national ethics and regulatory standards that these individuals must be offered as much choice in the decisional process as they are capable of exercising (17, 26–31). In other words, these considerations are not reducible to the question of whether individuals have the capacity to assimilate, rationally weigh, and appreciate the factual information with which they are presented. There is also the issue of whether they can make these decisions in a manner that is uncoerced and true to their personal beliefs and values. Guidelines for assessing the capacity for voluntarism have not previously been developed, despite the centrality of this concept for fulfilling informed consent and for resolving key ethical problems in mental illness research and clinical care. Indeed, the ethical meaning of informed consent and its merit as a safeguard respectful of the person—whether a patient or a research participant—derive largely from the way in which a person's choice and values may be recognized, expressed, and honored through authentic voluntarism (6).

Influences on Voluntarism

Influences on voluntarism are implicitly recognized in the characteristics of traditionally defined special populations (7, 8). Children, for instance, may not have developed an internal capability for free, deliberate choice, and developmentally disabled people, depending on the degree and nature of their deficits, may never acquire this ability (9). This is not simply a concept of cognitive maturity or sophistication but, rather, of emotional develop-

ment and the emergence of distinct personhood (10). People with dementia live out an erosion of the self, losing their personal history, beliefs, motivations, relationships, and independence along with their memory, intellect, and self-care skills (11). Institutionalized people and prisoners, by virtue of their external situations, have such an altered experience of freedom that the potential for genuine, uncoerced choice is diminished (12–14). Among some mentally ill people, the presence of certain symptoms, such as ambivalence, diminished motivation, disengagement, or impulsivity may interfere with the ability to make authentic, lasting, and meaningful choices at certain times (16, 17). Federal regulations have noted that the capacity for "free" decision making is potentially compromised in pregnant women and, by extension, in women of childbearing potential, because of the competing concerns of the woman and the dependent unborn child (12, 15, 18). Voluntarism may thus be diminished by many influences, such as developmental immaturity, cognitive deficits, illness symptoms, pressures intrinsic to certain settings, and needs of the dependent (19, 32). Because of these barriers to voluntarism, additional safeguards are intended to protect and enhance, to whatever extent possible, the autonomous decision making of members of these populations (12, 15, 17, 20).

Many other less well-recognized elements also affect voluntarism. These relate to the individual's emotional experience, life history, and personal psychological issues. Suffering and pain due to physical or mental health problems may cause one to move toward a decision out of desperation rather than deliberateness and adherence to personal values and previous life choices (23, 24, 33, 34). The barriers to voluntarism associated with emotional distress are similar when the anguished parent of a dying child makes critical health decisions on his or her child's behalf (35, 36). People who have been institutionalized or who have survived severe trauma of various forms may experience the world differently thereafter and feel less able to enact choices in their lives or even to feel entitled to possess choices (37, 38). Distinct psychological experiences of power relationships—for example, among some women, some individuals from ethnic minorities, and, of interest, among some people who have served in the military—may also limit the person's sense that he or she may decline a course of action recommended by a clinician, who is seen as a strong authority figure (39, 40). Immigrants coming from countries in which clinicians are perceived as very powerful, beneficent, and as rightly making decisions for their patients may also find the expectation of independent decision making unclear (37). More worrisome are expectations based on misplaced hope and misunderstandings (e.g., that a clinical treatment or research study will confer personal benefit or that a clinical researcher will always act in the best interests of the participant [the "therapeutic misconception"]) that may distort the values underlying the autonomous choice of the individual (4, 41, 42). Finally, some beliefs and psychological defenses that emerge in the process of dealing with an overwhelming illness may be a barrier to perceiving and considering alternatives (2, 43).

Beyond these considerations, an individual person experiences constraints on what can be chosen freely according to his or her own sense of self. These are not components that affect factual understanding per se but rather the discernment of the self and what is seen as possible, acceptable, and preferable when engaging in a life choice. The possibility of living life with physical disfigurement, or with permanent ventilator support, or without the ability to work or create, or without the capacity to bear children are not ever choices that some individuals can undertake freely. In a sense, these influences limit one's voluntarism, but more important, they also serve to define one's voluntarism through the expression of one's values and distinctly personal pattern of life choices.

Cultural and religious values are also important influences on voluntarism in a consent decision. Cultural views of the ideal self as interdependent, as opposed to independent, as are held by many Hispanic and Asian peoples, for example, challenge the concept of autonomy as predominant and affect the individual's capacity to project himself or herself into a separatist Western construction of the self (44–47). Beliefs held by many Native American peoples that illness derives from the person being out of balance with nature—threatening the well-being of the entire community and requiring native healing approaches—predictably affect the willingness of this patient to entertain nontraditional therapeutic interventions (48). Spiritual values and deeply held personal beliefs related to one's unique life experiences may furthermore alter what is understood to be possible and acceptable for the individual person (49). People from rural families and communities that value stoicism and courage may have greater difficulty accepting treatment for pain or mental health symptoms (50). Traditional Navajo people, for whom the prospect of entering the next world physically incomplete is unthinkable, may be unable to entertain amputation as a possible treatment choice (51). Jehovah's Witness patients who strictly hold to traditional guidelines within their religion may not intentionally accept blood products even in life-threatening situations because of their spiritual understanding (52, 53).

Last, external circumstances and pressures can dramatically affect voluntarism, either negatively or positively. Perhaps the most obvious factor extrinsic to the individual is the presence or absence of resources in a given situation. What is possible in a tertiary care center in Chicago is different from what is possible in Tucumcari, New Mex., irrespective of the personal wishes of the patient. In addition, the process of a making a decision itself may hamper or enhance the voluntarism of a person making a key consent decision. Rushed timing of a complex or highly important health decision, for example, may threaten the

person's ability to make a deliberate choice that is otherwise well informed and congruent with his or her life values (54). Alternatively, an unfolding and conscientious dialogue between a clinician and a patient who is suffering from a chronic illness may provide an optimal situation for authentic decision making (55). Large financial incentives may cause the individual to subordinate usual values to take on serious risks (56, 57). The presence of a supportive family member may improve the person's ability to identify and state his or her preferences, whereas the presence of an insensitive or domineering family member may have the opposite result (58, 59). Ill-defined but potent role conflicts inherent in dual or overlapping relationships create confusion about the intent of a consent decision and may create complex contextual pressures affecting the true voluntarism of the decision maker (60). This may be the case when a person enrolls in a study in which his or her personal clinician is also the principal investigator (61). Dual agency may also threaten voluntarism if a worker-participant is pressured by management to take part in a workplace-based study or when a prison official serves as a research "recruiter" (62). External features may thus serve to support or interfere with voluntarism.

A Framework for Understanding Voluntarism

Our evolving understanding of voluntarism has not received sufficient emphasis in discussions of informed consent within the medical profession (21, 63). This inattention may be due in part to the fact that we have not articulated the domains that constitute the "capacity for voluntarism" with the clarity and elegance in which the capacity for decision making has been stated. In a 1988 article, Appelbaum and Grisso (3) presented an analysis of decision-making competence for informed consent that entailed the abilities to communicate, understand, appreciate, and reason. This formulation was theoretically rigorous, intuitively resonant, clinically meaningful, and legally useful. It has shaped subsequent thought on consent decision making in this country and elsewhere (63–65).

Borrowing from the insights of this model, I suggest a framework for understanding an individual's capacity for voluntarism in clinical or biomedical research consent decisions. The framework is based on a definition of voluntarism as ideally encompassing the individual's ability to act in accordance with one's authentic sense of what is good, right, and best in light of one's situation, values, and prior history. Voluntarism involves the capacity to make this choice freely and in the absence of coercion. Deliberateness, purposefulness of intent, clarity, genuineness, and coherence with one's prior life decisions are implicitly emphasized in this construction. This definition seeks to capture a complex phenomenon that has biological, psychological, and sociocultural determinants, which themselves are richly heterogeneous by their nature. This construction also presupposes the observation that certain legitimate limits to one's liberty exist. These include the imperative to not harm others intentionally and the general responsibility to make choices within the accepted constraints of society and standards within the medical profession. In other words, the fact that a person may make a truly voluntary choice does not mandate that a health professional condone, support, or enact this choice. However, this framework seeks to clarify the capacity for such choice in a systematic manner.

The framework explicitly characterizes four domains influencing voluntarism in clinical and biomedical research settings. These categories naturally overlap and interact, and they are linked to the capacity for appreciation, the most sophisticated component of decisional capacity. Some of the influences are positive; many have the effect of diminishing the capacity for voluntarism. The framework places primacy on the ethics principles of respect for persons and voluntarism rather than on autonomy or self-determination per se, by giving support to the values that may be held dear by some patients and participants and, ironically, may challenge the relevance of separate, autonomous choice for these persons. The framework may also help in our efforts to develop strategies for evaluating and supporting voluntarism, thereby enhancing the ethical rigor of informed-consent decisions. Finally, the framework is presented with an invitation to my colleagues to help refine and develop it, as this task is indeed a challenge and one that will certainly be enriched from the wisdom of multiple perspectives.

Voluntarism: Four Domains of Influence

Voluntarism in consent decisions may be analyzed according to four domains of potential influence: 1) developmental factors, 2) illness-related considerations, 3) psychological issues and cultural and religious values, and 4) external features and pressures.

Developmental Factors

An individual's capacity for voluntarism is affected by the person's development in terms of cognitive abilities, emotional maturity, and moral character. While it is clear that even very young children can and do express desires, it is accepted that children are unable to make independent, cognitively complex decisions for themselves. As children mature and their intellect, self-understanding, and sense of separate personhood develops, they are increasingly able to express sustained preferences that meet some tests of discernment, logic, coherence, and emerging personal values (28). During late childhood and preadolescence, the capacity to accept a proffered choice (i.e., assent) becomes evident (66). A greater capacity for voluntarism accompanies the older adolescent's emerging abilities to think abstractly, to recognize personal values in re-

lation to those of others, to reflect on one's place in the world, and to begin to consider the repercussions of a decision based on some accumulated personal life experience. Reference points for personal decisions make the transition from parental values to incorporate those derived from social experience beyond the family in school, in interactions with peers, and within the broader culture (e.g., the media). In late adolescence and early adulthood, these young people often are capable not only of thoughtful judgment regarding their own safety and well-being but of making genuine and deeply committed altruistic choices (28). With time, adults ideally are increasingly able to identify their personal opinions and preferences, particularly when facing novel decisions, on the basis of the learning and mature self-knowledge that comes with life experience. Adults often have roles that entail making decisions of varying stakes and consequences, and these individuals have had many opportunities for learning, expressing, and practicing their capacity for voluntary choice. In later life, the capacity for voluntarism is less driven by developmental considerations but is affected primarily by the remaining three domains of influence.

Illness-Related Considerations

Many mentally and physically ill individuals speak of the personal resolve and discernment of life priorities that they feel as a result of the illness experience (67). Indeed suffering, or having survived a period of suffering, may midwife remarkable clarity about one's values in life choices (68). These illness-related phenomena may enhance the individual's voluntarism in consent decisions.

Symptoms associated with mental or physical illness may nevertheless serve as negative factors that seriously detract from voluntarism. Ambivalence and indecisiveness, poor energy, and negative thoughts are among the elements that define depression and physical disorders that mimic or become complicated by secondary depression. In a second example, psychotic disorders at times give rise to symptoms affecting voluntarism, such as apathy and avolition, inability to read one's own internal emotional state and preferences, impaired insight and judgment, social disengagement, bizarre beliefs or overvalued ideas, and abnormal perceptions (65, 69). These illness manifestations typically fluctuate, with multiple symptoms at some times and fewer at other times. However, taken together, these symptoms can prevent an individual from collecting his or her thoughts, feelings, and personal values to make a coherent and enduring choice (70, 71). Dementia and some other neuropsychiatric disorders that are characterized by impaired memory, inability to perform practical activities, and compromised executive functions cognitively wear away the core components of the self, greatly affecting the capacity for voluntarism in even moderately advanced stages (72). Serious substance abuse disorders are aggressively erosive to the capacity for voluntarism, as is reflected in their diagnostic criteria. This is evident in the patterns of apathy and diminished motivation, preoccupation with substance procurement and intake, and impaired judgment related to maladaptive behaviors (26, 73). Among physical symptoms, severe pain has a profound impact on voluntarism, as has been well demonstrated in studies in which adequate pain control radically changes the consent decisions of patients, including end-of-life-care preferences (24, 74). The degree of physical dependence that a person experiences—e.g., the ability to feed one's self, to attend to one's own hygiene—due to pain or debilitation also affects one's ability to make and insist upon choices (75).

Individually and in concert, these symptoms and illnesses such as these may greatly affect one's capacity to identify, feel committed to, voice, and enact upon one's preferences. They may also interfere with one's ability to ensure that the perceptions and motivations underlying a decision are accurate for a given situation. When psychopathological symptoms or maladaptive defenses interfere with the patient's ability to discern his or her preferences, time and support may be given and perhaps other clinical interventions should be undertaken to help the patient. Thus, specific mental and physical symptoms and their nature, severity, and temporal pattern may significantly affect an individual's capacity for voluntarism.

Psychological Issues and Cultural and Religious Values

Psychological issues and cultural and religious values influence voluntarism. They may contribute in a manner that enhances one's sense of individual autonomy and empowerment. Alternatively, these influences may diminish voluntarism or simply render less relevant various factors associated with voluntarism.

Psychological issues and values derived from an individual's cultural and spiritual milieu influence impressions of who is good and what choices are acceptable when he or she is facing life decisions. Relevant concepts of self, personhood, autonomy, and morality are shaped by the earliest of our internal and relational experiences and are revised over a lifetime. These factors may affect how symptoms are perceived, how illness is defined, and whether consenting to an intervention is acceptable. These representations and the individual's psychological defenses (e.g., denial) become particularly salient when coping with the significant stresses intrinsic to an illness. The level of commitment to a particular choice is affected by such factors. Further, specific beliefs inevitably define meaning and parameters for a person's choices. This is apparent in a decision regarding elective pregnancy termination or end-of-life care in patients who hold to strict Catholic beliefs or in a complex decision regarding the nonacceptance of treatment by a person who is a Christian Scientist. The influence of specific beliefs is also evident in the interpretation of mental symptoms among rural persons, the "true" causes of illness among many

Native American or Alaska native peoples, or the preferred way to inform a traditional Japanese elder of a diagnosis of a terminal illness.

Even seeing one's ideal self as a separate, autonomous individual—as an agent able to decide and act—is a perspective that some have characterized as distinctly "Western," culture bound, and masculine in its approach to decision making (76). In other societies, behaving in a manner that enhances the relationships in the family or defers to the judgment of elders has greater valence (45). The act of defining a preference separate from the needs of others or different from the traditions of the community, for some people, may be viewed as wrong or unthinkable. The process of expressing choices is shaped by these kinds of forces as well. Communication styles certainly vary across individuals but, perhaps even more dramatically, across regions, ethnicities, and larger cultures, e.g., the contrasting dialogue patterns of Navajo people in comparison with those of Italian Americans (77, 78). The issue of having a voice, or the ways of giving voice, in key health decisions is thus uncertain despite this presupposition in our society and in our formal construction of the model of informed consent. Studies of masculine and feminine styles of personal decision making (79) have also provided some evidence that women place greater importance on collaboration, adaptation, and relationship preservation in the face of moral decisions, while men place greater importance on self-reliance, assertiveness, and adherence to accepted rules. These psychological, cultural, and religious elements should be considered carefully for their impact on the patient's process of generating a purposeful, authentic, and coherent decision.

External Features and Pressures

Influences on voluntarism that are extrinsic to the self are diverse and potent. The most obvious external determinants are the resource limitations inherent in many health care settings. Local or regional legislation may also define the parameters for individual decision making. Granted, these factors determine the fundamental nature of the consent decision by defining what choices actually exist for an individual patient at a specific place and point in time. Nevertheless, they merit careful attention because they may also affect the individual's motivation for accepting a particular intervention simply because of the lack of viable alternatives. Other external factors reside within the nature of the decision itself, such as the novelty, complexity, seriousness, and timing of a consent decision, and whether it can be made stepwise without loss of significant options. Incentives or strongly reinforcing pressures within the context should also be considered for their impact on voluntarism (7). Institutional settings delimit the freedoms of individuals and may generate significant pressures on individuals—be they prisoners, nursing home residents, or mentally or physically ill people—engaging in consent decisions (80). The relationship with the caregiver or researcher, similarly, may have carefully hidden coercive influences that may be present, for example, when multiple roles or overlapping relationships exist (81). The presence or absence of loved ones may also affect the person's process of clarifying and expressing choice. In sum, qualities of the environment, relationships, and the decisional process may all serve to add to or detract from the individual's voluntarism in giving informed consent.

Conclusions

Voluntarism is critical for the fulfillment of the ideal of informed consent. From an ethical perspective, voluntarism is the principle that embodies respect for the person as a human being, as a self with a personal history and values, and as a moral agent with fundamental rights and privileges in our society. True voluntarism is a source of strength for the philosophical and legal safeguard of informed consent. On the other hand, diminished voluntarism in the consent process is a source of vulnerability for patients and research participants (81, 82). Stated differently, even the most well-informed and decisionally "fit" individual cannot realize the spirit of informed consent if his or her "choice" is inauthentic, symptom driven, compromised, or coerced (83).

Four aspects of the application of this model to clinical and research practice merit consideration. First, as with the assessment of decisional capacity for informed consent, the capacity for voluntarism is ideally understood in relation to a specific decision (84). When we consider influences on the capacity for voluntarism, the standard varies according to the nature of the decision. Greater ambivalence about adopting a certain course of action is acceptable if the situation is nonacute and the consequences are not dire. Greater clarity, authenticity, coherence, and commitment are necessary in a serious and high-stakes informed consent or refusal decision.

Second, this framework may give clues for strategies for enhancing voluntarism. For instance, supporting the voluntarism of children or developmentally disabled people in the decisions they are capable of requires attunement to their developmental strengths. Accurate assessment and initial treatment of physical and mental symptoms (e.g., pain, dysphoria) may serve to diminish barriers to voluntarism for subsequent, higher-stakes, or more enduring consent decisions. Clarifying personal values through dialogue about cultural and religious beliefs, psychological issues and personal history, and documents such as "The Values History" (85) or *Five Wishes* (86) may dramatically enhance the subject's ability to identify preferences in key decisions and improve our faithfulness to the patient's true wishes. Careful examination of the forces present in a given context may help to discern and minimize the potential coercive pressures experienced by the person whose voluntarism we wish to support.

Third, this formulation does not help to resolve the dissonance we may feel as clinicians and researchers when our patients make decisions that feel illogical, self-defeating, or morally unacceptable or will inevitably lead to a poor outcome. Nevertheless, the process of identifying barriers to voluntarism and of clarifying preferences and perspectives may help us to honor the authentic choices of our patients, an act that has its own rewards. Finally, on a cautionary note, voluntarism, like decisional capacity, should be understood for its dynamic nature; voluntarism does not represent an all-or-nothing phenomenon. Analyzing voluntarism through its elements—the developmental factors, illness-related considerations, psychological issues and cultural and religious values, and external features and pressures—without remaining mindful of how these come together meaningfully within a person may introduce the risk of distortion. The aim of this analysis should be to gain a richer sense of the true attributes and experience of the individual, not to deconstruct these in a manner that is unfaithful to the real qualities of the person before us. Consequently, this framework should be applied in a manner that involves appreciation for the meaning of the various elements taken together and as residing within a person.

Fostering voluntarism in clinical care and biomedical research entails our best skills: listening, sensing, clarifying, making the implicit explicit, and genuinely attending to the person before us. It is respectful of people and of differing experiences and values that they bring to decisions in their lives. It takes a willingness to observe our own biases and to evaluate the effects of the contexts in which we serve patients and interact with research participants. It is through such efforts that we will come closer to the hard, good work of fulfilling voluntarism and, more fundamentally, to achieving the principle of respect for persons in clinical care and biomedical research.

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