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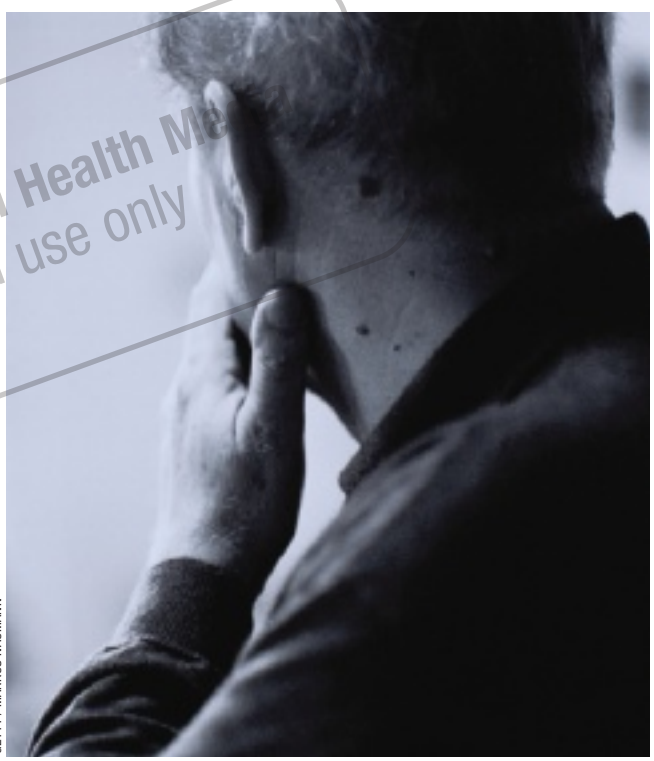
Informed consent: Is your patient competent to refuse treatment?

Adult patients with psychotic disorders are not automatically or always incompetent



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Mr. D, age 45 with a history of schizophrenia, is admitted to an inpatient psychiatric unit. The psychiatrist recommends an antipsychotic to help Mr. D with fears that the FBI has implanted a radio signal device into his tooth filling. She explains the risks and benefits of the proposed drug and alternate medications, as well as the risks of no treatment.

Mr. D calmly but consistently declines the treatment. He states that he recognizes the antipsychotic is used to treat psychotic symptoms, can help people who hear voices, and can have side effects such as tardive dyskinesia. His thoughts become disorganized and difficult to follow, however, as he explains that he does not believe the medication is needed for his situation because the FBI is involved in tracking his behavior.

Informed consent in clinical settings is designed to allow patients to make rational choices about their treatment before it begins. When a psychiatric patient such as Mr. D declines a treatment you recommend, how can you balance the 2 ethical principles in medicine: beneficence toward the patient and respect for individual autonomy?[1]

Some authors have raised concerns that informed consent in physician-patient interactions are at times an empty exercise undertaken solely to satisfy a legal expectation.[2] If executed properly, however, informed consent can enhance the therapeutic alliance and help improve treatment adherence.

continued

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Informed consent

Clinical Point

A consent form may not prove that you conveyed adequate information or that your patient understood that information

Box 1

How to reduce risk when obtaining informed consent

Because failure to provide informed consent can be grounds for a negligence claim, consider strategies to reduce the chance of successful litigation.

Although a written form can provide some proof that informed consent occurred, it may not prove that you conveyed adequate information or that your patient understood the information. Overly simplistic or complex forms can pose other difficulties in malpractice claims. Documenting aspects of the informed consent dialogue often provides the best "proof" that such a conversation occurred.

In retrospect, helpful evidence that adequate informed consent was obtained may include information related to the disclosed information and the patient's response to the information (such as might be seen in a quote that indicated his or her understanding of a particular side effect). Although a full accounting of the conversation would not be a reasonable expectation for documentation, you might wish to consider the risks and benefits inherent to the particular treatment and tailor the note related to the informed consent accordingly.

Patient-centered treatment

As patients have become more informed consumers, the "doctor knows best" model of care has given way to an expectation that patients know best what they would want done regarding their health. Lawsuits related to informed consent generally allege that physicians failed to provide appropriate informed consent for treatment the plaintiffs received. These complaints suggest that had the patient been more appropriately informed, he or she might have made a different choice and would not have suffered harm related to treatment.

In a patient-centered approach to treatment, informed consent allows the patient to make an autonomous decision with the appropriate information. Providing treatment without the patient's expressed consent could be viewed more seriously, potentially even as battery.[3] Recent informed consent cases tend to rely on negligence theories, however, rather than on claims of battery. Negligence cases helped set the stage of evolving expectations—first seen with surgical procedures, then medical interventions, then medication treatment, and now even with psychotherapy (***Box 1***)—that informed consent should be obtained in clinical settings.[4]

3 components of informed consent

Informed consent includes 3 components: voluntariness, disclosure, and competence.[5]

Voluntariness implies that the patient must make treatment-related choices of his or her own free will and without coercion. In *Kaimowitz v Michigan Department of Mental Health*,[6] the court ruled that involuntarily committed persons living in what was considered an inherently coercive institutional environment were not capable of providing voluntary consent to a high-risk experimental procedure. This case had a major impact on prison research.

In treatment settings as well, a patient's circumstances might be considered coercive. Historically, civilly committed patients did not have the right to refuse treatment. A movement in the 1980s helped to separate civil commitment and the right to refuse treatment, which is well-established in most jurisdictions today.[7] In psychiatric inpatient settings, even an involuntarily committed patient generally has a right to refuse recommended medications unless a legally permissible mechanism overrides the refusal.

Disclosure means that a person requires certain information to make a rational decision to accept or reject treatment. The question is: How much information needs to be disclosed for a patient to be adequately informed?

Disclosure requirements vary across jurisdictions. In 1960, *Natanson v Kline*

supported the standard that disclosure required that which a "reasonable practitioner" might disclose to patients about their treatment in similar circumstances.[8] Although some jurisdictions have maintained that standard,[5] subsequent cases identified a more patient-centered approach to disclosure called the "reasonable person" standard (***Box 2***).[5,9]

Competence. In many settings, clinicians use the construct of "capacity" rather than "competence" because competence is a legal term that can be determined only by a judge. When an individual is deemed incompetent, his or her right to make autonomous decisions can be overridden. Children are not competent by virtue of their status as minors, although exceptions may be made for certain older youth. Adults are presumed competent unless adjudicated otherwise.

Adult patients with psychotic disorders are not automatically or always incompetent. Research has shown that most inpatients with mental illness have capacities to make treatment decisions similar to persons with medical illness.[10] Patients with schizophrenia, however, have deficits relevant to capacity to make treatment decisions more often than patients with medical illnesses and depressive disorders. Patients with depressive disorders also are more likely to have some decision-making impairment compared with persons with medical illnesses.[10] Thus, in psychiatric settings, a heightened awareness of a patient's potential deficits related to competence is important.

Competence can be broken down into 4 component capacities (***Box 3, page 41***).[11] The degree of incapacity required for a finding of incompetence is complicated and difficult to codify. Instruments designed to standardize competence assessment are available[12] but not routinely used in clinical settings. Even with these instruments, no threshold of capacity clearly defines competence. Some authors have argued for a sliding scale of competence, with standards becoming more stringent as the degree of risk related to the treatment decision increases.[13,14]

Box 2

Typical elements of disclosure to meet the 'reasonable person' standard

The "reasonable person" standard endorses the obligation of the professional to disclose information that a reasonable person would want to know about a proposed treatment. This standard evolved in part from *Canterbury v Spence*,[9] in which a plaintiff who had become paralyzed alleged that he was not informed of the risks of a laminectomy. The court found that the patient must be able to rely on information that the physician holds that would be material to the patient in making an informed treatment decision in his or her best interest.

The typically required elements of disclosure include:

- diagnosis, if known
- nature and purpose of proposed treatment
- risks and benefits of proposed treatment
- alternatives to treatment and their risks and benefits
- risks and benefits of no treatment.

Disclosing information that is uniquely relevant to an individual's situation and would be generally unknown to the clinician might not be required. For example, a clinician might not realize that it is important for a particular patient to be able to make small art objects as a hobby, so the clinician might not reveal that a medication very rarely causes a tremor. Nevertheless, when you are aware of a need for such nuanced information, the usual general disclosure can be modified to include whatever details are relevant to that patient.[5]

Exceptions to informed consent

Emergencies. Informed consent is not required under some circumstances.[5] Consider the patient who is brought to the emergency room unconscious after a fall, with no family contact information. A neurosurgeon might need to intervene immediately to save the patient's life, using the emergency exception to informed consent.

In an emergency, when a person is unable to give informed consent or time does not allow for a full informed consent process, the clinician generally follows the principle of doing no harm. Treatment may be started in an emergency without full informed consent on the assumption that most competent people would consent to

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Box 3

4 abilities patients must have to be considered legally competent

Express and sustain a choice. To be considered competent to give informed consent, a person must be able to evidence a choice regarding the decision at hand. The choice need not be expressed verbally, but a patient must be able to communicate in some fashion (such as eye blinking or handwritten communication). The patient also must be able to maintain that choice over time, long enough for treatment to be implemented.

Understand presented information. A person must have a factual understanding of the information presented about the treatment. A full scientific understanding of diagnosis and subtleties of treatment likely would be an excessive expectation. For example, a patient would not be expected to understand the nuances of the serotonin neurotransmitter system. A physician should, however, assess whether the patient understands—in the patient's words—that a selective serotonin reuptake inhibitor could induce manic-type symptoms and that the patient should bring these symptoms to the prescribing physician's attention if they occur.

Appreciate one's situation. Individuals who are competent must have a realistic appreciation of their situation. Though a patient may understand the facts you have presented, he may fail to fully integrate why the information is relevant to him. Persons with schizophrenia who do not believe they are ill—such as Mr. D—might have a limited appreciation of why an antipsychotic would help them.

Rationally manipulate information. A person also must be able to rationally manipulate the information in a way that is not impaired by symptoms of illness. Patients faced with a treatment decision should be able to use reason to reach a logical and rational decision that they see as being in their best interest. This might not be the same decision you would make. For example, a patient with thought disorganization or one who psychotically believes that the color of a recommended medication signals that someone tampered with the pills might not be able to rationally manipulate information presented about treatment options.

Source: Reference 11

treatment, especially where life or limb was at risk. If time and circumstances permit in an emergency, obtaining the consent of available family members may be prudent.

Treating psychosis when no associated behavioral disturbance is placing a patient or others at risk might not constitute an emergency that would negate the need for informed consent. Thus, given Mr. D's calm demeanor in talking with the clinician about his treatment, an emergency exception probably would not apply in his case.

Incompetence. If a judge determines that a patient is incompetent to make his or her own treatment decisions, a substitute decision-maker—such as a guardian—could be appointed. In these cases, respect would suggest that to the extent possible and appropriate you would inform the incompetent ward about treatment in a way that he or she may understand.

In other circumstances, such as when a healthcare proxy has been invoked, previously designated surrogate decision-makers provide informed consent on behalf of the patient who clinically is found to lack the capacity to make healthcare decisions.

Waivers. Sometimes a competent patient decides to waive the right to further information and may turn the decision over to the clinician. To rely upon this exception, some documented assessment—even if brief—of the patient's capacity to waive information may be important.

Therapeutic privilege often is cited in the literature but should be an infrequently used exception to informed consent. In very limited situations, a physician might decide to not engage in an informed consent discussion, believing the information to be disclosed would be so damaging that it would directly harm the patient or so emotionally distressing as to foreclose the possibility of the patient making a rational decision.

As noted, informing patients of their health situations is expected and accepted. Even in psychiatric settings, receiving information about potentially serious medi-

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Do not avoid an informed consent process simply because you believe a patient will refuse to consent if informed about a proposed treatment

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cation side effects has not necessarily led to patient harm or refusal of treatment.[15] Therefore, use of this exception is only for very narrowly tailored circumstances, if used at all, and not simply because you believe a patient will refuse to consent if informed about a proposed treatment.

Some case law exists on the need to establish why the therapeutic privilege was justified as a rationale to not provide informed consent in a particular situation.[16] Therefore, though it should be rarely invoked, if you use therapeutic privilege, document why you invoked this exception for that particular patient and in that particular circumstance.

Building the therapeutic alliance

Although it may meet policy or legal informed consent requirements, simply providing the patient with a form to sign before treatment begins does little to enhance patient-clinician communication.[2] Providing detailed written information also might not be adequate to ensure that the patient understands the complexity of a treatment you have asked him to consider.[17] Instead, an informed consent model that relies on active, ongoing dialogue about treatment can maximize patient autonomy while working for the good of the patient (***Table***).

Lidz and colleagues[2] identified key conditions that must be present for such a process model of informed consent to work:

- the patient's role is understood as that of an inquisitive consumer who may challenge the physician's authority in the quest for information
- the clinician challenges the patient's preconceived beliefs about his or her illness and educates the patient so that both parties approach the medical issue from common ground.

A patient also must be allowed to consider his or her own values in weighing medical decisions. These values may include the patient's ability to tolerate side effects, willingness to take risks, and own sense of quality of life.[1] In this model of shared decision-making, the clinician reveals information material to the decision, and the patient helps the clinician understand the circumstances that make him or her prefer 1 treatment over another.[1,18]

Table

Using informed consent to build a therapeutic alliance

- **Use** the informed consent dialogue to establish trust and openness with patients while demonstrating respect for patient autonomy
- **Allow** patients to share their values and concerns as part of the risk/benefit analysis
- **Talk** with patients to understand their preconceived ideas about their illnesses and to seek a common understanding of the illness and its prognosis, with and without treatment

By engaging in ongoing informed consent, you may achieve greater gains within the therapeutic alliance and reduce the risk of liability.[19] Where uncertainties are related to treatment, share these ambiguities as an aspect of informed consent, especially when the patient plays an active role in treatment.[4] Similarly, an expanded informed consent process may be needed when:

- proposed treatments are particularly risky
- several treatment alternatives could be acceptable and effective
- evidence supports opposing views of a treatment's effectiveness.[4,20]

CASE CONTINUED

A question of competence

Mr. D is calm in his discussions with the psychiatrist, and the information she presents does not seem to cause him further harm. Thus, the emergency and therapeutic privilege exceptions do not eliminate the need for an ongoing informed consent process at this time.

Mr. D has a factual understanding of the risks and benefits of the recommended antipsychotic and is able to express a consistent choice about starting this treatment. He lacks, however, an ability to appreciate his situation and has difficulty manipulating information rationally. Overall, he has deficits in aspects of his decision-making competence, which could signal the need for an exception to obtaining informed consent.

Related Resources

- Pinals DA, Appelbaum PS. The history and current status of competence and informed consent in psychiatric research. Isr J Psychiatry Relat Sci. 2000;37(2):82-94.
- American Medical Association. Legal issues/patient physician relationship topics. www.ama-assn.org/ama/pub/physician-resources/legal-topics.shtml.

Disclosure

Dr. Pinals reports no financial relationship with any company whose products are mentioned in this article or with manufacturers of competing products.

The psychiatrist should continue to build an alliance with Mr. D as she works with him toward accepting treatment. Meeting with him regularly, trying to understand his concerns, and trying to help him understand how his symptoms may be interfering with his functioning can help build the alliance. If he continues to show competence-related deficits, she could pursue guardianship or other legal avenues to address his ongoing inability to provide informed consent. This approach would allow for a legally authorized mechanism to administer treatment to this patient.

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Bottom Line

Informed consent entails voluntary and competent decision-making by the patient and sufficient disclosure by the clinician. Its goal is to maximize the patient's ability to make a personal decision regarding treatment. Although the informed consent mandate may seem burdensome, it can foster a clinician/patient dialogue and enhance a therapeutic alliance from which successful treatment may emerge.

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Talk with the patient to seek a common understanding of the illness and its prognosis, with and without treatment