

BIOETHICS FOR CLINICIANS: 3. CAPACITY

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Abstract • Résumé

In the context of patient consent, "capacity" refers to the patient's ability to understand information relevant to a treatment decision and to appreciate the reasonably foreseeable consequences of a decision or lack of decision. A person may be "capable" with respect to one decision but not with respect to another. Clinicians can usually identify patients who are clearly capable or incapable, but in some cases a clinical capacity assessment is required. Such assessment may consist of cognitive status testing, general impressions of capacity or specific capacity assessment. Specific capacity assessment, in which the clinician evaluates the patient's ability to understand pertinent information and appreciate its implications, is probably the optimal method. When conducting a specific capacity assessment, the clinician must ensure that the disclosure of information is effective and must evaluate the patient's reason for his or her decision. If the assessment suggests that the patient is incapable, further assessment is generally recommended.

Dans le contexte du consentement des patients, on entend par «capacité» l'aptitude du patient à comprendre des renseignements au sujet d'une décision relative à un traitement et à apprécier les conséquences raisonnablement prévisibles d'une décision ou d'une absence de décision. Une personne peut être «capable» dans le cas d'une décision, mais non dans celui d'une autre. Les cliniciens peuvent habituellement identifier les patients qui sont clairement capables ou incapables, mais dans certains cas, une évaluation clinique de la capacité s'impose. Cette évaluation peut comprendre des tests de l'état cognitif, des impressions générales de la capacité ou une évaluation spécifique de capacité. L'évaluation spécifique de la capacité, au cours de laquelle le clinicien évalue l'aptitude du patient à comprendre les renseignements pertinents et à en apprécier les répercussions, est probablement la méthode optimale. Lorsqu'il effectue une évaluation spécifique de la capacité, le clinicien doit veiller à ce que la divulgation de renseignements soit efficace et doit évaluer les motifs que le patient donne pour justifier sa décision. Si l'évaluation indique que le patient est incapable, une évaluation plus poussée est en général recommandée.

Mr. G is 42 years old and is receiving neuroleptic therapy for chronic schizophrenia. Although he is unemployed he functions independently in the community. Because he believes that his neighbours break into his house and steal his money when he is out, he rarely leaves his apartment. He calls his family physician because of a sore throat. The physician makes a house call and obtains a throat swab, which reveals a *Streptococcus*

pyogenes infection. The physician recommends antibiotic therapy.

Mr. H is a 65-year-old man admitted to hospital because of acute imbalance and clumsiness in the left arm. He is diagnosed with atrial fibrillation and infarction of the left cerebellar hemisphere. His clinician recommends warfarin therapy, but Mr. H. repeatedly refuses.

Mrs. I is a 79-year-old woman with noninsulin-

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This is the third in a series of 14 articles on bioethics for clinicians. Subsequent articles will appear monthly.

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dependent diabetes mellitus who is admitted to hospital with gangrene of the first and second toes of her right foot. She lives alone and does not like doctors. She receives intravenous antibiotic therapy for 1 week without response. Her clinicians recommend amputation of the affected toes, but she says "I don't know what you will do with them after you cut them off."

Mr. J is 74 years old and has severe Parkinson disease. He is admitted to hospital with psychosis caused by bromocriptine therapy. His clinician wishes to start treatment with clozapine, an antipsychotic drug with minimal extrapyramidal side effects but potentially severe hematologic side effects. When the clinician attempts to obtain consent Mr. J is unable to respond to any questions.

WHAT IS CAPACITY?

"Capacity," or "decision-making capacity," is the ability to understand information relevant to a decision and

to appreciate the reasonably foreseeable consequences of a decision or lack of decision. Capacity is specific to particular decisions: a person may be capable with respect to deciding about a place of residence, for example, but incapable with respect to deciding about a treatment. Capacity can change over time. For example, a person may be temporarily incapable because of delirium but subsequently recover his or her capacity.

WHY IS CAPACITY IMPORTANT?

ETHICS

The ethical principles of patient autonomy and respect for persons require that capable people be allowed to make their own informed decisions. However, the ethical principle of physician beneficence requires that incapable people be protected from making decisions that are harmful or that they would not make if they were capable.

LAW

In law, capable patients are entitled to make their own informed decisions. If a patient is incapable, the physician must obtain consent from a designated substitute decision-maker. In common law and under some legislation patients are *presumed* capable. If it is unreasonable to presume capacity, then a capacity assessment should be undertaken.

In Canadian common law there is no age below which a person is not presumed capable. A minor can give consent if he or she is able to understand the information about a treatment and to appreciate the risks and likely consequences of the treatment.¹ Some provinces have legislation that establishes the age of consent to treatment (Table 1); clinicians should familiarize themselves with the legislative requirements in their own province.

POLICY

Capacity is an essential component of valid consent, and obtaining valid consent is a policy of the CMA² and other professional bodies.

HOW SHOULD I APPROACH CAPACITY IN PRACTICE?

A clinician develops a general impression of a patient's capacity during the clinical encounter. In most cases the clinician has little reason to question the patient's capacity and focuses on other aspects of the consent process. However, some patients, such as those who are comatose or who have severe dementia, are obvi-

Table 1: Age of consent for medical treatment in Canada

Prince Edward Island	A person must be at least 18 years of age or married to consent to surgery in a public hospital ²
New Brunswick	The age of consent for medical treatment is 16 years of age. A younger person may consent if, in the opinion of the attending physician or dentist and one other physician or dentist, he or she is capable of understanding the nature and consequences of treatment, and the treatment is in the person's best interests with respect to continued health and well-being ³
Quebec	The age of consent is 14 years of age if the treatment is required because of the patient's state of health. For a child under 14 years of age parental consent must be obtained unless a judge orders otherwise or the child's life is in danger ⁴
Saskatchewan	A person must be at least 18 years of age or married to consent to surgery in a public hospital ⁵
British Columbia	A person who has reached the age of 16 years can consent to treatment if the health care provider has made a reasonable attempt to obtain consent from the person with parental authority and a written opinion is obtained from a second physician or dentist that the treatment is in the person's best interests with respect to continued health and well-being ⁶
Other provinces	The remaining provinces have no legislation that establishes an age of consent to treatment. In common law there is no age of consent. A minor can consent if he or she is capable of understanding the information about a treatment and of appreciating the risks and likely consequences of the treatment ¹

ously incapable. In such cases the clinical assessment of capacity is straightforward, and substitute consent is required. (Substitute decision making is discussed in a later article in this series.)

In some situations clinicians may be unsure about a patient's capacity. The patient may have a neurologic or psychiatric disease or may be behaving in a way that indicates lack of understanding. Although refusal of recommended treatment may cause a clinician to *question* a person's capacity,⁸ refusal of treatment should not be considered evidence of incapacity.⁹ Most refusals are caused by factors other than incapacity.¹⁰

When a clinician is unsure about a patient's capacity an assessment is needed. The initial objective of assessment is to screen for incapacity. Patients who appear to be incapable after the screening assessment generally require further evaluation. Clinicians may use three different measures of capacity: cognitive function testing, general impressions of capacity and specific capacity assessments.

Cognitive function tests such as the Mini Mental State Examination¹¹ are reliable, easy to administer and familiar to clinicians in a wide variety of settings. However, although cognition and capacity are related, they are not identical.¹²⁻¹⁵ Most measures of cognitive status do not evaluate several cognitive functions, such as judgement and reasoning, that are relevant to capacity.¹⁶ A person may have a perfect cognitive test score but still be incapable by virtue of delusions that directly affect the treatment decision. Another limitation of cognitive status tests is that cut-off scores for identifying incapacity have not been established.

Gaining a general impression of a patient's capacity is a simple and quick method of assessment but can be unreliable,¹⁷ inaccurate^{13,14} and easily biased.¹⁸

In a specific capacity assessment the clinician discloses information relevant to the treatment decision and then evaluates the person's ability to understand this information and to appreciate the consequences of his or her decision. The Aid to Capacity Evaluation is a decisional aid to assist clinicians in carrying out specific capacity assessments.¹⁹ It prompts clinicians to probe seven relevant areas (Table 2), provides sample questions for the evaluation of each area and gives suggestions for scoring. Other decisional aids have been developed to assist with the assessment of the patient's capacity to complete an advance directive²⁰ and to consent to treatment,²¹⁻²⁶ and to assist with the simultaneous assessment of several types of capacity.²⁷

Specific capacity assessments have several strengths. First, they directly assess the patient's actual functioning while he or she is making a decision, which is exactly what the legal definition of capacity requires. Second, they are clinically feasible and quick: the median time for Aid to Capacity Evaluation assessments is 12 minutes.¹⁹

Finally, specific capacity assessments are flexible and can easily be adapted to various clinical circumstances.

However, specific capacity assessments have certain drawbacks. First, they are only as good as the accompanying disclosure. If the clinician does not disclose information effectively, the capacity assessment will be inaccurate. Therefore, excellent communication skills are critical to accurate assessment. In practice, the process of disclosure should continue throughout the capacity assessment. For example, if a patient does not initially appreciate that he or she may be able to walk after a below-knee amputation, then this information should be redisclosed. Then the clinician can re-evaluate whether this consequence of below-knee amputation has been understood.

A second problem with specific capacity assessments relates to the evaluation of a patient's reasons for a decision. The goal is to ensure that the decision is not substantially based on a delusion and is not the result of depression. However, some "delusions" may represent personal, religious or cultural values that are not appreciated by the clinician. Similarly, it is difficult to determine whether a decision is substantially affected by the cognitive features of depression, such as hopelessness and feelings of worthlessness, guilt and persecution.^{28,29}

A third problem is that a patient's capacity may fluctuate. If a person appears to be incapable the clinician should determine whether any reversible factors such as delirium or a drug reaction are at work. If such factors are identified the clinician should attempt to eliminate or minimize them and then repeat the assessment. There may also be factors that prevent a person from communicating effectively with the clinician, such as a language barrier or speech disturbance. Such factors must be addressed to ensure accurate capacity assessment.

Finally, clinicians may find it difficult to perform unbiased capacity assessments, particularly when the patient's choice goes against their recommendations. It is important to remember that agreement or disagreement

Table 2: Relevant areas of patient capacity specified in the Aid to Capacity Assessment¹⁹

Ability to understand the medical problem
Ability to understand the proposed treatment
Ability to understand the alternatives (if any) to the proposed treatment
Ability to understand the option of refusing treatment or of it being withheld or withdrawn
Ability to appreciate the reasonably foreseeable consequences of accepting the proposed treatment
Ability to appreciate the reasonably foreseeable consequences of refusing the proposed treatment
Ability to make a decision that is not substantially based on delusions or depression

with the patient's decision is not at issue; the purpose of capacity assessment is to evaluate the person's ability to understand relevant information and to appreciate the consequences of a decision.

If the result of screening indicates that a patient may be incapable, further expert assessment is generally recommended, particularly if the clinician is unsure about the assessment or if the person challenges the finding of incapacity. Expert assessments can be conducted by individual practitioners (e.g., psychiatrists and psychologists), hospital ethics committees or legal review boards. If a finding of incapacity is based primarily on the clinician's interpretation of the person's reason for his or her decision, then the clinician should seek further input from others, such as the patient's family or relevant representatives from the patient's cultural or religious group. If the clinician suspects that a decision is based substantially on delusions or depression, then psychiatric evaluation is recommended.

THE CASES

Mr. G's clinician notes that the patient has no known allergies and has taken penicillin in the past. The clinician explains that the pills are to treat the sore throat but may cause diarrhea or a rash. The clinician asks Mr. G to review the information to ensure that everything is clear. Mr. G says: "You're giving me these pills to help my throat. If I get diarrhea or any skin problems I should stop and let you know." The clinician concludes that Mr. G is able to understand the relevant information and to appreciate the reasonably foreseeable consequences of accepting treatment. Furthermore, the decision to accept is not based on a delusion, but on a desire for symptom relief. The entire capacity assessment takes less than 1 minute.

Mr. H's specific capacity assessment shows that he has the ability to understand his condition ("I have had a stroke to the left cerebellum, which has left me clumsy on the left side. It was caused by a blood clot from the heart"), the proposed treatment ("You want to thin my blood with warfarin"), the option of refusing ("I don't want it"), as well as the ability to appreciate the reasonably foreseeable consequences of refusing the treatment ("I might have another stroke without the pills, but I don't want them") and of accepting it ("You say that the pills might reduce the chance of stroke, but it can also cause bleeding"). Explaining the reason for his refusal, Mr. H says: "I think that the women who draw the blood are vampires. You want to thin my blood so it is easier for them to drink." Mr. H is subsequently evaluated by a psychiatrist, who diagnoses acute mania. Mr. H's wife later reveals that Mr. H had previously been diagnosed with manic depressive disorder but had stopped his lithium therapy several months before his stroke.

Mrs. I's specific capacity assessment showed that she had the ability to understand her condition ("My toes are dead. They are very smelly"), the proposed treatment ("You want to cut off my toes"), and the option of refusing ("I do not want you to cut them off"), as well as some ability to appreciate the reasonably foreseeable consequences of refusing ("You say I will die, but I don't know about this. I wonder what you will do with my toes after you cut them off. I don't really trust the doctors. I think they just want to give the students some practice"). Mrs. I reveals that she is a concentration-camp survivor with a deep mistrust of physicians. She also says that 7 years ago when she had gangrene of the left foot and refused amputation the foot had healed. Because the clinician remains unsure of Mrs. I's capacity and suspects depression, a psychiatric consultation is requested. Mrs. I admits to having a persistent depressed mood and several vegetative signs of depression. However, she denies feelings of hopelessness, guilt, persecution or worthlessness. Ultimately, Mrs. I is felt to be capable but depressed. She accepts treatment for depression. Her foot condition stabilizes and at 1 year of follow-up she is able to walk but still requires daily treatments for her foot.

Mr. J is re-evaluated 4 hours later, at which time he has gained maximum benefit from the medication for his Parkinson disease. At this time, he is able to communicate and answer questions, and is clearly capable.

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MONOPRIL* (fosinopril sodium) TABLETS, 10 and 20 mg

THERAPEUTIC CLASSIFICATION
Angiotensin Converting Enzyme Inhibitor

INDICATIONS AND CLINICAL USE

The treatment of mild to moderate essential hypertension. May be used with thiazide diuretics.

Use when treatment with a diuretic or a beta-blocker are contraindicated, were found ineffective or have been associated with unacceptable adverse effects.

Not recommended for CHF and renovascular hypertension.

When used in pregnancy during the second and third trimesters, ACE inhibitors can cause injury or even death of the developing fetus. When pregnancy is detected MONOPRIL should be discontinued as soon as possible.

CONTRAINDICATIONS

Hypersensitivity and history of angioedema related to previous ACE inhibitor therapy.

WARNINGS

Angioedema associated with laryngeal involvement may be fatal. If laryngeal stridor or angioedema of the tongue, or glottis occurs, discontinue immediately, administer epinephrine (0.3 - 0.5 mL 1:1000) and carefully observe patient until swelling disappears. Swelling confined to the face and lips generally resolves without treatment; antihistamines may be used.

Patients with a history of angioedema may be at increased risk.

Hypotension: Usually occurs after first or second dose or when the dose was increased. More likely in patients who are volume depleted by diuretic therapy, dietary salt restriction, dialysis, diarrhea, or vomiting. Patients with severe CHF, ischemic heart or cerebrovascular disease should start therapy under close medical supervision, then followed closely for the first weeks of treatment and whenever diuretic or MONOPRIL dose is increased.

Neutropenia/Agranulocytosis: Incidence is rare. Consider periodic monitoring of white blood cell counts.

PRECAUTIONS

Impaired Renal Function: Assess renal function before initiating therapy. Use with caution in patients with renal insufficiency, and closely monitor.

Surgery/Anesthesia: Hypotensive effects of anesthetics and analgesics may be augmented. Correct by volume expansion.

Hyperkalemia and Potassium-Sparing Diuretics: Use with caution. Risk factors include renal insufficiency, diabetes mellitus, and concomitant use of agents to treat hypokalemia or other drugs associated with increases in serum potassium (e.g. heparin).

Anaphylactoid reactions during membrane exposure: Anaphylactoid reactions have been reported in patients dialysed with high-flux membranes.

Anaphylactoid reactions during desensitization: There have been isolated reports of patients experiencing sustained life threatening anaphylactoid reactions while receiving ACE inhibitors during desensitizing treatment with hymenoptera (bees, wasps) venom.

Valvular Stenosis: Patients with aortic stenosis might be at particular risk of decreased coronary perfusion when treated with vasodilators.

Impaired Liver Function: Hepatitis (hepatocellular and/or cholestatic), elevations of liver enzymes and/or serum bilirubin have occurred. Investigate fully any unexplained symptoms particularly during first weeks or months of treatment. Use with particular caution in patients with pre-existing liver abnormalities, and closely monitor response and metabolic effects.

Cough: Consider as part of the differential diagnosis of the cough.

Nursing Mothers: Do not administer to nursing mothers.

Pediatric Use: Do not use in this age group.

DRUG INTERACTIONS

Agents Increasing Serum Potassium: Should be given cautiously only for documented hypokalemia and with frequent monitoring of serum potassium.

Agents Causing Renin Release: Antihypertensive effect of MONOPRIL is augmented.

Lithium: May result in increased serum lithium levels. Co-administer with caution and frequently monitor serum lithium levels.

Antacids: Antacids may impair absorption of fosinopril. If concomitant administration is indicated, dosing should be separated by two hours.

Digoxin: Concomitant administration did not alter the bioavailability of fosinopril.

Furosemide: Coadministration increased AUC of fosinopril by 26% and Cmax by 25%. Furosemide levels were decreased.

Warfarin: Bioavailability of fosinopril or warfarin was not altered by coadministration.

Other: Bioavailability of fosinopril was not altered by coadministration with chlorthalidone, nifedipine, propranolol, hydrochlorothiazide, cimetidine, metoclopramide and propantheline.

ADVERSE REACTIONS

The most severe adverse reactions occurring in all patients treated with MONOPRIL in clinical trials (1548 patients) were: angioedema (1 case), orthostatic hypotension (2.7%). Myocardial infarction (2 cases) and cerebrovascular accident (4 cases) occurred, possibly secondary to excessive hypotension in high risk patients.

Most frequent adverse experiences which occurred in 688 MONOPRIL-treated patients in placebo-controlled hypertension trials were nausea/vomiting, diarrhea, fatigue, musculoskeletal pain, headache, dizziness and cough. Discontinuation of therapy because of adverse events was required in 4.1% of the 688 patients.

Adverse reactions occurring in $\geq 1\%$ of 1048 hypertensive patients in controlled clinical trials treated with MONOPRIL monotherapy were: orthostatic hypotension (1.4%), rash (1.0%), sexual dysfunction (1.7%), nausea/vomiting (1.4%), diarrhea (1.4%), pyrosis (1.0%), dry mouth (1.0%), fatigue (2.8%), headache (4.6%), dizziness (3.8%) and cough (4.0%).

DOSAGE AND ADMINISTRATION

Individualize dosage. Consider recent antihypertensive drug treatment, extent of blood pressure elevation and salt restriction.

The recommended initial dose of MONOPRIL is 10 mg once daily. Adjust according to blood pressure response, at intervals of at least two weeks. Usual maintenance dose is 20 mg once daily. Do not exceed a dose of 40 mg daily.

If antihypertensive effect is not satisfactorily maintained for 24 hours, consider either twice daily administration with the same total daily dose, or an increase in dose. If blood pressure is not controlled with MONOPRIL alone, a diuretic may be added.

Concomitant Diuretic Therapy: If possible, discontinue diuretic for two to three days before beginning therapy with MONOPRIL to reduce likelihood of hypotension. If not, use an initial dose of 10 mg MONOPRIL with careful medical supervision for several hours and until blood pressure has stabilized. Titrate dosage of MONOPRIL to obtain optimal response.

Dosing Adjustment in Renal Impairment: With normal liver function no dosage adjustment is necessary. Initial dose is 10 mg once daily.

Dosing Adjustment in Hepatic Impairment: With normal renal function no dosage adjustment is necessary. Initial dose of MONOPRIL is 10 mg once daily.

No dosage adjustment is necessary in elderly hypertensives with normal renal and hepatic function.

AVAILABILITY

MONOPRIL 10 mg tablets are white to off-white, flat end diamond shaped, compressed tablets with a partial bisect bar engraved with BMS on one side and MONOPRIL 10 on the other.

MONOPRIL 20 mg tablets are white to off-white, oval shaped, compressed tablets engraved with BMS on one side and MONOPRIL 20 on the other.

Bottles of 100 tablets.

Full Product Monograph available upon request.



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