Chapter Two

Health Care Decisions – Patient Capacity and Proxy Decision Making

A. AD and Informed Consent

Under Maryland's common law doctrine of informed consent, a "mentally competent adult" is entitled to give or withhold consent to medical treatment after receiving a fair and reasonable explanation of the proposed treatment.[1] In this context, the term "competence" is potentially confusing, however, because it customarily refers to overall legal status, rather than the ability to make a particular treatment decision. Someone who is "incompetent" is deemed by the law to lack ability to make decisions, either because of status (a child) or because of a judicial finding. Every adult is presumed to be competent.

The Maryland Health Care Decisions Act of 1993 also uses the term "competent," but in a way that usefully redirects its meaning from a legal to a clinical context. A "competent individual" is an adult or emancipated minor "who has not been determined to be incapable of making an informed decision."[2] A patient is "incapable of making an informed decision" about a specific treatment or course of treatment if the patient is unable to do one or more of the three things that informed decision making requires: "to understand

the nature, extent, or probable consequences of the proposed treatment or course of treatment"; "to make a rational evaluation of the burdens, risks, and benefits of the treatment or course of treatment"; or "to communicate a decision."[3] Thus, the Act changed the focus from the legal concept of generalized incompetency to functional criteria for capacity, in the context of the specific treatment issues in question.[4]

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The Health Care Decisions Act's focus on functional criteria means that, except in clear-cut cases like persistent vegetative state, a diagnosis alone does not imply incapacity. This is true of AD. As one of the nation's leading experts on decisional capacity has pointed out, although patients with even mild AD "may evidence deficits in understanding relevant information and reasoning sufficient to call their capacities into question, ... the choices they make about treatment and research may not differ at this point from non-impaired populations" (Appelbaum 1999). A recent review article cites empirical data in support of this observation (Kim, Karlawish, and Caine 2002).

Hence, in patients with mild AD, capacity is best understood as a variable, dependent upon the complexity of the treatment issue, the effect of medical management on co-morbidities like depression, the physician's skill in conducting the clinical encounter, and the patient's ability to muster sufficient understanding and reasoning at the time of decision (Francis 2001). The attending physician should remain attentive to the possibility that the patient retains capacity to make a particular decision, especially one that is relatively simple and low-risk (Fellows 1998; Mazey, Teresi, Ramsey et al. 2000).[5] In addition, the capacity of a patient with mild AD might be enhanced

by an intervention to help the patient stay on task (Kim, Karlawish, and Caine 2002). If the patient can decide, the Health Care Decisions Act, with its mechanisms for obtaining a proxy decision, does not come into play. The physician should instead rely on the informed consent doctrine as the basis for the decision, although a patient with capacity is of course free to involve family members or others in the decision making process.[6]

The Act ... relies primarily on the attending physician, who ideally has the professional expertise and clinical wisdom to make well-reasoned judgment calls about capacity in marginal cases **(Roca 1994).**

Because the Health Care Decisions Act identifies the legal standards for incapacity, it implies that a physician who is assessing capacity must use a method that correlates with these standards (Marson, Earnst, Jamil et al. 2000). The Act does not attempt, however, to specify any particular method. Any statutorily specified method would likely be too inelastic for the variety of situations in which capacity questions arise. Moreover, there appears to be no consensus in the field about the superiority of one screening instrument over another (Mezey, Teresi, Ramsey et al. 2000). The Act instead relies primarily on the attending physician, who ideally has the professional expertise and clinical wisdom to make well-reasoned judgment calls about capacity in marginal cases (Roca 1994).

When a physician concludes clinically that the patient is incapable of making an informed decision about a health care issue, the physician should act promptly to gain the concurrence of a second physician so as to be able to certify in writing the patient's incapacity for purposes of the Health Care Decisions Act.[7] Under the Act, a certification of incapacity is a prerequisite to implementation of an instruction in an advance directive or decision making by a surrogate.

A health care agent is an individual chosen by the patient in an oral or written advance directive to make a health care decision when the patient lacks the capacity to do so ...

A surrogate decision maker is an individual who makes a health care decision when the patient lacks the capacity to do so and the patient had not selected a health care agent.

The Act allows individuals to execute an immediately effective advance directive naming a health care agent. An individual is also free to condition the exercise of the agent's authority on a finding of incapacity by a single physician. Either of these kinds of advance directives would eliminate the need for a two-physician certification of incapacity. In addition, we do not mean to imply that, until the two-physician certification is in place, reliance on all next-of-kin decision making about end-of-life treatments is unlawful. It may be that, once the patient's incapacity is recognized clinically, even if it is not yet documented in a two-physician certification, traditional next-of-kin decision making might be accepted as part of the "existing rights or responsibilities ... [of] a patient's family may have in regard to the provision, withholding, or withdrawal of life-sustaining procedures under the common law ... of the State," which the Act explicitly preserves.[8] At any rate, whatever a court might ultimately rule about this possibility, surely the two-physician certification is a prerequisite to gaining the protection of the Act's generous immunity provision.[9]

B. Proxy Decision Making in the Clinical Setting

1. Current law

In this report, we use the term "proxies" to refer collectively to those who are empowered by law to make health care decisions on behalf of an incapacitated patient. Thus, we refer to health care agents and surrogate decision makers.[10]

A health care agent is an individual chosen by the patient in an oral or written advance directive to make a health care decision when the patient lacks the capacity to do so. The selection of a health care agent is discussed in detail in Chapter 4.

A surrogate decision maker is an individual who makes a health care decision when the patient lacks the capacity to do so *and* the patient had not selected a health care agent.[11] The Health Care Decisions Act designates the following priority ranking: guardian of the person, if one has been appointed; spouse; adult children; parents; adult siblings; and a more distant relative or friend who, as evidenced by an affidavit, has maintained sufficient ties to the patient as to be able to make health care decisions under the Act's standards.[12] No individual may act as surrogate if someone with a higher priority is available to do so, although the Act certainly does not preclude a surrogate from consulting others who are close to the patient before deciding. If several individuals in a category are available (for example, adult children), all have equal decision-making authority.[13]

The decision should reflect the wishes of the patient, if known, or, if not, the patient's best medical interest.

For decisions other than those relating to life-sustaining procedures, a health care agent and a surrogate have the same authority and the same criteria for decision making. Each may decide any "health care" matter.[14] The decision should reflect the wishes of the patient, if known, or, if not, the patient's best medical interest.[15]

With regard to decisions to withhold or withdraw life-sustaining procedures when a patient has advanced AD, the authority and criteria for decision making are the same, but the procedures often differ. Before a health care provider carries out a surrogate's decision to withhold or withdraw a life-sustaining procedure, a certification that the patient is in a terminal or end-stage condition should be in the patient's chart.[16] This certification is to be made by the attending and a consulting physician.

A comparable decision by a health care agent may or may not require this certification. Because a health care agent's authority to make this decision is based on the advance directive appointing the agent, procedural prerequisites, if there are any, come from the directive itself. The directive might, for example, condition exercise of the agent's authority on a certification of terminal or end-stage condition by one or two physicians. This would be the consequence if an individual not only designated a health care agent in an advance directive but also completed a decisional advance directive like that set out as an option in the Act.[17] If, however, the directive grants the agent full and unrestricted authority to make decisions about life-sustaining procedures, no physician certification of condition is required.

2. Help in understanding the role of proxy.

It is one thing to have legal authority to act as a proxy; it is quite another to understand what the role entails, and to be supported in efforts to carry out the role well.

It is one thing to have legal authority to act as a proxy; it is quite another to understand what that role entails, and to be supported in efforts to carry out the role well. A health care agent or surrogate is called upon to act in ways that differ from everyday decision making and that might, for that reason, cause the role to be difficult or uncomfortable.

First, the proxy must understand that, in making health care decisions for the patient, a very natural question – "If I were in this situation, what would I do?" – is the wrong question. Rather, the proxy is required by the Health Care Decisions Act to ponder what the patient would do if he or she were capable of making the decision.[18] In trying to figure out the best answer to this question, the proxy should take into account the patient's current medical situation, expressed preferences and behavior, relevant experience, and religious and personal values.[19] Unless the patient has

talked to the proxy or written a directly applicable decisional advance directive, when it comes to difficult choices about the use of life-sustaining procedures, the proxy will have to make a decision with only an imperfect sense of what the patient would want.

Second, if the proxy is making a decision based on the best interests of the patient, the proxy should put aside preconceptions and attempt to understand the actual pros and cons of treatment alternatives.[20] For example, a proxy for a patient with advanced AD who has stopped eating should neither consent to placement of a feeding tube simply because the proxy assumes that prior levels of nutritional intake must be maintained nor reject a feeding tube simply because the proxy equates it with intrusive technology. Rather, the proxy should try to understand whether the patient's nutritional status would really improve with the tube, whether the patient would be more comfortable without the tube than with it, and whether a temporary trial would help clarify the situation (Lynn and Harrold 1999, at 113-114). This and similar health care problems are perplexing and stressful.

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Finally, a proxy has an overall duty to act as the patient's advocate, to ask hard questions and not simply accept indecipherable medical jargon, vague reassurances, or an unsatisfactory status quo. For example, if an AD patient is showing signs of significant pain, a proxy should insist on a skilled evaluation and an appropriate response, even if that requires contact with a facility's senior managers. For some proxies, this advocacy role is an uncomfortable one.

Under what circumstances, if any, may a health care agent or surrogate authorize an incapacitated patient to become a participant in human subject research? The answer to this question is particularly important to AD patients as clinical trials of a number of potentially therapeutic drugs get underway.

Materials to help proxies understand and carry out their role effectively are available from national organizations like Last Acts[21] and Partnership for Caring.[22] In addition, local chapters of the Alzheimer's Association provide the invaluable help of support groups. Nevertheless, we think that proxies for AD patients in Maryland would benefit from a well-designed, broadly endorsed guide to their authority and responsibilities. In addition to the general information that would be applicable to any proxy, it should help proxies for AD patients understand the issues that a proxy is likely to face as AD runs its course and the dimensions of frequently arising problems, like the tube feeding and pain management examples noted above.

In our view, the Department of Aging and the Office of the Attorney General are best positioned to direct this project, although the Advisory Council on Quality Care at the End of Life may also wish to participate. In addition, the Alzheimer's Association and a wide range of other organizations, including those that can bring forward the perspectives of Maryland's minority communities, should be invited to contribute their views and support. To the extent that resources permit, a draft version of the guide should be tested extensively with proxies from diverse backgrounds, and a follow-up survey should be planned to track the use and perceived value of the guide and to establish a basis for improved future versions.

RECOMMENDATION 2-1: The Department of Aging and the Office of the Attorney General, in conjunction with the Advisory Council on Quality Care at the End of Life, the Alzheimer's Association, and other interested groups, should develop a Maryland guide for serving as a health care proxy for a patient with AD.

C. Proxy Decision Making in the Research Setting

Under what circumstances, if any, may a health care agent or surrogate authorize an incapacitated patient to become a participant in human subject research? The answer to this question is particularly important to AD patients as clinical trials of a number of potentially therapeutic drugs get underway. For example, several of the 42 trials related to AD listed on the federal government web site of clinical trials involve drugs that are aimed at treating symptoms of the disease.[23] For some of these research efforts and, no doubt, many more in the future, people with AD will be the research subjects.

In our view, the Health Care Decisions Act authorizes health care agents and surrogates to consent to a patient's participation in research if, but only if, research participation presents a reasonable prospect of direct medical benefits.

To be sure, often research can be carried out with subjects who have mild AD. They may well retain capacity to give informed consent to their research participation (Appelbaum 1999). Even if they are able to do so, however, some participants will lose capacity mid-course.[24] Other clinical trials might be aimed at the symptoms of advanced AD, in which case presumably none of the subjects will have capacity to give informed consent. Consequently, enrollment of AD patients in some types of research can be accomplished only if health care agents and surrogates have legal authority to give consent on behalf of the subjects.

Such legal authority is not found in federal law. The pertinent federal regulations provide that, unless informed consent is waived under limited conditions, a researcher may not enroll a human subject in research without the informed consent of the subject "or the subject's legally authorized representative."[25] Neither the regulations nor any other federal law identifies the circumstances under which someone (other than the parent or guardian of a child) is a "legally authorized representative" (Hoffmann and Schwartz 1998).[26]

Especially when standard therapy is problematic or nonexistent, a reasonable health care agent or surrogate could judge that participation in a clinical trial of a new drug might be the best "health care" choice for the patient **(American College of Physicians 1989; Sugarman, Cain, Wallace et al. 2001).**

In our view, the Health Care Decisions Act authorizes health care agents and surrogates to consent to a patient's participation in research if, but only if, research participation presents a reasonable prospect of direct medical benefit. This is so because, as discussed above, the responsibility of health care agents and surrogates is to decide about "health care." The Health Care Decisions Act does not define "health care." This omission is perhaps unsurprising, for the term is hardly arcane and has the generally understood meaning of medical and related services aimed at the prevention, diagnosis, and treatment of disease. This conventional meaning is reflected in the definition of the term for purposes of Maryland's medical records law.[27] In most cases, health care agents, surrogates, and health care providers know perfectly well whether a decision is related to "health care" or not.

Unless research participation can reasonably be viewed, from the patient's perspective, as a species of "health care," health care agents and surrogates do not have authority under the Act to consent to the patient's research participation. In other words, they may not rely on the Act as a basis for consent to the patient's participation in research that presents no reasonable prospect of direct medical benefit (Schwartz 1995).

This conflation of research with "health care" is troubling to the extent that it promotes what has aptly been termed the "therapeutic misconception" – a research subject's or proxy's erroneous belief that the goal of research, like the goal of clinical care, is to promote the individual's well-being (Appelbaum, Roth, and Lidz 1982). Research, by definition, is aimed at the acquisition of knowledge to benefit society.[28] While researchers have an ethical and regulatory obligation

to minimize the risks and maximize the benefits to subjects,[29] research procedures are designed and carried out to test a hypothesis; they are not, and given the nature of research cannot be, tailored to the best interests of the subjects (National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research 1979). As two leading bioethicists recently characterized the distinction: "Clinical medicine aims at providing optimal medical care for individual patients.... Clinical research, in contrast, is not a therapeutic activity devoted to the personal care of patients. It is designed for answering a scientific question, with the aim of producing 'generalizable knowledge'" (Miller and Brody 2003).

The relevant questions, for any research procedure that offers a prospect of direct benefit, is whether the risks of the procedure are reasonable in relation to the potential benefit and how this balance compares to available alternatives outside the research setting
(Silverman, Luce, and Schwartz 2004).

Nevertheless, participation in some kinds of research can result in direct medical benefit to some of the participants. Many of the AD patients who, for example, received the active agent in the clinical trials of the cholinesterase inhibitors now on the market were directly benefitted by their participation. Especially when standard therapy is problematic or nonexistent, a reasonable health care agent or surrogate could judge that participation in a clinical trial of a new drug might be the best "health care" choice for the patient (American College of Physicians 1989; Sugarman, Cain, Wallace et al. 2001). The relevant questions, for any research procedure that offers a prospect of direct benefit, is whether the risks of the procedure are reasonable in relation to the potential benefit and how this balance compares to available alternatives outside the research setting (Silverman, Luce, and Schwartz 2004).

This analysis of the Act has particular importance for potential research participation by nursing home residents. One provision in what is often known as the Patient's Bill of Rights requires a facility to "have the informed consent of a resident before the

resident participates in any experimental research."[30] This provision implements the right granted under federal regulations for a resident "to refuse to participate in experimental research."[31] The federal regulations also provide, however, that, "in the case of a resident who has not been adjudged incompetent by the State court, any legal-surrogate designated in accordance with State law may exercise the resident's rights *to the extent provided by State law*."[32] Consequently, to the extent that the Health Care Decisions Act allows proxy consent to research participation, State and federal law, read together, make that consent effective within the nursing home setting.

To the extent that the Health Care Decisions Act allows proxy consent to research participation, State and federal law, read together, make that consent effective within the nursing home setting.

Our conclusion in this regard is not changed by the decision in *Grimes v. Kennedy Krieger Institute, Inc.*, 366 Md. 29, 782 A.2d 807 (2001). In this case, the Court of Appeals had before it the question whether, under appropriate facts, pediatric researchers might be held liable for breach of a legal duty to the children who participated in the research. Reversing a grant of summary judgment for the defendants, the Court quite correctly held that such a breach of duty was possible and that, therefore, the cases (involving a study of the comparative efficacy of lead paint abatement measures) ought to be tried.

Going beyond the question of legal duty, however, the Court wrote as follows: "We hold that in Maryland a parent, appropriate relative, *or other applicable surrogate*, cannot consent to the participation of a child *or other person under legal disability* in nontherapeutic research or studies in which there is any risk of injury or damage to the health of the subject." 366 Md. at 113 (emphasis added). The Court's inclusion of the italicized language is perplexing, for the case had nothing whatever to do with proxy consent for research participation by incapacitated adults. Moreover, the scope of this aspect of the "holding" is unclear. Given

no elaboration by the Court, we cannot say whether "other person under legal disability" refers only to adults under guardianship or, more broadly, to anyone who is incapacitated under the criteria of the Health Care Decisions Act. Based on a subsequent clarification by the Court, however, the decision in any event is not inconsistent with our conclusion that proxy consent for direct-benefit research is permissible.[33]

Maryland law should continue to allow proxy consent to participation in research that presents a reasonable prospect of direct medical benefit.

1. *Clarification of "health care"*

Maryland law should continue to allow proxy consent to participation in research that presents a reasonable prospect of direct medical benefit. Because we think it preferable that this conclusion be embodied explicitly in statute rather than remain supported solely by our office's interpretation of the Health Care Decisions Act, we recommend a suitable amendment to the Act.

RECOMMENDATION 2-2: The General Assembly should amend the Health Care Decisions Act by inserting the following definition of "health care" in § 5-601:

> (1) "Health care" means any care, treatment, or procedure by a health care provider:
>
> (i) To diagnose, evaluate, rehabilitate, manage, treat, or maintain the physical or mental condition of an individual; or
>
> (ii) That affects the structure or any function of the human body.

(2) "Health care" includes participation in research that, considering the risks and benefits of participation, presents a reasonable prospect of direct medical benefit to an individual.

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Endnotes

1. *Sard v. Hardy*, 281 Md. 432, 439, 379 A.2d 1014 (1977).

2. Health-General Article, § 5-601(f), Maryland Code.

3. Health-General Article, § 5-601(l).

4. These statutory criteria are consistent with benchmarks for capacity that are widely accepted among clinicians and ethicists (Appelbaum and Grisso 1988).

5. At the same time, clinicians must be attentive to the possibility that a patient with AD might have largely intact social skills but lack abilities more relevant to health care decision making.

6. The Health Care Decisions Act explicitly declares itself to be "cumulative with existing law regarding an individual's right to consent or refuse to consent to medical treatment ...." Health-General Article, § 5-616(a).

7. Under Health-General Article, § 5-606(a), a certification of incapacity is to be signed by the attending and a consulting physician, based on a timely personal examination of the patient by at least one of the two. If the patient is unconscious or unable to communicate by any means, only the attending physician need sign the certification.

8. Health-General Article, § 5-616(a).

9. Health-General Article, § 5-609.

10. The term "proxy" logically extends as well to a guardian of the person with authority from the court to make health care decisions for a ward. Given differing standards and procedures, however, we discuss guardianship separately in Chapter 3.

11. A surrogate may also be called upon to act when a health care agent had been selected but is unavailable.

12. Health-General Article, § 5-605(a)(2) and (3).

13. The Act provides that, if surrogates having equal decision-making authority disagree about a health care decision, a facility's ethics committee (formally known as a patient care advisory committee) may make a recommendation to resolve the dispute. The patient's attending physician is protected by immunity if the physician decides to carry out the committee's recommendation. Health-General Article, § 5-605(b)(1).

14. One exception to this general statement is that a surrogate "may not authorize ... treatment for a mental disorder." Health-General Article, § 5-605(d)(2). Although the issue has not been addressed in any legal analysis, surrogate authorization for treatments related to AD is a matter of accepted practice; AD, understood as a neurological disorder, is not viewed as the kind of "mental disorder" to which this limitation applies.

15. Health-General Article, §§ 5-602(h) and 5-605(c). An individual vesting authority in a health care agent is free to depart from these statutory criteria, but advance directives commonly do not do so.

16. Health-General Article, § 5-606(b). In this context, a third qualifying condition, persistent vegetative state, is not pertinent.

17. Health-General Article, § 5-603.

18. Health-General Article, §§ 5-602(h) and 5-605(c)(1).

19. Health-General Article, § 5-605(c)(2).

20. Health-General Article, § 5-601(e).

21. http://www.lastacts.org (accessed August 1, 2003).

22. http://www.partnershipforcaring.org (accessed August 1, 2003).

23. Information on these trials is available at http://www.clinicaltrials.gov (accessed August 1, 2003).

24. To some extent, this problem can be addressed by means of research advance directives, a topic discussed in Chapter 4 of this report.

25. 45 C.F.R. § 46.116 (applicable to research conducted or sponsored by the Department of Health and Human Services). The same phraseology is found in the regulations of the Food and Drug Administration. 21 C.F.R §§ 50.20.

26. The regulations define "legally authorized representative" as "an individual or judicial or other body authorized under applicable law to consent on behalf of a prospective subject to the subject's participation in the procedure(s) involved in the research." 45 C.F.R. § 46.102(c); 21 C.F.R. § 50.3(l). This definition is of no help in resolving the question of what "applicable" law grants this authority to proxies.

27. Health-General Article, § 4-301(f).

28. Federal regulations define research as "a systematic investigation ... designed to develop or contribute to generalizable knowledge." 45 C.F.R § 46.102(d).

29. 45 C.F.R § 46.111(a).

30. Health-General Article, § 19-344(f)(2)(i).

31. 42 C.F.R. § 483.10(b)(4).

32. 42 C.F.R. § 483.10(a)(4).

33. In an order dated October 11, 2001, the Court denied Kennedy Krieger's motion for reconsideration. In so doing, however, the Court explained that its decision was not intended to preclude proxy consent except in research "that promises no medical benefit ... whatever" and that presents more than minimal risk. 366 Md. at 120.