



AMA Journal of Ethics®

May 2020, Volume 22, Number 5: E423-429

HISTORY OF MEDICINE

What Does the Evolution From Informed Consent to Shared Decision Making Teach Us About Authority in Health Care?

James F. Childress, PhD and Marcia Day Childress, PhD

Abstract

This article examines the legal doctrine and ethical norm of informed consent and its deficiencies, particularly its concentration on physician disclosure of information rather than on patient understanding, which led to the development of shared decision making as a way to enhance informed consent. As a vague and imprecise rubric, shared decision making encompasses several different approaches. Narrower approaches presuppose an individualistic account of autonomy, while broader approaches view autonomy as relational and hold that clinician-patient relationships grounded in good communication can assist decision making and foster autonomous choices. Shared decision making faces conceptual, normative, and practical challenges, but, with its goal of respecting, protecting, and promoting patients' autonomous choices, it represents an important cultural change in medicine.

Informed Consent

Valid consent can authorize another person to do something that would otherwise be impermissible. A clear example in the medical context is a surgical intervention: cutting on a person's body requires that person's consent. The requirement to obtain patients' consent before medical interventions was expanded in the last half of the 20th century through judicial decisions, including *Salgo v Leland Stanford Jr University Board of Trustees* (1957), which added a crucial adjective to create the new term *informed consent*.¹ These decisions addressed cases in which patients alleged that they would not have consented to certain interventions (such as translumbar aortography or laminectomy) had they been informed about the risks involved.^{2,3}

Early on, informed consent as a legal doctrine focused almost exclusively on the physician's disclosure of information rather than on the patient's understanding of that information.^{2,3} The standard of information disclosure in many jurisdictions is still what prudent physicians consider normative practice (the professional practice standard) rather than what reasonable persons would want to receive (the reasonable person standard, a later judicial standard).^{2,3,4}

Analysts such as Alexander Capron have identified several functions of informed consent⁵:

- Promotion of individual autonomy
- Protection of patients and subjects
- Avoidance of fraud and duress
- Encouragement of self-scrutiny by medical professionals
- Promotion of rational decisions
- Involvement of the public (in promoting autonomy as a general social value and in controlling biomedical research)

While recognizing such an array of possible functions, many ethical and legal justifications for the requirement of informed consent are based primarily on the first function, respect for personal autonomy or self-determination.^{3,4,6} Others, such as Dickert et al, appeal to several of these functions to justify informed consent rules and practices in either clinical care or clinical research.⁷

By the last quarter of the 20th century, widespread reservations had emerged about informed consent as a legal doctrine—also stated as an ethical norm—and practice, particularly whether it actually respects, protects, and promotes patient autonomy.² Critics attacked the virtually exclusive attention to health professionals' duty to disclose information, particularly as interpreted through a professional standard rather than a reasonable person standard or the subjective preferences of particular patients. The duty to disclose was mainly discharged through the consent form, with less attention to both the *process* of consent and the patient's understanding of risks and benefits of and alternatives to a particular test or treatment.^{8,9} Moreover, the physician's involvement in the consent process appeared to be limited to serving as a conduit for the neutral disclosure of information, with little or no guidance about how the patient or subject might understand, process, and respond to the disclosed information.¹⁰ In practice, responsibility for "consenting" patients (an unfortunate and misleading verbal construction of this crucial activity) often devolved on residents and became routinized as one more preprocedure checklist item. In the end, patients could feel neglected, even abandoned, as they alone assumed and exercised the burden of decision making, as in Marcia Lynch's poem "Peau d'Orange," in which a patient with terminal breast cancer addresses her doctor:

We barter the difference
between black and gray.
"Surgery, radiation or
death," you say and leave
the decision to me.¹¹

Shared Decision Making

These and other perceived deficiencies of informed consent led to the development of what has come to be called shared decision making (SDM). In 1982, the President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research issued an influential report, *Making Health Care Decisions: A Report on the Ethical and Legal Implications of Informed Consent in the Patient-Practitioner Relationship*.¹² This report viewed informed consent as "active, shared decision making" and is widely considered to be the documentary origin of SDM in

health care: “Ethically valid consent is a process of shared decision making based upon mutual respect and participation, not a ritual to be equated with reciting the contents of a form that details the risks of particular treatments.”¹² This conception of SDM builds mainly on 2 ethical values manifest in the functions of informed consent: the patient’s self-determination and personal well-being.

The Silent World of Doctor and Patient, published in 1984 by lawyer-psychiatrist Jay Katz, on whose work the commission had drawn, called for an end to “the history of silence with respect to patient participation.”¹³ Instead, Katz proposed ideal medical relationships based on “sharing the burdens of decision” and “joint undertaking.”¹³ He focused more on “the entire give-and-take process than on whether a particular disclosure has or has not been made.”¹³

SDM, which as a practice continues to evolve, has since been praised as “the pinnacle of patient-centered care.”¹⁴ And, over many years, it has emerged as an ideal of clinician-patient relationships for a number of health care and professional organizations in the United States and Europe.^{15,16} SDM is often described as a middle way between a paternalistic approach (the physician knows best) and an autonomy-based approach (the patient knows best).¹⁶ It recognizes both physician beneficence and patient authority and respects, protects, and supports patients’ autonomous choices.

Narrow and Broad SDM

Nevertheless, to this day SDM remains vague and imprecise because it encompasses so many different approaches.¹⁶ One important distinction is between narrow and broad models of SDM. As Vikki Entwistle and Ian Watt draw this distinction, narrow models focus mainly on information exchange in which health professionals provide research-based information about options and their risks and benefits and patients indicate their value-based preferences and choose among options.¹⁷ These models aim to protect patients from health care professionals’ undue influence—hence their emphasis on the neutrality of the information provided. These narrow conceptions presuppose a highly individualistic view of personal autonomy; regard patient preferences as clear, settled, firm, and enduring; and hold that these preferences can reliably be used in decision making. Such models have particular importance in the acute care context.¹⁷

Drawing on Entwistle and Watt, with modifications and additions, we can say that broad models of SDM presuppose a less individualistic view of personal autonomy that recognizes positive and negative social impacts on self-determination.¹⁷ These models appreciate that patient preferences are often unclear, unsettled, changing, variable, and context and relationship dependent. They also acknowledge that health professionals might need to **support patients’ discernment**, criticism, and deployment of their own values and preferences—for instance, through recommendations and probing questions. If the decision-making process includes a more collaborative conversation, practitioners can invite patients to explore their preferences, expectations, and rationales. The 2 parties can then partner in determining the patient’s best choices in the circumstances.

Broad models overlap with and can helpfully draw on *relational autonomy*, as developed by feminists and other thinkers.¹⁸ Relational autonomists emphasize that autonomous choices are generally achieved or realized over time in the context of positive and negative social relations and are more fluid and less fixed than often supposed. A relational approach opens the door to modes of patient engagement and empowerment

beyond the narrow conception of SDM as chiefly information exchange. Indeed, we find goals-of-care conversations originating in broad, relational understandings of SDM. Broad models have particular value in chronic, longitudinal, or end-of-life care, in which patients' problems are often multiple, ill defined, and dynamic, requiring their—and often their **surrogate decision makers'**— active, continuing participation.¹⁵

Both narrow and broad models aim to protect patients' personal autonomy from paternalistic medical interference. Narrow models suffer from an inadequate account of personal autonomy and thus excessively limit potentially valuable clinician involvement. By contrast, clinicians' paternalistic tendencies might be harder to constrain and control in the broad models' pursuit of patient participation, engagement, and empowerment.

Challenges for SDM

SDM faces conceptual, normative, and practical challenges. Some ethicists contend that SDM might actually threaten patient autonomy because of its vagueness and incoherence: Exactly how can clinicians and patients share a medical decision?¹⁹ Some versions of SDM favor a division of labor, with health professionals providing research-based factual information and patients adding their personal value-based preferences.^{16,17} More often, SDM is characterized as patient and physician reaching a joint decision through collaborative, conversational deliberation.^{13,20} However, this approach could fail to sufficiently emphasize the patient's basic legal and ethical rights to know and to decide. Indeed, the term *sharing* sounds too weak when the patient actually has these rights to know and decide. In response, Peter Ubel and colleagues concede that SDM could be better described as “assisted decision making,”²¹ thus bringing informed consent and SDM closer together, as they were in the report of the President's Commission.

Serious practical barriers remain for SDM. These include the fundamental power differential between doctors and patients in clinical care or research, residual paternalistic tendencies among many clinicians,²² and the fears of many patients that they will be labeled “difficult” and receive less adequate care if they participate too actively or assertively in decision making.²³ Another critical barrier is the time SDM requires, given all the demands and constraints on physicians' time and limits on reimbursement for time spent conferring with patients.²⁴ Alston and colleagues identify still other obstacles, including uneven training of clinicians in the communicative skills needed for SDM, insufficient access to excellent decision aids, conflicting agendas in clinical encounters, and uncertainty about whether and how far to commit to SDM in clinical contexts.²⁰ For these and other reasons, Alston and colleagues stress that “the promise of SDM remains elusive.”²⁰

Conclusions

SDM's widely recognized goals are “to make decisions in a manner consistent with the patient's wishes”¹⁶ and “to respect patients as individuals and to deliver care consistent with their values and preferences.”²⁵ In an open communication process, patients might well choose their own mode of participating in SDM. At a minimum, they should be able to determine how much they want to know and what decisions to participate in. Nevertheless, any SDM activity will likely require the clinician to commit time and mindful attention to conversation that can elicit and explore the patient's values and preferences.

The word *from* in the title of this essay—“From Informed Consent to Shared Decision Making”—does not imply moving beyond informed consent to a totally different conceptual and procedural model. Instead, if conceived and practiced as “assisted decision making,”²¹ SDM as best practice actually validates, augments, and enriches the process of informed consent by emphasizing patients’ understanding and prioritizing of different medical interventions in light of their own values and lived experiences. Beyond improving informed consent, SDM can contribute to relationship building between health professionals and their patients through patient participation, engagement, and empowerment as well as through clinician presence, patient-specific focus, and improved communication. In addition to meeting ethical requirements, such constructive interactions of patients with their health professionals could actually improve outcomes and increase patients’ understanding, trust, and adherence to treatment plans.

In response to challenges to SDM, Ubel and colleagues contend that it is ethically dangerous to use SDM’s conceptual, normative, and practical problems to undermine its legitimacy.²¹ Since a primary goal of SDM is to respect, protect, and promote patient autonomy, “it would do more harm than good to question the legitimacy of the term ‘shared decision making’ at this point,” when SDM is finally being accepted “as part of standard medical practice.”²¹ Even if SDM is not the best term or clearest descriptor for the process by which clinicians and patients work together to arrive at the patient’s decisions, SDM does represent a significant evolution in medical culture such that patient autonomy is key and clinicians are expected to consider and, within appropriate limits, abide by their patients’ preferences.

References

1. *Salgo v Leland Stanford Jr University Board of Trustees*, 317 P 2d 170 (Cal Dist Ct App 1957).
2. Katz J. Informed consent—a fairy tale? Law’s vision. *Univ Pittsbg Law Rev.* 1977;39(2):137-174.
3. Faden RR, Beauchamp TL. *A History and Theory of Informed Consent*. New York, NY: Oxford University Press; 1986.
4. Beauchamp TL, Childress JF. *Principles of Biomedical Ethics*. 8th ed. New York, NY: Oxford University Press; 2019.
5. Capron AM. Informed consent in catastrophic disease research and treatment. *Univ PA Law Rev.* 1974;123(2):340-438.
6. Beauchamp TL. The idea of a “standard view” of informed consent. *Am J Bioeth.* 2017;17(12):1-2.
7. Dickert NW, Eyal N, Goldkind SF, et al. Reframing consent for clinical research: a function-based approach. *Am J Bioeth.* 2017;17(12):3-11.
8. Braddock CH III. Advancing the cause of informed consent: moving from disclosure to understanding. *Am J Med.* 1998;105(4):354-355.
9. Braddock CH III, Edwards KA, Hasenberg NM, Laidley TL, Levinson W. Informed decision making in outpatient practice: time to get back to basics. *JAMA.* 1999;282(24):2313-2320.
10. Manson NC, O’Neill O. *Rethinking Informed Consent in Bioethics*. New York, NY: Cambridge University Press; 2007.
11. Lynch M. Peau d’Orange. In: Mukand J, ed. *Articulations: The Body and Illness in Poetry*. Iowa City, IA: University of Iowa Press; 1994:130.
12. President’s Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research. *Making Health Care Decisions: A Report*

on the Ethical and Legal Implications of Informed Consent in the Patient-Practitioner Relationship. Volume One: Report. Washington, DC: US Government Printing Office; 1982.

https://repository.library.georgetown.edu/bitstream/handle/10822/559354/making_health_care_decisions.pdf?sequence=1&isAllowed=y. Accessed March 9, 2020.

13. Katz J. *The Silent World of Doctor and Patient*. Baltimore, MD: Johns Hopkins University Press; 2002.
14. Barry MJ, Edgman-Levitan S. Shared decision making—pinnacle of patient-centered care. *N Engl J Med*. 2012;366(9):780-781.
15. Sullivan MD. *The Patient as Agent of Health and Health Care*. New York, NY: Oxford University Press; 2017.
16. Kon AA. The shared decision-making continuum. *JAMA*. 2010;304(8):903-904.
17. Entwistle VA, Watt IS. Broad versus narrow shared decision making: patients' involvement in real world contexts. In: Elwyn G, Edwards A, Thompson R, eds. *Shared Decision Making in Health Care: Achieving Evidence-Based Patient Choice*. 3rd ed. New York, NY: Oxford University Press; 2016:7-12.
18. Sherwin S. A relational approach to autonomy in health care. In: Sherwin S; Feminist Health Care Ethics Research Network. *The Politics of Women's Health: Exploring Agency and Autonomy*. Philadelphia, PA: Temple University Press; 1998:19-47.
19. Childress JF. Needed: a more rigorous analysis of models of decision making and a richer account of respect for autonomy. *Am J Bioeth*. 2017;17(11):52-54.
20. Alston C, Berger Z, Brownlee S, et al. Shared decision-making strategies for best care: patient decision aids. *National Academy of Medicine Perspectives*. September 18, 2014. <https://nam.edu/perspectives-2014-shared-decision-making-strategies-for-best-care-patient-decision-aids/>. Accessed October 30, 2019.
21. Ubel PA, Scherr KA, Fagerlin A. Autonomy: what's shared decision making have to do with it? *Am J Bioeth*. 2018;18(2):W11-W12.
22. Barry M. Involving patients in medical decisions: how can physicians do better? *JAMA*. 1999;282(24):2356-2357.
23. Frosch DL, May SG, Rendle KA, et al. Authoritarian physicians and patients' fear of being labeled "difficult" among key obstacles to shared decision making. *Health Aff (Millwood)*. 2012;31(5):1030-1038.
24. Pieterse AH, Stiggelbout AM, Montori VM. Shared decision making and the importance of time. *JAMA*. 2019;322(1):25-26.
25. Beach MC, Sugarman J. Realizing shared decision-making in practice. *JAMA*. 2019;322(9):811-812.

James F. Childress, PhD is a professor emeritus at the University of Virginia in Charlottesville. He specializes in bioethics, with particular attention to methods and principles in bioethics, obtaining and allocating organs for transplantation, public health, and bioethical public policies.

Marcia Day Childress, PhD is an associate professor of medical education (health humanities) and a David A. Harrison III Distinguished Educator Award recipient at the University of Virginia School of Medicine in Charlottesville. A literature scholar, her interests include narrative medicine, narrative ethics, physicians' moral and ethical formation, and the arts in professional education.

Citation

AMA J Ethics. 2020;22(5):E423-429.

DOI

10.1001/amajethics.2020.423.

Conflict of Interest Disclosure

The author(s) had no conflicts of interest to disclose.

The viewpoints expressed in this article are those of the author(s) and do not necessarily reflect the views and policies of the AMA.