Informed Consent and Shared Decision-Making

Introduction

Informed consent to medical treatment is a fundamental part of the practitioner-patient relationship. It is a process of communication, and not merely signing a form. Informed consent involves a dialogue between the practitioner and the patient[1] by which information is exchanged concerning the risks, benefits, and alternatives of the tests or treatments being recommended. The obligation of a practitioner to obtain informed consent from a patient is rooted in the recognition of patients' autonomy. Patents who have decision-making capacity have the right to make decisions regarding their care, even when their decisions contradict their providers' recommendations. The practitioner "must supply the patient with material facts the patient will need to intelligently chart that destiny with dignity."[2]

The Washington Medical Commission (WMC) issues this policy to provide guidance to allopathic physicians and physician assistants to ensure that patients are being adequately informed of the risks, benefits, and alternatives of proposed tests and treatments, such that patients can make informed care decisions that best reflect their goals and preferences in entering the care agreement. This policy serves to ensure that practitioners and patients understand their role in the processes of informed consent and shared decision-making.

Elements of the Informed Consent Process

A valid process of informed consent has four elements:

1. **Voluntariness**. A patient's decision must be free from coercion or undue influences. For example, if a decision is instead made under duress from a clinician, family member, or other third party, a patient's decision is not voluntary and, as such, informed consent cannot be obtained.

2. **Disclosure.** The practitioner must share all information that "a reasonably prudent person in the position of the patient" would find significant for the patient to make an informed decision,[3] including the nature, character, and anticipated results of the proposed test/treatment; material risks inherent to the proposed test or treatment; and alternative courses of action, including no action, and the benefits and risks of those alternatives.

3. **Understanding.** The practitioner must ensure that the patient has not only been informed but also understands and appreciates the nature of the proposed test/treatment, in addition to associated risks,

[1] The term "patient" in this policy includes a person with a power of attorney for health care when the patient is incapacitated.
[2] *Miller v. Kennedy*, 11 Wn. App. 272, 281-82, 522 P.2d 852 (1974), *aff'd per curium*, 85. Wn.2d 151 (1975). For a comprehensive review of the legal aspects of informed consent, see Washington Health Law Manual, 4th ed., Chapter 2A.3 (2016).

[3] RCW 7.70.050(2)

benefits, and alternatives. The practitioner has a duty to ensure that informed consent is obtained using a form of communication (e.g., language) that the patient understands. Understanding can be difficult to ascertain with certainty. One way to gauge understanding is for the practitioner to ask the patient to state in their own words what they just discussed and what they understood. The practitioner should be aware that cultural differences can significantly impact understanding

4. Capacity. The practitioner must ensure that the patient has the ability to engage in reasoned deliberation (e.g., comparing the risks and benefits of the procedure with personal life goals). A patient who lacks the ability to engage in reasoned decision-making lacks the capacity to give informed consent.

Lack of capacity can take many forms. One form involves statutory criteria, which are required to determine lack of capacity (e.g., as declared by a court or by certain types of health care providers) regarding advance directives.[4] Outside of specific legal criteria, there are scenarios when patients may lack capacity to make reasoned medical decisions, such as the following two examples.

Health literacy is one example. Many patients may not understand complex medical information. Practitioners should explain medical information using plain language that a patient can understand. A patient who is confused by the medical terminology may be able to provide informed consent when these complex terms are explained using more basic terminology.

Another example involves a patient overwhelmed by complexity or volume of information at hand. An overwhelmed patient may lack the capacity to provide informed consent. This may create a challenge for practitioners, as it can be difficult to adequately explain all pertinent risks, benefits, and alternatives without overwhelming the patient. Practitioners should focus on explaining all concepts that a reasonably prudent patient would likely need to know to make an informed decision in a manner that promotes dialogue and understanding.

If a practitioner believes that a patient does not have the mental capacity necessary to make an informed decision, the practitioner may consider recommending the patient have a court-ordered guardian ad litem appointed before proceeding with any elective treatment.

Capacity is not an all-or-nothing phenomenon; a patient may have the capacity to make some decisions but not others.[5] The American Medical Association Code of Medical Ethics Opinion 2.1.2 provides excellent guidance to a practitioner who encounters an adult patient who seemingly lacks decision-making capacity.[6]

Shared Decision-Making

Washington became the first state to codify shared decision-making as an alternative to traditional informed consent. The statute, RCW 7.70.060 was first amended in 2012 and then again in 2022. The statute states that shared decision-making is a process in which a practitioner discusses with the patient, or his or her representative, information to make a decision that aligns with the patient's values and goals.

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[4] RCW 71.32.110
[5] "The Limits of Informed Consent for an Overwhelmed Patient: Clinician's Role in Protecting Patient and Preventing Overwhelm," AMA Journal of Ethics, Vol. 18, no. 9:869-886 (September 2016).
[6] AMA Code of Medical Ethics Opinion 2.1.2.

Both the Robert Bree Collaborative in Washington State and the National Institute for Health and Care Excellence have issued excellent guides to implementing shared decision-making into a practitioner's medical practice. As noted in the 2019 Bree Collaborative, "Shared decision making is a key component of patient-centered care, 'a process that allows patients and their providers to make health care decisions together, taking into account the best scientific evidence available, as well as the patient's values and preferences.'"[7]

Shared decision-making takes the traditional notion of informed consent a step further by encouraging practitioners and patients to undertake, not just an informed, but an active role in complex medical decisions that affect the patient's health. Shared decision-making requires a high-quality communication between a practitioner and a patient, and in some cases family members or others, about risks, benefits, values, and goals.

The goal of shared decision-making is to help patients arrive at informed decisions that respect what matters most to them.[8]Shared decision-making is especially useful in complex cases where a patient is faced with multiple options and high stakes decisions need to be made in a narrow window of time, such as the decision-making regarding which treatments to undergo when cancer is diagnosed.[9] Shared decision-making is appropriate for treatments that are (patient) preference-sensitive and either have (1) high-quality scientific evidence supporting more than one option, which may include no treatment, or (2) a lack of evidence and/or no clinical consensus on what is the best option.[10] The practitioner may encourage the patient to have a patient advocate involved in this process.

Shared decision-making is, however, not appropriate when there is clear evidence of a net benefit, or harm. For example, generally, a clear net benefit of immunization against measles, mumps, and rubella (MMR) excludes MMR vaccination as a shared decision-making opportunity, as does the clear net harm of using antibiotics to treat a common cold.[11]

Shared decision-making can sometimes be assisted with patient decision aids. Certified by one or more national certifying organization[12], the tool provides a balanced presentation of the condition and treatment options, benefits, and harms, including, if appropriate, a discussion of the limits of scientific knowledge about outcomes.[12] A decision aid can be in any format, including written, electronic, audio-visual, or web based. A decision aid is not essential for shared decision-making to occur, but studies have shown that patients who engaged in shared decision-making with a decision aid had a greater knowledge of the evidence, understood better about what mattered to them, had more accurate expectations of the risks and benefits, and

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[7] Dr. Robert Bree Collaborative, Shared Decision Making, 2019, at 3. (hereinafter Bree Collaborative paper) https://www.qualityhealth.org/bree/topic-areas/shared-decision-making/

[8] "The Limits of Informed Consent for an Overwhelmed Patient: Clinician's Role in Protecting Patient and Preventing Overwhelm," AMA Journal of Ethics, Vol. 18, no. 9:869-886 (September 2016).

[9] "Development of a Program Theory for Shared Decision-Making: a realist synthesis," Waldron, et al., BMC Health Services Research 20:59 (2020).

[10] Dr. Robert Bree Collaborative, Shared Decision Making, 2019, at 3. https://www.qualityhealth.org/bree/topic-areas/shared-decision-making/

[11] Bree Collaborative paper, at 4.

[12] RCW 7.70.060(4)(a).

participated more in the decision-making process.[13] The commission recommends that any use of patient decision aid be documented in medical record.

Generally, shared decision-making is associated with improved patient satisfaction, improved health outcomes, and better appropriateness of care.[14] When patients participate in decision-making and understand what they need to do, there are benefits to patients: they are more likely to follow through on their treatment plans,[15] there is a reduction in the chance of "preference misdiagnosis,"[16] and there is a reduction in health care disparities.[17] Shared decision-making may also benefit practitioners by improving doctor-patient relationships, improving communication, and providing certain legal protections to practitioners.

Practitioners should document shared decision-making in the patient's medical record as follows:

- A description of the services that the patient and provider jointly have agreed will be furnished;
- A description of the patient decision aid or aids that have been used by the patient and provider to address the needs for (a) high quality, up-to-date information about the condition, including risk and benefits of available options and, if appropriate, a discussion of the limits of scientific knowledge about outcomes; (b) clarification to help patients sort out their values and preferences; and (c) guidance or coaching in deliberation, designed to improve the patient's involvement in the decision process;
- A statement that the patient or his or her representative understand: the risk or seriousness of the disease or condition to be prevented or treated; the available treatment alternatives, including nontreatment; and the risks, benefits, and uncertainties of the treatment alternatives, including nontreatment; and
- A statement certifying that the patient or his or her representative has had the opportunity to ask the provider questions, and to have any questions answered to the patient's satisfaction, and indicating the patient's intent to receive the identified services.[18]

The Informed Consent Process Cannot be Delegated

Obtaining informed consent is an interactive process that is integral to the practitioner-patient relationship and cannot be delegated to others. For elective procedures, the treating practitioner is the one primarily responsible for the process of obtaining a patient's informed consent. At the end of that process, the treating practitioner may rely on ancillary personnel to obtain a patient's signature on a consent form. However, the practitioner is responsible for any act or statement made by the ancillary personnel when obtaining the

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[13] Spatz E, Krumholz H, Moulton B, The New Era of Informed Consent: Getting to aa Reasonable-Patient Standard Through Shared Decision Making, Viewpoint, JAMA Vol 315, No 19, May 17, 2016.
[14] Bree Collaborative paper at 4, citing Arterburn D, Wellman R, Westbrook E, Rutter C, Ross T, McCulloch D, et al. Introducing decision aids at Group Health was linked to sharply lower hip and knee surgery rates and costs. Health Aff (Millwood). 2012 Sep;31(9):2094-104; and Stacey D, Légaré F, Col NF, Bennett CL, Barry MJ, Eden KB, et al. Decision aids for people facing health treatment or screening decisions. Cochrane Database Syst Rev. 2014 Jan 28;(1):CD001431.
[15] Shared Decision-Making Fact Sheet, HealthIT.gov, National Learning Consortium (December 2013).
[16] C Brach, "Making Informed Consent an Informed Choice," Health Affairs bog April 4, 2019.
[17] Bree Collaborative paper, at 4-5, citing as an example the increasing rates of total knee replacement for black patients with osteoarthritis to rates closer to those of white patients.
[18] RCW 7.70.060.

patient's signature.[19] The practitioner retains responsibility for obtaining consent and for communications regarding consent.

Exceptions

There are certain situations in which informed consent is not required. For example, in an emergency when immediate treatment is necessary to preserve life or to prevent serious deterioration of a patient's condition, and the patient is unable to make an informed decision and a surrogate is not available, consent is not required.[20] Informed consent is also not required to detain a child without the consent of the parents when there is an imminent danger to the child,[21] when a patient is involuntarily committed to a psychiatric unit or facility under the Involuntary Treatment Act,[22] or when disclosure of information would be detrimental to the patient's best interests.[23]

Additionally, a patient may choose not to be informed about the details of a proposed treatment, including risks, benefits, and alternatives. A patient may also refuse treatment, or withdraw consent to treatment, no matter how unreasonable. In these scenarios, the practitioner should accept a patient's wishes and document their decision in the medical record.[24] The practitioner should consider having the patient confirm these types of decisions by documenting them in writing.

Special Considerations for Surgery or Invasive Procedures

When a practitioner proposes a surgery or an invasive procedure, the need for informed consent, or shared decision-making, is amplified. Barring an urgent or emergent situation, dialogue between the practitioner and the patient to discuss the proposed procedure, including the risks, benefits, and alternatives, should generally take place well in advance. Patients are naturally apprehensive and vulnerable on the day of a procedure, and may be reluctant or unable to ask questions, and engage fully in the decision-making process. Thus, for non-urgent procedures, having an informed consent discussion in advance optimizes a patient's ability to consider the information, ask questions, and seek advice from another practitioner, friend, or family member, prior to consenting.

Unexpected operative findings may be encountered during a procedure or surgery that require additional procedure(s) for which there is no consent. If these findings are significant and the patient is under anesthesia, an attempt should be made to obtain consent from appropriate patient representative . If that is either not appropriate or not possible, surgical judgment justifying the necessity of the additional procedure(s) for which there is no consent must be clearly documented. At the appropriate time following the procedure, the additional procedures performed and the rationale shall be discussed with the patient.

Another special consideration in obtaining consent includes the names and roles of practitioners to whom the patient consent to a procedure. The practitioner should advise the patient of the names of any other

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[19] Washington Health Law Manual, 4th ed., Chapter 2A.3 (2016). *See also, Shinal v. Toms*, 640 Pa. 295, 162 A.3d 429 (2017) (Pennsylvania court rules that the physician must obtain informed consent himself).
[20] RCW 7.70.050(4).
[21] RCW 26.44.056(1).
[22] RCW 71.05 (adults) and RCW 71.34 (minors age 13017). See also Washington State Health Care Authority, "The Involuntary Treatment Act," December 2021.
[23] *Holt v. Nelson*, 11 Wn. App. 230, 523 P.2d 211 (1974), *rev denied*, 84 Wn.2d 1008 (1974).
[24] RCW 7.70.060(1)(b).

practitioners who will perform surgical interventions or other important parts of the procedure, including anesthesia.[25] The primary surgeon may not know who will be involved in the procedure at the time informed consent is obtained, in which case, the primary surgeon should advise the patient that other practitioners may be involved and explain their planned scope of involvement in the procedure. The primary surgeon or practitioner should also discuss any applicable overlapping procedures.

The WMC issued a guideline on Overlapping and Simultaneous Elective Surgeries in 2018, in which the WMC recommended that the primary attending surgeon inform the patient of the circumstances of the overlapping or simultaneous surgery, including:

1. Who will participate in the surgery, including residents, fellows, physician assistants and nurse practitioners who are directly supervised by the surgeon;
2. When the primary attending surgeon will be absent for part of the surgery; and
3. Who will continue the surgery when the primary attending surgeon leaves the operating room.[26]

A surgeon should not allow a substitute surgeon to perform the procedure without the patient's consent.[27] According to the AMA Principles of Medical Ethics, patients are entitled to accept or refuse the care of a substitute practitioner,[28] and a patient is only able to do this with prior knowledge of its occurrence.

Regulations and Requirements of Other Regulators and Organizations

In addition to Washington statutes regarding informed consent and shared decision-making, it is important to remember that there may be additional requirements of other regulators or organizations. Healthcare organizations or regulatory bodies may have their own regulations or requirements that also must be followed. For example, a physician needs to honor Department of Health facility regulations, Department of Social and Health Services regulations, Joint Commission requirements, and Center for Medicare and Medicaid requirements regarding consent and shared decision-making. The practitioner is responsible for compliance with all applicable statutes, regulations, and requirements to help ensure that quality patient care is provided in the state.

Conclusion

Informed consent and shared decision-making are integral to a healthy practitioner-patient relationship. Evidence suggests that following these recommendations, as well as reviewing the resources cited, will enhance communication, improve practitioner-patient relationships, decrease legal risk, and result in better overall patient care.

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[25] The Center for Medicare and Medicaid Services has a detailed example of a well-designed informed consent process for surgical procedures. A-0392 Surgical Services, Interpretive Guidelines §482.51(b)(2). https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/downloads/SCLetter07-17.pdf

[26] Washington Medical Commission Guideline GUI2018-03, "Overlapping and Simultaneous Surgeries," adopted July 13, 2018.

[27] AMA Code of Ethics Opinion 2.1.6, *available at* https://www.ama-assn.org/system/files/2019-06/code-of-medical-ethics-chapter-2.pdf

[28] AMA Code of Ethics Opinion 2.1.6, *available at* https://www.ama-assn.org/system/files/2019-06/code-of-medical-ethics-chapter-2.pdf

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