

Slide 1: An Ethical Framework for Supporting Shared Decision Making When Clinical Evidence is Low

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Slide 2: Objectives

- Describe ethical tool kit: clinically relevant concepts
- Describe the continuum of meaning of “shared decision making”
- Define low and very low levels of evidence
- Describe concept of moral management of medical uncertainty
- Describe physician’s and patient’s roles in shared decision making when moral management of medical uncertainty is required
- Identify and address clinical challenges of shared decision making

Slide 3: Shared Decision Making

- phrase without a standardized meaning in the medical and ethics literature
 - Corrective to talking at not with patients in the informed consent process¹
 - Antipaternalistic^{2,3}
 - Assumes endorsement and history of medical paternalism
 - No recommendations
 - Autonomy-based⁴
 - Autonomy not constrained by beneficence-based clinical judgment: “guided by the patient’s values”

Slide 4: Shared Decision Making (2)

- Not always needed
 - Simple consent: The patient is offered clinical intervention and either authorizes or does not authorize it
 - Simple consent is adequate for authorizing routine clinical management of well understood clinical benefit and low risk¹
- Not always wanted
 - The most fundamental form of respect for autonomy is respect for the patient’s preferred decision making role²

Slide 5: Shared Decision Making (3)

- Autonomy-based model of shared decision making

Source: Eisenberg Center Conference Series 2011, Differing Levels of Clinical Evidence: Exploring Communication Challenges in Shared Decisionmaking, Effective Health Care Program Web site (<http://www.effectivehealthcare.ahrq.gov/index.cfm>)

- Deprofessionalizes medical ethics: patient autonomy not subject to restraint of professional integrity
 - The physician has no ethical obligation to protect the patient from the patient, no matter the patient's degree of imprudence, because deprofessionalized medical ethics does not support professional integrity
- Physician's role reduced to being a purveyor of technical information presented in strictly non-directive fashion
- Limit on cooperation based on personal comfort levels, not professional integrity
 - "Comfortable" and "uncomfortable" are the most elastic terms in medical discourse
- Poor quality: unmanaged (because unmanageable) and therefore very wide variation in processes and outcomes of decision making

Slide 6: Shared Decision Making (4)

- Informed consent process in professional medical ethics
 - Physician
 - Identify, present, and explain medically reasonable alternatives for the clinical management of the patient's condition, diagnosis, or injury, and the clinical benefits and risks of each alternative
 - Make recommendation when warranted in beneficence-based clinical judgment
 - Ensure that patient understands information and engages in voluntary decision-making process
 - Patient
 - Achieve cognitive understanding, appreciation, and evaluative understanding with physician's assistance as needed/wanted
 - Voluntarily accept or refuse offered/recommended clinical management
 - Plan of clinical management is agreed upon (co-constructed preferences), under constraints of
 - Professional integrity in its intellectual and moral dimensions
 - Patient's values and beliefs disciplined by evidence-based reasoning in the decision-making process, resulting in prudential decisions by patients/surrogates

Slide 7: Definitions of Levels of Evidence

- Low: "Our confidence in the effect estimate is limited: The true effect may be substantially different from the estimate of the effect."
- Very low: "We have little confidence in the effect estimate: The true effect is likely to be substantially different from the estimate of the effect."

Source: Eisenberg Center Conference Series 2011, Differing Levels of Clinical Evidence: Exploring Communication Challenges in Shared Decisionmaking, Effective Health Care Program Web site (<http://www.effectivehealthcare.ahrq.gov/index.cfm>)

Slide 8: Moral Management of Medical Uncertainty

- Concept introduced by E. Haavi Morreim
 - Uncertainty that cannot be eliminated by additional evidence requires evidenced-based and values-based judgments, to responsibly manage clinical uncertainty
 - Sometimes additional evidence will warrant reclassifying medically reasonable alternative as supported by moderate or very high evidence
 - Such an alternative can be recommended
 - Sometimes additional evidence will leave classification unchanged or lower it
 - Disciplined beneficence-based judgments must be made
 - Evidence-based and values-based judgments about clinical benefits and risks and their balancing

Slide 9: General Candor-Based Considerations

- Clinical judgments about medical reasonableness range along a continuum
- At very low and low levels of evidence, clinical management will be beneficial to different degrees and might not be beneficial in many cases
 - Clinical management supported by low or very low evidence is only weakly supported in beneficence-based clinical judgment
- Such clinical management carries disease-related risks (from ineffectively managed condition, disease, or injury) and iatrogenic risks
 - To prevent enthusiasm and inadequate risk assessment in reaching judgments about medical reasonableness, the physician should assume that these risks are clinically significant. Limits of beneficence-based clinical judgment might therefore be quickly reached in the course of clinical management
- Refusal by the patient of clinical management with very low or low levels of evidence is not automatically ruled out in beneficence-based clinical judgment as medically unreasonable

Slide 10: Informed Consent Process in Professional Medical Ethics

<u>Physician's Role</u>	<u>Patient's Role</u>	<u>Physician's Role</u>	<u>Patient's Role</u>	<u>Physician and Patient's Role</u>
Identify medically reasonable alternative using evidence-based, beneficence-based clinical judgment	Pay attention	Support	Select Medically reasonable alternative	Implement plan of care
	Absorb, retain, recall	Support	Or	Or
Present and explain medically reasonable alternatives to patient: offer trial of management, no recommendations	Cognitive understanding	Support	Reject all medically reasonable alternatives	Informed refusal; persuade
	Appreciation	Support		
	Evaluative understanding	Support		

Source: Eisenberg Center Conference Series 2011, Differing Levels of Clinical Evidence: Exploring Communication Challenges in Shared Decisionmaking, Effective Health Care Program Web site (<http://www.effectivehealthcare.ahrq.gov/index.cfm>)

Slide 11: Clinical Challenges

- Responding to patient's preferences for diagnosis or clinical management
 - "Every man has a right to speak where his life or his health is concerned, and every man may suggest what he thinks may tend to save the life of his friend. It becomes them to interpose with politeness, and a deference to the judgment of the physician; it becomes him to hear what they have to say with attention, and to examine it with candour; If he really approves, he should frankly own it, and act accordingly; if he disapproves, he should declare his disapprobation in such a manner, as shews it proceeds from conviction, and not from pique or obstinacy. If a patient is determined to try an improper or dangerous medicine, a physician should refuse his sanction, but he has no right to complain of his advice not being followed." (p. 32-33)

Slide 12: Clinical Challenges (2)

- Acknowledge the patient's right to make own judgments about his or her own healthcare and express preferences
- Follow the discipline of candor to create a preventive ethics response
 - Respectfully assess the patient's/surrogate's preferred plan of care, using evidence-based reasoning, to which intellectual authority the patient/surrogate should be willing to defer
 - Depending on continuum of authority in biopsychosocial clinical judgment
 - If clinically beneficial, approve it
 - If clinically benign but not unacceptably clinically risky, then explain evidence-based reasoning and allow without endorsement
 - If clinically unacceptably risky, then explain evidence-based disapproval, discourage, but do not abandon the patient
 - When evidence level for judgment of risk is low or very low, disapproval should take form of informing patient of inadvisability of patient's/surrogate's proposed plan of care and appeal to virtue of prudence
 - When evidence level is moderate or high, disapproval should take form of recommendation against patient's/surrogate' proposed plan of care

Slide 13: Clinical Challenges (3)

- Patient wants physician to play a leading role in the shared decision-making process
 - The patient is free to select his or her preferred decision-making role
 - Informed about the benefit of doing so
 - Relieved of the burden of decision making
 - Informed about the risk of doing so
 - Decision made might not be the one the patient would make

Source: Eisenberg Center Conference Series 2011, Differing Levels of Clinical Evidence: Exploring Communication Challenges in Shared Decisionmaking, Effective Health Care Program Web site (<http://www.effectivehealthcare.ahrq.gov/index.cfm>)

Slide 14: Role of Organizational Culture

- Promote informed decision making and prevent enthusiasm on the parts of the physician and patient:
 - Organizational resources should be committed to a collaborative effort by physicians to undertake conceptual and moral management of medical uncertainty about clinical management with low or very low levels of evidence
 - Guidelines should be developed for the informed consent process with patients
 - By collaboratively following guidelines for the informed consent process, physicians will help to prevent “gaming the system” by physicians and by patients

Slide 15: Role of Organizational Culture (2)

- Organizational leadership should support physicians in their adherence to guidelines for the informed consent process, to prevent “gaming the system” by physicians and by patients/surrogates
 - Physicians in pursuit of economic self-interest
 - Patients/surrogates in pursuit of clinical management that is not medically reasonable
- Organizational leadership should support physicians who have adhered to guidelines for the informed consent process when patients or family members complain, to prevent “gaming the system” by patients or family members

Slide 16: Policy Implication

- Adherence to such guidelines should provide presumptive defense against malpractice claims for defects of informed consent
 - Which are already rare

Slide 17: Are we Ready for Best Practices?

- There is evidence that patients can engage in scientifically sophisticated moral management of medical uncertainty
 - First-trimester risk assessment for trisomy 21 and decision making about subsequent invasive diagnosis by pregnant women¹

Slide 18: A Caution

- The expectation that an evidence-based, deliberative informed consent process with patients will produce “individuated decisions” or “personalized medicine” is misleading and this discourse should not be used
 - Evidence-based clinical judgment sorts patients into diagnostic, therapeutic, and prognostic subpopulations of a diagnosis
 - This allows for greater precision in clinical judgment and therefore in the informed consent process

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- But clinical judgment remains, always, about groups of patients
- There is no science of an individual patient and therefore no “individuated” or “personalized” clinical judgment to be reasonably expected as an outcome of informed consent process

Slide 19: Summary

- Ethical framework should be shared decision making: informed consent process as understood in professional medical ethics
 - Evidence-based offering of clinical management with low and very low levels of evidence
 - Recommendations should not be made, because of nature of low and very low levels of evidence
 - Not because making recommendations is inconsistent with respect for patient autonomy
 - Co-constructed biopsychosocially informed decisions under constraints of professional integrity and evidence-based, prudential patient’s/surrogate’s preferences
 - Trial of management: clinical ethical tool for responsibly managing uncertainty about plan of care
 - Candor-based responses to patient’s/surrogate’s preferences for clinical management
 - Preferences that do not meet test of “modicum of benefit” for medical reasonableness should not be implemented¹