Informed Consent from Theory to Practice
Conceptual, Communicative and Evaluative Challenges of an Ethical Ideal
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Rationale
- Informed consent is a universally acclaimed bioethical ideal, while empirical evidence indicates widespread failure to attain the ideal in clinical practice and in research.
- "Backward design," a curricular strategy that aligns all course materials and exercises to a final goal, could improve the capability of future clinicians/researchers to promote actualized informed consent in practice (the goal).

Description of Curriculum
ONE MODULE WITHIN AN INTEGRATED MEDICAL HUMANITIES CURRICULUM.
(A) Readings/presentations on philosophical elements of informed consent, and communicative/evaluative challenges of implementing.
(B) Visual teaching aids such as videos of informed consent processes in different contexts.
(C) Narrative teaching aids such as first-person accounts of consent process experience.
(C) Increased incorporation of informed consent challenges into PBLs and the simulation lab.
(D) Student practicum that requires execution of conceptual, communicative, and evaluative elements of informed consent.

PRACTICUM ASSIGNMENT:
For a clinical procedure or research protocol, create an informed consent tool to assist an informed consent process. The tool can be a document, or an alternative such as a pictorial tool, a video, or an e-active informed consent tool. The tool must address all conceptual elements of informed consent; must meet stringent length limitations; and must pass 8th-grade literacy-level tests. Create a short evaluation instrument to assess how well someone who goes through an informed consent process using that tool actually understood the material and choices. Pilot-test the tool and associated process, including the evaluation instrument, on one willing “lay” friend, one actual patient, or one actual research recruit.

Resources and Faculty Development
- RESOURCES:
  - Shadowing opportunities consonant with macro-curricular reform goal to integrate clinical experiences from Year 1.
  - Standardized patients.
  - Simulation lab.
  - GRIN. (Primary care research consortium—could be “win-win” to have students design, implement, and evaluate an informed consent process for a research protocol about to be executed through GRIN.)
- FACULTY DEVELOPMENT:
  - Pairing of clinical faculty with philosophically, anthropologically, or sociologically trained faculty to create forums for student practicum assignment and to create evaluation rubrics for that assignment.

Discussion
Bioethics is often characterized as a negotiation of philosophical dilemmas. However, many of the most trenchant ethical challenges in health care are not accurately characterized as dilemmas. (Dilemmas are cases in which two ethical ideals conflict.) Rather, they are “principle-practice gap” issues in which a widely endorsed ethical ideal fails to be implemented in practice. Informed consent is crucial not only because of its intrinsic ethical importance, but also because it serves as a paradigm example of such a “gap” issue—and of the need to integrate communicative sciences, organizational ethics, and bioethics in response. By requiring students to attend to that integration as they design, implement, and evaluate one specific real or hypothetical informed consent process, this curricular module encourages ongoing professional attention to challenges of execution for “gap” bioethical issues.

Curriculum Objectives
To familiarize students with conceptual elements of informed consent, communicative challenges of informed consent, and evaluative challenges of informed consent.
To explore particular challenges of informed consent in specific clinical settings, e.g., pediatrics, clinical care of partially competent patients, etc.
To consider how informed consent for research is similar to and different from informed consent for clinical medicine, with special attention to the dangers of therapeutic misconception. To engage students in real or simulated informed consent challenges that require them to execute conceptual, communicative, and evaluative products/practices.