Improving the Effectiveness of the Informed Consent Process in Elective Aesthetic Procedures

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Background: The informed consent process is a complex intersection of ethics, law, and practice. Ethical standards for informed consent instruct that it should be a process of bi-directional communication. During this process, the patient is informed of and understands the nature, risks, benefits, and alternatives of the proposed procedure; the clinician is informed of and understands the patient’s individual goals, values and preferences; with a resulting informed consent or refusal of proposed treatment(s) by the patient. 

Elective aesthetic procedures include both surgical (e.g., breast augmentation) and non-surgical (e.g., cosmetic botulinum toxin injection) medical services that aim to restore or enhance physical form to meet the aesthetic goals of the individual patient. Informed consent in this clinical environment is unique in that patients often seek consultation with preconceived expectations of desired procedure(s) and outcome.

In patients presenting for elective aesthetic procedures, miscommunication during informed consent leads to poor decisions made about treatments. These decisions are uninformed, discordant with patient goals and preferences, and are associated with decreased patient satisfaction and increased litigation. The purpose of this project is to improve the effectiveness of the informed consent process in elective aesthetic procedures. The global aim is to promote informed shared decision-making in which patients are meaningfully engaged, understand risks, benefits and alternatives of proposed treatment(s), and results in treatment decisions that align best practice with patient values.

Methods: An initial needs assessment was accomplished through review of relevant peer-reviewed publications and grey literature, informal interviews with plastic surgeons, plastic surgery residents, and patients. A critical review of the literature for best evidence for effective informed consent in the setting of elective aesthetic procedures was performed with the following search terms: informed consent, informed decision, informed decision making; procedure, surgery; shared decision making, decision quality; plastic, cosmetic, aesthetic, preference sensitive. Additional MESH terms were included as appropriate. Professional codes of ethics and legal doctrine were also reviewed. A gap analysis was conducted and included review of informed consent materials and informal interviews to assess local culture. A working casual and program theory was constructed to guide project development, implementation and future evaluation. Overarching theoretical, conceptual, and operational guidance drew from complexity science, quality improvement, and derivatives of knowledge translation theory.

Results: Deficits in the current practice of informed consent are a failure in preparation, conversation, presentation or documentation. Miscommunication occurs when there is a failure in one or more parts of the informed consent process. There is significant variability in the depth and breadth of content, presentation, and delivery of informed consent. The common practice of informed consent does not reflect ethical standards but regarded by both clinicians and patients as a legal formality of a signature on an informed consent document. Completion of some form of documentation to fulfill minimum legal requirements is universal. Malpractice concerns related to failures in informed consent are notable.
Evidence and ethics support a process of shared decision-making as being the gold standard for informed consent. When each component of this process is individually examined problems become clear and leverage points for improvement can be identified. Use of certified patient decision aids may be an effective method to ensure process reliability of informed consent execution and documentation. No patient decision aids that meet certification standards were found for use in elective aesthetic procedures.

**Discussion:** Improvement efforts should focus on replacing current informed consent documents with patient decision aids that meet certification standards as published by the International Patient Decision Aids Standards (IPDAS). We present a multiphase development process model for the creation of patient decision aids for use in elective aesthetic procedures. Specific ethical, legal, contextual, conceptual or theoretical, and operational guidance are described for each phase of the development process model.

**Conclusion:** This project seeks to narrow the gap between common practice and best practice of informed consent in elective aesthetic procedures. We present a development process model for creating a patient decision aid prototype to replace traditional informed consent documents. A pilot study is underway to determine the feasibility and acceptability of the development process model and decision aid prototype to replace informed consent documents for primary breast augmentation surgery. Potential implications for practice, research, education and policy are posited.

**Title:**
Improving the Effectiveness of the Informed Consent Process in Elective Aesthetic Procedures

**Keywords:**
Informed consent process, patient decision aid and shared decision-making

**References:**


**Abstract Summary:**
Informed consent is commonly reduced to a legal formality rather than upholding its ethical ideal of being a process of shared decision-making. We present a multiphase development process model for creating a patient decision aid prototype to replace the traditional informed consent documents for primary breast augmentation surgery.
Content Outline:

1. Introduction
   1. Informed consent is a complex intersection of ethics, law, and practice.
      1. Ethical standards
   2. Elective aesthetic procedures
      1. Define
      2. Practice of informed consent
      3. Rationale for improvement efforts

2. Methods
   1. Needs assessment
   2. Gap analysis
   3. Critical review of literature

3. Results
   1. Scope and significance of problem
      1. Deficits identified in informed consent documents
         1. Failure to acknowledge a decision is to be made
         2. Lack elements of informed consent
         3. Lack of process reliability
         4. Do not encourage or facilitate discussion of patient preferences and values
         5. Failure to incorporate decision science
         6. Not compliant with national health literacy standards
         7. Not evidence-based
      2. Perception of informed consent (culture)
         1. Providers: Legal formality; not meant to aid process of informed consent
         2. Patients: Legal formality; do not read it
      3. Lack of policy support
         1. Reasonable patient standard subject to debate
         2. Reasonable physician standard often fails to address common practice of disclosing information that is not based in evidence
            1. Inaccurate, incomplete, out-of-date
         3. A signature on an informed consent document does not constitute informed consent, nor confirms patient understanding
   2. Evidence for a solution
      1. Replace traditional informed consent documents with certified patient decision aids
         1. May reliably facilitate shared decision-making during informed consent
         2. Resolves current deficits described in informed consent documents

4. Discussion
   1. Pilot program currently underway for patient decision aid prototype for replacing primary breast augmentation informed consent documents
   2. Project protocol—development process model
      1. Ethics oversight: Emory University IRB exempt approval (IRB00105345)
      2. Phase 1: Expert consensus of procedure-specific content considered essential for informed decision-making will be achieved following a three-round Delphi process.
         1. Informed consent: Preparation and presentation
            1. Disclosure of information that is relevant, comprehensive, comprehensible and based on best available evidence
            2. Need a basic, foundational understanding to participate in shared decision-making
            3. How information is presented influences decision-making
         2. Context: Pervasiveness of misinformation; influence of digital and social media; informed consent content is highly variable
         3. Bioethics principles: Respect for autonomy, justice and nonmaleficence
1. Respect for autonomy: Informed patient choice
2. Justice:
   1. Distributive: Equal access to quality information
   2. Procedural: Fairness in process reliability
   3. Nonmaleficence: truthful, quality information that is based on the best available evidence
4. Law: Information disclosure
5. Theoretical and conceptual guidance:
   1. Core information set
   2. The Delphi technique sequence model
   3. Demonstrated use for informed consent information consensus in other specialties
6. Phase 2: Gaps in perception of information importance, preferences, and knowledge of treatment options, including associated risks and expected outcomes, will be assessed through a consumer [patient] survey: 2-cohorts: (1) had target procedure within previous 12-months, (2) considering target procedure
   1. Informed consent: Preparation and conversation
      1. Elicit patient goals, values and preferences
      2. Understanding of information
      3. Disclosure of relevant information
   2. Context: Clinician and patient opinion of best treatment option is often discordant1; unrealistic expectations
   3. Bioethics principles: Beneficence: decision quality; treatment decision aligned with patient goals, values and preferences
   4. Law: Right to self determination
   5. Theoretical and conceptual guidance:
      1. Core information set
      2. Decision science
      3. Patient-reported outcomes
6. Phase 3: Prototype patient decision aid will be developed that meets certification standards.
   1. Informed consent: Preparation, presentation, conversation and documentation
      1. Reformat the current informed consent to a model that: (1) captures patients’ existing knowledge and understanding of aesthetic concern(s) and available treatment options, (2) elicits patient’s goals and preferences, (3) allows for reconciliation of any misunderstanding of information, (4) assesses for patient comprehension of core information using “teach-back” [either in written/digital/verbal format], and (5) confirms a mutually [patient/clinician] agreed upon treatment plan
   2. Context: There is significant variability in the depth and breadth of content, presentation, and delivery of informed consent; Completion of some form of documentation to fulfill minimum legal requirements is universal.
   3. Bioethics principles: Procedural justice, respect for autonomy, nonmaleficence, beneficence
      1. Procedural justice: Fairness in process reliability
      2. Respect for autonomy: Informed patient choice
      3. Nonmaleficence and beneficence: Decision quality; meaningful involvement in decision-making
   4. Law: documentation (burden of proof)
      1. Precedent: Washington State
   5. Theoretical and conceptual guidance:
      1. International Patient Decision Aid Standards (IPDAS)
      Collaboration criteria for the certification of patient decision aids
1. IPDAS Model Development Process for Decision Aids\textsuperscript{14}
2. Framework for Informed Shared Decision-making\textsuperscript{15}
3. National Quality Forum (NQF) proposed national standards for endorsement of patient decision aids\textsuperscript{16}
4. National health literacy guidelines\textsuperscript{17,18}
5. High reliability; Human factors engineering
6. Complexity science

5. **Phase 4:** The patient decision aid prototype, as well as the process for its development, will be acceptable to both clinicians and patients
   1. **Context:** Formative
      1. If found unacceptable will not improve practice; If acceptable scale-up and spread; sustainability and effectiveness outcome evaluation future research
   2. Theoretical and conceptual guidance:
      1. Understanding-User-Context framework (derived from knowledge translation theory)

5. **Conclusions**
   1. **Implications [potential]**
      1. **Research**
         1. Formative for future research on improving informed consent
      2. **Future outlook:**
         1. Information technology: delivery of information how and when patients want to learn; real-time documentation, use of natural language processing
      3. Consideration of existing barriers, challenges and deficits in informed consent in relation to missed nursing care
         1. Environment of care; care coordination
         2. Defining the value of nursing during informed consent
            1. Nursing responsibility to protect the *process* of informed consent
      2. **Practice**
         1. Informed consent process that supports, rather than inhibits, shared decision making
         2. Clinician incentives
            1. Key opinion literature posit potential for premium discounts on professional liability insurance with demonstrated use of certified patient decision aids
            2. Increased liability protection
         3. More informed patients
            1. Increased patient satisfaction
            2. Improved decision quality
      3. **Policy**
         1. Update and revise state disclosure laws
            1. Expansion of Washington state legislation
               1. Use of certified patient decision aids as preferred alternative to traditional informed consent
                  1. Constitutes prime facie evidence of informed consent
            2. Funding for national independent certifying body for patient decision aids to ensure quality and effectiveness
               1. Affordable Care Act provisions; National Quality Forum
      4. **Education**
         1. Transdisciplinary education and research related to the informed consent process; as opposed to education and research in silos respective of home discipline-medicine, nursing, law, ethics, public health, policy
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**Professional Experience:** Terri Ades recently joined Emory University Nell Hodgson Woodruff School of Nursing after a stellar career with the American Cancer Society National Home Office. Dr. Ades was responsible for overseeing the development and maintenance of this cancer information – made available through the Society’s web site at cancer.org, their national toll-free call center, patient education/consumer awareness materials, and translations. She participated in the Society’s review and revision of their cancer prevention and early detection guidelines and was responsible for translating the guidelines into easy-to-understand consumer materials for the public. She is passionate about providing health-related information in a format and language that consumers can appreciation and understand so they can make informed decisions about their health. Over the past few years she has focused efforts on health literacy and readability and developed guidelines to use across the organization to provide easier-to-understand materials to constituents.

**Author Summary:** Dr. Ades serves as the project chair for this Doctor of Nursing Practice (DNP) scholarly project. She holds faculty positions in the Nell Hodgson Woodruff School of Nursing at Emory University as an Associate Clinical Professor and AMSN Program Director.

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