Informed Consent for Pediatric Endoscopy

Joel A. Friedlander, DO, MA-Bioethics*, David E. Brumbaugh, MD

KEYWORDS

• Informed consent • Endoscopy • Shared decision making
• Pediatric gastroenterology • Enteroscopy • Esophagogastroduodenoscopy
• Endoscopic retrograde cholangiopancreatography • Pediatrics

KEY POINTS

- Pediatric informed consent is a unique process that involves the provider, the parent/guardian, and the mature adolescent, if appropriate.
- Pediatric assent, in particular obtaining permission from an adolescent, is highly recommend for pediatric endoscopy.
- Each procedure has a general list of indications, methods, risks, benefits, and alternatives that should be discussed with the decision maker. The provider obtaining consent should evaluate a general sense of understanding from the parent/guardian, as well as from the patient, when appropriate.
- Endoscopic providers should be aware of relevant procedural risks and the specific frequencies with which each occur.

INTRODUCTION

Procedural or surgical informed consent is the process by which a practitioner obtains permission from an autonomous decision maker to allow a procedure or invasive test to be done on a patient or subject.[1] This concept is used frequently in the practice of pediatric gastroenterology as it is relates to procedures, transfusions, and transplants.

The general concept of informed consent most commonly finds its origins in ideas stemming from the Nuremberg Trials after World War II.[2] The term was greatly expanded subsequently based on laws relating to assault and battery.[1–3] The 1969 case of Canterbury v. Spence highlights the modern-day concept of informed consent and the more familiar discussion of risks, benefits, alternatives, indications, and methods. The case highlights the failure of Dr Spence to disclose the possible ramifications of back surgery and subsequent paralysis.[3] The patient was not informed of the risk of complications and

Digestive Health Institute, Children's Hospital Colorado, University of Colorado School of Medicine, 13123 E 16th Ave, B290, Aurora, CO 80045, USA
* Corresponding author.
E-mail address: joel.friedlander@childrenscolorado.org

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a lawsuit ensued. Such cases and history highlight the need for practitioners to share information with a rational, informed, and noncoerced decision maker, or else with a surrogate/proxy. This process is known as respect for autonomy.

Informed consent is part of the continual process of shared decision making that encompasses the transfer of information between practitioner and patient or patient surrogate/parents.[4,5] Informed consent is the finalization and obtaining of permission with probable documentation of the process that leads to a procedure or test. This consent process accompanies the right of that individual to make an informed refusal. Pediatric assent, a unique component to the care of children, is the process by which a consent modality is applied to an adolescent decision maker.[6]

In contrast, variations to this process in an emergent setting allow for deviations from this routine. One such an example is a life-threatening gastrointestinal bleeding event in which the family was not available. Because of the uniqueness of the pediatric setting and the legal interest of protecting children, formal consent is not always needed in emergency circumstances.[3]

Components of Informed Consent

There are several necessary components to informed consent (**Box 1**). Some of these are implicit or assumed in routine interactions between the provider and family, whereas others must be specifically transferred as information. Assumed components of the informed consent process include assessment of the decision-making capacity of the decision maker, as well as their voluntariness. Decision-making capacity is the ability to understand and process information and come to a decision. Voluntariness is the understanding of a decision maker that they are intended to make a decision that is free from pressure or coercion by the provider. Both assessments are informal and rarely documented.[1] These issues are not as problematic in pediatrics because of the presence of parental proxies, but can play a role in older adolescents or parents

Box 1
Components of pediatric informed consent

Preconditions: provider assessed:

1. Competence: decision-making capacity
2. Voluntariness: free from coercion, pressure

Information elements: provider disclosed:

1. Disclosure
   a. Indications
   b. Methods
   c. Risks
   d. Benefits
   e. Alternatives
2. Recommendation
3. Understanding

Consent achieved

1. Decision by parent/adolescent
2. Authorization/documentation

Form Beauchamp TL, Childress JF. Principles of biomedical ethics. New York: Oxford University Press, 2009.