PROBLEMS RELATED TO INFORMED CONSENT

The duty of healthcare providers to provide comprehensive information to patients regarding the material risks, benefits, side effects, and alternatives to surgical and some medical procedures is firmly established and well known among the members of the healthcare community. Act 13 of 2002, which established the Patient Safety Authority, also details the procedures for which informed consent is required (see Section 504). Yet, confusion still remains over what constitutes proper disclosure to patients and when this information must be disclosed.

During the test phase of PA-PSRS, we reviewed a sample of reports of inadequate or missing informed consent. Contrary to what one might expect, less than one-third of the reports indicated emergency situations or other circumstances where obtaining consent might be particularly difficult.

After excluding these emergency or otherwise problematic cases, the most commonly reported problem involved cases where patients received several procedures during the same episode of care and consented to some procedures but not others. For example, a patient who had consented to cystoscopy, possible transurethral resection of the prostate, and possible biopsy also underwent placement of bilateral ureteral catheters to which he had not consented.

A second type of problem occurs during a procedure when a need for additional, unconsented procedures becomes apparent and consent cannot be readily obtained—such as during surgery when a patient is already anesthetized. In one case reported to PA-PSRS, a patient who had consented only to a total vaginal hysterectomy also had a fallopian tube and ovary removed that were adhered to the uterus. Another report concerned a patient who had consented to a ventral hernia repair but also had a loose tooth removed due to risk of aspiration while under anesthesia. The surgery team obtained a dental consult before deciding to remove the tooth, but there was no consent for the tooth extraction.

Several reports address cases in which patients received a procedure different from that to which they consented. In one case, a patient underwent insertion of a different brand of catheter for hemodialysis access than that to which he had consented. In another case, a patient consented to placement of a left-side catheter but received bilateral catheters.

In limited circumstances, a physician may be justified in carrying out a different procedure from that which the patient authorized. However, these usually are medical emergencies and unanticipated events (such as during surgery) that necessitate immediate action to avoid endangering the life or health of the patient.

While Pennsylvania law regarding informed consent is unique in many respects, and literature addressing a physician’s obligations under other states’ laws may be inapplicable, the accompanying resources may be useful in reviewing or revising policies and procedures or in staff or patient education related to informed consent.

Available Resources

American Academy of Pediatrics—141 Northwest Point Blvd, PO Box 927, Elk Grove Village, IL 60009-0927, Phone (847) 228-5005, Fax (847) 228-5005, Web site www.aap.org, E-mail kidsdocs@aap.org

Consent by proxy for nonurgent pediatric care, Committee on Medical Liability Pediatrics 2003 Nov; 112(5):1186-95

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Available Resources (continued)

  
- American Association of Nurse Anesthetists—222 S Prospect Ave, Park Ridge, IL 60068-4001, Phone (847) 692-7050, Fax (847) 692-6968, Web site www.aana.com, E-mail info@aana.com.
  
  - Informed consent in anesthesia, 1991; Catalog: 1012 Price: $ 5.00

  
  - Informed consent, Price: N/C

- American College of Radiology—1891 Preston White Dr, Reston, VA 20191, Phone (703) 648-8900, Fax (703) 648-9176, Web site www.acr.org, E-mail info@acr.org.
  
  - Informed consent, 1987 (renewed 1997); Price: N/C single copy; $100.00/set
  
  - ACR practice guideline on informed consent for image-guided procedures, 2001; Price: Book $160.00; CD $40.00

- American College of Surgeons—633 N Saint Clair St, 27th Floor, Chicago, IL 60611-3211, Phone (312) 202-5000, Fax (312) 202-5001, Web site www.facs.org, E-mail postmaster@facs.org.
  

  
  - Informed consent, 1981; Price: N/C
  
  - Substitution of surgeon without patient’s knowledge or consent, revised 1994; Price: N/C

- American Psychiatric Association—1000 Wilson Blvd, Suite 1825, Arlington, VA 22209-3901, Phone (703) 907-7322 (800) 368-5777, Fax (703) 907-1091, Web site www.psych.org, E-mail apa@psych.org.
  
  - Consent to voluntary hospitalization, 1992; Price: N/C

- American Society for Gastrointestinal Endoscopy—36 W 44th St, Suite 630, New York, NY 10036, Phone (212) 921-0500, Fax (212) 921-0011, Web site www.surgery.org, E-mail media@surgery.org.
  

- American Society for Reproductive Medicine—1209 Montgomery Hwy, Birmingham, AL 35216-2809, Phone (205) 978-5000, Fax (205) 978-5005, Web site www.asrm.org, E-mail asrm@asrm.org Elements to be considered in obtaining informed consent for ART, 1998 Jan.

- AVSC International—440 Ninth Ave, New York, NY 10001, Phone (212) 561-8000, Fax (212) 561-8067, Web site www.avsc.org, E-mail info@avsc.org.
  
  - Informed consent and voluntary sterilization: An implementation guide for program managers, 1988; Catalog: IC-01 Price: $ 5.00

Notes

ECRI is an independent, nonprofit health services research agency dedicated to improving the safety, efficacy and cost-effectiveness of healthcare. ECRI's focus is healthcare technology, healthcare risk and quality management and healthcare environmental management. ECRI provides information services and technical assistance to more than 5,000 hospitals, healthcare organizations, ministries of health, government and planning agencies, and other organizations worldwide.

The Institute for Safe Medication Practices (ISMP) is an independent, nonprofit organization dedicated solely to medication error prevention and safe medication use. ISMP provides recommendations for the safe use of medications to the healthcare community including healthcare professionals, government agencies, accrediting organizations, and consumers. ISMP's efforts are built on a non-punitive approach and systems-based solutions.