International Journal of Gynecology and Obstetrics xxx (2014) xxx–xxx

Contents lists available at ScienceDirect

International Journal of Gynecology and Obstetrics

journal homepage: www.elsevier.com/locate/ijgo

www.figo.org

ETHICAL AND LEGAL ISSUES IN REPRODUCTIVE HEALTH

Types of consent in reproductive health care

Bernard M. Dickens *, Rebecca J. Cook

Faculty of Law, Faculty of Medicine and Joint Centre for Bioethics, University of Toronto, Toronto, Canada

ARTICLE INFO

Keywords:
Consent
Evidence of consent
Free consent
Implied consent
Informed consent
Presumed consent
Unlawful consent

ABSTRACT

Healthcare providers require prior consent to treat patients. Consent can be different for legal purposes, and be expressed in different ways. Simple consent affords providers protection from liability for assault, but negligence can arise if the consent is inadequately informed. Providers cannot coerce or improperly induce consent; patients' agreement that a provider wrongly influences is compliance, not true consent. Attempts to rescue patients in peril may be lawful on the presumption of their implied consent, unless patients negate the presumption. In special cases, laws may require that consent be written, but generally consent can be given by speech or conduct. Informed consent depends on patients' comprehension, but consent for treatment of uncomprehending patients may come from third parties, including legally recognized substitutes or judges. There may be legal limits to reproductive procedures to which patients may consent, under laws that can be respectfully tested, but have to be obeyed.

1. Introduction

Consent is usually considered ethically and legally indispensable for administration of reproductive health care, but there is a spectrum of types of consent. This article addresses consent only regarding therapeutic care of intellectually competent adults. Adolescent consent requires separate attention in general [1] and for reproductive health care in particular [2], and consent for therapeutic and nontherapeutic research on humans has generated a vast literature in books and journals [3]. Similarly, treatment of those incapable of providing and refusing consent for themselves has raised a volume of approaches at national [4] and international levels [5].

Types of consent to therapeutic reproductive health care are simple or bare consent, informed consent, freely given consent, implied consent, express or written consent, evidenced consent, comprehended consent, substitute consent, and unlawful consent.

2. (Simple) consent

Touching individuals without consent is in principle an assault in civil (noncriminal) law and possibly criminal law. Individuals often consent to assume the risk of being ordinarily touched, such as by voluntarily entering crowded transport vehicles (see implied consent below), but medical or health-related touching is more specific. Consent to touching negates assault under certain conditions. Consent must be to the types of treatments to which individuals intend to give their consent, such as to surgery on the infected fallopian tube but not on the healthy one; operating by error on the wrong tube can be both negligent and an assault. When a man poked holes in a condom in order to impregnate his partner, who allowed sex only on the condition that he used a condom, the Supreme Court of Canada unanimously upheld his conviction for sexual assault—the majority of the judges because her consent was induced by fraud, the minority because she gave no consent at all to intercourse that carried the risk of the pregnancy that resulted [6].

Consent is directed to the nature and quality of the proposed touching. Actors assume the natural risks of their voluntary conduct, for instance that contraceptive means such as condoms may fail, and that unprotected sexual intercourse carries the risk of suffering or causing pregnancy, and transmission of venereal infections. The latter risk can be reduced when prospective sexual partners are asked whether they are infected, and give honest answers. Prospective partners cannot escape liability for assault, including criminal sexual assault, by avoiding being tested, for instance for sexually transmitted infections (STIs) including HIV, because if they know or reasonably should know from their behavior of their exposure to infection, they will legally be deemed to know if in fact they are infected. The legal principle is that "willful blindness is implied knowledge," meaning that if individuals deliberately avoid learning the truth, knowledge of that truth is ascribed to them.

3. Informed consent

Assault is a form of medical malpractice often justifying only nominal or token damages, while serious assault tends to be pursued as a crime resulting on conviction in the assailant's punishment. Lawyers, initially in the USA [7], persuaded courts to enlarge consent into

* Corresponding author at: Faculty of Law, University of Toronto, 84 Queen's Park, Toronto, Ontario, Canada, M5S 2C5. Tel.: +1 416 978 4949; fax: +1 416 978 7899.
E-mail address: bernard.dickens@utoronto.ca (B.M. Dickens).

http://dx.doi.org/10.1016/j.ijgo.2014.11.001
0020-7292/

informed consent, so that liability for failure of consent also results in liability for negligence. This form of medical malpractice is more difficult to establish than simple or common assault, but liability for negligence can result in considerably higher awards of damages. While simple consent negates liability for assault, lack of informed consent exposes healthcare providers and their insurers to significant financial liability for negligence.

Negligence law requires proof of a legal duty of care, of breach of that duty, which often means that the defendant failed to meet the required standard of care, and that the breach of duty caused injury or damage. Healthcare providers can usually be shown to owe a legal duty of care to persons who have become their patients, but legal systems vary on whether a legal duty of care is owed to others such as patients' unborn children while in utero. Children born alive may have claims for prenatal negligence causing them injury once born, but if negligence causes stillbirth the only recognized injury may be to the woman and perhaps her partner, except in some US states that allow lawsuits on behalf of viable fetuses. Similarly, there may be less chance of liability if the negligence arose before a child's conception, such as in the transfer to an IVF patient of a grossly impaired embryo [8].

When a legal duty of care exists, information must be provided of care options. The purpose of informing is not to persuade the patient to consent, but to serve the patient's choice or autonomy [9], allowing choice to decide according to the patient's own assessment of competing interests and values [10]. The patient's decision, whether to consent to a recommended or alternative treatment or not, requires disclosure of the healthcare provider's diagnosis of the patient's condition, and:

1. the prognosis if the patient remains untreated;
2. alternative goals of treatment, and reasonably accessible alternative treatment methods to pursue such goals;
3. success and failure rates of different methods of treatment;
4. known effects, material risks, discomforts and incidental effects of different methods of treatment and the likelihood of occurrence, even when treatment is successfully undertaken;
5. the limits of relevant knowledge and the areas in which it appears that more needs to be learned;
6. the patient's means of asking (further) questions;
7. matters concerning which the patient specifically enquires; and
8. the healthcare provider's recommendation about whether, and if so which, treatment should be undertaken.

Medical literature sometimes refers to patients who agree to treatment having to give "fully informed consent." The criteria of "fullness" are not drawn from medical science, however, but from ethics and particularly relevant law. A better expression is "adequately informed consent," meaning adequate for satisfaction of the patient's need to know, with a focus on accessible options and material risks of which a reasonable person in the patient's circumstances would want to know. For instance, a young woman who is married or anticipating marriage would have to be informed how a proposed treatment would affect her childbearing, while this would be less material to a woman who considers her family complete or who is of postmenopausal age. Care and judgment are required, however, to protect particularly impressionable patients against disclosures that may inadvertently induce the adverse effects of which the disclosures warn—the so-called "nocebo" effect that counteracts any placebo effect [11].

When a risk is adequately disclosed, a patient who gives informed consent to accept it has no legal claim against the healthcare provider if the risked injury or loss of opportunity occurs. However, if patients can show that, had treatment risks been disclosed to them they would not have consented to the treatment, healthcare providers who failed to make such disclosures will bear legal liability for causing patients to be subject to those risks, including the irreducible minimum non-negligent risks that are inherent in the procedures. Accordingly, proper disclosure of risks protects patients' choices, and providers and their insurers from legal liability for negligent non-disclosure.

This article addresses only therapeutic treatments, not nontherapeutic such as research interventions; however, those who agree to nontherapeutic procedures may be treated as patients if invasive interventions are proposed [12].

4. Freely given consent

There is unresolved controversy among philosophers, psychologists, sociologists, and others regarding whether humans, being social creatures, are capable of free will, or whether their actions and motivations are determined or pre-conditioned by the social, psychological, familial, educational, religious, and other influences that have shaped them to become the individuals they are. Healthcare providers are not called upon to resolve or even to enter the free will versus determinism debate. They are required to respect their patient's rights to choice whether or not to consent to proposed treatment, however, by not themselves applying coercion or undue pressure, influence, or inducement regarding their patients' decisions on whether to consent to treatments.

Improper influence can arise for instance from providers exaggerating the likely benefits of proposed treatments, and/or from minimizing the chance of them being ineffective, or the risks to health and other interests they present. An appearance of improper influence may be created when healthcare providers have conflicts of interest in proposing treatments or choice of products, such as recommending and then undertaking genital cosmetic surgery, or collaborating with manufacturers in product promotion [13].

Providers should also take reasonable measures to preserve their patients' independent choices when family members attempt assertively to superimpose their preferences. Beyond maintaining ordinary confidentiality, providers may have to exclude third parties such as husbands, parents, and in-laws when counseling and advising patients, and correct any distortions or misperceptions that third parties introduce into joint discussions with patients. There is no duty, however, to isolate patients from the domestic environments in which they live, or to redress patients' willingness to defer to the preferences of others to whom they are close. Patients' free consent in essence means free from undue persuasion or pressure from providers.

5. Implied consent

Individuals' submission to medical or health-related interventions is different from the jostling to which they submit by voluntarily entering crowded areas. On the principle that "peril invites rescue," individuals are presumed to consent to others' efforts made in good faith to save them from harm. In many if not all legal systems, so-called Good Samaritan legislation or their general law provides legal immunity from liability for assault for those altruistically volunteering to assist others in danger or distress, and even from liability for negligence unless they intervene recklessly or with gross negligence. For instance, to slap a choking person on the back, or undertake the Heimlich maneuver, to dislodge an object from the person's windpipe, has the person's implied consent when it is reasonable to perceive that the person is actually choking.

An obstetric variant of presumed consent arises when severe complications suddenly occur in what began as routine childbirth, and preservation of the sedated woman's life or health, and/or survival and well-being of the fetus, show that an emergency cesarean delivery is indicated. In prior discussions, women may have indicated a strong preference for natural delivery, and perhaps rejected an option for episiotomy, but if it appears to the attending service providers that the survival of the women and/or their fetuses, and the well-being of both, require such interventions, they may be undertaken on the presumption that the women would favor them over the loss of their lives and/or loss of their fetuses, and over their subsequent severe impairment.

A limitation of implied consent is that the intervention must be necessary, not merely convenient. The law regarding medical necessity

Please cite this article as: Dickens BM, Cook RJ, Types of consent in reproductive health care, Int J Gynecol Obstet (2014), http://dx.doi.org/10.1016/j.ijgo.2014.11.001