INFORMED CONSENT: GENERAL CONCEPTS AND APPLICATION TO MALE INFANT CIRCUMCISION

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Introduction and Basic Concepts

In simple terms, the concept of informed consent refers to the competent patient’s right to voluntarily give (or withhold) consent for medical treatment based on adequate disclosure of relevant information (Meisel & Roth, 1981). The italicized terms in the above definition are the three main elements that contribute to the valid execution of the practice of informed consent (Svoboda et al., 2000). Competence refers to the patient’s capacities to “comprehend and process information and to reason about the consequences of one’s actions” (Beauchamp & Childress, 2009, p. 114). Voluntariness refers to the patient’s ability to “make health care choices free from manipulation or undue influence” (Svoboda et al., 2000, p. 71). Disclosure refers to the provision to the patient of all information material to his or her decision-making about whether to undergo a proposed treatment or procedure (Svoboda et al., 2000). Because of the importance that consent be based on the patient having adequate information with which to weigh the risks and benefits of various treatment alternatives, disclosure, i.e. information-giving, is often the primary feature of consent communication in the clinical setting. The goals of the practice of informed consent are, ethically, to enact respect for the autonomy of the individual who is a patient by protecting his or her rights to bodily integrity and self-determination; and practically, to involve the

1 Understanding is a fourth element often included in discussions of the concept of informed consent (Beauchamp & Childress, 2009). However, understanding can also be conceived of as being subsumed within the elements of information-giving and competence. It will not be discussed separately here.
A Brief Legal History of Informed Consent

Beginning in the early 20th century, litigation in cases relating to medical consent laid the foundation for the modern legal doctrine of informed consent. One of the most influential early cases was Schloendorff v Society of New York Hospital, decided in 1914 by Justice Cardozo. While the plaintiff had given permission for an abdominal examination under anesthesia, she had specifically requested “no operation”; the surgeon, however, did indeed remove a fibroid tumor while the patient was under
anesthesia. This case illustrates the significance of what is called “simple consent,” that is, the simple giving (or in this case, withholding) of permission for a physician to proceed with a treatment or procedure, without specific reference to the decider’s informational base. Simple consent is intended most directly to protect a patient’s right to bodily integrity, by requiring the physician to obtain the patient’s permission, for example, to invade or remove some part of his body. However, Cardozo’s opinion extended beyond the simple principle of the right to bodily integrity, having since been characterized as “a classic statement of the patient’s right to self-determination” (Faden & Beauchamp, 1986, p. 123). His opinion that “every human being of adult years and sound mind has a right to determine what shall be done with his own body” (Schloendorff v. Society of New York Hospital, 1914) continues to be referred to as a foundational principle of informed consent.

The first use of the term “informed consent” came in 1957 with the Salgo v Leland Stanford Jr. University Board of Trustees case. After an invasive diagnostic procedure, the plaintiff suffered permanent paralysis, the risk of which his physician had not informed him at the time he consented to the procedure. The court rendered the opinion that physicians had the duty not just to obtain simple consent, but had the affirmative duty to disclose “any facts that are necessary to form the basis of an intelligent consent by the patient to the proposed treatment” (Salgo v. Leland Stanford Jr. Univ. Bd. of Trustees, 1957) – in other words, the consent must also be “informed”. It was in the Salgo case that informational issues raised in previous isolated consent cases were consolidated into a cohesive statement of the significance of information-giving for the purposes of consent. According to Faden and Beauchamp, from Salgo on,

all pertinent topics of consent – the nature, consequences, harms, benefits, risks, and alternatives of a proffered treatment – were therefore conceived as information needed by patients in order that they know what they are choosing (1986, p. 126, emphasis in original).

In the decades surrounding the Salgo case, other social and legal developments coalesced to add form and force to the developing concept of informed consent, within the context of a surge of interest in a new approach to biomedical ethics that moved beyond the purely beneficence-based paternalism that had long held sway in medicine (Faden & Beauchamp, 1986). For example, the Nuremberg trials, which passed judgment on the abusive “medical” experiments conducted by Nazi physicians on concentration
camp detainees during the Second World War, led to the publication in 1947 of the Nuremberg Code, the first broadly accepted legal statement of the principles of ethical medical research. Among the key points found in the Code was the insistence that “the voluntary consent of the human subject is absolutely essential.” The element of voluntariness has since become a key element in informed consent in clinical as well as research settings. Along with the Nazi abuses, medical research abuses in the United States such as the Tuskegee syphilis experiment – divulged to the public in 1972 – fueled a trend toward mistrust of the medical profession and concern for protecting the rights of both research subjects and patients. The emergence of the civil rights, women’s rights, and other rights movements in the 1960s and 1970s further created an environment in which health-based rights also began to be demanded by consumers. One response to this was the publication in 1973 of the American Hospital Association’s “Patient’s Bill of Rights,” which included sections confirming the patient’s rights to information and participation in medical decision-making. By 1981, the American Medical Association had produced its first statement affirming the central importance of informed consent in medical practice, which made clear, among other points, the patient’s need for and autonomy-based right to “enough information to enable intelligent choice” (Judicial Council of the American Medical Association (AMA), 1984, cited in Faden & Beauchamp, 1986, p. 96). Around the same time, the specially established President’s Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research (1983) produced a series of reports, one of which dealt specifically with informed consent. This report affirmed that informed consent was not just a set of legal rules, but that its requirements were morally based, with the principle of self-determination described by Faden & Beauchamp (1986) as “the ‘bedrock’ of the Commission’s viewpoint” (p. 97).

The Ethical Underpinnings of Informed Consent

Before continuing to discuss the elements of informed consent doctrine in greater detail, the key ethical principles that underlie its practice will be reviewed here. The law and moral philosophy are the two distinct yet overlapping – and at times imperfectly related – conceptual streams out of which flow the current understanding and practice of informed consent. Moral philosophy not only defines the principles
by which the legal doctrine is justified, it serves as an extra-legal standard for ethical clinical practice where legal doctrine alone proves too fragmented or restrictive to truly support the rights of the patient.

The ethical principle most universally accepted as the justification for “informed consent” is that of respect for autonomy\(^2\) (J. W. Berg et al., 2001; Faden & Beauchamp, 1986). Rooted in the Western philosophical traditions of John Stuart Mill and Immanuel Kant, respect for autonomy as an ethical principle refers to the promotion of self-rule free from external constraints or internal limitations (Beauchamp & Childress, 2009; J. W. Berg et al., 2001). Kant (1724-1804) argued that respect for autonomy stems from an acknowledgment of the intrinsic value and self-determining dignity of the individual. Mill (1806-1873) argued for the importance of personal liberty in the seeking of one’s own good according to one’s own convictions. According to Beauchamp and Childress (2009), “to respect autonomous agents is to acknowledge their right to hold views, to make choices, and to take actions based on their personal values and beliefs” (p. 103). In the case of medical decision-making, the principle of respect for autonomy enjoins health professionals not only to refrain from subjecting patients to controlling constraints, but also to actively foster patients’ capacity for autonomous action, for example, through disclosure of information and removing barriers to understanding.

In medical ethics, the principle of respect for autonomy is weighed in balance with the principle of beneficence, the goal of which is the promotion of personal well-being. Indeed, however, the two are intimately entwined in medical decision-making via the assumption that “competent individuals are better judges of their own good than are others” (Buchanan & Brock, 1990, p. 29). It is this melding of the principles of autonomy and beneficence that underlies the steadfast deference to the self-determining choices of competent adults in many legal contexts, including situations involving medical consent. In addition, informed consent is sometimes justified by the consequentialist argument that autonomous participation in medical decision-making may actually lead to greater patient well-being through, for example, increased compliance or improved physician-patient relationships (J. W. Berg et al., 2001). On

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\(^2\) Biomedical ethics are usually analyzed in terms of four principles: beneficence, non-maleficence, autonomy, and justice. This discussion of informed consent is based primarily on the principles of autonomy and beneficence. Non-maleficence refers to the ethical obligation to avoid doing harm to patients. Justice most often refers to the ethical obligation to distribute healthcare resources fairly. (Beauchamp & Childress, 2009)
the other hand, the principle of beneficence can sometimes come into conflict with autonomy in the sense that patients may make medical decisions that might cause them harm or that are objectively not in their best interests. Faden and Beauchamp (1986), however, argue for autonomy as a *prima facie* principle in the case of informed consent for competent adults, demanding a heavy burden of proof upon those who would seek to intervene in another’s freedom of choice.

One further ethical and legal dimension of informed consent is the role of the physician as fiduciary. The ethical concept of the fiduciary role is concerned with the fact that physicians are more professionally knowledgeable – and therefore more powerful – than the patients who seek their assistance. This power imbalance in turn defines the fiduciary obligation of the physician, that is, the obligation to act, when exercising one’s professional power, so as to put the best interests of the patient as one’s highest priority (Faden & Beauchamp, 1986). McCullough et al. (1998b) assert that “the concept of acting as moral fiduciary of the patient is central to virtually all of surgical ethics” (p. 5), noting especially the potential in surgery for financial conflict of interest.

*The Elements of Informed Consent*

Three key prerequisites, necessary to protect the patient’s autonomy, underlie the valid execution of informed consent. As previously mentioned, these are that: 1) the patient must have an adequate informational base upon which to make the decision, 2) the patient must be allowed to make the decision voluntarily, and 3) the patient must be competent to make the decision. A deeper understanding of each of these is needed to appreciate the importance of the proper execution of informed consent in the case of neonatal circumcision.

*Information-giving*

While the concept of informed consent was born out of litigation in cases of intentional or negligent failure to disclose information to patients, Beauchamp and Childress (2009) note that “from the
moral viewpoint, informed consent has less to do with liability of professionals as agents of disclosure and more to do with the autonomous choices of patients and subjects” (p. 121). However, they state, disclosure still plays “a pivotal role” in informed consent (p. 121). In terms of communication between physician and patient in the clinical context, adequate disclosure of relevant information is crucial to patients’ autonomous decision-making. Lay persons who are patients do not have the specialized scientific and technical knowledge of health professionals. They cannot be expected, for example, to have prior knowledge of the anatomy or physiology associated with their disease process, the details of how a given surgery or medication might affect a person over the short- or long-term, nor the uncertainties in the state of the medical evidence on their health concern. Yet, when a treatment is proposed, knowledge of these and other facts may be very necessary for appreciating the implications of what they are being asked to agree to. While an abbreviated medical education is not required, patients do require sufficient explanation, in terms that they can understand, to help them have an adequate understanding of essentially “what is at stake” (Canterbury v Spence, 1972), both cognitively and in terms of their personal values. Physicians, on the other hand, are the party expected to be in possession of the technical, scientific, and experiential knowledge relevant to patient decision-making. Because of this, and out of their duty as fiduciary to promote the best interests of their patients, physicians have the ethical obligation to provide patients the information needed to support meaningful, rational, and autonomous decision-making, an obligation enacted through legally defined disclosure requirements.

It is important to note that, while physicians do have a duty to disclose information material to the patient’s decision-making process, patients may also legitimately inform themselves for the purposes of consent according to other sources to which they have been exposed. For example, some patients may seek information on their problem independently, or may apply the advice of family, friends, or health educators to their decision-making. Informational handouts too are part of the body of information that ultimately may contribute to a patient being informed enough to give valid consent. Nonetheless, as the party ultimately responsible for assuring that a patient’s consent is adequately informed, physicians are expected to assess the patient’s pre-existing level of understanding, and correct any misinformation,
misconceptions, or false beliefs under which the patient may be operating, as part of the disclosure element of the informed consent process (McCullough et al., 1998a).

The courts have employed several standards to legally define what information should be disclosed to patients. The professional practice standard and the reasonable patient standard are the most commonly used in legal cases, although a subjective standard has on occasion been applied in the courts, and several states have adopted hybrid standards. The following review of these standards casts light on what the ideal approach to information-giving might be, and why.

According to the professional practice standard, the customary practices of the professional’s community are used to determine the adequacy of disclosure, as defined by an expert witness (Beauchamp & Childress, 2009; J. W. Berg et al., 2001). This was the standard initially employed in the early years after the Salgo case, and continues as the legal standard in roughly half of the states today (King & Moulton, 2006). The professional practice standard has been criticized on several grounds (Beauchamp & Childress, 2009; J. W. Berg et al., 2001; Faden & Beauchamp, 1986; King & Moulton, 2006). First, not all physicians are indeed in agreement on a standard of care for treatment and information disclosure. Second, “if custom alone were conclusive, pervasive negligence could be perpetuated with impunity” (Beauchamp & Childress, 2009, p. 122). Third, physicians are not in a position to make the values-based judgments necessary for weighing treatment options. These are judgments that should properly be based the individual patient’s own life goals and preferences. This feeds into the fourth and most fundamental criticism, that the professional practice standard undermines the patient’s right of autonomous choice, the very principle that informed consent is intended to protect.

In response to these problems, the reasonable person standard (or so-called objective standard) for informational disclosure was developed based on what information would be judged material to the decision-making of a hypothetical reasonable patient, as defined by a jury. This patient-oriented standard was first expressed in the landmark Canterbury v Spence opinion rendered in 1972, and is used today in about half the states (King & Moulton, 2006). While such a standard improves upon the professional standard by making the patient the point of reference, this standard has its own problems (Beauchamp & Childress, 2009; J. W. Berg et al., 2001; Faden & Beauchamp, 1986; King & Moulton, 2006). First, there
is no agreement on what the reasonable patient would consider material in making a decision. What might not matter to one patient in making a medical decision might be very important to another. Because this standard is embodied by the norms subscribed to by the deciding jury, it has its limitations in supporting the informational needs of individual patients, which may be driven by atypical values or circumstances. Also, medical decisions impact not just physical health outcomes, but affect important quality of life issues as well, such as employment and financial status, sexuality, physical appearance, mental function, or valued activities such as hobbies. These quality of life issues may understandably be evaluated in highly individualized ways by different persons. A second problem with the reasonable person standard is that its “abstract and hypothetical character makes it difficult for [physicians] to use because they have to project what a reasonable patient would need to know” (Beauchamp & Childress, 2009, p. 123), a situation made all the more difficult when decisions are complex and involve quality of life concerns (King & Moulton, 2006).

The subjective standard is an attempt to tailor disclosure to assure the decision-making rights of persons as unique individuals. It judges the adequacy of disclosure by referring to the specific informational needs of the particular patient, in as much as a physician can reasonably be expected to know them. This standard has been applied by only a few courts and legislatures out of concern that it would be even harder to implement in practice than the reasonable person standard, and that it would be a difficult standard to apply in court, where it would be subject to hindsight abuse by disgruntled patient-plaintiffs (J. W. Berg et al., 2001). However, several commentators have argued that “the subjective standard is the preferable moral standard of disclosure, because it alone meets persons’ specific informational needs” (Beauchamp & Childress, 2009, p. 124, emphasis in original) and, as such, in practice, “should represent the ultimate goal of an informed consent system” (King & Moulton, 2006, p. 445).

Materiality
The concept of “materiality” is inherent in the legal standards of disclosure and requires some additional exploration. Materiality as a criterion for disclosure is generally understood to mean whether a person would deem a particular piece of information “worthy of consideration” in the process of deliberation about treatment options (Faden & Beauchamp, 1986, p. 303). According to Faden and Beauchamp (1986), core disclosure should cover both facts that are deemed material by the professional as well as facts that are subjectively material to the patient. While materiality is often interpreted in the courts via the legal concept of “decision-causation”\(^3\) (J. W. Berg et al., 2001), Faden and Beauchamp argue that materiality does not necessarily have to refer to just information that would make a concrete difference in the patient’s decision outcome.

Various medical and legal commentators have expanded upon the concept of materiality, some from the point of view of how a practitioner may protect himself from litigation, others from the point of view of the patient’s needs and rights. Nixdorf (1990) writing in the context of chiropractic care, defines materiality according to the objective gravity of the potential consequences of treatment, however infrequent. He also states that risks that are probable, special, unusual, or relevant to the patient’s specific circumstances must be disclosed. Dickens and Cook (2004) assert that what a prudent person would consider a material risk is affected by the risk’s likelihood and severity. Importantly, they also affirm that the criteria for what constitutes materiality entail a broader definition of health that transcends the physical or purely biomedical dimensions to include psychological, sexual, social, and economic aspects of well-being. These are, again, the quality of life factors that may be affected by treatments or procedures, which patients should be able to knowledgeably weigh when making medical decisions. McCullough et al. (1998a) describe material information in terms of what the lay patient would be unlikely to know from daily life, but which would be needed for medical decision-making. Svoboda et al. (2000) argue that a physician has a duty to disclose all information that he or she knows – or should know – would be regarded as material by a reasonable person, which implies a duty of physicians to keep up to date with the relevant literature. Kettle (2003) states that physicians have a duty to disclose areas of

\(^3\)“Decision-causation refers to the nexus between the physician’s failure to disclose and the decision made by the patient. When it can be said that if the physician had made proper disclosure, the patient would have made a different choice, decision-causation exists” (J. W. Berg et al., 2001, p. 138).
uncertainty in the scientific evidence regarding a given treatment. Gert (2002) argues for the moral (i.e. extra-legal) obligation to disclose based on what she calls the “Principle of Avoiding Surprises,” out of respect for the dignity of the patient, even if the information might not make a difference in the patient’s decision. According to this approach, “patients should receive enough information that they will not be surprised by whatever happens – unless the physician is also surprised” (p. 23).

The specific categories of information legally expected to be disclosed usually include the nature of the proposed procedure, and its risks and benefits, plus similar information about any medically reasonable alternatives to the given procedure (J. W. Berg et al., 2001). While it is understood that the physician need not educate the patient about every detail of applicable medical concepts (McCullough et al., 1998a), it is clear, however, from the above discussion of materiality that a wide-ranging exposition of information and considerations may legitimately be needed or desired by the person who is put in the position of having to make a significant medical decision.

As part of the valid execution of informed consent, physicians are legally expected to provide patients with information about any medically acceptable and reasonably available treatment alternatives for addressing the patient’s health problem, including the option of doing nothing (J. W. Berg et al., 2001; Wear, 1998). For each therapeutic option, the same spectrum of information should be disclosed, so that the patient has enough information about the nature of each approach, and its relative merits and disadvantages, to make a valid comparison. Informing the patient about alternatives in this way allows him to make decisions by weighing the potential implications of each – both medically and in terms of quality of life issues – according to his personal values, risk-tolerance, preferences, life goals, etc.
McCullough et al. (1998b) note that, as a general principle of surgery, offering only one alternative in non-emergency cases is, flatly, an ethically flawed approach.

The term “alternative” implies the existence of a primary physician-recommended treatment. Certainly, in some cases, only one medically reasonable course of care may seem to exist, as when the evidence of efficacy is overwhelming. Still, at least in theory, the alternative of doing nothing always exists and, if time allows (i.e. in a non-emergency situation), the patient should always be informed of the prognosis with no treatment. As one court’s opinion put it,

How can a patient give an informed consent to treatment for a condition if the patient is not informed that the condition might resolve itself without any treatment at all? (Cited in J. W. Berg et al., 2001, p. 59)

At the very least, discussing the option of doing nothing provides a backdrop against which the patient can gain perspective on the relative necessity or value of the one offered therapeutic option.

On the other hand, valid treatment alternatives do exist for many medical situations, for example, surgical versus medical treatment, less invasive versus more invasive procedures, or different drug regimens. Such alternatives may have different profiles in terms of differing short- and long-term outcomes, differing types of side effects, risks, and complications, differing effects on quality of life outcomes, and other dimensions. It has been estimated that about 30-35% of medical decision-making involves a valid choice between at least two treatments with differing balances of outcomes and risks, including, sometimes, situations in which there is scientific uncertainty about treatment effects (King & Moulton, 2006). This type of medical circumstance has come to be known as “preference-sensitive” care, because a clear scientific indication of the proper course to pursue is lacking, and therefore decisions are best made according to the well-informed preferences of the patient (Center for the Evaluative Clinical Sciences, 2007). In such cases, the patient’s subjective judgment of the various factors is what ultimately matters most, because it is his body and his life that will be affected by the decision. However, the weighing of the medical and quality of life tradeoffs between more than one viable option compounds the level of decision-making complexity. Thus, when more than one medically reasonable therapeutic option exists, out of respect for the patient's right to autonomous self-determination, an even more careful examination and informational disclosure of each option is necessary to assist patient decision-making.
(Whitney, McGuire, & McCullough, 2003). Decision-making between alternatives in “preference-sensitive” circumstances most appropriately involves a high level of involvement by the patient (Wennberg & Peters, 2002), and consciously incorporates the patient’s evaluative understanding of the alternatives – that is, the appreciation of how each will impact the values he holds important – in conjunction with his cognitive understanding (McCullough et al., 1998a).

Voluntariness

In addition to adequate information-giving, a second key prerequisite for valid informed consent is that the decision be made voluntarily. Faden and Beauchamp (1986) have provided the most comprehensive exposition of the factors involved with voluntariness and the validity of informed consent (pp. 161-162, pp. 337-381), upon which most of the following discussion is based, except where otherwise noted.

For a patient’s decision-making to be voluntary, it must free of coercive or undue manipulative influences by other persons or circumstances, such that the decision is freely and authentically made – in short, that it is autonomous. Coercion or manipulation might be applied consciously with the deliberate intent to exert control over a patient’s decision, or it might be applied unintentionally through subtle or unconscious communicational or social effects. In either case, the patient’s decision is altered from what she would have chosen of her own accord. Consent given under the influence of such pressures is considered legally and ethically invalid.

All human behavior, including decision-making, is subject to external influences, but such influences exist on a spectrum in terms of their compatibility with autonomous action, and therefore the acceptability of their effects on voluntariness. For example, persuasion is considered an acceptable form of influence upon an individual contemplating a medical decision, because it appeals to the person’s faculty of reason. Because no attempt is made to exert control over the deciding patient, and she is free to accept or reject the arguments given without fear of reprisal or loss, persuasion does not impinge on the voluntariness of the patient’s decision-making. On the other hand, coercion is a type of influence that is
not compatible with voluntariness, because it presents “a credible threat of unwanted and avoidable harm so severe that the person is unable to resist acting to avoid it” (Faden & Beauchamp, 1986, p. 261) – an obvious constraint on autonomy. The threatened harm may be physical, psychological, economic, legal, or of other types. An example of coercion, from the history of research ethics, is the forced participation in the Nazi medical experiments of concentration camp detainees, whose only other choice would have been certain, perhaps immediate, death.

*Manipulation* is the term Faden and Beauchamp use for a third category of influence that covers a large gray area between these two extremes. According to them, manipulation consists of “influence of a person by noncoercively altering the actual choices available to the person or by nonpersuasively altering the person’s perceptions of those choices” (p. 261). Various types of manipulation exist. *Manipulation of options* operates through modification of the environment, particularly by offering rewards or punishments. *Manipulation of information* alters a person’s perception of options by affecting his or her understanding of the situation. *Psychological manipulation* influences mental processes other than understanding, such as via subliminal suggestion, appeals to emotional weaknesses, or inducing feelings of guilt. In the health care setting, the most likely form of manipulation is informational manipulation, which is recognized by a number of authors as “a major problem for informed consent” (Faden & Beauchamp, 1986, p. 261). It is an especially important problem in that it affects two of the elements required for valid informed consent – information-giving itself and the principle of voluntariness.

Only minor manipulations – those that affect autonomy in minor ways only, or not at all – are considered compatible with valid informed consent. What standard should be used to determine whether a manipulation is compatible with the requirement that informed consent be voluntary? The ability to resist an applied threat is a standard useful in distinguishing a coercive from a non-coercive influence. However, since some informational manipulations are of the type such that they may not be consciously perceived by the person being manipulated, the ability to resist the manipulation is not a valid criterion for deciding whether a given informational manipulation is compatible with voluntariness. A more appropriate approach focuses on the need for a deciding patient to have a substantial enough understanding of the implications of his choices, such that one may say that he is making an autonomous
decision. The question is then, to what degree is the substantiality of a person’s understanding affected by a given informational manipulation? Faden and Beauchamp propose that both objective and subjective criteria be applied. An influence is thus considered incompatible with the requirement of voluntariness if it affects, in more than a minor way, the objective adequacy of the disclosure made by the professional, or if it adversely affects understanding of information subjectively material to a patient’s decision-making.

Deception is the most common form of informational manipulation, encompassing a variety of strategies that have the conscious intent to cause persons to believe things that are not true. Lying, withholding of information, consciously promulgating partial truths, or deliberately exaggerating or unduly minimizing risks or benefits are clearly forms of deception. Manipulation, however, can shade into less blatant but no less distorting forms of influence, such as subtler misrepresentation or slanting, or simple omission of information, which may be brought about either intentionally or unintentionally. Similarly, and even more subtly, “formulation effects” or “framing effects” – where information is couched in terms that distort the patient’s cognitive processes – can result in responses involuntarily altered from what would rationally be expected (Faden & Beauchamp, 1986; Haward, Murphy, & Lorenz, 2008; Lustig & Scardino, 1998; McCullough et al., 1998a). An example of the effect of framing is the difference in the proportion of patients choosing one treatment alternative over another, depending on whether the outcomes of the treatment options are presented in term of their mortality rates or their survival rates (Haward et al. 2008; Moxey, O’Connell, McGettigan, & Henry, 2003).

Besides direct manipulation of information, the process of informing is subject to influences and variations in execution such that patients may participate in a more or less autonomous way. For example, the timing, manner, and order of a presentation may tend to steer a patient toward one or another choice, or overwhelm his ability to understand the information or consider it judiciously – all of which undermine the requirement of voluntariness (Svoboda et al., 2000). On a broader level, certain factors in the health care context itself may put patients at increased risk of undue influence. According to Faden and Beauchamp (1986), in comparison to many commercial transactions, health care contexts exhibit an imbalance of knowledge and power; these contexts are often imbued with a background of credibility, trust, and dependency. Thus, attempted informational
manipulations are more likely to be both successful and more controlling in health care contexts (p. 363).

Because of these concerns, they conclude that “as a practical matter, it is not likely that many informational manipulations would be judged compatible with […] informed consent” (p. 363).

**Competence**

Competence is the third element required to ensure legally valid informed consent. This element is intended to protect patients’ well-being by ensuring that they have the cognitive capacities necessary to support rational decision-making. As a general legal presumption, adults are considered to be competent for the purpose of medical decision-making, thus warranting that their decisions are respected by others, unless some specific finding calls their competence into question. This presumption is based on the *prima facie* principle of respect for autonomy in association with the principle of beneficence, on the premise that the competent adult will be the best judge of his or her own best interests.

However, certain conditions, such as mental illness, developmental disability, or brain damage, might so impair an adult’s cognitive capacity as to render him incompetent to make medical decisions, thus justifying an exception to the right to give one’s own informed consent. Here the principle of beneficence is judged to outweigh the principle of autonomy in determining the best course of action to fulfill the incompetent person’s best interests. In such cases, a competent surrogate (proxy) is assigned to make medical decisions for the incompetent patient, either through pre-designation by the patient at a time when he was competent, or through institutional or judicial channels. While adults are presumed to be competent to give informed consent unless proven otherwise, children are generally legally regarded as incompetent to give informed consent. In the case of children, the parents are most often designated as surrogate decision-makers when medical decisions are necessary. The same elements of adequate informational disclosure and voluntariness are required for valid informed consent in the case of surrogates, as for informed consent by a competent patient for himself.

Decision-making by surrogates is guided by reference to several standards (Beauchamp & Childress, 2009; Buchanan & Brock, 1990). The *subjective*, or *pure autonomy*, standard directs surrogates
to make decisions based on previously articulated decisions of their wards, such as via legally issued advance directives. This standard is based on respect for the previously competent patient’s self-determined and express preferences. Lacking advance directives, the preferred standard to guide surrogate decision-making is the *substituted judgment* standard, in which surrogates are directed to choose what they believe the patient would have wanted for himself, based on their familiarity with evidence of the previously competent patient’s values and preferences. Note that, under the substituted judgment standard, surrogates are directed to refer only to what they believe the patient would want under the circumstances, not what the surrogates would themselves want. The substituted judgment standard is also based on the principle of respect for autonomy and fosters the self-determination of the patient. When no evidence of the patient’s preferences or values is available, or when the patient has never been competent, as in persons developmentally disabled since birth, or in the case of infants, decision-making guidance reverts to the *best interests* standard. Under the best interests standard, surrogates are directed to make necessary decisions based on what in their estimation would produce the highest net benefit to the incompetent patient, by their careful and informed weighing of the patient’s interests against the risks and costs of available treatment options. Thus, the best interests standard is based on the principle of beneficence, and not on respect for autonomy, as the patient’s personal preferences are not able to be known or reliably intuited.

Surrogate decision-making in relation to children will be discussed further later in this article, as part of the discussion of the special challenges that neonatal circumcision poses for informed consent.

**Exceptions to Informed Consent**

Besides situations involving *incompetent* patients, there are several other legally accepted exceptions to the patient’s right to informed consent. Several are based on the principle of beneficence and are applicable in cases where the best interests of the individual or society are deemed significant enough to take priority over the patient’s right to self-determination (Faden & Beauchamp, 1986). These exceptions include *public health emergencies*, such as when individuals with TB are legally required to be
quarantined and treated, out of a need to promote public safety; and medical emergencies, in which a delay in order to obtain informed consent would place the patient at imminent risk of death or significant harm. Another exception, based on the principle of non-maleficence, is the so-called therapeutic privilege, in which a physician withholds material information out of concern for its possible harmful effects on the patient, such as causing emotional destabilization (Beauchamp & Childress, 2009). However, a too casual invocation of the therapeutic privilege exception risks a return to the paternalism that produced the need for informed consent in the first place. Most commentators hold that therapeutic privilege should only be applied under very narrowly formulated circumstances (Beauchamp & Childress, 2009; J. W. Berg et al., 2001). The final exception allowed for informed consent is patient waiver, in which the competent patient voluntarily waives his right to information and/or cedes decision-making to the physician or a designated other. The justification for this exception is not beneficence or non-maleficence, but is an extension of the competent patient’s right to self-determination that is the underlying principle of informed consent itself. However, in the same way that the power imbalance between patients and physicians may increase the risk of informational manipulation, the risk of improper solicitation of patient waiver also exists (Beauchamp & Childress, 2009, p. 132), thus careful oversight of the waiver exception is necessary.

Informed Consent for Neonatal Circumcision: Special Challenges

Neonatal circumcision differs from most medical decision-making situations in a number of specific ways. First, neonatal circumcision is commonly considered to be an elective surgery (AAP, 1999; AAP, American College of Obstetricians and Gynecologists (ACOG), 2002), that is, surgery that is not clearly medically indicated and is therefore optional. Second, it is a non-therapeutic procedure (Council on Scientific Affairs, American Medical Association (AMA), 1999), that is, it is not performed to treat an existing medical problem. Third, it is a procedure that is decided upon not by the patient himself, but by parental proxy. Individually and in conjunction with each other, these factors pose special challenges to
the proper conduct of informed consent, and raise the standard of care with which information about circumcision and the alternative of not circumcising must be disclosed.

*Informed Consent and Elective Surgery*

Elective surgery refers to surgery as a possible treatment option for non-emergent disease, in which evidence on “the ratio of risks to benefits has not reached a decisive balance in favor of surgical management” (Lustig & Scardino, 1998, p. 133). Lustig and Scardino (1998) describe two types of medical situations in which surgery may be judged elective. The first type is in the case of chronic and slowly progressive conditions that are relatively benign, thus allowing for at least a trial of nonsurgical management. The second type relates to conditions in which surgery could be used to avoid a rarely seen but very bad outcome, but where the risks of morbidity and the potential for adverse effects on the patient’s quality of life militate against making an outright recommendation. The physician’s fiduciary role is of special importance in the case of informed consent for elective surgery, with the attendant need of the surgeon to guard against financial self-interest when surgery is not clearly indicated. The surgeon must take care to make clear the elective nature of the surgical management route – i.e. that it is not clearly required or recommended – and to present all reasonable alternatives and the implications of each, without bias (Lustig & Scardino, 1998).

Because of the lack of certainty about the relative merits of treatment options and the greater availability of time for deliberation, Lustig and Scardino (1998) have argued that elective surgery demands a more stringently “process-oriented” rather than “discrete event” model of informed consent. In other words, information-giving should involve a relatively extensive dialogue over sufficient time to allow the patient to fully assimilate, appreciate, and deliberate upon the relevant information, so as to gradually come to a settled response to his options in the light of his own values and life plan (J. W. Berg et al., 2001). In regard to decision-making in the case of elective surgery, Lustig and Scardino argue unequivocally for the centrality of the patient’s own values in determining the choice of treatment. They therefore endorse a subjective rather than reasonable person standard of disclosure in elective situations,
so that the patient’s individual preferences and values may be appropriately respected and incorporated into the decision-making process. Indeed, elective surgery is subsumed within the category of “preference-sensitive” care, discussed previously. As previously discussed, decision-making in preference-sensitive care requires a higher degree of patient involvement and of attention to incorporating the patient’s values, as well as a higher standard of disclosure in exploring the therapeutic options, so that patients may fully appreciate the potential impact of their decisions on the things they value in life.

A number of legal and medical scholars have suggested that the duty of care for disclosure should be higher when the procedure is elective (Berry, 2005; Ciesielski-Carlucci et al., 1996; Haberfield, 1996; Schuck, 1994; Somerville, 1981; Svoboda et al., 2000). Schuck (1994), seeking to reconceive informed consent so as to make it more tenable within the time and cost constraints of modern health care, has suggested that the extent of disclosure should vary according to certain factors present in the clinical context. He lists elective procedures and procedures with a controversial risk-benefit ratio as medical situations that would merit a higher legal standard of disclosure. Whitney et al. (2003) argue that, ethically and practically, the added attention to disclosure and patient involvement, in consent situations where more than one valid therapeutic option exists, shows respect to patients who are confronted with complex decisions, and enables them to have more control over their medical care.

As previously noted, neonatal circumcision is regularly characterized as elective surgery. As such, the above discussion makes the case for an elevated standard of informational disclosure for circumcision of newborns, not only in terms of the adequacy of disclosure, but also in terms of allowing time for a process-oriented pattern of disclosure and deliberation that attempts to consciously consider the patient’s (the child’s) values.

Beyond its elective nature, however, several additional aspects of the practice of neonatal circumcision differentiate it from most other surgeries. These include the facts that neonatal circumcision is a non-therapeutic procedure, and that it is not chosen by the patient himself, but by his parents for him. Both of these features of neonatal circumcision pose further challenges to the practice of informed consent.
Informed Consent and Non-therapeutic Procedures

Neither of the two medical categories mentioned above, into which elective surgeries are suggested to fall (Lustig & Scardino, 1998), applies to neonatal circumcision. The intact newborn penis is typically not diseased; it is simply a normal, healthy body part. Nor can it be rationally said that a genitally intact boy is at risk of some rare but potentially very bad outcome because of his possession of a foreskin, any more than he would be for the possession of any other normal body parts. The usual practice of informed consent and disclosure of treatment alternatives is based on the premise that a medical problem exists that requires therapeutic intervention of some type for relief or correction of the problem. Yet in the case of neonatal circumcision, no medical problem exists, making the procedure by definition non-therapeutic. The world’s major medical organizations, having reviewed the evidence on the possible medical merit of neonatal circumcision acknowledge this fact, variously describing it as “non-therapeutic” (Council on Scientific Affairs, AMA, 1999; Medical Ethics Committee, BMA, 2006), as having “no medical indication” (RACP, 2002), or likening it to a “cosmetic” procedure (American Academy of Family Physicians (AAFP), 2002), i.e. primarily for appearance, rather than for health reasons.

Since neonatal circumcision is categorized as an elective procedure, we have already seen that a higher standard for informational disclosure is expected. When the procedure is, moreover, understood to be non-therapeutic, additional disclosure expectations are overlaid on this already elevated standard. According to legal scholar and bioethicist Somerville (1981), the non-therapeutic nature of the procedure must be carefully made clear to the patient, particularly because patients tend to identify physicians with therapy, and find it hard to believe that a physician would carry out a non-therapeutic procedure on them, even when they are expressly informed of this fact (page number not available).

Note that this comment evokes concerns about the patient-physician power imbalance mentioned previously. As for information-giving, Somerville (1981) states, in general, “a very full disclosure is needed when non-therapeutic medical intervention is involved” (page number not available), justifying this assertion on the grounds of giving patients a chance to more carefully consider deciding against
procedures that have no therapeutic function. The disclosure expectations generated by the non-
therapeutic nature of neonatal circumcision are compounded to an additional degree by the fact that
consent is provided by a proxy. According to Somerville,

> when one moves outside the competent adult model, then whether a medical
> intervention is therapeutic or non-therapeutic becomes most important. [...] It must
> always be kept in mind that more care is needed in giving permission for an
> intervention on another person than when we consent to have something done to
> ourselves (page number not available, emphasis added).

Pediatric Proxy Consent

As already noted, children are legally regarded as incompetent to give informed consent, due to
their lack of cognitive capacity and experience, although some exceptions to this rule may be instituted in
dereference to circumstance or the child’s advancing development (Buchanan & Brock, 1990). For
example, both the American Academy of Pediatrics (AAP) (Committee on Bioethics, 1995) and the
Canadian Paediatric Society (CPS) (Bioethics Committee, 2004) acknowledge the ethical and practical
importance of including children in information-giving and the decision-making process (termed “child
assent”), as developmentally appropriate. Parents are most often designated as the surrogate or proxy
decision-makers for a child, in recognition of their role of responsibility and presumed concern for the
child’s well-being, absent any evidence of incompetence, negligence, abuse, or conflict of interest
(Buchanan & Brock, 1990). Technically, parents are not giving “consent” derived from an examination of
their own values and preferences, as they would for a procedure on themselves, but are giving permission
as guardians on behalf of the child for procedures deemed necessary to ensure the child’s well-being
(AAP, Committee on Bioethics, 1995).

As we have seen above, the preferred standards for surrogate decision-making – advanced
directives and substituted judgment – are modeled on decision-making by competent adults, in that they
are based on the principle of respect for autonomy and place a priority on carrying out the incompetent
patient’s explicit or inferred preferences. However, in the case of pediatric medical ethics, the prima facie
principle of autonomy takes a secondary position to the principle of beneficence (R. B. Miller, 2006). This
shift is justified by the concern for protecting children from making ill-considered medical decisions for
themselves, and the assumption that a competent and caring surrogate would be in a better position to
make any necessary decisions in a manner that best protects the child’s interests (Buchanan & Brock, 1990; R. B. Miller, 2006). In the case of young children, since no pre-existing evidence of maturely considered preferences exists and a substituted judgment cannot therefore be made directly, decision-making guidance typically reverts to the beneficence-based best interests standard.

Various authors and medical organizations have proposed guidelines for factors to be considered in determining a child’s best interests (Bouclin, 2005; AAP, Bioethics Committee, 2004; Medical Ethics Committee, BMA, 2006; Mercurio, 2006). Overall, the concept of best interests should guide surrogates to make necessary medical decisions in such a way as to attempt to maximize benefits while minimizing harms to the child patient. Factors to be considered include, for example: the balance of the harms and benefits of treatment options; the evidence on long- and short-term outcomes of treatment options; long-term implications for the child’s suffering and quality of life; how likely the proposed treatment is to improve or prevent deterioration of the child’s condition; the child’s chances of survival; and whether the proposed treatment is the least restrictive and least intrusive way to obtain the hoped-for benefits. These factors suggest some of the content necessary to assure an adequate level of informational disclosure to surrogates. The British Medical Association (BMA) (Medical Ethics Committee, 2006), reviewing criteria for best interests specifically in the case on non-therapeutic circumcision, includes the family’s views and cultural background as part of the context that defines best interests (as in the case of religious circumcision), along with the child’s physical and emotional well-being. The BMA additionally states that the best interests standard also entails “the prioritising of options which maximize the patient’s future opportunities and choices” (p. 4).

Despite this guidance, in actual practice, what constitutes a child’s best interests is not always easy to define (AAP, Committee on Bioethics, 1995). In circumstances where a child’s best interests are unclear, the CPS recommends that “when it is possible to defer or delay acute treatment, such a delay is encouraged while further information is gathered to clarify the issues” (Bioethics Committee, 2004, p. 100). A number of authors have argued for a heavy burden of proof by surrogates regarding decisions made based on the best interests standard, because of the fundamental legal and ethical presumption against invasion of an individual’s bodily integrity (Medical Ethics Committee, BMA, 2006; R. B. Miller,
2006; Svoboda et al., 2000). In regard to circumcision, the BMA specifically states that “parents must explain and justify requests for circumcision, in terms of the child’s interests” (2006, p.4).

As with other child-rearing scenarios, parents are generally given wide discretionary authority in medical decision-making, not only from the presumption that they are in the best position to further the well-being of their children, but in respect for the privacy of the family and for the right of parents to raise their children according to their own values and standards, within reasonable limits (Bouclin, 2005; Buchanan & Brock, 1990; Schoeman, 1985). While acknowledging the strong legal presumption against intervention into parental decision-making, various authors and professional organizations have voiced concerns about the ethical issues raised by pediatric proxy consent (AAP, Committee on Bioethics, 1995; CPS, Bioethics Committee, 2004; Svoboda et al., 2000). The AAP has stated the ethical dilemma of proxy consent in pediatric practice in this way:

“[P]roxy consent” poses serious problems for pediatric health care providers. Such providers have legal and ethical duties to their child patients to render competent medical care based on what the patient needs, not what someone else expresses. [...] The pediatrician's responsibilities to his or her patient exist independent of parental desires or proxy consent (Committee on Bioethics, 1995, p. 315).

This passage makes clear that it is not the parents’ personal beliefs, values, goals, or preferences that should drive the medical decision-making process, but that the focus should be on the child himself, and the effect of the proposed intervention on his actual needs and on his life’s potentials.

Surrogate decision-making, in general, raises concerns for consent in several ways. First, the risk of surrogates making decisions for incompetent patients based on their own concerns and values, instead of those of the patient, is real (McCullough et al., 1998a). The ethical principle of best interests is problematic in this regard because it relies on the decision-maker referring to his or her own conception of quality of life, and then being able to appropriately apply this conception to the patient and his future life (S. Bailey, 2006). According to nursing ethicist Bailey (2006), in cases involving surrogate consent, “there is clearly great potential for moral errors to be made in these circumstances” (p. 289). This is especially so because a surrogate has no intrinsic motivation to fully consider the impact of a medical decision made for a ward, as it is not his or her own body or life that will be affected. Thus there may be
more of a tendency for surrogates to overlook or minimize harms that may result from decisions made for others.

A further problem with decisions made by surrogates is that there is considerable evidence to show that surrogates do not always make choices that conform to what their wards would actually have chosen for themselves. A review of 16 studies involving 2595 pairs of still-competent patients and their pre-designated surrogates, found that nearly one third of the surrogates failed to predict the treatment preferences of their designated wards, when presented with hypothetical end-of-life treatment decision scenarios (Shalowitz et al., 2006). An even greater lack of accuracy in surrogate decision-making has been found in research on hypothetical situations concerning elective surgery (Mantravadi, Sheth, Gonnering, & Covert, 2007).

It is the concern with countering such risks that justifies a more stringent standard for informed consent in cases of consent by proxy. Careful, process-oriented attention to comprehensive and unbiased information-giving is the foundation for helping surrogate decision-makers become well-informed enough to have a realistic appreciation of the ways that their decisions may impact the lives of the incompetent persons who are dependent on them. As we have seen, concerns regarding proxy consent are compounded when associated with decision-making for elective and non-therapeutic procedures (Somerville, 1981), as is the case with neonatal circumcision. In such cases, disclosure must meet the highest possible standards.

Additional Ethical Concerns with Neonatal Circumcision

While this article specifically addresses the topic of informed consent, two further aspects of parental consent for neonatal circumcision – which move the issue into a more deeply controversial moral realm – deserve to be noted. A detailed exploration of these issues is beyond the scope of this article. [For further discussion, please see other articles and links on the medical ethics of neonatal circumcision found on the NRC website.] However, the key point is that they reinforce the need for scrutiny of the implementation of valid informed consent, if neonatal circumcision is to be offered.
The first ethical issue brings into question the very validity of parental consent for neonatal circumcision. The current AAP position is that,

in the case of circumcision, in which there are potential benefits and risks, yet the procedure is not essential for the child’s current well-being, parents should determine what is in the best interest of the child. […] It is legitimate for parents to take into account cultural, religious, and ethnic traditions, in addition to the medical factors, when making this decision (1999, p. 691).

However, according to Bouclin (2005), in Canada, legal precedent limits parental authority to consent to “therapeutic” treatment only, or in situations of “imminent and serious danger requiring immediate treatment” (p. 214). Similarly, Svoboda et al. (2000) argue that in the case of elective or cosmetic surgery, U.S. legal precedent suggests that only the patient (not a proxy) can give consent, and conclude that parents have no legal authority to consent to medically unnecessary procedures on their children.

Recently, in Australia, the Tasmania Law Reform Institute has released a legal review of non-therapeutic male circumcision that concludes that “there is uncertainty as to whether the consent of a parent for the circumcision of their child is sufficient to allow a circumciser to legally perform the procedure” (Marshall, 2009, p. 6). While these papers are geared exclusively to circumcision and its legal interpretation, British pediatrician Jones (2000) proposes a related ethical argument stemming from a discussion of parental consent to cosmetic (i.e. non-therapeutic) facial surgery for children with Down’s syndrome. He compares this to both female and male circumcision in terms of being a form of surgery undertaken with the primary intent of helping a child “fit in” to society. He argues that parental authority to consent to treatment is invalid if it is not possible to demonstrate personal benefit to the child, or that the public interest is in any way served. Despite the questions that these arguments raise, neonatal circumcision by parental proxy consent continues in the United States without any effective legal challenge, although several foreign jurisdictions are considering or have implemented regulatory restrictions (Marshall, 2009).

The second ethical issue that affects the adequate execution of informed consent for neonatal circumcision has to do with the appropriate standard for decision-making, and the moral status of the child. While the best interests standard is generally viewed as the only valid standard that can be applied in the case of infants, on the grounds that the preferences of infants cannot be known, the principle of
autonomy cannot be overlooked in guiding parental decision-making for children. On this point, and citing Joel Feinberg’s argument for the child’s “right to an open future” (Feinberg, 2007), Berg et al. (2001) have written:

It may seem strange to speak of promoting the autonomy of incompetent patients. Yet some patients are only temporarily incompetent and non-autonomous, as when they are briefly unconscious or are infants. These patients will regain consciousness or mature; decisions made on their behalf should, therefore, safeguard their future autonomy and their opportunities to make future autonomous decisions. For this reason, for example, parents generally may not elect to sterilize their children; to do so would infringe on the future reproductive autonomy of their children (p. 94).

This echoes the best interests guidance from the British Medical Association (Medical Ethics Committee, 2006), in regard to the “prioritising [sic] of options which maximize the patient’s future opportunities and choices” (p. 4).

As an irreversible and medically unnecessary amputative procedure that alters not only the appearance but also the function of the penis, neonatal circumcision can be seen as infringing on the future autonomy of the child to make his own decisions about how much of his natural penis he prefers to have. Feelings about body appearance and sexuality are quality of life factors that are highly “preference-sensitive,” and likely to be very individual. As the best interests standard recognizes, in the case of very young children, it cannot be known with any certainty whether a child would prefer to be circumcised or not. The AAP has stated that

parents and pediatricians should not exclude children and adolescents from decision-making without persuasive reasons. […] A [minor] patient’s reluctance or refusal to assent should […] carry considerable weight when the proposed intervention is not essential to his or her welfare and/or can be deferred without substantial risk (Committee on Bioethics, 1995).

These ideas may reasonably be extrapolated to encompass giving some weight to the infant’s inability to assent. The simple fact that an infant is not able to give consent is not a persuasive enough reason, in itself, to justify excluding the infant – who will one day become competent – from decision-making about his own body. Therefore, in the absence of evidence that circumcision is essential to the child’s welfare, or that its deferral entails substantial risk, the most conservative approach – and the one that is most respectful of his future autonomy – would be to let the child be the definer of his own best interests, leaving the decision to him when he is old enough to give his own informed consent.
In the U.S., the ethical quandaries associated with parental decision-making for circumcision are rarely acknowledged. However, these issues are weighty, and can only add to the need for the impeccable conduct of informed consent, if the procedure is to be offered.

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