

# Informed Consent for Pediatric Genitoplasty or Gonadectomy in Patients with DSDs

*An extensive and careful informed consent process is appropriate where pediatric genitoplasty or gonadectomy is contemplated, due to the absence of consensus about the necessity and timing of most procedures and the lack of outcome data.*

This document offers general information only and is not intended to provide guidance or legal advice regarding anyone's specific situation. Please bear in mind that this is an evolving area of law in which there is bound to be uncertainty. Do not rely on this information without consulting an attorney or the appropriate agency.

The timing and necessity of genitoplasty for patients born with ambiguous or atypical genitalia related to DSDs is currently a subject of debate. The lack of outcome data, the irreversibility of the procedure, and its sensitive and elective nature create uncertainty about whether parental consent alone is legally sufficient to authorize elective genitoplasty. A legal consult and/or involvement of a bioethics committee is indicated where these procedures are contemplated. If the decision is made to proceed on the basis of parental consent, an extensive and careful informed consent process will serve the best interests of the child and family, improve patient care and the doctor-parent relationship, and reduce exposure to liability.

## Elements of Informed Consent

There are two common standards for informed consent: the “reasonable physician” standard and the “reasonable patient” standard. The reasonable patient standard is somewhat broader and is the preferred standard. Under this standard, a doctor must disclose those risks, benefits, and alternatives that a reasonable person in the patient’s position would be likely to consider significant (or “material”) in deciding whether or not to undergo treatment, including :

- diagnosis and prognosis
- common risks of the proposed procedure
- remote risks with grave consequences
- probable outcomes and expected post-treatment course
- risks, benefits and unknowns of alternative treatments and non-treatment

Where a patient is incapable of giving consent, as is the case with a child, a surrogate offers consent on behalf of the patient. When the patient is a child, the parents or guardians are usually the ones who offer surrogate consent. In such a case, the physician’s responsibility is to disclose all material information to the parents/guardians.

Under the reasonable patient standard, the physician must disclose all information that a reasonable person would consider “material” to the patient’s decision. There is no “bright line” test for materiality; it is a question for the jury. A risk is more likely to be found material

- where it is severe
- where it is common
- where outcomes are uncertain
- where treatment is elective/non-therapeutic, experimental, or controversial

## What do reasonable parents need to know?

### Diagnosis

- Full details of their child’s diagnosis, including information about the child’s chromosomes, internal and external organs, and possible hormone exposure before birth.
- Failure to provide full information about diagnosis was once common in cases of DSDs. Such failure now is a clear violation of ethical and legal principles.

### Prognosis

Information about the child’s prognosis, including:

- potential for fertility, together with options for assisted reproduction that exist now or seem likely during the child’s reproductive lifetime;
- potential for sexual function, including the capacity for sexual pleasure, orgasm, and emotional fulfillment as well as for penetration;
- gender identity outcomes in other children with the same condition;
- psychological outcomes in other children with the same or similar conditions, to the extent data are available.

### Rationale for Proposed Procedure(s)

- Information about the purpose of proposed interventions. (i.e., to improve cosmesis, to allow voiding of urine, to allow standing urination, to allow for future menstrual flow, to allow for future sexual intercourse, to support gender identity development)
- Where multiple or repeat procedures are proposed, the rationale for each must be disclosed.
- Where outcome data in support of the rationale are lacking, it is important to clarify the basis for assertions made to parents:
  - ◆ Where assertions are based on the provider’s opinion or experience, rather than evidence-based studies, this fact must be disclosed.
  - ◆ If medical opinions and/or available data are conflicting, this uncertainty must also be disclosed.

### Risks and Benefits of Proposed Procedures

- All material risks of proposed procedures must be disclosed, including minor risks if they are common, and remote risks if the potential harm is serious.
- Disclosure of suspected risks is recommended, even if they are not proven.
- Potential benefits should also be disclosed. Where benefits are speculative, this information must be disclosed as well.
- In particular, parents need to understand that evidence is lacking to support the view that early genitoplasty will ensure adoption of the assigned gender or development of a heterosexual identity.
- The likelihood of various outcomes must be discussed where this is known. Where an outcome is uncertain, this uncertainty must be disclosed.

- Where known or suspected, psychological risks must be disclosed. For example, if a surgery or its possible complications will increase the necessity for multiple genital exams in childhood, the risk for psychological trauma from such exams should be disclosed.
- Disclosure should include risks and benefits throughout the patient’s lifespan, including known or suspected risk of damaging adult sexual sensation and the risk of psychological trauma if the patient later regrets the decision. If the parents are not able to contemplate the child’s future sexuality (or if their doctor is not able to discuss the subject), their ability to provide true informed consent to genitoplasty is questionable.
- Many parents assume that genitoplasty is “reversible.” It is important that they understand the limitations of such procedures.

### A Note on Privacy

Consent to treatment does not automatically encompass consent to examinations for purposes unrelated to patient care, such as extra examinations for the purpose of educating medical residents. Additional consent for such procedures must be obtained. Many hospitals incorporate this consent into their standard consent forms. However, it has been widely reported that patients with DSDs may be at increased risk for suffering harmful effects from excessive unnecessary genital examinations. Therefore, informed consent for such examinations for a child with a DSD requires that the parent understand that the examination is unrelated to the child’s health care and carries a risk of psychological harm. Where the child is of age to understand what is happening, the child’s assent must also be obtained.

### Alternative Treatments

- Where alternative procedures are available, these must be discussed, along with their risks and benefits as described above.
- The alternatives of non-treatment, watchful waiting and delayed treatment must be discussed when available, along with their risks and benefits. Parents need to know that some children have adapted successfully to DSDs without genitoplasty.

- Non-surgical treatment options, including psychological counseling for the child and family, must be discussed.
- Parents need to know that children born with DSDs have enjoyed healthy relationships and a well-adjusted childhood without surgical treatment.
- Alternative treatments must be disclosed, regardless of the patient's ability to pay or the availability of insurance coverage for alternatives. (However, where insurance may cover a procedure in childhood but not in adulthood, this possibility should be discussed.)
- Parents should be informed of their right to receive a second opinion and their right to change clinicians if disagreements cannot be resolved.

### *Post-surgical Care*

- Parents need to know what will be involved in aftercare, including length of hospital stay, need for pain control, and potential for post-surgical complications.
- In particular, where the need for ongoing catheterization or vaginal dilation is a possibility, parents need to know about the associated challenges and potential for psychological damage from these procedures. If the parents will be expected to perform the dilations or catheterization, they should know this in advance.

### *Clinician Experience*

- This is a rapidly evolving area of medicine, and surgeons should be forthcoming about their level of experience with the proposed procedures along with the surgeon's and hospital's success rates and rates of complication.
- Where there is evidence of better outcomes at centers of excellence, this information must be disclosed.

### *Referrals to Professional and Peer Support*

- It has been widely recommended that parents who face these decisions have access to both professional psychological support and peer-based organizations as part of their decision-making process. Where much of the decision-making process is based on speculation about the child's future quality of life, such access may provide vital aspects of fully informed consent. Failure to refer to such resources could be found to compromise the quality of informed consent or even to violate the standard of care.

### **The Older Pediatric Patient**

- As the child with a DSD matures, it is appropriate to involve him or her in decisions about ongoing treatment. There is uncertainty about the validity of parental consent alone for genitoplasty or gonadectomy at any age; it is clearly inappropriate, and possibly a violation of civil rights, to perform these procedures on an older child or teen without assent.
  - When the patient reaches the age of 18, he or she will have the right to access the entire medical record. Parents who are considering limiting disclosure to the child need to be aware of this.
  - Where state or constitutional law accords mature minors the authority to make their own informed choices, the information necessary to make an informed decision must be fully provided to the minor in understandable language.
  - Where a mature minor and a parent disagree over treatment choices, or where disagreement over treatment arises between parents, the provider must obtain legal advice, and if necessary a court determination, before treatment is performed.
  - Where state or constitutional law accords mature minors the authority to make their own informed choices, the information necessary to make an informed decision must be fully provided to the minor in understandable language and with due respect for their authority, privacy, and autonomy.
- Discussions of the popular and medical controversies about appropriate treatment for children with DSDs are widely available. Parents might not access these materials in the early stages of coping with their child's condition, but they (or the child) are likely to come across them eventually. If they have not been informed of these controversies by their clinician before making their

decisions, they are likely to be dissatisfied and may feel they were misled, exposing the physician to possible litigation.

## Special Cases

### *Where Vaginoplasty is Contemplated*

- Patient groups have reported that the different available techniques for vaginoplasty (self-dilation, skin substitution, and bowel vaginoplasty) have different lifelong advantages and drawbacks. Adults who have made choices for themselves about these procedures have demonstrated that this area is one where idiosyncratic personal preferences play a big role. Parents need to understand this when making decisions about vaginoplasty on behalf of a child.
- Where the clinician’s recommendation regarding vaginoplasty is based on personal preference for one technique rather than on outcome data about patient satisfaction, this must be disclosed.
- It has been widely reported that vaginal dilation in childhood is no longer recommended, due to the potential for psychological trauma. Where a clinician does recommend vaginal dilation, this risk should be disclosed. If the parents will be expected to perform dilations, they should know this fact in advance.

### *Where Gonadectomy is Contemplated*

- In most jurisdictions, parental ability to authorize elective sterilization on behalf of a child or ward has been limited by law. While the law is unsettled in the case of gonadectomy in children with DSDs, there may be a risk of legal liability for parents who authorize elective sterilization of a child or ward and for clinicians who rely on such authorization. Legal consultation is recommended.
- Parents must be informed if there is any potential for fertility that will be compromised by gonadectomy. Options for assisted reproduction should be disclosed, including likely future developments in assisted reproduction during the child’s lifetime.
- If deferring or avoiding gonadectomy will reduce the child’s future dependence on exogenous hormones, this should be disclosed.

## Specific Diagnoses:

### *Androgen Insensitivity Syndrome*

- Parents need to be informed about options for gonadectomy and for watchful waiting. In order to make an informed decision about gonadectomy, parents need to know the statistical risk factors for gonadal cancer in childhood and after puberty. They also need to know about the potential for assisted fertility if gonadectomy is deferred.
- Use of misleading terminology (i.e., referring to testes as “twisted ovaries” or referring to an XY genotype as “female chromosomes”) is contrary to principles of informed consent and is ethically inappropriate.

### *Congenital Adrenal Hyperplasia*

- Parents of girls with CAH who are considering genitoplasty need to be informed of the percentage of 46,XX children with CAH who ultimately develop a male gender identity.
- Where a “one-stage repair” is contemplated, parents need to be informed of the distinct procedures involved (i.e., vaginoplasty and clitoroplasty), and the differing rationales for each. Specifically, they need to understand that clitoroplasty is a separate procedure done for cosmetic or psychosocial, rather than physiological reasons.
- Where vaginoplasty is recommended for functional reasons, parents need to understand whether the functional issue is immediate (i.e., to allow for urine flow) or anticipated in the future (i.e.: to avoid possible UTIs; to allow for eventual menstrual flow; to allow for future heterosexual intercourse).

### *Hypospadias*

- Parents of boys with hypospadias need to know about even remote risks of surgery where these are severe. An example would be the risk for hypospadias cripple.
- Parents need to know of the risk for complications that would make repeat surgeries non-elective, and of the associated psychological risks if multiple genital surgeries in childhood should that become necessary.
- It is not factually accurate to suggest that a child with hypospadias will be infertile without hypospadias repair. If it is felt that hypospadias repair will improve fertility, parents need to understand the mechanism for this, as well as other options for addressing impaired fertility due to hypospadias (i.e., alternative insemination).

- If hypospadias repair is recommended in order to increase the probability that the child will be able to stand for urination, parents need to know of the possibility that the child will be able to stand to urinate without the repair, and of the possibility of fanning or spraying of the urine stream after repair which could make standing urination difficult. Where evidence-based studies are available, parents should be made aware of these results.

### Pitfalls to Avoid

These recommendations are based on reports by parents and doctors of counseling strategies which could undermine the validity of informed consent. A negative outcome in such a case could lead to a finding of failure to obtain informed consent, even in the absence of negligent performance of the procedures involved.

### Unwarranted Pressure

- While it is appropriate to recommend a course of treatment based on the provider's clinical experience or opinion, it is inappropriate to pressure or coerce a patient or his/her surrogate. This is especially true in situations where the recommended treatment is both controversial and elective. From both an ethical and a legal standpoint, informed consent must be both fully informed and voluntary.
- Urging parents to decide quickly when the condition is in fact non-emergent is an example of inappropriate pressure.
- Be straightforward about the rationale(s) for a proposed treatment. For example, there have been cases where a provider urged a reluctant parent to consent to genitoplasty in order to prevent urinary tract infections when in fact the risk of UTI was speculative (or minor in comparison to the risks of surgery), but the provider was convinced that genitoplasty was necessary for psychological functioning or parental comfort. Such practices violate the obligation to obtain informed consent.
- It is highly unlikely that state authorities will intervene just because a parent declines to authorize elective surgery. Threats to involve child protective services in such a case could invalidate parental consent by rendering it involuntary and/or uninformed.
- Suggestions that a child will commit suicide if surgery is declined, in the absence of evidence for such a claim, could be seen as coercive.

### Excessive Optimism

- Excessive optimism about functional and cosmetic outcomes of genitoplasty could lead to parental or patient dissatisfaction in the future, and to possible long-term exposure to liability.
- It is appropriate to be objective when presenting factual data, and to distinguish this information from the clinician's subjective opinion. Putting a "spin" on factual data can compromise the quality of consent.
  - ◆ For example a statement like, "In favorable cases, the maximum number of operations can be two or three," could leave a parent with the impression that the maximum number of operations will be two or three.
  - ◆ A statement like, "it is possible to achieve both favorable functional and favorable cosmetic outcomes," without qualification, may leave parents with the impression that such an outcome is likely or even assured.

### Practicing Outside the Field of Competency

- If a surgeon with no specialized training in Child Psychology, Child Development or a related field recommends genitoplasty primarily for psychosocial reasons or for reasons of ensuring normal sexual development, this could be found to be practicing outside the field of competency. In such a case, the physician would be held to the standard of care of a specialist in the field. Consultation with an appropriate specialist is recommended if surgery is contemplated for psychosocial reasons.

### A Final Note

The decision-making process around surgical treatment of DSDs can be overwhelming for parents. In order to give meaningful informed consent, they must be able to understand and assimilate the information given to them. Given the complexity of the procedures, and the uncertainty about outcomes, it is recommended that parents be given this information at least twice, with a week or more in between, before signing informed consent documents.