Informed Consent for Research and Care for Children with DSD

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How Law and Bioethics Can Support Quality Improvement in Medicine

- Ensure standards address legal rights of patients/subjects
- Encourage outliers to adopt up-to-date practices
- Provide incentive for health care systems to devote adequate resources to quality care

What do I mean by "elective"?

Cases where non-intervention is a medically viable option

Informed Consent for Treatment

Informed consent is an ethical and a legal concept.

Informed Consent for Treatment

Competent patients have the right to make their own decisions about medical treatment.

Informed Consent for Treatment

The physician must disclose all information that is "material" to the patient's decision.

Informed Consent for Treatment

Generally considered to include:

- Nature of the condition

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Generally considered to include:

- Nature of the condition
- Nature and purpose of the proposed treatment

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- Common risks of the proposed treatment

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- Likelihood of success, including short- and long-term outcomes

Informed Consent for Treatment

Generally considered to include:

- Nature of the condition
- Nature and purpose of the proposed treatment
- Common risks of the proposed treatment
- Remote risks with serious consequences
- Likelihood of success, including short- and long-term outcomes
- Risks, benefits and unknowns of alternative treatments and non-treatment

Informed Consent for Treatment

Information is more likely to be found material:

- Where there are serious risks

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- Where outcomes are uncertain

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- Where there are serious risks
- Where outcomes are uncertain
- Where there is no emergency requiring immediate treatment

Informed Consent for Treatment

Information is more likely to be found material:

- Where there are serious risks
- Where outcomes are uncertain
- Where there is no emergency requiring immediate treatment
- Where treatment is elective, experimental, or controversial

Informed Consent for Treatment of Children

The law generally presumes that parents have the authority to make these decisions on behalf of their children when the decision is not against the child's best interest.

Informed Consent for Treatment of Children

"Only patients who have appropriate decisional capacity and legal empowerment can give their informed consent to medical care. In all other situations, parents or other surrogates provide informed permission for diagnosis and treatment of children with the assent of the child whenever appropriate."

- American Academy of Pediatrics

Informed Consent for Treatment of Children

"Decision-making involving the health cane of older children and adolescents should include, to the greatest extent feasible, the assent of the patient as well as the participation of the parents and the physician."

- American Academy of Pediatrics

Informed Consent for Treatment of Children

"As children develop, they should gradually become the primary guardians of personal health and the primary partners in medical decision-making, assuming responsibility from their parents."

- American Academy of Pediatrics

Informed Consent for Treatment of Children

"Social forces tend to concentrate authority for health care decisions in the hands of physicians and parents and this tendency diminishes the moral status of children."

- American Academy of Pediatrics

Informed Consent for Treatment of Children

"The informed permission of parents includes all of the elements of standard informed consent."

- American Academy of Pediatrics

Emerging Issues: Common Problems with Informed Consent

a. **excessive provider optimism**

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"In favorable cases, the maximum number of operations can be two or three."

Emerging Issues: Common Problems with Informed Consent

a. **excessive provider optimism**

"Our approach to the clitoroplasty leaves the patient with intact clitoral sensation, painless sexual arousal, a viable and sensate glans clitoris and appropriate erectile function during sexual arousal."

Emerging Issues: Common Problems with Informed Consent

a. excessive provider optimism
b. failure to tell parents about medical controversies and explore all treatment options

Emerging Issues: Common Problems with Informed Consent

What is the treatment for ambiguous genitalia?

Sometimes, there is an increased risk for tumors in the gonads. Treatment for ambiguous genitalia depends of the type of the disorder, but will usually include corrective surgery to remove or create reproductive organs appropriate for the gender of the child. Treatment may also include hormone replacement therapy (HRT).

Emerging Issues: Common Problems with Informed Consent

a. excessive provider optimism
b. failure to tell parents about medical controversies and explore all treatment options
c. need to be clear about what is necessary for physical health and what is being recommended for other reasons

Emerging Issues: Common Problems with Informed Consent

d. **inadequate information about doctor's level of experience with DSD and possibility for better outcomes at centers of excellence**

Emerging Issues: Common Problems with Informed Consent

d. **inadequate information about doctor's level of experience with DSD and possibility for better outcomes at centers of excellence**

e. **failure to warn parents about the potential for psychological trauma with excessive exams or photography**

Emerging Issues: Common Problems with Informed Consent

f. **discomfort discussing sexual function, sexuality, and gender**

Emerging Issues: Common Problems with Informed Consent

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g. **underestimating children's capacity and need for input into decisions about their bodies**

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h. **cultural differences between providers and parents**

Emerging Issues: Common Problems with Informed Consent

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g. **underestimating children's capacity and need for input into decisions about their bodies**

h. **cultural differences between providers and parents**

i. **not understanding parents' assumptions or real concerns**

Emerging Issues: Common Problems with Informed Consent

Families need time and emotional support, as well as information!

Emerging Issues: Questions to Answer about the Informed Consent Process

What do reasonable parents need to know to make informed decisions?

- **Better to ask before things go wrong!**

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What do reasonable parents need to know to make informed decisions?

- **Better to ask before things go wrong!**
- **What parents consider relevant isn't always obvious to physicians.**
- **What child will consider relevant isn't always obvious to parents or physicians.**

Emerging Issues: Questions to Answer about the Informed Consent Process

- **How can we make sure parents have the best available knowledge?**

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- **How can we help parents understand the complex medical issues so they can make informed decisions?**

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- **How can we help parents understand the complex medical issues so they can make informed decisions?**
- **How can we help parents deal with the emotional aspects of the situation so they have the clarity they need to make the best decisions?**

Emerging Issues: Questions to Answer about the Informed Consent Process

- **How can we support children's participation in decision-making, and prepare them to assume responsibility for their own care?**

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- **When is immediate treatment necessary, and when can we wait for the child to make decisions?**

Emerging Issues: Questions to Answer about the Informed Consent Process

- **How can we support children's participation in decision-making, and prepare them to assume responsibility for their own care?**
- **When is immediate treatment necessary, and when can we wait for the child to make decisions?**
- **How can we incorporate the perspective offered by adults who have experience living with DSD?**

Emerging Issues: Tools to Improve Informed Consent

- **Model forms for informed consent.**

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- **Tools for shared decision-making**
- **Mechanisms for ongoing feedback**
- **Multi-disciplinary teams**

Emerging Issues: How the law supports improved access to behavioral health care

The more behavioral health is included and emphasized as part of standards of care and practice guidelines, the easier it is to argue that it is legally as well as ethically necessary to provide it.

Emerging Issues: How the law supports improved access to behavioral health care

We need input from mental health experts to ensure informed consent.

- **Where there are known or suspected psychological risks from treatment, informed consent requires that this be discussed.**

Emerging Issues: How the law supports improved access to behavioral health care

We need input from mental health experts to ensure informed consent.

- **Where there are known or suspected psychological risks from treatment, informed consent requires that this be discussed.**
- **When we offer medical treatment for psycho-social reasons, we need to be sure that the reasoning is in line with what we know about child development.**

Emerging Issues: How the law supports improved access to behavioral health care

Parents who are completely distraught may not be able to give meaningful informed consent – this is a legal as well as an ethical issue.

Emerging Issues: How the law supports improved access to behavioral health care

Emotional and psychological support leads to better decisions and less regret – therefore less risk of liability.

Informed Consent for Research on Children with DSD

Standards for informed consent for research are even more extensive than for treatment.

Informed Consent for Research on Children with DSD

Categories of Research Involving Children:

- No benefit to child, minimal or no risk

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Categories of Research Involving Children:

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- Minor increase over minimal risk, possible benefit to individual child

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- Minor increase over minimal risk, possible benefit to individual child
- Minor increase over minimal risk, no benefit to child, likely to lead to knowledge about child's disorder or condition

Informed Consent for Research on Children with DSD

Categories of Research Involving Children:

- No benefit to child, minimal or no risk
- Minor increase over minimal risk, possible benefit to individual child
- Minor increase over minimal risk, no benefit to child, likely to lead to knowledge about child's disorder or condition
- Greater than minimal risk, opportunity to understand, prevent, or alleviate a serious problem affecting health of children.

Informed Consent for Research on Children with DSD

Research design and consent process must be approved by an institutional review board (IRB) to ensure legal and ethical standards are followed.

Informed Consent for Research on Children with DSD

Child's assent is necessary:

- **if she is capable,**

Informed Consent for Research on Children with DSD

Child's assent is necessary:

- if she is capable,
- *unless* there is a possibility of important direct benefit to the child

Informed Consent for Research on Children with DSD

Child's assent is necessary:

- if she is capable,
- *unless* there is a possibility of important direct benefit to the child
- *And* that benefit is only available through the research study.

Informed Consent for Research on Children with DSD

"minimal risk" = harm or discomfort no greater than children generally encounter in daily life or routine exams

Informed Consent for Research on Children with DSD

When is a minor increase over minimal risk considered acceptable?

- When there is potential benefit to the child:
  - must be enough to justify the risk

Informed Consent for Research on Children with DSD

When is a minor increase over minimal risk considered acceptable?

- When there is no potential benefit to the child:
  - will produce knowledge about the child's medical condition

Informed Consent for Research on Children with DSD

When is a minor increase over minimal risk considered acceptable?

- When there is no potential benefit to the child:
  - will produce knowledge about the child's medical condition
  - risks are comparable to those inherent in the child's medical situation

Emerging Issues in Informed Consent and DSD Research

How can we ensure that necessary research doesn't cause harm to subjects?

Emerging Issues in Informed Consent and DSD Research

As we develop recommendations for a research agenda, we must also develop recommendations for research design.

Emerging Issues in Informed Consent and DSD Research

Questions to consider:

- Are there special concerns in defining "minimal risk" for subjects with DSD?

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Emerging Issues in Informed Consent and DSD Research

Questions to consider:

- Are there special concerns in defining "minimal risk" for subjects with DSD?
- What are the risks of proposed research, and what potential benefits would justify those risks?
- Where research offers no benefit to the subject (but might yield knowledge about DSD) what kinds of knowledge are important enough to the community of children with DSD to justify even small risks to the subjects?

Emerging Issues in Informed Consent and DSD Research

Questions to consider:

- How can we incorporate the insights of adults with DSD to minimize research-related risk to children?

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- How can we be sure that children's right to assent (or refuse assent) is protected?

Emerging Issues in Informed Consent and DSD Research

Questions to consider:

- How can we incorporate the insights of adults with DSD to minimize research-related risk to children?
- How can we be sure that children's right to assent (or refuse assent) is protected?
- Given the limited pools of research subjects and funding, how can we ensure research that will provide the most benefit to people with DSD is prioritized?

Links for Informed Consent

American Academy of Pediatrics, "Informed Consent, Assent, and Parental Permission in Pediatric Practice" - http://aappolicy.aappublications.org/cgi/reprint/pediatrics;95/2/314

FDA Standards for Special Ethical Protections for Pediatric Research Participants - http://www.fda.gov/oc/opt/presentations/subpartd.html

Contact Information

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