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Ethical Dilemmas in Retrospective Studies on Genital Surgery in the Treatment of Intersexual Infants

SHARON SYTSMA

Intersexual infants and infants with other genital abnormalities often receive genital surgery for sex assignment or for normalizing purposes.¹ The wisdom and beneficence of these practices have been questioned by intersexual individuals, support groups, some doctors, and the media.² Because the practices have been developed without long-term studies to evaluate them, pediatric urologists and parents of such children must face decisions with very little guidance from empirical support. In the face of ignorance about what is really the best medical response to intersexuality or genital abnormalities, some have argued for a moratorium on infant genital surgery until empirical studies are available.³ The urgent need for retrospective studies is now being recognized in medical journals.⁴ Because genital surgery may be appropriate and beneficent in some of these conditions, or in some degrees of these conditions, but not in others, retrospective studies must be devised to examine the degree of success of surgery for each of these conditions, or levels thereof.

However, an ethical requirement of participation in retrospective studies is the informed consent of the research subjects, and procuring informed consent of potential participants seems to be impossible. Motivated by the beneficent concerns to prevent parental rejection, spare the child embarrassment, and ensure the success of sex reassignment, medical textbooks and authors of articles on the treatment of intersexuality have traditionally advocated withholding information from parents and their intersexual children.⁵⁻¹⁸ From the presence of scar tissue and abnormalities of their external genitalia, intersexuals know they have been operated on, but they do not know why or what exactly was done in the course of the surgery. Because they lack full knowledge and understanding of their medical conditions and histories, they cannot give truly informed consent to participate. Therefore, retrospective studies are both practically and ethically problematic. The dilemma is so onerous as to lead some to claim that these retrospective studies cannot be ethically justified.¹⁹

In their 1998 article, Kenneth Kipnis and Milton Diamond acknowledge that escaping the "epistemological 'black hole' that entraps parents, patients, and physicians in lies, secrets, and avoidable ignorance" will require integrity and courage on the part of pediatric practitioners, but they fully expect the profession to "rise to the occasion."²⁰ The North American Task Force on Intersexuality (NATFI) under the direction of Ian Aaronson, urologist at the Medical University of South Carolina, has attempted to unify researchers at medical centers specializing in infant genital surgery to make meaningful retrospective studies possible. As a result of this cooperation, members have

designed protocols for retrospective studies that NATFI hopes to encourage in the future.

This article begins by summarizing the ethical dilemmas faced in organizing retrospective studies on medical practices involving infant genital surgery. Arguments will be given to show how the dilemmas can be overcome and how retrospective studies can be morally justified. These arguments were presented to NATFI in my role as Chair of the Ethics Subcommittee and at a workshop on the issue sponsored by the National Institute of Child Health and Human Development (NICHD).

The First Dilemma

To be ethical, human research studies require the informed consent of their subjects.²¹ Subjects can give informed consent only if they know the nature of, and the reasons for, the studies in which they participate, as well as all of the risks and benefits associated with their participation. So the crux of the problem is that procuring informed consent from prospective participants requires giving them information they have formerly been denied—information that may very well be not only unwelcome, but in some cases greatly traumatic.

To appreciate the seriousness of the ensuing dilemma, it is important to realize that potential research subjects may be in extremely vulnerable psychological states. Many such individuals report always having felt freakish and unloved. They often feel estranged from their parents, who have remained silent about their medical conditions, often on the recommendations of the physicians. Intersexuals who try to understand the reason for the great secrecy sometimes come to believe they are suffering from a terminal illness. Others believe that the secrecy signifies the degree of repugnance others experience toward those who have such conditions. Many have not adjusted to their sex assignment and feel extremely confused and isolated. For persons suffering the ill effects of their medical histories, sudden information, like that they were born with XY chromosomes, even though they have been raised as females, is likely to evoke disorientation, trauma, and anger. This is not just the view of old-school psychologists working with such individuals, but of intersexual activists who have suffered from both the secrecy as they were raised and the pain of discovery achieved through their own research.

Given the veritable risk of psychological harm of untimely disclosure, researchers would prefer to conduct studies without providing such sensitive medical information. So the question becomes: Is it morally permissible to conduct retrospective studies that do not inform participants of their own medical histories and data? To avoid such disclosures, research subjects would be contacted by their physicians inviting them to participate in a retrospective study on people who have had genital surgery and are taking hormones. They would not be informed of the specific goals of the studies. For example, they would not be told that one of the purposes of the studies is to determine whether males born with micropenis are truly better off raised as girls and having received sex reassignment surgery. If this information is withheld, then the studies do not permit informed consent of its participants and therefore seem to be contrary to ethical guidelines.

The problem can now be stated in the form of a dilemma: The studies must be conducted either with or without informed consent. If the studies are done

with informed consent, they are unethical because of the veritable risk of harm to the subject. If the studies are done without informed consent, they are unethical because informed consent is necessary for ethical studies. Therefore, retrospective studies on genital surgery in infants and children are immoral.

The Second Dilemma

Although the argument appears to be valid, the conclusion cannot be the end of the matter, because there are equally persuasive reasons for why the retrospective studies are ethically mandatory. Surgery without the informed consent of the patient or proxy is unethical. No adequate studies have been done to provide evidence that genital surgery for infants for normalizing or sex assignment purposes is truly beneficent, and therefore the grounds for these surgeries are epistemically deficient.²² So genital surgery on infants for these purposes is dubious and, given the lack of scientific evidence, may even open physicians up to legal charges.²³ Surgeons cannot recommend surgery on scientific grounds, nor can parents opt for surgery on scientific grounds.²⁴ According to intersex activists, infant genital surgery (whose estimated frequency is between one and two per 1,000 live births) are mutilating and maleficent.²⁵

Before forsaking the project on the basis of the first dilemma, it must be recognized that a second dilemma is lurking: Retrospective research on this issue appears to be immoral because of the problems in the first dilemma, but failure to do retrospective studies would seem to violate our moral obligations as well. What we have here is a conflict of duties, and the issue needs to be treated in full awareness and appreciation of that conflict.

Some conflicts of duties are easy to resolve, as when one of the duties obviously outweighs the other. They are more challenging when the conflicting duties approximate each other in weight and significance. Some situations may involve a conflict of equally important duties, in which case the choices are more aptly described as existential rather than moral. However, as I will argue, this dilemma does not involve a conflict of incommensurable duties and is therefore not irresolvable. Conflicts of duties resisting resolution must be approached with sensitivity, imagination, and careful judgment. Sensitivity guards against belittling the importance of the duty to be overridden and ignoring the moral traces such duties continue to hold. Imagination leads the way to creative alternatives by which we can "escape through the horns of the dilemma." Careful judgment can "grasp the horns of the dilemma" by offering considerations that weaken the force of one or the other, or both, of the moral concerns.

Addressing the Second Dilemma

Before grappling with the first dilemma, it is worth considering whether the second dilemma is convincing. If we really do not have an obligation to conduct the retrospective studies, then we need not confront the Scylla and Charybdis of the first. Is it possible to deny our obligation to conduct these troubling studies? Only on the condition that there is another way our obligations toward intersexual infants and their parents can be met. Two possible ways of escaping through the horns of the dilemma suggest themselves. One is

to declare a moratorium on infant genital surgery unless necessary for medical reasons, as Kipnis and Diamond have suggested.²⁶ Retrospective studies would then be unnecessary, because we would no longer be putting infants at risk of potentially harmful surgery. The other escape route is to limit the studies to those who have been fully informed about their medical histories and conditions. This way there would be no risk of psychological harm due to “inflicted insight” of learning disturbing information. Both alternatives are deserving of consideration.

First, however, a moratorium on unnecessary infant genital surgery is not feasible. A moratorium would be perceived as an illegitimate restriction on parental autonomy, because parents will continue to request such surgeries, given that they have been common practice for 40 years and have not been proven to be truly harmful. We only have anecdotal, but not scientific, evidence that such surgery is undesirable. Certainly, a moratorium against performing surgeries without having procured the informed consent of the parents is entirely reasonable, especially because so much of the suffering reported by intersexuals has been a result of the secrecy surrounding their conditions. However, parents can give informed consent to such surgery if they are properly informed about (1) the lack of evidence supporting current practices, (2) the existence of support groups critical of the practices, and (3) the reports of some intersexuals who claim that they would have been better off not having been surgically treated because of the resulting elimination or diminishment of sexual pleasure (especially if repeated surgeries are required), or because of the discordant feelings they have with their assigned gender. After all, there are obvious difficulties with going through life with abnormal genitals.

Although it was clearly morally irresponsible to perform genital surgery on infants without a commitment to perform long-term studies in the beginning, nevertheless, a “standard of care” did arise and provides some *prima facie* justification for current practices. Physicians performing these surgeries in good faith need to be shown through good scientific study that their assumptions are unjustified and that their perception of success has been illusory. It would be unduly critical of the medical profession to think that their practices were without any kind of support and evidence, however controversial.

Second, restricting retrospective studies to those who have been fully informed about their medical histories would not only have the moral advantage of preventing the harms of “inflicted insight” but would have epistemic advantages as well.²⁷ Fully informed individuals who have had time to adjust to the information relating to their conditions and medical histories would arguably be more reliable sources, because their understanding would likely free them up to express the difficulties they face in terms of gender identity and sexual satisfaction. Having data from fully informed patients thus would ensure the scientific integrity of the studies. Another reason people who do not have a full comprehension of their medical histories are going to be less able to judge the adequacy of their treatment is because they do not know what alternatives could have been pursued.

Unfortunately, the following major difficulties beset this proposal. Doctors do not always know whether their patients are aware of the truth about their histories and conditions. Doctors treating patients with hormones often are not the same doctors who initially proposed or performed surgery. These doctors do not think that it is their obligation to disclose sensitive information to

potential research subjects, especially because of the fear of inflicting trauma on patients who only appear to be coping well. Further, they would be reluctant to disclose such information unless they were already convinced that the current practices are medically and ethically dubious, but that would require empirical evidence gained by retrospective studies. Even if doctors do know of some savvy patients who are willing to volunteer for studies, given the relative rarity of the conditions thought to have warranted surgery and the considerations above, there will not be enough subjects to provide adequate empirical evidence to guide our practices. Researchers on the subject concur that requiring that retrospective studies be done only on fully informed patients would not yield adequate empirical information for decades, because only recently has there been a movement toward full disclosure. If this is true, there is no avoiding the risks of the first dilemma. Given the apparent impossibility of escaping the horns of the first dilemma, there is no choice but to confront Scylla and Charybdis.

Addressing the First Dilemma: The Second Horn

The second horn of this dilemma is considered here first, because its treatment does not require extensive discussion. The issue is that, if the studies were done with full disclosure, there would be too great a risk of harm for the subjects. Given that this is not only a concern of some of the researchers but also of individuals who have been surgically altered as infants or children, the concern cannot be dismissed. Timing is of great importance, and although it may very well be true that intersexed or other people having had such surgery would be better off in the long run in becoming more fully informed, that does not mean it is appropriate to ignore the reality that future well-being may depend on the manner in which the information is received. On a practical note, physicians treating prospective research subjects would be reluctant to approach patients to solicit their participation if they thought the patients would be given information likely to cause them harm.

Addressing the First Dilemma: The First Horn

The first horn of the first dilemma asserts that performing the studies without informed consent would be unethical because informed consent is a necessary condition of ethical research. To evaluate this premise, two questions must be considered: First, is it true that "informed consent" is always necessary for medical research? Second, even if "informed consent" is morally required for retrospective studies on genital surgery, what does "informed consent" actually demand for these studies? It may be that full disclosure of patients' medical histories and conditions is not necessary to meet the requirement of informed consent for retrospective studies.

Given the history of paternalism and secrecy surrounding these cases, it is crucial that researchers painstakingly and assiduously dissociate themselves from any tincture of deception or paternalism, whether in the form of lies or of withholding information required for informed consent. We do not want participants to be, or to feel like they have been, "sinned against twice." Indeed, even the *appearance* of deception must be avoided. Whatever studies are conducted must guard trust in the medical profession.

Two other points must accordingly be kept in mind: First, partial disclosure cannot be justified merely on the basis of the physician's paternalistic opinion about what is best for the patient but must take into consideration both the rights and reasonable concerns of the patient. Second, it must be remembered that withholding information can be a form of deception, and regardless of whether the intention is to deceive, it may nevertheless be perceived as such, especially by disgruntled patients, unfriendly critics, zealous NIH inspectors, or institutional review boards.

We must consider, then, whether as long as no lies have been told, as long as there is no intent to deceive, and as long as a general, though somewhat incomplete, description of the aims and purposes of the studies is presented, withholding details of the purposes of our studies really violates the requirements of informed consent. Although the subjects are not being fully informed as to all of the goals of the research, they are being told the general purposes, which is enough to allow fair opportunity to decide whether to participate. The questions are relevant to many conditions, some not involving intersexuality, so the questions will not reveal potentially harmful information. The subjects are not being taken advantage of nor are they being "treated as a means only."

Although informed consent is a universally recognized ideal, there are justifiable exceptions allowing for incomplete disclosure. Federal codes recognize that *it is sometimes* morally permissible to waive or modify conditions of the informed consent requirement.²⁸ The conjunctive requirements are the following: (1) The research cannot involve more than minimal risk to the subjects; (2) the participants must have access to all information relevant to the decision to participate; (3) the research could not practicably be carried out without the waiver or modification; (4) any risk of harm or discomfort must be disclosed; (5) all questions must be answered truthfully; (6) information should not be withheld for the purpose of securing the cooperation of the subjects; and (7) in general, debriefing after the studies are over is desirable where deception has been necessary.

Given that prospective subjects are at genuine risk of psychological harm resulting from untimely information for which they are not poised to receive, the requirement of informed consent cannot be waived altogether. Can it be modified? Do prospective participants need to know *all* of the purposes behind the proposed studies?

In general, the reason for requiring that subjects be told all the purposes of the studies is so they can be aware of all risks and can judge whether the research is safe enough or important enough to make the sacrifices of time and energy. The generalized account of the studies is enough to assure the research subjects of the importance of the studies. Given that the studies are retrospective only, there are no physical risks. The only dangers involved would be psychological.

Researchers plan to employ several precautions to minimize the risk of psychological harm to the research subjects. The initial contact letter inviting them to participate will indicate that the questions they will be asked in the course of the study will be sensitive in nature. The letter would invite further questions about the study before deciding to participate, but those questions would be referred to the attending physician. Individuals who are unstable about sexual and gender issues would most likely then decide not to partici-

pate. If the subjects do not ask, they could be considered as having given their consent to remain less strictly informed. Granted, lack of information can undermine a subject's ability to ask relevant questions, so the lack of questions is not in general sufficient evidence of adequate understanding or consent to remain less than strictly informed. However, because the subjects were told before agreeing to participate that the interview would pertain to sensitive matters, and they freely chose to participate regardless, their ability to ask relevant questions was not undermined.

The particular goals of the study are omitted, not to trick anyone into participation, but to protect the subjects from the harm of traumatic information they may not be equipped to hear. Moreover, there is no other feasible way to conduct the studies. No lies will be told; rather, all questions before and after the study would be referred to the primary physician.

To protect confidentiality, the interviewers would not be privy to the information regarding the research subjects' precise condition and medical history. Additionally, trained, sensitive, respectful, and skilled professionals would conduct the interviews. Participants who receive disturbing information in the course of the interviews could be referred for counseling, therapy, and information regarding support groups. Thus, what begins as an unwelcome and disturbing experience can be the first step toward psychological health and lead to liberating and therapeutic experiences. In this regard, retrospective studies may be an ideal milieu within which to learn this information.

Suppose it was argued that researchers involved in the retrospective studies would be harming their research subjects by allowing their ignorance to continue. It may very well be that continued ignorance will cause confusion, anxiety, fear, and other forms of psychological suffering. Patients do indeed have a right to know the important facts about their medical conditions and histories.²⁹ Rights, however, are correlative with duties, and the duty to extend such information belongs properly to physicians and parents. The function of the research studies is to provide the best guidelines for physicians and parents to follow based on empirical findings from retrospective studies. If continued ignorance is harmful, that harm is not being promulgated by the researchers—rather, it would continue anyway. Members of NATFI and other physicians are now, or should be, well aware of the legal and moral responsibility to inform parents fully before consenting to surgery.³⁰

Although debriefing is suggested for studies involving incomplete disclosure, it is not mentioned as a requirement. Given that debriefing would defeat the whole purpose of attempts to protect the subjects, it cannot be part of the retrospective study's protocol. However, researchers could plan to have the subjects give their reactions to the study so that they might make changes to further protect the patient or, if need be, to bring the studies to a halt.

Whichever protocol researchers deem best could be submitted to a group of people similar to the participants but who know the details of the studies and of their own medical conditions and histories, or to secure the approval of such representatives of such people. Attempts of this nature are referred to as surrogate community consultation.³¹ Any remaining risk of harm must be offset by the recognition that continued ignorance also poses significant risks. Incomplete disclosure leads to confusion, fear, feelings of queerness, shame, isolation, vulnerability, and also incapacity for authenticity in personal relationships.³²

Conclusions

This analysis supports the moral permissibility, and even the moral necessity, of conducting retrospective studies on genital surgery for infants and children for sex assignment or genital normalizing purposes. Now that the objection regarding informed consent has been defused, NATFI or other researchers must address many other practical issues to get the needed research under way. Cooperation between centers where infant genital surgery is performed will be necessary to gather enough research subjects to do meaningful studies. Eliciting the cooperation of specialists in the field is difficult for many reasons. There is a natural reluctance to face the possibility that one's practices have been misguided. Many physicians fear violation of confidentiality and possible harm to their patients. Some feel strongly that the success of sex assignment treatment depends on the quality of the doctor-patient relationship and do not want their patients grouped in studies with patients who might have had doctors who did not spend as much time with their patients as they did.³³

Coordinating research must guard against bias in subject selection for the studies. Intersexuals may be "lost to follow-up," often because they have come to distrust physicians. Limiting research to subjects with healthy relationships with their doctors will undoubtedly skew the results. Unless the studies have scientific integrity and yield sound conclusions, even the slightest risk of harm cannot be justified. Incentives would have to be in place for encouraging research on individuals who are clearly unhappy with their medical treatment. Even contacting such individuals may be challenging. Although organizations like the Intersex Society of North America could solicit participation from its members, there may be many other unhappy individuals who are unaware of their histories, conditions, or the alternatives that could have been taken. Retrospective studies must not only review outcomes for each type of intersex condition, but also take into consideration that the severity of the conditions might have a determining effect on functional and psychological outcomes. Scientific integrity also requires that the studies have some way of discriminating between negative effects caused by surgical intervention and those caused by attempts of the parents and others to cover up the truth. We have seen that the most reliable information would be procured from fully informed patients, so the studies must be designed in a way that takes into consideration the research subjects' actual or potential ignorance and yet provides meaningful data for assessing our practices.

These barriers are not insurmountable. Natural beneficence, the desire for truth, the awareness of the need for the research, and fear of lawsuits are some of the incentives that will help us overcome them. Courageous and effective leadership will help to evoke these incentives to allow for more informed responses to intersexual conditions.

Notes

1. Conditions leading to infant genital surgery include cloacal exstrophy, aphallia, micropenis, ambiguous genitalia resulting from gonadal dysgenesis, congenital adrenal hyperplasia, 5 alpha-reductase deficiency, androgen insensitivity syndrome, Klinefelter's disease, mosaicism or other chromosomal aberrations, or from prenatal externally induced exposure to androgens or antiandrogens. The traditional standard of practice, articulated as recently as 1996 by the

- American Academy of Pediatrics, relies on evidence supplied mainly by articles having John Money as the lead author. Money had recommended sex reassignment surgery for a baby male twin whose penis was ablated accidentally during circumcision, and reported the decision to raise the child as a girl as a success. See: Money J, Ehrhardt AA. *Man and Woman, Boy and Girl*. Baltimore, MD: Johns Hopkins University Press; 1972; Money J. Prenatal hormones and postnatal socialization in gender identity. *Nebraska Symposium on Motivation* 1973;21:2211-95; Money J. Ablatio penis: normal male infant sex-reassignment as a girl. *Archives of Sexual Behavior* 1975;5-71.
2. Colapinto J. The true story of John/Joan. *Rolling Stone Magazine* 11 Dec 1997:56-97; Colapinto J. *As Nature Made Him: The Boy Who Was Raised as a Girl*. New York: Harper Collins; 2002. See also: Preves S. *Intersex and Identity*. Piscataway, NJ: Rutgers University Press; 2003:chap. 4.
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 15. Dreger A. Ambiguous sex—or ambivalent medicine? ethical issues in the treatment of intersexuality. *Hastings Center Report* 1998;283:24-35.
 16. See: Dreger A, ed. *Intersex in the Age of Ethics*. Hagerstown, MD: University Publishing Group; 1999; in particular, chapters by: Dreger A. A history of intersex: from the age of gonads to the age of consent; Groveman SA. The Hanukkah bush: ethical implications in the clinical management of intersex; Preves S. For the sake of the children: destigmatizing intersexuality; Coventry M. Finding the words; and Wilson B, Reiner W. Management of intersex: a shifting paradigm.
 17. See note 16, Dreger 1999:16-7; Groveman 1999:26; Preves 1999:53-7, Wilson, Reiner 1999:125. See also: Dreger A. *Hermaphrodites and the Medical Invention of Sex*. Cambridge, MA: Harvard University Press; 1998.
 18. See: Diamond M, Sigmundson K. Sex reassignment at birth: a long term review and clinical implications. *Archives of Pediatric and Adolescent Medicine* 1997;151:298-304; see note 2, Colapinto 1997; Colapinto 2000.
 19. Lawrence McCullough of the Baylor Institute of Medicine expressed this view with regard to NATFI's proposed retrospective studies in personal communications with the author on several occasions.
 20. See note 3, Kipnis, Diamond 1998:407.
 21. The Nuremberg Code. *Trials of War Criminals before the Nuremberg Military Tribunals under Control Council Law*. Washington, DC: U.S. Government Printing Office, 1949:181-2; World

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- Medical Association. Declaration of Helsinki, I, 9 and 10; Department of Health and Human Services (DHHS). *Rules and Regulations*. 45 CFR 46.116.
22. See note 3, Kipnis, Diamond 1998, on the weak epistemic grounds of our present practices.
 23. See: Beh H, Diamond M. An emerging ethical and medical dilemma: should physicians perform sex assignment surgery on infants with ambiguous genitalia? *Michigan Journal of Gender and Law* 2000;7(1):1-63. See also: Greenberg J. Legal aspects of gender assignment. Presented at the first Congress on the Hormonal and Genetic Basis of Sexual Differentiation Disorders, May 2002.
 24. See note 4, Sytsma 2002:5-7.
 25. See: Blackless M, Charuvastra A, Derryck A, Fausto-Sterling A, Lauzanne K, Lee E. How sexually dimorphic are we? review and synthesis. *American Journal of Human Biology* 2000;12(2):151-66; also see note 15, Dreger 1998:26.
 26. See note 3, Kipnis, Diamond 1998:405. They suggest a moratorium on infant genital surgeries unless parents give truly informed consent.
 27. The term "inflicted insight" was coined by Baumrind. See: Baumrind D. Research using intentional deception. *American Psychologist* 1985;40:165-74.
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 32. See note 16, Preves 1999.
 33. These concerns were expressed by physicians present at the November 2000 meeting of the North American Task Force on Intersexuality at Columbia University in New York.

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