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REVIEW ARTICLE

Evidence regarding cosmetic and medically unnecessary surgery on infants

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Abstract The *Journal of Pediatric Urology* has recently published several articles from the Annecy (France) Working Party on DSD. We question several of the presented findings and recommendations. In two key articles summarizing their review, the authors concluded that identified studies are not representative and suffer from methodological weaknesses, such that they "lack the necessary detail to base further recommendations". In a third article, the Working Party reported that the science supporting early surgery is "scanty", and that "no studies" support the belief that gender variant children require early genital surgery. Nevertheless, the Working Party warned that without long-term research, "if no effort is made, we will be left, in the next generation, to continue making the same judgment, based on 'experience' and 'expert opinion'". None of the studies cited in the articles support such assertions as we read them. We maintain that reviewed evidence suggests a moratorium on early surgical intervention is imperative for children with differences in sex development, and that the best ethical and scientific considerations require that gender surgery should be delayed until the child can consent. We further present evidence that UN and case law presently under way in the USA support such a moratorium.
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The *Journal of Pediatric Urology* has recently published (vol. 8, no. 6) several articles from the Annecy (France) Working Party on DSD. We significantly question several of the findings and recommendations as presented.

The Working Party reviewed a selection of studies from 1974 to 2012 that purport to assess the validity of surgery for children with differences of sex development. Based on that review, the Working Party concluded that the selected studies suffer from methodological weaknesses and "lack the necessary detail to base further recommendations" on care for individual child patients [1,2]. The Working Party further reported that the science supporting early surgery is "scanty", that critical long-term studies are "scarce" and unlikely to emerge, and, most significantly, that "no

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studies" support the belief that gender variant children require early genital surgery for societally favored gender development [3]. Nevertheless, the Working Party warned that without long-term research, "if no effort is made, we will be left, in the next generation, to continue making the same judgment, based on 'experience' and 'expert opinion'" [2], leaving patients subjected to surgical decisions on a "case-by-case basis with individual surgeons relying on their own professional expertise and opinions" [3].

Taken together, these articles represent candid and unequivocal statements from some of the world's best-known practitioners of surgery on gender variant children. They conclude, without qualification, that current surgical practices on children with differences of sex development lack sufficient scientific support. The implication of these findings is that the research that was in existence when early surgical intervention had started to become the standard of care could not reasonably have been interpreted as clear scientific validation of such surgery, and that representations in studies once heralded as that validation, particularly those from the Johns Hopkins University Hospital [4—6], were wrong. As early as 1965, the theory that sex neutrality in newborns provided a basis for early gender surgery on children had been directly, scientifically challenged, along with a recommendation for "extensive clinical reappraisal" [40]. Remarkably, these latter findings were not seriously examined again until the end of the 20th century [7—9]. To say the least, then, the Working Party's review was needed long ago. Indeed, the U.S. National Institute of Health (NIH) reported in 2006 that there is a "crisis of clinical management" for children with atypical genitals precisely because "there are insufficient data to guide the clinician and family in sex assignment" and "optimal application of surgery and its timing remain unclear" [10].

In this light, we must register our strong disagreement with the Party's assertions that scientific uncertainty precludes detailed recommendations for present and future clinicians. On the contrary, the Party's review of evidence resoundingly supports one recommendation — that any medically unnecessary cosmetic surgery should be delayed until the patient can consent to all of the risks involved. This is the only scientifically sound and ethical way to ensure that the surgery coincides with each child's gender identity and interests in how his or her body might appear. Indeed, in 2006, when the NIH declined to support a moratorium on early surgery, it did so with the assumption that new research would produce findings that could guide clinicians [10]. At that time, it was already nearly a decade after a clinical call for a moratorium on early surgery was first made [7]. (The first call for a moratorium on cosmetic infant surgery for ambiguous genitalia was in a 1998 print publication, the *Journal of Clinical Ethics* [7]. That same year, at an invitational presentation to the American Academy of Pediatrics, Section on Urology, a direct appeal was made to cease such surgery as the procedure lacked validation [8]. The following year, in 1999, a conference was specifically called for Dallas, Texas (USA) to reappraise the issue of pediatric gender assignment and reassignment and how to manage infant ambiguous genitalia [11]. At that conference the American Academy of Pediatrics Section on Urology and the Society for Fetal Urology were said to have formed committees that were to work on developing a registry of how such cases were managed and study long-term outcomes [11].) We maintain that a moratorium on early surgical intervention is imperative for children with differences of sex development, and that the best ethical and scientific considerations require that any gender surgery should be delayed until each child can consent to it.

The Working Party has indicated that "most" former patients who have been surveyed also favored early cosmetic surgery. None of the studies cited in the articles support such assertions, even as a statistical matter. For example, Wisniewski et al. reported that a minority of respondents to their survey gave the most common response to the question of the time for surgery as "during infancy" [12]. A majority of patients gave a wide array of responses on questions of surgical timing or declined to respond at all. We doubt if an option of "never" was offered to respondents in connection with the disclosure that doing so would have allowed full retention of erotic sensitivity. (We think it necessary that all questionnaires are included with any survey study so the meanings of the presented findings can be properly evaluated. If that is not done then at least each potential answer should be provided with the exact wording of the question evaluated.) Similarly, Warne et al. based their findings on a 53% participation rate to a mailed survey, attributing the substantial lack of response to possible patient dissatisfaction with surgery or poor questionnaire design [13]. Fagerholm et al. based their review on another mailed survey that also recorded a 53% response rate. Many of their respondents had their first surgery from age four to their late teens. The authors reported that their respondents "prefer" early surgery despite finding a risk of impaired sensitivity in all genital surgery. They further found that 23% of patients were dissatisfied with their surgical outcomes [14]. Given the thousands of patients who have not been surveyed, we think the negative responses and lack of patient participation in these surveys speaks volumes about the clinical significance of their findings.

Most notably, of the four studies cited by the authors as favoring early surgery, the significant work of Nordenström et al. made no such sweeping claim [15]. On the contrary, nearly all the patients assessed by that study said that genital sensitivity was negatively affected by surgery. The authors' findings grew out of a project that had earlier concluded that the surveyed patients were less than satisfied with genital function and appearance "whether operated or not" [16]. Nordenström et al. thus concluded that gender identity and quality of life considerations were likely as important to patients as mere surgical outcome statistics [15]. The authors expressly recommended that surgery should be "restrictive", and warned that their data demonstrated that clinicians' perceptions of surgical outcomes differed significantly from patients' perspectives on their own bodies. These findings cast substantial doubt on the ability of physicians to fully represent patients' wishes without patient input and, thus, weigh against early surgical intervention.

The characterization of these and other studies as favoring early surgery is not only at odds with the Working Party's overall findings, but also with several of the Party members' own studies, which are not given equal space in the Working Party's reports. For example, Houk and Lee have reviewed cases of highly virilized 46 XX, CAH children

raised as males without surgery, reporting that many of these patients are satisfied as males [17]. Acknowledging that the Chicago Consensus Statement was based on tentative findings and the weakest form of scientific evidence, Hoch and Lee urged "bold" reconsideration of presumptively feminizing the studied children, instead recommending to parents that their children could be raised as males, with full disclosure of the risk of gender dysphoria and physical injuries from early surgical feminization. While this proposal had been made before (with counseling for all involved) [18], Hoch and Lee noted that traditional standards of care during past decades had rigidly excluded such alternatives. Today, the authors explained, "the proposal for less invasive surgery also aligns well with the message heard from patient advocate groups that propose limited surgery until the patient is old enough to consent. The recent Consensus Statement makes it clear that all gender reassignments must be patient initiated" [17,19].

Similarly, Sarah Creighton's works have repeatedly concluded that evidence shows high risk involved in making such surgical decisions for a child without the child's consent. In 2001 she wrote, "Adult patients are unhappy and feel mutilated and damaged by surgery performed on them as young children, however worthy the clinician's motives" [20]. In 2006 she wrote, "Early infant vaginoplasty may be justified if there were good evidence it produced better long-term anatomical, cosmetic and functional outcomes than later delayed surgery. However, this does not seem to be the case.... Many adult intersex people with first-hand experience of infant genital surgery vehemently condemn this approach" [21]. Along with Christine Minto, Creighton wrote, "Most vaginal surgery can be deferred until after adolescence unless haematocolpos is a risk... Children with mild clitoromegaly should have surgery deferred until they are old enough to be involved in the decision" [22]. Creighton and Minto further expressed their feelings with an editorial in the *British Medical Journal* entitled "Most vaginal surgery in childhood should be deferred" [23]. And with Lih-Mei Liao and others, Creighton wrote that "asymptomatic adult women with CAIS" are increasingly choosing not to remove their gonads when given the choice, in light of "very limited evidence based on which clinicians can advise ... [about] gonadectomy" [24].

We have serious doubts that clinicians will be open to these concerns and adjust their practices in light of the evidence without strong formal leadership urging them to do so. In 2010, the Endocrine Society wrote, "There are no randomized controlled studies of either the best age or the best methods for feminizing surgery", "there are no data comparing psychosexual health in girls and women who have undergone early and late surgery" and "[t]here is no evidence at this time that either early surgery or late surgery better preserves sexual function" [25]. And yet, on the very pages it documented this lack of evidence, the Society continued, "We suggest that for severely virilized females, clitoral and perineal reconstruction be considered in infancy" and that vaginoplasty "should be simultaneously done at an early age". The Society not only recommended early surgery but also advocated studying only early surgery. That recommendation is not evidence-based medicine [26] but is, rather, the purposeful favor of one practice, in the hope of gathering data that will support that practice, without any reasonable basis for believing that such data will emerge.

It is undeniably appropriate that the Working Party now questions the role that physicians may play in encouraging patients to choose surgery. The Working Party has advised that clinicians should be open to the fact that patients might prefer to sacrifice sexual sensitivity in order to "look normal" [2]. For males with micropenis, the Working Party has asked whether clinicians should encourage patients to transition to female [2]. These are the very problems that clinicians struggled with generations ago before surgery became "preemptive". But from the patients' perspectives, the questions of whether they should receive deference in regard to their own surgeries are transparently bypassed by performing such surgery on very young children. It should be obvious that the questions the Working Party now raises are meaningful to patients who have been given a chance to grow up and become sexual beings with a gender identity, so that they have the needed perspective about how they wish their genitals to be in ways that suit them for the rest of their lives.

More than two decades ago, Suzanne Kessler recruited a large random population of young adults to objectively test that very hypothesis [27]. On the question of surgical reduction of a clitoris between 1.0 and 2.5 cm in length, 93% of women would not have wanted their parents to agree to surgery unless the condition were life-threatening, even if it resulted in loss of orgasm or pleasurable sensitivity. And when given a choice as to when they might have wanted such surgery done, almost half would have wanted to be able to make their own decisions. Most of the women would not have wanted vaginal surgery even if the condition made them uncomfortable or limited their ability to have intercourse. Males were asked the comparable question of whether they would have wanted surgery for hypospadias. A third of the males would not have wanted the surgery even if it kept them from standing up to urinate, and three-quarters would not have wanted the surgery if it meant the loss of pleasurable sensitivity. Almost none of the men would have wanted sex reassignment for micropenis or other reason if it meant loss of orgasm or reduction in pleasurable sensitivity [27]. Today, the Working Party [1,2], like the Chicago Consensus before it [19], has finally questioned much clitoral reduction surgery and feminization of males with micropenis — not because patients with atypical sex development were asked — but because injuries to untold numbers of patients proved it was unnecessary and harmful, at the patients' expense.

The knowing continuation of unproven surgery on children in the search for evidence is experimentation, and should not be done in unmonitored, uncontrolled clinical practice. Indeed, the continuation of early surgical intervention on children without their consent has only increased the uncertainty surrounding the current standards of care, not the reverse. As a result, objective scientific research cannot continue in this field without a moratorium on early surgery, precisely because favoritism for early surgery seems to have closed many clinician-researchers' minds to the scientific possibility — indeed, the reality — that children with differences in sex

development can thrive without surgery. Decades ago, although unpublished, one well-known Harvard dissertation documented the health and stability of such individuals unaltered by surgery [28]. This was even at a time dominated by dogmatic and archaic notions of gender and sexuality. The Working Party's findings now make abundantly clear that the model of surgery-in-a-state-of-uncertainty is not reliable, particularly for cosmetic surgery for which no evidence of medical need exists, as cosmetic surgery is an imperfect mix of art and science. As Schober, another Working Party member, has written, a "reliable, successful genitoplasty procedure that can be performed early in childhood for either feminization or masculinization has not yet been developed" [29].

The priority of research, therefore, should be a commitment to delay surgery and determine how patient participation in surgical decisions can be incorporated into practice. The Working Party has recommended a multidisciplinary registry of surgeries [30], along with a systematic recording of long-term outcomes of treatment from birth to adulthood [2]. They have, however, recommended that these steps be taken prospectively and without a moratorium in place. A registry already exists in Europe, has already been proposed for the USA, and should be available everywhere surgery is performed [31]. But we cannot support the notion that early surgeries continue in the midst of systematic documentation while we await evaluation of long-term outcomes. Too many patients will be negatively affected in the interim. Even if all practitioners were to commit today to delay all surgery until each patient consents, we would have more than enough patients who have undergone early surgery to follow prospectively, while practitioners focus their energy on documenting patient histories that have been lost to follow-up. Several participants in the Working Party already have more than enough cases from their own practices that they could review and register, if not publish. The combined results would rapidly displace any claim of lack of data in securing the best evidentiary bases to medical practice relative to infant cosmetic surgery.

In the past, legal authorities have been slow to take a stance in this field. That is now changing. The Colombian Constitutional Court — the first in the world to require the consent of many young children to genital cosmetic surgery [32] — has requested a consult with one of us (MD) with regard to future management of intersex identity [33]. The German Ethics Council has proposed increased legal controls of genital and gonadal surgery for all children [34]. The UN "Special Rapporteur for Torture and Other Cruel, Inhuman, Degrading Treatment" has called for all nations to reform laws in order to prevent medically unnecessary and nonconsensual genital surgery [35]. Most recently, the Parliamentary Assembly of the Council of Europe has called on all Member States to take measures regarding "early childhood medical interventions in the case of intersexual children" to "ensure that no-one is subjected to unnecessary medical or surgical treatment that is cosmetic rather than vital for health during infancy or childhood" [36].

Perhaps most significantly, in recently filed litigation in the USA, a federal court has already held that nonconsensual genital and gonadal surgery may violate the constitutional rights of affected children [37]. The facts of that case [38] are compelling:

> "Despite the fact that M.C.'s condition did not threaten his health, the defendant doctors planned and decided to perform a 'feminizing-genitoplasty' on the sixteen-month-old M.C. During this surgery, [the surgeon, Dr. X] cut off M.C.'s phallus to reduce it to the size of a clitoris, removed one of M.C.'s testicles, excised all testicular tissue from M.C.'s second gonad, and constructed labia for M.C. The surgery eliminated M.C.'s potential to procreate as a male and caused a significant and permanent impairment of sexual function....
>
> The defendant doctors knew that sex assignment surgeries on infants with conditions like M.C.'s pose a significant risk of imposing a gender that is ultimately rejected by the patient. Indeed, one of the doctor defendants who performed the surgery on M.C. had previously published an article in a medical journal wherein he recognized that 'carrying out a feminizing-genitoplasty on an infant who might eventually identify herself as a boy would be catastrophic.'
>
> Since a young age, M.C. has shown strong signs of developing a male gender. He is currently living as a boy ... Defendants' decision to perform irreversible, invasive, and painful sex assignment surgery was unnecessary to M.C.'s medical well-being."

M.C.'s legal case is the first of its kind, but is likely not to be the last. Nevertheless, physicians with knowledge of the lack of sufficient evidence to justify early surgical intervention can avoid harm to patients — and thus avoid litigation or sanctions — by allowing patients to decide, on their own, if they wish gender surgery or not.

The Working Party's findings are, therefore, important to read in detail precisely because they document that there is no evidentiary basis to continue early sex assignment and genital surgery. The inescapable conclusion of those findings is that a moratorium on such surgery is overdue as both a scientific and medical matter. Patients' human rights must be seen as compatible with the best ethical considerations for medical practice [7,9,39]. We continue to support the clinical guidelines for medical management of differences in sex development in children, as presented in 1997 [18]. We urge, in the absence of imminent dangers to patients' lives or health, that gender variant conditions must be managed with the least invasive means available and respect for each patient's autonomy.

Conflict of interest

None.

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