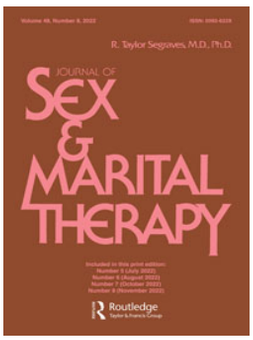

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BRIEF REPORT

Commentary on Levine et al: Festina Lente (Rush Slowly)

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Quidquid agis, prudenter agas et respice finem

Whatever you do, do it deliberately and consider the end

Lately, we have lived in times of increasingly ideologized debates that weaponize various medical and ethical issues. Data in these debates are misinterpreted, overinterpreted, forgotten, or are not available. Some of these debates are presented as evidence-based, even when the evidence is weak or not available. Unfortunately, patient benefits may get, to various degrees, lost in these debates. Examples of such debates also include gender dysphoria, gender identity, transgenderism, and gender transition. These debates have permeated media, schools, sports, and a host of other areas. It seems that most of the time ideology, emotions and personal convictions beat knowledge and evidence in these debates, which makes important related issues muddy and "unimportant" by pushing them aside or into the background.

Dr. Levine (2022) discusses an important issue in the area of gender transition, and interventions related to transgenderism – the issue of *informed* consent. I am emphasizing the word *informed* as it is central to the issue of consent for numerous reasons. I would also like to emphasize that in my (and clearly Dr. Levine's) opinion, the word informed does not relate "just" to patients' (and their families) side of the informed consent equation, but also to the clinicians' side. It is obvious that our state of knowledge regarding appropriate and timely gender transition (whatever the intervention is) and its consequences is not where we would like it to be. Simply said, the ship has sailed, and we assume that its course is correct and landing will be correct and the life after will be happy. Is that so, though?

What should clinicians include in informed consent?

As noted by Katz et al (2016), "informed consent should be seen as an essential part of health care practice." Katz also reminds us that "Physicians must realize that informed consent/permission/assent/refusal constitutes a process, not a discrete event, and requires the sharing of information in ongoing physician-patient-family communication and education" (Katz et al, 2016). It is also important to note that, as Levine (2022) writes, informed consent should be explicit and not implied, especially in this area, because of the complexity, uncertainty, and risk involved, and because informed consent for social transition represents gray area.

Similar to Levine (2022), I am also not sure whether, with the increased incidence of gender identity variation, all parties involved in the informed consent process are well and appropriately informed and educated. As Levine (2022) notes, there are models of the informed consent

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process that do not require mental health evaluation, and hormones can be provided just after one visit following the collection of a patient's or guardian's consent signature. Similarly, Yarbrough (2018, p 208) notes that that the World Professional Association for Transgender Health Standards of Care do not suggest that someone be in therapy or have a psychiatric evaluation prior to starting hormone therapy. This is an interesting notion at times when patients requiring much simpler intervention in terms of possible outcome, bariatric surgery, are frequently required to have a psychiatric evaluation. How does one rule out neurodevelopmental abnormalities or mental health problems in patients looking toward gender transition? It is also a significant deviation from the protocols used in the original sex reassignment surgeries (e.g., Cohen-Kettenis & van Goozen, 1997), also noted by Levine (2022).

I will provide a brief summary of the protocol used by Cohen-Kettenis and van Goozen to illustrate the complexity of the approach to the process and procedure involved. Cohen-Kettenis and van Goozen (1997), proponents of proper sex reassignment procedure, pointed out first a host of important issues to consider – that most children with gender identity disorder (gender dysphoria) "will not grow up to become transsexuals," that "Adolescence is a phase in which many identities, e.g., political or religious, are developed," and that "The chance of making the wrong diagnosis and the consequent risk of postoperative regret is therefore felt to be higher in adolescents than in adults, as a consequence of the developmental phase itself." They advocated for sex reassignment procedure and surgery, but they also advocated for careful and detailed evaluation in several phases.

During the first phase, they conducted careful interviews (using a semi-structured interview) of the child/adolescent and family, including a detailed developmental history, psychodiagnostic testing and a self-developed gender dysphoria scale. The first phase could take "several weeks, months or even years." (Cohen-Kettenis & van Goozen, 1997). To progress to the second phase, patients had to be clearly diagnosed "extreme and complete cross-gender identity/role and be psychologically stable (with the exception of depression due to living in the unwanted gender role) and "function socially without problems." Once applicants met these criteria, they were allowed to proceed into the second diagnostic phase even if they were younger than 18 years, but they had to be older than 16. If they were diagnosed transsexuals but did not meet the additional criteria, the second phase was postponed. The "real-life test" supported by a partial hormone treatment was the beginning of the second phase. The partial hormone treatment was designed to block the action of sex steroid in a reversible way. The authors considered the full, nonreversible hormonal treatment before the age of 18 only when the patient responded favorably to the partial hormone treatment. During the real-life test applicants had to "live full-time in the desired gender role," to discover all advantages and disadvantages of their new life. The minimal duration of the real-life test was 1 year for the female-to-male transition and 1 and1/2 year to male-to-female transition. Finally, if the real-life test was successful, the patient was referred to surgery. Cohen-Kettenis concluded that "Starting the sex reassignment procedure before adulthood results in favorable postoperative functioning, provided that careful diagnosis takes place in a specialized gender team and that the criteria for starting the procedure early are stringent" (Cohen-Kettenis & van Goozen, 1997, p. 263).

The question is whether this entire process and procedure of transition is properly discussed and explained during the informed consent process these days. Even the authoritative and informative text by Yarbrough (2018) focused its discussion of informed consent mostly on the physical side effects of hormonal therapy. However, it also recommends a number of open-ended questions regarding the surgical procedure, and possible capacity evaluation, as this may be required by insurance companies and/or surgeons. One also wonders whether possible negative psychosocial consequences may be omitted from the informed consent discussion.

Finally, as the literature regarding benefits of puberty blocking and subsequent surgery does not provide definite answers and is rapidly evolving, the clinician acquiring the informed consent must be very careful about the interpretation of results of various studies and present them in

an objective manner. Recent reaction to an optimistic review by Rew and colleagues (2021) regarding the use of puberty blockers triggered reaction from a group of authors (Clayton et al., 2021) who brought up the fact that the evidence of the benefits of puberty blockers is weak. They (Clayton et al., 2021) noted that the National Institute for Health Care and Excellence (NICE) (National Institute for Health Care and Excellence, 2021a, 2021b) reviews concluded that "studies investigating the benefits or adverse effects of GnRH analogs (puberty blockers) were of 'very low certainty using modified GRADE.' They noted that any outcome differences that were found could have represented changes of 'questionable clinical value,' or could have been 'due to confounding bias or chance.' Clayton et al. (2021) also noted that the National Health Service in England suspended the use of puberty blockers for new patients under the age of 16, "following the High Court's judgment that children so young could not consent to the unknown risks of these drugs." They added that the Karolinska Institute in Sweden suspended the use of puberty blockers in gender dysphoria youth outside of clinical trials, and that Finland also sharply curtailed the use of these drugs.

Thus, the situation regarding timing of interventions for gender transition is confusing. One wonders what the standards of care should be, and whether knowledge of those involved in obtaining informed consent in one visit is up to date, and not rushed through.

Conclusion

A simple answer to the question of what should be included in the process of informed consent in preparation for transition (and probably for detransition, too) is" A lot." Numerous issues involved in this process - the complexity of the original well-designed study (ies), lack of solid results in scientific literature, rapid developments in this area, and unspoken pressure from media and especially social media that could be detrimental (Ostergaard, 2017), and possibility of underlying belief systems replacing scientific evidence - underscores the necessity of requiring a serious, thorough, and careful informed consent process advocated by Levine (2022). Informed consent process should be deliberate, and one should not rush through it and remember its purpose and goal.

Finally, I would like to say that I have been puzzled and a bit disquieted by the certainty of all "sides" of the gender issue debates and the lack of ability to hear the other side(s). I believe that we should agree with Sir Karl Popper, that "the growth of knowledge depends entirely on disagreement." We should agree to disagree and through our disagreement and continuous study of gender and transgender issues continue to improve the care of our patients…as this is, hopefully, our ultimate goal. There is, ultimately, just one side to this debate…the patient side. I believe that Dr. Levine's well-thought-of informative article brings to all of us a lot of food for thought and reminds us that there is a lot of work ahead us.

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