

Eligibility and Readiness Criteria for Sex Reassignment Surgery: Recommendations for Revision of the WPATH *Standards of Care*

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ABSTRACT. In a review of the literature on follow-up studies of sex reassignment surgery (SRS) with regard to regret, suicide, and prognosis, this article evaluates the eligibility and readiness criteria of the WPATH *Standards of Care—Sixth Version*. Because the literature shows a lack of high-quality follow-up studies on large numbers of operated transsexuals, it offers no evidence-based research above evidence Level B or Level C. Nevertheless, our review allows us to conclude that most of the eligibility criteria are evidence-based. Although psychiatric co-morbidity is consistently mentioned in the literature as a negative predictive factor, it is barely addressed in the eligibility and readiness criteria for SRS. Therefore this paper suggests some changes and a shift in emphasis in the eligibility and readiness criteria of the *Standards of Care*.

KEYWORDS. Transsexual, gender identity disorder, sex reassignment surgery, follow-up study, WPATH standards of care, eligibility criteria

INTRODUCTION

The general goal of sex reassignment surgery (SRS) for persons with gender identity disorder (GID) is to enhance their overall psychological well-being and self-fulfillment by relieving their gender dysphoria. Only persons with a genuine gender identity disorder can benefit from sex change therapy. Considering the irreversibility of SRS, the *Standards of Care (SOC)* take great care in establishing a treatment procedure. After the diagnosis of GID is made, the therapeutic

approach usually includes three elements or phases (sometimes labeled “triadic therapy”): a real-life experience in the desired role, hormones of the desired gender, and surgery to change the genitalia and other sex characteristics (Meyer et al., 2001). After the diagnostic work, it is generally the task of the mental health professional to ascertain the eligibility and readiness for hormone and surgical therapy, with the aim of ensuring that no applicants regret their decision and that their overall psychological well-being is achieved. In Version 5 of the *SOC*

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(Levine et al., 1998) of the WPATH (World Professional Association of Transgender Health (formerly the Harry Benjamin International Gender Dysphoria Association) a distinction was proposed between eligibility and readiness criteria.

1. Eligibility: the specified criteria that must be documented before moving to a next step in a triadic therapeutic sequence
Readiness: the specified criteria that rest upon the clinician's judgment prior to taking the next step in a triadic therapeutic sequence

The minimum eligibility criteria for various genital surgeries described in the WPATH's latest edition, Version 6, of the *SOC* (Meyer et al., 2001) equally apply to biologic males and females. The criteria are listed on page 28. To establish whether the eligibility and readiness criteria for surgery formulated in the *SOC* are evidence based, we first need to review the literature on follow-up studies that include a large number of applicants to allow us to analyze the positive and the negative predictive factors. While there are no randomized controlled clinical trials that prove that SRS is effective and under which conditions, there are sufficient indications in the literature that if the *SOC*, and especially the eligibility and readiness criteria for SRS, are adhered to with care, the individual with GID will feel psychologically better after the SRS than before it. Secondly, exploration of case studies of patients who report regret can further refine our criteria. The case studies constitute only indirect methods to determine the validity of the criteria proposed by the *SOC*, as they do not test the eligibility criteria themselves. Only the study by Ann Lawrence (2003) explicitly tests the eligibility criteria for surgery, though only for male-to-female SRS.

Evidence-based medicine is "the conscientious, explicit and judicious use of current best evidence in making decisions about the care of individual patients" (CEBM, 2001). It seeks to apply the methods that ensure the best prediction of outcomes of medical treatment. The Oxford Centre for Evidence-Based Medicine suggests levels of evidence, or LOEs, (CEBM, 2001) according to the study designs and critical ap-

praisal of prevention, diagnosis, prognosis, therapy, and harm studies.

- Level A: consistent Randomised Controlled Clinical Trial, Cohort Study, All or None, Clinical Decision Rule validated in different populations.
- Level B: consistent Retrospective Cohort, Exploratory Cohort, Ecological Study, Outcomes Research, Case-Control Study; or extrapolations from Level A studies.
- Level C: Case-Series Study or extrapolations from Level B studies
- Level D: Expert opinion without explicit critical appraisal, or based on physiology, bench research or first principles.

Applying these distinctions to the evaluation of the eligibility and readiness criteria for SRS, we find in the literature that either B or C is the highest level of evidence to be found in outcome studies with a focus on the negative prognostic factors, and in case series of persons who regret.

METHODS

Pfäfflin and Junge (1998) produced an excellent review of all follow-up studies between 1961 and 1991, including 1,000 to 1,600 male-to-female (MtF) and 400 to 500 female-to-male (FtM) subjects. We used their well-documented publication to examine the positive and negative predictive factors and the case reports about regret and suicide after SRS. For follow-up studies between 1991 and the present we searched Medline and Embase using the following keywords: "transsexual, gender identity disorder, sex reassignment surgery, follow-up study, regret, standards of care, eligibility criteria." We made a selection of these follow-up studies, retaining only those papers that contained information "on whom and under what circumstances SRS is effective." Besides this Web search we also consulted the abstracts of the WPATH Biennial Symposia from 1995 onwards, as well as all the *International Journal of Transgenderism (IJT)* issues from 1997 to 2007.

RESULTS

Analysis of Persons Who Regret (Case-Series Study)

How is regret defined? Who are the patients who regret? Can regret be predicted? Pfäfflin (1992) distinguishes between “big” and “little” regrets. “Little” regrets are difficulties and indirect signs that do not challenge the outcome of SRS as such. A “big” regret is defined by Pfäfflin (1992) as “gender dysphoria in the new gender role and after SRS which is expressed in behavior” (p. 70). Both Kuiper and Cohen-Kettenis (1998) and Lawrence (2003) stress that the subjective experience of regret is the most important feature in its measurement. In this article, we want to focus on those subjects who show “big” regret and who reverted to their original gender role.

In their extensive review of follow-up literature, Pfäfflin and Junge (1998) report less than 1% of regrets in FtM subjects (5) and between 1% and 1.5% in MtF subjects (18). The percentage of persons who regret may be underreported due to the low response-rate in these follow-up studies. Analysis of these 23 cases reveals three major sources of regret:

1. inadequate diagnosis, that is, major comorbidity such as psychosis or alcohol dependency,
2. an absence of or a disappointing real-life experience, and
3. disappointing surgical results (aesthetic and functional).

In their review of follow-up studies since 1990, Gijs and Brewaeys (2007) reach the same conclusion about the predictors of regret.

Kuiper and Cohen-Kettenis (1998) interviewed in-depth ten persons who regretted. These individuals had been traced through advertisements in newspapers/magazines and by announcing the study at meetings of self-help groups of transsexuals. Nine out of the ten interviewees declared they would never again start with the sex reassignment procedure. Five thought they had been wrongly diagnosed with transsexualism and consequently had been given

the wrong treatment. When the authors examined these subjects for possible indicators for regret, they found that seven among them had felt doubts before or during the SR procedure, but had not dared to share their feelings with their psychologist or psychiatrist. A combination of several risk factors including stress-related late onset of the gender conflict, fetishistic cross-dressing, psychological instability and/or social isolation underlines the need for caution. The authors conclude that, rather than a mental health professional in the role of controller or gatekeeper, a multidisciplinary team could reduce the risk of decisions based on personal views or on insufficient information.

In a study by Lawrence (2003), 232 MtF persons after SRS were studied. The results showed that “no participants reported consistent regret” and “only 15 persons were sometimes regretful. . . . Eight regretful participants cited disappointing physical or functional outcomes of surgery as the reason for their regret, while five others cited familial or social problems” (p. 305).

Gijs’s analysis of the profiles of five persons (among 147 who had undergone SRS) who regretted and reapplied for SRS found that these patients attributed their regret to ego-dystonic homosexuality, to general identity problems, and to social pressure. He suggested more attention should be paid to these risk factors in the treatment procedure (Gijs, 2005).

In the sample studied by De Cuypere et al. (2006), among 62 persons assessed postoperatively, one MtF person regretted the treatment occasionally, but went on living as a woman nevertheless. She had had psychotic periods before SRS (axis I diagnosis: delusional disorder, erotomanic type) and had scored very low on credibility. The case report by Borrás, Huguelet, and Eytan (2007) demonstrates also that persons with delusions of sex change should be treated with caution, because they often prove to regret their genital operation.

In their case report of a person who regretted SRS, Olsson and Möller (2006) conclude that a strict interpretation of the *SOC* is needed with regard to evaluating the patient’s mental health apart from the evaluation of GID, as well as the patient’s subsequent need for treatment interventions.

The case studies of persons who regret SRS lead us to conclude that inadequate diagnosis and major psychiatric co-morbidity are the major indicators for regret. But the fact remains that data on the number and characteristics of persons who regret their SRS will be lacking until all operated patients are systematically studied over a well-defined time and with a clearly defined method.

Suicide

Very few studies report suicide in persons who have had SRS. In a review by Pfäfflin and Junge (1998), they report a total of 16 deaths “in which it is questionable if each was a suicide and if the reason was connected to transsexualism” (chap. 6.2.6., p. 11). After examination of these case studies, they conclude that post-operative suicides were related to other problems than gender identity issues. SRS had only alleviated the gender dysphoria.

In a long-term follow-up study by Eldh, Berg, and Gustafsson (1997), three persons were found to have committed suicide postoperatively for reasons related to depression and anxiety. All three had made many unsuccessful suicide attempts before their SRS. The case reported by Levine (1984) was one of transsexualism as a failed solution to the individual's lifelong problems.

The literature definitely lacks systematic documentation on (the rate of) suicide after SRS. The scarce reports do not allow any conclusions to be drawn about the motives for suicide in these patients.

Negative Predictive Factors

From a large number of papers that explore the prognostic risk factors (which in empirical studies are associated with an unsatisfying outcome of SRS, i.e. a non-favorable psychological development including feelings of regret) we retained only those factors that were mentioned in more than one paper. They were the following (see also review papers by Cohen & Gooren [1999] and Michel, Ansseau, Legros, Pitchot, & Mormont [2002]):

- Choice of a heterosexual sex partner before SRS, which results in a homosexual couple after SRS (Wålinder, Lündström, & Thuwe, 1978; Pauly, 1981; Kockott & Fahrner, 1987; Blanchard, Steiner, Clemmensen, & Dickey, 1989; Muirhead-Allwood, Royle, & Young, 1999; Smith, Van Goozen, Kuiper, & Cohen-Kettenis, 2005)
- GID with transvestism or autogynephilic transsexualism (Sörensen, 1981; Lundström, Pauly, & Wålinder, 1984; Green & Fleming, 1990; Landèn, Wålinder, Hambert, & Lundström, 1998; Pfäfflin & Junge, 1998)
- An age over 30 years at first request for SRS (Lundström et al., 1984; Lindemalm, Körlin, & Uddenberg, 1987; Kuiper & Cohen-Kettenis, 1988; Eldh et al., 1997; Schroder & Carroll, 1999; Krege, Bex Lümme, & Rübber, 2001; De Cuypere et al., 2006)
- Psychiatric co-morbidity and personal instability (Wålinder et al., 1978; Bodlund & Kullgren, 1996; Eldh et al., 1997; Landèn et al., 1998; Pfäfflin & Junge, 1998; Muirhead-Allwood et al., 1999; Smith et al., 2005; Olsson & Möller, 2006; De Cuypere et al., 2006)
- Inadequate social functioning, indicated by periodical or full dependence on social assistance (Wålinder et al., 1978; Eldh et al., 1997; Cohen & Gooren, 1999)
- Poor support from the patient's family (Wålinder et al., 1978; Eldh et al., 1997; Landèn et al., 1998)
- Dissatisfaction with secondary sex characteristics at initial assessment (Wålinder et al., 1978; Eldh et al., 1997; Smith et al., 2005; De Cuypere et al., 2006)
- Unsatisfactory surgical results (Lundström et al., 1984; Ross & Need, 1989; Eldh et al., 1997; Lawrence, 2003; Althaus, 2006)

In a review by Cohen and Gooren (1999), they add “a non-cooperative attitude toward clinicians and enduring resistance against transsexualism” (p. 329). Such an attitude and resistance will often make the person hesitate and postpone his or her request for SRS (Spengler, 1980). This

negative factor was described in studies with small group size, but its existence has not been confirmed in larger studies.

Some comment on these negative factors is called for. In most of these studies the predictive factors are called “negative” because they are associated with a non-favorable psychological outcome or with regret. Only more recently have authors used a logistic regression analysis to identify predictors (Bodlund & Kullgren, 1996; Landén et al., 1998; Muirhead-Allwood et al., 1999; Lawrence, 2003; Smith et al., 2005; De Cuypere et al., 2006). Landén et al. (1998) was unable to prove that persons with heterosexual experience before SRS more often had regret than those with homosexual experience only. Also Coleman, Bookting, and Gooren (1993), in their follow-up study of 9 FtM persons, came to the conclusion that sexual orientation to men does not constitute a risk for the outcome.

Lawrence (2003) evaluated 232 MtF operated transsexuals, and she stressed that in her research the results of MtF SRS appear to be so uniformly good that looking for factors predictive of satisfaction or regret might seem a pointless exercise. Not all participants in this study had met the minimum eligibility criteria of the SOC when they came for surgery. They did, however, comply with the SOC in one respect: they had received two letters from two mental health professionals addressed to the surgeon. No participants reported outright regret and only 6% expressed occasional regret. Her conclusion was that “dissatisfaction was most strongly associated with unsatisfactory physical and functional results of surgery” (p. 299). Age at surgery and sexual orientation were not correlated with absence of regret and improved quality of life. Childhood femininity in the participant’s own opinion and age at first wish to change sex were the only preoperative variables related with the absence of regret. The shortcomings of this study are its low rate of response and a possible lack of objectivity because of the author’s personal involvement with the surgeon whose patients were studied.

All the studies mentioned here are retrospective studies, some are cohort studies, and all of them suffer from methodological draw-

backs: (a) a lack of preoperative data, which makes comparison between pre- and post-SRS impossible and (b) a likely bias of the selection of the study population. The study by Smith et al. (2005), which is a prospective controlled study, is methodologically superior. The authors conclude that “non-homosexual applicants with much psychopathology and body dissatisfaction reported the worst post-operative outcomes.”

Considering all the risk factors, most authors agree that regret is induced, not by a single, but by a combination of factors. The more negative factors are combined, the higher the probability that a person will regret SRS. However, no study has been conducted with a group that is large enough to calculate which combination of risk factors is the most decisive.

Positive Predictive Factors

The following positive predictive factors (factors that in empirical studies are associated with a satisfying outcome of SRS, that is, a better psychological and social functioning of the subjects) are adduced in a number of papers:

- Sexual attraction to same-sex partner before SRS, that is, GID with homosexual orientation (Blanchard et al., 1989; Muirhead-Allwood et al., 1999; De Cuypere et al., 2006)
- Early onset of transsexualism (Sörensen, 1981; Lundström et al., 1984)
- Age under 30 years at first request for SRS (Lundström et al., 1984; Rehman, Lazer, Benet, Schaeffer, & Melman, 1999)
- Absence of coexisting mental illness (psychosis) and emotional stability in life history (Lundström et al., 1984, Green & Fleming, 1990)
- Good familial and social support after SRS (Wålinder et al., 1978; Kockott & Fahrner, 1987; Ross & Need, 1989; Botzer & Vehrs, 1995; Eldh et al., 1997; Carroll, 1999)
- Satisfactory surgical results (Lundström et al., 1984; Green & Fleming, 1990; Botzer & Vehrs, 1995; Eldh et al., 1997; Pfäfflin & Junge, 1998; Lawrence, 2003)

The Necessity of Compliance with Established Treatment Regimens

Fewer papers have reported on compliance with established treatment regimes (real-life experience, hormone treatment, preoperative psychotherapy). As the eligibility criteria in the *SOC* also concern these regimens, we surveyed the literature with special attention to the relationship between regimen compliance and outcome of SRS. Lawrence, in her 2003 paper, remarked the following:

1. Favorable outcome after MtF SRS was associated with
 - consistent use of hormones (Carroll, 1999),
 - a real-life experience in the desired gender role of one year or longer (Green & Fleming, 1990; Botzer & Vehrs, 1995), and
 - adequate preoperative psychotherapy (Green & Fleming, 1990; Pfäfflin & Junge, 1998; Muirhead-Allwood et al., 1999; Michel et al., 2002).
2. Increased dissatisfaction or regret was associated with
 - failure to maintain continuous hormone therapy (Wålinder et al., 1978),
 - absence of any real-life experience in the desired gender role (Pfäfflin & Junge, 1998),
 - irregular or inadequate psychotherapy (Pfäfflin, 1992).

Kuiper and Cohen-Kettenis (1998) and Michel et al. (2002) indicate the lack of ability to live in the desired gender role as the key factor in persistent regret following SRS. Lawrence (2003), however, declares that “the duration of preoperative real-life experience in the desired gender role showed a significant association with Happiness with Result but not with any other outcome measure. Greater amounts of preoperative psychotherapy were associated with poorer subjective outcomes” (p. 311). She adds that “this result could be due to applicants with more severe psychological problems undergoing more psychotherapy, rather than psychotherapy itself causing negative outcomes” (Lawrence, p. 311). When comparing the participants who met the minimum eligibility criteria of the *SOC* with

those who did not, she did not find any significant differences in outcome.

In their review, Green and Fleming (1990) mention that another predictor of successful SRS outcome is “an adequate understanding of what surgery can and cannot do” (p. 171) a criterion that is included in the *SOC*.

Pfäfflin and Junge (1998), in their review, state that there is no scientific knowledge (i.e., there are no control studies) about how long the contact with the treatment center, real-life experience, hormonal treatment, and counseling had to last in order to obtain a good result. More than 15 years later, Gijs and Brewaeys (2007) came to the same conclusion.

There is unquestionably a lack of scientific research into the necessity for and the characteristics of the different treatment regimes.

DISCUSSION: TO WHAT EXTENT ARE THE ELIGIBILITY CRITERIA EVIDENCE BASED?

Age

Mainly for ethical, legal, and insurance reasons, there is no large body of scientific evidence that a minimum age is a *sine qua non* requirement for SRS. Based on case studies, Meyenburg (1999) makes a recommendation about an age criterion. We were unable to find any other instance of a link with the “regret” parameter, probably because SRS is not executed before adulthood, due to the legal restrictions on operating on a minor as well as insurance reasons. At the Amsterdam Gender Clinic, however, Delemarre-van de Waal and Cohen-Kettenis (2006) have developed a protocol to treat GID-adolescents from puberty onwards, which consists of first administering a GnRH analog to suppress puberty and, then, adding cross-sex steroid hormones from the age of 16 onwards. This results in favorable postoperative functioning. However, the age of actual sex reassignment surgery is not mentioned in their paper. On the other hand, an application for SRS later in life (older than 30 years) is associated with an increased likelihood of regret, as already mentioned.

The criterion of “legal age of majority in the patient’s nation” must be maintained mainly for legal and insurance reasons, and can never be the subject of evidence-based research. The “age criterion” can confirm to level of evidence C or D (see “Introduction”).

Hormone Therapy Criterion

The SOC do not regard the “hormone therapy criterion” as a *sine qua non*. The paragraph “Can surgery be provided without hormones and the real-life experience?” of the SOC mentions exceptions: “Surgery can be provided without prior hormone therapy if a person has lived convincingly as a member of the preferred gender for a long period of time and is assessed to be psychologically healthy after a requisite period of psychotherapy” (p. 29). Even so, patient satisfaction after SRS has been reported to be associated with consistent use of preoperative hormones (Carroll, 1999) and conversely, an increased likelihood of dissatisfaction or regret with failure to maintain continuous preoperative hormone therapy (Wålinder et al., 1978). In her more recent paper, Lawrence (2003) was unable to prove that MtF participants who reported fewer than 12 months of preoperative hormone therapy had a less favorable outcome than participants who had had more. Hers is the only study that focused on preoperative hormone therapy (and the only study of MtF subjects!). Its result has not been replicated.

We must conclude that preoperative hormone therapy is an eligibility criterion, although not “*sine qua non*.”

The research on this criterion reaches Level C (extrapolation of Level B retrospective Cohort Study).

Real-Life Experience

Unlike hormone therapy, the real-life experience criterion is a *sine qua non* for SRS. Green and Fleming (1990), Botzer and Vehrs (1995) and even Lawrence (2003) found that a real-life experience in the desired gender role of 1 year or longer had a positive impact on the outcome. Also Pfäfflin & Junge (1998), after analysis of an extensive number of case studies, stated that postoperative regret could have been reduced by

an adequate real-life test. Real-life experience provides an opportunity to assess the impact of transition on the transsexual’s support network (loved ones, friends etc.) and the impact of the stresses of transition on the transsexual’s psychological resilience (Bowman & Goldberg, 2006). Therefore this criterion must definitely be preserved.

The research on this criterion reaches a Level C (extrapolation of Level B retrospective cohort study).

Psychotherapy

As stated in the SOC, psychotherapy per se is not an absolute eligibility criterion for surgery. But let us consider this criterion in the broader perspective of

- the detection of mental illnesses or instability and
- the use of psychotherapy.

The Detection of Mental Illnesses or Instability

Most authors agree that a careful differential diagnosis and screening for co-morbidity is imperative for good clinical practice. The different retrospective studies, case studies, and one prospective study (Smith et al., 2005) lead us to conclude that the worst postoperative outcome is related to much psychopathology and that a careful diagnostic procedure and screening for co-morbidity can reduce the risk of postoperative regret (level of evidence of this research is B = consistent retrospective cohort). To optimize this diagnostic process, a multidisciplinary team can be helpful. Such a team consists of a nucleus of professionals who see the patient frequently and who are involved in the differential diagnostic process: the psychiatrist, the psychologist, the endocrinologist, the plastic surgeon, the urologist, and the gynecologist. Especially endocrinologists and surgeons with a specialized training in transgender health issues may help detect inconsistencies in the applicant’s life story, and, more particularly, contribute to reaching a decision when different risk factors are present. They often also have a more objective view of the applicant’s mental health.

The Use of Psychotherapy

According to Pfäfflin (1992), irregular or inadequate psychotherapy is associated with a higher likelihood of regret. Consequently, supportive adequate preoperative psychotherapy is regarded as protection against regret. Both applicants and the professionals involved must realize that surgery is not the solution to everything. It is therefore appropriate to prepare the applicants during the real-life test to help them to confront the emotional, social, and sexual difficulties created by their new appearance (Michel et al., 2002). Even so, Lawrence (2003) could not find any evidence for this assumption.

Rehman et al. (1999) concludes in a follow-up study that a period of postoperative psychotherapy can be beneficial in reinforcing the social and psychological readjustment the patients need to become their own true selves. They even suggest including this postoperative psychotherapy in the *SOC*. Cohen-Kettenis and Gooren (1999) also emphasize “offering psychological guidance after SRS” (p. 331). But the study by Lawrence (2003) provides little support for such a suggestion.

The research on this criterion reaches Level C (extrapolation of Level B retrospective cohort studies). The criterion of postoperative psychotherapy is an “expert opinion” and thus meets Level D criteria.

Informed Consent

All the items of the fifth eligibility criterion of the *SOC*—demonstrable knowledge of the cost, required lengths of hospitalizations, likely complications, and postsurgical rehabilitation requirements of various surgical approaches—can be assembled in the concept of informed consent. Informed consent is a legal condition whereby a person can be said to have given consent based upon an appreciation and understanding of the facts and implications of an action. The individual needs to be in possession of relevant facts and also of his or her reasoning faculties. Recently it has been accepted as an indispensable condition for good clinical practice and actually needs no evidence-based grade.

Especially for SRS, it is necessary for individuals to be aware of these items (Rachlin, 1999), since this surgery removes or damages “healthy” organs irreversibly and since individuals with GID may have an unrealistic view of these surgical interventions.

Surgeon's Competence

Poor quality of surgery causes unhappiness and dissatisfaction in patients (Eldh et al., 1997; Lawrence, 2003; Althaus, 2006). In 1992, Pfäfflin and Junge stated that a reasonable quality of surgery, following a careful differential diagnosis and an adequate real-life test, could prevent most cases of postoperative regret. Ross and Need (1989) established that the surgical results are the major determinant of postoperative psychopathology.

Good cosmetic and functional results of surgery are associated with patient satisfaction (see above), while poor surgical results and the number of significant surgical complications are associated with an increased likelihood of regret and dissatisfaction (see above). The requirements for the surgeon performing genital reconstruction, according to the *SOC*, are “that the surgeon should be a urologist, gynaecologist, plastic surgeon or general surgeon, and Board-Certified as such by a nationally known and reputable association. The surgeon should have specialized competence in genital reconstructive techniques as indicated by documented supervised training with a more experienced surgeon” (Meyer et al., 2001, p. 27).

All authors agree that transsexual surgery should be performed only in centers where a sufficient amount of experience has been gathered (Althaus, 2006) and where there is an understanding attitude towards transsexualism.

The literature provides sufficient evidence to support the statement that the individual who seeks genital surgery must be aware of different competent surgeons and of the chosen surgeon's competence.

The research on this criterion reaches Level C (extrapolation of Level B, retrospective cohort study).

TO WHAT EXTENT ARE THE READINESS CRITERIA EVIDENCE BASED?

The readiness criteria formulated in the *SOC* contain basically the same elements as the eligibility criteria. They are: demonstrable progress in consolidating the evolving gender identity, progress in real-life items, and concerns about the improvement in mental health. The decision whether an individual is “ready” to undergo surgery is the result of a subjective and complex process that rests equally upon the clinician’s and the patient’s judgment.

Mainly because the readiness criteria are subjective and/or very individual, the difference between eligibility criteria and readiness criteria has never been scientifically investigated. Pfäfflin and Junge (1998) conclude from their review article that there is no scientific knowledge about how long real-life experience, hormonal treatment, and counseling have to last to obtain a good result (see above). The *SOC* criteria of “demonstrable progress in consolidating one’s gender identity, demonstrable progress in dealing with work, family and interpersonal issues resulting in a significantly better state of mental health” (Meyer et al., 2001, p. 29) transcend strict standards, concern the uniqueness of the individual, and recognize the importance of the relationship between mental health professional and patient. Meeting these readiness criteria reduces the regret rate as they optimize the timing of surgery (Bodlund & Kullgren, 1996; Rakic, Starcevic, Maric, & Kelin, 1996; Eldh et al., 1997; Pfäfflin & Junge, 1998; Rehman et al., 1999).

The research on this criterion reaches Level C (extrapolation of Level B, retrospective cohort study).

RECOMMENDATIONS BASED ON EVIDENCE

The *SOC* is widely accepted, not in the least because they provide flexible guidelines for the treatment of individuals with gender identity disorder. In the introductory concepts of Version 6

of the *SOC*, this flexibility is described as follows: “Clinical departures from the guidelines may come about because of a patient’s unique anatomic, social or psychological situation, an experienced professional’s evolving method of handling a common situation, or a research protocol” (Meyer et al., 2001, p. 3).

On this account, the minimum eligibility and readiness criteria in the *SOC* must be explicit in order to guide and support the professionals in their difficult task of offering assistance to individuals with a gender identity disorder and alleviating their suffering and maximizing their overall psychological well-being and self-fulfillment.

In this review of the literature on follow-up studies of postsurgical functioning of transsexuals, we have focused on regret, suicide, and prognostic criteria in order to evaluate the eligibility and readiness criteria for surgery. We have observed that there is a lack of follow-up study involving large numbers of operated transsexuals and also that those studies that exist (focusing on a small number of individuals) lack methodological rigor. Furthermore, it has become clear that prospective studies are definitely needed to better evaluate the outcome of SRS. These studies should reach Level of Evidence A.

From the papers and reviews presently available, we can conclude that the eligibility criteria are to a large extent based on evidence. However, “psychiatric co-morbidity” is hardly addressed in the eligibility or readiness criteria for genital surgery, even though it has been proved to be a major negative predictive factor.

Therefore, we suggest that these eligibility criteria should pay more attention to persons with a psychopathology other than GID and to persons showing a combination of negative predictors. Not all types of psychiatric co-morbidity and degrees of severity have the same impact on the decision-making process for SRS. Persons with a psychosis, for instance, should receive pharmacotherapy and should have totally remitted from their psychosis before they can be elected for SRS. If applicants with GID also suffer from depression (with or without suicidality), from substance abuse, from an eating disorder, or from any other Axis I diagnosis, they need pharmacotherapy and/or psychotherapy. Before

they become eligible for surgery, they must demonstrate that their psychopathology has improved. If they have a personality disorder (Axis II), psychotherapy is an absolute eligibility criterion for surgery. Psychotherapy not only provides introspection and support but can also promote contact with peers and the larger community.

In contrast with MtF subjects, there are no operative standards available for genital reassignment in FtM subjects (Sohn & Bosinski, 2007). Before undergoing genital surgery, FtM subjects need to be aware of the different operative possibilities (different neophallus reconstructions or metoidioplasty) and their implications. A change in the formulation of criterion 5 is proposed.

Finally, we recommend the addition of another eligibility criterion: "diagnosis of gender identity disorder according to the latest DSM criteria." This additional criterion emphasizes the need for a correct diagnosis and, thus, makes the criteria more comprehensive and explicit.

CONCLUSION

While surveying the literature on the SOC Eligibility and Readiness Criteria for genital surgery, it became clear that the research is sometimes Level of Evidence B, but mostly Level of Evidence C. Large follow-up studies with methodological uniformity are lacking, and randomized control trials are not feasible, sometimes even unethical. The literature shows that the eligibility criteria of the SOC have paid too little attention to "psychiatric co-morbidity" as a negative predictor.

Therefore, our recommendations to modify the eligibility criteria are the following:

- Add a criterion: "Diagnosis of GID according to the latest DSM version."
- Modify the fourth criterion: "If in the initial assessment of the patient, psychiatric co-morbidity has been detected, pharmacotherapy and/or psychotherapy is required until total remission in case of psychosis or until improvement and/or

stabilization of the symptomatology in case of any other co-morbidity."

- Modify the fifth criterion: "Demonstrable knowledge of the different surgical possibilities and their implications (cost, required lengths of hospitalizations, likely complications, and postsurgical rehabilitation requirements)."

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