

Detailed Analysis: CMS PDM Gender Dysphoria and Gender Reassignment Surgery (CAG-00446N)

We have globally grouped error types as follows:

- 1) Major - a significant error - reported incorrect numbers, reported groups incorrectly (who was compared to who), even some basic math issue
- 2) Biased - significant and obvious examples such as presented positive findings in a negative light or reported only negative findings while not presenting positive ones, misrepresenting positives as negatives
- 3) Wrong analysis - type of study or analysis reported by CMS - said post hoc when not, described study incorrectly (downgraded).
- 4) Secondary research - CMS could have (and should have) easily gotten information (e.g. easy to find on google, referenced another paper cited in primary article).
- 5) Not germane - the study didn't actually assess what CMS was interested in (that is, whether surgery is beneficial)
- 6) Response rate - incorrectly described the study population (for example, study said patients more than 1 year post-op, clinic has 200 patients, but only 100 of them are 1 year post op, then 50% agree to participate, but reports participation rate as 25 rather than 50%.)
- 7) Historical issues - there is something really well known about the authors or the measures used in the paper that was a source of bias, and was not noted or mentioned.
- 8) Context missed - authors put findings in important context which changes interpretation which CMS didn't note, or alternatively a subject matter expert in transgender care would have had important context to interpret findings.

Paper	Major	Biased	Wrong analysis	Secondary research	Not Germane	Resp rate	Hx issues	Context missed
Ainsworth								
Motmans				x				
Weyers			x					
Wierckx	x		x					
Salvador						x		
Blanchard	x					x	x	
Tsoi								
Gómez-Gil 12		x						
Gómez-Gil 14****						x		x
Mate-Kole 1988								x
Eldh	x	x	x			x		

Hepp								
Rakic		x				x		
Wolfradt								x
Beatrice		x					x	
Kraemer								
Kuhn	x		x					
Hess			x*					
Lawrence								
Heylens								x
Smith		x				x		
Udeze****								
Megeri****								
Kockott				x				
Meyer			x			x	x	x
Johansson	x	x	x					
Newfield		x	x					
Ruppin		x**						
Haraldsen					x			
Leinung					x			x
Asscherman	x	x**						x
Dhejne 2011	x	x				x		
Dhejne & Landen	x	x		x				x
Mate-Kole 1990				x***				

* actually was one of the few instances where it was a theoretically positive bias - said it was blinded, but it wasn't - or at least not any more than any of the "surveys handed to patient" studies were.

** substantial example

*** specifically could have done the analysis as numbers given, also stated stat sig in words, but didn't give numbers.

**** Studies were reviewed late, so only included comments in line by line analysis accompanying paper.

Ainsworth TA, Spiegel JH. Quality of life of individuals with and without facial feminization surgery or gender reassignment surgery. Qual Life Res. 2010 Sep;19(7):1019-24.

“The blind status is unknown.”

The blind status is meaningless because it was a study of people using a self administered questionnaire. Patients could not be blinded and there was no specific assessment on the part of the researchers where being unblinded could have introduced additional bias.

Motmans J, Meier P, Ponnet K, T'Sjoen G. Female and male transgender quality of life: socioeconomic and medical differences. J Sex Med. 2012 Mar;9(3):743-50. Epub 2011 Dec 21.

“Participants included subjects who were living in accordance with the preferred gender and who were from a single, unspecified, Belgian university specialty clinic.”

The authors referenced their prior papers which explained this was the Ghent clinic. Ref: 13 De Cuypere G, T'Sjoen G, Beerten R, Selvaggi G, De Sutter P, Hoebeke P, Monstrey S, Vansteenwegen A, Rubens R. Sexual and physical health after sex reassignment surgery. Arch Sex Behav 2005;34:679–90.

“Whether there is overlap with the Ghent populations studied by Heylens et al., Weyers et al., or Wierckx et al. is unknown.”

Same population, different type of study

“Non-blinded” Again this is a self administered survey to people who know their surgical status, so blinding is immaterial.

Weyers S, Elaut E, De Sutter P, Gerris J, T'Sjoen G, Heylens G, De Cuypere G, Verstraelen H. Long-term assessment of the physical, mental, and sexual health among transsexual women. J Sex Med. 2009 Mar;6(3):752-60. Epub 2008 Nov 17.

“Non-blinded” Again a self administered survey. Blind status does not influence beyond the study design.

Wierckx K, Van Caenegem E, Elaut E, Dedeker D, Van de Peer F, Toye K, Weyers S, Hoebeke P, Monstrey S, De Cuypere G, T'Sjoen G. Quality of life and sexual health after sex reassignment surgery in transsexual men. J Sex Med. 2011 Dec;8(12):3379-88. Epub 2011 Jun 23.

“several measurement instruments (a non-specific quality of life tool with reported normative data along with 3 self-designed tools).”

We address the more general issue of instruments used in Ruppert below, however many studies like this one use Likert scales - which have been validated in general as a way of assessing subjective concepts (e.g. patient satisfaction, pain, etc). The use of Likert scales for subjective data has been well demonstrated which is likely the reason for example that CMS not only requires hospitals to assess patient experience with instruments that use Likert scales, but even use this information to determine payment to hospitals.

“The SF-36 survey was completed by 47 (95.9%) participants. The “Vitality” and the “Mental Health” scales were lower than the Dutch male population: 62.1 ± 20.7 versus 71.9 ± 18.3 and 72.6 ± 19.2 versus 79.3 ± 16.4 respectively. These subscale scores were equivalent to the mean scores of the Dutch women.”

This is not necessarily a problem with the PDMs analysis, however this would have been a good opportunity for them to address the issue of comparison groups. In many studies, of mental health issues, suicide, physical aspects of the body, and even lab tests, transgender patients' scores are often between

that of cisgender men and cisgender women. So for example, should suicide rates for transmen be compared to cisgender women or men? (As it turns out they more resemble men post treatment). Certainly if transmen or transwomen score outside the range for both cisgender men and cisgender women, that represents a significant difference, but when the means are between the two this makes it harder to distinguish.

“Post hoc assessments suggested that being in relationship or having undergone phalloplasty did not impact the scores of the SF-36 domains.”

This statement is factually incorrect and represents a significant misinterpretation of the study. The assessment compared men who had a phalloplasty *and who had had an erectile prosthesis* to those who had a phalloplasty *without* a prosthesis. There were so few men who had a metatidioplasty or no surgery at all that you couldn't compare phalloplasty vs no phalloplasty.

Salvador J, Massuda R, Andreazza T, Koff WJ, Silveira E, Kreische F, de Souza L, de Oliveira MH, Rosito T, Fernandes BS, Lobato MI. Minimum 2-year follow up of sex reassignment surgery in Brazilian male-to-female transsexuals. *Psychiatry Clin Neurosci*. 2012 Jun;66(4):371-2. PMID: 22624747.

“Out of the 243 enrolled in the clinic over a 10 year interval, 52 patients agreed to participate in the study.” The study had a 75% response rate for eligible patients, so this is a complete misrepresentation of the quality of the study. From Salvador: “243 people were enrolled in this program, 82 of whom underwent SRS”, and “There were 69 participants with a minimum 2-year follow up. Fifty-two patients were contacted and agreed to participate in this study (75.40%). Seventeen participants (24.60%) were lost to follow up.”

Blanchard R, Steiner BW, Clemmensen LH. Gender dysphoria, gender reorientation, and the clinical management of transsexualism. *J Consult Clin Psychol*. 1985 Jun;53(3):295-304.

Blanchard reported two studies (aptly named 1 and 2). The entirety of the CMS review was the #2 study despite the fact that the first was better to answer the question CMS put forth and was a positive finding.

CMS also again seriously misrepresented the loss to f/u numbers. **“Of the 294 patients (111 natal females and 183 natal males, ratio: 1:1.65) initially evaluated, 79 patients participated in the study”**

Over a 3 year period, 294 people presented to the Clarke Institute in Toronto. They were all asked as a standard procedure at the clinic ““At the present time, do you feel that you would rather live as [the opposite biological sex]?” 263 patients answered yes, so those were the people called “gender dysphorics” who were the subject of the study. So the baseline 294 is wrong. For example, if studying people with DM at a primary care clinic, the N would be those with DM, not everyone who came to the clinic for any problem. Additionally, as below, study 1 (which was ignored in the analysis) had a 100% rate because it was data collected on everyone who presented to the clinic and study 2 has a 77.5% follow up (of the 102 patients who met criteria - that is were 1 year or more out from SRS).

Study 1:

Patients with gender dysphoria were given an SCL-90 as part of standard clinic assessment, so this is 100% response rate. Blanchard then did regression analysis to see if there were differences between groups based on where they were in the transition process (interpersonal - a real life experience, documental, and physical (SRS and HRT) - essentially proceeding in that

order) as well as age and education. Looking at data Tables 1 and 2: a negative number means they improved - positive means after that step they did worse. In summary transwomen did better - had statistically significant improvements in SCL-90 scores after physical treatments (SRS/HRT). Transmen made the biggest gains with social transition (though they don't specifically say that they did worse or equivocal - study just doesn't present that data). Again, this entire portion of the study was not discussed in CMS

Study 2:

"Study 2, a conventional follow-up study of postoperative transsexuals." Of the ones who got surgery: "1 postoperative patient is known to be dead; this was a male-to-female with a presurgical history of psychiatric hospitalization, substance abuse, and repeated suicide attempts. She finally killed herself after a lengthy period of various medical problems (including two operations) unrelated to reassignment surgery. Apart from that patient, 55 male-to-female and 47 female-to-male patients have been surgically reassigned for at least 1 year." (45 straight MTFs and 10 lesbians). "Followup data collected at least 1 year after surgery were available for 79 (77.5%) of the 102 subjects: 38 (80.9%) of the 47 biological females, 32 (71.1%) of the 45 homosexual males, and 9 (90.0%) of the 10 heterosexual males." Mean f/u: 47.4 months for all subjects; 26.8 months for the lesbian MTF, 54.3 months for the straight MTF, and 46.6 months for the FTMs. "In the combined group of all subjects, 93.7% indicated that they "definitely would" undergo reassignment surgery if they had it to do over. The remaining 6.3% (1 homosexual male, 3 heterosexual males, and 1 biological female) indicated that they "probably would.""

While it doesn't have to do with the study itself, it should have been noted at least in passing that Dr Blanchard has a very questionable name in the transgender community (including among researchers and providers of transgender care). He proposed the autogynephilia theory that transgender women are subdivided into "homosexual transsexuals" (i.e. heterosexual transgender women who are attracted to men) and autogynephilia (describing lesbian transgender women) which is "a man's paraphilic tendency to be sexually aroused by the thought or image of himself as a woman." From a scientific perspective this is a fine study to include (as long as it is reported completely - including the positive results in study 1), but this could be a political problem for CMS.

Tsoi WF. Follow-up study of transsexuals after sex-reassignment surgery. Singapore Med J. 1993 Dec;34(6):515-7.

No specific concerns for this study.

Gómez-Gil E, Zubiaurre-Elorza L, Esteva I, Guillaumon A, Godás T, Cruz Almaraz M, Halperin I, Salamero M. Hormone-treated transsexuals report less social distress, anxiety and depression. Psychoneuroendocrinology. 2012 May;37(5):662-70. Epub 2011 Sep 19.

"The HAD-Anxiety score was borderline elevated"

Mean HAD-A score was 9 in non-treated and 6.4 in treated patients. A meta analysis of the scoring for HAD-A showed that 8 was the optimal cut-off in that it had 80% sensitivity and 80% specificity. This means that of 100 people who get an 8 or higher, 80% will have clinical anxiety. So no, 9 isn't 'borderline elevated'. [http://www.jpsychores.com/article/S0022-3999\(01\)00296-3/abstract](http://www.jpsychores.com/article/S0022-3999(01)00296-3/abstract)

“ANOVA revealed that results did not differ by whether the patient had undergone a gender related surgical procedure or not.” The authors stated: “In the subgroup of patients under hormonal treatment, 58% of the MF transsexuals and 78% of the FM transsexuals had undergone at least one SR surgery procedure. To assure the comparability of these two groups, possible confounding factors were controlled in statistical analysis.” So the authors were using this post hoc analysis to ensure that SRS didn’t interfere with what they were actually evaluating (which it did not). It seems therefore that this was perhaps a post hoc interpretation by the CMS reviewers.

Gómez-Gil E, Zubiaurre-Elorza L, de Antonio I, Guillaumon A, Salamero M. Determinants of quality of life in Spanish transsexuals attending a gender unit before genital sex reassignment surgery. Qual Life Res. 2014 Mar;23(2):669-76. Epub 2013 Aug 13.

“Of the 277 patients recruited, 260 (93.9%) agreed to participate. Of this number, 193 were included in the study” The 277 was consecutive patients in the clinic who agreed to participate. However the study was of people who had not had genital SRS, so there were 10 patients excluded based on this criteria. So either should have said specifically that going from 260 -> 193 was partially because of people who did not meet the inclusion criteria, or just give the entire numbers. When presenting information on response rate, people who did not meet the inclusion/exclusion criteria shouldn’t be included (or this should be explained specifically), otherwise it inappropriately makes study look worse.

While it was the case that they found HRT but not non-genital SRS was associated with improved QOL, there was significant overlap of the two groups, which the authors stated in their discussion as a limitation: “Moreover, since in our sample most of the patients who received at least one SR surgery are on hormonal treatment (94 %), our model does not permit us to evaluate the specific contribution of both variables, hormonal and surgical treatment, individually.” In addition, the study takes ALL non-genital SRS as a single surgery, so it would not be able to say if specific surgeries were more beneficial when others weren’t. For example if there are 4 surgeries: A, B, C, D, and A and C had a significant benefit but B and D didn’t (or had a negative effect), if analyzed together this could easily give an equivocal answer as this study did. These limitations would have been better to spend time on in the limited space for analysis rather than just saying what the scores were and the percentage of MTFs versus FTMs as this is not something that helps in answering the question CMS raised.

Mate-Kole C, Freschi M, Robin A. Aspects of psychiatric symptoms at different stages in the treatment of transsexualism. Br J Psychiatry. 1988 Apr;152:550-3.

“The Bem Sex Role Inventory masculinity score for the combined cohorts was lower than for North American norms for either men or women. The femininity score for the combined cohorts was higher than for North American norms for either men or women. Those who were undergoing evaluation had the most divergent scores from North American norms and from the other treatment cohorts. Absolute differences were small. All scores of gender dysphoric patients averaged between 3.95 and 5.33 on a 7 point scale while the normative scores averaged between 4.59 and 5.12.” This should have been interpreted contextually. A subject matter expert in transgender health care would have known this was very likely because at the time of the study, transgender women had to present hyperfeminine in order to get referral for HRT and SRS. So it is not surprising that people who completed all necessary treatment feel less pressure to present themselves in an overly feminine fashion.

Eldh J, Berg A, Gustafsson M. Long-term follow up after sex reassignment surgery. Scand J Plast Reconstr Surg Hand Surg. 1997 Mar;31(1):39-45.

Another instance of incorrectly presenting the response rate: **“Of the 175 patients who underwent reassignment surgery in Sweden, 90 responded.”**

Sweden keeps public records of those who have had legal sex change (which requires genital SRS to obtain). Eldh notes that 175 people in Sweden had sex reassignment from 1965 to 1995 (a matter of public records). Of these 136 had their treatment at Karolinska Hospital, Stockholm (where the authors practice and where the study was done). Patients who underwent treatment at the Karolinska Hospital are the only group that had surveys sent to them. So they actually had a 66% response rate (90 of 136). Because of good public records, the authors were able to provide some information about the 175 total, so when available they did (such as surgical complications). However the only point where response rate applicable in the entire study was to the surveys.

“A total of nine (18%) patients had doubts about their gender orientation;” Eldh: “Nine patients still had doubts about their sexual orientation”. Sexual orientation is not the same as gender identity (or gender orientation). This is an odd way to word this and the term “gender orientation” is not used at all in Eldh. It seems to imply that patients doubted their gender - which was not the case. However as has been noted in other studies, sexual orientation sometimes does expand after HRT and SRS, which it seems this 18% expressed).

Eldh: “Family status. Twenty-three of the 40 male-to-female patients (58%) and 23 out of 50 female-to-male ones (46%) were married or lived in a steady relationship” CMS: “44 (27 [61.3%] female-to-male and 17 [38.6%] male-to-female) were unmarried or without a steady partner;” The numbers (27 FTM and 17 MTF) of patients that were not in steady partnerships correctly, but the N (and thus the denominator) was 90 - 40 MFT and 50 FTM.

Here’s the calculation:

MTF 17/40 = 42.5% were not in a steady partnership, so 57.5% were.

FTM 27/50 = 54% were not in a steady partnership, so 46% were.

This information is available in the paper’s Table VI as well.

The PDM did not mention at all that: “Sixty-five of 90 (72%) of patients were fully accepted by their families, friends, and other people.” An additional 10 (11%) were partially accepted.

Surgical result: FTM 35/50 satisfied, 7 in early group were dissatisfied, but none in the later group (with improved surgical technique as noted in the paper. Eight patients did not answer.

The PDM report only that “Of the patients who had undergone surgery prior to 1986, seven (14%) were dissatisfied with shape or size of the neo-phallus; 8 (16%) declined comment.” The fact that with new/improved surgical technique there were no patients who were dissatisfied was an important and positive point that should have been mentioned. With MTFs they did report the difference: “There were 14 (35%), with 12 having surgery prior to 1986 and two between 1986 and 1995 inclusive, were moderately satisfied because of insufficient vaginal volume; 8 (20%) declined comment.”

Hepp U, Kraemer B, Schnyder U, Miller N, Delsignore A. Psychiatric comorbidity in gender identity disorder. J Psychosom Res. 2005 Mar;58(3):259-61.

No specific concerns for this study

Rakic Z, Starcevic V, Maric J, Kelin K. The outcome of sex reassignment surgery in Belgrade: 32 patients of both sexes. Arch Sex Behav. 1996 Oct;25(5):515-25.

“The criteria to qualify for gender surgery were delineated (1985 standards from the Harry Benjamin International Gender Dysphoria Association) and included cross-gender behavior for at least 1 year.”

Actually there was another criteria (that in my mind was a limitation) that they only treated straight transgender patients.

“Of the 38 patients who had undergone reassignment surgery, 32 participated in the study” This is another example of misstating the response. Four of the 38 who had surgery did not actually meet inclusion criteria because they were less than 6 months out from surgery. So of 34 eligible patients, 32 participated and 2 were lost to follow up.

“Of the total participants, four (12.5%) (all male-to-female) and 8 (25%) (87.5% male-to-female) reported complete dissatisfaction or partial satisfaction with their appearance.” The questions (in the appendix of the study) allowed patients to answer “yes”, “to some extent”, or “no”. The authors state: “All patients (100%) in our sample were satisfied with the sex change. However only 20 (62%) were satisfied with the way their bodies looked, 8 (25%) were satisfied to some extent, and 4 (13%) were not satisfied at all.” This presentation in the PDM seems biased, and given the wording of the question was specified in the paper, saying “to some extent” would have been more appropriate. In addition, they did not mention that there was 100% satisfaction with the treatment. A subject matter expert would also be able to interpret this (as was also interpreted in the paper) that transgender women often have trouble passing in society as female because of masculine aspects of the body that are not well treated with standard HRT and SRS. As an comparison, assessing the results of reconstructive surgery after mastectomy for breast cancer might find that while 100% of patients were satisfied with having had the treatment that a certain percentage were not happy or were only “to some extent happy” with the cosmetic results. However the fact that treatments provide imperfect cosmetic results does not imply that patients would not still wish to have them.

“Fifty percent of female-to-male and 54.5% of male-to-female patients reported being either unemployed or not being a student full-time prior to surgery. After surgery, no female-to-male patients and 7 (31.8%) male-to-female patients reported being either unemployed or not being a student full-time. The change was due to student status. Six (60%) of female-to-male patients and 15 (68.2%) of male-to-female patients reported being unemployed before and after surgery.” This while presented in a somewhat negative light here represents a significant benefit. The fact that 10/32 of the participants went from unemployed to full time schooling, and the description of why in the discussion mirrors findings on the National Transgender Discrimination Survey¹ in the United States. The NTDS showed “Despite high levels of harassment, bullying and violence in school, many respondents were able to obtain an education by returning to school. Although fewer 18 to 24-year olds were currently in school compared to the general population, respondents returned to school in large numbers at later ages, with 22% of those aged 25-44 currently in school (compared to 7% of the general population).” Moreover, since there were specific numbers of full time students, unemployed, and employed, the statement of 60% of FTMs and 68.2% of MTFs were unemployed is inaccurate - people who are currently full time students and thus not looking for work are not included in the figures for unemployed. Also, in another paper reviewed for the PDM (Leinung), CMS states “Of participants 36.4% were employed in jobs requiring a high school degree or less; 28.1% (excluding students) were on disability and/or unemployed.”

Wolfradt U, Neumann K. Depersonalization, self-esteem and body image in male-to-female transsexuals compared to male and female controls. Arch Sex Behav. 2001 Jun;30(3):301-10.

This is not an error per se in the interpretation of this study. However there are many studies showing that transgender patients have significant mental health symptomatology. This is something a subject matter

¹ Grant, Jaime M., Lisa A. Mottet, Justin Tanis, Jack Harrison, Jody L. Herman, and Mara Keisling. Injustice at Every Turn: A Report of the National Transgender Discrimination Survey. Washington: National Center for Transgender Equality and National Gay and Lesbian Task Force, 2011. http://www.thetaskforce.org/static_html/downloads/reports/reports/ntds_full.pdf

expert may have added, but even in the papers reviewed for the PDM, this should have been fairly apparent. Yet in this group of patients that have had vocal surgery, they are indistinguishable from a non-clinical control population. While this was not a comparative study of treated and nontreated patients, this suggests vocal surgery (and in general ability to speak with a female range voice) is a big driver of patients being misgendered (presumed to be their birth-assigned gender) which can add to their mental health troubles. This is a fairly obvious point to anyone who treats transgender women in any numbers.

Beatrice J. A psychological comparison of heterosexuals, transvestites, preoperative transsexuals, and postoperative transsexuals. J Nerv Ment Dis. 1985 Jun;173(6):358-65. (United States study)

“As measured by the T-scored MMPI instrument (50 ± 10), levels of paranoia and schizophrenia were higher for post-operative (GRS) patients (63.0 and 68.8) than transvestites (55.6 and 59.6) and heterosexual males (56.2 and 51.6). Levels of schizophrenia were higher for pre-operative patients (65.1) than heterosexual males (51.6). There were no differences between patients with gender dysphoria by surgical status. Scores for the Masculine-Feminine domain were equivalent in those with transvestitism and gender dysphoria with or without surgery, but higher than in heterosexual males. The analysis revealed that despite the high level of socio-economic functioning in these highly selected subjects, the MMPI profiles based on the categories with the highest scores were notable for antisocial personality, emotionally unstable personality, and possible manic psychosis in the pre-operative GRS patients and for paranoid personality, paranoid schizophrenia, and schizoid personality in the post-operative GRS patients. By contrast, the same MMPI profiling in heterosexual males and transvestites was notable for the absence of psychological dysfunction.”

Firstly, contextually the MMPI (especially MMPI-1 used in this study) was a well known test to root out LGBT people (particularly gay men) and was used in the military, employment screening, and was used to exclude gay and gender nonconforming individuals. This is somewhat improved in the MMPI-2 though it has still never been normed to transgender and gender non-conforming populations - and still must be scored differently for men and women. However use of MMPI-1 in transgender women is going to produce higher scores. This is partially because these tests are scored with reference to gender (and in Beatrice were scored in the male fashion) and because they also test deviance from social norms which again transgender people do by their very existence - and certainly by the time they have been cross living if this is scored with male norms. For example wearing a dress in public would be considered abnormal for men, but normal for women. The fact that they are even using the MF domain as an ‘abnormal’ is seems ridiculous today. Moreover, neither the retired MMPI-1 used in this analysis nor the current MMPI-2 have been normed to transgender patient populations. While scoring transgender patients according to their gender identity rather than birth-assigned sex improves the validity of scoring, true norms for these populations are unknown. Unfortunately Beatrice et al. did not use appropriate female scoring for transgender participants in their study.

Secondly, the scales on the MMPI do not correspond to diagnoses. So the schizophrenia scale is not necessarily indicative of a diagnosis of schizophrenia. This should be noted in the PDM explicitly to allow appropriate interpretation of scores.

Also while they made a point of saying that in Gomez-Gil 2012 that almost all patients in either group were in non-clinical range (even when they weren’t), yet in this largely negative study it was not mentioned that of the 10 subscales on the MMPI, in only 3 were the MTF patients in clinical range and one of those was MF. The comparison with how this was reported in Gomez-Gil 2012 seems to suggest bias.

Kraemer B, Delsignore A, Schnyder U, Hepp U. Body image and transsexualism. *Psychopathology*. 2008;41(2):96-100. Epub 2007 Nov 23.

No specific comments about this interpretation, however see comments in Newfield.

Kuhn A, Bodmer C, Stadlmayr W, Kuhn P, Mueller M, Birkhäuser M. Quality of life 15 years after sex reassignment surgery for transsexualism. *Fertil Steril*. 2009 Nov;92(5):1685-1689.e3. Epub 2008 Nov 6. Of Kuhn 2009, the PDM states: "There were statistically and biologically significant differences for 4 of the 8 domains between the patients and controls: physical limitation: 37.6 ± 2.3 versus 20.9 ± 1.9 ($p < 0.0001$), personal limitation: 20.9 ± 1.9 versus 11.6 ± 0.4 ($p < 0.001$), role limitation: 27.8 ± 2.4 versus 34.6 ± 1.7 ($p < 0.5$), and general health: 31.7 ± 2.2 versus 41.0 ± 2.3 ($p < 0.02$). Information as to whether a high or low score was positive for the various domains was not provided. Wording from the abstract suggests that these 4 differences all reflected lower quality-of-life." (Underline ours).

The appendix of the study provided the survey instrument which is also readily available online. From this the directionality of each score can easily be determined. Moreover, in the discussion sections Kuhn et al state: "Role limitations were significantly lower in TS compared with controls, which could be a sign for good gender assimilation and well-being". Given that this information was available in the paper (though we agree not obvious in the abstract) that raises concern that this study may have only been assessed in abstract form. In addition when reporting levels of statistical significance the PDM states: "role limitation: 27.8 ± 2.4 versus 34.6 ± 1.7 ($p < 0.5$)" which is not statistically significant. However the actual p value in this score which demonstrated transgender patients doing better was $p < 0.05$.

In addition, the authors called it a case-control study and from my reading it seems to be that, so the PDM seems to be downgrading the level of evidence by not calling it a case control study.

Hess J, Rossi Neto R, Panic L, Rübber H, Senf W. Satisfaction with male-to-female gender reassignment surgery. *Dtsch Arztebl Int*. 2014 Nov 21;111(47):795-801.

CMS called this blinded, despite no where in the paper did the authors say that. However this is no more or less blinded than the other surveys because blinding would seem to be less important. Otherwise interpretation seems fine.

Lawrence A. Patient-reported complications and functional outcomes of male-to-female sex reassignment surgery. *Arch Sex Behav*. 2006 Dec;35(6):717-27. Epub 2006 Nov 16. (United States study)

"Intermittent regret regarding reassignment surgery was associated with vaginal hair and clitoral pain. "

Not a specific problem with the PDMs interpretation but this is actually a good argument that should CMS or any other payer cover vaginoplasty, preoperative electrolysis should also be covered.

Heylens G, Verroken C, De Cock S, T'Sjoen G, De Cuypere G. Effects of different steps in gender reassignment therapy on psychopathology: a prospective study of persons with a gender identity disorder. *J Sex Med*. 2014 Jan;11(1):119-26. Epub 2013 Oct 28.

The PDM makes the correct point that in this study the most significant improvement was going from diagnostic phase to starting HRT, without significant improvement when going from HRT to surgery. However an important point (raised by the authors, but also would have been added by a subject matter expert) is that all the people in the Heylens study knew they were going to be able to get surgery once they started HRT. The authors: "Costs of psychiatric consultations, hormonal therapy, genital surgery, and breast augmentation and removal are reimbursed." The authors state: "The findings that, after SRS, somatization is returning to normal again and psychoticism is almost higher compared with a general

population ($P = 0.051$) could be explained by an initial euphoria caused by the relief they experience after starting hormonal treatment.” The authors also state: “On the whole, our study population is a selected group that is not fully representative for the larger group of gender dysphoric people: they all fulfilled criteria for GID and were eligible for SRS. This perspective might certainly have an influence on the level of psychoneurotic distress. If there had been less certainty, at the end of the diagnostic phase and after initiation of hormonal treatment, about results could have been different.”

Smith YL, Van Goozen SH, Kuiper AJ, Cohen-Kettenis PT. Sex reassignment: outcomes and predictors of treatment for adolescent and adult transsexuals. Psychol Med. 2005 Jan;35(1):89-99.

Of Smith 2005, the PDM states “Most of the MMPI scales were already in the normal range at the time of initial testing. SCL global scores for psycho-neuroticism were minimally elevated before surgery 143.0 ± 40.7 (scoring range 90 to 450) and normalized after surgery 120.3 ± 31.4 .” While this was true, the PDM fails to mention that all MMPI subscales except for one were statistically significantly improved. While on average they started in the non-clinical range, given that patients begin at a range of scores from the non-clinical to the clinical range, decreases of the magnitude reported for some patients would take them from the clinical range into the non-clinical range. (Comparison with analysis of Beatrice above.)

The PDM also states “The size of the pool of available patients was not identified. Overall 325 consecutive adolescents and adults initially were ‘involved.’” However the methods clearly state that the 325 were consecutive applications to the clinic for sex reassignment constituted the study pool and not a subset and nowhere do the authors use the term specifically quoted by the PDM: “involved”.

Since CMS notes in other studies the authors used non-validated scales, the fact that this used a validated scale (Utrecht Gender Dysphoria Scale) bears mentioning.

Megeri D, Khoosal D. Anxiety and depression in males experiencing gender dysphoria. Sexual and Relationship Therapy. 2007 Feb; 22(1):77-81. (Not in PubMed) and Udeze B, Abdelmawla N, Khoosal D, Terry T. Psychological functions in male-to-female people before and after surgery. Sexual and Relationship Therapy. 2008 May; 23(2):141-5. (Not in PubMed)

We were unable to obtain a copy of this study and thus unable to review it.

Kockott G, Fahrner EM. Transsexuals who have not undergone surgery: a follow-up study. Arch Sex Behav. 1987 Dec;16(6):511-22.

“The Psychological Integration of Trans-sexuals (PIT) instrument was not otherwise described in the publication or in other citations.” The authors provided the citation: Hunt, D. D., and Hampson, J. L. (1980). Follow-up of 17 biologic male transsexuals after sex-reassignment surgery. *Am. J. Psychiat.* 137: 432-438.

Meyer JK, Reter DJ. Sex reassignment. Follow-up. Arch Gen Psychiatry. 1979 Aug;36(9):1010-5. (United States study)

Of Meyer 1979, the PDM states “The objective criteria, which were the subject of the publication, included employment status (Hollingshead job level), cohabitation patterns, and need for psychiatric intervention.” However there are significant flaws in the methodology of Meyer that have been published in the

peer reviewed literature and not been addressed.² Briefly, the objective scoring system actually used 4 criteria - the ones named in the PDM and a fourth category: assessment of legal problems. This is demonstrated in this table from Meyer:

Table 3.—Adjustment Scoring System	
Category	Score
Legal	
Arrested only	−1
Arrested and jailed	−2
Economic	
Hollingshead job level	
1 or 2	+3
3 or 4	+2
5 or 6	+1
7 or 8	0
Cohabitation	
Cohabit	
Gender-appropriate	+1
Nongender-appropriate	−1
Marriage	
Gender-appropriate	+2
Nongender-appropriate	−2
Psychiatric	
Contact	−1
Outpatient treatment	−2
Hospitalization	−3

Specific problems with this scale include the fact that gay or lesbian transgender people are inappropriately penalized for being in a relationship. For example a lesbian transgender woman in a relationship with a female partner would have moved -2 to -4 points simply by remaining in a long term relationship through and after sex reassignment surgery. In contrast, a person who had no partner at the beginning or end of the study would have scored 0 post-operatively. However perhaps most concerning is that the operated group were followed for 62 months, residual unoperated 27, and subsequently operated for 21. Given that many of these events (e.g. psychiatric hospitalization or being arrested) were events that occur over time, the fact that Meyer did not correct for this follow-up time difference would inevitably cause any group followed for a significantly longer period of time to have a higher incidence even if the rate of event per period of time were the same in both groups. (It should be noted that Meyer counted each negative event towards the score, so someone arrested and jailed twice would have a -4. This was not directly stated in the article, but can be inferred from one patient having a baseline score of -18, a greater score than possible if events were counted only once.) So if in all three groups, the average number of arrests per 6 month period was 1, the operated group would have an average score of -10, residual unoperated -5, and subsequently operated -4.

Additionally: from Meyer "From the medical point of view, because of the serious and irreversible nature of the surgery, random assignment to the operative group was not possible. From the patient's perspective, the passionate demands for reassignment did not allow random assignment to the nonoperative group." It is instructive that even in what is considered both a heavily biased study, and which historically did tremendous damage to transgender care in the United States - specifically resulting in closure of many academic programs in transgender care³ still noted that a RCT is not possible.

² Fleming, Michael, Carol Steinman, and Gene Bocknek. "Methodological problems in assessing sex-reassignment surgery: A reply to Meyer and Reter." *Archives of Sexual Behavior* 9.5 (1980): 451-456.

³ Gorton, R. Nick. "Transgender health benefits: Collateral damage in the resolution of the national health care financing dilemma." *Sexuality Research & Social Policy* 4.4 (2007): 81-91.

The PDM also states “Nine investigators used self-designed tools as their only test instrument (Eldh et al., 1997; Hess 2014; Johansson et al, 2009; Kockott, Fahrner, 1987; Lawrence, 2006; Meyer, Reter 1979; Rakic 1996; Salvador 2012; Tsoi 1993).” This is technically incorrect as Meyer used the Hollingshead socioeconomic level as one of his measures (of the 4 in the table above).

There is also a reporting error in the PDM:

Meyer	Longitudinal Controlled	Recruitment pool: 100 52 excluded.	50	15 (30%) had undergone surgery 14 (28%) underwent surgery later	The assessments of all were complete
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In actuality 50 were excluded: 48 lost to f/u and 2 refused to have their data used.

Johansson A, Sundbom E, Höjerback T, Bodlund O. A five-year follow-up study of Swedish adults with gender identity disorder. Arch Sex Behav. 2010 Dec;39(6):1429-37. Epub 2009 Oct 9.

“Johansson et al. conducted non-blinded, observational study using a semi-cross-sectional design (albeit over an extended time interval) using a self-designed tool and Axis V assessment. The study was prospective except for the acquisition of baseline Axis V data. There were no formal controls in this mixed population with and without surgery.” Authors describe: “The study was prospective and longitudinal and focused on relief of gender dysphoria, satisfaction with the SR process, social functioning, work, relationships, and sexuality after a minimum of 5 years in the process and/or 2 years after SRS.” AND “The format was supplemented by a GAF estimation (Axis V in the DSM-IV) made by the clinician at both index and follow-up.” It is uncertain why the PDM calls it a semi-cross sectional when it’s a prospective cohort study. In addition, the GAF was at index and at follow up. There was one patient for whom the GAF was missing data, but it was still prospective.

“...from two disparate geographic regions. No other information regarding the sites of care was provided.”

The authors state: “The patients in this study were consecutively selected from two geographic regions of Sweden, one in the north and one in the south. At the time of inclusion, both centers had about five new referrals per year that were approved for SRS. About the same number of patients was excluded yearly from the SR process, due, for instance, to other diagnoses.” The authors are also from two locales: “Department of Psychiatry, Sexology Clinic, St. Lars-omr, MC-huset, 221 85 Lund, Sweden”, and “Department of Clinical Sciences, Division of Psychiatry, University of Umea°, Umea°, Sweden”. In addition they tells us a lot more regarding the sites of care, for example cost to patients, professional standards/beliefs about gender dysphoria treatment.

“Changes or differences considered to be biologically significant were not pre-specified.” The authors prespecified: “An increase in GAF points of five or more was considered to be an improvement and a decrease of five points was considered as worse.”

In addition, the clinicians did not just use the GAF. They looked at 4 other areas in addition to the GAF. They determined a “Global Outcome” score from these 5 subscores: SES, work/study, relationships, psychiatric care, GAF, patients own assessment. “Global improvement” was that patients improved in at least 2 areas of the “Global Outcome” and worsened in no areas. This was an important finding that was not reported in the PDM.

“None of these nine (eight male-to-female) had completed reassignment surgery because of ambivalence secondary to lack of acceptance by others and dissatisfaction with their appearance.” This is incorrect - the patients were either not yet completed OR were ambivalent because of lack of acceptance or masculine features that made it hard to live as a woman. The authors state: “These patients had not yet

completed the SR procedure or had interrupted the process, and stated that they felt ambivalent due to a perceived lack of acceptance from other people or dissatisfaction with their physical appearance, which still indicated their biological sex.”

Newfield E, Hart S, Dibble S, Kohler L. *Female-to-male transgender quality of life. Qual Life Res.* 2006 Nov;15(9):1447-57. Epub 2006 Jun 7. (United States study)

The PDM called Kraemer a “**Prospective, non-blinded, observational, cross-sectional studies with controls**” which they described thus: “The investigators assessed body image, and patients were required to meet DSM III or DSM IV criteria as applicable to the time of entry into the clinic. Post-surgical patients were from a long-term study group (Hepp et al., 2002). Pre-surgical patients were recent **consecutive referrals**.” They also compared the pre-op and post-op patients with normative male and female control data.

Newfield also compared a preoperative with a postoperative group to each other and to normative male and female data. It is not certain why the PDM felt that Kraemer was “with controls” and Newfield is “**a mixed, population with and without reassignment surgery. There were no formal controls.**”

The PDM described study participants as “**natal female participants identifying as male**” No where did Newfield use the term “natal female” to describe patients. Given that female-to-male is used elsewhere in the PDM and is used by Newfield et al, the use of “natal female” seems inappropriate. It is certainly the case that prior papers referred to transgender men by as now inappropriate terms such as “female transsexuals”. However as it is the case that both clinicians and researchers currently would generally not refer to transgender men as [anything] female, this should be corrected in the PDM. It would be best in addition if when using historical papers where transgender patients were referred to with what would be considered inappropriate terms that this be noted and corrected in the presentation.

“A total of 379 U.S. respondents classified themselves as males or females to males with or without therapeutic intervention. The mean age of the respondents who classified themselves as male or female-to-male was 32.6 ± 10.8 years. 89% were Caucasian, 3.6% Latino, 1.8% African American, 1.8% Asian, and 3.8% other. 254 (67.0%) reported any testosterone use in the past or currently; and 242 (63.8%) reported current testosterone use. In addition, 136 (36.7%) reported having had “top” surgery and 11 (2.9%) reported having “bottom” surgery. The Physical Summary Score (53.45 ± 9.42) was statistically higher (better) than the natal gender unspecified SF-36 normative score (50 ± 10) ($p < 0.001$), but was within 1 standard deviation of the normative mean. The Mental Summary Score (39.63 ± 12.2) was statistically lower (worse) than the natal gender unspecified SF-36 normative score (50 ± 10) ($p < 0.001$), but was well within 2 standard deviations of the normative mean. Subcomponents of this score: Mental Health (42.12 ± 10.2), Role Emotional (42.42 ± 11.6), Social Functioning (43.14 ± 10.9), and Vitality (46.22 ± 9.9) were statistically lower (worse) than the SF-36 normative sub-scores, but well within 1 standard deviation of the normative sub-score means. Interpretive information for these small biologic differences in a proprietary assessment tool was not provided.

Additional intragroup analyses were conducted, although the data were not stratified by type of therapeutic intervention (hormonal, as well as, surgical). Outcomes of hormone therapy were considered separately and dichotomously from reassignment surgery. The Mental Summary Score was statistically higher (better) in those who had “Ever Received Testosterone” (41.22 ± 11.9) than those with “No Testosterone Usage” (36.08 ± 12.6) ($p = 0.001$). The Mental Summary Scores showed a trend towards statistical difference between those who “Ever Received Top Surgery” (41.21 ± 11.6) and those without “Top Surgery” (38.01 ± 12.5) ($p = 0.067$). These differences were well within 1 standard deviation of the

normative mean. Interpretive information for these small biologic differences in a proprietary assessment tool was not provided.”

The first paragraph goes into great detail saying how transmen do compared to cisgender women - even delving into subscores (and unsurprisingly, people with a mental health diagnosis who are subject to significant minority stress do worse on mental health subscores than the general population). The second paragraph (smaller) is the PDM’s description of the most important part of the study. Unlike the first paragraph, they only describe changes in the summary scores when talking about how well transmen with SRS or HRT do compared with those who have not had treatment. However Newfield states: “Those who had received top surgery reported higher QOL scores than those who had not received surgery, with statistically significant findings ($p<0.01$) for the General Health, Social Functioning, and all three mental health concepts.” So the PDM seems to gloss over the actual benefits that SRS gives (and similarly for HRT) when it states “Those who had received testosterone at any time reported higher health-related QOL scores than those who had not, with statistically significant differences ($p<0.01$) in the Vitality, Social Functioning, Role Emotional, and Mental Health domains.”

Ruppin U, Pfäfflin F. Long-term follow-up of adults with gender identity disorder. *Arch Sex Behav*. 2015 Jul;44(5):1321-9. Epub 2015 Feb 18.

Like many other studies, the PDM noted that tools used in the assessment of transgender patients are “non-specific psychometric tests” (and non-specific quality of life indicators). Given that gender dysphoria is a rare disease (as defined in the United States), the lack for many years of disease specific psychometric and quality of life measures is not surprising. In the last few years new scores have been proposed and preliminarily validated, like the Utrecht Gender Dysphoria Scale (UGDS) and the Gender Identity/Gender Dysphoria Questionnaire for Adolescents and Adults (GIDYQ-AA)⁴. However, it has been noted that in the instance of rare diseases, lacking a prospectively validated disease specific instrument, the next best option is a combination of non-specific instruments combined with measures determined by patients or clinical experts in the field often as a self-designed instrument⁵. It is this approach that is taken by Ruppin and many of the studies cited in the PDM. While this combination of measures is not as optimal as measures that are now available like the UGDS and the GIDYQ-AA, especially when interpreting studies from as long ago as 1979, this should be qualified. Given that “Evidence based medicine is defined as the conscientious, explicit, and judicious use of current best evidence in making decisions about the care of individual patients”⁶, it would provide a more nuanced and fair interpretation of the research on this rare disease to acknowledge this. While it is true that Ruppin used “non-specific psychometric tests and a self-designed interview tool and questionnaire”, it would be helpful to place this in context. The PDM states in general of studies it assessed: “Only four investigator groups used only these psychometric tools validated in other large populations as their test instrument (Beatrice, 1985; Haraldsen, Dahl, 2000; Motmans et al., 2012; Newfield et al., 2006). Nine investigator groups used a mix of psychometric tools validated in large normative populations, less well validated tools, and/or self-designed tools (Ainsworth, Spiegel, 2010; Blanchard et al., 1985a; Gomez-Gil et al., 2014; Heylens 2014a; Ruppin, Pfäfflin, 2015; Smith et al., 2005a (Udeze et al., 2008; Megeri 2007; Weyers 2009a; Wierckx et al., 2011b). Nine investigators used self-designed tools as their only test instrument (Eldh et

⁴ Schneider, Catharina, et al. "Measuring gender dysphoria: a multicenter examination and comparison of the Utrecht Gender Dysphoria Scale and the Gender Identity/Gender Dysphoria Questionnaire for Adolescents and Adults." *Archives of sexual behavior* 45.3 (2016): 551-558.

⁵ Rajmil, Luis, Lilisbeth Perestelo-Pérez, and Michael Herdman. "Quality of life and rare diseases." *Rare Diseases Epidemiology*. Springer Netherlands, 2010. 251-272.

⁶ Sackett DL, Rosenberg WM, Gray JA, Haynes RB, Richardson WS. Evidence based medicine: what it is and what it isn't. *BMJ*. 1996;312(7023):71-2.

al., 1997; Hess 2014; Johansson et al, 2009; Kockott, Fahrner, 1987; Lawrence, 2006; Meyer, Reter 1979; Rakic 1996; Salvador 2012; Tsoi 1993). A single investigator did not use any type of testing tool and provided only descriptive statistics (Leinung et al., 2013).” This would have been an idea place to discuss the fact that while the ideal is to have well validated disease specific instruments, in a rare condition such as gender dysphoria that lacking a prospectively validated disease specific instrument, the next best option is one or more non-specific instruments along with measures noted to be important clinical experts and patients.

Ruppin is in fact a good example of this in that they used a combination of a non-validated but disease specific in house tool combined with non-diseases-specific (though validated in general populations) instruments to assess gender role stereotypes with the BSRI, depression and anxiety with the SCL-90, interpersonal difficulties with the IIP, and the FPI-R a personality questionnaire which uses the following subscales: Life satisfaction, Social orientation, Need for achievement, Shyness, Irritability, Aggressiveness, Stress, Physical troubles, Health sorrows, Openness, Extraversion, and Emotionality.

CMS describes what is done: “Although these tools had been validated in a reference population, none had been validated in populations with gender dysphoria.” AND “Many of the instruments that are most specific for the condition were designed by the investigators themselves or by other investigators in the field. In addition, the relevant diagnostic cut-points for scores and changes in scores that are clinically significant should be delineated to permit adequate interpretation of test results. As such, these studies were not definitive in nature.” However again they do not place this in context of a rare disease. In addition, while we agree that such studies are not definitive, this is not the standard which should be applied to treatments which are covered in a general sense. For example, using the US Preventative Services Taskforce’s Grade system, moderate certainty of a moderate benefit is adequate for a service to receive the grade B and be recommended by USPSTF.⁷

In addition, regarding Ruppin’s results, the PDM states: “A total of 68 patients ranked their well-being as 4.35 ± 0.86 out of five (three patients did not respond to this question). Of respondents, 40% reported not in a steady relationship. Regular sexual relationships were reported by 57.1% of 35/36 female-to-male respondents and 39.4% of 33/35 of male-to-female respondents (three patients did not respond to this question). A total of 11 patients reported receiving out-patient psychotherapy; 69 did not express a desire for gender role reversal (two did not respond to this question). The response rate was less than 100% for most of the self-designed survey questions.”

That 69 who “did not express a desire for gender role reversal” was stated by the authors of the paper as: “None of the participants expressed a desire for gender-role reversal (n=69),” It seems in looking over the entirety of the PDM, it seems to us as readers that more positive things may be expressed in ways that make this not as obvious. For example unless the reader was careful to remember the total N this seems less impressive. Similarly Ruppin states: “Overall, 60.0 % of the participants reported being in a steady relationship”, but this was not reported (despite worse figures being reported in other studies for relationship status).

Similarly while in Rakic, the reviewers took pains to explain away the gains in employment (specifying that the gains were all due to people going back to school): “Fifty percent of female-to-male and 54.5% of male-to-female patients reported being either unemployed or not being a student full-time prior to surgery. After surgery, no female-to-male patients and 7 (31.8%) male-to-female patients reported being either unemployed or not being a student full-time. The change was due to student status. Six (60%) of female-

⁷ <http://www.uspreventiveservicestaskforce.org/Page/Name/grade-definitions>

to-male patients and 15 (68.2%) of male-to-female patients reported being unemployed before and after surgery.” However in Ruppín they completely failed to mention: “When asked about their vocational situation, 78.6 % of the participants indicated that they were employed full- or part time or self-employed, 14.3 % received a pension, and 7.1 % were unemployed. Satisfaction with this situation was measured on a rating scale ranging from 1 (“very dissatisfied”) to 5 (“very satisfied”). The mean was 4.07 (SD=0.93; n=61).”

Similarly in Hepp, CMS reviewers made room in their analysis to talk substantially about levels of substance abuse: “Lifetime diagnosis of substance abuse and mood disorder were more common in male-to-female patients (50% and 55% respectively) than female-to-male patients (36.4% and 27.3% respectively). Current diagnosis of substance abuse and mood disorder were present in male-to-female patients (15% and 20% respectively) and absent in female-to-male patients.” However in Ruppín they failed to mention “Present problems with alcohol or illegal drugs were stated by two participants” - that is 2.8%. It is in comparison to how similar (though more negative) results were reported in other studies that a bias seems to emerge. In only a few instances (like what was noted in the tabular presentation of the data) did an error seem to advantage transgender treatments.

Similarly, the PDM seems to rapidly gloss over some of the most positive findings. Of the psychometric tests used by Ruppín, they state: “Changes from the initial visit to the follow-up visit were assessed for the SCL-90R in 62 of 71 patients. Changes from the initial visit to the follow-up visit were assessed for the IIP in 55 of 71 patients. Changes from the initial visit to the follow-up visit were assessed for the FPI-R in 58 of 71 patients. The effect size was large only for the “Life Satisfaction” scale. Changes from the initial visit to the follow-up visit were assessed for the BSRI in 16 of 36 female-to-male patients and 19 of 35 male-to-female patients. The “Social Desirability” score increased for the female-to-male respondents. At endpoint, both categories of respondents reported androgynous self-images.”

However, per the authors:

Re: SCL-90: “Participants’ values were lower at follow-up on all scales, except for the scale Somatization, all differences were statistically significant. The effect sizes were small for the scales Phobic anxiety and Paranoid ideation, medium for Obsessive–compulsive, Depression, Anxiety, Hostility, and Psychoticism, and large for Interpersonal sensitivity”

Re: IIP: “Participants’ values were lower at follow-up, and the differences reached statistical significance on all scales. Effect sizes were small for the scale Domineering/ controlling, medium for Vindictive/self-centered, Cold/distant, Socially inhibited, Nonassertive, Self-sacrificing, and Intrusive/ needy, and large for Overly accommodating”

FPI-R: “This comparison showed a significant increase in Life satisfaction with a large effect size. The decreases on the scales Irritability, Openness, and Emotionality were also statistically significant. The effect sizes were small for Irritability and Openness and medium for Emotionality”

Haraldsen IR, Dahl AA. Symptom profiles of gender dysphoric patients of transsexual type compared to patients with personality disorders and healthy adults. Acta Psychiatr Scand. 2000 Oct;102(4):276-81.

The PDM does not state anything incorrectly or even slanted in this article, but they do not describe the actual point of the study. Transgender patients are often assumed to have high levels of psychopathology (and in particular personality disorders). This study was to assess this question so it is questionable why it was included as it did not address the question CMS posed (is SRS beneficial for Medicare recipients?) However the ultimate finding was that the misconception about high levels of co-existing pathology are not upheld (at least among those patients approved for surgery at this clinic - which may not be true for the global population of patients with gender dysphoria).

Leinung M, Urizar M, Patel N, Sood S. Endocrine treatment of transsexual persons: extensive personal experience. Endocr Pract. 2013 Jul-Aug;19(4):644-50. (United States study)

Firstly, this study isn't really germane to the question CMS asked as it is primarily a study of complications of HRT. However the PDM's interpretation missed an important point in this study (which was part of the conclusion in the abstract): "However, significant barriers exist, such as insufficient insurance coverage, which limit comprehensive care." That is, Leinung presents us with a study of the natural history of an untreated disease, although the cause of non-treatment in this case is the refusal of public and private health insurers to cover treatments rather than a decision to withhold treatment to study the natural history.

"Forty patients were on disability (17%), the vast majority for mental health issues. Overall, psychiatric disease was present in 56.2% of all patients, consisting mostly of mood disorders (depression, dysthymia, adjustment disorder, mania)."

"The average time from initiation of hormone therapy to vaginal surgery was 4.9 years, with a maximum of 13.4 years; for orchiectomy only, the average was 5.1 years, with a maximum of 11.5 years." AND MTF: "None of the breast augmentations and <5% of the vaginoplasties and orchiectomies were paid for by insurance." FTM: "None of the surgical procedures were covered by insurance, using transsexualism as the diagnosis."

This was a cohort with a great deal of psychopathology - (compared for example to Haraldson), and the obvious substantial difference between this group and Haraldson's and other European groups (e.g. Dhejne) is that in the US at the time of this study, the vast majority of patients cannot get surgery despite medical necessity and a desire for it.

"Transsexual persons seeking hormonal therapy are being seen with increasing frequency in our clinic. Recent experience with transsexualism has led to the development of effective treatment guidelines by the WPATH and the Endocrine Society. However, there are significant barriers in the United States to implementation of these guidelines. The dysphoria present in many transsexual persons is associated with significant mood disorders that interfere with successful careers. Fortunately, it appears that starting therapy at an earlier age may lessen the negative impact on mental health and lead to improved social outcomes. With increased awareness and social acceptance, we believe long-term outcomes for transsexual persons should improve."

If anything this study should stand in stark relief to cohorts from European centers. As is the case with many transgender samples from the US, there are high rates of mental health problems and suicidality. For example in the above cited NTDS (a 2010 survey of 6,450 transgender and gender non-conforming American people in cited above), 41% of respondents reported *attempting* suicide compared to 1.6% of the general US population. This high rate of suicide is also born out in the clinical experience of the authors of this document. While suicide rates remain high in Europe, American rates dwarf them. It is certainly possible that there are other social differences in the US that make transgender people more vulnerable to depression, anxiety and suicidality, but the lack of adequate care is an obvious contributor. We would not be surprised that a group of patients with untreated diabetes or bipolar disorder have higher mortality, hospitalization, and other complication rates compared with diabetics and people with bipolar disorder who receive treatment. Similarly, instead of focusing on the studies in isolation, comparing the results and complication rates for US studies to those from European centers should also inform the decisions made by CMS.

Asscheman H, Giltay EJ, Megens JA, de Ronde WP, van Trotsenburg MA, Gooren LJ. A long-term follow-up study of mortality in transsexuals receiving treatment with cross-sex hormones. Eur J Endocrinol. 2011 Apr;164(4):635-42. Epub 2011 Jan 25.

While the PDM did not contextually interpret other results of Asscheman 2011, a particularly egregious misleading presentation of the data is in reporting substance abuse related deaths in transgender men. The PDM repeatedly reports the Standardized Mortality Ratio reported by Asscheman et al in the form: (n=X, SMR X [95% CI X-X]). For example the PDM states (our bold): “**The major known contributors to the mortality difference between male-to-female patients and the Dutch population at large were completed suicide (n=17, SMR 5.70 [95% CI 4.93-6.54]), AIDS (n=16, SMR 30.20 [95% CI 26.0-34.7), and illicit drug use (n=5, SMR 13.20 [95% CI 9.70-17.6]).**” In a couple of instances this was written out, but regardless, they consistently reported the number of patients (or percentage of, from which the number could be deduced). However in a single instance the absolute number was not reported: reporting deaths from drug use in transgender men. The PDM states: “**Although overall mortality was not increased in the hormone-treated female-to-male patients, there were more deaths due to illicit drug use than expected (SMR 25 [6.00-32.5]).**” The absolute number of cases was not presented, although the SMR is quite high. It is *especially concerning* that this was omitted given that the n in this case is a single patient. Had the PDM reported this in the same way they reported other SMRs, the very high SMR would be less misleading.

There is also a factual mistake: “**All-cause mortality was 51% higher and statistically significant (Standardized Mortality Ratio [SMR] 95% confidence interval [CI] 1.47-1.55) for males-to-females when compared to females in the general Dutch population. The small increase in all-cause mortality (12%) for females-to-males when compared to males in the general Dutch population was not statistically significant; 95% CI 0.87-1.42.**” This is incorrect and reverses the comparisons in that FTMs were compared to cisgender women and MTFs to cisgender men. The PDM in fact got this right in their initial paragraph “**The gender of the general Dutch population comparator group was the natal sex of the respective gender dysphoric patient groups.**”

In addition, the PDM states: “**The major known contributors to the mortality difference between male-to-female patients and the Dutch population at large were completed suicide (n=17, SMR 5.70 [95% CI 4.93-6.54]), AIDS (n=16, SMR 30.20 [95% CI 26.0-34.7), and illicit drug use (n=5, SMR 13.20 [95% CI 9.70-17.6]). An additional major contributor was “unknown cause” (n=21, SMR 4.00 [95% CI 3.52-4.51]).**”

Ischemic heart disease was a major disparate contributor to excess mortality in male-to-female patients in older patients (n=18, SMR 1.64 [95% CI 1.43-1.87], mean age [range]: 59.7 [42-79] years. Current use of a particular type of estrogen, ethinyl estradiol, was found to contribute to death from myocardial infarction or stroke (Adjusted Hazard Ratio 3.12 [95% CI 1.28-7.63], p=0.01). There was a smaller, but statistically significant increase in lung cancer that was thought to possibly be related to higher rates of smoking in this cohort.”

The focus seems to be behavioral health issues (suicide, smoking, and substance abuse), heart disease, and HIV - all of which carry a great deal of stigma or are related to treatment. They did not report issues that are not stigmatizing diagnoses namely that the rate was increased for hematological cancer (n=6 SMR 2.58) and they decrease for colon cancer. The way this was stated also seems slanted in that there were more excess cases of ischemic heart disease than illicit drug use - so this actually contributed just as much but the less stigmatizing condition was secondarily listed. Specifically saying that (1st paragraph) mostly the reason MTFs died was suicide, AIDS, and illicit drug use promotes stigma especially when rates of ischemic heart disease exceed each of those number of deaths. However even worse, the PDM fails to make the point that the authors of the study did with regard to deaths from suicide, substance abuse, and HIV: “Comparing our cohort with the general population was probably the

best available option for this research but it should be noted that this comparison is potentially biased and confounded by lifestyle factors, prone to associated pathology and other factors specific for the transsexual population besides cross-sex hormone treatment. Transsexual subjects, in particular MtF, differed in a number of regards with the general population. Before they presented themselves for sex reassignment, they have an increased history of suicide attempts, more psychopathology, and substance abuse, probably associated with the psychological burden of gender dysphoria, as well as an increased prevalence of HIV infection.” The lack of describing the bias that the authors of the study explicitly stated produces bias in the PDM itself.

Dhejne C, Lichtenstein P, Boman M, Johansson A, Långström N, Landén M. Long-term follow-up of transsexual persons undergoing sex reassignment surgery: cohort study in Sweden. PLoS One. 2011;6(2):e16885. Epub 2011 Feb 22.

Of Dhejne 2011, the PDM states: “All-cause mortality was higher for patients who underwent gender reassignment surgery (n=27 [8.3%]) than in controls (hazard ratio 2.8 [1.8-4.3]) even after adjustment for covariants (prior psychiatric morbidity and immigration status).” The PDM also states: “Suicide attempts were more common in patients who underwent gender reassignment surgery (n= 29 [9.0%]) than in controls (adjusted hazard ratio 4.9 [2.9–8.5]).” While these are factually true statements, the PDM does not explain these in context and by doing so they overemphasize the potential harms. Dr Dhejne (who joined us in our analysis of the PDM) made this important point in her original paper from 2011 cited by the PDM:

“It is therefore important to note that the current study is only informative with respect to transsexuals persons health after sex reassignment; no inferences can be drawn as to the effectiveness of sex reassignment as a treatment for transsexualism. In other words, the results should not be interpreted such as sex reassignment per se increases morbidity and mortality. Things might have been even worse without sex reassignment. As an analogy, similar studies have found increased somatic morbidity, suicide rate, and overall mortality for patients treated for bipolar disorder and schizophrenia. This is important information, but it does not follow that mood stabilizing treatment or antipsychotic treatment is the culprit.”

This particular misinterpretation has been debunked not only by WPATH, but GLAAD and the popular media as well.^{8,9,10,11}

Moreover in addition to failure to discuss this crucial caveat, the PDM also leaves out a significant finding from this study. Dhejne divided their 30 year cohort in half and assessed morbidity and mortality differences in the early and later group. They found that the statistically significant higher mortality, and specifically suicide rate, was confined to those who had surgery in 1973-1988, and was not found in those having surgery in 1989-2003. That is, transgender persons operated on after 1989 had an overall mortality rate and suicide rate indistinguishable from a non-clinical sample. This is despite the fact that a higher mortality and suicide rate would generally be expected in any clinical sample of patients with a mental health diagnosis who are well known from numerous studies in the literature to already have high suicidality pre-treatment. In fact the only thing that the PDM stated about this difference from the early to

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http://www.wpath.org/site_page.cfm?pk_association_webpage_menu=1635&pk_association_webpage=4905

⁹ <http://lgbtweekly.com/2015/05/06/learning-the-bad-science-of-dr-paul-mchugh/>

¹⁰ <http://www.thedailybeast.com/articles/2016/05/12/why-was-the-media-so-quick-to-accept-caitlyn-jenner-detransition-rumors.html>

¹¹ <http://www.glaad.org/blog/wall-street-journal-runs-op-ed-longtime-anti-trans-psychiatrist-paul-mchugh>

the late cohort was, “The increased risk for conviction of any crime or violent crime observed during the 1973-1988 interval was not seen later.”

In addition, the PDM states incorrectly: “The criteria required to obtain the initial certificate for reassignment surgery and change in legal status from the National Board of Health and Welfare were not delineated” However Dhejne did provide this information: “In Sweden, a person presenting with gender dysphoria is referred to one of six specialised gender teams that evaluate and treat patients principally according to international consensus guidelines: Standards of Care.[3] With a medical certificate, the person applies to the National Board of Health and Welfare to receive permission for sex reassignment surgery and a change of legal sex status.” [3] cites HBIGDA SOC V6 2002.

The PDM also incorrectly represents the rate of treatment: “There were 804 patients identified with gender identity disorder (or related disorder) in Sweden during the period from 1973 to 2003 inclusive. Of these patients, 324 (40.3%) underwent gender-reassignment surgery (133 female-to-male [41.0%]; 191 male-to-female [59.0%]; ratio 1:1.4).” This is incorrect: “The 480 persons that did not shift gender variable comprise persons who either did not apply, or were not approved, for sex reassignment surgery. Moreover, the ICD 9 code 302 is a non specific code for sexual disorders. Hence, this group might also comprise persons that were hospitalized for sexual disorders other than transsexualism.” Calling other 302 coded conditions “related to” GID/GD is quite inappropriate especially in this context. Other 302.XX codes in the ICD-9 include pedophilia, bestiality, sadism, and exhibitionism.

“The investigators assessed mortality, suicide attempts, psychiatric hospitalization, and substance abuse in gender-reassigned persons” Actually they assessed a great deal more, but PDM only mentioned the ones that are more pathologizing. The authors assesses (our underlines) “mortality, psychiatric morbidity, accidents, and crime following sex reassignment. More specifically, we investigated: (1) all-cause mortality, (2) death by definite/uncertain suicide, (3) death by cardiovascular disease, and (4) death by tumour. Morbidity included (5) any psychiatric disorder (gender identity disorders excluded), (6) alcohol/drug misuse and dependence, (7) definite/uncertain suicide attempt, and (8) accidents. Finally, we addressed court convictions for (9) any criminal offence and (10) any violent offence.”

Dhejne C, Öberg K, Arver S, Landén M. An analysis of all applications for sex reassignment surgery in Sweden, 1960-2010: prevalence, incidence, and regrets. Arch Sex Behav. 2014 Nov;43(8):1535-45. Epub 2014 May 29 and Landén M, Wålinder J, Lambert G, Lundström B. Factors predictive of regret in sex reassignment. Acta Psychiatr Scand. 1998 Apr;97(4):284 (Dhejne et al., 2014; Landen et al., 1998) Sweden-All

The PDM states: “The specific criteria to qualify for gender surgery were not delineated.” However this is incorrect. The authors in Landen stated: “The study subjects and procedure have previously been described in detail (17)” which is a reference to Dhejne.

“Dhejne et al. in 2014 reported that the female-to-male: male-to-female ratio among those who made formal applications for reversal was 1:2.” This is also factually incorrect. Dhejne 2014: “The regret rate defined as application for reversal of the legal gender status among those who were sex reassigned was 2.2 % for the whole period 1960–2010 with no significant sex difference.” Dhejne 2014 also said: “A total of 15 individuals (5 FM and 10 MF) out of 681 who received a new legal gender between 1960 and 2010 applied for reversal to the original sex (regret applications). This corresponds to a regret rate of 2.2 % for both sexes (2.0 % FM and 2.3 % MF).” It seems that this 1:2 number was from the 5:10 number cited, but that wasn't per capita. It would not be a problem to report this raw data as long as the fact that percentages were essentially identical in both populations was also noted.

However more importantly, the PDM seemed to miss the take-home points from both articles. Of all the putative risk factors, the one most important was family acceptance and support, so they recommend that providers should include education/support programs to family of transgender patients. In addition they noted that those with a psychotic disorder and 'non-core' transgender women are at greater risk. However even in the highest risk group: with both poor family support and non-core group, 84% still did well. Per Dhejne after the 1998 article family support was included in treatment and regret rate fell subsequently. The PDM misses this and the obviously important point that over time things improved, though they did note the authors' statement that the final 10 year group might have a higher regret rate in coming years because average time to application for reversal was 8 years in those with regrets.

Mate-Kole C, Freschi M, Robin A. A controlled study of psychological and social change after surgical gender reassignment in selected male transsexuals. Br J Psychiatry. 1990 Aug;157:261-4.

"The investigator-designed survey assessed changes in social and sexual activity of the prior 2 years, but the authors only compared patients in a given cohort to themselves. Though the researchers did not conduct statistical studies to compare the differences between the 2 cohorts, they did report increased participation in some, but not all, types of social activities such as sports (solo or group), dancing, dining out, visiting pubs, and visiting others. Sexual interest also increased. By contrast, pre-operative patients did not increase their participation in these activities. Work status remained the same for post-operative patients which unemployment increased in the standard wait pre-operative cohort."

The PDM is correct that between group analysis would be better. This lack of detailed statistics reflects less emphasis on this at the time of the study. However the numbers are there to do that comparison and so doing the between group analysis would have been pertinent given that this is perhaps the highest quality study in the literature given that it was controlled. With what we know now about the efficacy of SRS, a controlled study would be unethical and would never pass by a modern IRB. So it would behove analysts of the literature to calculate this. In addition, Mate-Kole may have done that (albeit unreported) because they say "Significant differences were also seen *between* the groups at follow-up, with group A more active than group R on all items mentioned above except social drinking and work." (italics in original)

The following is an incomplete list of studies that we suggest may have been useful. We had inadequate time to fully perform a search, so multiple germane studies are very likely not included. This is simply a listing of articles that came to mind to the authors and contributors of this analysis. We would be more than happy to provide a more complete list if CMS requests.

Aydin, Dogu, et al. "Transgender Surgery in Denmark From 1994 to 2015: 20-Year Follow-Up Study." *The journal of sexual medicine* 13.4 (2016): 720-725.

Beek, Titia F., et al. "Partial treatment requests and underlying motives of applicants for gender affirming interventions." *The journal of sexual medicine* 12.11 (2015): 2201-2205.

Abramowitz, S. I. (1986). Psychosocial outcomes of sex reassignment surgery. *Journal of Consulting and Clinical Psychology*, 54(2), 183–189. doi:10.1037/0022-006X.54.2.183

Garaffa, G., Christopher, N. A., & Ralph, D. J. (2010). Total phallic reconstruction in female-to-male transsexuals. *European Urology*, 57(4), 715–722. doi:10.1016/j.eururo.2009.05.018

Pfafflin, F., & Junge, A. (1998). Sex reassignment. Thirty years of international follow-up studies after sex reassignment surgery: A comprehensive review, 1961–1991. *International Journal of Transgenderism*.

Green, R., & Fleming, D. (1990). Transsexual surgery follow-up: Status in the 1990s. *Annual Review of Sex Research*, 1(1), 163–174

Brown, George R. "Breast cancer in transgender veterans: a ten-case series." *LGBT health* 2.1 (2015): 77-80.

O'Hanlan KA, Dibble SL, Young-Spint M 2007 Total laparoscopic hysterectomy for female-to-male transsexuals. *Obstet Gynecol* 110:1096–1101

McNeill EJ 2006 Management of the transgender voice. *J Laryngol Otol* 120:521–523

Castellano, E., et al. "Quality of life and hormones after sex reassignment surgery." *Journal of endocrinological investigation* 38.12 (2015): 1373-1381.

Wolter, A., et al. "Sexual reassignment surgery in female-to-male transsexuals: An algorithm for subcutaneous mastectomy." *Journal of Plastic, Reconstructive & Aesthetic Surgery* 68.2 (2015): 184-191.

Djordjevic, Miroslav L., et al. "Metoidioplasty as a single stage sex reassignment surgery in female transsexuals: Belgrade experience." *The journal of sexual medicine* 6.5 (2009): 1306-1313.

van der Sluis, Wouter B., et al. "Long-Term Follow-Up of Transgender Women After Secondary Intestinal Vaginoplasty." *The journal of sexual medicine* 13.4 (2016): 702-710.

Morrison, Shane D., et al. "Long-term outcomes of rectosigmoid neocolporrhaphy in male-to-female gender reassignment surgery." *Plastic and reconstructive surgery* 136.2 (2015): 386-394.

Morrison, Shane D., et al. "Facial Feminization: Systematic Review of the Literature." *Plastic and reconstructive surgery* 137.6 (2016): 1759-1770.

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