

Surgical gender reassignment for male to female transsexual people

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This report has been prepared as part of the Development and Evaluation Service funded by the Research and Development Directorate South and West. It is intended to provide rapid, accurate and usable information on health technology effectiveness to purchasers, clinicians, managers and researchers in the South and West.

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The South and West Development and Evaluation Service

Purpose

The Development and Evaluation Service is funded by the Research and Development Directorate of the NHS Executive (South and West Regional Office) to provide rapid, accurate and usable information on the cost effectiveness of health technologies in response to the needs of NHS commissioners and providers.

The service

The service has two elements: a structured review, typically prepared in three to six months, and the Development and Evaluation Committee (DEC) made up of senior clinicians and other independent individuals which meets quarterly. The DEC considers the quality of available evidence and the likely value for money offered by the intervention presented in the report, and reaches a justified conclusion on the support it gives the intervention.

Methods

DEC reports are informed by online literature search, a review of bibliographies and reference lists and consultation with clinical experts. Evidence is sought on the effectiveness of interventions, their cost and the epidemiology of the health problem concerned. Appraisal of evidence for effectiveness is guided by standard checklists (particularly those developed for the Critical Appraisal Skills Programme). Detailed and fully accurate cost information is often not available. Extracontractual referral tariffs and other less precise cost estimates are used when they are the only source of costings to the required level of detail.

The results of relevant studies are presented individually and the most plausible results used in further analysis. The Index of Health Related Quality of Life is used to estimate benefits as Quality Adjusted Life Years (QALYs) where possible. QALY estimates are combined with cost data to provide an estimate of cost utility, allowing comparison of the value for money of the intervention in providing health gain. Uncertainties in estimates of costs and benefits (and therefore the value for money associated with implementation of the intervention concerned) are explored in sensitivity analyses.

The conclusions of the DEC fall into one of five predefined categories:

- Strongly supported
- Supported
- Limited support
- Not supported
- Not proven

Reports are circulated widely throughout the South and West Region by the NHS Executive and are published in full on the DEC internet site:

<http://www.soton.ac.uk/~dec/>

InterDEC

The Wessex Institute for Health Research and Development has now joined a wider collaboration with three units in other Regions (the Trent Working Group on Acute Purchasing, the Scottish Health Purchasing Information Centre and the University of Birmingham Institute for Public Environmental Health) to share the work on reviewing the effectiveness and cost-effectiveness of clinical interventions. This group, "InterDEC", will share work, avoid duplication and improve the peer reviewing and quality control of these reports.

This report was prepared based on literature available up to April 1988 by

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SURGICAL GENDER REASSIGNMENT FOR MALE TO FEMALE TRANSEXUAL PEOPLE

Conclusion of the Development and Evaluation Committee

Conclusion: Not proven

Commentary:

It is clear that a small number of people may experience important benefits from this technology. However, the potential hazards of treatment are considerable and more rigorous research is required into the long term risks and benefits to support case selection and justify service development. Where surgery is performed it should be restricted to specialist centres with proven technical expertise and which have clear protocols for patient selection and good clinical audit in place.

Pending improvements to the evidence base in this area, the Committee noted the value of guidelines such as those promulgated by the Harry Benjamin Gender Dysphoria Association in identifying minimum standards of care for people applying for surgery.

Summary of the report

- The proposal is for surgical gender reassignment to be available for carefully selected transsexual people. Surgery is not a cosmetic intervention, but one that attempts to reconcile an individual's core identity and their physical characteristics.
- There is no comparable alternative to gender reassignment surgery in those who are eligible for surgery. Individuals who are refused NHS treatment may approach private clinics, both in the UK and abroad.
- The prevalence of transsexualism has not been studied in this country in recent years. European studies suggest that there may be 150 male transsexual people in the South and West region, and we may expect five requests for surgical gender reassignment each year.
- Current evidence consists of one prospective controlled study, numerous case series, and one cross-sectional study. Most studies about the effectiveness of surgical gender reassignment have not collected data prospectively and are hampered by losses to follow up and lack of validated outcome measures.
- It is evident that a number of male to female transsexual people experience a successful outcome following surgery in terms of subjective well-being, cosmetic appearance and sexual function. Some patients have reported postoperative complications, dissatisfaction and regrets.

- The published studies cannot be relied upon to provide valid estimates of benefit and harm. We have not attempted to summarise the results in terms of QALYs.
- Surgical gender reassignment surgery costs in the region of £9,600 (ECR prices). Following successful surgery the need for psychiatric and hormonal treatment may be reduced, thereby resulting in savings of up to £950 per patient per year.
- There is a need for high quality controlled trials to determine the risks and benefits of gender reassignment surgery. Potential patients should be identified using standardised selection criteria.

SURGICAL GENDER REASSIGNMENT FOR MALE TO FEMALE TRANSEXUAL PEOPLE

1 Introduction

The term 'transsexual' is defined by Roberto¹ as a composite set of characteristics including

“the belief that one is a member of the opposite sex dressing and appearing in the opposite gender role..... perceiving oneself as heterosexual although sexual partners are anatomically identical..... repugnance of one's own genitals and the wish to transform them..... history of cross-gender activities... and a persistent desire for sex-conversion surgery”

A child becomes aware of its gender identity before or around the age of five years. In most people their gender identity is the same as their sex, i.e. a man or boy feels he is male and a woman or girl feels she is female, but in a few people their gender identity and sex do not match.

Male-to-female transsexual people feel incapable of functioning as biological men, and this deep rooted feeling of belonging to the opposite sex is often associated with aversion to their own body. Unlike the transvestite person, who finds relief from their distress by wearing garments considered appropriate to the opposite gender, transsexual people request all possible means available for reassignment to the opposite gender. Some transsexual people will have been aware of their gender dysphoria since childhood (primary transsexualism) while in others the need for reassignment will be realised later in life (secondary transsexualism).

Despite the offer of psychosexual counselling and psychotherapy a substantial number of transsexual people remain convinced that only sexual transformation can effect meaningful relief from their anguish and despair. Without intervention these individuals suffer considerable distress, and rates of drug abuse and attempted suicide are reported to be raised². Methods of gender reassignment consist of hormonal and surgical interventions. It is important to stress that surgery is not a cosmetic intervention, but one that attempts to reconcile an individuals core identity and physical characteristics³.

Surgical gender reassignment is a major procedure, and potential candidates must be carefully assessed prior to acceptance for surgery. Most gender reassignment procedures take place in national centres, the largest being Charing Cross hospital.

This report will consider the effectiveness of surgical genital gender reassignment in male to female transsexual people. This is commonly performed in the UK as a single stage operation involving penectomy, orchidectomy and construction of a neo-vagina⁴.

Findings cannot be generalised to female-to-male surgery, which has a separate body of evidence and may have a different morbidity profile. The surgical construction of a neophallus is difficult and the cosmetic effects are not always

satisfactory⁵. There is anecdotal evidence to suggest that women find it easier to live in the opposite gender role without medical assistance. Approximately 20% of patients seen at Charing Cross are female-to-male transsexuals⁶.

For the purpose of this report, transsexual people will be referred to as patients although it is recognised that many services use the term clients.

2 Incidence/prevalence

Data collected on transsexualism are usually classified according to the International Classification of Diseases code (ICD-10) or the Diagnostic and Statistical Manual of Mental Disorders (DSM-IV) classification. The former coding system is used in the United Kingdom (Appendix 1).

Very little routine data are available in the UK which may be used to estimate the prevalence of transsexualism. A study in the Netherlands⁷ estimates the prevalence of male-to-female transsexualism as 1:11,900 men over 15 years of age^a. The authors acknowledge that this is a relatively high prevalence rate, and attribute this to the benevolent climate for the treatment of transsexualism in the Netherlands. Earlier estimates by the same authors have suggested a prevalence of only 1:18,000 men.

Assuming that the rate of male-to-female transsexualism in the South and West is similar to the lower rates for Holland, then there may be approximately 150 male transsexual people within the region^b. However, only a proportion of these will request and meet current criteria for gender reassignment surgery. A Swedish study suggests that the number of individuals requesting gender reassignment is 0.17 per 100,000⁸. Applying this proportion, there may be approximately 5 requests for surgery per year in the South and West region.

The number of operations performed for sexual transformation is recorded in the Hospital Episode statistics (Table 1). Procedures carried out in the private sector are not included. Experts consulted for this report have been unable to estimate the proportion of surgical procedures that are performed privately.

Table 1: Hospital episode statistics 1994–5, Operations for sexual transformation (both Male to Female and Female to Male)

	Completed hospital episodes	Total number of bed days	Mean duration of admissions
England	62*	508	8.6 days
South and West region	7	40	7.3 days

* 20 of these 62 episodes were performed in people under 20 years and may represent surgical correction of congenital defects.

a Defined as diagnosed transsexuals who are receiving hormonal treatment. The prevalence of female-to-male transsexualism is lower at approximately 1:30,000⁷.

b Calculated using population estimates for the South and West region (estimated 2,646,838 males aged 15+).

3 Outline of current alternative service

Patients who present to their General Practitioner are commonly referred to a psychiatrist for assessment and confirmation of the diagnosis. In some cases, transsexualism is not recognised by primary care professionals and therapeutic interventions are not offered. Diagnosed individuals commonly receive counselling and may be recommended for hormonal therapy in the first instance.

There is significant geographical variation in the provision of services. Some health authorities do not routinely fund surgical reassignment procedures, while others have imposed a limit on the number of procedures that they will fund per year³. Where this is the case, patients may approach private centres both in the UK and abroad. The criteria for access to private surgery is variable and quality standards are difficult to monitor^c. There is anecdotal evidence to suggest that patients who cannot afford private treatment can become psychiatrically disturbed and even suicidal⁹.

It could be argued that there is no comparable alternative to gender reassignment surgery in those who are deemed to be eligible. Many people will have already received psychotherapy and hormonal therapy, and will have remaining gender identity problems and a persistent desire for gender reassignment surgery.

A number of support networks are available for people with gender identity problems (whether or not they are having surgery). These include³:

- Beaumont Trust - a registered charity which provides referrals to appropriate organisations, professional counsellors, and self help groups. It aims to advance public education and to protect the mental and physical health of those with gender dysphoria
- Gendys Network - provides an interface between people who have encountered gender dysphoria and related professionals (such as psychiatrists, psychotherapists, physicians, surgeons, social workers, endocrinologists and counsellors). The network offers support and a network for information and research.

4 Proposed service

Surgical gender reassignment is not provided on demand. Prospective patients are generally required to live and work for at least 12 months (preferably 24 months) in the social role of a woman. This is commonly referred to as the “real life” test. It is at this point that patients begin to self-select for surgery, either by continuing with a gender role change, or by remaining in their original gender role. Approximately one-third of patients drop out while undergoing this test³. One reason may be the inability to ‘pass’ as a woman, as it may be difficult to hide inherent male characteristics such as a masculine build and large hands and feet.

The reasons for requesting such services are carefully examined. Patients should be seen and referred by two independent psychiatrists prior to acceptance for hormones or surgery. Exclusion of psychiatric instability is important as requests

c Personal communication with the Beaumont Trust, 1998.

for surgery may sometimes arise through short-term beliefs which may later be reversed. Information may be obtained from family members and significant others to help with the process of selection.

The Harry Benjamin International Gender Dysphoria Association (HBIGBA) have laid down minimum standards of care for those applying for hormonal or surgical gender reassignment (Appendix 2). Our experts have confirmed that these criteria are used within UK gender identity centres^d. It is reported that only approximately 1 in 10 of those who apply are accepted for surgery³. However, we are not aware of any regulations governing the competence, training and experience of the surgical team.

Hormones are commonly given prior to surgery in order to i) suppress male characteristics and ii) induce female characteristics. These antiandrogens and oestrogens may be continued after surgery, although doses are reduced, particularly following orchidectomy. This endocrine service is not limited to surgical centres, as hormones are commonly prescribed by general practitioners and local gender identity clinics.

A multidisciplinary approach is required when planning gender reassignment procedures. Endocrinology and psychiatric teams will be involved in the care of each patient, both before and after surgery. Although only limited follow up is recommended after surgery, patients can be difficult to contact as many relocate to start a new life elsewhere.

In addition to genital surgery, other procedures may be requested such as enlargement of the breasts, electrolysis to remove facial and body hair, reshaping of the nose, hair transplants, facial remodelling, and speech therapy to raise the pitch of the voice. The kind of treatment provided depends on individual needs and are subject to negotiation between the patient and health care professionals.

In the UK, it is reported that individuals spend approximately 2-3 years on the NHS waiting list before surgery is performed⁴. The minimum age for surgery is 18 years.

5 Quantity and quality of research

Numerous studies have been published in the area of male-to-female reassignment surgery. This review is restricted to studies published after 1980, in which results for male-to-female surgery can be isolated. The search sources are shown at Appendix 3.

There are no randomised controlled trials in this area. Randomisation (to include a 'no surgery' or 'delayed surgery' arm) would be extremely difficult because of strong patient preference.

The current evidence consists of one prospective controlled study, numerous case series, and one cross-sectional study. Individual case reports also feature in the literature although these have been excluded from this review as they are unlikely

d We are aware of three gender identity clinics in England (in Leeds, Torbay and London). Only the London centre offers surgery for NHS patients at the present time. We have been unable to obtain information about the private provision of surgery.

to be representative. A number of non-systematic reviews have also been conducted¹⁰⁻¹³.

5.1 Controlled study

Mate-Kole (1990)⁴ presents a prospective controlled study (n=40) in which subjects receiving early surgery were compared with those on the waiting list. Changes in social, sexual and work activity were assessed, although baseline scores are not presented. Instruments were administered to measure psychoneurotic symptoms and personality characteristics.

After 2 years, significant differences were noted in some social activities between the operated group compared with the waiting list group. Examples are given below in Table 2. The operated group had significantly reduced scores on the psychoneurotic index^e, although the clinical significance of this result is not reported. Scores on the personality characteristics scale^f were not significantly different.

These results should be viewed with caution as treatment allocation was not randomised, and assessors were not blinded to treatment group. Adverse effects were not reported in this study, and there were no opportunities for subjects to express regrets following surgery. It is important to note that many of the outcomes tested were not significantly different between the operated and waiting list groups. The choice of outcome measures has not been justified in this study, and we cannot be sure that the measures above are important in people with gender dysphoria.

Table 2: Examples of significant* differences during the Mate-Kole comparative study⁴

		More active (no. of subjects)	Same (no. of subjects)	Less active (no. of subjects)
Visits to family, friends, etc.	Operated	15	3	2
	Waiting list	3	14	2
Eating out	Operated	15	3	2
	Waiting list	1	15	4
Sport in company	Operated	16	2	2
	Waiting list	1	16	3
Sexual interest	Operated	16	4	0
	Waiting list	0	17	3

* Non-significant outcomes included social drinking, work record, cinema/theatre attendance, club membership, church attendance, spectator sports, reading and watching TV.

5.2 Non-controlled studies

Numerous studies have been published (see Appendix 5). Only a small number of these have collected baseline data with which to compare outcomes¹⁴⁻¹⁷. The methods of these studies are described very briefly. In some studies it seems that

e This index measures free-floating anxiety, phobic anxiety, obsessionality, somatic anxiety, depression and hysteria.

f This scale consists of self-assessments of 60 personality characteristics defining 'femininity' and 'masculinity'.

the pre-operative status was recorded retrospectively, creating the opportunity for recall bias. In the absence of valid premeasurements it is impossible to determine the exact extent and direction of changes.

The remaining studies have collected data at only one point in time¹⁸⁻²⁴. Two studies have been excluded from this review as methods have not been described^{25,26}.

All of the non-controlled studies have serious methodological limitations. Common weaknesses include:

- recruitment procedures and selection criteria are often inadequately described;
- use of non-validated assessment instruments - we cannot be certain the measures reported would be important to individuals with gender dysphoria;
- assessments are rarely confirmed with other sources such as relatives and independent psychological opinion;
- large losses to follow up raise the strong possibility of response bias - patients who have dropped out may differ from those who have chosen to continue;
- heterogeneity in diagnosis, with some studies giving no description of diagnostic criteria;
- little description of adjunctive therapies which may have been used as part of multidisciplinary gender reassignment package (e.g. counselling, psychotherapy).

In light of the above criticisms the results from these studies should be interpreted with extreme caution.

In summary the evidence surrounding male-to-female gender reassignment surgery is poor. The study methods have allowed opportunity for selection bias (as a result of biased sampling and losses to follow up), recall bias (through retrospective data collection), and response bias (as assessors have not been blinded to operative status). Measurement tools have not been validated and many of these lack face validity to measure changes in gender dysphoria e.g. by focusing questions of cosmesis and sexual functioning rather than global measures of well being. The high rates of improvement, of over 80% in many series, should be interpreted in light of these methodological limitations.

6 Benefits

It is clear that some patients will benefit from gender reassignment surgery as indicated by the results in Appendix 5. Positive outcomes have been reported in areas such as cosmetic appearance, sexual functioning, self-esteem, body image, socioeconomic adjustment, family life, social relationships, psychological status and satisfaction.

The published studies cannot be relied upon to provide valid estimates of benefit, and therefore we have not attempted to summarise the results from these studies. It would be misleading to convert results into 'Quality Adjusted Life Years' gained as it is unclear how many patients gain significant benefits from surgery.

Given that a proportion of individuals will have negative consequences from surgery, the key issue may be in patient selection. It has been proposed that the following criteria are prerequisites for a good outcome of gender reassignment²⁷, i) a stable personality, ii) adequate support from family, iii) body build appropriate to new sex role, iv) young age (<30) at first medical contact, v) patient motivation re: use of vaginal dilators. Although some studies have performed regression analysis in order to identify these factors, their predictive value has not been established with certainty.

7 Disbenefits

Postoperative complications include infection, haemorrhage, urethral stenosis, urinary incontinence, rectal fistula, vaginal stenosis, and erectile tissue around the urethral meatus. The incidence of events cannot be ascertained with confidence due to variability between the studies, and the high rates of losses to follow up. The thrombotic risk of oestrogen therapy should be considered when estimating the potential harms of gender reassignment interventions.

Serious postoperative incidents include request for reversal, hospitalisation and suicide. Case series in Appendix 5 give some indication on the frequency of these events, although there is great variation in the figures presented (e.g. attempted suicide rates range from 0% to 18%). This data should be interpreted with extreme caution, as figures are derived from small studies in which there are no control groups^g, incomplete follow up and the possibility for bias in reporting.

New problems may emerge following reassignment surgery. Some individuals may need to come to terms with painful loss including jobs, families, partners, children and friends. Many are forced to move away from their familiar environment and, despite being confident in their new gender role, may have difficulty with social adaptation and acceptance by others²⁸. The extent of these problems has not been recorded in the published studies.

8 Costs and savings

Patients requesting surgical gender reassignment will usually already be attending a gender identity clinic and may be receiving counselling, hormones and group support. It is difficult to separate the additional costs of surgery from those which would be incurred without surgery. Extracontractual referral costs from a large UK surgical unit can be used as a guide :

1998 ECR costs:

Single stage operation (penectomy, orchidectomy and vaginoplasty)	£9,580
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These costs do not include costs for psychiatric assessment and follow up. It is likely that psychiatric costs will decrease following surgery. Consultations may only

^g The inclusion of a control group would be particularly important when interpreting suicide rates.

be required annually (rather than 3-4 times per year), which may result in a saving of approximately £500 per patient per year^h.

A proportion of patients will require additional surgical services such as breast enlargement and laryngoplasty. Costs may also be incurred for the correction of complications, although the frequency of these events cannot be estimated using the available evidence.

Hormone requirements are reduced following surgery; the dose of Premarin is reduced to 2.5mg daily and anti-androgens are discontinued⁶. Savings may range from £210 to £450 per year depending upon the pre-operative dose. Drug costs are given below in Table 3.

Table 3: Costs of hormone treatment prior to surgery

	Pre-surgery requirements²⁹	Price in BNF (Sept 1997)	Annual cost
Cyproterone acetate (Androcur)	50 mg - 100mg daily	£32 for 50mg (56-tab pack)	£210-£420
Premarin*	2.5 mg - 7.5mg daily	£10 for 2.5mg (3x28-tab pack)	£15-£45

* Other oestrogen therapies may be more expensive.

The above figures suggest that psychiatric and pharmacological savings may result from successful gender reassignment surgery. These savings may be up to £950 per patient per year.

9 Implications for other parties

Gender reassignment surgery can be expected to affect the life of partners, children and social contacts. This may result in both positive and negative experiences. Wider society may be involved if there are employment issues or difficulty in changing documentation to reflect the gender change e.g. on driving licenses and passportsⁱ. It is important to recognise that opposition to sex-reassignment surgery can be found in many areas, which may lead to discrimination and social exclusion.

10 Conclusion

The evidence to support gender reassignment surgery is limited in that most studies are non-controlled and have not collected data prospectively. In addition they are hampered by losses to follow up and a lack of validated assessment measures. It is evident that a number of transsexual people experience a successful outcome in terms of subjective well-being, cosmesis and sexual function. The

h Appointment with consultant psychiatrist £150 (ECR)⁶.

i In England and Wales, birth certificates can not be changed after reassignment surgery. The passport office will consider an application for change of name on its merits. It is possible to change details on documents such as the electoral register, bank accounts, exam certificates and driving license although a statutory declaration and medical records are often required²⁹.

magnitude of benefit and harm cannot be estimated accurately using current evidence.

Gender reassignment surgery is a relatively cheap procedure. If successful, the need for psychiatric and hormonal treatment may be reduced, thereby resulting in savings to the NHS.

An important issue is the selection of patients for surgery. In this country, acceptance for surgery depends on receiving a diagnosis of transsexualism, referral from two psychiatrists, and passing the 'real life' test. Many of the studies have not used these rigorous criteria, and therefore may not reflect the current 'success' rates in the UK. There is a pressing need for high quality controlled studies in this area.

11 Acknowledgements

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Ms Alice Purnell, Counsellor / psychologist, The Beaumont Trust

Dr Richard Orr, Consultant psychiatrist, Newton Abbott

Professor R Green, Consultant psychiatrist, Gender Identity Clinic, Charing Cross Hospital

Dr Russell Reid, Consultant psychiatrist, Hillingdon Hospital, London

Appendix 1:

DSM and ICD classifications

International Classification of Diseases (ICD–10), category F64.0

Transsexualism is defined as:

A desire to live and be accepted as a member of the opposite sex, usually accompanied by a sense of discomfort with, or inappropriateness of, one's anatomic sex, and a wish to have surgery and hormonal treatment to make one's body as congruent as possible with one's preferred sex.

Diagnostic and Statistical Manual of Mental Disorders (IV) category 302.85

All of the following criteria must be met for the diagnosis of gender identity disorder to be made:

- A A strong desire or persistent cross-gender identification (not merely a desire for any perceived cultural advantages of being the other sex).
- B Persistent discomfort with his or her sex or sense of inappropriateness in the gender role of that sex.
- C The disturbance is not concurrent with a physical intersex condition.
- D The disturbance causes clinically significant distress or impairment in social, occupational or other areas of functioning.

Appendix 2:

Harry Benjamin International Gender Dysphoria Association standards of care for those applying for hormonal or surgical gender reassignment, revised 1990³⁰

Standard 1

Hormonal and/or surgical sex reassignment on demand (i.e. justified simply because the patient has requested such procedures) is contraindicated. It is herein declared to be professionally improper to conduct, offer, administer or perform hormonal sex reassignment and/or surgical sex reassignment without careful evaluation of the patient's reasons for requesting such services and evaluation of the beliefs and attitudes upon which such reasons are based.

Standard 2

Hormonal and surgical (genital and breast) sex reassignment must be preceded by a firm written recommendation for such procedures made by a clinical behavioural scientist who can justify making such a recommendation by appeal to training or professional experience in dealing with sexual disorders, especially the disorders of gender identity and role.

Standard 3

Hormonal and surgical sex reassignment may be made available to intersexed patients and to patients having non-transsexual psychiatric/psychological diagnoses if the patient and therapist have fulfilled the requirements of the herein listed standards; if the patient can be reasonably expected to be habilitated or rehabilitated, in part, by such hormonal and surgical sex reassignment procedures; and if all other commonly accepted therapeutic approaches to such intersexed or non-transsexual psychiatrically/psychologically diagnosed patients have been either attempted, or considered for use prior to the decision not to use such alternative therapies. The diagnosis of schizophrenia, therefore, does not necessarily preclude surgical and hormonal sex reassignment.

Standard 4

The initiation of hormonal sex reassignment shall be preceded by recommendation for such hormonal therapy, made by a clinical behavioural scientist

Standard 5

The physician prescribing hormonal medication to a person for the purpose of effecting hormonal sex reassignment must warn the patient of possible negative complications which may arise and that physician should also make available to the patient (or refer the patient to a facility offering) monitoring of relevant blood

chemistries and routine physical examinations including, but not limited to, the measurement of SGPT in persons receiving testosterone and the measurement of SGPT, bilirubin, triglycerides and fasting glucose in persons receiving estrogens.

Standard 6

The clinical behavioural scientist making the recommendation in favour of hormonal sex reassignment shall have known the patient in a psychotherapeutic relationship for at least 3 months prior to making the said recommendation.

Standard 7

The clinical behavioural scientist recommending that a patient receive surgical (genital and breast) sex reassignment must obtain peer review, in the format of a clinical behavioural scientist peer who will personally examine the patient applicant, on at least one occasion, and who will, in writing, state that he or she concurs with the decision of the original clinical behavioural scientist. Peer review (a second opinion) is not required for hormonal sex reassignment. Non-genital/breast surgical sex reassignment does not require the recommendation of a behavioural scientist. At least one of the two behavioural scientists making the favourable recommendation for surgical (genital and breast) sex reassignment must be a doctoral level clinical behavioural scientist.

Standard 8

The clinical behavioural scientist making the primary recommendation in favour of genital (surgical) sex reassignment shall have known the patient in a psychotherapeutic relationship for at least 6 months prior to making said recommendation. That clinical behavioural scientist should have access to the results of psychometric testing (including IQ testing of the patient) when such testing is clinically indicated

Standard 9

Genital sex reassignment shall be preceded by a period of at least 12 months during which time the patient lives full-time in the social role of the genetically-other sex.

Standard 10

Prior to genital sex reassignment a urological examination should be conducted for the purpose of identifying and perhaps treating abnormalities of the genito-urinary tract.

Standard 11

The physician administering or performing surgical (genital) sex reassignment is guilty of professional misconduct if he or she does not receive written recommendations in favour of such procedures from at least two clinical behavioural scientists; at least one of which is a doctoral level clinical behavioural

scientist and one of whom has known the patient in a professional relationship for at least 6 months

Standard 12

It is unethical for professionals to charge sex reassignment applicants "whatever the traffic will bear" or excessive fees far beyond the normal fees charged for similar services by the professional. It is permissible to charge sex reassignment applicants for services in advance of the tendering of such services even if such an advance fee arrangement is not typical of the professional's practice. It is permissible to charge patients, in advance, for expected services such as post-therapy follow-up care and/or counselling. It is unethical to charge patients for services which are essentially research and which services do not directly benefit the patient.

Standard 13

It is permissible for a professional to charge only the normal fee for services needed by a patient in pursuit of his or her civil rights. Fees should not be charged for services for which, for other patient groups, such fees are not normally charged

Standard 14

Hormonal and surgical sex reassignment may be conducted or administered only to persons obtaining their legal majority (as defined by state law) or to persons declared by the courts as legal adults (emancipated minors).

Standard 15

Hormonal and surgical sex reassignment may be conducted or administered only after the patient has received full and complete explanations, preferably in writing, in words understood by the patient applicant, of all risks inherent in the requested procedures.

Standard 16

The privacy of the medical records of the sex reassignment patient shall be safeguarded according to the procedures in use to safeguard the privacy of any other patient group.

The Harry Benjamin International Gender Dysphoria Association, Inc. (HBIGDA) is a professional organisation devoted to the understanding and treatment of gender identity disorders. There are approximately 300 members from around the world from the fields of psychiatry, endocrinology, surgery, psychology, sociology, and counselling. These standards are internationally accepted guidelines which promote the health and welfare of individuals with gender dysphoria.

Appendix 3:

Search sources

1	Electronic databases	
	Cochrane Library	1998/issue 2
	Medline (OVID)	1993 - April 1998
	Healthstar (OVID)	1975 - April 1998
	EMBASE (Silverplatter)	1980 - January 1998
	Social Science Citation Index (BIDS)	1980-1998
	Psychlit	1980 - December 1997
	National Research Register	1997 prototype
	GEARS	1998 edition
2	Other sources	
	Personal communication with clinical experts	
	Personal communication with Beaumont Trust	

Appendix 4:

Prospective controlled study

Reference design	Intervention	Subjects	Outcome measures	Results
<p>Mate-Kole (1990)⁴</p> <p>Prospective non-randomised controlled study</p> <p>Charing Cross hospital, UK</p>	Gender reassignment surgery	<p>40 male transsexual people</p> <p>Alternate patients on waiting list allocated to: Gp1: offered early surgery Gp2: dealt with routinely, still on waiting list at time of evaluation.</p> <p>Evaluated after 2 years.</p>	<p>Standard history form: personal and family medical and psychiatric history, education, work record, social and sexual relationships, onset and progress of transsexualism (psychiatrist).</p> <p>Psychoneurotic symptoms (Crown-Crisp Experiential Index), includes free-floating anxiety, phobic anxiety, obsessionality, somatic anxiety, depression, and hysteria.</p> <p>Personality characteristics (Berm Sex Role Inventory), 20 items are stereotypically feminine and 20 are stereotypically masculine.</p> <p><i>Measured at first attendance, on acceptance to waiting list, and after 2 years.</i></p>	<p>At 2 year follow up, the 'early' group were significantly more active than 'routine' group in sports, visits to family, dancing, eating out and sexual activity (sig. level not reported).</p> <p>No differences were seen in the other items of social activities surveyed - social drinking, work, cinema, club membership, church attendance etc.</p> <p>The 'routine' group showed a significant trend towards unemployment compared to baseline, while no difference was seen in the 'early' group.</p> <p>Scores on the BSRI did not change significantly in either group.</p>
<p>Comments</p> <ul style="list-style-type: none"> • Non-randomised treatment allocation to 'early' versus 'routine' treatment • Assessors were not blinded to treatment group - although this would be difficult • Questions on social, sexual and work activity answered in all patients at 2 year follow up. Completeness of follow up for BSRI and CCEI not reported • Groups were similar with regard to family and personal psychiatric history, employment status, social activity, mean BSRI and CCEI scores • It is unclear whether groups were treated equally (apart from intervention). The early surgery group may have received psychotherapy and counselling before and after surgery which may influence responses • The validity and reliability of Crown-Crisp and Berm measures are not discussed • Selection for surgery followed recommendations from HBIGDA • At time of assessment, the 'early' group had had surgery about 18 months earlier and the 'routine' group were still on waiting list • Intervention not adequately described - extent of surgery, adjunctive counselling etc. 				<p>Scores on CCEI increased in operated group and decreased in unoperated group - mean change between groups was stat. significant $p < 0.05$ (maximum difference on subscale was 5 points).</p>

Appendix 5:

Non controlled studies of male-to-female gender reassignment (where baseline data used for comparison)

Reference	Subjects	Outcome measures	Results	Notes on quality
Cohen-Kettenis (1997) ¹⁴ Holland	7 M-to-F 15 F-to-M Adolescent transsexual people	Gender dysphoria scale Body image scale Psychological functioning scale Semi-structured interview - satisfaction, social life, relationships, sexuality, work status, occupational status Follow up : mean 2.6 years	Mean gender dysphoria scores sig. lower post-surgery c.f. pre-surgery Sig. increase in extroversion score on psychological scale post-surgery c.f. pre-surgery (both MF and FM combined) 100% were satisfied with their general appearance, 60% satisfied with vaginoplasty (remaining 40% not reported). None of the subjects expressed feelings of regret Results also presented for occupational status, living situation, relationships, social life (does not compare with pre-surgery situation)	Data from only 5 M-to-F available (2 MF lost to follow up) Limited population (adolescents) Changes on scales difficult to interpret Difficult to assess quality of interview assessment Baseline data available for gender dysphoria scale, psychological functioning scale and body image scale
Stein (1990) ¹⁵ USA	22 M-to-F	Structured interview - economic, social, sexual, function, cosmesis, postoperative recovery Information from records taken where unavailable for interview Physical examination (cosmesis, complications) Follow up : range 0.4 to 3.8 years	Patient evaluation of cosmesis: 3 'excellent', 4 'very good', 5 'good', 1 'fair', 1 result not known. Doctor ratings were largely in agreement Difficult to interpret outcomes of psychological interview (poorly presented in paper) 4 pts (29%) had vaginal stenosis, no instances of rectal fistula, 1 pt had spontaneous pneumothorax, 1 pt had urethral stenosis	Large losses to follow up - only 10 pts available for interview, complete record information available for 14 pts Non-validated assessment tools Difficult to assess quality of interview assessment Some comparison with baseline psychosocial status - may have been collected retrospectively through interview

Reference	Subjects	Outcome measures	Results	Notes on quality
Lindemalm (1986) ¹⁶ Sweden	15 M-to-F	<p>Surgery and Sexual adjustment - outcome of surgery, strength of libido, sexual activity, number of partners, capacity for orgasm, object choice, partner relations, overall rating of sexual adjustment</p> <p>Psychosocial outcome - working capacity, mental health</p> <p>Semi-structured interview Medical records Physical examination Median follow up : 12 years (min. 6 years)</p>	<p>Patient reported outcome of surgery: 'good' (2), 'fair' (1), 'poor' (1), 'very poor' (8)</p> <p>Overall rating of sexual adjustment : 1 pt deteriorated, and 3 were improved. The majority of pts (9) were judged unchanged, most of which remained as 'poor'</p> <p>Global psychological assessment : 1 pt had deteriorated, 4 pts had improved, and majority of pts (8) were judged unchanged</p> <p>Repentance : 1 pt definite repentance, 3 pts signs of ambivalence about sex change or expressed repentance, 9 pts had no repentance</p>	<p>2 patients lost to follow up (1 suicide)</p> <p>Vaginal construction attempted in only 9 subjects</p> <p>Surgery took place between 1954 and 1974 (techniques have advanced since then)</p> <p>Non-validated outcome measures</p> <p>Data collected both pre- and post- surgery for sexual adjustment and psychosocial adjustment</p>
Hunt (1980) ¹⁷ USA	17 M-to-F	<p>Interview MMPI (both before and after surgery) Hunt and Hampson standardised rating scale</p> <p>Mean time since surgery: 8.2 years</p>	<p>The subjects as a whole improved in the areas of economic adjustment, interpersonal relationships, sexual adjustment and acceptance by family E.g. mean scores for economic adjustment moved from 3.2 to 4.5 (on 6 point scale)</p> <p>There were no changes in levels of psychopathology as measured by criminal activity, drug use and degree of psychopathology.</p> <p>Little difference in MMPI scores between pre- and post-surgery scores</p> <p>None of the 17 transsexual people regretted the decision to have surgery. 2 subjects had doubt about their sense of being female, but none wished to be other than female. 2 subjects attempted suicide (judged to be unrelated to surgery)</p>	<p>Did not use standardised diagnostic criteria</p> <p>Only 13 subjects available for interview</p> <p>Only 12 subjects completed the follow up MMPI</p> <p>Surgery performed between 1968 and 1972 (techniques improved in recent years)</p> <p>Baseline MMPI scores collected</p> <p>Baseline Hunt and Hampson score retrospectively assigned by investigator</p>

Appendix 5:

Studies of male-to-female gender reassignment (no comparison with baseline)

Reference	Subjects	Outcome measures	Results	Notes on quality
Eldh (1997) ¹⁸ Sweden	Pre-1986: 47 M-to-F 25 F-to-M After 1986: 46 M-to-F 57 F-to-M	Medical records - complication rates, pre-op characteristics Questionnaire - functional and cosmetic results, sexual function, social adaptation, family status, working and economic circumstances. Sent only to those attending one hospital (n=136) Follow up : mean 5.8 years	Of MF who completed questionnaire (n=50), 31 (62%) had no sexual identity problem, 17 out of 50 (34%) stated that their sex life was acceptable, and 28 (56%) were fully accepted by their families, friends and other people. 64/74 pts (both MF and FM) who responded to questionnaire were content with overall life situation while 10 were discontented 2 MF regret the gender reassignment and continue to live in their previous sexual appearance socially. 2MF committed suicide postoperatively Complications included infection (12%), haemorrhage (10%), fistula (1%), partial necrosis (3%), vaginal stenosis (4%), prolapse of scrotal flap (4%) and long urethra (12%) - post-1986 rates. In 31 cases out of 175 (18%) surgical correction was required	Diagnostic criteria not reported Patient selection unclear Large losses to follow up (only 66% response rate for questionnaire) Questionnaire was not validated Baseline data available for family, social and psychological status (from medical records), although no comparison made between pre-and post surgery status
Racic (1996) ¹⁹ Yugoslavia	22 M-to-F 10 F-to-M	Self report questionnaire - body image, relationships, sexual activity, occupational functioning Follow up : mean 22 months	All patients were satisfied with the sex change. 50% were satisfied with the way their bodies looked, 32% were satisfied to some extent, and 18% were not satisfied Greater proportion satisfied with interpersonal relationships (0% before surgery to 50% after) Greater proportion successful in finding sexual partners (27% before surgery to 73% after) Similar proportion had a job pre- and post- surgery (32%) Greater proportion were full time students (14% before surgery and 36% after)	Questionnaire was not validated (and lacks face validity) Patient group not representative, as only homosexual transsexual people accepted (attracted to same anatomical sex pre-operatively) No baseline data collected - individuals asked if their status is 'better/worse than before' 2 pts lost to follow up, excluded from analysis
Snaith (1994) ²⁴ Leeds, UK	12 M-to-F	Structured interview by independent assessor Attitudes to experience and management of their gender reassignment Social relationships, self confidence, enjoyment of leisure activities Self-assessment scales (GHQ-28 and HAD) Mean time lapse since operation 19 months	All GHQ and HAD ratings were within range for good emotional health Out of 11 pts, 1 did not record any improvement in the areas of social relationships, self confidence and enjoyment of leisure activities. All other pts had 'some improvement' or 'marked improvement' All pts expressed a positive outlook and were relieved that surgery had been available to them	One patient could not be traced (relatively high follow up rate) No baseline data collected Diagnostic and selection criteria not reported

Reference	Subjects	Outcome measures	Results	Notes on quality
Tsoi (1993) ²⁰ Singapore	45 M-to-F 36 F-to-M	Semi-structured questionnaire - work, partner, cross dressing, sex organ function, satisfaction with surgery, satisfaction with new sex status Follow up : 2-5 years	'Better than before' or 'same as before' outcome in work/finance (96%), partner relationship (67%), sexual activity (64%), sex organ function (91%), sex status satisfaction(82%)	Diagnostic criteria not reported Patient selection unclear Questionnaire was not validated (and lacks face validity) No baseline data collected - individuals asked if their status is 'better/worse than before'
Ross (1989) ²¹ Australia	31 M-to-F	Psychosocial evaluation -includes economic variables, interpersonal relationships, psychopathology, sexual adjustment, additional surgery and current family reactions (Hunt and Hampson rating scale) Five point visual analogue scale to include voice, breast size/shape, genital hair growth, cosmetic appearance, urinary stream, urethral meatus, urinary incontinence, sexual satisfaction Mean time after surgery : 3.7 years (range 2-6 years)	Psychosocial evaluation does not compare outcomes with pre-surgery status Common problems included erectile tissue around the urethral meatus (6 pts), urethral stenosis (3 pts), incontinence (4 pts) and spraying of urine (3 pts) (Visual analogue scale) Regression analysis performed to determine predictors of postoperative psychopathology	Possibility for bias in selection of sample Only 14 patients attended for follow up Assessments completed by surgeon (for 7 pts) and gynaecologist (for 7 pts) Baseline psychosocial status not assessed
Kuiper (1988) ³¹ Holland	105 M-to-F 36 F-to-M	Semi-structured interviews (independent investigators) Subjective well being, self perception, integration of gender role, confidence in new gender role, body satisfaction, attitude towards surgical intervention, evaluation of therapy, suicide Body Image scale Mean time since surgery not reported	Of MF who had completed treatment (n=55): 60% 'happy' or 'very happy', 2% 'very unhappy' 56% never had doubts about sense of being a woman, 44% hardly had any doubts 33% very satisfied with own behaviour as a woman 4% dissatisfied with own behaviour as a women 40% thought integration 'very good', 42% 'good', 4% 'very poor' 87% much confidence in new gender role, 11% moderate confidence, 2% no confidence 91% no doubts about having operation, 9% occasional but moderate doubts 18% very satisfied with care provided, 40% satisfied, 13% dissatisfied, 13% very dissatisfied 18% attempted suicide since therapy Those who had completed surgery were not happier or less happy than those still in the initial phase of therapy None of the subjects regretted decision to undergo surgery	Diagnostic criteria not reported Of all MF contacted, 4 refused to cooperate, 33 did not respond and 33 could not be traced Not all persons were in same stage of therapy - only 55/105 had completed surgery (vaginoplasty) Degree of gender dysphoria prior to therapy unknown (no baseline data collected)

Reference	Subjects	Outcome measures	Results	Notes on quality
Mate-Cole (1988) ²³	Male transsexual people	Psychoneurotic symptoms (Crown-Crisp Experiential Index)	The operated group scored sig. lower on all subscales of the CCEI than both the assessment and waiting list groups, $p < 0.05$ (max difference approx. 6 points)	Non-prospective study. Cannot be certain of the time-sequence of changes
Charing Cross hospital, UK	Group 1 (n=50), undergoing assessment	Personality characteristics (Berm Sex Role Inventory)	On the femininity scale of BSRI, the assessment group scored sig. higher than those on waiting list ($p < 0.05$), but were not sig. different to postoperative group.	No evidence that assessors were blinded to treatment group
Cross-sectional study	Group 2 (n=50), changed gender role, on waiting list for surgery	Tested by psychologist and psychiatrist	On masculinity scale of BSRI, the assessment group scored sig. lower than both the waiting list and the operated group ($p < 0.05$)	Method of sampling was not clearly described
	Group 3 (n=50), post-operative patients - at least 6 months after surgery			Criteria for surgery not described Groups were similar in background (retrospective judgement) Intervention not adequately described e.g. extent of surgery, adjunctive counselling

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