



Australian Government

Department of Health

MBS Reviews

VULVOPLASTY

REPORT

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ABBREVIATIONS

ACHI	Australian Classification of Health Interventions
ACOG	American College of Obstetricians and Gynecologists
ACT	Australian Capital Territory
AIHW	Australian Institute of Health and Welfare
BDD	Body dysmorphic disorder
CMFM	Comprehensive Management Framework of the MBS
DRG	Diagnosis Related Group
EMSN	Extended Medicare Safety Net
FGCS	Female genital cosmetic surgery
GP	General Practitioner
HTA	Health Technology Assessment
MBS	Medicare Benefits Schedule
MOOSE	Meta-analysis of Observational Studies in Epidemiology
MSAC	Medical Services Advisory Committee
NHMD	National Hospital Morbidity Database
NHMRC	National Health and Medical Research Council
NHS	National Health Service (United Kingdom)
NSW	New South Wales
PASC	Protocol Advisory Sub-Committee (of MSAC)
PICO	Population, Intervention, Comparator, Outcomes
QUOROM	Quality of Reporting Meta-analyses
RANZCOG	Royal Australian and New Zealand College of Obstetricians and Gynaecologists
RCC	Review Consultation Committee
RCT	Randomised controlled trial
SD	Standard deviation
TGA	Therapeutics Goods Administration

EXECUTIVE SUMMARY

In the 2011-12 Budget, the Australian Government announced a further commitment to the Comprehensive Management Framework for the Medicare Benefits Schedule [MBS] (CMFM), to continue the systematic review of MBS items to ensure that they reflect contemporary evidence, improve health outcomes for patients and represent value for money.

MBS Reviews aim to ensure the clinical and financial sustainability of the MBS. The Reviews assess specific MBS services (i.e. MBS items) and associated policy issues using a focussed, fit-for-purpose, evidence-based process. Findings recognise that the MBS funding should align with contemporary evidence, reflecting appropriate patient groups and best clinical practice.

The Reviews have a primary focus on improving health outcomes and the financial sustainability of the MBS, through the following criteria:

- assess patient safety risk;
- identify services that have limited health benefit and/or are used inappropriately;
- be evidence-based and fit-for-purpose;
- be conducted in consultation with key stakeholders including, but not limited to, the medical profession and consumers;
- include opportunities for public submission; and
- use Government resources efficiently.

Purpose of the review

This Review Report outlines the rationale behind conducting the review of the MBS item relevant to vulvoplasty services (refer to Appendix 3 for MBS item descriptor) and the process undertaken to identify and appraise the available information on the MBS item to ensure that it reflects contemporary evidence, improves health outcomes for patients and represents value for money.

Vulvoplasty and labioplasty services

Vulvoplasty refers broadly to any surgery performed on the outside female genital structures. One specific type of vulvoplasty is labioplasty (or labiaplasty), which is used to describe plastic surgery to alter the labia minora and less commonly, the labia majora, the paired tissue structures bounding the vestibule of the vulva. Labioplasty usually involves reduction of the size of the labia but may also be requested and/or performed to address asymmetry. Occasionally, vulvoplasty may involve reconstruction after obstetrical injury or vulvar trauma, or (rarely) enlargement, via injection of bulking agents or autologous fat transfer.

Concerns about vulvoplasty

The MBS item for vulvoplasty and labioplasty has been selected to assess whether the MBS appropriately targets service delivery. Currently, the item stipulates that services should only be claimed for medically indicated services; however, guidance is not provided on what constitutes a medically necessary procedure. Other concerns identified with this service are the marked increase in utilisation of MBS item 35533 which raises concerns that vulvoplasty services may be being accessed inappropriately for cosmetic reasons rather than clinically

relevant indications. MBS General Explanatory Note G13.1 lists ‘non-therapeutic cosmetic surgery’ among services which do not attract Medicare benefits.

This review focuses on identifying appropriate clinical indications for vulvoplasty services and gaining an understanding of current Australian practice in relation to vulvoplasty services.

Review methodology

The review methodology comprised consulting with key stakeholders; developing a review protocol document, which outlined the detailed review methodology (including specifying the key clinical/research questions for the systematic review, preparing the clinical flowcharts, and documenting the economic review strategy); analysing secondary data sources (Medicare Australia and National Hospital Morbidity Database (NHMD)); conducting an evidence-based systematic literature review; and undertaking an assessment and synthesis of all of the evidence to draw conclusions in relation to the clinical/research questions.

Stakeholder consultation

Stakeholder engagement is a pivotal part of the MBS Reviews process, particularly as feedback helps to inform the Review Report. During the review process the stakeholders were informed of the progress of the MBS items being considered. This included ensuring that the relevant documents were released for public consultation at the appropriate time and that comments were incorporated into the review process.

As part of the Reviews process, the Department established a Review Consultation Committee (RCC). The RCC is a time-limited committee of nominated representatives, established to provide advice to the Department to inform the review. A list of members is found at Appendix 2.

Summary of findings

The number of claims for MBS item 35533 (vulvoplasty and labioplasty) have increased by 105% from 744 in 2003/04 to 1,588 in 2012/13. New South Wales and Victoria represent the highest proportion of claims (31% and 26% respectively). During this same ten-year timeframe, benefits paid for item 35533 have increased nearly five and half times (446%) from \$142,682 in 2003/4 to \$778,607 in 2012/13. The largest increases in benefits paid were seen in New South Wales and Victoria. In Victoria, the amount of benefits paid for item 35533 over the past five years was disproportionately higher than the number of claims.

While the majority of vulvoplasty surgeries are performed in hospital, 13% of surgeries over the past five years were performed out-of-hospital.

When changes over time (2008/09 to 2012/13) were analysed it was found that the average fee per service increased by 36%, while the average benefit paid per service increased by 12% and average out-of-pocket expenses increased 54%. An EMSN cap of \$279.90 was introduced on 1st November 2012 for the vulvoplasty MBS item; however, it is too early to determine the impact of this change on trends in benefits paid.

The highest number of claims was equally distributed between three age groups (15-24 years, 25-34 years and 35-44 years), with these groups accounting for 72% of all claims, followed

by women aged 45-54 years (16%). Since 2007/08, the greatest increases in claims occurred in the following age categories: 15-24 years, 35-44 years and 45-54 years.

Over the past five years, the majority of vulvoplasty surgery services were provided by obstetrics and gynaecology specialists (51%), followed by plastic surgeons (32%), vocationally registered GPs (5%), and then 'other' providers (12%). The patterns in benefits paid did not reflect the patterns in MBS claims. While plastic surgeons and obstetrics and gynaecology specialists provide 83% of all services for item 35533, they represented only 35% of total benefits paid. However, vocationally registered GPs and 'other' providers accounted for 17% of services provided (combined) yet represented 65% of benefits paid.

The vast majority of vulvoplasty separations were for private patients (82%); of these, 76% were funded by private health insurance and the remainder were self-funded.

The top five principal diagnoses (ICD codes) associated with vulvoplasty (ACHI code 35533-00) over the past five years were 'hypertrophy of the vulva' (27%), 'non-inflammatory disorders of the vulva and perineum' (17%), 'other plastic surgery for unacceptable cosmetic appearance' (7%), 'rectocele or cystocele' (4%) and 'fusion of the labia or other congenital malformation of the vulva' (4%).

No Australian guidelines on vulvoplasty or labioplasty were identified in the literature search; however, two Australian position statements were identified, one produced by the Royal Australian and New Zealand College of Obstetricians and Gynaecologists (RANZCOG) and the other by the Australian Federation of Medical Women (AMFW). The RANZCOG statement outlines a number of gynaecological conditions that merit surgery, including genital prolapse, female genital mutilation, and labioplasties with clinical indications. Sexual counselling was recommended for anyone seeking surgery for enhancing sexual gratification. The AFMW position statement supports the use of gynaecological and plastic surgery techniques where the primary aim is to repair or reconstruct normal female anatomy following trauma, harmful traditional practices, pathologic processes, or congenital anomalies.

Position statements from the Royal College of Obstetricians and Gynaecologists (UK) and the American College of Obstetricians and Gynaecologists leave it to individual practitioners to define the clinical or medical indications for which female genital surgery should be undertaken. The National Health Service (NHS) developed clinical guidelines which allow surgery for specified anatomical, functional, symptomatic reasons, and 'exceptional' psychological reasons; however, no further detail is provided on these indications.

A search of the published literature was undertaken to identify articles on the safety and effectiveness of vulvoplasty or labioplasty. Only 42 publications were found, which included either level IV clinical studies or other relevant publications. No systematic reviews or health technology assessments on vulvoplasty or labioplasty were identified. In the absence of high level evidence, data and information relevant to the clinical questions were extracted from the 42 publications despite them not meeting the eligibility criteria outlined in the protocol.

The majority of publications were focussed on labioplasty specifically. The reasons patients sought labioplasty could be classified into three key areas:

- aesthetic dissatisfaction associated with (actual or perceived) anatomy abnormality (hypertrophy or asymmetry of the labia minora)

- medical/functional (interference/pain with intercourse, poor hygiene/chronic infection, discomfort in clothing and/or whilst exercising); and/or;
- psychosocial factors/distress (embarrassment, anxiety and/or loss of self-esteem).

In some cases, anatomy abnormalities may be due to congenital malformation (adrenogenital syndrome and vaginal agenesis), Paget's disease, injury, hermaphroditism or vulvar vestibulitis; however, there is very little literature on these indications.

Overall, there was limited reporting of methods used to assess patients' reasons for seeking surgery and no formal assessment pre- and post-surgery. The literature revealed no standard methods for assessing labia minora hypertrophy or the motivations of patients for seeking surgery. Likewise, there are no standard cutpoints for defining hypertrophy of the labia minora. Studies also revealed that wide variation in labial length is common.

There are a number of medical conditions that warrant vulvoplasty including congenital malformations, dyspareunia and other non-inflammatory disorders; however, there is limited literature on vulvoplasty surgery in the treatment of these conditions.

Major complication rates from the relevant studies identified were $\leq 7\%$ and, although minor complications were also reported, they were resolved spontaneously in most cases during the recovery phase and did not interfere with overall patient satisfaction.

Conclusions

In conclusion, analysis of the data indicates that 27% of vulvoplasty separations over the past five years were for hypertrophy of the vulva, whilst 7% were for 'plastic surgery for unacceptable cosmetic appearance'. The literature suggests that these surgeries are likely to be labioplasties performed for the reduction of the labia minora. The large increase in claims over the past ten years indicates that more women are seeking labioplasty from a wide range of ages (15-54 years). There are no standard methods or tools for assessing hypertrophy of the labia minora or women's motivation for seeking surgery. Decisions regarding the necessity for surgery lies with the clinical judgement of medical practitioners. There are a number of clinically relevant indications for vulvoplasty including non-inflammatory disorders of the vulva and perineum, congenital disorders and dyspareunia.

1 BACKGROUND ON VULVOPLASTY SERVICES

1.1 Justification for review

Following the recent review of capping arrangements under the Extended Medicare Safety Net (EMSN) Report, the MBS item for vulvoplasty or labioplasty (item 35533) was identified as among the top 15 most expensive MBS items, in terms of average EMSN benefit per out-of-hospital service, with more than ten out-of-hospital services claimed in 2010. The average EMSN benefit per service was \$2,238 and 191 services were performed out-of-hospital. The primary focus of this review is whether the existing item for this service is appropriate, aligns with contemporary evidence, and targets service delivery to the most appropriate patient groups. The review of the vulvoplasty/labioplasty surgery item will inform recommendations aimed at strengthening the evidence base of Medicare-funded vulvoplasty or labioplasty surgery services and their use.

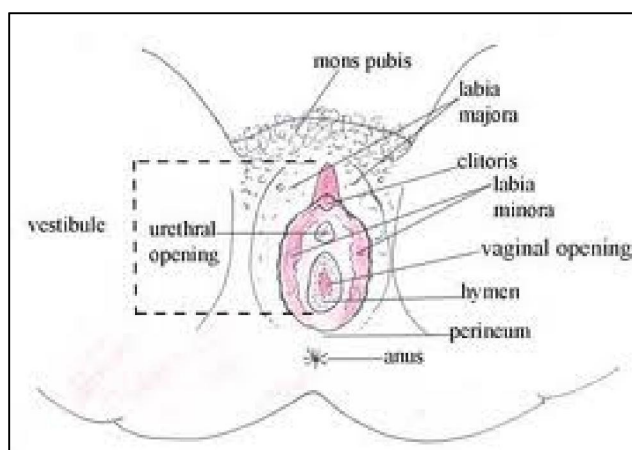
1.2 Description of current services

1.2.1 Vulvoplasty and labioplasty

The vulva consists of the external genital organs of the female mammal.⁽¹⁾ The vulva has many major and minor anatomical structures, including the labia majora, mons pubis, labia minora, clitoris, bulb of vestibule, vulval vestibule, greater and lesser vestibular glands, and the opening of the vagina (Figure 1.1). Hence, vulvoplasty broadly refers to any surgery performed on the outside female genital structures. Labioplasty is a surgical procedure for altering the labia minora and/or the labia majora, the paired tissue structures bounding the vulval vestibule. The surgery typically involves reduction of the labia minora and/or less frequently, the labia majora. Occasionally, labioplasty may be involved in reconstruction after obstetrical injury or vulva trauma, or (rarely) enlargement, via injection of bulking agents or autologous fat transfer.

There is a wide range of normality in vulvar and vaginal anatomy.⁽²⁾ Protrusion of the labia minora beyond the labia majora (labia minora hypertrophy) is the main reason women seek labioplasty.⁽³⁾ The labia minora are two longitudinal, cutaneous folds that are situated internally between the labia majora, and extend from the clitoris laterally and posteriorly on either side of the vulval vestibule (Figure 1.1).⁽³⁾

Figure 1.1: Diagram of the external female genitalia



Source: <http://labspace.open.ac.uk/mod/oucontent/view.php?id=450484§ion=3.5>

There is little consensus on the definition of labia minora hypertrophy, with a wide variation on what is considered normal.⁽⁴⁾ In deciding on the need for surgical intervention, the symptoms described by the patient are generally considered to be more important than the specific size or measurements of the labia. These issues can be functional, aesthetic and/or psychological.⁽⁵⁾

1.2.2 The surgical techniques for vulvoplasty and labioplasty

Labioplasty (also labiaplasty) involves surgical alteration, usually reduction, of the size of the labia minora and, less frequently, the labia majora. Overall goals of labioplasty include:

- (1) reduction of the hypertrophic labia minora,
- (2) maintenance of neurovascular supply,
- (3) preservation of introitus (i.e. vaginal entrance),
- (4) optimal colour/texture match of labial edge, and
- (5) minimal invasiveness.⁽³⁾

The majority of labioplasty surgeries are performed via sculpted linear resection or modified V-wedge excision.^(2, 6) Sculpted linear resection involves a cutting tool such as a focused laser, plastic surgery scissors, electrocautery needle (i.e. needle heated by an electrical current), or radio frequency generator which is utilised to linearly resect and “sculpt” the labia, removing as much redundant tissue as desired. The resected edges are repaired with a resorbable fine suture.⁽²⁾ The modified V-wedge resection involves the excision of a V-shaped “wedge” of redundant labium, with the superior edge beginning slightly inferior to the prepuceal or frenular folds flowing downward from the clitoral hood and the inferior edge beginning above the posterior commissure (where the two labia minora meet).⁽²⁾ Repair involves securing the subcutaneous tissue and matching the edges. A variation of this procedure to prevent post-operative stenosis (i.e. narrowing in blood vessel) of the introitus, is ‘Z-plasty’.⁽⁶⁾ Such de-epithelialisation techniques also remove a wedge of skin, but the aim is to preserve the interstitial tissues.⁽⁶⁾ Other techniques have also been described but are not as widely used.^(7, 8) These procedures are offered mainly by gynaecologists and plastic surgeons. Surgery is generally presented as an unproblematic solution for women’s concerns about their genitals.^(2, 9)

Another technique known to be used in Australia involves each labium being gently retracted with forceps, and a Kelly clamp or similar haemostat being used to cross clamp the labium in a gently curved path approximately parallel to the labia majora. After the clamp is in place for a minute or so, the excess labia are excised, either with curved scissors or a blade. It is rarely necessary to cauterise this area because the clamping leaves it relatively haemostatic. It is then possible to suture the internal and external edges of the labia with continuous locked stitches. No dressing is applied. A W-shaped incision may be used, depending on the surgeon’s preference.⁽¹⁰⁾ The patient is instructed to shower daily and apply antibiotic ointment to the suture lines.

It is not known whether one technique fares better than another.⁽²⁾ One study in the literature compares the two most commonly performed procedures, i.e. modified V-wedge and linear resection, and found little difference in short-term outcomes between the two procedures.⁽⁶⁾

Some of the risks associated with labioplasty include over-repair, disfigurement, scarring and ‘scalloping’ of the labial edge, hypersensitivity or hyposensitivity, dyspareunia (painful

sexual intercourse)⁽¹¹⁾, partial splitting of scar⁽¹²⁾, infection and/or cosmetic results not meeting a patient's expectations.

1.3 The conditions requiring vulvoplasty and labioplasty

Labioplasty corrects clinical conditions wherein a woman presents with labia minora that are disproportionately greater than her labia majora; with the aim being that the labioplasmic correction of the disproportions will lead to functional and aesthetical satisfactory outcomes to the woman.⁽¹³⁾ Protruding or hypertrophic labia minora may lead to psychological, cosmetic, or functional problems.⁽¹⁴⁾ Labial hypertrophy can cause loss of self-esteem and embarrassment for some women.⁽¹⁵⁾ Even in the absence of psychosocial factors, enlarged labia minora can lead to patients reporting functional discomfort and pain.⁽¹⁶⁾ Issues that may arise secondary to labial hypertrophy include interference with sexual intercourse, chronic local irritation, problems with personal hygiene during menses or after bowel movements, and discomfort during walking, cycling, or sitting.⁽³⁾

The aetiology of labia minora hypertrophy is varied and can be multi-factorial. Some women are born with protruding labia minora that may be congenital, as described in Table 1.1. In other women, hypertrophy of the labia minora may be acquired and has been attributed to factors such as childbirth, lymphatic stasis, and chronic irritation and inflammation from dermatitis or urinary incontinence.^(15, 17) Childbirth by the vaginal route causes some women to develop hypertrophy, which in some cases is due to haematoma formation at the time of birth.⁽³⁾ Table 1.1 presents common aetiologies that may cause variation in labial appearance, including labia minora hypertrophy.

Table 1.1: Common aetiologies of variation in labial appearance

Aetiology	Examples	Brief explanation of condition
Idiopathic	Arising from an unknown cause	Not applicable.
Congenital	Bladder exstrophy ⁽¹⁸⁾	Congenital anomaly in which part of the urinary bladder is present outside the body. The diagnosis involves a spectrum of anomalies of the lower abdominal wall, bladder, anterior bony pelvis, and external genitalia.
	Congenital adrenal hyperplasia (CAH) ⁽¹⁹⁾	A genetic disorder (i.e. autosomal recessive disease) in which girls are masculinised because the adrenal glands secrete large amounts of androgen during prenatal development. The extra androgen in baby girls can result in enlargement of the clitoris so that it resembles a penis.
	VATER Syndrome or VACTERL association ⁽²⁰⁾	A non-random association of birth defects. One of the birth defects can be malformed female genitalia.
	Cloacal exstrophy ^{(21)*}	A severe birth defect wherein much of the abdominal organs (the bladder and intestines) are exposed. It often causes the splitting of both male and female genitalia (specifically, the penis and clitoris respectively), and the anus is occasionally sealed.
	Epispadias ^{(22)*}	A rare defect involving the opening of the urethra. The urethra does not develop into a full tube and urine exits the body from the wrong place, usually between the clitoris and the labia, but it may be in the belly area. It results in females having an abnormal clitoris and labia.

Aetiology	Examples	Brief explanation of condition
		They may have trouble controlling urination (urinary incontinence).
Medical related	Exogenous androgenic hormones in infancy ⁽²³⁾	i.e. steroid hormone
	Pigmented lesions on the labia minora and/or majora ^ε	Labioplasty required to achieve sufficient biopsy. Excised tissue sent for histopathology.
Inflammation related	Dermatitis secondary to urinary incontinence ⁽³⁾	Women with genetic predispositions to allergies and hypersensitivity may be at greater risk of developing vulval dermatitis. Initial symptoms typically include itching, and treatment is typically via corticosteroid creams or antihistamines. ⁽²⁴⁾
	Vulval oedema ⁽³⁾	Fluid accumulating in the vulva. Can be caused by Crohn's disease. ^(25,26)
Chronic/repetitive stretching or overexpansion	Multiple pregnancies ⁽³⁾	Stretching of labia due to stress caused by pregnancy.
Iatrogenic	Adverse condition in a patient resulting from treatment by a physician or surgeon ⁽³⁾	For example, following orthopaedic lower limb procedures with pressure necrosis of the labia and clitoral hood against the supporting post of the orthopaedic table.
Post traumatic	Following untreated/unrecognised straddle injuries in childhood ⁽³⁾	Straddle injuries occur when a child straddles an object as he or she falls (during bicycle riding, falls, and playing on monkey bars), striking the urogenital area with the force of his or her body weight. Injury is caused by the compression of soft tissues against the bony margins of the pelvic outlet.

*The following conditions have associated MBS items that are not within scope of the current review of the item number for vulvoplasty or labioplasty: Bladder exstrophy, MBS item 37050; Cloacal exstrophy, MBS item 43882; Female epispadias, MBS item 37836.

^εdermatologists and skin clinics refer female patients to plastic surgeons to perform the biopsy

Most women present for labioplasty for one or more of the following indications^(2, 5, 13, 17, 27-31).

- correction of congenital defects and congenital abnormalities;
- exterior cosmetic refinement of the vulvo-vaginal complex for the diminishment of perceived large, irregular, cosmetically unappealing vulvar structures as a result of the tear and stretching of the labia minora caused by the mechanical stresses of childbirth, accident, age; and/or
- for functional purposes including dyspareunia (painful sexual intercourse), pubic discomfort and/or irritation with certain clothing, and/or discomfort or pain with some activities (bicycling, running, etc.).

1.3.1 Incidence and prevalence of conditions requiring vulvoplasty

The correction of some congenital abnormalities may require labioplasty. However, congenital abnormalities of the vulva and surrounding area are rare and the data for them is scarce. Based on Australian Institute of Health and Welfare (AIHW) morbidity data, separations are very low for congenital abnormalities of the vulva and surrounding area. For some codes, the condition is grouped into 'not elsewhere classified', therefore diagnosis is not specific to the vulva region. Furthermore, management and treatment varies and labioplasty is not always indicated for these conditions.

The prevalence of labial hypertrophy (whether acquired or congenital) is difficult to estimate, but the annual frequency of labioplasty procedures appears to be increasing along with the number of clinicians who offer this service. Furthermore, it is difficult to determine whether procedures performed are for cosmetic purposes only or are deemed medically necessary. Difficulties in determining the incidence and prevalence of labia hypertrophy are related to difficulties in defining ‘anatomic normality’ in vulva anatomy. Labial hypertrophy is generally a normal variant. Asymmetry of the female genitalia is a natural occurrence, thus making a clear distinction between normal and abnormal anatomy challenging.

1.4 Concerns about vulvoplasty and labioplasty services

The MBS item for vulvoplasty and labioplasty has been selected to assess whether the MBS appropriately targets service delivery. Currently, the item stipulates that services should only be claimed for medically indicated services. However, guidance is not provided on what constitutes a medically necessary procedure. MBS General Explanatory Note G13.1 lists ‘non-therapeutic cosmetic surgery’ among services which do not attract Medicare benefits.

Labioplasty may be viewed as elective or indicated, depending on whether one looks upon self-perceived genital ‘disfigurement’ as a sexual or body image dysfunction qualifying for indicated or medically necessary therapy, or as a cosmetic dissatisfaction issue, subject to elective revision.⁽²⁾ A recent literature review showed that labioplasty appeared to have been offered on demand, justified by verbal reports of physical and psychological difficulties that were not formally evaluated, pre- or post-surgery.⁽⁹⁾

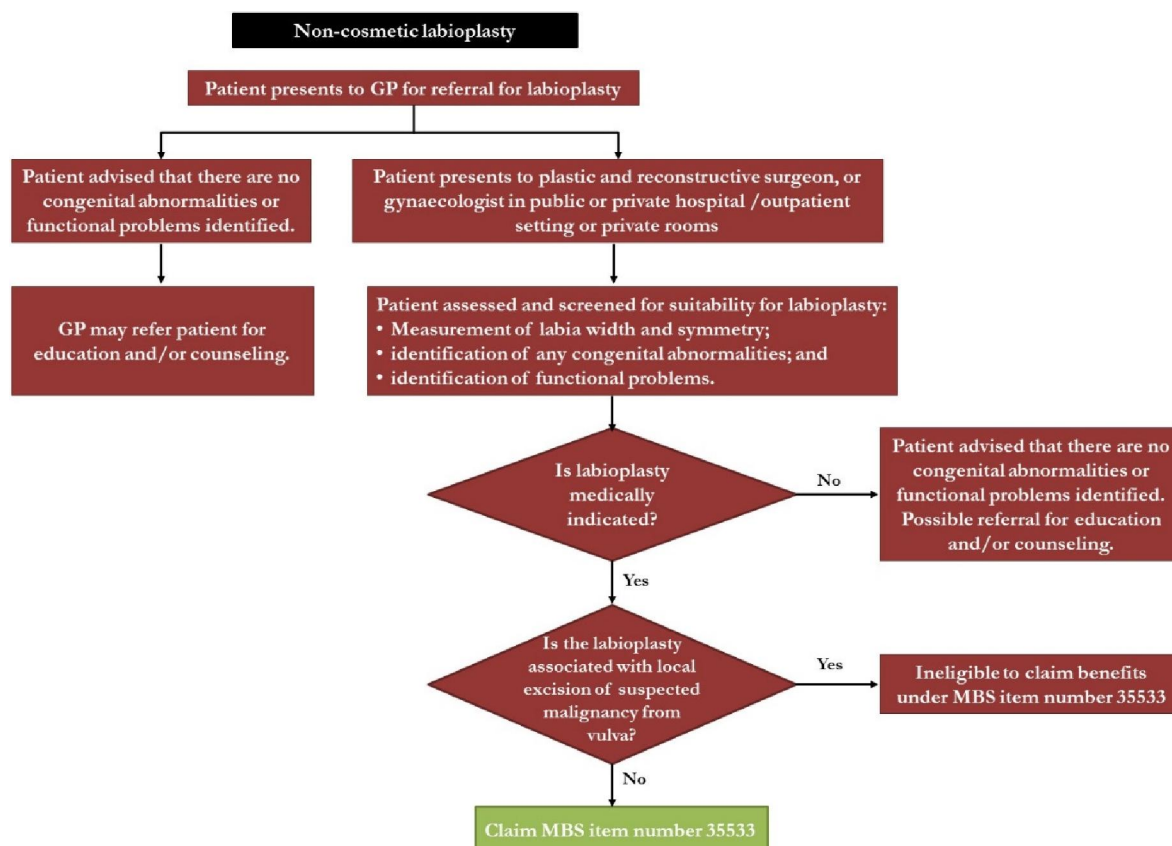
Other concerns identified with this service are the marked increase in utilisation and location of service delivery, with a significant proportion of vulvoplasty and labioplasty services procedures performed out-of-hospital. Further concern surrounds the limited evidence base on the long-term safety and effectiveness of the procedure. Most published reports on labioplasty look only at technical aspects of surgery^(13, 32) and outcome data are sparse. There is also some unease around some practitioner groups that currently perform the surgery. A recent letter to the editor of the Medical Journal of Australia (MJA) captures these issues, indicating that in the context of female genital cosmetic surgery, there is a blurring between disease and dissatisfaction, with an absence of evidence on clinical effectiveness.⁽¹⁴⁾

Recent changes in fashion trends, including more revealing attire, are also believed to be contributing to an increased demand for contouring of the labia minora.⁽³⁾ Some stakeholders claim that the restrictions placed on the media by the Classification Board, which restricts adult media to show frontal nudity with “only discreet genital detail” and where the female genitals are presented in a “neat and tidy fashion”, may be having an impact on women’s perception of what is the normal appearance of a labia.^(33, 34) The Classification Board consider the showing of the labia minora as being offensive for soft porn. Therefore, Photoshop professionals completely remove the labia from the images by airbrushing the entire area to a “single crease”, thus reducing the labia minora size and any asymmetry. Consequently, this censorship conveys an inaccurate depiction of the vulva and labia^(33, 34). Women may feel that they deviate from this norm, leading to unnecessary concern and an increase in medical care (possibly for cosmetic purposes only), all of which is further enforced by increased media attention.⁽³⁵⁾ However, a recent report claims that the majority of patients are undergoing reduction of the labia minora for functional reasons, with minimal outside influences affecting their decision for treatment.⁽¹⁶⁾

1.5 The clinical pathway

The clinical decision pathway that determines whether vulvoplasty or labioplasty surgery is performed is provided in Figure 1.2. The figure only applies to non-cosmetic indications for labioplasty. Determination of whether vulvoplasty or labioplasty is ‘medically indicated’ is at the discretion of the clinician, but may include congenital abnormalities and functional problems, as discussed in Chapter 1.3.

Figure 1.2: Clinical flow chart for non-cosmetic vulvoplasty or labioplasty surgery



2 REVIEW METHODOLOGY

The review methodology comprises an analysis of secondary data (e.g. MBS claims, hospital separations), a guideline concordance analysis, a systematic literature review for clinical and economic evidence, and a search of grey literature (for Government or independent reports). This Chapter presents clinical research questions and the methodology used for each of these review components.

2.1 Secondary data analysis

Data from Medicare Australia and the National Hospital Morbidity Database (NHMD) were analysed to determine whether the existing MBS item number for vulvoplasty or labioplasty (35533) are appropriate.

2.1.1 The research questions for the MBS analysis

The MBS data were examined to determine:

- (1) Whether the existing MBS item for service (35533) is appropriate?
 - a. how frequent are claims made for the MBS item number under review?
 - b. the temporal or geographic trends associated with usage of the item number?
 - c. the characteristics of patients undergoing vulvoplasty or labioplasty?
 - d. whether the MBS claims data are consistent with trends in the incidence/prevalence of the conditions/diseases being addressed by the service?
 - e. the medical specialities providing services for vulvoplasty or labioplasty?
 - f. whether other procedures are being claimed in association with vulvoplasty and labioplasty?

2.1.2 Methods for analysis of MBS data

MBS data are available for MBS item number 35533 from the early 1990's. MBS data relates to private medical services (provided in- or out-of-hospital), where the services are provided to patients regardless of whether or not they have private health cover. MBS in-hospital services are mainly provided in private hospitals and day surgery clinics, but patients can elect to be treated as a private patient in a public hospital.

MBS data were analysed by patient gender, age group, patterns of use and discipline of provider claiming the benefit. Results of the analysis of the MBS data are presented in Chapter 3.

2.1.3 The research questions for the NHMD analysis

The NHMD, which covers public and private hospitals, was examined to determine:

- (1) What are the characteristics of the service profile under the Australian Classification of Health Interventions (ACHI) code 35533-00?
 - a. the number of separations where vulvoplasty was performed by year;
 - b. the principal diagnosis profile of patients for whom vulvoplasty was performed; and
 - c. the age profile of patients for whom vulvoplasty was performed.
- (2) Whether the relevant ACHI code profile was different to the analysis of MBS item 35533?

2.1.4 Methods for analysis of NHMD

The NHMD is compiled by AIHW from data supplied by state and territory health authorities. It is a collection of electronic confidentialised summary records for separations (i.e. episodes of care) in public and private hospitals in Australia. The data available within the NHMD includes patient's principal diagnosis, the associated Diagnosis Related Group (DRG) and the procedure they underwent during the separation (i.e. ACHI code). The vulvoplasty procedure code within the ACHI is 35533-00 (Table 2.1). There is no specific ACHI code for labioplasty.

Table 2.1: ACHI codes associated with vulvoplasty or labioplasty

ACHI code	ACHI description
35533-00	Vulvoplasty

The NHMD data were analysed by patient gender, age group and principal diagnosis.

Results of the analysis of the NHMD data is presented in Chapter 3.

2.2 Guideline concordance

2.2.1 The research questions for the guideline concordance analysis

The research question addressed as part of the Review using guideline concordance analysis is:

- (1) Is the existing MBS item for service (35533) appropriate?
 - a. is the descriptor for the MBS item number/service under review consistent with evidence-based (or in the absence of evidence, consensus-based) recommendations provided in relevant clinical practice guidelines?

2.2.2 Methods for guideline concordance analysis

Searches of guidelines databases¹ and relevant discipline websites were undertaken to locate any existing guidelines relevant to the delivery of vulvoplasty or labioplasty surgery. Analysis of MBS item number 35533 was undertaken relative to 'best practice', as recommended in relevant Australian clinical practice guidelines. Where Australian clinical practice guidelines do not exist, other guidelines in operation in comparable health systems overseas were included. Where guidelines existed, they were assessed for quality using the AGREE II instrument⁽³⁶⁾. Differences in the purpose and intended audience of any such guidelines were considered, documented and acknowledged.

See Chapter 4 for results of the concordance analysis for vulvoplasty/labioplasty.

2.3 Systematic literature review for clinical evidence

2.3.1 The clinical/research questions for the systematic literature review

The clinical/research questions that were the focus of the literature review are:

¹ The search included: Guidelines International Network (G-I-N) at <http://www.g-i-n.net/library/international-guidelines-library/>; National Guidelines Clearinghouse at www.guidelines.gov; National Health and Medical Research Council (NHMRC) at <http://www.nhmrc.gov.au/guidelines-publications>

- (1) What are appropriate clinical indications for medically necessary vulvoplasty and labioplasty surgery?
- (2) What is the strength of evidence for the effectiveness of vulvoplasty and labioplasty in improving outcomes in each target population across the patient journey?
 - a. what impact does the procedure have on patient quality of life (including patient satisfaction with vulva/labial size and aesthetic result, reduction in pain or discomfort etc.)?
- (3) What are the safety and quality implications (including morbidity, mortality and patient satisfaction) associated with vulvoplasty and labioplasty in each target population? How do safety and quality outcomes of vulvoplasty and labioplasty vary according to:
 - a. the surgical technique used (e.g. sculpted linear resection, modified V-wedge etc.)?
 - b. the procedural volumes of the surgeon (e.g. gynaecologist, plastic and reconstructive surgeons)?
 - c. accreditation/training processes?
 - d. location of service delivery (e.g. inpatient and non-admitted patient setting)?
- (4) Is the existing MBS item for service (35533), including the associated explanatory notes, appropriate?

2.3.2 Search strategy

A comprehensive search of peer-reviewed scientific literature was conducted to identify relevant studies addressing the key questions. Electronic databases were searched for original research papers including systematic reviews, as shown in Table 2.2. Searches were restricted to studies published in the English language between January 2000 and May 2013. Databases maintained by Health Technology Assessment (HTA) agencies were searched to identify existing assessments of vulvoplasty or labioplasty.

Table 2.2: Databases searched

Database	Search period
MEDLINE and EMBASE	January 2000 – May 2013
PreMEDLINE	Up to May 2013
The Cochrane Library (includes Cochrane Database of Systematic Reviews, Database of Abstracts of Reviews of Effects, Cochrane Central Register of Controlled Trials, NHS Economic Evaluation Database, Health Technology Assessment, Cochrane Methodology Register)	January 2000 – May 2013
Relevant HTA websites and databases ²	Up to May 2013

Reference lists of systematic, semi-systematic and selected narrative reviews were also reviewed. In addition, during the consultation process, clinicians were asked if they were aware of any relevant clinical guidelines, unpublished studies or reviews relevant to this review of vulvoplasty.

² The following HTA websites were searched: Agency for Healthcare Research and Quality (AHRQ) at www.ahrq.gov; Canadian Agency for Drugs and Technologies in Health (CADTH) at <http://www.cadth.ca/en>; National Institute for Health and Care Excellence (NICE) at www.nice.org.uk; Australasian College of Surgeons (ASERNIP-S) at <http://www.surgeons.org/for-health-professionals/audits-and-surgical-research/asernip-s/>

2.3.3 Eligibility criteria for studies

The PICO (Population, Intervention, Comparator, Outcomes) criteria⁽³⁷⁾ was used to develop well-defined questions for the search of published literature. This involved focusing the question on four elements:

- the target population for the intervention;
- the intervention being considered;
- the comparator for the existing MBS service (where relevant); and
- the clinical outcomes that are most relevant to assess safety and effectiveness.

The PICO criteria were determined on the basis of information provided in the literature, as well as clinical advice. The PICO criteria for the review of vulvoplasty or labioplasty surgery is shown in Table 2.3.

Table 2.3: PICO criteria for the vulvoplasty or labioplasty surgery item under review

Population	Intervention	Comparator	Outcomes
(1) Female patients with congenital anomalies	Vulvoplasty/ labioplasty	No vulvoplasty/ labioplasty	<u>Safety</u> <ul style="list-style-type: none"> • Adverse physical health outcomes as a consequence of the procedure (e.g. functional problems); • Complications associated with the procedure (e.g. infection, bleeding, wound dehiscence, functional problems). <u>Effectiveness</u> <p><i>Primary</i></p> <ul style="list-style-type: none"> • Mortality; • Quality of life (including patient satisfaction with vulva/labial size and aesthetic result); reduction in pain or discomfort. <p><i>Secondary</i></p> <ul style="list-style-type: none"> • Length of hospital stay; • Subsequent procedures.
(2) Female patients with labia hypertrophy that causes functional problems including dyspareunia			
(3) Female patients dissatisfied with genital appearance			

The detailed search strategy and terms used are presented in Appendix 4. Separate searches were undertaken for each of the PICO populations.

Studies were excluded on the basis of citation information and/or abstract, where it was obvious that they did not meet the inclusion criteria. Where there was any doubt about any reference based on the title and/or abstract, the full paper was retrieved and evaluated by two independent reviewers. Table 2.4 lists the pre-specified inclusion and exclusion criteria.

Table 2.4: Inclusion/exclusion criteria for identification of relevant studies

Characteristic	Criteria
Search period	January 2000 – May 2013
Publication type	<p>Clinical studies included. Non-systematic reviews, letters, editorials, animal, in vitro and laboratory studies excluded.</p> <p>Systematic reviews Systematic reviews that have been superseded were excluded.</p> <p>Primary studies Primary studies published during the search period of included systematic reviews were excluded.</p> <p>Effectiveness studies included if:</p> <ul style="list-style-type: none"> • prospective, comparative trial • >20 patients <p>Safety studies included if:</p> <ul style="list-style-type: none"> • >50 patients.
Intervention	Vulvoplasty or labioplasty surgery
Comparator	No vulvoplasty or labioplasty surgery
Outcome	<p>Studies must report on at least one of the following outcomes:</p> <ul style="list-style-type: none"> • Patient outcomes: length of hospital stay, morbidity, mortality, quality of life, etc. • Safety: adverse physical health outcomes or complications associated with the procedure
Language	Non-English language articles excluded

2.3.4 Process for classifying the evidence

All eligible studies were assessed according to the National Health and Medical Research Council (NHMRC) Dimensions of Evidence (refer to Appendix 5). There are three main domains: strength of the evidence, size of the effect, and relevance of the evidence. One aspect of the ‘strength of the evidence’ domain is the level of evidence, which is assigned using the NHMRC Levels of Evidence (Appendix 5). For any eligible publications, study quality was evaluated and reported using the NHMRC Quality Criteria (Appendix 5) for randomised controlled trials (RCTs), cohort studies, case-control studies and systematic reviews.

The results of the review of clinical evidence for vulvoplasty and labioplasty are presented in Chapter 5.

2.3.5 Grey literature

An advanced Google search using the following terms “vulvoplasty” or “labioplasty” or “labiaplasty” or “genital cosmetic surgery” was conducted. The resulting Google returns were then searched in an attempt to locate any ‘grey’ unpublished research or reports regarding vulvoplasty or labioplasty.

2.4 Systematic review for economic evidence

The research question for the review of economic literature is:

- (1) What is the evidence regarding the cost implications associated with vulvoplasty surgery in each target population across the patient journey?

Consistent with the terms of reference, a formal modelled economic evaluation of vulvoplasty or labioplasty was not in scope. The review relied on published costing studies and economic

analyses identified through a systematic literature search of the databases shown in Table 2.2. The detailed search strategy and terms used are presented in Appendix 4.

Citations were reviewed to identify acceptable evidence including: trial-based costing studies, cost analyses and economic modelling studies. Acceptable outcomes were limited to: cost, incremental cost-effectiveness ratio (e.g. cost per event avoided, cost per life year gained, cost per quality adjusted life year or disability adjusted life year).

The results of the search for economic evaluations of vulvoplasty or labioplasty are presented in Chapter 5.

3 SECONDARY DATA ANALYSIS

This Chapter presents an analysis of the available secondary data (including Medicare Australia and NHMD) that describes the use of vulvoplasty or labioplasty in Australia.

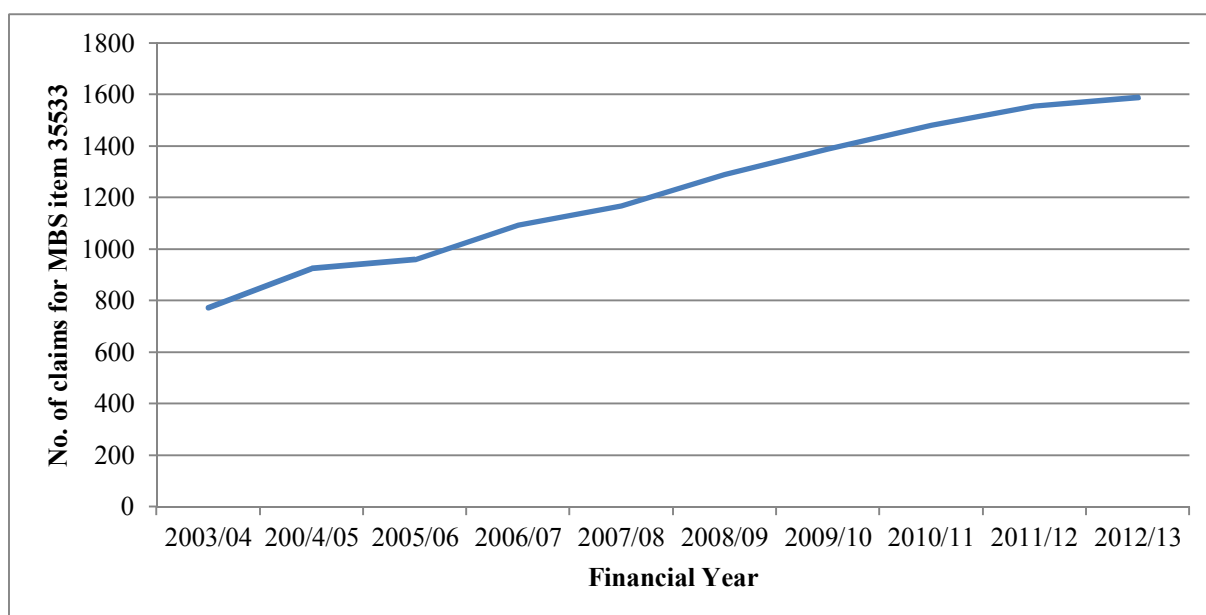
3.1 MBS item number usage and expenditure

MBS data provides claiming information on patients with private health cover irrespective of whether the service was provided in a public or private hospital. MBS data was analysed by patient gender, age group, patterns of use and medical speciality providing the service. Results of the analysis of the MBS data are presented in the following sections.

3.1.1 Number of claims and benefits paid for vulvoplasty services

Figure 3.1 shows the number of claims for MBS item 35533 (vulvoplasty or labioplasty) from 2003/04 to 2012/13. During this ten year timeframe the number of claims per financial year increased by 105% (doubled) from 774 in 2003/04 to 1,588 in 2012/13.

Figure 3.1: Claims for MBS item number 35533, 2003/2004 to 2012/13



Source: Department of Human Services – Medicare Australia

Figure 3.2 shows the benefits paid per financial year for MBS item 35533 (vulvoplasty or labioplasty) from 2003/04 to 2012/13. During this ten year timeframe the benefits paid per financial year increased nearly five and half times (446%) from \$142,682 in 2003/04 to \$778,607 in 2012/13. The magnitude of the increase in benefits paid for vulvoplasty was disproportionate to the increase in claims.

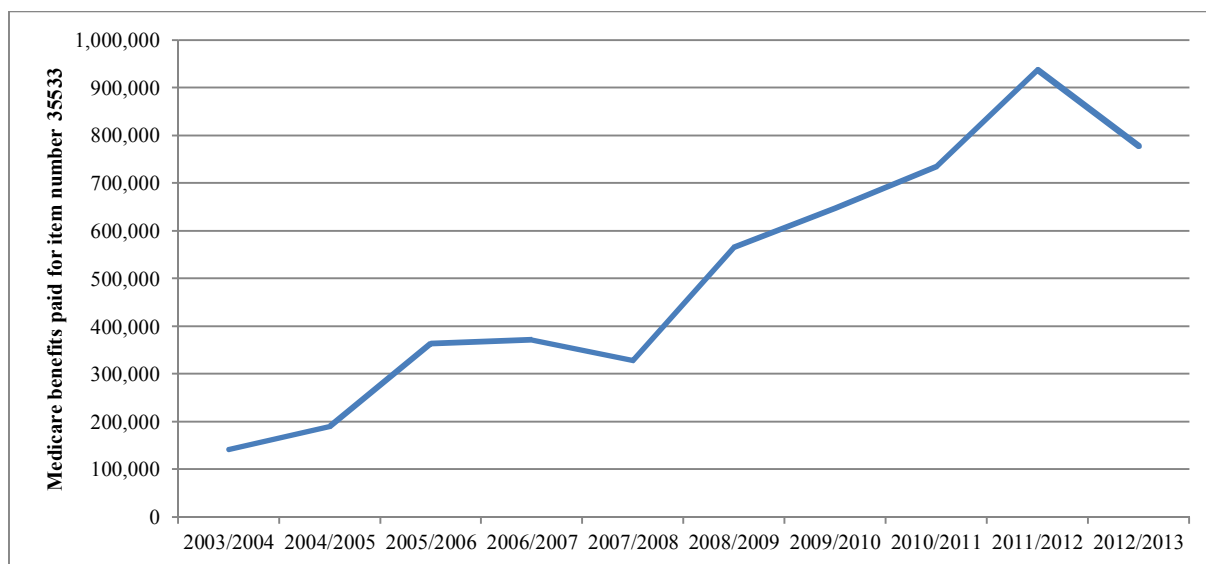
Figure 3.2: Benefits paid for MBS item number 35533, 2003/2004 to 2012/13

Table 3.1 shows the number of vulvoplasty services, location of service, fees charged, benefits paid, proportion of services bulk billed and average out-of-pocket-costs for the period 2008/09 to 2012/13. During this timeframe, there was a 23% increase in the total number of vulvoplasty services and a 38% increase in total benefits paid. The majority (87%) of services for vulvoplasty were performed in-hospital and only a small proportion of services were bulk billed ($\leq 5\%$). The average fee charged per service over the period from 2008/09 to 2012/13 was \$1,230.00, whilst the average benefit paid per service was \$502.00 (41% of the average fee charged per service). The average ‘out-of-pocket cost’³ for the patient was \$728.35. An EMSN benefits cap for item number 35533 was announced in the 2012-13 Budget and implemented on 1st Nov 2012.

When changes over time (2008/09 to 2012/13) were analysed, it was found that the average fee per service increased by 36%, while the average benefit paid per service increased by 12% and average out-of-pocket expenses increased 54%.

In 2013, An EMSN cap of \$279.90 was introduced on 1st November 2012 for the vulvoplasty MBS item however, it is too early to determine the impact of this change on trends in benefits paid.

³ Average out-of-pocket cost is calculated as ‘fees charged’ minus ‘benefits paid’ divided by ‘number of services’. It does not take into consideration private health insurance benefits.

Table 3.1: Fees charged and benefits paid for MBS item number 35533, 2008/09 to 2012/13

	Financial year						Change 2008/09 to 2012/13
	2008/09	2009/10	2010/11	2011/12	2012/13	Total/ average	
Number of services	1291	1389	1481	1556	1588	7305	+23%
Out-of-hospital (%)	12.3	12.1	12.4	14.9	12.6	12.9	+2%
In-hospital (%)	87.7	87.9	87.6	85.1	87.4	87.1	0%
Fees charged	\$1,322,122	\$1,564,092	\$1,747,172	\$2,141,293	\$2,213,162	\$8,987,841	+67%
Average per service	\$1,024	\$1,126	\$1,180	\$1,376	\$1,394	\$1,230	+36%
Benefits paid	\$566,076	\$648,427	\$736,057	\$938,081	\$778,607	\$3,667,248	+38%
Average per service	\$438	\$467	\$497	\$603	\$490	\$502	+12%
Services bulk billed (%)	5.2	4.5	4.7	3	2.8	4.0	-46%
Average out-of-pocket cost*	\$585.63	\$659.23	\$682.72	\$773.27	\$903.37	\$728.35	+54%

Source: Department of Human Services – Medicare Australia

* Average out-of-pocket cost is calculated as 'fees charged' minus 'benefits paid' divided by 'number of services'. It does not take into consideration private health insurance benefits.

3.1.2 Number of claims and benefits paid for vulvoplasty by state and territory

Figure 3.3 shows the increase in the number of claims for MBS item number 35533 over the past ten years by state and territory. During this timeframe, New South Wales (NSW) has consistently had the highest number of claims for vulvoplasty followed by Victoria (VIC), Queensland (QLD), South Australia (SA) and Western Australia (WA). Tasmania (TAS), the Australian Capital Territory (ACT) and the Northern Territory (NT) had the least number of claims each year (Figure 3.3). NSW represented 31% of all claims in the last ten years followed by 26% in VIC, 18% in QLD, 12% in SA and 9% in WA. TAS, ACT and NT combined represented only 4% of all claims.

Figure 3.3: Number of claims for MBS item number 35533 by state and territory, 2003/04 to 2012/13

Source: Department of Human Services – Medicare Australia

Table 3.2 provides a summary of the growth in MBS claims for vulvoplasty by state and territory over the last 10 years. The highest growth occurred in SA with an increase in claims of 191% over the ten year period. Increases of 100-103% occurred in NSW, VIC and QLD, whilst TAS had the smallest increase (35%). There were substantial increases in the ACT and

NT; however, combined the territories accounted for only 2% of all claims in the past ten years so this increase is not significant overall.

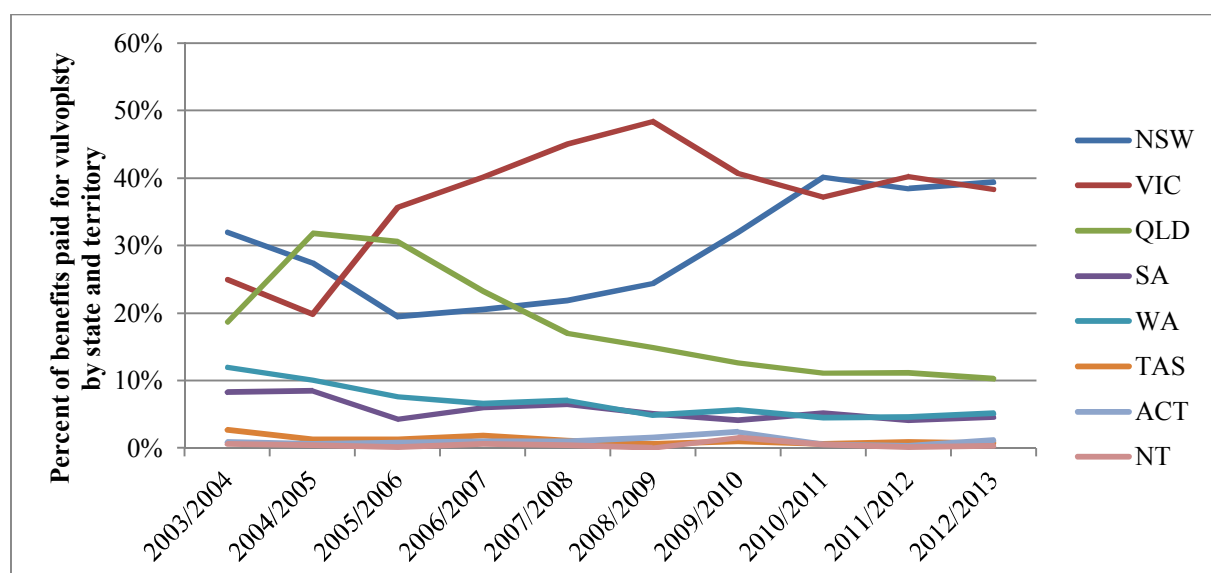
Table 3.2: Growth in claims for MBS item number 35533 by state and territory, 2003/04 to 2012/13

State/ Territory	Claims for MBS item number 35533				
	2003/2004	2007/2008	2012/2013	Growth 2003/ 04 to 2007/08	Growth 2003/04 to 2012/13
NSW	256	349	513	+36%	+100%
VIC	184	309	370	+68%	+101%
QLD	143	200	290	+40%	+103%
SA	68	138	198	+103%	+191%
WA	91	132	160	+45%	+76%
TAS	20	17	27	-15%	+35%
ACT	7	16	16	+129%	+129%
NT	5	7	14	+40%	+180%
Total	774	1,168	1,588	+51%	+105%

Source: Department of Human Services – Medicare Australia

Figure 3.4 shows trends over the past 10 years in the relative proportion of benefits paid (per financial year) by state and territory. The largest increase in benefits paid was in NSW and VIC.

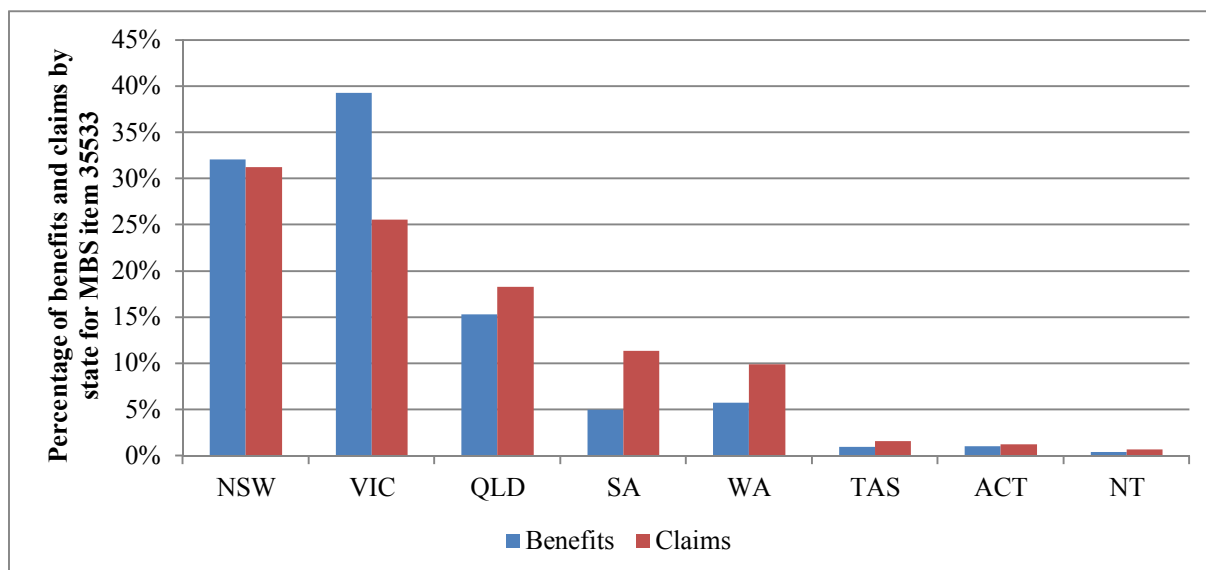
Figure 3.4: Relative proportion of benefits paid for MBS item number 35533 by state and territory, 2003/04 to 2012/13



Source: Department of Human Services – Medicare Australia

Figure 3.5 shows the percent of total claims and benefits paid for MBS item number 35533 by state and territory from July 2007 to June 2013. Over the past ten years, the proportion of benefits paid for services in VIC is disproportionate to the proportion of claims in this state.

Figure 3.5: Relative proportion of all claims and benefits paid for MBS item 35533 by state and territory (July 2007 to June 2013)



Source: Department of Human Services – Medicare Australia

Table 3.3 shows the number of claims for MBS item 35533 per capita (i.e. per 100,000 population) in 2012/13, according to the address of the patient to whom the service was rendered at the time of claiming. Compared to other states and territories, South Australia had the highest rate of claiming of the vulvoplasty item per 100,000 people enrolled in Medicare.

Table 3.3: Services per capita* for MBS item 35533 by state and territory, 2012/13

Services per 100,000 population

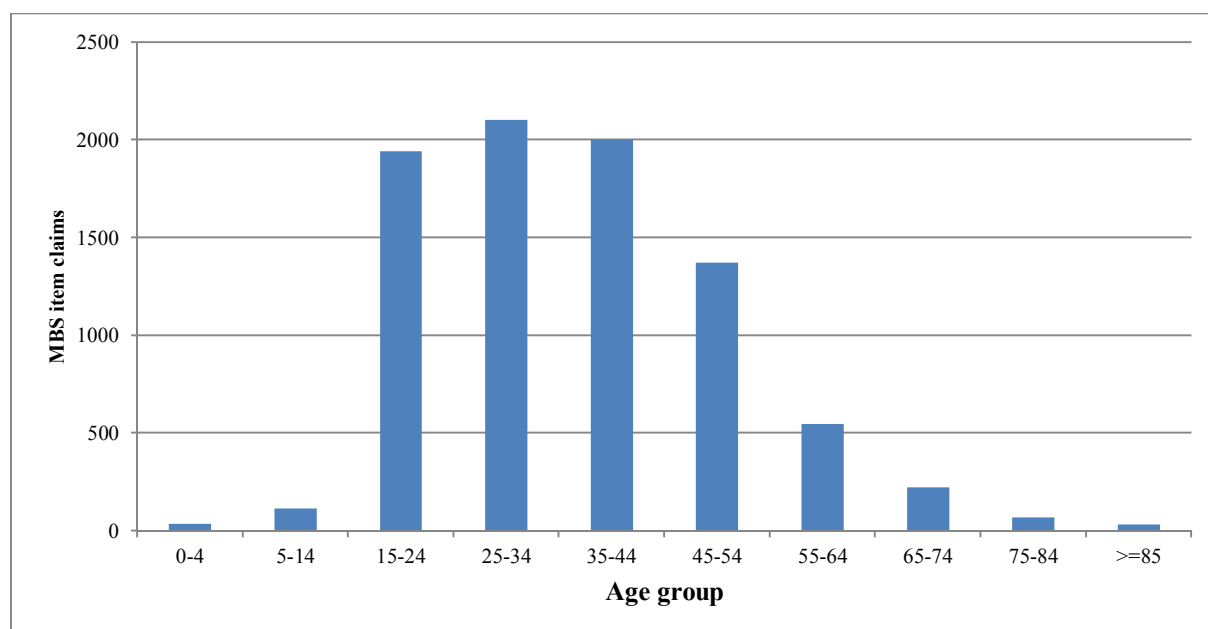
MBS item number	NSW	VIC	QLD	SA	WA	TAS	ACT	NT	Total
35533	7	6	6	12	7	5	4	6	7

Source: Department of Human Services – Medicare Australia

* Services per capita (i.e. per 100,000 population) is calculated by dividing the number of services processed in a month by the number of people enrolled in Medicare at the end of that month.

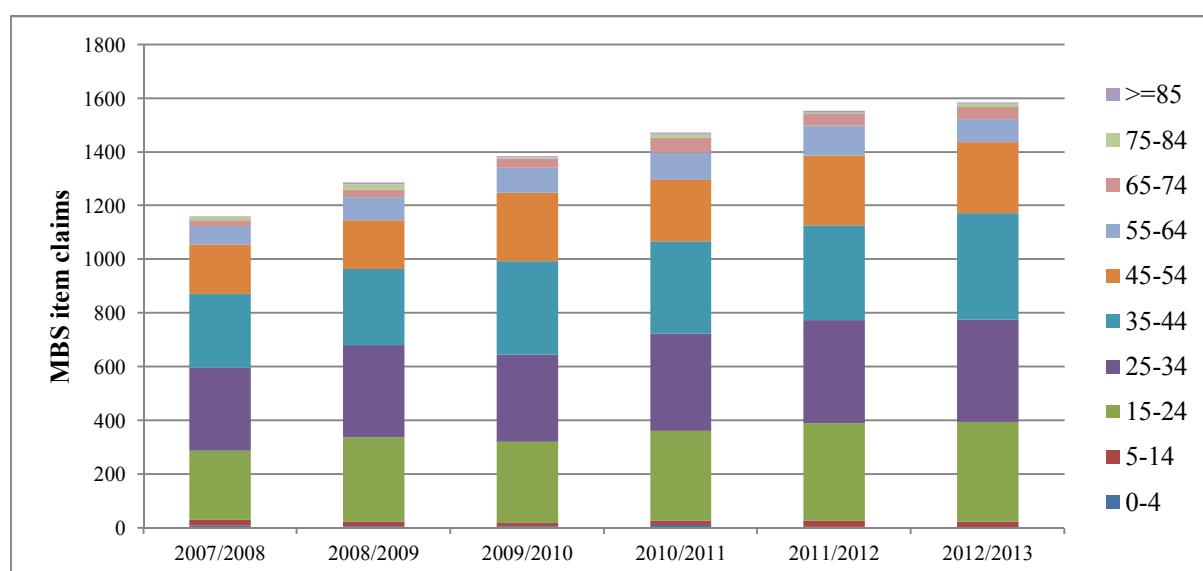
3.1.3 Age patterns in claims for vulvoplasty

Figure 3.6 shows the age distribution of claims for MBS item number 35533 from July 2007 to June 2013. During this timeframe there were 8,446 claims where the age was recorded (the age was unknown for 27 claims). The highest proportion of claims were in women aged 15-24 years (23%), 25-34 years (25%) and 35-44 years (24%). These three age groups accounted for (72%) claims and those aged 45-54 years accounted for a further 16% of claims.

Figure 3.6: Total claims for MBS item number 35533 by female age (July 2007 to June 2013)

Source: Department of Human Services – Medicare Australia

Figure 3.7 shows claims by age category from 2007/08 to 2012/13. For those age categories with the highest proportion of claims, the largest increases over time were in women aged 15-24 years (44%) and 35-44 years (44%), versus a 24% increase in those aged 25-34 years. There was a 45% increase in women aged 45-54 years and a 24% increase in women aged 55-64 years. The largest increase from 2007/08 to 2012/13 was in women aged 65-74 years (96%); however, they make up only a small proportion of total claims (3%). There was no change in the number of claims for all the remaining age categories.

Figure 3.7: Claims for MBS item number 35533 by female age category, 2007/08 to 2012/13

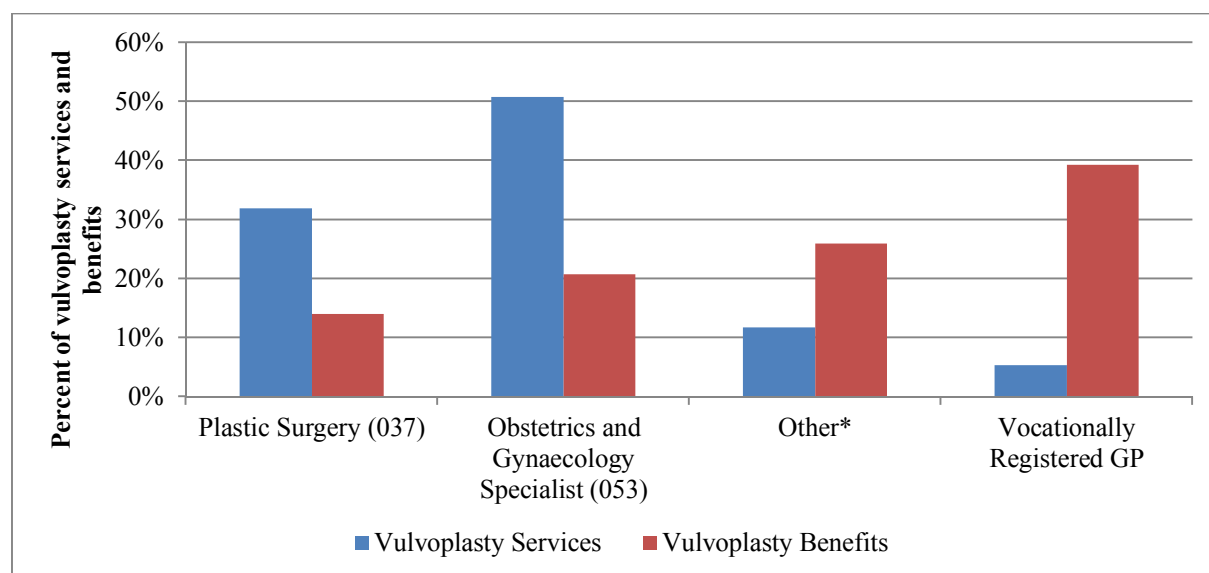
Source: Department of Human Services – Medicare Australia

3.1.4 Vulvoplasty surgery services and benefits by provider

Figure 3.8 shows the medical specialities providing vulvoplasty services according to services provided and benefits paid from July 2008 to June 2013. Plastic surgeons provided less than a

third (32%) of all vulvoplasty services. The majority of vulvoplasty surgery services were provided by obstetrics and gynaecology specialists (51%). Vocationally registered GPs provided 5% of services. Other medical specialists (including IVF specialists, general surgeons and non-specialist surgeons) accounted for 12% of services. This pattern of service provision by medical speciality was similar each year from 2008/09 to 2012/13. The patterns for benefits paid did not reflect the data for claims/services. While plastic surgeons and obstetrics gynaecology specialists account for 83% of all services they represented only 35% of total benefits paid. However, vocationally registered GPs and ‘other’ specialists accounted for 17% of services provided (combined) yet represented 65% of benefits.

Figure 3.8: Vulvoplasty services and benefits paid by medical specialty (July 2008 to June 2013)



Source: Department of Human Services – Medicare Australia

*Includes IVF specialists, general surgeons and non-specialist surgeons

3.1.5 Surgery items co-claimed with vulvoplasty

An analysis was undertaken to determine whether vulvoplasty or labioplasty is undertaken in conjunction with other surgical procedures. The literature indicates that labioplasty may be undertaken with hysterectomy or vaginal tightening. The relevant MBS item numbers were identified as 35653 and 35657 (hysterectomy) and 35560 (removal of vagina); however, the MBS item for removal of the vagina was claimed too infrequently for analysis. Examination of MBS data from the past five years shows that vulvoplasty was co-claimed with hysterectomy in an extremely low proportion of cases (0.9%-1.1%).

3.2 National hospital morbidity data relevant to vulvoplasty

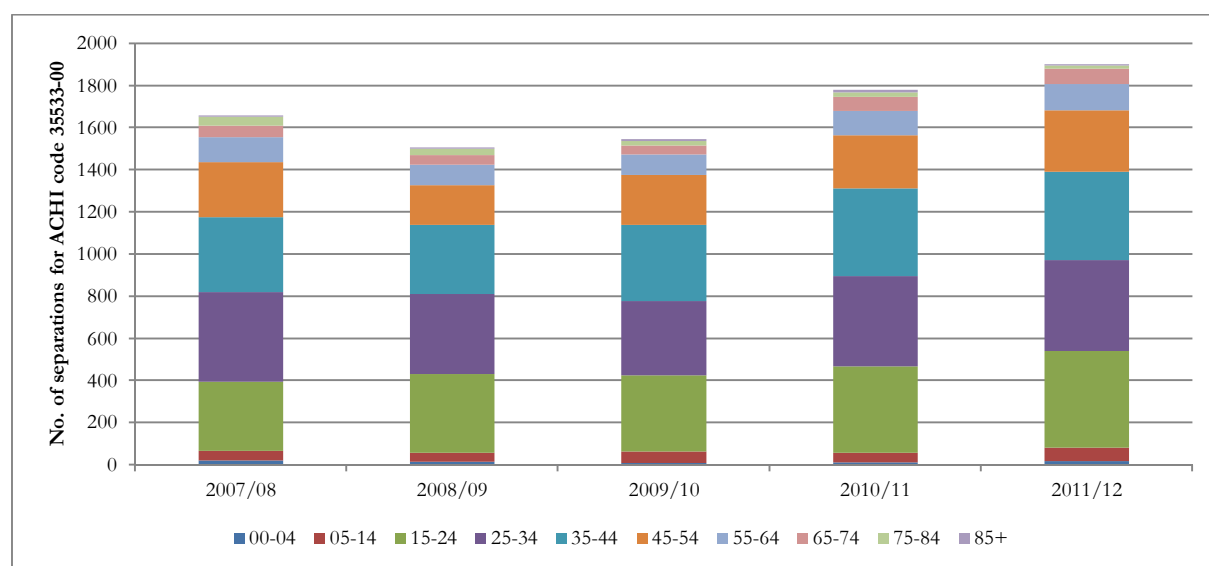
3.2.1 Characteristics of patients undergoing vulvoplasty

ACHI code 35533-00 (vulvoplasty) was analysed by patient type and funding source from 2007/08 to 2011/12. Over this time period, the majority of vulvoplasty procedures (82%) were for private patients. Of the private patients who underwent a vulvoplasty procedure, approximately 76% were funded by private health insurance and the remainder were self-funded.

Figure 3.9 shows the number of separations by age category for vulvoplasty (ACHI code 35533-00) from 2007/08 to 2011/2012. The total number of separations was 8,395 in this time frame, with the highest number occurring in those aged 15-24 years, 25-34 years and 35-

44 years. Combined, these three age categories represented 70% of all separations over the five years. This reflects the MBS data where these age categories represented 72% of all claims for vulvoplasty. Women aged 45-54 years represented 15% of all separations for vulvoplasty (ACHI code 35533-00), with each of the remaining age categories representing less than 10% of all separations. The number of separations remained stable for the majority of age categories, except for a small increase from 20% to 24% in women aged 15-24 years.

Figure 3.9: Number of separations for ACHI code 35533-00 by female age category, 2007/08 to 2011/12



Source: Department of Health, NHMD data

3.2.2 Principal diagnosis (ICD codes) for vulvoplasty

Table 3.4 shows the number and percentage of separations for vulvoplasty (ACHI code 35533-00) from 2007/08 to 2011/12 by principal diagnosis. In each year, the most common principal diagnosis was 'hypertrophy of vulva', which increased from 23% in 2007/08 to 33% in 2011/12. The second most common principal diagnosis was 'non-inflammatory disorders of vulva and perineum' (17% of all separations from 2007/08 to 2011/12), followed by 'other plastic surgery for unacceptable cosmetic appearance' (7%). Overall, there was a broad range of principal diagnosis codes used, with 31% of all separations being classified as 'other', of which the majority represented $\leq 1\%$ of all separations.

Table 3.4: Principal diagnosis for ACHI code 35533-00 by percentage, 2007/08 to 2011/12

Number of separations (%)

Principal diagnosis	ICD code	2007/08	2008/09	2009/10	2010/11	2011/12	Total
Hypertrophy of vulva	N906	382	(23%)	395	(26%)	428	(28%)
Non-inflammatory disorders of vulva and perineum	N908 or N909	273 (16%)	299 (20%)	260 (17%)	480 (27%)	634 (33%)	2319 (27%)
Plastic surgery for unacceptable cosmetic appearance	Z411	102 (6%)	68 (5%)	90 (6%)	260 (15%)	259 (14%)	1351 (17%)
Rectocele or Cystocele	N811 or N816	119 (7%)	52 (4%)	49 (3%)	169 (10%)	117 (6%)	546 (7%)
Fusion of labia or other congenital malformation of the vulva	Q52-Q529	80 (5%)	36 (2%)	54 (3%)	72 (4%)	79 (4%)	371 (4%)
Uterovaginal prolapse	N812-19	93 (6%)	53 (4%)	41 (3%)	83 (5%)	92 (5%)	345 (4%)
Menstruation or bleeding disorder (N948 or N920)	N91-N939	41 (3%)	41 (3%)	53 (3%)	64 (4%)	84 (4%)	335 (3%)
Dyspareunia ()	N941	40 (2%)	33 (2%)	29 (2%)	46 (3%)	55 (3%)	236 (3%)
Open wound (S314)		40 (2%)	36 (2%)	39 (3%)	23 (1%)	21 (1%)	146 (2%)
Vulva dysplasia, leukoplakia, atrophy	N900-N905	35 (2%)	31 (2%)	20 (1%)	38 (2%)	45 (2%)	196 (2%)
Vulvar Cyst	N907	23 (1%)	16 (1%)	17 (1%)	39 (2%)	24 (1%)	149 (2%)
Other diagnosis		432 (26%)	446 (30%)	436 (28%)	28 (2%)	24 (1%)	108 (1%)
Total		1660 100%	1506 100%	1546 100%	478 (27%)	478 (25%)	2270 (31%)

Source: Department of Health, NHMD data

4 REVIEW OF GUIDELINES AND REPORTS RELEVANT TO VULVOPLASTY OR LABIOPLASTY

This Chapter presents the results of the literature search for clinical practice guidelines and the guideline concordance analysis conducted for vulvoplasty/labioplasty. It also discusses relevant reports identified through a search of the grey literature.

4.1 Guideline concordance

4.1.1. Australian Guidelines

No Australian guidelines on vulvoplasty or labioplasty were identified. Two Australian position statements on cosmetic vaginal procedures were identified; one produced by the Royal Australian and New Zealand College of Obstetricians and Gynaecologists (RANZCOG)⁽³⁸⁾ and the other by the Australian Federation of Medical Women.⁽³⁹⁾ Both of the position statements did not meet the definition of a comprehensive clinical practice guideline.⁽³⁶⁾

In 2008, RANZCOG released a position statement on ‘*Vaginal ‘rejuvenation’ and cosmetic vaginal procedures*’.⁽³⁸⁾ This position statement outlines a number of gynaecological conditions that merit surgery, including genital prolapse, female genital mutilation and labioplasties with clinical indications.⁽³⁸⁾ The statement recommends sexual counselling for patients requesting surgery that is for enhancing sexual gratification. In the statement, the College strongly discourages the performance of any surgical procedure that lacks current peer review scientific evidence other than in the context of an appropriately constructed clinical trial.⁽³⁸⁾

The Australian Federation of Medical Women issued a brief position statement in 2012 which supported the use of gynaecological and plastic surgical techniques where the primary aim is to “repair or reconstruct normal female anatomy following trauma, harmful traditional practices, pathologic processes or congenital anomalies”.⁽³⁹⁾

Neither position statement specifically mentioned potential functional/medical indications for labioplasty.

4.1.2 International Guidelines

No international guidelines were identified; however, several position statements were identified and described below.

The Royal College of Obstetricians and Gynaecologists in the UK issued a statement in 2009 on ‘*Hymenoplasty and labial surgery*’⁽⁴⁰⁾ advocating that any decision for female genital surgery be based only on clinical grounds. However, the statement leaves it to individual practitioners to define these grounds. In 2003, the UK parliament made it an offence to excise, infibulate or otherwise mutilate the whole or any part of a women’s labia majora, labia minora or clitoris whether the woman has consented or not.⁽⁴¹⁾ For a person found guilty of an offence under the Act, the penalty is a prison sentence of up to 14 years. However, no offence is committed if the surgical operation is necessary for her physical or mental health.⁽⁴¹⁾ Physical or mental health is not defined; rather, this is left to the medical professional to determine.⁽⁴¹⁾

Due to the increasing demand for publicly funded elective cosmetic surgery, the National Health Service (NHS) in the UK developed clinical guidelines to assist surgeons identify patients for whom surgery is suitable.⁽⁴²⁾ These guidelines allow surgery for specified anatomical, functional or symptomatic reasons and permitted surgery for ‘exceptional’ psychological reasons. However, the ‘exceptional’ indication was not further defined, or how the surgeon should make this assessment. A study analysing the NHS guidelines concluded that further development of the guidelines should provide additional detail and support for surgeons on assessing the degree of abnormality of appearance, importance of appearance to the patient’s future quality of life, and whether the patient seeks to improve or to restore their appearance.⁽⁴³⁾

The American College of Obstetricians and Gynaecologists (ACOG) published a committee opinion on ‘*Vaginal ‘rejuvenation’ and cosmetic vaginal procedures*’ in 2007⁽⁴⁴⁾ which, similar to the UK and Australian position statements, provided no specific information on what constitutes medical indications for surgery. The guideline recommends that clinicians who receive requests from patients for these procedures should evaluate the patient for any physical signs or symptoms that may indicate the need for surgical intervention.⁽⁴⁴⁾ The statement also recommends that women be informed regarding the lack of data supporting the efficacy of these procedures and potential complications such as infections, altered sensation, dyspareunia, adhesions and scarring.⁽⁴⁴⁾

4.1.3 Appropriateness of the descriptor for the MBS item for vulvoplasty or labioplasty

The MBS item descriptor for vulvoplasty or labioplasty (Appendix 3) states that the service should be used ‘*where medically indicated*’; however, there is no evidence-based or consensus-based guidelines in Australia which define what those medical indications are. Currently, in Australia, the decision as to whether there is a medical indication for vulvoplasty or labioplasty surgery is at the discretion and clinical judgement of the medical professional undertaking the surgery.

4.2 Relevant reports

To supplement the review of relevant guidelines, a comprehensive search was undertaken to locate any relevant Australian reports, policies or other relevant literature relating to vulvoplasty or labioplasty that would not emerge in the search of peer-reviewed literature databases. Two Australian reports on female genital cosmetic surgery were identified^(45, 46), along with two state policy documents on cosmetic/elective surgery^(47, 48), and a draft guideline and code of conduct for medical practitioners undertaking cosmetic surgical procedures⁽⁴⁹⁾.

4.2.1 Reports

One report⁽⁴⁶⁾ was produced in 2011 by the Australian Health Ministers’ Advisory Council Inter-jurisdictional Cosmetic Surgery Working Group. The other Australian report⁽⁴⁵⁾ was produced by Women’s Health Victoria (<http://whv.org.au/>) and describes current evidence and issues relating to women and genital cosmetic surgery. Women’s Health Victoria is a not-for-profit organisation, supported by the Victorian Government to undertake strategic health promotion and advocacy to improve the lives of women. The following sections provide a brief description of these reports and their findings.

In 2011, the Australian Health Ministers' Advisory Council Inter-jurisdictional Cosmetic Surgery Working Group was requested to make recommendations to the Australian Health Ministers' Conference on the need for, and nature of, additional safeguards for consumers in relation to cosmetic surgery, and to identify options for progressing such safeguards through a national framework or baseline of requirements.⁽⁴⁶⁾ A report was published titled '*Cosmetic Medical and Surgical Procedures: A National Framework*'.⁽⁴⁶⁾ For the purpose of scoping its task, the Working Group defined cosmetic surgery as a procedure performed to reshape normal structures of the body or to adorn parts of the body, with the aim of improving the consumer's appearance and self-esteem and confidence and not driven by medical need.⁽⁴⁶⁾ The report addresses cosmetic surgery generally – and includes mention of rhinoplasty and abdominoplasty – but labioplasty is not referred to specifically. The report recommends a national framework based on five interdependent elements – the procedures, the promotion of the procedures, the practitioner, the patient and the place.⁽⁴⁶⁾

One of the recommendations in the report was directed to the Medical Board of Australia regarding the development of a code of conduct for medical practitioners who perform cosmetic and surgical procedures in Australia.⁽⁵⁰⁾ The guidelines were designed to be a supplement to existing guidelines and code of conduct for doctors in Australia.⁽⁴⁹⁾ The draft supplementary guidelines on cosmetic medical and surgical procedures have been made available for consultation on the website of the Medical Board of Australia and a number of submissions on the draft guidelines have been made and are also available on the website⁴. The definition of cosmetic medical and surgical procedures in the draft guidelines is as follows:

“Cosmetic medical and surgical procedures are operations and other procedures that revise or change the appearance, colour, texture, structure or position of normal bodily features with the sole intention of achieving what the patient perceives to be a more desirable appearance or boosting the patient's self-esteem”

The guidelines recommend that both external reasons (e.g. a perceived need to please others) and internal reasons (e.g. strong feelings about appearance) should be explored and if there are indications that the patient has self-esteem or mental health problems then the person should be referred to a GP or an appropriately qualified health professional (e.g. psychiatrist, psychologist or special counsellor) for review.

The other Australian report on women and genital cosmetic surgery, produced by Women's Health Victoria (<http://whv.org.au/>)⁽⁴⁵⁾, critically explores female genital cosmetic surgery in the Victorian context to better understand what it is and who is undertaking it. The reason for undertaking the report was the increase in incidence of female genital cosmetic surgery (FGCS).⁽⁴⁵⁾ The report highlights that whilst this trend has been the subject of substantial analysis and opinion, there is a lack of rigorous evidence on risks, efficacy, complications, and patient satisfaction. The report discusses the fact that both individual and sociocultural factors are likely to contribute to the emerging trend, and provides suggestions for how professional bodies, health professionals, and advocates might respond. The authors state the report (issues paper) is intended as a starting point for further conversation, evidence-gathering, and action.⁽⁴⁵⁾

⁴ <http://www.medicalboard.gov.au/News/Past-Consultations/2012/Consultation-March-2012.aspx>

The report uses both published and grey literature to examine issues relating to FGCS, including reasons for seeking surgery, sociocultural context, regulatory environment, risks and complications, and standards of evidence. The report concludes with 14 recommendations, including increased public awareness regarding the low standard of evidence and risks associated with FGCS, and the diverse natural range of female genital appearance and how images of genitals are altered when they appear in restricted publications. The report recommends that relevant professional bodies issue statements on FGCS and regulate provision of FGCS, and advocates for research to improve the evidence base for interventions to encourage safe and responsible medical practice in relation to FGCS.

4.2.2 Policies on cosmetic surgery

In Australia, the states and territories are responsible for determining the types of elective surgery that can be performed in public hospitals. A number of states, have publicly available policies, including Western Australia⁽⁴⁸⁾ and New South Wales⁽⁴⁷⁾. The Western Australian policy does not list labioplasty as a surgery that should be excluded. The New South Wales policy directive published by the Ministry of Health in 2012 classifies labioplasty as a discretionary procedure and indicates that it “should not routinely be performed in public hospitals in NSW unless there is a clear clinical need to improve a patient’s physical health”. However, no further clarification regarding specific medical indications for improving a patient’s health in relation to labioplasty is provided.

5 REVIEW OF THE CLINICAL AND ECONOMIC EVIDENCE FOR VULVOPLASTY OR LABIOPLASTY

This Chapter presents the results of the systematic literature review on vulvoplasty or labioplasty, in relation to the clinical and economic research questions.

5.1 Evidence base

5.1.1 Search results

The search strategy retrieved a total of 133 non-duplicate citations published between January 2000 and May 2013. Appendix 6 provides a Quality of Reporting Meta-analyses (QUOROM) flowchart describing the sequence of steps undertaken to select relevant studies for the review of vulvoplasty or labioplasty. Only 42 publications relating to vulvoplasty or labioplasty for appearance, hypertrophy or congenital reasons were found; however, none of these were systematic reviews or primary effectiveness studies with >20 patients. Therefore, none of the 41 publications on vulvoplasty or labioplasty obtained through the search process met the review inclusion criteria described in Chapter 2.

5.1.2 Assessment of retrieved studies against eligibility criteria

The 42 publications found on vulvoplasty and labioplasty included level IV clinical studies and other relevant publications. Although outside the scope of this review, in the absence of high level evidence it was considered useful to extract data and information from the available studies in relation to the clinical research questions of the review. All information needs to be considered in the context of the limitations of this evidence base.

The 42 relevant publications identified consisted of:

- four non-systematic reviews^(2, 9, 51, 52);
- 25 surgical papers/reports^(5-7, 11, 12, 15, 17, 28, 31, 32, 53-67);
- two studies reporting on surveys of physicians on labioplasty^(68, 69);
- four studies reporting on women's indications for seeking labioplasty^(14, 16, 70, 71);
- one study of variation in labial length⁽³⁵⁾;
- one qualitative study on women's expectations and experience of labioplasty⁽⁷²⁾;
- two studies on the validation of a genital appearance satisfaction scale and cosmetic procedure screening scale for women^(73, 74); and
- three expert commentary/opinion papers.^(4, 75, 76)

The 25 surgical papers consisted of case reports, case series, retrospective, observational or descriptive studies, and all lacked a control group. They comprised:

- 18 papers on labioplasty for hypertrophy and/or asymmetry of labia minora, of which 2 were case reports for a single patient^(55, 60) and 2 were case reports with less than 10 patients^(32, 59);
- two studies on labioplasty for labia majora^(54, 65);
- two studies on vulval surgery relating to lymphangioma^(63, 64);
- one study on labioplasty for treatment of hermaphroditism⁽⁵⁸⁾;
- one study on surgical treatment of vulvar vestibulitis⁽⁶⁶⁾; and
- one paper reporting on different surgical techniques for performing reduction labioplasty.⁽⁶²⁾

5.1.3 Existing health technology reports and systematic reviews

No systematic reviews or HTAs on vulvoplasty or labioplasty were identified. Four non-systematic reviews were found (see Table 5.1). One of these was on labial surgery specifically⁽⁹⁾, while the other three had a broader focus on female genital cosmetic and plastic surgery in general.^(2, 51, 52) The review published on labioplasty by Liao et al. 2010⁽⁹⁾ was intended to be a systematic review; however, the authors reported that the available literature was “extremely rudimentary” and precluded the use of the recommended methodology on the Meta-analysis of Observational Studies in Epidemiology (MOOSE) and QUOROM checklists.⁽⁹⁾ Likewise, Ostrzenski (2011) stated that the objective had been to conduct a systematic review; however, this was changed to be a methodological review due to insufficient existing scientific literature on cosmetic gynaecology.⁽⁵²⁾ Table 5.1 describes the characteristics and quality of the four reviews found. No level II studies were identified for inclusion in the reviews; therefore, none of the reviews could be classified as level I according to the NHMRC designation of levels of evidence for an intervention (see Appendix 5).

Table 5.1: Characteristics of existing non-systematic reviews

Author and year	Review Type	Rating ^a	Objective	Included studies	Search period	Details
Liao et al. (2010)⁽⁹⁾	Systematic	Fair	To investigate the quality and content of reports relating to labial surgery for women	40 articles identified; the review was restricted to 18 surgical studies	1900-2009	Planned as a systematic review but lack of RCTs precluded use of methodology for systematic meta-analysis.
Braun (2010)⁽⁵¹⁾	Non-systematic	Not Applicable	To review published literature on female genital cosmetic surgery (FGCS)	Unclear	Not reported	Covers FGCS but main focus is labioplasty. Discussion focused on ethical debate.
Goodman (2010)⁽²⁾	Non-systematic	Not Applicable	To discuss procedures designed to alter female genital appearance and function and investigate sexual, philosophical, ethical issues and outcomes	30 articles Series reports with <10 patients, most procedure modifications, and the paediatric population were excluded	Not reported	Covers reduction labioplasty, clitoral hood reduction, perineoplasty, vaginoplasty and hymenoplasty.
Ostrzenski (2011)⁽⁵²⁾	Systematic	Fair	To conduct a methodological review of existing scientific literature within the field of cosmetic gynaecology in view of evidence-based American College of Obstetricians and Gynecologists (ACOG) committee opinion	43 studies ^b	1900-Jan 2010	Highlights weakness of existing studies in establishing safety and effectiveness of labioplasty.

^aNHMRC quality criteria for assessing systematic review (Appendix 5)

^bDescriptive study, case reports, opinions of respected authorities, reports of expert committees

5.2 Clinical indications for vulvoplasty and labioplasty

As no studies that met the eligibility criteria described in the methodology section (Chapter 2) were identified, a decision was made to extract information from the available literature in relation to the clinical indications for vulvoplasty or labioplasty and to present this in a narrative form. All results in this section need to be considered in the context of the limitations of the available literature.

In the majority of 18 studies on labioplasty, the surgery was undertaken for reduction of the labia due to reported enlargement or hypertrophy of the labia minora. Some studies also reported asymmetry in labia length as a reason for seeking surgery.⁽⁵⁾ Most surgery was bilateral; however, some unilateral surgery was also reported for a small proportion of patients (3-15%).^(15, 17) Labioplasty was generally performed on its own; in some studies it was performed in conjunction with other types of surgery including hysterectomy, perineoplasty, clitoral hood reduction or vaginal tightening.^(6, 15, 61)

Of the 18 studies on labioplasty, the majority reported the reasons for seeking surgery which were either medical/functional and/or aesthetic and/or psychosocial. Table 5.2 presents the proportion of patients reporting each type of reason for labioplasty, for those studies where the information was available.

Table 5.2: Summary of indications for labioplasty

Author & year	Description	No. of cases	Age (years)	Indications for labioplasty		
				Medical / functional	Aesthetics	Psychological / social
Choi et al. 2000 ⁽³²⁾	Case report on patients undergoing reduction labioplasty	6	13-40 (mean 26)	6 (100%)	Not reported	6 (100%)
Maas et al. 2000 ⁽³¹⁾	Case report on patients undergoing reduction labioplasty	13	19-42	13 (100%)	9 (69%)	9 (70%)
Rouzier et al. 2000 ⁽¹⁷⁾	Records of 163 patients who underwent reduction labioplasty were reviewed. Bilateral surgery for 85% and unilateral for 15% patients	163	12-67 (median 26)	43% interference with sexual intercourse; 64% discomfort in clothing; 26% discomfort exercising.	87%	Not reported
Giraldo et al. 2003 ⁽⁵⁷⁾	Case report on patients undergoing reduction labioplasty	15	22-45 (mean 34)	7 (47%)	Not reported	15 (100%)
Pardo et al. 2006 ⁽⁶¹⁾	Case report on patients undergoing labioplasty for hypertrophy (n=18) or asymmetry (n=37) of the labia minora	55	10-55	32 (58%)	53 (96%)	13 (24%)
Munhoz et al. 2006 ⁽⁷⁾	Case report on reduction labioplasty	21	Not reported	13 (62%) interference with sexual intercourse; 10 (48%) poor hygiene; 7 (33%) difficulty wearing tight clothing.	21 (100%)	Not reported

Author & year	Description	No. of cases	Age (years)	Indications for labioplasty		
				Medical / functional	Aesthetics	Psychological / social
Rezai et al. 2007 ⁽²⁸⁾	Comparative study of two different surgical methods for labioplasty	100	17-45	25 (25%) interference with intercourse; 16 (16%) interference with physical activity; 15 (15%) poor hygiene; 17 (17%) intermittent urinary.	55 (55%)	Not reported
Alter et al. 2008 ⁽¹⁵⁾	Case report on aesthetic labia minora and clitoral hood reduction	407	13-63 (mean 32.4)	348 (86%) aesthetic plus discomfort; 5 (1%) for discomfort only	54 (13%) aesthetic only	Not reported
Jothilakshmi et al. 2009 ⁽⁵⁹⁾	Retrospective review of six cases of unilateral or bilateral reduction labioplasty	6	11-16	4 (67%)	Not reported	2 (33%)
Ellsworth et al. 2010 ⁽⁵⁶⁾	Case report on reduction labioplasty	12	Not reported	8 (67%)	12 (100%)	Not reported
Goodman et al. 2010 ⁽⁶⁾	Multi-centre outcome study of female genital plastic surgery	177 ^a	Not reported	134 (76%)	94 (53%)	58 (33%)
Trichot et al. 2010 ⁽¹²⁾	Retrospective descriptive study of patients undergoing reduction labioplasty	18	15-52 (mean 29)	18 (100%)	16 (86%)	14 (78%)
Solanki et al. 2010 ⁽⁵⁾	Retrospective review of patients undergoing reduction labioplasty	12	15-52 (mean 32)	4 (33%)	4 (33%)	4 (33%)
Cao et al. 2012 ⁽⁵³⁾	Retrospective review of medical records of patients undergoing reduction labioplasty	167	20-43	Not reported	Not reported	Not reported
Gress (2013) ⁽⁴³⁾	Retrospective review of patients undergoing reduction labioplasty	812	Not reported	27% functional only; 62% functional and psychological stress.	Not reported	Psychological only (11%)

^a 24 patients with clitoral hood reduction only are included in this group, as results were reported together with 153 patients having labioplasty

Fourteen studies reported on the proportion of patients undergoing surgery for medical/functional reasons.^(6, 7, 11, 12, 15, 17, 28, 31, 32, 56, 57, 59, 61) In these 14 studies, representing 1793 patients, the proportion of patients reporting a functional/medical reason for seeking surgery ranged from 27% to 100%. In the ten studies reporting the number of patients indicating aesthetic dissatisfaction as a reason for undergoing labioplasty, the proportions ranged from 13% to 100%. Nine studies, including 1090 patients in total, reported the proportion of patients seeking surgery for psychological factors/distress, this ranged from 11% to 100%.^(5, 6, 11, 12, 31, 32, 57, 59, 61) Psychological factors as a reason for seeking surgery, appeared to be related to a 'feeling of being abnormal' and the desire to 'be more normal'.⁽⁶⁾

The most common functional reasons were interference/pain with sexual intercourse^(56, 72), poor hygiene/chronic infection,^(28, 31, 56) discomfort in clothing and/or whilst exercising.^(7, 11, 15, 73) Psychosocial factors were embarrassment, anxiety and a loss of self-esteem.^(5, 31)

Munhoz et al. (2006) reported on 21 patients undergoing reduction of the labia minora between 1998 and 2004. In this study, 19 (91%) patients had congenital labia minora hypertrophy, one patient had congenital genital malformation associated with vaginal agenesis, and one patient had Paget's disease with a unilateral intraepithelial vulvar carcinoma.⁽⁷⁾ Giraldo et al. (2003) reported that 7 of the 15 patients undergoing labioplasty had congenital malformations (adrenogenital syndrome and vaginal agenesis).⁽⁵⁷⁾ Only one study was found referring to labioplasty of the labia minora as part of surgical treatment for 25 patients with a congenital condition (hermaphroditism).⁽⁵⁸⁾

Miklos et al. (2008) undertook a retrospective review of the medical records of 131 patients who had undergone labia minora reduction surgery between January 2005 and March 2007, to examine patients motivation for pursuing labioplasty.⁽¹⁶⁾ Patients were allocated to one of three groups, based on information provided by patients in response to a pre-surgery questionnaire administered by the clinician. The three groups were 'aesthetic reasons only', 'functional impairment only' or 'both aesthetic and functional' reasons.⁽¹⁶⁾ It was found that 37% of patients were motivated by aesthetic reasons only, 32% sought to undertake the surgery for functional impairment only, and 31% undertook it for both aesthetic and functional reasons.⁽¹⁶⁾

However, across the studies described there was limited reporting of methods used to assess patients' reasons for seeking surgery. In the majority of studies, surgery appeared to be undertaken on the basis of verbal reporting of functional or psychosocial distress with no formal assessment undertaken pre or post-surgery. Only a few studies reported the use of a questionnaire to assess reasons for undertaking labioplasty^(6, 61); however, the questionnaire was not validated or a standard questionnaire.

Deans et al. (2011) examined referral letters in a NHS gynaecology clinic in the UK to determine clinician's reasons for referring patients for labioplasty.⁽¹⁴⁾ Of 48 letters reviewed for women aged 9-50 years (mean age 25 years), physical discomfort was mentioned in 48% of letters, and complaints regarding genital appearance and embarrassment were identified in 71% of letters.⁽¹⁴⁾ In 44% of the letters, sexual problems were mentioned.⁽¹⁴⁾

In a prospective study, Crouch et al. (2011) explored the characteristics and motivation for surgery of 33 women seeking labial reduction surgery.⁽⁷⁰⁾ In terms of motivation for seeking surgery:

- 57% indicated pain or discomfort;
- 21% experienced difficulties with intercourse;
- 15% experienced difficulties with exercise;
- 15% had problems with clothing;
- 78% reported they wanted to improve the appearance of their labia⁽⁷⁰⁾; and
- 9% reported anxiety, embarrassment or distress.⁽⁷⁰⁾

Bramwell et al. (2007) undertook qualitative interviews with six women undergoing labioplasty.⁽⁷²⁾ It was found that the women were motivated by the perception that their labial appearance was 'abnormal' and that surgeons may unwittingly reinforce this perception.⁽⁷²⁾

Another study investigating female attitudes regarding labia minora appearance and reduction in 482 women found that 14% considered their labial appearance to be ‘abnormal’. The perceptions of ‘normality’ in regards to labial length varies, not only among patients but also among physicians.⁽⁶⁹⁾ A total of 164 physicians (80 general practitioners, 41 gynaecologists and 43 plastic surgeons) were surveyed and asked to rate photos with labia of varying length in relation to whether it was ‘normal’ and the likelihood that they would refer for, or perform, a labia minora reduction. It was found that plastic surgeons were significantly more likely than general practitioners and gynaecologists, to rate the photograph with largest labia distasteful and unnatural, and more likely to regard the women as a suitable candidate for labioplasty.⁽⁶⁹⁾

There has been preliminary work undertaken on developing and testing the reliability and validity of several questionnaires that may assist in determining patient eligibility for labioplasty.^(73, 74, 77) These questionnaires aim to identify and differentiate between functional and psychosocial/ distress indications and have the potential to identify women with body dysmorphic disorder (BDD).^(73, 74)

Overall, the reasons patients seek labioplasty for reduction of the labia minora can be categorised as follows:

- anatomy abnormality^(17, 59) (e.g. enlargement, asymmetry or deformation);
- functional anatomical discomfort and pain^(12, 56, 70) (e.g. superficial dyspareunia, pain and/or discomfort during exercise and whilst wearing tight clothing);
- psychosocial factors⁽¹⁴⁾ (e.g. embarrassment, decreased self-esteem, decreased self-confidence); and
- aesthetic dissatisfaction.^(16, 56)

However, there appears to be no standard methods for assessing these factors, and wide variation in clinical cut-points for defining enlargement of the labia minora.

There is a number of other medical conditions warranting vulvoplasty or labioplasty surgery including congenital malformations^(54, 58, 64, 66); however, there is very little literature on these indications.

5.2.1 Assessment of hypertrophy of the labia minora

Only four of the studies reporting on labioplasty surgery for the reduction of the labia minora measured and graded the labia according to the level of hypertrophy prior to surgery.^(7, 17, 56, 61) The grading system differed in each study. Ellsworth et al. (2010)⁽⁵⁶⁾ used a classification developed by Franco et al. (1993)⁽⁷⁸⁾ which grades the protrusion of the labia minora through the labia majora as follows:

- | | |
|----------------------------------|------------------------------|
| • Grade 1 is < 2 cm; | • Grade 2 is from 2 to 4 cm; |
| • Grade 3 is from 4 to 6 cm; and | • Grade 4 is > 6 cm. |

Pardo et. al. (2006) used a different classification when reporting on the labial length of 53 women undergoing labioplasties.⁽⁶¹⁾ Labia minora ≤ 2 cm was defined as “lacking true hypertrophy”, “moderate hypertrophy” between 2 and 4 cm, and “severe hypertrophy” 4 cm or more.⁽⁶¹⁾ Using this classification system, 21% of the 53 women undergoing surgery for reduction of labia minora were classified as ‘lacking true hypertrophy’, 66% had moderate hypertrophy, and 13% had ‘severe hypertrophy’.

In the studies by Pardo et al. (2006)⁽⁶¹⁾ and Ellsworth et al. (2010)⁽⁵⁶⁾, surgery was offered to patients irrespective of magnitude of labia hypertrophy.

Rouzier et al. (2000) reported on labioplasties for the reduction of labia minora in 163 women.⁽¹⁷⁾ They classified labia hypertrophy as width >4 cm with surgery only offered to patients if the labia was >4 cm.⁽¹⁷⁾ Munhoz et al. (2006) used labia width >3 cm as an indication of labia hypertrophy, with surgery only being undertaken if labial width was >3 cm.⁽⁷⁾

Only a few studies reported on the amount of labial reduction undertaken in the surgery. Two studies reported that the labia minora was reduced to 1 cm.^(28, 31) Another two studies reported on the mean resection length.^(5, 57)

Another study investigating women's motivation for undertaking labioplasty reported that, in the clinic where the study was undertaken, labia reduction surgery is only offered to women (over 18 years) with either or both of the following: labial width >50 mm or labial asymmetry with > 30 mm difference.⁽⁷⁰⁾

Across the studies, complaints of discomfort or pain with intercourse, clothing or exercise and repeated infection were reported with labia length < 3 cm⁽⁷⁾ and < 4 cm⁽⁵⁶⁾, indicating high variation of women's experiences in relation to symptoms and labial hypertrophy.

The literature also indicates that variation in labial length is common.⁽³⁵⁾ Lloyd et al. (2005)⁽³⁵⁾ undertook a study of 50 premenopausal women (aged 18-50 years) where labia length was measured under general anaesthetic during gynaecological procedures not involving the external genitalia.⁽³⁵⁾ Labial minora length ranged from 2-10 cm and the mean \pm standard deviation (SD) was 6.1 ± 1.7 cm. Murariu et al. (2012) reported on the mean \pm SD labial length of 24 females requesting labioplasty and 15 patients not seeking labioplasty. In patients seeking labioplasty, the mean \pm SD labial length was 3.52 ± 0.71 cm and in the 'control' group 1.54 ± 0.34 cm.⁽⁶⁷⁾

5.2.2 Age of women seeking or undergoing labioplasty

The age range of women undergoing labioplasty in the studies identified was 11 to 67 years (Table 6.2). Mean age, where reported, ranged from 24 to 26 years.^(15, 32, 57, 79) One author recommended that labia reduction should not be conducted in women younger than 18 years of age because the shape of external genitalia changes during puberty, and also for issues relating to consent from a minor.⁽⁷⁵⁾

5.2.3 The vulvoplasty and labioplasty clinical flowchart and medical indications for surgery

The clinical decision pathway that determines whether vulvoplasty or labioplasty surgery is performed is shown in Figure 2.2 (Chapter 2). The review of the literature highlights a number of issues in relation to the decision-making processes in the flowchart which will require further clarification. In the flowchart, assessment and screening on suitability for labioplasty includes measurement of labia width and symmetry, and identification of functional problems to determine if labioplasty is medically indicated. The available literature would suggest that measurements may not be useful, as there is no clinical cut-point for defining hypertrophy and that 'functional problems' may require further clarification. In addition, psychosocial issues arising from hypertrophy of the labia minora for some women are not currently addressed in the flowchart. The flowchart suggests possible referral for

education and/or counselling; some studies have suggested that physicians themselves should provide patients seeking labioplasty with counselling regarding the wide variation in labia size.⁽⁷⁵⁾

5.2.4 Congenital conditions

Congenital conditions such as bladder exstrophy and cloacal exstrophy are associated with labia hypertrophy; however, both of these conditions have individual MBS items (37050 and 43882) and thus would not be expected to be claimed under the MBS item for vulvoplasty and labioplasty.

5.3 Effectiveness of vulvoplasty and labioplasty in improving patient outcomes

As no studies were identified that met the eligibility criteria described in the methodology section (Chapter 2), a decision was made to extract information from the available literature in relation to the effectiveness of vulvoplasty and labioplasty in improving patient outcomes and to present this in a narrative form. All results in this section need to be considered in the context of the limitations of the available literature.

Of the surgical studies on labioplasty published between January 2000 and May 2013 and examined for this review, effectiveness was evaluated in terms of patient satisfaction either generally or in relation to specific complaints (functional, psychosocial or aesthetic). Table 5.3 presents a summary of the studies reporting on post-operative outcomes following labioplasty surgery. As shown, some studies used a post-operative questionnaire and others reported verbal, anecdotal interactions with patients. Where questionnaires were implemented, there were variations in factors assessed and types of questions asked. Methods for obtaining satisfaction ratings were not reported in some studies.^(32, 57) In others, questionnaires were used to collect data^(6, 12, 17); however, the questionnaires were not standardised. Where reported, levels of patient satisfaction were high across the studies.

Table 5.3: Summary of studies reporting on post-operative outcomes following labioplasty surgery

Author & year	Surgical method	No. of cases	Post-operative assessment of outcomes	Completion rate	Satisfaction outcomes
Choi et al. 2000 ⁽³²⁾	De-epithelialisation of central portion	6	Anecdotal	Not reported	Anecdotal reporting by authors that all patients were satisfied with post-operative appearance, improved hygiene, and relief from chronic irritation.
Maas et al. 2000 ⁽³¹⁾	Running W-shaped resection with inter-digitated suturing of protuberant labium	13	Not reported	Not reported	Not reported
Rouzier et al. 2000 ⁽¹⁷⁾	Amputation	163	Post-operative questionnaire	98 (60%)	91% satisfied with aesthetic result. Of those reporting medical/functional reason for undertaking surgery, 96% reported surgery had corrected.
Giraldo et al.	Central wedge	15	Yes	Not reported	Anecdotal reporting by authors

Author & year	Surgical method	No. of cases	Post-operative assessment of outcomes	Completion rate	Satisfaction outcomes
2003 ⁽⁵⁷⁾	resection of the labia minora with a 90-degree Z-plasty				that all patients were fully satisfied with the aesthetic appearance.
Munhoz et al. 2005 ⁽⁷⁾	Inferior wedge resection and superior pedicle flap reconstruction	21	Questionnaire	21 (100%)	Authors reported 20 patients 'very satisfied' and one patient 'satisfied'.
Pardo et al. 2006 ⁽⁶¹⁾	Laser	55	All patients completed a satisfaction and acceptance questionnaire	Not reported	Not reported
Rezai et al. 2007 ⁽²⁸⁾	De-epithelialised reduction (n=50) Running W-shaped resection (n=50)	100	Not reported	Not reported	Anecdotal reporting by authors that patients in both groups experienced improvement in chronic irritations, sexual intercourse, hygiene.
Alter et al. 2008 ⁽¹⁵⁾	Extended central wedge resection	407	Post-operative mailed questionnaire	166 (41%)	71.6% (106/148) of patients seeking surgery for discomfort pre-operatively reported it had resolved.
Ellsworth et al. 2010 ⁽⁵⁶⁾	3 techniques used based on degree of hypertrophy	12	Yes – method unclear	Not reported	One patient not satisfied as felt labia minora had been overly reduced. Authors report that all women who had previously had discomfort with clothing or sexual intercourse had their symptoms resolved.
Goodman et al. 2010 ⁽⁶⁾	Not reported	177 ^a	Yes – questionnaire	177 (100%)	97% satisfied
Trichot et al. 2010 ⁽¹²⁾	Labioplasty with pedicle flap reconstruction	18	Yes – mailed questionnaire	18 (100%)	All patients reported overall satisfaction with the outcome mean rating 8.7 on a scale ranging from 0-10. All patients who previously reported discomfort reported improvement.
Solanki et al. 2010 ⁽⁵⁾	Not reported	12	Yes – method unclear	9 (75%)	Anecdotal reporting by authors that all patients were very satisfied with the functional and aesthetic outcome of the surgery.
Cao et al. 2012 ⁽⁵³⁾	De-epithelialised technique	167	Yes – method unclear	Not reported	Two patients not satisfied and underwent further reduction surgery. Anecdotal reporting by authors that all other patients satisfied.
Gress (2013) ⁽¹¹⁾	Composite reduction technique	812	Yes – mailed questionnaire	Not reported	Functional problems resolved in 92.3% of patients. Psychological distress completely relieved in 89.7% of patients.

^a 24 patients with clitoral hood reduction only are included in this group as results were reported together with 153 patients having labioplasty.

5.4 Adverse effects of vulvoplasty and labioplasty

As no studies were identified that met the eligibility criteria described in the methodology section (Chapter 2), a decision was made to extract information from the available literature in relation to the adverse effects of vulvoplasty or labioplasty and to present this in a narrative form. All results in this section need to be considered in the context of the limitations of the available literature.

Some of the risks associated with labioplasty include over-repair, disfigurement, scarring and “scalloping” of the labial edge, hypersensitivity or hyposensitivity, dyspareunia (painful sexual intercourse), partial or complete separation of the repair, infection and/or cosmetic results not up to the patient’s expectations.^(2, 3) Major complication rates from the studies obtained in this review were $\leq 7\%$. A higher percentage of minor complications has been reported, but do not appear to interfere with overall patient satisfaction.^(2, 61) Table 5.4 presents information on the nature and incidence of complications for studies that published this information.

Table 5.4: Studies reporting adverse effects and complications of labioplasty

Author & year	Surgical method	No. of cases	Adverse effects/complications
Maas et al. 2000 ⁽³¹⁾	Running W-shaped resection with inter-digitated suturing of protuberant labium	13	Minor events post-operatively. Minimal discomfort, no pain 2 weeks after surgery.
Choi et al. 2000 ⁽³²⁾	De-epithelialisation of central portion	6	None reported
Rouzier et al. 2000 ⁽¹⁷⁾	Amputation	163	11 patients (7%) had to undergo a second procedure due to minimal wound dehiscence resulting in an aesthetic result that warranted improvement.
Giraldo et al. 2003 ⁽⁵⁷⁾	Central wedge resection of the labia minora with a 90-degree Z-plasty	15	2 patients had minimal dehiscence of the surgical borders of the internal mucosal surface which epithelialised completely by two weeks.
Pardo et al. 2006 ⁽⁶¹⁾	Laser	55	3 patients had minimal suture dehiscence that did not require further suture.
Munhoz et al. 2006 ⁽⁷⁾	Inferior wedge resection and superior pedicle flap reconstruction	21	5 complications: including distal flap necrosis in 1 patient, small local haematoma in 1 patient, superficial infection in 1 patient and wound dehiscence between flap and the resected area in 2 patients.
Rezai et al. 2007 ⁽²⁸⁾	De-epithelialised reduction (n=50) Running W-shaped resection (n=50)	100	3 patients suffered post-operative infection resolved with antibiotics.
Alter et al. 2008 ⁽¹⁵⁾	Extended central wedge resection	407	18 (4.4%) significant complications. 12 (2.9%) required reoperation.
Ellsworth et al. 2010 ⁽⁵⁶⁾	3 techniques used	12	Minimal complications: 3 patients experiencing minor wound-healing difficulties which resolved spontaneously.
Goodman et al. 2010 ⁽⁶⁾	Not reported	177 ^a	In post-operative questionnaire 15 patients (9%) reported they had complications from surgery.
Trichot et al. 2010 ⁽¹²⁾	Labioplasty with pedicle flap reconstruction	18	3 patients had partial splitting of scar in post-operative period with 1 patient requiring further surgery with favourable outcome.
Solanki et al. 2010 ⁽⁵⁾	W-shaped resection	12	3 had minor post-operative events reported (haematoma, urinary retention and minor wound oozing). No major complications reported.

Author & year	Surgical method	No. of cases	Adverse effects/complications
Cao et al. 2012 ⁽⁵³⁾	De-epithelialised technique	167	One patient developed a minor dehiscence of the wound which healed spontaneously.

^a 24 patients with clitoral hood reduction only are included in this group as results were reported together with 153 patients having labioplasty.

Mirzabeigi et al. (2012) undertook a survey of members of the American Society of Plastic Surgeons via electronic mail in 2009 to assess surgeon demographics, practice guidelines for labioplasty, and measures of self-reported outcomes.⁽⁶⁸⁾ A total of 750 surgeons responded to the survey (19.7% response rate) with 51% of those reporting they currently offered labioplasty. The two most common reasons for surgeons to re-operate were inadequate resection and wound dehiscence. Surgeons using plain gut suture material had the highest reported rates of reoperation.⁽⁶⁸⁾

5.5 Variation in safety and quality according to surgical technique

There were no RCTs comparing safety, quality or complication outcomes according to surgical technique. One study undertook two different types of labioplasty surgery in 100 women, with 50 undergoing W-shaped resections with inter-digitated suturing and the other 50 women undergoing de-epithelialised reduction labioplasty.⁽²⁸⁾ Whilst patients in both groups were satisfied the surgery had addressed their reason for surgery, five (10%) patients undergoing W-shaped resections with inter-digitated suturing were unhappy with the appearance of the edge of the labia minora and in eight patients it took up to two years for sensation to be restored to the labia minora.⁽²⁸⁾

5.6 Location of service delivery

No reliable information on the location of service delivery in Australia or overseas was identified. However, the majority of providers advertising labioplasty surgery services in Australia indicate they are performed on an outpatient basis under local anaesthetic. Of the studies obtained in the systematic review, very few reported on the location of the surgery. Of those that did, surgery was undertaken in both hospitals⁽⁷⁾ and outpatient clinics.⁽⁵³⁾

6 FINDINGS AND CONCLUSIONS

This Chapter sets out the findings and conclusions of the review of vulvoplasty – as represented by MBS item number 35533 – based on the analysis of the available MBS and hospital morbidity data; evidence obtained through systematic literature review; and the information derived from the stakeholder consultations.

6.1 Current usage of vulvoplasty services in Australia

The analysis of MBS data showed that the benefits paid for vulvoplasty have increased from \$142,682 in 2003/04 to \$778,607 in 2012/13, with the majority of services (87%) performed in hospital. The total number of claims for the vulvoplasty item doubled from 774 in 2003/04 to 1,588 in 2012/13. During this timeframe, NSW has consistently had the highest number of claims for vulvoplasty; however, SA had the highest growth rate over the ten-year period and the highest rate of claiming per capita (calculated by the number of people enrolled in Medicare). However, Victoria and NSW showed the largest increases in benefits paid. In Victoria, the amount of benefits paid was disproportionately higher than the number of claims over the past five years.

MBS data from 2007/08 to 2012/13 were examined to determine the patient and provider profile for vulvoplasty services. In terms of patient age, women within the age group 15-44 years accounted for 72% of claims and those aged 45-54 years accounted for a further 16%. The largest increase over the past five years was in those aged 65-74 years (96%); however, they make up only a small proportion of total claims (3%).

Over the past five years, the majority of vulvoplasty surgery services were provided by obstetrics and gynaecology specialists (51%) followed by plastic surgeons (32%), vocationally registered GPs (5%), and ‘other’ medical specialists (12%). The patterns in benefits paid did not reflect the pattern in claims for services. While plastic surgeons and obstetrics gynaecology specialists account for 83% of all services, they represented only 35% of total benefits paid. However, vocationally registered GPs and ‘other’ specialists (combined) accounted for 17% of services provided yet represented 65% of benefits. Although the literature indicates that vulvoplasty may be undertaken with hysterectomy, vulvoplasty was co-claimed with hysterectomy in an extremely low proportion of cases (0.9%-1.1%).

Data from the NHMD were analysed from 2007/08 to 2011/12 to determine the profile of patients undergoing vulvoplasty. Over this time period, the majority of vulvoplasty procedures (82%) was undertaken by private patients. Of the private patients who underwent a vulvoplasty procedure, approximately 76% were funded by private health insurance with the remainder being self-funded. The age profile of patients was very similar to that from the MBS claims data, with women aged 15- 44 years representing 70% of all separations over the five years.

In each year from 2007/08 to 2011/12, the principal diagnosis that occurred most frequently for the vulvoplasty procedure was ‘hypertrophy of the vulva’, followed by ‘specified and unspecified non-inflammatory disorders of the vulva and perineum’. ‘Plastic surgery for unacceptable cosmetic appearance’ represented 5-10% of the separations. Other medical

indications were ‘fusion of the labia’, and ‘other congenital malformation of the vulva, rectocele or cystocele’.

6.2 Appropriateness of the descriptor for the MBS item for vulvoplasty or labioplasty

Vulvoplasty refers broadly to any surgery performed on the outside female genital structures. The vulva has many major and minor anatomical structures, including the labia majora, mons pubis, labia minora, clitoris, bulb of vestibule, vulval vestibule, greater and lesser vestibular glands, and the opening of the vagina. Labioplasty is one specific type of vulvoplasty, which is used to describe plastic surgery to alter the labia minora and, less commonly, the labia majora. The existing MBS item descriptor includes both of these terms, and thus it is not possible to determine the services that relate to surgery on structures other than the labia.

The MBS item descriptor stipulates that services should only be claimed for medically indicated services; however, guidance is not provided on what constitutes a medically necessary procedure.

There are no Australian clinical practice guidelines on vulvoplasty or labioplasty surgery; however, the Royal Australian and New Zealand College of Obstetricians and Gynaecologists (RANZCOG) released a position statement in 2008 on cosmetic vaginal procedures which refers to labioplasty. The RANZCOG position statement lists ‘labioplasties with clinical indications’ among gynaecological conditions that merit surgery. The clinical indications are not defined in the statement.

The literature search did not identify any international clinical practice guidelines on vulvoplasty or labioplasty. However, the UK Royal College of Obstetricians and Gynaecologists released a statement in 2009 on ‘hymenoplasty and labial surgery’ advocating that any decision for female genital surgery be based only on clinical grounds as determined by individual practitioners. The American College of Obstetricians and Gynaecologists (ACOG) committee opinion on ‘vaginal rejuvenation and cosmetic vaginal procedures’ (2007) recommends that clinicians evaluate patients for any physical signs or symptoms that may indicate the need for surgical intervention and inform women of potential complications. The ACOG statement also recommends that women be informed regarding the lack of data supporting the efficacy of these procedures and potential complications such as infections, altered sensation, dyspareunia, adhesions and scarring.

In the absence of evidence-based or consensus-based clinical practice guidelines for labioplasty or vulvoplasty in Australia, the appropriateness of the descriptor for the MBS item number for vulvoplasty or labioplasty could not be determined with certainty. The descriptor for the MBS item number for vulvoplasty or labioplasty is consistent with position statements that recommend vulvoplasty or labioplasty where ‘medically indicated’; however, ‘medical indications’ are not well-defined.

A report on FGCS produced by Women’s Health Victoria recommends relevant professional bodies issue statements to regulate provision of FGCS; provide education to increase public awareness on the low standard of evidence and risks associated with FGCS; the diverse natural range of female genital appearance; and how images of genitals are altered when appearing in restricted publications.

6.3 Clinical indications for medically necessary vulvoplasty or labioplasty

No HTAs, systematic reviews, clinical or economic studies met the eligibility criteria developed for the review. However, a total of 42 relevant publications on vulvoplasty or labioplasty were identified, which included case reports, non-systematic reviews, studies investigating women's motivation for seeking labioplasty and several commentaries/expert opinions on the issue of labioplasty. In the absence of studies meeting the eligibility criteria for the systematic review, information from these publications was extracted in relation to the clinical research questions.

In the majority of reports, labioplasty surgery was undertaken for reduction of the labia due to reported enlargement or hypertrophy of the labia minora. Some studies also reported asymmetry in labia length as a reason for patients seeking surgery. Most labioplasty surgery was bilateral; however, unilateral surgery was also reported (for asymmetry) for a small proportion of patients (3-15%). Labioplasty for reduction of the labia minora was generally performed on its own; however, in some studies it was performed in conjunction with other types of surgery including hysterectomy, perineoplasty, clitoral hood reduction, or vaginal tightening.

There is no standard questionnaire used for assessing patient's motivation for undertaking or requesting labioplasty for reduction of the labia minora. The reasons for seeking surgery can be categorised as follows:

- aesthetic dissatisfaction associated with (actual or perceived) anatomy abnormality (hypertrophy or asymmetry of the labia minora)
- functional anatomical discomfort and pain (e.g. superficial dyspareunia, pain and/or discomfort during exercise and whilst wearing tight clothing, poor hygiene/chronic infection); and/or
- psychosocial factors (e.g. embarrassment, decreased self-confidence, decreased self-esteem).

In some cases, abnormal anatomy may be due to congenital malformation (adrenogenital syndrome and vaginal agenesis), Paget's disease, hermaphroditism or vulvar vestibulitis; however, there is very little literature on these indications.

Psychosocial factors for seeking surgery appeared to be related to a feeling of being abnormal and the desire to 'be more normal'. There is variation in patients' perceptions of 'normality' regarding labia minora, and also variation in clinicians' perceptions on 'normality' in relation to labial length and their likelihood to refer or perform labioplasty.

Very few studies reporting on labioplasty surgery for reduction of the labia minora indicated that the labia minora was measured and/or graded according to the level of hypertrophy prior to surgery. Where measurement and classification was undertaken, there was variation in methods of classifying the degree of hypertrophy. In some studies, labioplasty was offered to all presenting patients irrespective of degree of hypertrophy, with other factors being taken into account (e.g. functional and/or psychosocial complaints). Where criteria were applied, cut-points varied from >3 cm to >5 cm. Variation in length of labia minora in the general population is common.

The review of the literature highlights a number of issues in relation to the decision-making processes for vulvoplasty or labioplasty. In the clinical decision flowchart, assessment and screening on suitability for vulvoplasty/labioplasty includes identification of functional problems and measurement of labia width and symmetry. However, functional problems and clinical cut-points to define labial hypertrophy are not well-defined.

6.4 Effectiveness of vulvoplasty and labioplasty in improving patient outcomes

The effectiveness of labioplasty is typically evaluated in terms of patient satisfaction, either generally or in relation to specific complaints (functional, psychosocial or aesthetic). Evaluation of patient satisfaction is undertaken either by questionnaire or verbal interactions with patients. Where questionnaires were implemented, there were variations in factors assessed and types of questions asked.

6.5 Safety and quality implications of vulvoplasty and labioplasty

Labioplasty surgery may be undertaken in the admitted or non-admitted (i.e. outpatient clinics) setting. There were no studies comparing outcomes across the two settings. Common risks associated with labioplasty include over-repair, disfigurement, scarring and “scalloping” of the labial edge, hypersensitivity or hyposensitivity, dyspareunia (painful sexual intercourse), partial or complete separation of the repair, infection, and/or cosmetic results not up to the patient’s expectations.

Major complication rates from the studies obtained in this review were $\leq 7\%$. A higher percentage of minor complications have been reported, but do not appear to interfere with overall patient satisfaction. The two most common reasons for surgeons to re-operate were inadequate resection and wound dehiscence. Surgeons using plain gut suture material had the highest reported rates of reoperation.

6.6 Conclusions

In conclusion, analysis of the data indicates that 27% of vulvoplasty separations over the past five years were for hypertrophy of the vulva, whilst 7% were for ‘plastic surgery for unacceptable cosmetic appearance’. The literature suggests that these surgeries are likely to be labioplasties performed for the reduction of the labia minora. The large increase in claims over the past ten years indicates that more women are seeking labioplasty from a wide range of ages (15-54 years). There are no standard methods or tools for assessing hypertrophy of the labia minora or women’s motivation for seeking surgery. Decisions regarding the necessity for surgery lies with the clinical judgement of medical practitioners. There are a number of clinically relevant indications for vulvoplasty including ‘non-inflammatory disorders of the vulva and perineum’, congenital disorders’ and dyspareunia.

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APPENDIX 2 – Review Consultation Committee Members

As part of the MBS Review process, the Department established a Review Consultation Committee (RCC). The RCC is a time-limited committee of nominated representatives to provide advice to the Department to inform the review process, such as the development of review reports, i.e. scope and protocol documents, clinical practice and policy issues.

Name	Representing
Professor Ajay Rane	Royal Australian and New Zealand College of Obstetricians and Gynaecologists
Dr Louise Farrell	Royal Australian and New Zealand College of Obstetricians and Gynaecologists
Dr Sonia Grover	Royal Australian and New Zealand College of Obstetricians and Gynaecologists
Dr Paul Belt	Australian Society of Plastic Surgeons
Dr Gino Pecoraro	Australian Medical Association
Chair and Secretariat	Department of Health

APPENDIX 3 – MBS information

The vulvoplasty and labioplasty surgery MBS item number in scope of this review is 35533 (refer to Table A3.1). Table A3.2 shows the item start date, descriptor start date and schedule fee start date for the MBS item number under review. Other services on the MBS relating to the vulva are shown in Table A3.3.

Table A3.1: Vulvoplasty or labioplasty services listed on the MBS

Item number	MBS item number description
35533	VULVOPLASTY or LABIOPLASTY, where medically indicated, not being a service associated with a service to which item 35536 applies (Anaes.) [Multiple services rule] Fee: \$349.85 Benefit: 75% = \$262.40 85% = \$297.40 Extended Medicare Safety Net Cap: \$279.90

Source: Department of Human Services – Medicare Australia, August 2013

Note: MBS item number 35536 refers to 'VULVA, wide local excision of suspected malignancy or hemivulvectomy, 1 or both procedures' (see Table A3.3)

Table A3.2: Item number, descriptor and schedule fee start dates for MBS item numbers

Item number	Type of date	Date
35533	Item Start Date	01-Dec-1991
	Current Descriptor Start Date	01-Dec-1991
	Current Schedule Fee Start Date	01-Nov-2012

Source: Department of Human Services – Medicare Australia, accessed August 2013.

Table A3.3: Related services listed on the MBS

Item number	MBS item number description
35507	VULVAL OR VAGINAL WARTS, removal of under general anaesthesia, or under regional or field nerve block (excluding pudendal block) requiring admission to a hospital, where the time taken is less than or equal to 45 minutes - not being a service associated with a service to which item 32177 or 32180 applies (Anaes.) Fee: \$174.45 Benefit: 75% = \$130.85 85% = \$148.30
35508	VULVAL OR VAGINAL WARTS, removal of under general anaesthesia, or under regional or field nerve block (excluding pudendal block) requiring admission to a hospital, where the time taken is greater than 45 minutes - not being a service associated with a service to which item 32177 or 32180 applies (Anaes.) (Assist.) Fee: \$256.95 Benefit: 75% = \$192.75 85% = \$218.45
35509	HYMENECTOMY (Anaes.) Fee: \$89.45 Benefit: 75% = \$67.10 85% = \$76.05
35530	CLITORIS, amputation of, where medically indicated (Anaes.) (Assist.) Fee: \$269.85 Benefit: 75% = \$202.40

Item number	MBS item number description
35536	VULVA, wide local excision of suspected malignancy or hemivulvectomy, 1 or both procedures (Anaes.) (Assist.) Fee: \$348.45 Benefit: 75% = \$261.35 85% = \$296.20
35548	VULVECTOMY, radical, for malignancy (Anaes.) (Assist.) Fee: \$834.05 Benefit: 75% = \$625.55

Source: Department of Human Services – Medicare Australia, June 2013

APPENDIX 4 – Search term strategy

The literature search strategies focused on the safety and effectiveness of vulvoplasty or labioplasty (Table A4.1) and the cost implications associated with vulvoplasty or labioplasty (Table A4.2).

Table A4.1: Search strategy for clinical evidence

Population	Search terms
Patients with congenital abnormalities <ul style="list-style-type: none"> • Bladder exstrophy • Congenital adrenal hyperplasia <ul style="list-style-type: none"> VATER Syndrome Cloacal exstrophy Epispadias Disorders of sex development 	<p>Medline</p> <p><u>Population</u> – ((‘Bladder exstrophy’/exp OR ‘Bladder exstrophy’) OR ‘Congenital adrenal hyperplasia’ OR ‘VATER Syndrome’ OR ‘VACTERL association’ OR ‘Cloacal exstrophy’ OR ‘Epispadias’ OR (‘sex differentiation disorder’/exp OR ‘sex differentiation disorder’) OR ‘intersex conditions’ OR (‘congenital abnormalities’/exp OR ‘congenital abnormalities’))</p> <p>AND</p> <p><u>Intervention</u> – (vulvoplas* OR labioplast* OR labia* OR ((labia OR vulva) AND (‘surgical correction’ OR ‘surgical alteration’ OR ‘plastic surgery’ OR ‘plastic surgeries’ OR reduc* OR alter*))) OR labia* NEAR/3 surg*</p> <p>NOT ((‘esthetic surgery’/exp OR ‘esthetic surgery’) OR (‘cosmetic’/exp OR ‘cosmetic’))</p> <p>AND</p> <p><u>Limits</u> – ([cochrane review]/lim OR [controlled clinical trial]/lim OR [meta analysis]/lim OR [randomized controlled trial]/lim OR [systematic review]/lim) AND [article]/lim AND [humans]/lim AND [english]/lim AND [2000-2013]/py</p> <p>Cochrane Library</p> <p><u>Population</u> – (((Bladder exstrophy) OR (Bladder exstrophy):kw) OR (((Congenital adrenal hyperplasia) OR (Congenital adrenal hyperplasia):kw) OR (((VATER Syndrome) OR (VATER Syndrome):kw) OR (((VACTERL association) OR (VACTERL association):kw) OR (((Cloacal exstrophy) OR (Cloacal exstrophy):kw) OR (((Epispadias) OR (Epispadias):kw) OR ((sex differentiation disorder) OR (sex differentiation disorder):kw) OR ((intersex conditions) OR (intersex conditions):kw) OR ((congenital abnormalities) OR (congenital abnormalities):kw) OR (MeSH description Disorders of Sex Development explode all trees) OR (MeSH description Congenital Abnormalities explode all trees))</p> <p>AND</p> <p><u>Intervention</u> – (vulvoplas* OR labioplast* OR labia* OR ((labia OR vulva) AND (‘surgical correction’ OR ‘surgical alteration’ OR ‘plastic surgery’ OR ‘plastic surgeries’ OR reduc* OR alter*))) OR labia* NEAR/3 surg*</p> <p>NOT (((esthetic surgery) OR (esthetic surgery):kw) OR ((cosmetic) OR cosmetic):kw) OR (MeSH description Surgery, Plastic explode all trees))</p> <p>AND</p> <p><u>Limits</u> – from 2000 to 2013</p>

Population	Search terms
<p>Patients with labia hypertrophy due to medically related conditions</p> <ul style="list-style-type: none"> • Dyspareunia • Labia asymmetry • Vulvar lymphoedema • Vulval oedema 	<p>Medline</p> <p><u>Population</u> – (('dyspareunia'/exp OR 'dyspareunia') OR 'labia asymmetry' OR (labia NEAR/6 asymmetry) OR 'vulvar lymphoedema' OR 'vulvar lymphedema' OR (vulvar NEAR/6 lymphoedema) OR (vulva NEAR/6 lymphoedema) OR (vulvar NEAR/6 lymphedema) OR (vulva NEAR/6 lymphedema) OR 'vulval oedema' OR 'vulval odema' OR (vulval NEAR/6 oedema) OR (vulva NEAR/6 oedema) OR (vulvar NEAR/6 oedema) OR (vulva NEAR/6 oedema) OR 'labia hypertrophy') OR (labia* NEAR/6 hypertrophy)</p> <p>AND</p> <p><u>Intervention</u> – (vulvoplas* OR labioplast* OR labia* OR ((labia OR vulva) AND ('surgical correction' OR 'surgical alteration' OR 'plastic surgery' OR 'plastic surgeries' OR reduc* OR alter*))) OR labia* NEAR/3 surg*</p> <p>NOT (('esthetic surgery'/exp OR 'esthetic surgery') OR ('cosmetic'/exp OR 'cosmetic'))</p> <p>AND</p> <p><u>Limits</u> – ([cochrane review]/lim OR [controlled clinical trial]/lim OR [meta analysis]/lim OR [randomized controlled trial]/lim OR [systematic review]/lim) AND [article]/lim AND [humans]/lim AND [english]/lim AND [2000-2013]/py</p> <p>Cochrane Library</p> <p><u>Population</u> – (((dyspareunia) OR 9dyspareunia):kw) OR ((labia asymmetry) OR (labia asymmetry):kw) OR ((vulvar lyphoedema) OR (vulvar lymphoedema):kw) OR ((vulvar lyphedema) OR (vulvar lymphedema):kw) OR ((labia hypertrophy) OR (labia hypertrophy):kw) OR (MeSH description Dyspareunia explode all trees) OR (MeSH description Vulvar Neoplasms explode all trees) OR (MeSH description Vulvar Diseases explode all trees))</p> <p>AND</p> <p><u>Intervention</u> – (((vulvoplasty) OR (vulvoplasty):kw) OR ((labioplasty) OR (labioplasty):kw) OR ((labiaplasty) OR (labiaplasty):kw) OR ((vulva OR labia) NEAR/6 ((surgical correction) OR (surgical alteration) OR alter* OR reduc* OR (plastic surgery))))</p> <p>NOT (((esthetic surgery) OR (esthetic surgery):kw) OR ((cosmetic) OR cosmetic):kw) OR (MeSH description Surgery, Plastic explode all trees))</p> <p>AND</p> <p><u>Limits</u> – from 2000 to 2013</p>
<p>Patients dissatisfied with vaginal appearance (may be acquired)</p> <ul style="list-style-type: none"> • chronic stretching due to childbirth • age 	<p>Medline</p> <p><u>Population</u> – (('vaginal injury'/exp OR 'vaginal injury') OR (dissatisf* NEAR/6 ('vaginal appearance' OR 'genital appearance')) OR ((age OR childbirth) NEAR/6 ('chronic stretching' OR stretch* OR 'vaginal stretching' OR 'vaginal injury')) OR (('esthetic surgery'/exp OR 'esthetic surgery') OR ('cosmetic'/exp OR 'cosmetic'))</p> <p>AND</p> <p><u>Intervention</u> – (vulvoplas* OR labioplast* OR labia* OR ((labia OR vulva) AND ('surgical correction' OR 'surgical alteration' OR 'plastic surgery' OR 'plastic surgeries' OR reduc* OR alter*))) OR labia* NEAR/3 surg*</p> <p>AND</p> <p><u>Limits</u> – ([cochrane review]/lim OR [controlled clinical trial]/lim OR [meta analysis]/lim OR [randomized controlled trial]/lim OR</p>

Population	Search terms
	<p>[systematic review]/lim) AND [article]/lim AND [humans]/lim AND [english]/lim AND [2000-2013]/py</p> <p>Cochrane Library</p> <p><u>Population</u> – (((vaginal injury) OR (vaginal injury):kw) OR ((dissatisfy*) NEAR/6 ((vaginal appearance) OR (genital appearance))) OR (((age) OR (childbirth)) NEAR/6 ((chronic stretching) OR (stretch*) OR (vaginal stretching) OR (vaginal injury)))) AND</p> <p><u>Intervention</u> – (((vulvoplasty) OR (vulvoplasty):kw) OR ((labioplasty) OR (labioplasty):kw) OR ((labiaplasty) OR (labiaplasty):kw) OR ((vulva OR labia) NEAR/6 ((surgical correction) OR (surgical alteration) OR alter* OR reduc* OR (plastic surgery))) OR(((esthetic surgery) OR (esthetic surgery):kw) OR ((cosmetic) OR cosmetic):kw) OR (MeSH description Surgery, Plastic explode all trees)) AND</p> <p><u>Limits</u> – from 2000 to 2013</p>

Table A4.2: Search strategy for economic evidence

Population	Search terms
Patients undergoing vulvoplasty or labioplasty	<p>Medline</p> <p><u>Intervention</u> – (vulvoplas* OR labioplast* OR labia* OR ((labia OR vulva) AND ('surgical correction' OR 'surgical alteration' OR 'plastic surgery' OR 'plastic surgeries' OR reduc* OR alter*))) OR labia* NEAR/3 surg* AND</p> <p><u>Economic Terms</u> – ('economic aspect'/exp OR 'cost benefit analysis' OR cost* OR 'cost effectiveness') AND</p> <p><u>Limits</u> – [humans]/lim AND [english]/lim AND [2006-2012]/py</p> <p>Cochrane Library</p> <p><u>Intervention</u> - (((vulvoplasty) OR (vulvoplasty):kw) OR ((labioplasty) OR (labioplasty):kw) OR ((labiaplasty) OR (labiaplasty):kw) OR ((vulva OR labia) NEAR/6 ((surgical correction) OR (surgical alteration) OR alter* OR reduc* OR (plastic surgery)))) NOT (((esthetic surgery) OR (esthetic surgery):kw) OR ((cosmetic) OR cosmetic):kw) OR (MeSH description Surgery, Plastic explode all trees)) AND</p> <p><u>Economic Terms</u> – (((economic aspect) OR (economic aspect):kw) OR ((cost benefit) OR (cost benefit):kw)) OR ((cost effectiveness) OR (cost effectiveness):kw) OR (MeSH description Cost-Benefit Analysis explode all trees) OR (MeSH description Costs and Cost Analysis explode all trees)) AND</p> <p><u>Limits</u> – from 2000 to 2013</p>

APPENDIX 5 – NHMRC tools for assessing the evidence

Table A5.1: NHMRC Dimensions of Evidence⁽⁸⁰⁾

Type of evidence	Definition
Strength of the evidence	
➤ Level	The study design used, as an indicator of the degree to which bias has been eliminated by design.
➤ Quality	The methods used by investigators to minimise bias within a study design.
➤ Statistical precision	The p-value or, alternatively, the precision of the estimate of the effect (as indicated by the confidence interval). It reflects the degree of certainty about the existence of a true effect.
Size of effect	The distance of the study estimate from the “null” value and the inclusion of only clinically important effects in the confidence interval.
Relevance of evidence	The usefulness of the evidence in clinical practice, particularly the appropriateness of the outcome measures used.

Table A5.2: Designations of levels of evidence for an intervention (NHMRC)⁽⁸⁰⁾

Level	Intervention
I	A systematic review of level II studies
II	A randomised controlled trial
III-1	A pseudo randomised controlled trial (i.e. alternate allocation or some other method)
III-2	A comparative study with concurrent controls: <ul style="list-style-type: none"> • Non-randomised, experimental trial • Cohort study • Case-control study • Interrupted time series with a control group
III-3	A comparative study without concurrent controls: <ul style="list-style-type: none"> • Historical control study • Two or more single arm study • Interrupted time series without a parallel control group
IV	Case series with either post-test or pre-test/post-test outcomes

Source: Hierarchies adapted and modified from: NHMRC 1999; Blandier 1999; Lijmer et al. 1999; Phillips et al. 2001

Table A5.3: Quality criteria for RCTs, cohort studies, case-control studies and systemic reviews⁽⁸⁰⁾

Study type	Quality criteria
Randomised controlled trials ^a	<p>Was the study double blinded?</p> <p>Was allocation to treatment groups concealed from those responsible for recruiting the subjects?</p> <p>Were all randomised participants included in the analysis?</p>
Cohort studies ^b	<p>How were subjects selected for the 'new intervention'?</p> <p>How were subjects selected for the comparison or control group?</p> <p>Does the study adequately control for demographic characteristics, clinical features and other potential confounding variables in the design or analysis?</p> <p>Was the measurement of outcomes unbiased (i.e. blinded to treatment group and comparable across groups)?</p> <p>Was follow-up long enough for outcomes to occur?</p> <p>Was follow-up complete and were there exclusions from the analysis?</p>
Case-control studies ^b	<p>How were cases defined and selected?</p> <p>How were controls defined and selected?</p> <p>Does the study adequately control for demographic characteristics and important potential confounders in the design or analysis?</p> <p>Was measurement of exposure to the factor of interest (e.g. the new intervention) adequate and kept blinded to case/control status?</p> <p>Were all selected subjects included in the analysis?</p>
Systematic reviews ^c	<p>Was an adequate search strategy used?</p> <p>Were the inclusion criteria appropriate and applied in an unbiased way?</p> <p>Was a quality assessment of included studies undertaken?</p> <p>Were the characteristics and results of the individual studies appropriately summarised?</p> <p>Were the methods for pooling the data appropriate?</p> <p>Were sources of heterogeneity explored?</p>

Source: National Health and Medical Research Council (NHMRC), 2000. How to review the evidence: systematic identification and review of the scientific literature, NHMRC, Commonwealth of Australia, Canberra.

^aBased on work of Schulz et al (1995) and Jadad et al (1996).

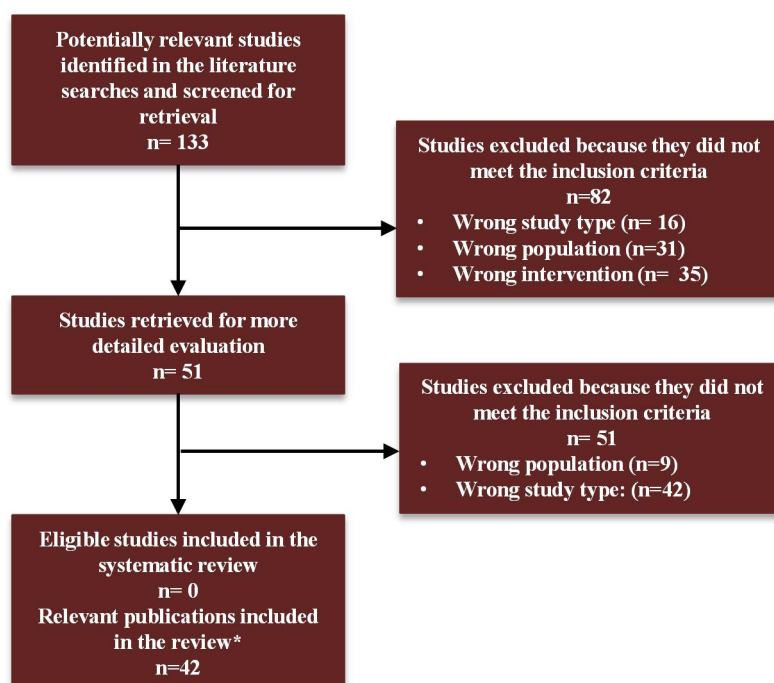
^bBased on quality assessment instruments developed and being tested in Australia and Canada.

^cBased on articles by Greenhalgh (1997) and Hunt and McKibbin (1997).

APPENDIX 6 – QUOROM flowchart

The QUOROM flowchart below shows the process used to select studies that were eligible for the clinical review of vulvoplasty or labioplasty.

Figure A6.1: QUOROM flowchart for the review of the clinical evidence



*As no eligible studies were identified, information from the available relevant publications was extracted in relation to the clinical research questions. All results in Chapter 5 need to be considered in the context of the limitations of this literature.