Australian Government

Department of Health and Ageing

MBS Reviews

Vulvoplasty

Protocol

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Prepared by HealthConsult Pty Ltd (ACN 118 337 821) for the Department of Health and Ageing

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Introduction

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

Reviews support the public funding of evidence-based, cost-effective clinical practice through the MBS.

The MBS Reviews process includes the consideration of policy issues related to services funded under the MBS and is designed to have flexibility depending on the complexity of the issues pertaining to the particular review. For example, where there is a single MBS service or item the review may be focussed and with shorter timeframes than a review that include multiple MBS items with related policy issues or non MBS issues. Non MBS issues that require a different process (such as pharmaceuticals or prostheses), and policy issues that are not appropriately dealt with by the Medical Services Advisory Committee (MSAC) process will be identified and addressed in separate processes which will feed into the MBS process where appropriate.

The first stage of a review is the identification of the scope. Reviews with single MBS services/issues will follow the MBS pathway and will be considered by MSAC using the MSAC process. For reviews with multiple MBS services or policy issues, the scope and pathway (MBS pathway and policy pathway) will be confirmed by the Consultation Review Committee (CRC), a time limited committee of nominated experts, determined and chaired by the Department of Health and Ageing (the Department).

The MBS pathway will follow the MSAC process and include the:

- development of a protocol;
- collection and evaluation of evidence; and
- advice and recommendations to the Minister through the Department.

The pathway for policy and other issues depends on the scope. Where a CRC is required, it will provide expertise to the Department in the development of the policy issues paper. There will be interactions between the MBS and policy pathways and stakeholders will be consulted throughout the review process; ensuring alignment of processes and consistency in deliberations.

Engagement with stakeholders is a critical component of the reviews process and issues will be dealt with in a consultative fashion. Where a CRC is established, it will advise the Department on policy issues and the MSAC and its subcommittees will advise on MBS matters. The review process is flexible, ensuring that new and emerging issues and feedback from the CRC, MSAC or public consultations can be incorporated into the reports.

The advice and recommendations provided by the CRC and MSAC to the Department informs the advice for the Minister.

PRINCIPLES TO GUIDE MBS REVIEWS

Reviews will:

- have a primary focus on improving health outcomes and the financial sustainability of the MBS, through consideration of areas potentially representing:
    - patient safety risk;
    - limited health benefit; and/or
    - inappropriate use (under or over use)
- 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;
- be published; and
- use Government resources efficiently.

OBJECTIVES OF MBS REVIEWS

To ensure the clinical and financial sustainability of the MBS, reviews will assess specific services and associated policy issues in a focused, fit-for-purpose, evidence based process. Findings will recognise that MBS funding should align with contemporary evidence, reflecting appropriate patient groups and best clinical practice.

PURPOSE OF THE PROTOCOL

This document outlines the methodology for providing evidence based analysis to support the review of services for vulvoplasty. The Protocol outlines the review methodology, clinical research questions the review will focus on, methods to identify and appraise the evidence and key stakeholder groups and experts to be consulted during the conduct of the review.

The vulvolplasty services in scope of this review include MBS items 35533 (refer Appendix 1)

STAKEHOLDER CONSULTATIONS

The Department is responsible for the review process including documents developed for policy and MBS issues and contractual arrangements for the development of the protocol and other report documents for the review. This includes ensuring that the relevant documents are available online for public consultation at the appropriate time and that comments are incorporated into informing the review process.

The Department's management of stakeholder engagement and negotiations with the relevant medical craft groups and key stakeholders will ensure the review findings are informed by consultations.

Following the finalisation of the review process, the advice to the Minister for Health on the findings of the review will be informed by the review reports, advice and recommendations from MSAC and CRC, public consultations and also other information that is relevant to the review including budgetary considerations.

PUBLIC CONSULTATIONS

The invitations to the general public (which include all stakeholders - patients, consumer groups, individual service providers, health professionals and manufacturers) to provide comment on the draft documents during the review process are critical to the review process. The documents will be available on the MSAC website (www.msac.gov.au) inviting the public to submit written

comments. The purpose of the feedback is to inform the final reports and recommendations to the Minister.

MEDICAL CRAFT GROUPS/ KEY STAKEHOLDERS

The following clinical craft groups and key stakeholders have been identified as having an interest in this review:

- Australian Society of Plastic Surgeons;
- Australian Medical Association;
- Consumers Health Forum of Australia;
- Royal Australasian College of Surgeons; and
- Royal Australian and New Zealand College of Obstetricians and Gynaecologists.

VULVOPLASTY

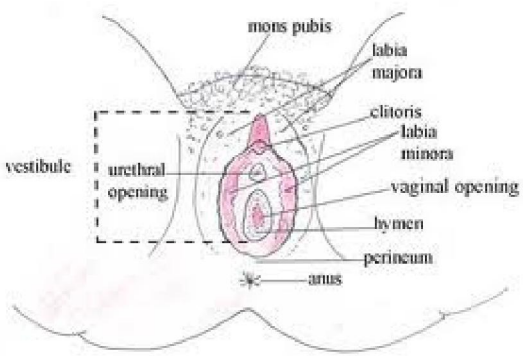
BACKGROUND

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 (refer Figure 1). Hence, vulvoplasty is any surgery performed on the external female genitalia. Labioplasty is a surgical procedure for altering the labia minora and the labia majora, the paired tissue structures bounding the vestibule of the vulva. The procedure involves surgical alteration, usually reduction, of the size of the labia. Although this usually involves reduction of the labia minora and/or (less frequently) majora, occasionally, labioplasty involves reconstruction after obstetrical injury or vulva trauma, or (rarely) enlargement, via injection of bulking agents or autologous fat transfer.[2]

Women present for labioplasty for one of more of the following indications; the correction of congenital defects and congenital abnormalities; the exterior cosmetic refinement of the vulvo-vaginal complex (i.e. caused by genital prolapse); or for functional problems including dyspareunia (i.e. pain during intercourse), discomfort and/or irritation with certain types of clothing and/or discomfort and pain with some physical activities (such as cycling).[3, 4]

The vulvoplasty and labioplasty MBS item stipulates that services should only be claimed when medically indicated, however, guidance is not provided on what constitutes a medically necessary procedure. There is concern around the appropriate indications for the surgery, a limited evidence-base on the long-term safety and effectiveness of the procedure, and unease around some practitioner groups that currently perform the surgery. A recent letter to the editor of the Medical Journal of Australia captures these issues, indicating that in the context of female genital cosmetic surgery there is a blurring between disease and dissatisfaction[5], with an absence of evidence on clinical effectiveness.[6]

Figure 1: Diagram of the external female genitalia



Source: http://labspace.open.ac.uk/mod/oucontent/view.php?id=450484&section=3.5

There is a wide range of normality in vulva and vaginal anatomy.[2] Protrusion well beyond the labia majora (labia minora hypertrophy) with the thighs abducted is often a cause of dissatisfaction, and is one of the main reasons for which women seek alteration.[7] The labia minora are two longitudinal, cutaneous folds that typically vary in size. They are situated internally between the labia majora, and they extend from the clitoris laterally and posteriorly on either side of the vulval vestibule.[7]

Labioplasty (also labiaplasty) is a surgical procedure for altering the labia minora and the labia majora, the paired tissue structures bounding the vestibule of the vulva. Labia minora reduction is an increasingly common, straightforward procedure that is believed to yield a high degree of patient satisfaction.[7]

There is little consensus on the definition of labia minora hypertrophy, with a wide variation on what is considered normal. A distance of more than 4-5 cm from the base to the edge of the labium when under mild lateral traction has been suggested in an attempt to provide an objective definition[8, 9] but is still widely debated. In deciding on the need for surgical intervention the symptoms described by the patient are generally considered to be more important than the measurements alone. These issues can be functional, aesthetic and/or psychological.[10]

How is vulvoplasty and labioplasty surgery performed?

Labioplasty involves surgical alteration, usually reduction, of the size of the labia. Although this usually involves reduction of the labia minora and/or (less frequently) majora, occasionally, labioplasty involves reconstruction after obstetrical injury or vulva trauma, or (rarely) enlargement, via injection of bulking agents or autologous fat transfer.[2] 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.[7]

The majority of labioplasty surgeries are performed via sculpted linear resection, or modified V-wedge excision.[2, 11] 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 are 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, the superior edge beginning slightly inferior to the prepucial or frenular folds flowing downward from the clitoral hood, 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 postoperative stenosis (i.e. narrowing in blood vessel) of the introitus), is 'Z-plasty' (refer to Figure 3.2b).[11] Such de-epithelialisation techniques also remove a wedge of skin, but the aim is to preserve the interstitial tissues.[11] Other techniques have also been described but are not as widely used.[12, 13] 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, 6]

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. No effort is made to remove all the labia minor but only the tissue protruding beyond 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.[14] The patient is instructed to shower daily and apply antibiotic ointment to the suture lines.

It is not known how altered labia perform during childbirth, and whether one technique fares better than another.[2] One study[11] in the literature compares the two most commonly performed procedures, modified V-wedge and linear resection and found little difference in short-term outcomes between the two procedures.

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, 7] Major complication rates from all published labioplasty reports have been under 5 per cent.[9, 11, 15] A higher percentage of minor complications have been reported, but do not appear to interfere with overall patient satisfaction.[2] Overall labioplasty can be safely performed any time after sexual maturity (to a woman who is minimally 18 years of age).[16]

The conditions/diseases that vulvoplasty and labioplasty surgery treats

Labioplasty corrects the clinical conditions wherein a woman presents labia minora that are disproportionately greater than her labia majora; the labioplastic correction of the disproportions creates less asymmetrical labia minora that are functionally and aesthetically satisfactory to the woman.[16, 17] A protruding labia minora may lead to psychological, cosmetic, or functional problems. Labial hypertrophy causes loss of self-esteem and embarrassment for some women.[8] Even in the absence of psychosocial factors, enlarged labia minora can lead to functional difficulties. 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.[7]

The aetiology of labia minora hypertrophy is varied and can be multi-factorial. Some women are born with protruding labia minora this may be congenital as described in Table 1. In other women, hypertrophy of the labia minora may be acquired and has been attributed to factors such as mechanical irritation by intercourse or masturbation, childbirth, lymphatic stasis, and chronic irritation and inflammation from dermatitis or urinary incontinence.[8, 9, 16] Childbirth by the vaginal route causes some women to develop hypertrophy, in some cases, due to haematoma formation at the time of birth.[7] Table 1 presents common aetiologies that may cause variation in labial appearance including labia minora hypertrophy.

Table 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]	• CAH is 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.

Aetiology	Examples	Brief explanation of condition
	• Epispadias[22]	• A rare defect involving the opening of the urethra. In this condition, the urethra does not develop into a full tube and urine exits the body from the wrong place. It results in females having an abnormal clitoris and labia. The opening is usually between the clitoris and the labia, but it may be in the belly area. 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*	• Labioplasty required to achieve sufficient biopsy. Excised tissue sent for histopathology.
Inflammation related	• Dermatitis secondary to urinary incontinence[7]	• 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[7]	• Fluid accumulating in the vulva. Can be caused by Crohn's disease[25, 26].
Chronic/repetitive stretching or overexpansion	• Multiple pregnancies[7]	• Stretching of labia due to stress caused by pregnancy.
Iatrogenic	• Adverse condition in a patient resulting from treatment by a physician or surgeon. [7]	• Examples may include, 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[7]	• 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

* dermatologists and skin clinics refer female patients to plastic surgeons to perform the biopsy

Most women present for labioplasty for one of more of the following indications:[2, 8, 10, 16, 17, 27-30]:

- the correction of congenital defects and congenital abnormalities;
- the exterior cosmetic refinement of the vulvo-vaginal complex for the diminishment of perceived large, irregular, cosmetically unappealing vulva structures as a result of the tear and stretching of the labia minora caused by the mechanical stresses of childbirth, accident, age;
- for functional purposes; women present with labial asymmetry that causes poor hygiene; pubic discomfort when wearing tight clothes; pubic-area pain when practicing sport (bicycling, running, etc.); either a disrupted or a diffused urinary stream; and dyspareunia (painful sexual intercourse)[17].

Service delivery setting

Based on preliminary investigations, it appears that vulvoplasty and labioplasty surgery is provided in public and private hospitals in Australia, within the inpatient and non-admitted patient setting. However the service settings will be further explored through consultation with clinicians and consumers during the review process.

Service providers claiming MBS benefits for vulvoplasty and labioplasty surgery

The main service providers involved in performing vulvoplasty and labioplasty surgeries are plastic and reconstructive surgeons; and gynaecologists.

Incidence and prevalence of diseases relevant to the services under review

The correction of some congenital abnormalities may require labioplasty. However congenital abnormalities of the vulva and surrounding area are rare and the data on 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 and 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.[16] 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.

Concerns about vulvoplasty and labioplasty surgery

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. Labioplasty may be viewed as elective or indicated, depending on whether one looks upon self-perceived genital 'disfigurement' or 'sensation of a wide vagina' 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.[6]

In a 2008 position statement, the Royal Australian and New Zealand College of Obstetricians and Gynaecologists outline that gynaecological conditions that merit surgery include genital prolapse, female genital mutilation and labioplasties with clinical indications. Medical practitioners performing any vaginal surgery should be appropriately trained". However clinical indications are not defined. Similarly in 2009 the Royal College of Obstetricians and Gynaecologists[31] in the UK issued a statement advocating that any decision for surgery be based only on clinical grounds. However, the statement leaves it to individual practitioners to define these grounds for themselves. The British Association of Aesthetic Plastic Surgeons advises the need to determine whether a problem exists or whether an alternative solution may be preferable, but offers no advice on how to judge the problem.[32] Without clear guidance the increased demand for cosmetic labioplasty may reflect a narrow social definition of normal, or a confusion of what is normal and what is idealised.[33]

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 appropriate indications for surgery, a 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[8, 34] 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.[5]

Also recent changes in fashion trends, including more revealing attire, are believed to be contributing to an increased demand for contouring of the labia minora[7]. 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" which may be having an impact on women's perception on what is the normal appearance of a labia[35, 36]. The Classification Board considered 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" and consequently reducing labia minora size and asymmetry. Consequently, this censorship is conveying an inaccurate depiction of the vulva and labia[35, 36]. 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.[37] However, functional considerations are also important with a recent report stating that the majority of patients are undergoing reduction of the labia minora today for functional reasons, with minimal outside influences affecting their decision for treatment.[38]

Previous assessment of vulvoplasty and labioplasty surgery

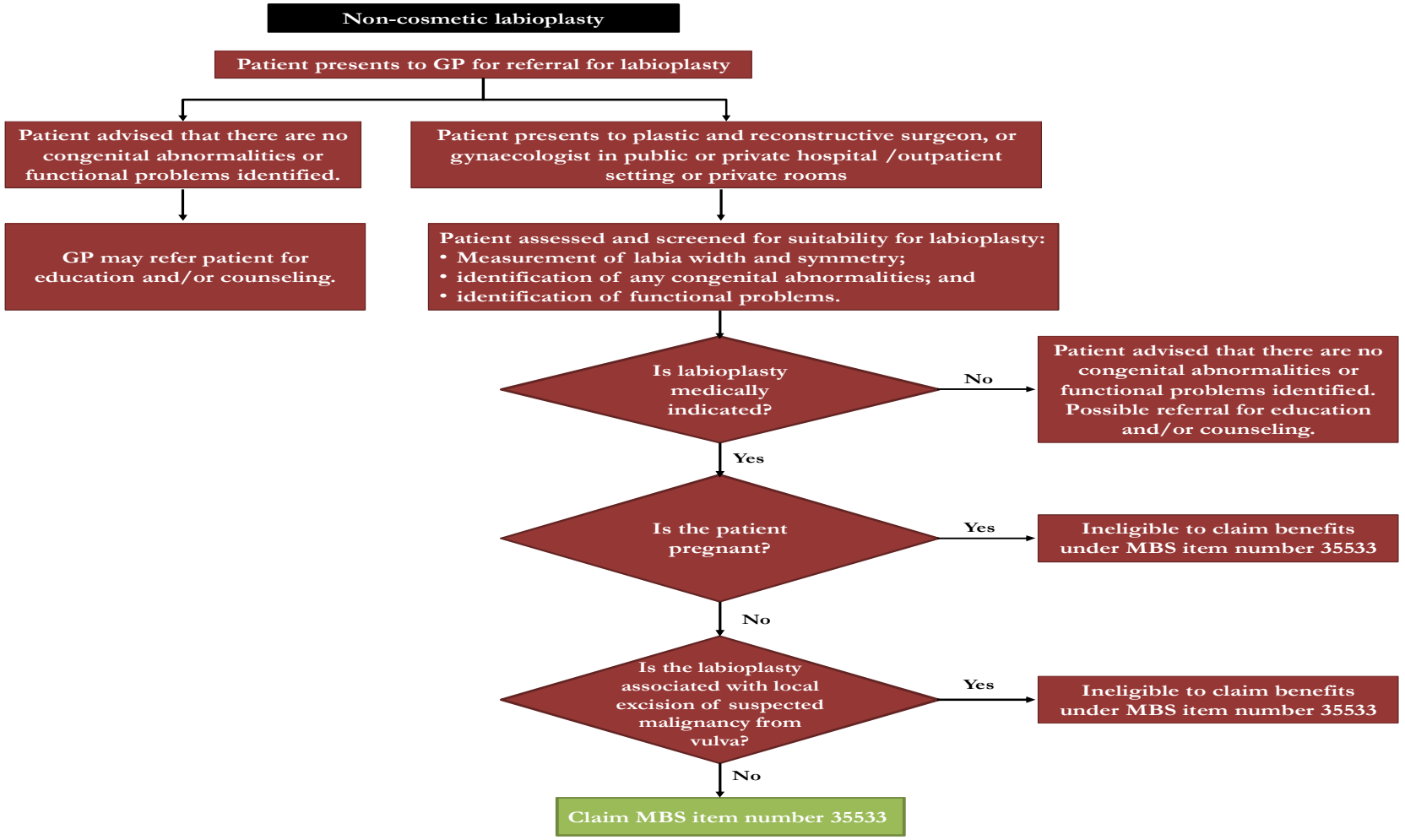
Liao et al [6] published a literature review on labioplasty. Their preliminary intention had been to conduct a systematic review however it soon became clear that the available literature was extremely rudimentary and precluded the use of the recommended methodology on the Meta-analysis of Observational Studies in Epidemiology (MOOSE) and Quality of Reporting Meta-analyses (QUORUM) checklists.[6] No further systematic reviews and/or health technology assessments were identified.

Where outcome studies of labioplasty existed they were retrospective, observational, and not case controlled.[2] All tended to have a relatively short-term follow-up of sexual satisfaction, none delve more than superficially into body image issues, and all lack a control group.[2] This finding is the reason that this protocol for the review of the existing MBS item numbers for vulvoplasty and labioplasty extends beyond a systematic literature review and includes an analysis of existing secondary data sources, consultation with clinicians and review and assessment of available clinical guideline documentation.

CLINICAL FLOWCHARTS

As shown in Table 2 there are three populations where vulvoplasty and labioplasty surgery may be performed. The clinical decision pathway which determines whether vulvoplasty and labioplasty surgery is performed is provided in Figure 1.

Figure 2: Clinical flow chart for non-cosmetic vulvoplasty and labioplasty surgery



Methodology

The review will be primarily based on a fit-for-purpose, evidence based methodology. Fit-for-purpose in this context means that where comprehensive, high quality literature is found which clearly addresses the clinical questions, less work will be undertaken to find and analyse lower quality evidence or grey papers. The less comprehensive or lower quality the evidence relating to a clinical question (or where the evidence is not directly comparable to the Australian context), more work will be undertaken in finding and analysing lower quality evidence to ensure robust findings.

The main methodology for the review will be Mini-health technology assessments:

- a comprehensive systematic search of the scientific literature will be conducted to identify relevant studies addressing the key clinical/research questions.

To translate the evidence into the Australian context, the review will consider:

- Secondary data analysis:
  - MBS and National Hospital Morbidity data will be analysed to examine the existing population utilisation of services and assess whether existing MBS item numbers for the services are appropriate.
- Guideline concordance:
  - an analysis of the MBS services will be assessed relative to 'best practice' as recommended in relevant Clinical Practice Guidelines and relevant practice in Australia.
- Stakeholder consultation:
  - clinician engagement (e.g. CRC, MESP and submission authors) to understand existing services and practices in Australia; and
  - consumer engagement to determine consumer experiences with the services under review.
- Economic evaluation
  - preliminary economic evaluation will be conducted as part of the review, relying on studies identified through the systematic literature review.

The above information will take on additional significance when there is a lack of clear, high quality evidence.

It is important to note that no clinical guidelines were identified in the literature search conducted to develop this rapid review protocol. However, guideline concordance has been included in this review protocol to guide the clinical research questions that should be answered if guidelines are identified in the course of conducting the systematic literature review.

CLINICAL/RESEARCH QUESTIONS

The PICO (Population, Intervention, Comparator, Outcomes) criteria[39] are used to develop well-defined questions for each review. This involves focusing the question on the following 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 have been determined on the basis of information provided in the literature, as well as clinical advice. These criteria will be applied when selecting literature for the mini-HTA. Additional criteria for selecting literature have also been outlined (i.e. relevant study designs for assessing the safety and effectiveness of the service, time period within which the literature will be sourced, and language restrictions in the Methodology section). The PICO for the review of vulvoplasty and labioplasty surgery is shown in Table 2.

Table 2: Research questions for the vulvoplasty and labioplasty surgery item under review

Population	Intervention	Comparator	Outcomes
(1) Female patients with congenital anomalies (2) Female patients with labia hypertrophy that causes functional problems including dyspareunia (3) Female patients dissatisfied with genital appearance	Vulvoplasty/ labioplasty	No vulvoplasty/ labioplasty	Safety • 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). Effectiveness *Primary* • Mortality; • Quality of life (including patient satisfaction with vulva/labial size and aesthetic result); reduction in pain or discomfort. *Secondary* • Length of hospital stay; • Subsequent procedures.

The clinical/research questions that will be the focus of this review are as follows:

1. What are appropriate indications for clinically relevant 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. What is the evidence regarding the cost implications associated with vulvoplasty and labioplasty in each target population across the patient journey?
5. Is the existing MBS item for service (35533) appropriate?
6. For what clinical indications are current MBS funded services used?

SYSTEMATIC LITERATURE REVIEW (MINI-HTA)

The clinical/research questions to be addressed as part of the rapid review using the systematic literature review include:

(1) What are appropriate indications for clinically relevant 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 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. linear resection, modified v-wedge, Kelly clamp 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)?

A comprehensive search of the scientific literature will be conducted to identify relevant studies addressing the key questions. The databases to be included in the search are: MEDLINE® (from 1966 to present), MEDLINE® In-Process & Other Non-Indexed Citations, EMBASE (Excerpta Medica published by Elsevier) and Cochrane databases. The search will be restricted to English language studies of humans. In electronic searches we will use various terms for vulvoplasty and labioplasty (vulvoplasty, labioplasty, labiaplasty etc.), limited to humans, and relevant research designs.

Reference lists of related systematic reviews and selected narrative reviews and primary articles should be reviewed. Databases maintained by health technology assessment (HTA) agencies should be reviewed to identify existing assessments of vulvoplasty and labioplasty surgery. In terms of supplementary search strategies, as part of consultations with clinicians, clinicians should be asked if they are aware of any clinical guidelines, unpublished studies and reviews relevant to vulvoplasty and labioplasty surgery.

Search strategies generally include a combination of indexing terms (e.g. MeSH or Emtree headings) and text word terms. Table A.1 (see Appendix B) sets out proposed terms to identify papers in the proposed databases. Limits will be employed in a hierarchical manner according to the type of literature being sourced (i.e. Limit 1, and if no relevant literature then Limit 2 and if no relevant literature, then Limit 3). This is outlined in Appendix B.

The selection criteria in Table 3 will be applied to all publications identified by the literature search to identify studies eligible for inclusion in the systematic review. Study eligibility will be assessed by at least two reviewers.

Table 3: Inclusion/exclusion criteria for identification of relevant studies

Characteristic	Criteria
Search period	2000 – 6/2012 Should there be limited data available during this period, the search will be extended back in five year increments until sufficient data are sourced. If the service is only used infrequently, then a targeted search will be undertaken to determine the current 'state-of-play' of the procedure. The most recent narrative reviews and/or systematic reviews (if any) and Clinical Practice Guidelines will be identified and analysed to determine what international opinion is with respect to the service.
Publication type	Clinical studies included. Non-systematic reviews, letters, editorials, animal, in vitro and laboratory studies excluded. **Systematic reviews** Systematic reviews that have been superseded will be excluded. **Primary studies** Primary studies published during the search period of included systematic reviews excluded. **Effectiveness studies** included if: • prospective, comparative trial • >20 patients **Safety studies** included if: • >50 patients included.
Intervention	Vulvoplasty or labioplasty surgery
Comparator	No vulvoplasty or labioplasty surgery
Outcome	Studies must report on at least one of the following outcomes: • 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

All eligible studies will be assessed according to the National Health and Medical Research Council (NHMRC) Dimensions of Evidence, which are described in Table 4. There are three main domains: strength of the evidence, size of the effect and relevance of the evidence. The first domain is derived directly from the literature identified for a particular intervention. The last two require expert clinical input as part of their determination.

Table 4: Dimensions of Evidence

Type of evidence	Definition
Strength of the evidence ➢ Level ➢ Quality ➢ Statistical precision	The study design used, as an indicator of the degree to which bias has been eliminated by design. The methods used by investigators to minimise bias within a study design. 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.

One aspect of the 'strength of the evidence' domain is the level of evidence, which will be assigned using the NHMRC levels of evidence outlined in Merlin et al 2009.[40] Study quality will be evaluated and reported using the NHMRC Quality Criteria (shown in Table 5) for randomised controlled trials, cohort studies, case control studies and systematic reviews.

Table 5: Quality criteria for RCTs, cohort studies, case-control studies and systemic reviews

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

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. [a]Based on work of Schulz et al (1995) and Jadad et al (1996) [b]Based on quality assessment instruments developed and being tested in Australia and Canada [c]Based on articles by Greenhalgh (1997) and Hunt and McKibbon (1997).

Data will be extracted from individual studies using a standardised data extraction form designed specifically for this review. Data extraction will be performed by one reviewer and checked by a second reviewer.

The overall body of research evidence will be assessed and synthesised to address each clinical question according to Table 6. An evidence rating from A (excellent) to D (poor) will be assigned to the evidence, considering each of the components outlined in the body of evidence matrix. In the absence of such literature, expert opinion and narratives will be synthesised according to the credibility of the source of such material.

Table 6: Body of evidence assessment matrix (adapted from [41])

Component	A	B	C	D
	Excellent	**Good**	**Satisfactory**	**Poor**
Evidence base[1]	one or more level I studies with a low risk of bias or several level II studies with a low risk of bias	one or two level II studies with a low risk of bias or a SR/several level III studies with a low risk of bias	one or two level III studies with a low risk of bias, or level I or II studies with a moderate risk of bias	level IV studies, or level I to III studies/SRs with a high risk of bias
Consistency[2]	all studies consistent	most studies consistent and inconsistency may be explained	some inconsistency reflecting genuine uncertainty around clinical question	evidence is inconsistent
Clinical impact	very large	substantial	moderate	slight or restricted
Generalisability	population/s studied in body of evidence are the same as the target population	population/s studied in the body of evidence are similar to the target population	population/s studied in body of evidence differ to target population but it is clinically sensible to apply this evidence to target population[3]	population/s studied in body of evidence differ to target population and hard to judge whether it is sensible to generalise to target population
Applicability	directly applicable to Australian healthcare context	applicable to Australian healthcare context with few caveats	probably applicable to Australian healthcare context with some caveats	not applicable to Australian healthcare context

SR = systematic review; several = more than two studies [1] Level of evidence determined from the NHMRC evidence hierarchy. [2] If there is only one study, rank this component as 'not applicable'. [3] For example, results in adults that are clinically sensible to apply to children OR psychosocial outcomes for one cancer that may be applicable to patients with another cancer

MBS DATA

MBS data are available for vulvuplasty and labioplasty (MBS item number 35533) since the early 1990's. MBS data can be analysed by patient gender, age group, discipline of provider claiming the benefit etc. The clinical/research questions to be addressed for this review using MBS data include:

a. How frequent are claims made for the vulvoplasty and labioplasty MBS item numbers?

b. Are there any temporal or geographic trends associated with usage of these item numbers?

c. What are the characteristics of patients undergoing vulvoplasty or labioplasty?

d. Are the MBS claims data consistent with trends in the incidence/prevalence of the conditions/diseases being addressed by the services?

e. What is the specialist profile of benefits claimed for vulvoplasty or labioplasty?

f. Are there other procedures being claimed in association with vulvoplasty and labioplasty?

g. What are the expected patient health outcomes with regard to patient groups, type of intervention (including surgical technique where relevant), and practitioners performing (accreditation and training) the vulvoplasty and labioplasty surgery?

h. What are the clinical indications for medically necessary vulvoplasty or labioplasty surgery? (i.e. not cosmetic);

i. What are suitable locations for service delivery? Should the MBS item number be restricted to a particular setting (i.e. admitted patients only)?

NATIONAL HOSPITAL MORBIDITY DATA

The National Hospital Morbidity Database (NHMD) is compiled by AIHW from data supplied by the state and territory health authorities. It is a collection of electronic confidentialised summary records for separations (that is, episodes of care) in public and private hospitals in Australia. Data are held for the years 1993-94 to 2009–10.[14] 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. Australian Classification of Health Interventions (ACHI) code). The vulvoplasty procedure code within the ACHI is 35533-00. There is no specific ACHI code for labioplasty.

The clinical/research questions to be addressed in this rapid review using NHMD data include:

(1) What are the characteristics of the service profile under ACHI code 35533-00?

a. How many separations of vulvoplasty were performed by year from 2001/02 to 2009/10?

b. What is the principal diagnosis profile of patients for whom vulvoplasty was performed?

c. What is the age profile of patients for whom vulvoplasty was performed?

(2) Is the ACHI code 35533-00 profile different to the analysis of MBS item 35533?

GUIDELINE CONCORDANCE

An analysis of vulvoplasty and labioplasty i.e. (MBS item number 35533) will be undertaken relative to 'best practice' as recommended in relevant Clinical Practice Guidelines and relevant practice in Australia. Where formalised Clinical Practice Guidelines do not exist, the review should take account of other guidelines in operation in comparable health systems overseas. Differences in the purpose and intended audience of any such guidelines should be considered, documented and acknowledged in the process of undertaking the review.

The clinical/research questions to be addressed in this review using guideline concordance include:

(1) What is current clinical practice for vulvoplasty and labioplasty?

ECONOMIC EVALUATION

Only a preliminary economic evaluation will be conducted as part of conducting the rapid review, relying on studies identified through the systematic literature review. In the literature searches, acceptable evidence would include trial-based costing studies, cost analyses and economic modelling studies. Acceptable outcomes would include: 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 applicability of any identified economic analyses to the Australian health system will be assessed.

The clinical/research questions to be addressed as part of the rapid review using the economic evaluation component include:

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

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Appendix A – MBS Items

Table 7: 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.) **Fee:** $343.35 **Benefit:** 75% = $257.55 85% = $291.85

Note: MBS item number 35536 refers to 'VULVA, wide local excision of suspected malignancy or hemivulvectomy, 1 or both procedures'

Table 8: Year of adoption in health system

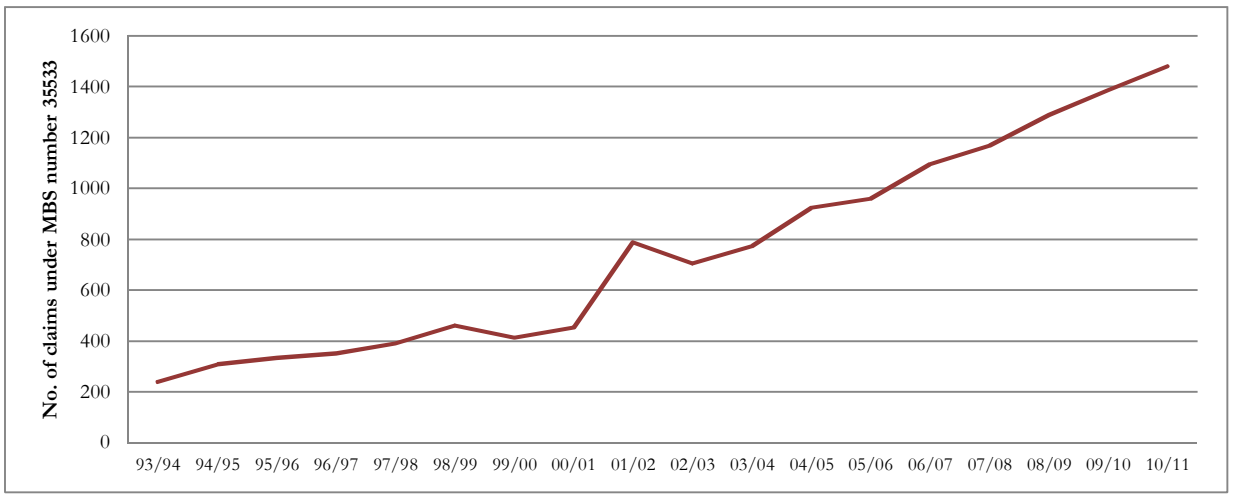
MBS Item number	Type of date	Date
35533	Item Start Date	01-Dec-1991
	Description Start Date	01-Dec-1991

Source: Medicare Australia

MBS item number usage and expenditure

Figure 3 shows that the number of claims for the MBS item number 35533 has increased substantially from 1993/94 to 2010/11. In fact, there has been a 517 per cent increase in the total number of claims for the item number over the 18 year period (Table 3.4).

Figure 3: Number of claims for MBS item number 35533 since 1993/1994



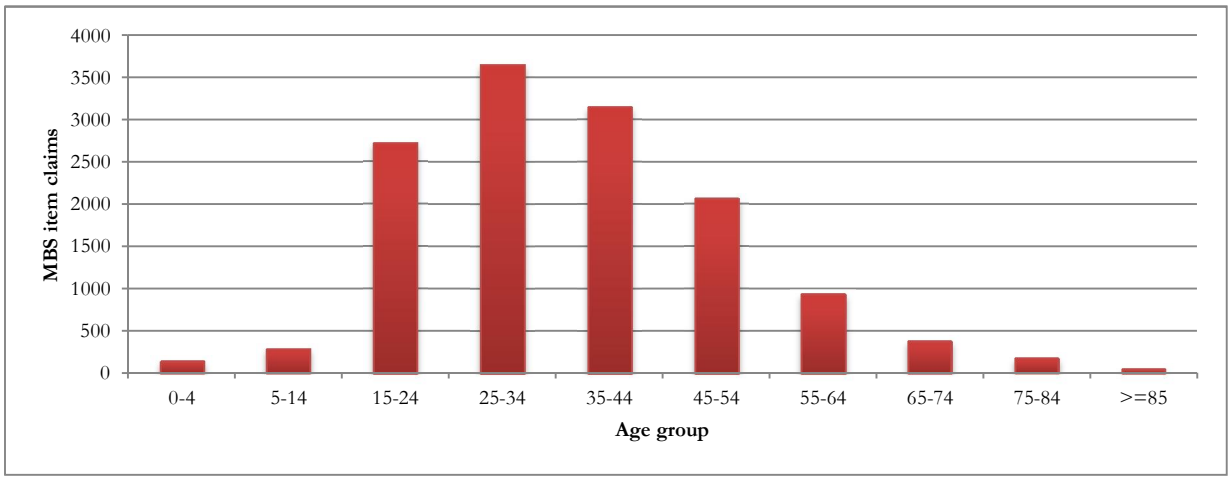
Source: Department of Human Services Medicare

Claims for MBS item number 35533 by female age (July 1993-June 2011)

Figure 4 shows the claims for MBS item number 35533 by age from July 1993 to

June 2011. Women aged 25-34 account for the highest number of vulvoplasty or labioplasty procedures with 3,654 claims over the previous 18 year period. This is followed by women ages 35-44 with 3,152 claims followed by women ages 15-24 with 2,721 claims over the 18 year period.

Figure 4: Number of Claims for MBS item number 35533 by female age (July 1993-June 2011)

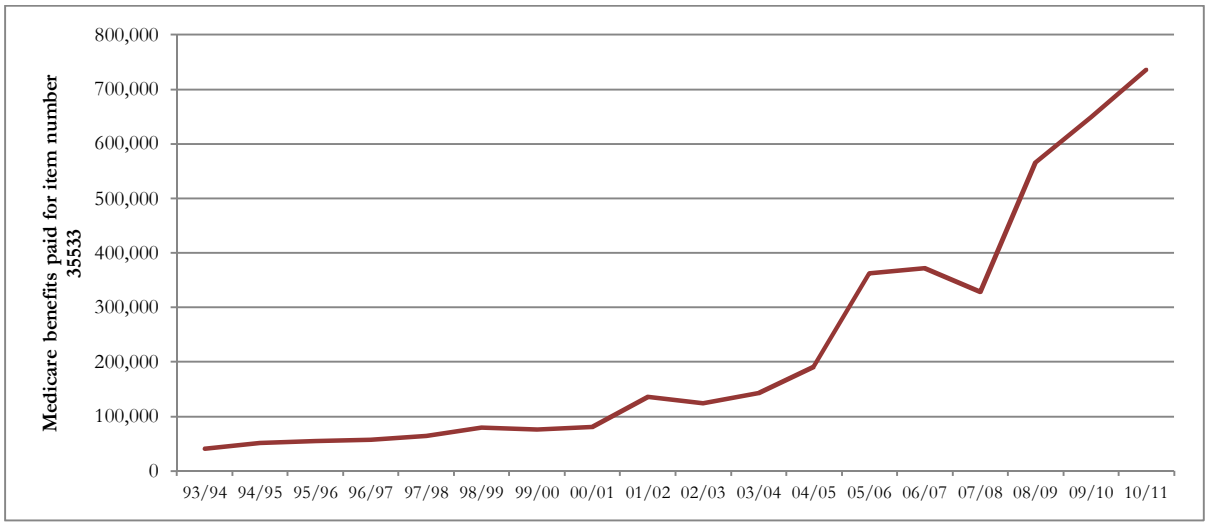


Source: Department of Human Services Medicare

Benefits paid for MBS item number 35533 since 1993/1994

Figure 5 shows the Medicare benefits paid for the vulvoplasty or labioplasty MBS item number. The data show that there has been a significant increase in the benefits paid for 35533 consistent with the increase in volume. Overall the total of benefits paid in 2010/11 was $0.74m; up 17 fold from $0.04m in 1993/94.

Figure 5: Benefits paid for MBS item number 35533 since 1993/1994



Source: Department of Human Services Medicare

Growth in claims for MBS item number 35533 since 1993/1994

The table below shows the growth in MBS claims for vulvoplasty of labioplasty by state/territory over the last 18 years. The highest growth has occurred in South Australia with an increase in claims of almost 1,100 per cent over the 18 year period. This is followed by the ACT and the Northern Territory with a 950 per cent and 750 per cent increase respectively. NSW makes up the highest proportion of MBS claims for item number 35533 (32%) followed by Victoria (27%). The proportion of claims in these states aligns with population statistics. South Australia reports the same number of claims as Western Australia, however the South Australian population only accounts for 7 per cent of the Australian population with Western Australia accounting for 10 per cent.

Table 9: Growth in claims for Vulvoplasty since 1193/94

State/ territory	Claims for MBS item number 35533							
	1993/1994	2001/2002	Growth since 1993/1994	2010/2011	Growth since 2001/2002	Growth since 1993/1994	Total number of claims since 1993/1994	Proportion of total claims
NSW	73	265	263%	458	73%	527%	4,563	32%
VIC	70	216	209%	382	77%	446%	3,901	27%
QLD	49	113	131%	270	139%	451%	2,524	17%
SA	16	70	338%	191	173%	1094%	1,473	10%
WA	25	82	228%	120	46%	380%	1,466	10%
TAS	3	21	600%	22	5%	633%	231	2%
ACT	2	8	300%	21	163%	950%	199	1%
NT	2	13	550%	17	31%	750%	108	1%
Total	**240**	**788**	**228%**	**1,481**	**88%**	**517%**	**14,465**	**100%**

Source: Department of Human Services Medicare

Appendix B – Systematic review search term strategy

Clinical/research questions

1. **What is the safety and effectiveness of vulvoplasty or labioplasty in patients undergoing the procedure for functional conditions?**

Table 10: Search strategy

Population	Search Terms
Patients with congenital abnormalities • Bladder exstrophy • Congenital adrenal hyperplasia • VATER Syndrome • Cloacal exstrophy • Epispadias • Disorders of sex development	**Embase and Medline** Population – (('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')) AND Intervention – (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* NOT (('esthetic surgery'/exp OR 'esthetic surgery') OR ('cosmetic'/exp OR 'cosmetic')) AND Limits – ([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 [2000-2012]/py **Cochrane** Population – (((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)) AND Intervention – (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* NOT (((esthetic surgery) OR (esthetic surgery):kw) OR ((cosmetic) OR cosmetic):kw) OR (MeSH description **Surgery, Plastic** explode all trees)) AND Limits – from 2000 to 2012
Patients with labia hypertrophy due to medically related conditions • Dyspareunia • Labia asymmetry • Vulva lymphoedema • Vulval oedema	**Embase and Medline** Population – (('dyspareunia'/exp OR 'dyspareunia') OR 'labia asymmetry' OR (labia NEAR/6 asymmetry) OR 'vulva lymphoedema' OR 'vulva lymphedema' OR (vulva NEAR/6 lymphoedema) OR (vulva NEAR/6 lymphoedema) OR (vulva 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 (vulva NEAR/6 oedema) OR (vulva NEAR/6 oedema) OR 'labia hypertrophy') OR (labia* NEAR/6 hypertropy) AND Intervention – (vulvoplas* OR labioplast* OR labia* OR ((labia OR vulva) AND ('surgical correction' OR 'surgical alteration' OR 'plastic surgery' OR

Population	Search Terms
	'plastic surgeries' OR reduc* OR alter*))) OR labia* NEAR/3 surg* NOT (('esthetic surgery'/exp OR 'esthetic surgery') OR ('cosmetic'/exp OR 'cosmetic')) AND Limits – ([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 [2000-2012]/py **Cochrane** Population – (((dyspareunia) OR 9dyspareunia):kw) OR ((labia asymmetry) OR (labia asymmetry):kw) OR ((vulva lyphoedema) OR (vulva lymphoedema):kw) OR ((vulva lyphedema) OR (vulva lymphedema):kw) OR ((labia hypertrophy) OR (labia hypertrophy):kw) OR (MeSH description **Dyspareunia** explode all trees) OR (MeSH description **Vulva Neoplasms** explode all trees) OR (MeSH description **Vulva Diseases** explode all trees)) AND Intervention – (((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 Limits – from 2000 to 2012
Patients dissatisfied with vaginal appearance (maybe acquired) • chronic stretching due to childbirth • age	**Embase and Medline** Population – (('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')) AND Intervention – (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 Limits – ([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 [2000-2012]/py **Cochrane** Population – (((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 Intervention – (((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 Limits – from 2000 to 2012

2. What is the evidence regarding the cost implications associated with vulvoplasty or labioplasty surgery?

Population	Search Terms
Patients undergoing vulvoplasty or labioplasty	**Embase and Medline** Intervention – (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 Economic Terms – ('economic aspect'/exp OR 'cost benefit analysis' OR cost* OR 'cost effectiveness') AND Limits – [humans]/lim AND [english]/lim AND [2006-2012]/py **Cochrane** Intervention - (((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 Economic Terms – (((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 Limits – from 2000 to 2012

PLEASE NOTE:

- Both Embase and Medline should be searched via Embase.com.
- The approach taken to identify the required search terms and to develop the search strategies was more 'sensitive' rather than 'specific'.
- Limits may not be necessary given the apparent lack of controlled trial evidence
- The search line from the Embase and Medline search strategies "NOT (('esthetic surgery'/exp OR 'esthetic surgery') OR ('cosmetic'/exp OR 'cosmetic'))" is not necessary but can be used to identify publications/studies that focus on vulvoplasty/labioplasty for non-cosmetic reasons. However, "NOT (('esthetic surgery'/exp OR 'esthetic surgery') OR ('cosmetic'/exp OR 'cosmetic'))" may be replaced with "OR (('esthetic surgery'/exp OR 'esthetic surgery') OR ('cosmetic'/exp OR 'cosmetic'))" to identify publications/studies that include vulvoplasty/labioplasty for cosmetic reasons.
- The search line from the Cochrane search strategies "NOT (((esthetic surgery) OR (esthetic surgery):kw) OR ((cosmetic) OR cosmetic):kw) OR (MeSH description Surgery, Plastic explode all trees))" is not necessary but can be used to identify publications/studies that focus on vulvoplasty/labioplasty for non-cosmetic reasons. However, "NOT (((esthetic surgery) OR (esthetic surgery):kw) OR ((cosmetic) OR cosmetic):kw) OR (MeSH description Surgery, Plastic explode all trees))" may be replaced with "OR (((esthetic surgery) OR (esthetic surgery):kw) OR ((cosmetic) OR cosmetic):kw) OR (MeSH description Surgery, Plastic explode all trees))" to identify publications/studies that include vulvoplasty/labioplasty for cosmetic reasons.