Guidelines for the Use of Support Pessaries in the Management of Pelvic Organ Prolapse

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Section 1: Background to the development of the 'Guidelines for the Use and Support of Pessaries in the Management of Pelvic Organ Prolapse'

1.1. Background

Pelvic organ prolapse is a condition which affects up to 50% of parous women (Thakar & Stanton 2002), with prolapse symptoms being reported by 21% of women (Slieker-ten Hove et al 2009). It is the most common reason for hysterectomy, after cancer, for menopausal women in the United States (Swift et al 2005). Pelvic organ prolapse is characterised by descent of any of the pelvic organs inside the vagina or beyond the vaginal introitus. It rarely results in significant morbidity and essentially in no mortality, but pelvic organ prolapse can have a great impact on the quality of life (QoL) of women (Swift et al 2005).

Pelvic organ prolapse is treated by surgery or conservative measures, which includes support pessaries, pelvic floor muscle training, lifestyle management or expectant waiting. Support pessaries are to be distinguished from other types of pessary e.g. for administration of hormones. The term pessary in this document refers only to support pessaries, specifically for the management of pelvic organ prolapse and does not refer to the management of urinary incontinence with pessaries. Pessaries can be made from a great variety of materials and have been used since ancient times in the management of pelvic organ prolapse, with the modern pessary, usually made of silicone, in a range of shapes and sizes (Shah et al 2006).

Following a Pessary Workshop at the 18th National Conference on Incontinence in Adelaide 2009, attended by continence and women's health physiotherapists (C&WHP), continence nurse advisors (CNA) and medical practitioners, there was considerable interest in the potential for pessaries to be used more widely in Australia in the conservative management of pelvic organ prolapse. Women with pelvic organ prolapse are commonly seen by physiotherapists and nurses in public clinics and private practices for management by conservative measures, which generally include pelvic floor muscle training and lifestyle management, although pessaries may also be indicated. Pessaries are predominantly prescribed and fitted by gynaecologists or general medical practitioners (GPs) with a special interest in women's health. There are some clinics where nurses are responsible for the review of women fitted with pessaries by gynaecologists and urogynaecologists. However, pessaries are not readily available from primary care practitioners as a first line management option for women with pelvic organ prolapse and gynaecologists with an interest in prescribing and fitting pessaries may not be accessible.

1.2. Need for the development of guidelines for health care professionals.

At the 18th National Conference on Incontinence, a need was identified for health practitioners, in particular C&WHPs, CNAs and GPs as well as gynaecologists, to be trained in the prescription and fitting of vaginal pessaries to provide a potential alternative to surgery for women with pelvic organ prolapse. Surgery carries inherent risks, has a considerable failure rate of 30-50% (Olsen et al 1997; Whiteside et al 2004) and is a significant cost to the individual and the community (Moore et al 2009).

There is precedence for the fitting of pessaries by non-gynaecologists. Pessaries were successfully fitted in up to 83% of women presenting for management of pelvic organ prolapse in a nurse-run primary care clinic in Canada (Hanson et al 2006). In Australia, primary health care practitioners who are qualified to prescribe and fit pessaries, could provide a more comprehensive and cost-effective service to women with pelvic organ prolapse, potentially reducing the need for tertiary referral and surgical intervention. Currently a C&WHP needs to refer a woman to her GP, who then refers her on to a gynaecologist to have a pessary fitted. A number of fitting trials by a gynaecologist may be needed before a successful fit is achieved.

Relevant training is needed to ensure appropriate patient selection, pessary fitting and long term follow-up to minimise the potential for uncommon but sometimes serious side-effects of long term pessary use such as erosion and infection (Atnip 2009; Vierhout 2004; Wu et al 1997). There are currently no known accredited or approved courses for the fitting of pessaries in Australia for any health professional. Prior to considering the establishment of a training course, it is necessary to develop evidence-based guidelines to underpin the prescription of pessaries to ensure best-practice standards are met and to provide more widely available public access to accredited clinicians from a range of disciplines.

1.3. Guideline purpose

The *Guidelines for the Use and Support of Pessaries in the Management of Pelvic Organ Prolapse* (herein referred to as The Pessary Guidelines) specifically address the use, selection and fitting of ***support*** pessaries in the management of women with pelvic organ prolapse. Therefore The Pessary Guidelines ***do not consider*** the use of pessaries which are intended to manage urinary incontinence.

1.4. Target users

The Pessary Guidelines are intended for use by Australian health practitioners from the medical, nursing and physiotherapy professions who have already undertaken accredited training in the management of incontinence and pelvic floor dysfunction. For nursing and physiotherapy providers, this may mean that they are already working in advanced scope practice roles, with skills in pelvic floor muscle assessment. For these practitioners, training in pessary prescription and use may allow them to work in extended scope roles, where their activities are similar to those health practitioners already prescribing pessaries for POP.

Currently the only inter-disciplinary training available is a one-day workshop with theoretical and practical components, run under the auspices of the Continence Foundation of Australia. The next training course is to be held on Friday 27.7.2012.

The clinical context of the primary health care provider needs to be taken into account when using The Pessary Guidelines. The clinical context (i.e. private practice, hospital) of the primary health care provider will influence the referral pathway. Physiotherapists in a private practice will have different referral procedures in place, compared with continence nurses based in a hospital setting. A team approach between CNA/C&WHP providers and gynaecologists or GPs with a special interest in pelvic floor dysfunction is required. It is important for health care providers to seek advice from suitably qualified medical specialists should there be concerns regarding the assessment and management of women with incontinence and POP.

Thus target users will need to consider their level of competency and their clinical context when implementing The Pessary Guidelines. It is essential that the primary health care provider always works within their level of competency, taking into account the clinical context when performing their duties.

1.5. Funding sources

The Continence Foundation of Australia (CFA) is a multi-disciplinary organisation, supported by Commonwealth Government funding, with a mandate to promote education about incontinence and associated conditions such as pelvic organ prolapse. As such, the CFA provides an ideal umbrella organisation for the development of clinical practice guidelines and the subsequent implementation of The Pessary Guidelines. This will occur through a training programme which should be suitable for and endorsed by the physiotherapy, nursing and medical professions.

Funding has been committed to the project by Mr Barry Cahill, CEO of CFA for the development of The Pessary Guidelines.

1.6. Guideline development

A team of methodologists and content experts from the International Centre for Allied Health Evidence (*i*CAHE), University of South Australia has developed The Pessary Guidelines in collaboration with the Expert Working Party. *i*CAHE has been responsible for the literature searching and drafting of The Pessary Guidelines evidence statements. The Expert Working Party assisted *i*CAHE to appropriately word and present the evidence as '**Evidence Statements'** for the target users. The Expert Working Party drafted **'Practice Points'** throughout The Pessary Guidelines, to provide guidance where there was insufficient evidence from the literature. The Pessary Guidelines have been distributed to a broader reference group (comprising representatives of relevant professional and consumer bodies) for comment and endorsement. The relevant professional bodies include the Royal Australian College of General Practitioners, Royal Australian & New Zealand College of Obstetricians & Gynaecologists (RANZCOG), Australian Nurses for Continence Group, and National Group of C&WH Physiotherapy, Australian Physiotherapy Association (APA) and the CFA as representing consumer interests. Endorsement (or 'support', in the case of the APA) was obtained from all these groups, other than the

Urogynaecological Society of Australasia (UGSA). This is a representative body of the RANZCOG. This group endorsed the scientific process and content of the Pessary Guidelines but noted its concerns with the issue of training. This issue is outside the scope of the guideline (See Appendix H). The final Pessary Guidelines were made available for a public consultation phase for a period of 60 days, before final amendments incorporating the feedback from the public consultation process were made.

The final Pessary Guidelines, together with a clinical management pathway (algorithm) are freely available on the *i*CAHE website www.unisa.edu.au/cahe and the Continence Foundation of Australia website www.continence.org.au.

Members of the methodology team (*i*CAHE research team)

Dr Patricia Neumann	Ms Anthea Worley
Professor Karen Grimmer-Somers	Ms Olivia Thorpe

Members of the Expert Working Party

Dr Katrina Allen (GP)	Dr Christopher Barry (Gynaecologist with a special interest in Pelvic Floor Dysfunction)
Ms Donna Coates (Continence Nurse Practitioner)	Ms Virginia Gill (Titled C&WHP)
Assoc Prof Kate Moore (Urogynaecologist)	Ms Leigh Pretty (CNA)
Dr Charmaine Sargent (GP)	Dr Elvis Seman (Gynaecologist with a special interest in Pelvic Floor Dysfunction)

Dr Patricia Neumann (Physiotherapist, Specialist C&WHP, *i*CAHE member) chaired the Expert Working Party on behalf of the methodology team.

Comments were also received from members of the Australian Nurses for Continence (ANFC): Margaret Wilson, Elizabeth Thomas, Christine Conway and Christine Murray.

1.7. Guideline implementation and evaluation

The Pessary Guidelines are presented in the form of evidence statements and practice points. Subsequent training programs will be based on this structure, and conducted by clinicians with expertise in pessary fitting and training. The value of The Pessary Guidelines will be tested after their dissemination and the completion of training by compliance of individual clinicians with the pessary-fitting process as recorded on clinical records, on occurrence of sentinel events and on patient outcomes. It is hypothesised that The Pessary Guidelines will provide a framework for safer clinical

practice with fewer sentinel events, streamlined and best practice processes and improved patient outcomes.

It is envisaged that The Pessary Guidelines will undergo revision in four years time to incorporate new evidence into clinical practice.

Section 2: Methodology: literature search and guideline development

A literature review and the opinion of the Expert Working Party were used to inform the development of The Pessary Guidelines.

The literature review was undertaken to find the evidence to answer key questions relating to the use of pessaries. The process of reviewing the literature review is outlined below. The evidence was collated and analysed to inform the development of The Pessary Guidelines. The Expert Working Party layered the evidence and filled in gaps with their expert opinion. The mechanics of the Expert Working Party are also outlined below.

After combining the literature review evidence and expert opinion, the document was then sent to a wider reference group for consideration and endorsement, as well as for public consultation. After further amendments from these processes, the finalised Pessary Guidelines document was made freely available in the public domain on various websites.

2.1. Literature review

The key questions to be answered from the search for evidence were:

- What defines a pessary for pelvic organ prolapse?
- What is the current best practice management of pelvic organ prolapse?
- What are the indications for pessary use?
- What are the effects of pessary use?
- What are the predictors of a successful fitting?
- What is the best evidence for the method of inserting different types of pessaries?
- What is the best evidence for follow-up and by whom?
- What are the current recommended measures of outcome from pessary use for pelvic organ prolapse?

2.2. Search

Database search

Two keywords were used in the search. Articles that were published from 2000 onwards and in the English language were sought.

Keyword 1

- Pelvic organ prolapse OR vaginal prolapse OR prolapse OR genital prolapse.

Keyword 2

- Pessary

The following databases were searched:

- OVID Database including: Embase (1996 to 2010), AARP Ageline, AMED, OVID Medline (1950 to Dec 2009), Ovid nursing database
- Cinhal

Secondary search

In addition to conducting the electronic database search, some of the key websites (i.e. Continence Foundation of Australia, the International Continence Society) were searched in relation to pelvic organ prolapse. On the International Continence Society website (http://www.icsoffice.org/ASPNET_Membership/Membership/Home.aspx) two key publications were identified; 'Incontinence 4th International Consultation on Incontinence, Paris July 5-8 2008 (4th Edn)' and 'An International Urogynecological Association (IUGA)/International Continence Society (ICS) joint report on the terminology for female pelvic floor dysfunction' (Haylen et al 2010). Several relevant chapters from the first publication and the reference list of the second publication were searched to identify other relevant studies. There were no date restrictions considered when conducting the secondary search.

A consort diagram of the search results is provided in Appendix E (Figure A). In summary, there were 82 articles identified from the databases as potentially being suitable for inclusion. Of these 82 articles, 15 were duplicates, 6 were excluded as upon review of the full-text they did not meet the inclusion criteria and 12 were unable to be located in full-text within the specified timeframe. Thus there were 49 papers identified as relevant and available in full-text from the database search. The secondary search identified 45 articles that were potentially relevant and available in full-text. Thus there were a total of 94 papers that were used to inform the development of the guidelines, by answering the review questions. A complete list of all the included papers is available in Appendix E. Appendix F contains a

complete list of all references that were used to inform the development of this guideline, including the methodology and background chapters.

2.3. Data extraction and critical appraisal

Data extraction was undertaken using excel spreadsheets. The papers were reviewed and their study design noted (see Appendix E Table A) to interpret the strength of the evidence. There were very few high level studies such as systematic reviews or randomised controlled trials. The majority of the papers were case-studies or opinion pieces. No critical appraisal of these papers was undertaken because of their low-level on the evidence hierarchy.

2.4. Wording

The extracted data was synthesised into themes that would form the structure of The Pessary Guidelines; background, management, types of pessaries and selection, fitting and care. The format of The Pessary Guidelines includes background text which supports the evidence statements, as well as the practice points which were framed by the Expert Working Party.

2.5. Expert Working Party

The Expert Working Party (see Chapter 1 for membership) reviewed drafts of The Pessary Guidelines, and informed the wording of the Evidence Statements and the Practice Points. The Expert Working Party comprised representatives of the health professional target users, and thus provided input into these guidelines from their discipline/expertise perspectives. They layered the evidence with expert opinion when there were gaps in the evidence, or when it required operationalisation. This allowed the evidence to be contextualised and/or operationalised for Australian clinical practice. Contentious issues were debated within the Expert Working Party, and agreement was facilitated by the Chair, who represented the *i*CAHE methodology team.

2.6. Evidence statements

Where evidence statements were able to be made on the basis of current peer-reviewed literature, these statements were framed to reflect a synthesis of the available evidence. The relevant references are cited for each evidence statement, along with the level of evidence for each study, using the appropriate NHMRC hierarchy (Merlin et al 2009).

2.7. Practice Points

Practice points represent the Expert Working Party position on contextualising and operationalising evidence statements, or defining best practice where the evidence is insufficient. These practice points represent the consensus viewpoints of the Expert Working Party.

Section 3: Background to pelvic organ prolapse

3.1. What is pelvic organ prolapse?

Pelvic organ prolapse refers to loss of support for the pelvic organs (bladder, uterus, bowel) and their descent into the vagina. The following definitions are extracted from the International Urogynecological Association (IUGA)/International Continence Society (ICS) Joint Report on the Terminology for Female Pelvic Floor Dysfunction (Haylen et al 2010).

The sign of pelvic organ prolapse is defined as the descent of one or more of the anterior vaginal wall, posterior vaginal wall, and apex of the vagina (cervix/uterus) or vault (cuff) after hysterectomy. The presence of any such sign should be correlated with relevant pelvic organ prolapse symptoms. Most commonly this correlation relates to the level of the hymen or beyond.

Types of prolapse (Haylen et al 2010)

1. **Uterine/ cervical prolapse:** Observation of descent of the uterus or uterine cervix.
2. **Vaginal vault (cuff scar) prolapse:** Observation of descent of the vaginal vault (cuff scar after hysterectomy).
3. **Anterior vaginal wall prolapse:** Observation of descent of the anterior vaginal wall. Most commonly this would be due to bladder prolapse (cystocele, either central, paravaginal or a combination). Higher stage anterior vaginal wall prolapse will generally involve uterine or vaginal vault (if uterus is absent) descent. Occasionally, there might be anterior enterocele formation after prior reconstructive surgery.
4. **Posterior vaginal wall prolapse:** Observation of descent of the posterior vaginal wall. Most commonly, this would be due to rectal protrusion into the vagina (rectocele). Higher stage posterior vaginal wall prolapse after prior hysterectomy will generally involve some vaginal vault (cuff scar) descent and possible enterocele formation. Enterocele formation can also occur in the presence of an intact uterus.

Pelvic organ prolapse occurs most commonly in the anterior compartment, then in the posterior compartment and least commonly in the apical compartment (Milsom et al 2009).

The preference of the International Consultation on Incontinence (ICI) to describe the aspect of the vaginal wall which is prolapsing rather than to use the term cystocele or rectocele, highlights the difficulty for the clinician in knowing which organ has descended (Staskin et al 2009a).

Web links to exemplar diagrams of prolapse are provided in Appendix C.

Prolapse symptoms are a departure from normal sensation, structure or function, experienced by the woman in reference to the position of her pelvic organs. Symptoms are generally worse at the times when gravity might make the prolapse worse (e.g. after prolonged periods of standing or exercise) and better when gravity is not a factor (e.g. lying supine). Prolapse may be more prominent at times of abdominal straining (e.g. defecation). Pelvic organ prolapse may co-exist with symptoms of both urinary and faecal incontinence. Symptoms are typically:

1. **Vaginal bulging:** Complaint of a "bulge" or "something coming down" through the vaginal introitus. The woman may state that she can either feel the bulge by direct palpation or see it aided with a mirror.
2. **Pelvic pressure:** Complaint of increased heaviness or dragging in the suprapubic area, perineum and/or pelvis.
3. **Bleeding, discharge, infection:** Complaint of vaginal bleeding, discharge or infection related to dependent ulceration of the prolapse.
4. **Splinting/digitation:** Complaint of the need to digitally replace the prolapse or to otherwise apply manual pressure, e.g. to the vagina or perineum (splinting), or rectally (digitation) to assist voiding or defecation.
5. **Low backache:** Complaint of low, sacral (or "period-like") backache associated temporally with pelvic organ prolapse.
6. **Other symptoms** can include urinary hesitancy, slow urine stream, history of recurrent urinary tract infections, post-defaecation soiling.

(Extracted from Haylen et al 2010)

3.2. Measurement of pelvic organ prolapse

Several methods of quantifying pelvic organ prolapse have been described. The ICI-recommended method of pelvic organ prolapse quantification (POP-Q) is used in these Guidelines (Bump et al 1996). The POP-Q provides a system for describing and quantifying the descent of the vaginal walls within the pelvis and an objective method for staging pelvic organ prolapse. Validation of the POP-Q system has shown it to be highly reliable (Hall et al 1996), including when performed by a nurse (Kobak et al 1996) and by physiotherapists (Stark et al 2010). The descent of specific segments of the reproductive tract is measured during maximal valsalva strain relative to a fixed point, the hymen. The POP-Q system is further described in detail by Bump et al (1996). The stages of pelvic organ prolapse are described below.

The following description is taken from Haylen et al (2010), from which illustrations of POP-Q staging can be sourced.

POP-Q staging

Stage 0: No prolapse is demonstrated.

Stage I: Most distal portion of the prolapse is more than 1cm above the level of the hymen.

Stage II: Most distal portion of the prolapse is 1 cm or less proximal to or distal to the plane of the hymen.

Stage III: The most distal portion of the prolapse is more than 1cm below the plane of the hymen.

Stage IV: Essentially complete eversion of the total length of the lower genital tract is demonstrated.

Evidence Statement

Health care providers should determine the stage of pelvic organ prolapse for each patient prior to treatment.

Level of Evidence: Expert Opinion (Haylen et al 2010).

3.3. Measurement of symptom severity and impact on quality of life

The POP-Q describes anatomic findings but objective assessment does not always correlate with symptoms or the degree of bother perceived by the woman (Milsom et al 2009; Cundiff et al 2007; Staskin et al 2009b). A patient's awareness of an actual bulge has the highest correlation with pelvic organ prolapse severity (Cundiff et al 2007) and has high positive and negative predictive values for stage III or IV prolapse (but not the affected compartment of the prolapse) (Payne et al 2009). Protrusion of the leading edge 0.5 cm distal to the hymen accurately predicts bulging/protrusion symptoms but there is not a degree of descent which predicts other pelvic floor symptoms (Payne et al 2009).

Evaluation of symptom severity, impact of the prolapse on quality of life (QoL) and sexual function using valid and reliable measures is recommended in clinical practice, although no specific outcome measures have been identified (Staskin et al 2009b). The ICI Questionnaire specific to vaginal symptoms (ICIQ-VS) covers a range of vaginal symptoms associated with pelvic organ prolapse, including sexual function, but does not ask about bladder or bowel symptoms (Price et al 2006). The Pelvic Organ Prolapse Symptom Score (POPSS) (Hagen et al 2009b) and Pelvic Floor Distress Inventory (PFDI-20) (Barber et al 2005) include questions about vaginal, bladder and bowel symptoms but not sexual function. It is suggested that patient goals are assessed prior to pessary management e.g. with the Patient Specific Functional Scale (PSFS). The Australian Pelvic Floor Questionnaire (Baessler et al 2009) is a comprehensive pelvic floor questionnaire, tested for validity and reproducibility, and suitable for self- administration. It includes questions about pelvic organ prolapse and sexual function. The Pelvic Organ Prolapse/Urinary Incontinence Sexual Questionnaire (PIS-Q) (Rogers et al 2003) can be used to specifically evaluate sexual function but its validity remains to be established. It is suggested that patient goals are assessed prior to pessary management e.g. with the Patient Specific Functional Scale (PSFS) (Stratford et al 1995).

Practice point

Health care providers should measure the outcomes of treatment from pessary use for each patient using a validated questionnaire. The following Patient Reported Outcome Measures are appropriate for use by clinicians:

- ICIQ-Vaginal Symptoms
- Pelvic Organ Prolapse Symptom Score
- PFDI-20
- Australian Pelvic Floor Questionnaire.

Copies of these outcome measures, which are freely available, are provided in Appendix D.

3.4. What are the prevalence, incidence and risk factors for pelvic organ prolapse?

There is scant published information about the prevalence of pelvic organ prolapse in the Australian population. McLennan et al (2000) found the prevalence of pelvic organ prolapse to be 8.8% in a population of 3010 randomly sampled adult South Australians, based on the symptom of "something coming down in the vagina", with the highest prevalence among women aged 50-70 years of age. A history of bladder, uterine, vaginal and bowel repairs was found in 9.4%, 3.1% and 11.2% respectively of the females surveyed. By contrast, in a Dutch community-dwelling female population, the prevalence of clinically relevant pelvic organ prolapse, based on the symptom of "something at or bulging beyond the hymen" was 21% (Slieker-ten Hove et al 2009). Some degree of pelvic organ prolapse is thought to be common in women of all ages, with the following prevalence found in a broad population of women in the United States: Stage 0 24%, Stage I 38%, Stage II 35%, Stage III 2%, Stage IV 0% (Swift 2005).

Prolapse symptoms may vary over time in an individual. Incidence rates over eight years of new anterior wall, posterior wall and uterine prolapse of 9%, 6% and 2% have been reported. Remission of pelvic organ prolapse has also been reported with annual remission rates of 24%, 22% and 48% for each type of prolapse proximal to the introitus but less common (9%, 3% and 0% respectively) for prolapse when the prolapse extended beyond the introitus (Handa et al 2004). One and three year incidence rates of 26% and 40% were found in a population of community-based postmenopausal women. However, prolapse symptoms resolved in some of these symptomatic women, with remission rates at one and three years of 21% and 19% respectively (Bradley et al 2007). As there are no reports on the natural history of pelvic organ prolapse in Australian women, the generalisability of these data to the Australian population is not known.

The aetiology of pelvic organ prolapse is considered to be multifactorial. Pelvic organ prolapse is strongly associated with vaginal birth but other risk factors include pregnancy, lifestyle and socio-economic factors which expose women to raised intra-abdominal pressure such as chronic constipation, chronic coughing, obesity, heavy lifting, prolonged standing and increasing age (Milsom et al 2009). Recently childbirth trauma, resulting in rupture of the puborectal muscle from the pubic rami, has been identified as a risk factor for anterior vaginal wall prolapse (Dietz & Simpson 2008; Morgan et al 2010).

Furthermore, genetic predisposition, connective tissue disorders, ethnic background, hysterectomy and surgery for pelvic organ prolapse have been causally associated with the development of pelvic organ prolapse.

Section 4: Management of pelvic organ prolapse

There are a number of treatments reported in the literature for pelvic organ prolapse. The Pessary Guidelines deal with the use of pessaries, however for completeness it outlines other forms of treatment.

4.1. Conservative Management

Pessaries

A pessary is a device inserted into the vagina to support the walls and related pelvic organs (Hay-Smith et al 2009). The modern pessary may be made of silicone, rubber, or plastic but silicone has advantageous properties of having a long half-life and resistance to autoclaving and repeated cleaning. Silicone also has non-absorbent properties in relation to secretions and odours, it is inert and hypoallergenic (Shah et al 2006). Although pessaries are apparently widely used, there is little high level evidence about their efficacy in treating pelvic organ prolapse (Adams et al 2004).

According to a US survey, 77% of gynaecologists in the US prescribe pessaries as first-line therapy for women with pelvic organ prolapse (Cundiff et al 2000), although training in pessary use is limited (Bash 2000). Similarly in the UK 86.7% of obstetricians and gynaecologists surveyed, prescribed pessaries in the management of pelvic organ prolapse (Gorti et al 2009). Pessaries are considered to be a relatively safe method of managing pelvic organ prolapse without serious side effects (Atnip 2009; Hanson et al 2006; Vierhout 2004; Gorti et al 2009; Fernando et al 2006; Sitavarin et al 2009). The practices of Australian gynaecologists with respect to pessary prescription have not been reported.

There are several reports supporting the role of nurses in the provision and management of pessaries in primary care (Hanson et al 2006; Kuhn 2009; Richardson & Hagen 2009; Nguyen et al 2005) but none to date where physiotherapists have been involved in the prescription and fitting.

Pelvic floor exercises

Despite the strong evidence for pelvic floor muscle training for the treatment of stress urinary incontinence, high quality evidence to support the role of pelvic floor muscle training for the management of pelvic organ prolapse is only just emerging (Dumoulin & Hay-Smith 2010; Braekken et al 2010; Piya-Anant et al 2003; Jarvis et al 2005; Hagen et al 2009a). There is recent evidence from two high quality randomised controlled trials that pelvic floor muscle training can reduce the stage and

symptoms of pelvic organ prolapse in some women (Braekken et al 2010; Hagen et al 2009a). Currently the international, multicentre POPPY (Pelvic Organ PhysiotherapY) trial is investigating the effects of pelvic floor muscle training compared with lifestyle management for women with pelvic organ prolapse (Hagen et al 2009a). A further PEPPY trial (PEssary Plus PhysiotherapY for Pelvic Organ Prolapse) is investigating the role of a pessary (fitted by a gynaecologist) with or without pelvic floor muscle training for the management of pelvic organ prolapse. Results from these trials are not yet available.

It is hypothesised that improved pelvic floor muscle strength may play a role in the prevention of pelvic organ prolapse but there is currently limited evidence from intervention studies to support the role of pelvic floor muscle training or other physical therapies in the prevention of pelvic organ prolapse (Hay-Smith et al 2009; Braekken et al 2010).

Lifestyle management

Lifestyle interventions aim to reduce the effect of raised intra-abdominal pressure which exacerbate prolapse symptoms. Such measures include weight loss, avoidance of heavy lifting and straining at stool caused by constipation and the management of chronic coughing. However at this stage, there is no evidence from intervention studies on the effect of lifestyle management for either the prevention or management of women with pelvic organ prolapse (Hay-Smith et al 2009).

The term 'expectant management' has been used to describe any management for pelvic organ prolapse other than surgery or pessaries and may include lifestyle management and pelvic floor muscle training (Heit et al 2003).

4.2. Surgery

Surgery has been the mainstay of prolapse management for many years, especially for symptomatic or advanced stages of prolapse. Women have a lifetime risk of surgery for pelvic organ prolapse of 11% by the age of 80 years (Thakar & Stanton 2002). Although there is increasingly high-quality evidence to guide surgical practice, the longevity of prolapse repairs remains unclear with some experts suggesting that re-operation for recurrent prolapse will be inevitable for some women (Brubaker et al 2009). Reports suggest that prolapse repair surgery may fail in 30% (Olsen et al 1997) to 58% (Whiteside et al 2004) of patients, with the anterior vaginal wall regarded as the most vulnerable to failure (Whiteside et al 2004). Failure of surgery is thought to be associated with increased intra-abdominal pressure (Weir et al 2006; Gerten et al 2008; Mouritsen & Larsen 2003) but other factors such as a wide levator hiatus and pelvic floor muscle weakness (Ghetti et al 2005) have also been identified. In contrast to conservative management, surgery also carries the attendant risks of serious complications (Brubaker et al 2009). To improve the longevity of surgery, synthetic mesh materials are increasingly being used but there is an increased risk of complications with these products and uncertainty about their long term functional outcomes (Brubaker et al 2009).

There are no common factors predicting which women will opt for pessary management or surgery. About two thirds of women choose conservative management rather than surgery (Kapoor et al 2009) but a third of women who initially desired surgery changed their mind and opted to continue pessary

use (Clemons et al 2004a). Reports suggest that previous prolapse surgery, more severe prolapse, the need for vaginal digitation and incomplete bowel emptying are factors associated with a choice of surgery over a pessary (Heit et al 2003; Kapoor et al 2009). Surgery was chosen if women were sexually active, and had more quality of life impairment due to sexual dysfunction (Kapoor et al 2009). However, increasing age increased the likelihood of a woman choosing a pessary rather than surgery (Heit et al 2003).

Section 5: Pessaries for pelvic organ prolapse

The following section outlines the evidence for different aspects of pessary use for pelvic organ prolapse.

5.1. Indications for pessary prescription and patient selection

Pessaries are widely considered to be a safe and effective management option for women with pelvic organ prolapse (Wu et al 1997; Fernando et al 2006; Atnip 2009; Bai et al 2005; Sitavarin et al 2009), including those with advanced pelvic organ prolapse (Powers et al 2004). However, women are only suitable for pessary management if they have been examined by an appropriate medical practitioner to exclude abdominal or pelvic pathology as a cause of the prolapse (Abrams et al 2009). There are groups of women for whom a pessary may be particularly suitable, as indicated below. The main contra-indication is the likelihood of non-compliance with follow-up, which is mandatory to avoid complications (Atnip 2009; Bordman et al 2007; Sarma et al 2009; Fernando et al 2006; Bai et al 2005). Women whose preference is for surgery at the time of pessary fitting are more likely to discontinue pessary use (Clemons 2004a).

Evidence Statement

It is important to consider the small percentage of women in whom serious pelvic or abdominal pathology is associated with their POP. Thus women with POP should be referred to a GP or gynaecologist for pelvic/abdominal examination

Evidence source: Opinion (Abrams et al ICI 2009)

Evidence Statement

Pessaries are a first-line management option for women with pelvic organ prolapse. In particular, pessary prescription is appropriate for women:

- with symptomatic pelvic organ prolapse
- who decline surgery
- who are unfit for or awaiting surgery
- who have failed surgery
- who have not completed childbearing
- who are pregnant or postpartum
- who are of older age and with co-morbidities.

Evidence sources: Level III-3 (Bai et al 2005; Fernando et al 2006; Wu 1997); Level IV (Sarma et al 2009); Opinion (Atnip 2009; Bordman et al 2007; Clemons 2004a)

Evidence Statement

Patient selection - Women should be assessed on a range of factors regarding their suitability for pessary management, including:

- willingness for self-management and regular follow-up
- intact cognition
- physical mobility and manual dexterity.

Evidence sources: Level I: (Thakar & Stanton 2002); Level III-2 (Kuhn 2009); Opinion (Vierhout 2004; Bash 2000; Bordman & Telner 2006; Viera & Larkins-Pettigrew 2000)

Evidence Statement

Contra-indications for pessary use are:

- active vaginal infection
- pelvic inflammatory disease
- undiagnosed vaginal bleeding
- when follow-up cannot be assured.

Evidence sources: Level III-3 (Bai et al 2005; Fernando et al 2006); Level IV (Sarma et al 2009); Opinion (Atnip 2009; Bordman et al 2007)

Pessary use for patients with dementia

The use of pessaries for patients suffering dementia is unclear.

Practice Point

The Expert Working Party considers that pessaries should only be fitted as an emergency procedure by an appropriately trained health professional for a patient with dementia where informed consent has been obtained from the legal guardian/medical power of attorney. The procedure should trigger an immediate specialist review. Self-care is not appropriate in this group of patients.

5.2. Successful fitting

There is no agreed definition of a successful fit. However, a pessary is deemed to fit when the following criteria are met:

Evidence Statement

A successful fit is when the:

- biggest pessary is comfortably retained during upright, provocative activities such as walking, squatting, valsalva and coughing
- pessary is not felt by the woman and does not cause any pain or discomfort
- pessary does not obstruct bladder or bowel emptying
- pessary does not provoke occult urinary incontinence.

Evidence sources: Level III-2 (Clemons et al 2004b); Level III-3 (Fernando et al 2006; Maito et al 2006; Wu et al 1997); Level IV (Hanson et al 2006); Opinion (Bash 2000)

Reports of successful fitting at the first consultation vary from 74% - 94% (Wu et al 1997; Clemons et al 2004b). Cundiff et al (2007) reported successfully fitting 92% of women at the first visit. However, several trials may be required to find the best fit. For those women who have not retained the pessary or when the pessary is uncomfortable or causes low abdominal pain, a further trial with a different size or type of pessary is recommended (Wu et al 1997; Jones et al 2008). Reports suggest that 76% of women can be successfully fitted at the follow-up visit (average 1.5 (range 1-4) pessaries). If occult urinary incontinence is provoked, an incontinence pessary may be tried, but these are outside the scope of this document. In this case, referral to a suitable medical practitioner is indicated to exclude other issues such as obstructed voiding.

The number of women continuing to use a pessary reduces with time (Cundiff et al 2007; Clemons et al 2004a, Wu et al 1997; Fernando et al 2006; Nguyen et al 2005). One study suggests that 66% of women using a pessary at 1 month continued for 1 year and 53% of these continued for 3 years (Wu et al 1997). There are few studies reporting pessary use over longer periods, but one suggests a very low rate of continued use over 14 years (Sarma et al 2009).

Practice Point
The Expert Working Party indicates that pessaries should be used with caution and medical supervision is advised in patients

- with mesh implants
- on warfarin or potent antiplatelet therapy due to increased risk of bleeding.

5.3. Factors predicting success

Success or failure will depend on appropriate pessary selection, patient characteristics, provider training and experience, thorough counselling, as well as the achievement of an adequate fit and patient satisfaction (Atnip 2009; Sitavarin et al 2009).

Patient factors

There is little agreement in the literature regarding factors such as patient age, parity, obesity or hormone use predicting a successful pessary fitting (Mutone et al 2005; Wu et al 1997; Friedman et al 2010; Hanson et al 2006; Clemons 2004c; Nguyen et al 2005).

The following factors have been reported in some studies as negatively impacting on the likelihood of successful fitting:

- short vaginal length (=/<6cm) (Clemons et al 2004c)
- wide vaginal introitus (>4 finger width) (Clemons et al 2004c)
- prior hysterectomy (Maito et al 2006; Fernando et al 2006)
- prior vaginal prolapse surgery (Maito et al 2006; Wu et al 1997; Hanson et al 2006; Nguyen et al 2005)
- severe posterior vaginal prolapse (Maito et al 2006; Mutone et al 2005)
- stress urinary incontinence (Nguyen et al 2005).

Others have found that the stage of prolapse (Friedman et al 2010; Komesu et al 2007; Mutone et al 2005; Clemons et al 2004c; Nguyen et al 2005; Powers et al 2004), predominant compartment (Mutone et al 2005) and genital hiatus size (Mutone et al 2005) did not predict successful fitting.

Women were less likely to continue pessary use if there was pre-existing (Nguyen et al 2005), or de novo urinary incontinence and if they expressed a desire for surgery at the first visit (Clemons et al 2004a). However, even in women who opted for pessary use rather than surgery, and were successfully fitted, half had discontinued pessary use by 24 months (Nguyen et al 2005). Pessary use was found to improve sexual function in some women (Fernando et al 2006; Kuhn et al 2009) and to be acceptable long-term in sexually active women (Brincat et al 2004).

Levator childbirth trauma e.g. unilateral or bilateral avulsion injuries, is associated with pelvic organ prolapse (Dietz 2008; Morgan et al 2010) but no studies to date have considered whether the presence or severity of these defects influences the successful fitting of one type of pessary over another.

Achievement of at least one of a patient's pre-selected goals in terms of pelvic floor symptoms was associated with continued pessary use at 6 and 12 months (OR 17.5) and with symptom relief on a Patient Global Impression of Improvement Scale (PGI-I) (Komesu et al 2008).

Practice Point

There are no factors which will absolutely predict the successful fitting of a pessary.

Oestrogens

There is no high level evidence to guide the prescription of local oestrogens when fitting pessaries, although they are commonly prescribed by gynecologists (Cundiff 2000) and by GPs in clinical practice (Bordman et al 2007; Bordman & Telner 2007). Local oestrogen is thought to be important in preventing complications due to erosions and infections (Arias et al 2008). Local oestrogen may be prescribed and used for several weeks prior to fitting, especially if the vaginal tissues are atrophied or at the time of fitting in postmenopausal women (Sarma et al 2009; Arias et al 2008; Farrell 2006). Progestogen is not generally indicated with the administration of low-dose vaginal oestrogen cream (NAMS 2007).

Practice Point

The Expert Working Party advocates the prescription of vaginal oestrogen therapy (pessary or cream) either prior to or at the time of fitting in post menopausal women or with women with vaginal atrophy.

In women with a history of breast cancer, communication with the patient's breast surgeon is advised to seek clarification about the appropriateness of topical oestrogen.

Discontinuation

The most common reasons for discontinuation of pessary use are:

- desire for surgery
- development or persistence of incontinence
- failure to retain the pessary
- inadequate support of prolapse
- dislike of the changing procedure
- discomfort
- pain
- vaginal discharge.

Practice point

Heath care providers need to be aware of the factors that can lead to the discontinuation of pessary use and to monitor progress in order to provide options to promote their continued use.

5.4. Symptom relief and patient satisfaction

Several studies have used validated questionnaires to investigate change in symptoms of pelvic organ prolapse (Kuhn et al 2009; Cundiff et al 2007; Komesu et al 2007; Fernando et al 2006). Both the ring-with-support and Gellhorn pessaries provided symptom relief across all domains of the PFDI-20 and the PFIQ-7 questionnaires (Cundiff et al 2007). Symptom relief measured on the PFDI-20 was reported by women successfully fitted with pessaries and was associated with continued pessary use (Komesu et al 2007). Symptoms of posterior vaginal wall prolapse may be relieved by both ring and Gellhorn pessaries (Cundiff et al 2007), contradicting anecdotal reports that they are not effective for posterior vaginal wall prolapse (Cundiff et al 2000).

5.5. Morphological changes associated with pessary use

There are suggestions in the literature that pessaries may prevent progression of a prolapse or result in improvement in the severity (Shah et al 2006). One study reported improvement in POP-Q stage in all women after one to four years of pessary use, with no deterioration in the stage of prolapse reported in any of the women (Handa & Jones 2002).

Change in genital hiatus size after three months of pessary use has been observed. There was a decrease in hiatus size from 4.8cm to 4.1 cm at two weeks after fitting and a further decrease to 3.9cm at three months. Changes were most marked with the Gellhorn pessary (Jones et al 2008).

Evidence statement

Pessaries change the vaginal dimensions and may prevent the progression of pelvic organ prolapse.

Level of Evidence: Level I (Shah et al 2006); Level III-3 (Handa & Jones 2002; Jones et al 2008)

5.6. Side effects and complications

Pessaries are generally considered to be a safe management option for women with pelvic organ prolapse with few complications. Complications are generally minor although complications have been reported in as many as 56% of a series of patients over 14 years (Sarma et al 2009). However, the Expert Working Party noted that complications were more frequent in long term users. A high rate (71.3%) of complications was found in a series of high-risk patients but complications were generally considered to be minor and the women reported a high level of satisfaction (70.2%) (Bai et al 2005). Serious complications have generally been associated with neglected pessaries although erosion has also been reported in a woman after only two months of pessary use (Arias et al 2008).

Practice point

Health care providers should record side effects or complications of pessary use.

The vaginal pH is normally mildly acidic (pH3.8 – 4.5) due to the presence of lactobacilli, which inhibit the growth of coccoid bacteria. The presence of a foreign body such as a pessary in the vagina can cause a change in the pH with the growth of excessive numbers of coccoid bacteria, leading to bacterial vaginosis. A significantly higher rate of bacterial vaginosis has been reported in pessary users (32%) compared with controls (10%) (OR 4.37 (95% CI 2.15-9.32) (Alnaif & Drutz 2000). While bacterial vaginosis may be asymptomatic, the presence of a copious, foul-smelling discharge is indicative of its presence and treatment is necessary as complications are potentially serious (Alnaif & Drutz 2000).

Evidence Statement

A swab must be taken of any discharge which is discoloured, foul-smelling or bothersome to diagnose and treat bacterial vaginosis.

Level of Evidence: Level III-2 (Alnaif & Drutz 2000)

Practice Point

The Expert Working Party recommends that where a health professional does not have the service/facility available to take a vaginal swab, patients should be referred to a medical practitioner.

Common complications:

- mild vaginal discharge
- constipation
- erosion
- vaginal bleeding
- denovo or worsening urinary incontinence.

More serious but less common complications, generally occurring when patients do not attend for regular follow-up, include:

- severe vaginal discharge associated with infection e.g. bacterial vaginosis
- urological complications associated with more severe prolapse (Arias et al 2008)
- cervical incarceration (by a ring pessary) (Hassler & Michael 2005; Yu & Chung 2004)
- septicaemia (Wheeler et al 2004)
- impacted-embedded pessaries, causing vesicovaginal or rectovaginal fistulae (Arias et al 2008; Roehl & Buchanan 2006)
- vaginal or cervical cancer (Arias et al 2008).

Practice Point

Common side effects, such as mild erosion, vaginal discharge and constipation, are minor in nature and generally respond to treatment. Erosion should be managed by removal of the pessary and use of topical oestrogen until the lesion has resolved. However, health care providers should be aware of the potential for more serious complications from pessary use and therefore should monitor patient

Section 6: Pessary selection, fitting and care

6.1. Pessary selection

The ring pessary (with or without support) is often advocated for the initial fitting as it is considered to be easier for women to remove and reinsert themselves (ACOG 2007; Wu et al 1997; Clemons et al 2004b; Komesu et al 2007; Fernando et al 2006; Hanson et al 2006; Jones et al 2008). One trial found that 70% of women could be fitted successfully with a size 64mm, 70mm, 76mm ring pessary (2-3 trials were often needed) (Wu et al 1997). However, in a clinical controlled trial, the ring-with-support and

Gellhorn were used with equal success for all types and stages of prolapse (Cundiff et al 2007). A Gellhorn or cube is often advocated for stage III or IV prolapse (Roehl & Buchanan 2006; Clemons et al 2004a) with Gellhorn sizes 64mm, 70mm, 76mm most commonly used (Atnip 2009; Clemons et al 2004c). However, cube pessaries have been used for any type or grade of prolapse with 44% of women continuing use at 12 months (Kuhn et al 2009). Other types of pessary are used at the discretion of the health care provider.

Three commonly used pessaries are discussed in this section; ring, Gellhorn and cube.

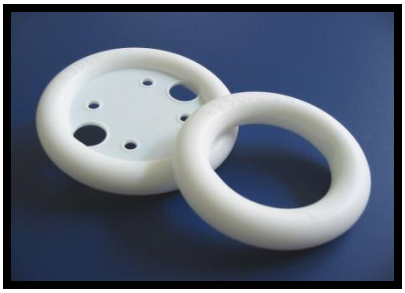


Figure 1. Ring pessary with and without support

Figure 2 Gellhorn pessary

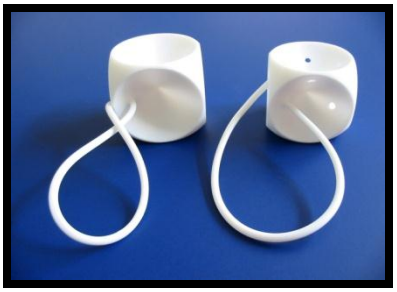


Figure 3. Cube pessary

Figures reproduced with permission from Sayco Pty Ltd distributers of Bioteque pessaries in Australia

Ring pessary

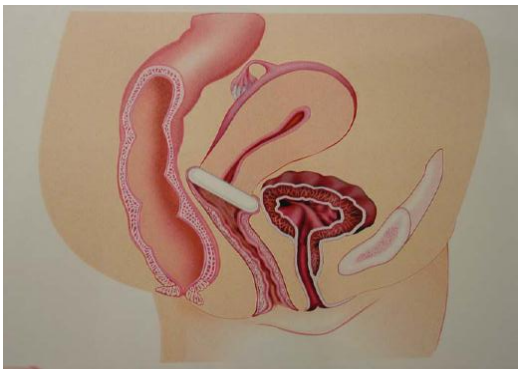


Figure 4 Ring pessary inserted. *Reproduced with permission from Bioteque /H. Carcio*

With and without central support diaphragm.

- Easiest to use for provider and user
- Can be used for any type of prolapse
- Intercourse is generally possible
- Sizing varies with the brand of pessary (Sizes 0-9: approx. 44mm-101mm).

Gellhorn pessary

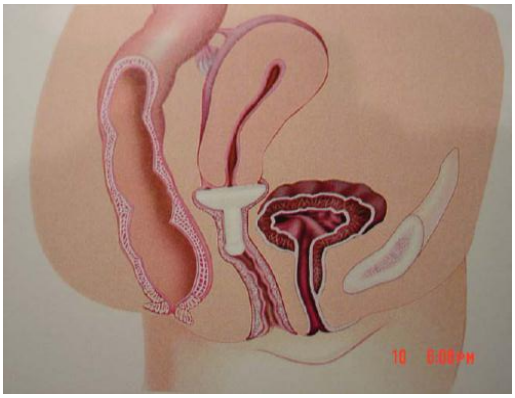


Figure 5 Gelhorn pessary inserted. *Reproduced with permission from Bioteque/H. Carcio*

- A space-filling pessary with a wide base and either a long or short stem
- The base creates suction onto the vaginal walls so that it stays in place without relying on the symphysis to keep it in place
- The cervix rests in the concave upper surface of the base, while the knob at the end of the stem rests on the posterior vaginal wall and perineal body
- Can be difficult for the inexperienced provider and user to insert and remove. Sponge or ring forceps can be used to facilitate removal
- Useful for all types of prolapse
- Must be removed for intercourse, which makes them less suitable for sexually active women
- Sizing varies with the brand of pessary (Sizes 0-8: approx. 38mm-89mm).

Cube pessary

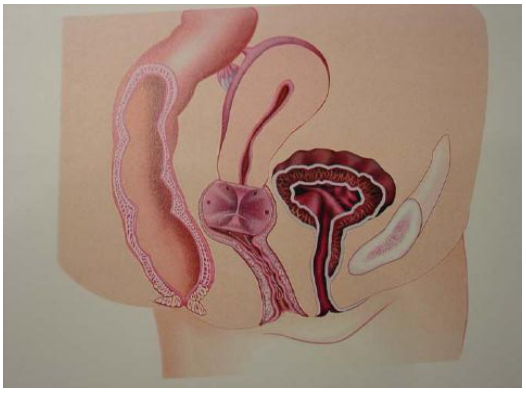


Figure 6 Cube pessary inserted. *Reproduced with permission from Bioteque/H. Carcio*

A space-filling pessary in the shape of a uniform square with six concave surfaces. It comes with perforations to allow passage of some vaginal secretions and with a loop, like a tampon string, to locate it and assist removal.

- The concave surfaces provide suction onto the vaginal walls to hold it in place
- Must be removed for intercourse
- Should be removed nightly (Bash 2000)
- It may be difficult to insert and remove (Atnip 2009; Farrell 2006)
- Sizing varies with the brand of pessary (Sizes 0-10: approx. 25mm-75mm).

Practice Point

- There are no patient characteristics to help guide the selection of the type or size of pessary for a particular women, although previous vaginal repair may make fitting more difficult
- The provider should use trial and error, expert opinion and past experience as a guide
- For novice practitioners:
    - For Stage I or II pelvic organ prolapse initially fit/use a ring pessary
    - For Stage III or IV pelvic organ prolapse or if a ring pessary has failed, fit/use a Gellhorn pessary
- Stage III and IV pelvic organ prolapse should trigger a specialist review.

If a woman is considered to be a suitable candidate for a pessary, she should:

- be fully informed about the benefits, risks, need for long term follow-up, and be an active participant in the process (Vierhout 2004; Bash 2000)
- be shown the pessary and allowed to handle and bend it
- be shown how it will sit in the body using pelvic diagrams or models
- be prescribed local oestrogens prior to fitting in the case of atrophic or scarred vaginal tissues
- give informed consent (Anders 2004).

Procedure

1. To assist in selection of the pessary style and size, estimate the vaginal dimensions:

    a) Determine the vaginal width; spread the index and middle fingers horizontally high in the upper vagina.

b) Determine vaginal length: palpate the posterior fornix (or vaginal vault in the absence of the cervix) with the index or middle finger and estimate the distance to the pubic symphysis.
c) Then visually compare the mental image of the vaginal vault size and shape with the actual pessaries, trying the pessary that most closely represents the visual image (Atnip 2009).

2. Wash the pessary in soap and water to remove any corn starch used for packaging.

3. Apply water-based lubricant to the leading edge of the pessary, or to the introitus, to make insertion easier, but avoid lubricant on the gloved hand holding the pessary.

4. Separate the labia and insert the pessary at the introitus and, with gentle pressure, slide it up the posterior vaginal wall. Ease the pessary right up into position in the upper part of the vagina and behind the pubic symphysis (Atnip 2009).

5. If it is difficult to fit a pessary e.g. in the case of very advanced prolapse, two pessaries may be tried together e.g. two ring pessaries (Vierhout 2004).

Note

- Specific instructions for different types of pessaries can be found in Appendix A
- Silicone pessaries can be autoclaved but manufacturers' instructions, which may indicate "Single Patient Use", should be followed
- Fitting kits, which allow for re-use after sterilizing, are available from manufacturers (Qureshi 2008)
- Manufacturers' reference guides can be used to cross-reference pessary types and sizes
- If several pessaries are tried and the skin is atrophic, topical oestrogen should be continued and fitting delayed. Lidocaine ointment/gel can also be used on the vaginal introitus to reduce discomfort.

Practice Point

The Expert Working Party acknowledges that, while manufacturers' instructions may state that pessaries are "Single Patient Use" items, routine clinical practice in Australia may allow for re-use of silicone pessaries after sterilization.

To test for correct fit

1. Ask the woman to cough and valsalva in dorsal lithotomy or bent knee lying position. A correctly sized pessary may descend in the vagina, however it should recede on relaxation.

2. Ask the woman to stand up and walk around. There should be no discomfort and it should not be expelled with coughing, Valsalva, bending or squatting.

3. A larger size or different type should be tried if it is nearly or completely expelled.

4. A smaller size or different type should be tried in the event of discomfort in the vagina or low abdominal pain.

5. A vague sensation of discomfort or irritation may be due to irritation from the actual fitting procedure. Clinical judgment will determine whether removal and refit is necessary.

6. Ask the woman to void. Ideally, the Post Void Residual (PVR) should be checked with ultrasound to ensure that there is no significant residual urine due to obstruction (McIntosh 2005; Hanson et al 2006). If symptoms of voiding dysfunction are reported, the patient should be referred for an ultrasound scan. A PVR of <100 ml is recommended by the Expert Working Party.

***Note**:*
A correctly fitted pessary (Atnip 2009):

- Should not be tight against the vaginal walls
- Should have enough room to allow a fingertip between the edges and the vaginal wall (Vierhout 2004) or to be able to rock it
- Should be retained and not felt by the woman at rest or on standing, sitting, walking around, squatting or coughing (Roehl & Buchanan 2006; Thakar & Stanton 2004)
- Should not dislodge during voiding.

6.3. Self-care

Self-care consists of periodic removal of the pessary for cleaning and replacement. While some authors suggest nightly or weekly removal (Bash 2000), there is no research to support an optimum routine, so self-care should be individualised (Atnip 2009). Manufacturer's instructions should be followed although some authors suggest that this can be varied on assessment of individual needs (Wu et al 1997). Women at high risk of pelvic organ prolapse or recurrence of pelvic organ prolapse such as women engaging in heavy lifting, regular but intermittent high impact sport or women with periodic exacerbation of chronic coughing may only need to use a pessary during times of increased risk.

Self-care is widely advocated to reduce the possibility of complications as the pessary can be cleaned and left out overnight or for longer intervals before re-insertion (Wu et al 1997; Hanson et al 2006; Bash 2000; Kuhn et al 2009; Vierhout 2004; Roehl & Buchanan 2006; Bordman & Telner 2007). While some authors consider that the Gellhorn and cube pessaries are more difficult to self-manage (Clemons et al 2004b), others report that Gellhorn (Atnip 2009) and cube (Kuhn et al 2009) pessary users can be taught self-care satisfactorily. Patients may be more ready to perform self-care when they realise that they do not need to attend for more frequent office visits (Atnip 2009).

Practice Point

- Self-care can be individualised and is best taught at second visit or whenever a successful fit has been achieved
- The woman should be reassured that the pessary "can't go anywhere". Illustrations of the vagina help to reassure her
- Have the patient wash her hands, assume a comfortable position, standing with knees bent or one knee up, or supported lying
- Show her how to insert and then remove the pessary herself, ensuring correct placement
- The pessary should be removed regularly e.g. once a week (or more often if indicated by manufacturer's instructions), washed, dried and reinserted
- Further advice about self-care is to be found in Appendix B: 'Patient Information Sheet'

Practice Point

It is time consuming to educate patients and to teach them self-care but a well educated patient is more satisfied with pessary treatment and more aware of potential problems and the need to seek professional help.

6.4. Recording

Enter the type and size of any pessary trialled in the woman's file and into a database to facilitate follow-up. (See page 31 for follow-up protocol). Provide the patient with a handout (See Appendix B) detailing the type and size of pessary, as well as care instructions, to facilitate ongoing care with other health care providers.

Practice point

Ensure that pessary details are appropriately recorded on provider's notes and practice database to permit regular monitoring.

Communicate management with other members of the patient's health care team as appropriate.

6.5. Follow-up

There is no consensus in the literature about the optimal frequency of care, although routine follow-up is mandatory due to the potential for side-effects and complications (Bordman & Telner 2007; Atnip 2009). Some have advocated follow-up at 2 weeks, then 3 monthly for the first year, and 6 monthly

thereafter (Wu et al 1997), while others have suggested 9-12 monthly follow-up as long as there are no adverse symptoms (Thakar & Stanton 2002).

- At the follow-up visit, ask about symptoms of vaginal bleeding, discharge, or odour that might indicate infection or erosion. Check for defaecation or voiding difficulty and any abdominal discomfort.
- Check the pessary for position and fit, then remove it and wash with soap and water.
- A speculum examination should look for evidence of abrasions or erosions caused by the pessary (Farrell 2006; Atnip 2009).
- If abrasions or erosions are found, the pessary should be removed and local oestrogens applied until healed. Salt baths or antibiotics may be indicated. Pessary management with a different size or type can be resumed. A swab will be indicated if a discoloured or foul-smelling discharge is present.
- If no abrasions or erosion are found and the pessary is intact and flexing normally, it can be washed under running water with soap, dried and reinserted (Farrell 2006).
- Modern pessaries are generally made of silicone, which makes them non-allergenic and able to be autoclaved (Bash 2000; Atnip 2009).
- Mild discharge and odour can be treated with vaginal acidifiers (Roehl & Buchanan 2006; Bash 2000).
- If vaginal oestrogen is contraindicated, a water-based gel may be used (Bash 2000).

Practice Points

- Regular follow-up of patients fitted with a pessary is mandatory (See protocol page 31).
- Patients should be alerted to contact the health practitioner immediately in the event of any symptoms.

The Expert Working Party suggests the following protocol for follow-up:

- All patients should be reviewed after 1-2 weeks to check the size and review any symptoms:
    - For women wishing to practise self-care, training can be given in insertion and removal at this or a subsequent session. If there are no symptoms, then review at 4 months and then annually.
    - For women <u>not</u> suitable for, or <u>not</u> willing to, perform self-care, review every 4-6 months for removal and refitting of the cleaned pessary. Speculum review at the time of pessary change may be performed by an appropriately trained and equipped CNA or C&WHP.
    - Annual review with speculum examination should be performed by a gynaecologist or GP with a special interest in Pelvic Floor Dysfunction.
    - A new pessary should be fitted when it cannot be satisfactorily cleaned e.g. due to a build-up of debris.
- Written communication with the patient's GP or gynaecologist is required.

Appendix A: Instructions for specific pessaries

Specific instructions are provided for three types of pessaries: the ring, Gellhorn and cube. For other types of pessaries, manufacturers' instructions should be followed. The following section has been collated from Atnip 2009; Farrell 2006; Bash 2000; and Bordman et al 2007.

Ring Pessary

- Two notches to allow it to be folded for insertion.
- For the ring with support, fold along the axis of the large holes.

To insert:

1. Lubricate leading edge of pessary
2. Fold the pessary over, concave side down, introduce it at the introitus, gently slide it up the posterior vaginal wall as far as possible before releasing. The index finger can help to push up the ring anteriorly behind the symphysis so that it sits parallel to the vaginal axis and behind the cervix in the posterior fornix. When correctly in situ, the cervix should sit in the ring or on the supportive diaphragm when the ring with support is used (Farrell 2006; Bash 2000).
3. Rotate the ring so the indentations are laterally to prevent expulsion (Bash 2000).

To remove:

1. Rotate the ring with indentations to be anterior-posterior to allow folding and easier removal.
2. Hook the index finger under the leading edge and draw it down while the woman gently valsalvas. Rotate the pessary obliquely to remove with gentle traction. A loop of dental floss can be attached to make removal easier (Bordman et al 2007).

Gellhorn Pessary

To insert:

1. Lubricate leading edge of pessary
2. Holding the stem with the dominant hand, separate the labia with the non-dominant hand. With the convex base perpendicular to the introitus and slightly oblique to avoid the urethra, the leading edge enters the vagina with pressure directed along the posterior vaginal wall and easing the pessary in under the inferior pubic rami.
3. To get the Gellhorn into position, use the index finger to push the knob up the axis of the vagina.

4. When properly seated, the base of the Gellhorn pessary will be orientated at right angles to the vaginal canal and the stem and knob will lie along the vaginal canal and be visible at the introitus when the labia are separated (Farrell 2006).

5. There is usually no descent of the Gellhorn with a valsalva because of the suction maintaining it in the upper vagina (Farrell 2006).

6. If the Gellhorn provides good support but the stem is too long and projecting out of the vagina, the same sized model with a short stem can be substituted (Farrell 2006).

To remove:

1. Grasp the knob with the dominant hand and pull it down towards the introitus while the index finger of the non-dominant hand sweeps behind the base to release the suction. Once the suction is released, reverse the steps used for insertion in order to remove it. It is not usually possible to pull it straight down, so the suction must be broken first. Sometimes sponge or ring-forceps may be needed to grasp the knob, break the suction and remove the pessary.

Cube Pessary

To insert:

1. Lubricate the top edge of the cube or the vaginal introitus with a water-based gel.

2. Compress the cube as much as possible with two gloved hands and insert at the introitus with downward pressure on the posterior vaginal wall, pushing it into the upper vagina with the index finger. Ensure that the loop is visible in the vaginal lumen and accessible for removal later.

To remove:

1. Locate the loop and sweep around the sides of the pessary with the non-dominant index finger to break the suction. Pull down gently on the loop, grasping the edge of the cube with fingers to remove it.

2. Do not just pull on the string for removal but grip the actual pessary (Bash 2000).

Appendix B: Patient information sheet

Adapted from Viera & Larkins-Pettigrew (2000).

How to Use a Pessary

What is a pessary?

A pessary is a device that fits into the vagina to help support a prolapse of the uterus (womb), bladder and/or rectum (bottom of the bowel). A prolapse of the bladder is also known as a cystocele, and a prolapse of the rectum is known as rectocele. A prolapse develops when one or more of the pelvic organs loses its ligamentous support so that it pushes down into the vagina. Prolapse is commonly caused by childbirth, aging, or following pelvic surgery and may take years to develop. Changes due to ageing and repeated force such as chronic coughing or straining can gradually worsen the prolapse over many years until it becomes noticeable. A prolapse may be fixed with surgery, or a pessary can be inserted to support the prolapse and relieve the symptoms coming from it.

Note: It is important to have an abdominal and pelvic examination by a medical practitioner to make sure there is no other cause of the prolapse.

What kind of pessary will I use?

You have been fitted with a: (Type)……(size)……

The decision about which type of pessary each woman should use depends on the type of prolapse and the symptoms it causes. The pessary has to be fitted correctly and it may take several tries to get the right one.

After the first fitting, you'll need to return in a week or two to the health practitioner's office to have the pessary checked. After that you may need to be checked every few months. Sometimes a different size or shape of pessary will have to be fitted.

How do I care for my pessary?

It's important that you follow the instructions about caring for your pessary.

Many pessaries can be removed at night and replaced in the morning – or as directed. This is usually done weekly or as needed.

After removal, wash the pessary with liquid soap and water, rinse with clear water, being sure to clean any holes. Dry the pessary and store it overnight. Re-insert after using your bowels if convenient. Don't use any chemicals to clean the pessary.

Make sure you keep your check-up appointments.

Does the pessary cause any side effects?

You may notice more vaginal discharge than normal. Your vaginal discharge may also develop an odour. Vaginal irritation is another possible side effect. Women who are past menopause may need to use oestrogen cream.

If you have a bad vaginal odour, lots of discharge or blood, you should immediately remove the pessary and contact your health care provider.

Can the pessary get lost or fall out?

The vagina is a closed tube so that the pessary can't go anywhere else inside the body. The pessary can fall out of the vagina, for example, if you strain on the toilet or bend or squat to lift something heavy. This usually means that your pessary is too small. Check in the toilet that it hasn't fallen out (retrieve it if it has as it can be sterilised and reused). You can also hold one hand under the vaginal opening when using your bowels to keep the pessary in place. Consult your health care provider if your pessary keeps falling out.

What else should I know?

Be sure to tell your doctor straight away if you have any discomfort with the pessary or if you have trouble urinating or having a bowel movement.

You should continue with pelvic floor exercises as prescribed by your health professional

Some pessaries, e.g. ring pessaries, can be worn during intercourse. Your health care provider will tell you if your pessary needs to be removed for intercourse or not.

The next appointment for review of your pessary is:

Contact phone number for this clinic is:

Appendix C: Resources

Pictures of prolapse

http://my.clevelandclinic.org/ob_gyn/womens_health/urogynecology_pelvic_floor_disorders/pelvic_organ_prolapse.aspx?utm_campaign=emailfriend&utm_medium=email&utm_source=ccf

Appendix D: Outcome measures

The International Consultation on Incontinence Vaginal Symptoms Questionnaire (ICIQ-VS) below is copyright protected and should not be altered in any way. It may be used if it is quoted clearly, and it must be used in its entirety, as presented in the copy below. It is not possible to use parts of the questionnaire in isolation in any studies without the written permission of the ICIQ study group. The scoring system is clearly stated on the questionnaire. If any researchers or clinicians wish to use the ICIQ-VS, the authors ask to be informed of the details of the study and any results that are presented or published. Correspondence to: Dr Nikki Cotterill, Bristol Urological Institute, Southmead Hospital, Westbury-on-Trym, Bristol BS10 5NB, UK (nikki_cotterill@bui.ac.uk).

CONFIDENTIAL

VAGINAL SYMPTOMS QUESTIONNAIRE

Many people experience vaginal symptoms some of the time. We are trying to find out how many people experience vaginal symptoms, and how much they bother them. We would be grateful if you could answer the following questions, thinking about how you have been, on average, over the PAST FOUR WEEKS.

Please write in today's date: ☐☐ ☐☐ ☐☐

DAY MONTH YEAR

Please write in your date of birth : ☐☐ ☐☐ ☐☐

DAY MONTH YEAR

Vaginal symptoms

1a. Are you aware of dragging pain in your lower abdomen?

never ☐ 0

occasionally ☐ 1

sometimes ☐ 2

most of the time ☐ 3

all of the time ☐ 4

1b. How much does this bother you?

Please ring a number between 0 (not at all) and 10 (a great deal)

0 1 2 3 4 5 6 7 8 9 **10**

not at all — a great deal

2a. Are you aware of soreness in your vagina?

never ☐ 0

occasionally ☐ 1

sometimes ☐ 2

most of the time ☐ 3

all of the time ☐ 4

2b. How much does this bother you?

Please ring a number between 0 (not at all) and 10 (a great deal)

0 1 2 3 4 5 6 7 8 9 **10**

not at all — a great deal

3a. Do you feel that you have reduced sensation or feeling in or around your vagina?

not at all ☐ 0

a little ☐ 1

somewhat ☐ 2

a lot ☐ 3

3b. How much does this bother you?

Please ring a number between 0 (not at all) and 10 (a great deal)

0 1 2 3 4 5 6 7 8 9 **10**

not at all — a great deal

Prolapse is a common condition affecting the normal support of the pelvic organs, which results in descent or 'dropping down' of the vaginal walls and/or the pelvic organs themselves. This can include the bladder, the bowel and the womb. Symptoms are usually worse on standing up and straining (e.g. lifting, coughing or exercising) and usually better when lying down and relaxing.

Prolapse may cause a variety of problems. We are trying to find out how many people experience prolapse, and how much this bothers them. We would be grateful if you could answer the following questions, thinking about how you have been, on average, over the PAST FOUR WEEKS.

4a. Do you feel that your vagina is too loose or lax?

not at all ☐ 0

a little ☐ 1

somewhat ☐ 2

a lot ☐ 3

4b. How much does this bother you?

Please ring a number between 0 (not at all) and 10 (a great deal)

0 1 2 3 4 5 6 7 8 9 **10**

not at all — a great deal

5a. Are you aware of a lump or bulge coming down in your vagina?

never ☐ 0

occasionally ☐ 1

sometimes ☐ 2

most of the time ☐ 3

all of the time ☐ 4

5b. How much does this bother you?

Please ring a number between 0 (not at all) and 10 (a great deal)

0 1 2 3 4 5 6 7 8 9 **10**

not at all — a great deal

6a. **Do you feel a lump or bulge come out of your vagina, so that you can feel it on the outside or see it on the outside?**

never ☐ 0

occasionally ☐ 1

sometimes ☐ 2

most of the time ☐ 3

all of the time ☐ 4

6b. **How much does this bother you?**

Please ring a number between 0 (not at all) and 10 (a great deal)

0 1 2 3 4 5 6 7 8 9 **10**

not at all — a great deal

7a. **Do you feel that your vagina is too dry?**

never ☐ 0

occasionally ☐ 1

sometimes ☐ 2

most of the time ☐ 3

all of the time ☐ 4

7b. **How much does this bother you?**

Please ring a number between 0 (not at all) and 10 (a great deal)

0 1 2 3 4 5 6 7 8 9 **10**

not at all — a great deal

8a. **Do you have to insert a finger into your vagina to help empty your bowels?**

never ☐ 0

occasionally ☐ 1

sometimes ☐ 2

most of the time ☐ 3

all of the time ☐ 4

8b. **How much does this bother you?**

Please ring a number between 0 (not at all) and 10 (a great deal)

0 1 2 3 4 5 6 7 8 9 **10**

not at all — a great deal

9a. **Do you feel that your vagina is too tight?**

never ☐

occasionally ☐

sometimes ☐

most of the time ☐

all of the time ☐

9b. **How much does this bother you?**
Please ring a number between 0 (not at all) and 10 (a great deal)

0 1 2 3 4 5 6 7 8 9 **10**

not at all — a great deal

Sexual matters

We would be grateful if you could answer the following questions, thinking about how you have been, on average, over the PAST FOUR WEEKS.

10. **Do you have a sex life at present?**

yes ☐ 1

no, because of my vaginal symptoms ☐ 0

no, because of other reasons ☐ 2

If NO, please go to question 14

11a. **Do worries about your vagina interfere with your sex life?**

not at all ☐ 0

a little ☐ 1

somewhat ☐ 2

a lot ☐ 3

11b. **How much does this bother you?**
Please ring a number between 0 (not at all) and 10 (a great deal)

0 1 2 3 4 5 6 7 8 9 **10**

not at all — a great deal

12a. **Do you feel that your relationship with your partner is affected by vaginal symptoms?**

not at all ☐ 0

a little ☐ 1

somewhat ☐ 2

a lot ☐ 3

12b. **How much does this bother you?**

Please ring a number between 0 (not at all) and 10 (a great deal)

0 1 2 3 4 5 6 7 8 9 **10**

not at all a great deal

13. *How much do you feel that your sex life has been spoilt by vaginal symptoms?*

Please ring a number between 0 (not at all) and 10 (a great deal)

0 1 2 3 4 5 6 7 8 9 **10**

not at all a great deal

Quality of life

We would be grateful if you could answer the following questions, thinking about how you have been, on average, over the PAST FOUR WEEKS.

14. *Overall, how much do vaginal symptoms interfere with your everyday life?*

Please ring a number between 0 (not at all) and 10 (a great deal)

0 1 2 3 4 5 6 7 8 9 **10**

not at all a great deal

Thank you very much for answering these questions.

Vaginal symptoms questionnaire

SCORING

(This section is for administrative use only)

Patient number

Vaginal symptoms score

Vaginal symptom score = 2×(dragging pain) + 2×(soreness in vagina) + (reduced sensation) + 2×(vagina too loose) + 2×(lump felt inside) + 2×(lump seen outside) + 2×(vagina too dry) + (faecal evacuation)

symptom*	score	weighted score
Q1. 'dragging pain'		x 2 =
Q2. 'soreness in vagina'		x 2 =
Q3. 'reduced sensation'		x 1 =
Q4. 'vagina too loose'		x 2 =
Q5. 'lump felt inside'		x 2 =
Q6. 'lump seen outside'		x 2 =
Q7. 'vagina too dry'		x 2 =
Q8. 'faecal evacuation'		x 1 =
Total vaginal symptoms score		

*(Note: Q9, 'vagina too tight', is primarily for detecting a potential post-treatment complication and is therefore not included in the scoring)

Sexual matters score

Sexual matters score = (sex-life spoilt) + 8×(worries about vagina interfere with sex-life) + 8×(relationship affected)

sexual matter	score	weighted score
Q11. 'worries about vagina interfere with sex-life'		x 8 =
Q12. 'relationship affected'		x 8 =
Q13. 'sex life spoilt'		x 1 =
Total sexual matters score		

Quality of life score

quality of life	score
Q14. 'quality of life affected'	

PELVIC FLOOR DISTRESS INVENTORY – SHORT FORM 20

Instructions: Please answer all of the questions in the following survey. These questions will ask you if you have certain bowel, bladder or pelvic symptoms and, if you do, how much they bother you. Answer by putting an X in the appropriate box or boxes. While answering these questions, please consider your symptoms over the last three months.

Name: _____ Date:_____

1. Do you usually experience *pressure* in the lower abdomen?

   □ **No**; □ **Yes**

   If yes, how much does it bother you?

   □ Not at all □ Somewhat □ Moderately □ Quite a bit

---

2. Do you usually experience *heaviness* or *dullness* in the pelvic area?

   □ **No**; □ **Yes**

   If yes, how much does it bother you?

   □ Not at all □ Somewhat □ Moderately □ Quite a bit

---

3. Do you usually have a bulge or something falling out that you can see or feel in the vaginal area?

   □ **No**; □ **Yes**

   If yes, how much does it bother you?

   □ Not at all □ Somewhat □ Moderately □ Quite a bit

---

4. Do you usually have to push on the vagina or around the rectum to have, or complete, a bowel movement?

   □ **No**; □ **Yes**

   If yes, how much does it bother you?

   □ Not at all □ Somewhat □ Moderately □ Quite a bit

---

5. Do you usually experience a feeling of incomplete bladder emptying?

□ **No**; □ **Yes**

<u>If yes</u>, how much does it bother you?

□	□	□	□
Not at all	Somewhat	Moderately	Quite a bit

---

6. Do you ever have to push up on a bulge in the vaginal area with your fingers to start or complete urination?

□ **No**; □ **Yes**

<u>If yes</u>, how much does it bother you?

□	□	□	□
Not at all	Somewhat	Moderately	Quite a bit

---

7. Do you feel you need to strain too hard to have a bowel movement?

□ **No**; □ **Yes**

<u>If yes</u>, how much does it bother you?

□	□	□	□
Not at all	Somewhat	Moderately	Quite a bit

---

8. Do you feel you have not completely emptied your bowels at the end of a bowel movement?

□ **No**; □ **Yes**

<u>If yes</u>, how much does it bother you?

□	□	□	□
Not at all	Somewhat	Moderately	Quite a bit

---

9. Do you usually lose stool beyond your control if your stool is well formed?

□ **No**; □ **Yes**

<u>If yes</u>, how much does it bother you?

□	□	□	□
Not at all	Somewhat	Moderately	Quite a bit

---

10. Do you usually lose stool beyond your control if your stool is loose or liquid?

□ **No**; □ **Yes**

<u>If yes</u>, how much does it bother you?

□	□	□	□
Not at all	Somewhat	Moderately	Quite a bit

---

11. Do you usually lose gas from the rectum beyond your control?

□ **No**; □ **Yes**

<u>If yes</u>, how much does it bother you?

□	□	□	□
Not at all	Somewhat	Moderately	Quite a bit

---

12. Do you usually have pain when you pass your stool?

□ **No**; □ **Yes**

<u>If yes</u>, how much does it bother you?

□	□	□	□
Not at all	Somewhat	Moderately	Quite a bit

---

13. Do you experience a strong sense of urgency and have to rush to the toilet to have a bowel movement?

□ **No**; □ **Yes**

<u>If yes</u>, how much does it bother you?

□	□	□	□
Not at all	Somewhat	Moderately	Quite a bit

---

14. Does a part of your bowel ever pass through the rectum and bulge outside during or after a bowel movement?

□ **No**; □ **Yes**

<u>If yes</u>, how much does it bother you?

□	□	□	□
Not at all	Somewhat	Moderately	Quite a bit

---

15. Do you usually experience frequent urination?

□ **No**; □ **Yes**

<u>If yes</u>, how much does it bother you?

□	□	□	□
Not at all	Somewhat	Moderately	Quite a bit

---

16. Do you usually experience urine leakage associated with a feeling of urgency; that is, a strong sensation of needing to go to the toilet?

□ **No**; □ **Yes**

<u>If yes</u>, how much does it bother you?

□	□	□	□
Not at all	Somewhat	Moderately	Quite a bit

---

17. Do you usually experience urine leakage related to coughing, sneezing, or laughing?

□ **No**; □ **Yes**

If yes, how much does it bother you?

□	□	□	□
Not at all	Somewhat	Moderately	Quite a bit

---

18. Do you usually experience small amounts of urine leakage (that is, drops?)

□ **No**; □ **Yes**

If yes, how much does it bother you?

□	□	□	□
Not at all	Somewhat	Moderately	Quite a bit

---

19. Do you usually experience difficulty emptying your bladder?

□ **No**; □ **Yes**

If yes, how much does it bother you?

□	□	□	□
Not at all	Somewhat	Moderately	Quite a bit

---

20. Do you usually experience *pain* or *discomfort* in the lower abdomen or genital region?

□ **No**; □ **Yes**

If yes, how much does it bother you?

□	□	□	□
Not at all	Somewhat	Moderately	Quite a bit

Thank you for taking the time to complete this questionnaire.

Your responses are confidential.

[Barber et al. Short forms of two condition-specific quality-of-life questionnaires for women with pelvic floor disorders. Am J Obstet Gynecol.(2005) 193, 103-13]

Pelvic Organ Prolapse Symptom Score

We would be grateful if you could answer the following questions, thinking about how you have been, on average, over the **PAST FOUR WEEKS**. ***(Please cross one box in each row)***

How often during the last four weeks have you had the following symptoms:		**Never**		**Occasionally**		**Sometimes**		**Most of the time**		**All of the time**	
A1	a feeling of something coming down from or in your vagina?	☐	1	☐	2	☐	3	☐	4	☐	5
A2	an uncomfortable feeling or pain in your vagina which is worse when standing?	☐	1	☐	2	☐	3	☐	4	☐	5
A3	a heaviness or dragging feeling in your lower abdomen (tummy)?	☐	1	☐	2	☐	3	☐	4	☐	5
A4	a heaviness or dragging feeling in your lower back?	☐	1	☐	2	☐	3	☐	4	☐	5
A5	a need to strain (push) to empty your bladder?	☐	1	☐	2	☐	3	☐	4	☐	5
A6	a feeling that your bladder has not emptied completely?	☐	1	☐	2	☐	3	☐	4	☐	5
A7	a feeling that your bowel has not emptied completely?	☐	1	☐	2	☐	3	☐	4	☐	5

A8 which of the symptoms above (questions A1 to A7) causes you most bother? **A** ☐ Not applicable ☐ 99
Please enter a number from 1 to 7 in the box, or cross "Not applicable"

[Hagen S, Glazener C, Sinclair L, Stark D, Bugge C. Psychometric properties of the pelvic organ prolapse symptom score. *An International Journal of Obstetrics and Gynaecology.* 2009b; 116: 25-31.]

The Australian Pelvic Floor Questionnaire

Please circle your most applicable answer.

Consider your experiences during the last month.

Bladder function

1. How many times do you pass urine in the day?
   - 0 up to 7
   - 1 between 8-10
   - 2 between 11-15
   - 3 more than 15

2. How many times do you get up at night to pass urine?
   - 0 0-1
   - 1 2
   - 2 3
   - 3 more than 3 times

3. Do you wet the bed **before** you wake up at night?
   - 0 never
   - 1 occasionally (less than once per week)
   - 2 frequently (once or more per week)
   - 3 always (every night)

4. Do you need to rush or hurry to pass urine when you get the urge?
   - 0 can hold on
   - 1 occasionally have to rush (less than once per week)
   - 2 frequently have to rush (once or more per week)
   - 3 daily

5. Does urine leak when you rush or hurry to the toilet or can't you make it in time?
   - 0 not at all
   - 1 occasionally (less than once per week)
   - 2 frequently (once or more per week)
   - 3 daily

6. Do you leak urine with coughing, sneezing, laughing or exercising?
   - 0 not at all
   - 1 occasionally (less than once per week)
   - 2 frequently (more than once per week)
   - 3 daily

7. Is your urinary stream (urine flow) weak, prolonged or slow?
   - 0 never
   - 1 occasionally (less than once a week)
   - 2 frequently (once or more per week)
   - 3 daily

8. Do you have a feeling of incomplete bladder emptying?
   - 0 never
   - 1 occasionally (less than once a week)
   - 2 frequently (once or more than once a week)
   - 3 daily

9. Do you need to strain to empty your bladder?
   - 0 never
   - 1 occasionally (less than once a week)
   - 2 frequently (once or more per week)
   - 3 daily

10. Do you have to wear pads because of urinary leakage?
   - 0 none - never
   - 1 as a precaution
   - 2 when exercising/during a cold
   - 3 daily

11. Do you limit your fluid intake to decrease urinary leakage?
   - 0 never
   - 1 before going out
   - 2 moderately
   - 3 always

12. Do you have frequent bladder infections?
   - 0 no
   - 1 1-3 per year
   - 2 4-12 per year
   - 3 more than one per month

13. Do you have pain in your bladder or urethra when you empty your bladder?
   - 0 never
   - 1 occasionally (less than once a week)
   - 2 frequently (once or more than once a week)
   - 3 daily

14. Does the urine leakage affect your routine activities like recreation, socialising, sleeping, shopping etc.?
   - 0 not at all
   - 1 slightly
   - 2 moderately
   - 3 greatly

15. How much does your bladder problem bother you?
   - ❒ not applicable, I do not have problems
   - 0 not at all
   - 1 slightly
   - 2 moderately
   - 3 greatly

Bowel function

16. How often do you usually open your bowels?
    - 0 every other day or daily
    - 1 less than every 3 days
    - 2 less than once a week
    - 0 more than once a day

17. How is the consistency of your usual stool?

0	soft	0	firm	0	hard (pebbles)
2	watery	1	variable		

18. Do you have to strain a lot to empty your bowels?
    - 0 never
    - 1 occasionally (less than once a week)
    - 2 frequently (once or more than once a week)
    - 3 daily

19. Do you use laxatives to empty your bowels?
    - 0 never
    - 1 occasionally (less than once a week)
    - 2 frequently (once or more than once a week)
    - 3 daily

20. Do you feel constipated?
    - 0 never
    - 1 occasionally (less than once a week)
    - 2 frequently (once or more than once a week)
    - 3 daily

21. When you get wind or flatus, can you control it or does wind leak?
    - 0 never
    - 1 occasionally (less than once a week)
    - 2 frequently (once or more than once a week)
    - 3 daily

22. Do you get an overwhelming sense of urgency to empty your bowels?
    - 0 never
    - 1 occasionally (less than once a week)
    - 2 frequently (once or more than once a week)
    - 3 daily

23. Do you leak watery stool when you don't mean to?
    - 0 never
    - 1 occasionally (less than once a week)
    - 2 frequently (once or more than once a week)
    - 3 daily

24. Do you leak normal stool when you don't mean to?
    - 0 never
    - 1 occasionally (less than once a week)
    - 2 frequently (once or more than once a week)
    - 3 daily

25. Do you have a feeling of incomplete bowel emptying?
- 0 never
- 1 occasionally (less than once a week)
- 2 frequently (once or more than once a week)
- 3 daily

26. Do you have to use finger pressure to help empty your bowels?
- 0 never
- 1 occasionally (less than once a week)
- 2 frequently (once or more than once a week)
- 3 daily

27. How much does your bowel problem bother you?
- ❒ not applicable, I do not have problems
- 0 not at all
- 1 slightly
- 2 moderately
- 3 greatly

<u>Prolapse symptoms</u>

28. Do you have a sensation of tissue protrusion or a lump or bulging in your vagina?
- 0 never
- 1 occasionally (less than once a week)
- 2 frequently (once or more than once a week)
- 3 daily

29. Do you experience vaginal pressure or heaviness or a dragging sensation?
- 0 never
- 1 occasionally (less than once a week)
- 2 frequently (once or more than once a week)
- 3 daily

30. Do you have to push back your prolapse in order to void?
- 0 never
- 1 occasionally (less than once a week)
- 2 frequently (once or more than once a week)
- 3 daily

31. Do you have to push back your prolapse to empty your bowels?
- 0 never
- 1 occasionally (less than once a week)
- 2 frequently (once or more than once a week)
- 3 daily

32. How much does your prolapse bother you?
- ❒ not applicable, I do not have a prolapse
- 0 not at all
- 1 slightly
- 2 moderately
- 3 greatly

Sexual function

33. Are you sexually active? *(No scoring of this question)*

- ❒ no
- ❒ less than once per week
- ❒ once or more per week
- ❒ daily or most days

If you are not sexually active, please continue to answer questions 34 and 42 only

34. If you are not sexually active, please tell us why: *(No scoring of this question)*

- ❒ do not have a partner
- ❒ I am not interested
- ❒ my partner is unable
- ❒ vaginal dryness
- ❒ too painful
- ❒ embarrassment due to the prolapse or incontinence
- ❒ other reasons: _____

} 18

35. Do you have sufficient natural vaginal lubrication during intercourse?

0 yes
1 no

36. During intercourse vaginal sensation is:

0 normal / pleasant
1 minimal
1 painful
3 none

37. Do you feel that your vagina is too loose or lax?

0 never
1 occasionally
2 frequently
3 always

38. Do you feel that your vagina is too tight?

0 never
1 occasionally
2 frequently
3 always

39. Do you experience pain with sexual intercourse?

0 never
1 occasionally
2 frequently
3 always

40. Where does the pain during intercourse occur?

0 not applicable, I do not have pain
1 at the entrance to the vagina
1 deep inside, in the pelvis
2 both at the entrance and in the pelvis

41. Do you leak urine during sexual intercourse?
    0 never
    1 occasionally
    2 frequently
    3 always

42. How much do these sexual issues bother you?
    ❒ not applicable, I do not have problems
    0 not at all
    1 slightly
    2 moderately
    3 greatly

[Baessler K, O'Neill SM, Maher CF, Battistutta D. Australian pelvic floor questionnaire: a validated interviewer-administered pelvic floor questionnaire for routine clinic and research. *International Urogynecology Journal and Pelvic Floor Dysfunction*. 2009; 20(2): 149–158]

For professional use:

Australian Pelvic Floor Questionnaires

Interviewer or self administered for clinical assessment of patients with pelvic floor symptoms

This questionnaire has been developed for assessment of pelvic floor function in women to be applied during an interview or to be completed by the patient. It encompasses bladder, bowel and sexual function, prolapse symptoms and symptom-specific quality of life issues.

The psychometric properties have been tested and published (Baessler K, O'Neill SM, Maher CF, Battistutta D. A validated self-administered female pelvic floor questionnaire. Int Urogynecol J Pelvic Floor Dysfunct. 2010 Feb;21(2):163-72. Epub 2009 Sep 12; Baessler K, O'Neill SM, Maher CF, Battistutta D. Australian pelvic floor questionnaire: a validated interviewer-administered pelvic floor questionnaire for routine clinic and research. Int Urogynecol J Pelvic Floor Dysfunct. 2009 Feb;20(2):149-58. Epub 2008 Oct 29.).

If required, scores for the bladder, bowel, prolapse and sexual function domains and a global pelvic floor dysfunction score can be calculated. However, the Pelvic floor questionnaire can also be used without scoring.

Instructions for scoring:
Frequency, severity, and bother of pelvic floor symptoms are assessed using a four-point scoring system for most items in the questionnaire, apart from defecation frequency, bowel consistency, sufficient lubrication, and the reason for sexual abstinence, for which such scoring was inappropriate. Please note that these scores represent values and might not be suitable codes if used in an electronic database. For example, dyspareunia might occur at the introitus or deep inside. Both are probably bothersome but we cannot assume that one is worse than the other. Therefore, both conditions are scored with 1. If they both occur, we assumed this to be more bothersome and scored it with 2.

If women are not sexually active because of pelvic floor dysfunction, they will get a score of 8.5 (18/21) in the sexual domain. This takes into account that it is difficult to achieve the highest possible score in that domain because some questions assess reverse symptoms. Additive scores are calculated separately for bladder, bowel, pelvic organ prolapse, and sexual symptom domains. Resulting scores are divided by the number of relevant questions within each domain and multiplied by 10, giving a value between 0 and 10 for each of the four domains and a maximum total pelvic floor dysfunction score of 40. If a woman is not sexually active, the maximum score is 30. However, if she is not sexually active because of pelvic floor problems, the maximum score is 40.

Appendix E: Study design and results of the search

Table A. Study design of included studies

Number	Author	Type of Study	Comments	NHMRC level
1	Atnip (2009)	Opinion	good background info	Opinion
2	Bordman et al (2007)	Opinion	definitions and processes	Opinion
4	McIntosh et al (2005)	Literature review – no method		Expert-literature review
6	Clemons et al (2004)	prospective descriptive		III-2
7	Brincat et al (2004)	case series –chart audit		IV
8	Adams et al (2004)	Systematic review	cochrane	I
9	Kuhn et al (2009)	Prospective		III-2
11	Sarma et al (2009)	retrospective case series		IV
12	Quresh et al (2008)	prospective descriptive		III-2
13	Komesu et al (2007)	pre-post		III-3
14	Lukban et al (2006)	Pre-Post	survey	III-3
15	Bai et al (2005)	Pre-Post		III-3
16	Handa & Jones (2002)	Pre-Post		III-3
17	Whitworth et al (2002)	retrospective case study		IV
19	Bash (2000)	opinion	definitions and processes	Opinion
22	Jones et al (2008)	Pre-Post		III-3
27	Popli et al (2008	retrospective case study		IV
28	Kaaki & Mahajan (2007)	case study		IV
29	Komesu et al (2008)	prospective descriptive study		III-2
31	ACOG (2007)	opinion	review of current Rx options	Opinion
33	Roehl et al (2006)	opinion	review	Opinion
34	Fernando et al (2006)	Pre-Post		III-3
35	Maito et al (2006)	Pre-post		III-3
36	Mutone et al (2006)	prospective descriptive study		III-2
37	Nguyen et al (2005)	retrospective case series		IV
38	Hassler et al (2005)	Retrospective case series		IV
39	Clemons et al (2004)	prospective descriptive study		III-2
40	Clemons et al (2004)	prospective epi descriptive study		III-2

41	Heit et al (2003)	cross sectional descriptive study		III-2
44	Gorti et al (2009)	survey of clinicians		IV
45	Sitavarin et al (2009)	prospective descriptive study		III-2
46	Bordman et al (2007)	opinion	how to do it paper	Opinion
50	Vierhout (2004)	opinion		Opinion
51	Viera et al (2000)	opinion		Opinion
54	Cundiff et al (2007)	CCT		III-1
56	Powers et al (2006)	retrospective case series		IV
57	Anders (2004)	opinion	good diagrams and history	Opinion
60	Thakar et al (2002)	systematic review		I
62	Alnaif et al (2000)	case control study		III-2
63	Arias et al (2008)	systematic review plus case study		I
64	Cundiff et al (2000)	survey		IV
66	Wheeler et al (2004)	case study		IV
67	Espuna (2009)	opinion		Opinion
73	Nallendran et al (2006)	case study		IV
74	Shah et al (2006)	systematic review		I
77	Yu et al (2004)	case study		IV
79	Richardson et al (2009)	opinion	useful paper for definitions and diagrams	Opinion
81	Storey et al (2009)	qualitative (lived experienced of 11 females)		Qualitative
82	Stephan et al (2007)	case study		IV
83	Hanson et al (2006)	retrospective audit	>1300	IV
84	Friedman (2010)	retrospective audit	= 150	IV
85	Wu et al (1997)	pre-post		III-3
86	Kapoor et al (2009)	survey		IV
87	Fernando et al (2007)	case study		IV
88	Sinha (2004)	case study		IV
89	Barber et al (2005)	Psychometric property of new instrument		III_3
90	Baessler et al (2009)	Psychometric property of new instrument		III_3
91	Bradley et al (2007)	Prospective follow-up		III_3
92	Braekken et al (2010)	RCT		II
93	Brubaker et al (2009)	Expert opinion & practice standards		Expert opinion
94	Bump et al (1996)	Use of standard nomenclature		IV
95	Carcio (2010)	Conference presentation		Opinion

96	Dietz (2008)	Position paper on available evidence		Expert opinion
97	Dietz & Simpson (2008)	Retrospective audit		IV
98	Dumoulin & Hay-Smith (2010)	Cochrane review		I
99	Farrell (2006)	handbook		Expert Opinion
100	Gerten et al (2008)	correlational		III_3
101	Ghetti et al (2005)	Retrospective audit		IV
102	Hagen et al (2009a)	Psychometric property of new instrument		III_3
103	Hagen et al (2009b)	RCT (pilot)		I
104	Hall et al (1996)		This is more a diagnostic design and doesn't really fit well in the intervention hierarchy	In an intervention hierarchy it is III_3, but in a diagnosis hierarchy it would be higher (probably III_1)
105	Haylen (2010)	Practice standards		Expert Opinion
106	Hay-Smith et al (2009)	SR		I
107	Jarvis et al (2005)	RCT		II
108	Kobak et al (1996)		This is more a diagnostic design and doesn't really fit well in the intervention hierarchy	In an intervention hierarchy it is III_3, but in a diagnosis hierarchy it would be higher (probably III_1)
109	McLennan et al (2000)	Cross-sectional survey		III_3
110	Milsom et al (2009)	Expert committee		Expert opinion
111	Morgan et al (2010)	Case-control study		III_2
112	Mouritsen & Larsen (2003)	Correlation study		III_2
113	North American Menopause Society (2007)	Practice standards		Expert Opinion
114	Olsen et al (1997)	Retrospective audit		IV
115	Payne et al (2009)	Systematic review		I
116	Piya-Anant et al (2003)	prospective descriptive		III-2
117	Price et al (2006)	Psychometric property of new instrument		III_3
118	Rogers et al (2003)	Psychometric property of new instrument		III_3
119	Slieker-ten Hove et al (2009)	Survey		IV
120	Stark et al (2010)	This is more a diagnostic design and doesn't really fit well in the intervention	In an intervention hierarchy it is III_3, but in a diagnosis hierarchy it would be higher (probably	

		hierarchy	III_1)	
121	Staskin et al (2009a)	Systematic review		I
122	Staskin et al (2009b)	Systematic review		
123	Swift (2000)	prospective descriptive		III-2
124	Swift et al (2005)			III_3
125	Weir et al (2006)	Correlational		III_3
126	Whiteside et al (2004)	prospective descriptive		III-2
127	Handa et al (2004)	longitudinal study	III-3	

Search results

Step 1 Search results from Keyword 1 and Keyword 2 and seminal papers provided:

- 82 requiring further review for inclusions

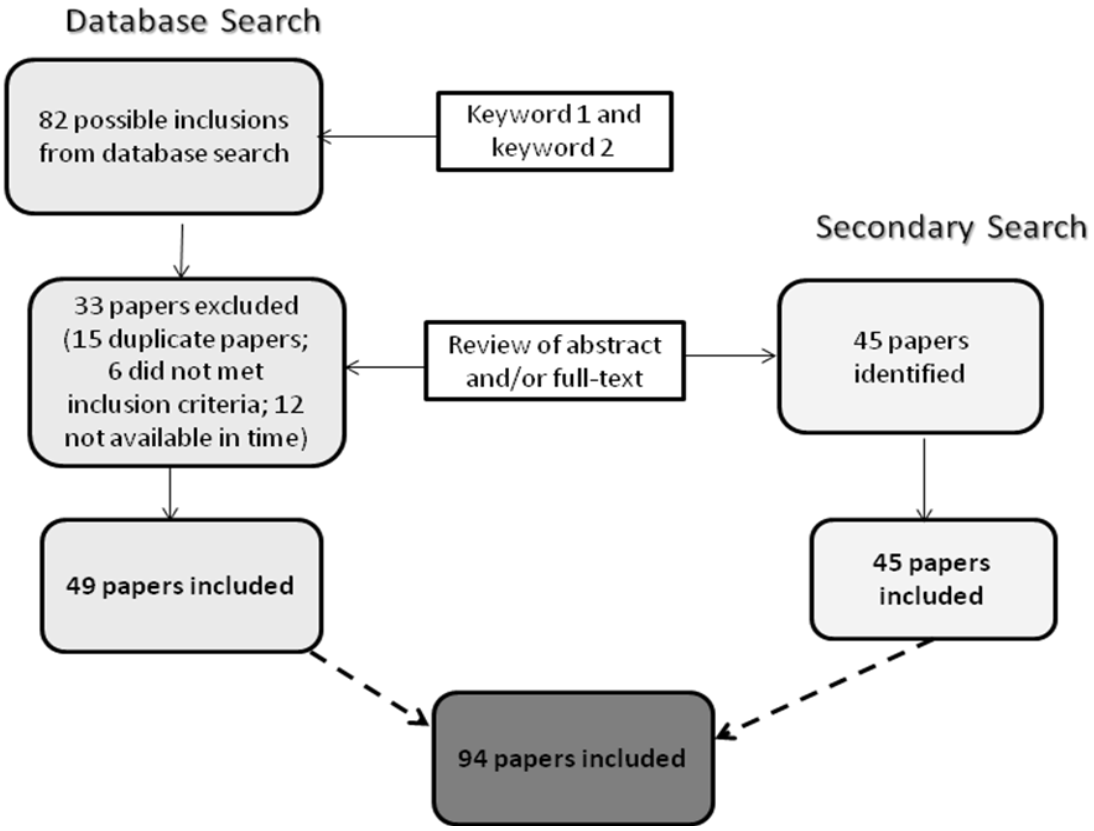
Step 2 Full review of papers:

- 33 papers excluded (15 were duplicates; 6 didn't meet inclusion criteria on further review; 12 were unable to be located in full-text within time frame)
- Leaving 49 papers for inclusion

Step 3 Secondary searching

- Key organisational websites were searched and two key documents were identified
- Pearling of the reference lists of these documents occurred
- 45 papers were identified for inclusion

Figure A Consort diagram



Final inclusion list of papers to inform the development of this guideline

Papers identified from database search

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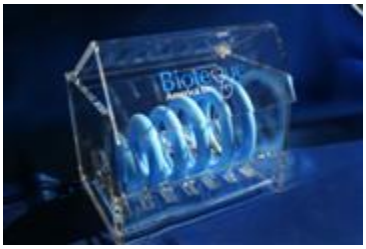
Appendix G: Different types of pessary



Fitting Set

Marlands

Shaatz

Dish

Gehrung

Gellhorn

Ring

Hodge

Cup

Cube

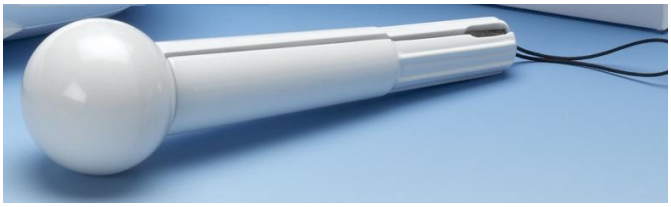
Donut

Oval

Ring w/knob

Figures reproduced with permission from Sayco Pty Ltd distributers of Bioteque pessaries in Australia

Simpson's shelf pessary *(from website)*



Colpexin Sphere. *Figure provided with permission from Colpexin*

A Tandem-Cube (Silicone)
B Hodge w/Knob (Silicone)
C Risser (Silicone)
D Smith (Silicone)
E Hodge w/Support (Silicone)
F Hodge (Silicone)
G Cube (Silicone)
H Hodge w/Support & Knob (Silicone)
I Regula (Silicone)
J Gehrung (Silicone)
K Gehrung w/Knob (Silicone)
L Gellhorn Flexible (Silicone)
M Gellhorn 95% Rigid (Silicone)
N Inflatoball (Latex)
O Shaatz (Silicone)
P Ring w/Support (Silicone)
Q Ring w/Knob (Silicone)
R Incontinence Dish (Silicone)
S Incontinence Dish w/Support (Silicone)
T Ring w/Support & Knob (Silicone)
U Ring (Silicone)
V Donut (Silicone)
W Incontinence Ring (Silicone)

Milex pessaries. *Figure provided permission from Coopers Pty Ltd, distributors of Milex pessaries*

Appendix H: Letter from Urogynaecology Association of Australasia re endorsement

Urogynaecological Society of Australasia
RANZCOG College House
254-260 Albert Street
East Melbourne 3002

Trish Neumann
Specialist Continence & Women's Health Physiotherapist
32 Kensington Road
Rose Park SA 5067

8th Nov 2011

Dear Ms Neumann,

Re: UGSA Endorsement of Pessary Guidelines

We thank you for your invitation for UGSA to comment and to consider endorsing the pessary guidelines written by you and some of the leaders in pelvic floor dysfunction in Australasia. We would also like to sincerely apologize for the long delay in getting back to you with a decision.

Over the last few months, the UGSA advisory board members have conducted a thorough examination of the document and we all felt that it is a very well researched and written document. We also made some recommendations for amendments of which you and your co- authors have gracefully taken onboard and carried out. However, the issue of UGSA officially endorsing such a document was the subject of intense debate within the board and hence the frustrating delay in reply to you and your co-authors.

Whilst the board acknowledges that the pessary guidelines will serve as an excellent reference for practitioners interested in the field of pelvic floor medicine, the board has concluded that UGSA is not able to endorse the document itself; the main reason being that there is currently no credentialing process for practitioners using vaginal pessaries for managing pelvic organ prolapse in Australasia. As such, it could become a quality assurance issue with potential medicolegal implications to the association.

We appreciate your patience with this matter and we sincerely regret that UGSA will not be able to endorse your document.

Yours sincerely,

Dr Yik Lim
Honorary Secretary of UGSA