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# Guideline No. 422d: Menopause and Sexuality

*(En français : Directive clinique nº 422b : Ménopause et sexualité)*

The English document is the original version. In the event of any discrepancy between the English and French content, the English version prevails.

This clinical practice guideline was prepared by the authors and overseen by the Menopause Working Group. It was reviewed by the SOGC's Clinical Practice Gynaecology committee, SOGC's Family Physician Advisory Committee, and the SOGC's Urogynaecology Committee and approved by the SOGC Guideline Management and Oversight Committee and SOGC Board of Directors.

This clinical practice guideline supersedes No. 311, published in September 2014.

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## RECOMMENDED CHANGES IN PRACTICE

1. This guideline has been updated to include new options for treatment, including the usage of the newly approved pharmaceutical options, flibanserin, for the treatment of low sexual desire and dehydroepiandrosterone and ospemifene for genitourinary syndrome of menopause. This update provides information on additional approvals for the prescription of testosterone as a therapeutic option for new, distressing decreased sexual desire at menopause by multiple medical societies.

## KEY MESSAGES

1. A brief sexual history is recommended during the menopausal assessment.
2. The most common sexual dysfunctions in menopausal women are hypoactive sexual desire disorder and painful intercourse.

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This document reflects emerging clinical and scientific advances as of the publication date and is subject to change. The information is not meant to dictate an exclusive course of treatment or procedure. Institutions are free to amend the recommendations. The SOGC suggests, however, that they adequately document any such amendments.

**Informed consent:** Everyone has the right and responsibility to make informed decisions about their care together with their health care providers. In order to facilitate this, the SOGC recommends that health care providers provide patients with information and support that is evidence-based, culturally appropriate, and personalized.

**Language and inclusivity:** The SOGC recognizes the importance to be fully inclusive and when context is appropriate, gender-neutral language will be used. In other circumstances, we continue to use gendered language because of our mission to advance women's health. The SOGC recognizes and respects the rights of all people for whom the information in this document may apply, including but not limited to transgender, non-binary, and intersex people. The SOGC encourages healthcare providers to engage in respectful conversation with their patients about their gender identity and preferred gender pronouns and to apply these guidelines in a way that is sensitive to each person's needs.

3. New-onset dyspareunia, if caused by genitourinary syndrome of menopause, can be treated with moisturizers, lubricants, vaginal estrogens, vaginal dehydroepiandrosterone, or ospemifene.
4. For postmenopausal women who are distressed by decreased desire, the best current options include management of co-existing pain and biopsychological or relationship factors, sexual counselling, and/or off-label use of transdermal testosterone or flibanserin.

## ABSTRACT

**Objective:** Provide strategies for improving the care of perimenopausal and postmenopausal women based on the most recent published evidence.

**Target Population:** Perimenopausal and postmenopausal women.

**Benefits, Harms, and Costs:** Target population will benefit from the most recent published scientific evidence provided via the information from their health care provider. No harms or costs are involved with this information since women will have the opportunity to choose among the different therapeutic options for the management of the symptoms and morbidities associated with menopause, including the option to choose no treatment.

**Evidence:** Databases consulted were PubMed, MEDLINE, and the Cochrane Library for the years 2002−2020, and MeSH search terms were specific for each topic developed through the 7 chapters.

**Validation Methods:** The authors rated the quality of evidence and strength of recommendations using the Grading of Recommendations Assessment, Development and Evaluation (GRADE) approach. See online Appendix A (Tables A1 for definitions and A2 for interpretations of strong and weak recommendations).

**Intended Audience:** physicians, including gynaecologists, obstetricians, family physicians, internists, emergency medicine specialists; nurses, including registered nurses and nurse practitioners; pharmacists; medical trainees, including medical students, residents, fellows; and other providers of health care for the target population.

**SUMMARY STATEMENTS:**

1. Low sexual desire in combination with distress is most common in women in mid-life (*high*).
2. Vaginal atrophy is a common cause of sexual pain in menopausal women (*high*).
3. Sexual dysfunction in menopausal women can be categorized as disorders involving desire, arousal, pain, and orgasm. These categories often overlap (*high*).
4. A brief sexual history is part of the evaluation of menopausal women (*moderate*).
5. The treatment of sexual dysfunctions involves a multifaceted approach that addresses medical, psychological, and relationship issues (*high*).
6. Local estrogen therapy treats genitourinary syndrome of menopause (*high*).
7. Pelvic physiotherapy is an excellent adjuvant treatment for hypercontracted pelvic floor muscles (often referred to as *vaginismus*) and genito-pelvic pain (*low*).
8. Flibanserin has been shown to improve desire in women (*moderate*).
9. Transdermal testosterone has been shown to increase desire, arousal, and satisfying sexual events, and to decrease personal distress (*high*).
10. Psychological therapies, including cognitive behavioural therapy, mindfulness-based therapy, couples' therapy, and sexual therapies, are useful for treating sexual dysfunctions (*moderate*).
11. Sexual dysfunction is common in patients with depression, those on selective serotonin reuptake inhibitors (SSRIs), women with primary ovarian insufficiency, and those with a history of breast cancer (*high*).

**RECOMMENDATIONS:**

1. The patient's problem should be categorized as related to desire, arousal, pain, or orgasm, in order to facilitate treatment and to triage care (*strong, moderate*).
2. Health care providers should include a sexual screening history and physical examination in the initial evaluation of menopausal women (*strong, low*).
3. Vaginal estrogens, lubricants and moisturizers, vaginal dehydroepiandrosterone, and ospemifene may be used as treatments for vaginal atrophy related to menopause (*strong, high*).
4. For postmenopausal women with hypoactive sexual desire disorder, the best current options include managing pain, addressing any biopsychological factors, counselling, and prescribing transdermal testosterone (off-label) or flibanserin (*strong, moderate*).
5. Patients with breast cancer and symptomatic genitourinary syndrome of menopause can be offered local vaginal estrogen if local lubricants and moisturizers are ineffective, after consulting with the patient's oncologist (*conditional, moderate).*

## INTRODUCTION

Many perimenopausal and postmenopausal women voice concerns about changes in sexual desire or pain with intercourse that affect their relationships and quality of life.[1] The most common sexual problems in women in mid-life are loss of libido and dyspareunia.[2–6] In one U.S. survey, 52.4% of naturally menopausal women, versus 26.7% of premenopausal women, reported low sexual desire, but only 8.3% reported low desire in combination with distress (hypoactive sexual desire disorder [HSDD]); the highest prevalence of HSDD was among women who had undergone surgical menopause (12.5%).[2] This change in sexual desire occurs, on average, 20 months before the last menstrual period.[6] As well, about 50% of women report vulvovaginal discomfort within 3 years of menopause.[7]

Sexual problems are strongly associated with aging. Older women have the greatest prevalence of any sexual problems but the least distress associated with these problems.[6,8] Women in mid-life (aged 45–64 y) experience the highest prevalence of distress at 14.8% overall (12.3% for desire, 7.5% for arousal, 5.7% for orgasm); prevalence decreases to 8.9% in women aged 65 to 85 years.[5] Globally, high rates of sexual dysfunction have been found for postmenopausal women.[7–9]

Decline in sexual function during menopause is caused by multiple factors, categorized as biological, psychological, and interpersonal. Some of these factors include the presence of a partner, his or her sexual function, and the quality of the relationship;[9] the woman's mental and physical health, including vulvovaginal atrophy, weight gain, stress, medications, and past sexual experiences; and the woman's socioeconomic and cultural background.[9–11] Drugs that may affect sexual function include opioids, psychotropics and antidepressants, chemotherapeutic drugs, hormonal drugs, cardiovascular drugs, and antihistamines, as well as alcohol and other recreational drugs.[12] Medical conditions that can affect sexuality include anxiety, depression, urinary incontinence, thyroid problems, cancer, cardiovascular disease, and diabetes.[12]

### ABBREVIATIONS

| | |
|---|---|
| DHEA | dehydroepiandrosterone |
| FSAD | female sexual arousal disorder |
| GSM | genitourinary syndrome of menopause |
| PLISSIT | Permission, Limited Information, Specific Suggestions, and Intensive Therapy |
| HSDD | hypoactive sexual desire disorder |
| SSRI | selective serotonin reuptake inhibitors |

The prevalence of sexual problems is also higher in women who have undergone surgical menopause, especially those who have undergone oophorectomy before age 45.[2,13] After menopause, the vulva and vagina undergo physical changes from the decreases in estrogen and testosterone; these decreases also affect the bladder, pelvic floor musculature, vaginal lubrication, elasticity, and microbiome, and genital sensitivity.[14,15] Arousal takes longer, and the intensity of orgasm is reduced. Education about these normal changes may alleviate some concerns.

Clinical intervention is warranted only when a woman is distressed about some aspect of sexual function. However, studies have also shown the importance of sexuality and of interest in sexuality for aging women. Continuation of sexual activity depends on the presence of a partner and their sexual function, as well as the woman's health.[9]

### SUMMARY STATEMENTS 1 AND 2

## PHYSIOLOGY OF SEXUAL RESPONSE

Sexual arousal involves neural, sensory, cognitive, hormonal, and genetic factors. Regulation of sexual desire in the brain appears to be a dynamic neuroendocrine process, balanced between excitatory and inhibitory neurons. Excitatory neurotransmitters include dopamine (considered the main neurotransmitter that mediates arousal), norepinephrine, oxytocin, melanocortins, and possibly estrogen, progesterone, and testosterone; serotonin, prolactin, and opioids are inhibitory. Decreased desire may be caused by an increase in the inhibitory activity of reward pathways or a decrease in excitatory factors.[16,17] An alteration in any of these could result in dysfunction.[16]

Arousal depends on an interplay between the brain and local pelvic nerve stimulation. It requires adequate blood supply, producing engorgement of the clitoris, vestibular glands, and spongiosal tissue around the urethra, followed by clitoral smooth-muscle relaxation, and, ultimately, tumescence and protrusion of the clitoris[16] and resolution.

## TYPES OF SEXUAL DYSFUNCTION IN WOMEN

Women's sexual dysfunction has been defined by several organizations and publications, including the *Diagnostic and Statistical Manual of Mental Disorders,* 5th edition (DSM-5) published by the American Psychiatric Association,[18] the fourth International Consultation on Sexual Medicine,[19] the International Society for the Study of Women's Sexual Health, and the World Health Organization's *International*

*Classification of Disease and Related Health Problems* (ICD-11).[20] See Table.

Satisfactory sexual functioning is defined in the ICD-11 as being unique to the individual; that is, the person can participate in sexual activity and in a sexual relationship, as desired. There is no normative standard for sexual activity.[20] Sexual dysfunctions are defined as those with chronic symptoms (minimum of 3 mo); that occur in 75% of sexual events, and are associated with personal distress.[21] They are categorized according the classical female response cycle as those involving desire (HSDD), arousal (female sexual arousal disorder [FSAD]), orgasm (delayed or absent), and sexual pain (dyspareunia or vaginismus). Dysfunctions may be lifelong or acquired, situational or generalized. Multiple areas of sexual dysfunction may overlap at any time.[21] The DSM-5 combines HSDD and FSAD into a single entity called *sexual interest/arousal disorder*. Traditionally, HSDD refers to the persistent lack of sexual thoughts and desires, leading to personal distress. ISSWSH has endorsed keeping HSDD and FSAD as two separate categories.[22]

## SUMMARY STATEMENT 3 AND RECOMMENDATION 1

## EVALUATION OF SEXUAL DYSFUNCTIONS

Assessment of sexual health is part of good medical care and includes a comprehensive gynaecologic, sexual and gender identity, social, relationship, and medication history. There are several validated self-administered questionnaires available for screening (Box), including the 5-question Decreased Sexual Desire Screener,[23] the 5-question Brief Sexual Symptom Checklist,[24] the 19-question Female Sexual Function Index,[25] the revised Female Sexual Distress Scale,[26] and the Pelvic Organ Prolapse/Urinary Incontinence Sexual Questionnaire.[27]

**Box. Validated questionnaires for sexual function in women**

| |
|---|
| Decreased Sexual Desire Screener[23] |
| Brief Sexual Symptom Checklist[24] |
| Female Sexual Function Index[25] |
| Female Sexual Distress Scale[26] |
| Pelvic Organ Prolapse/Urinary Incontinence Sexual Questionnaire[27] |

PLISSIT (an acronym for Permission, Limited Information, Specific Suggestions, and Intensive Therapy) is a model developed by psychologist Jack Annon to address sexuality issues with patients.[28] The Process of Care Recommendations Model from ISSWSH builds on the PLISSIT and outlines recommendations for clinicians who are not sexual medicine specialists.[29] This model provides a useful 4-step guide for approaching the problem. These steps involve taking the history; identifying the problem; listening empathetically and acknowledging the sexual dysfunction; and referring the patient for assessment and treatment, if necessary. During this process the nature of the sexual problem, onset, relationship to menopause, presence or nature of pain, as well as orgasmic history, are elucidated and a complete and targeted physical examination is performed with special attention to anatomy of the vulva, localized tender areas, ulcers or other skin lesions, hypertonicity of the pelvic floor, as well as visible or palpable lesions.[12] To make a diagnosis, most laboratory tests are unnecessary. Communication is facilitated by starting with open-ended statements that assure the patient that many menopausal women have sexual concerns and then asking the patient if she has had any sexual difficulties.[12,15] Adequate time or a separate appointment to address the patient's issues is recommended.

**Table. Classification of Sexual Dysfunction in Women**

| Domain | Etiology of dysfunction | Available treatments |
|---|---|---|
| Desire | Psychosocial stress, HSDD, hormonal changes, aging, endocrinopathies (thyroid, proloactin), medication-induced (SSRI, OCP), other medical comorbidities | Talk therapy, correction of medical or psychosocial causes, flibanserin, off-label testosterone |
| Arousal | Psychosocial stress, diabetes, vascular disease, medication-induced (SSRI, OCP), iatrogenic (pelvic surgeries) | Talk therapy, off-label use of PDE5 inhibitor, pelvic physiotherapy |
| Pain | GSM, pelvic floor muscle hypertonicity, psychosocial stress, trauma, lichen sclerosus, lichen planus | Correct underlying medical or psychosocial causes, local hormone application, pelvic physiotherapy, talk therapy |
| Orgasm | Psychosocial distress, medication-induced (SSRI), comorbidities, iatrogenic (pelvic and neurological surgeries) | Talk therapy, medication changes, off-label use of PDE5 inhibitor |

GSM: genitourinary syndrome of menopause; HSDD: hypoactive sexual desire disorder; OCP: oral contraceptive pill; PDE5: PDE5: phosphodiesterase 5; SSRI: selective serotonin reuptake inhibitor.

## SUMMARY STATEMENT 4 AND RECOMMENDATION 2

### TREATMENT OF SEXUAL DYSFUNCTION IN WOMEN

Initial treatments include education about the effects of menopause, aging, and medication on sexual function, as well as basic information about foreplay, non-penetrative alternatives, and use of vibrators. Discussion should include treatments for genitourinary syndrome of menopause (GSM) and suggestions for improving communication with partners. Relationship problems, psychiatric conditions, longstanding sexual dysfunction, unresolved sexual trauma, sexual boredom, infidelity, or cultural or religious issues may be within or beyond the scope of primary care physicians.[15]

## SUMMARY STATEMENT 5

#### Painful Sex

Vulvovaginal atrophy and pain can affect the sexuality of both partners, resulting in avoidance of sex. Sexual dysfunction has been shown to be 3.8 times more common in women with vulvovaginal atrophy.[11]

History taking, physical examination, and laboratory testing, including cultures and biopsy (if necessary) provide diagnostic possibilities for vulvar pain. Visible lesions, other vulvar skin conditions, and ulcers should be managed first. Pain during intimacy may be localized to the vulva or may be deeper, occurring during penetration. Low-dose local estrogen, lubricants and moisturizers, vaginal ovules of dehydroepiandrosterone (DHEA), or oral ospemifene, which has now been approved by Health Canada, are the preferred treatments for GSM (see "Guideline No. 422b: Menopause and Genitourinary Health").[30]

Pelvic pain associated with deeper penetration is often multifactorial. Patients experiencing such pain should receive a complete biopsychosocial assessment and physical examination. Individuals with pelvic floor muscular dysfunction may have a combination of sexual pain and bladder and bowel dysfunction that requires a multidisciplinary approach involving pelvic floor physiotherapy, the use of vaginal dilators, mindfulness, and yoga.[31,32] There is emerging evidence regarding onabotulinum toxin as treatment for pelvic floor muscle hypertonicity.[33]

Introduction of penile intercourse after a period of abstinence may cause new vulvar pain in a postmenopausal woman. Couples should be advised that sexual interactions that do not involve penetration can be a rewarding alternative.

## SUMMARY STATEMENTS 6 AND 7 AND RECOMMENDATION 3

#### Low Libido or Hypoactive Sexual Desire Disorder

Individuals with persistent, bothersome low desire in the absence of an identifiable cause may be diagnosed with HSDD. A thorough history and physical examination may elicit reversible medical causes (e.g., thyroid disease, use of selective serotonin reuptake inhibitors [SSRIs] or oral contraceptive pills) or psychosocial factors that can be treated to improve desire.

There has been interest in measuring androgens (e.g., testosterone levels) to diagnose HSDD. However, androgen levels decline slowly with age rather than precipitously at menopause, as estrogen levels do. Surgical menopause, however, eliminates all ovarian androgen production.[34] There are currently insufficient data to show a correlation between endogenous androgen concentrations with current assays and sexual function. Therefore, measuring androgens as a diagnostic tool for HSDD is not recommended.[35]

A Cochrane review involving 4768 participants, as well as a systematic review and meta-analysis, concluded that the addition of transdermal testosterone improves sexual function in postmenopausal women.[36,37] Eleven leading medical organizations have recently endorsed the efficacy of transdermal testosterone for the treatment of low sexual desire, arousal, orgasmic dysfunctions, pleasure, and sexual responsiveness.[38] However, there are no Health Canada–approved formulations. The suggested off-label dosage is 1 half pump of 1% androgen gel, preferably on the posterior calf (one-tenth the male dosage). Other preparations that are not recommended include oral testosterone, which may have detrimental lipid effects, and intramuscular testosterone, which may cause supraphysiologic levels.[38] Oral DHEA has not been shown to improve sexual function.[12,15,38] Contraindications to testosterone therapy include pregnancy, severe acne, hirsutism, androgenic alopecia, and high baseline free testosterone levels. Testosterone therapy is associated with mild increases in acne and body/facial hair in under 5% of women but is not associated with alopecia, clitoromegaly, or voice change.[38] Usage should be monitored, with assessment of

total testosterone at baseline, 3–6 weeks after initiation, and every 6 months thereafter, with the aim of limiting testosterone levels to those no higher than those found in young women (2.8 nmol/L).[38] Patients should be advised that positive effects may not be felt until 3 months after beginning therapy. Safety data are not available beyond 24 months of treatment.[39] If there are no benefits after 6 months, the therapeutic trial should be discontinued.[38]

Flibanserin (a combined serotonin agonist and antagonist) has been approved for the treatment of premenopausal women with HSDD and has been shown in 3 large clinical trials to increase desire scores and sexually satisfying events.[40] One study has demonstrated its efficacy in postmenopausal women as well.[41] While unavailable in Canada at this time, bremelanotide, a melanocortin 4-receptor agonist, has been approved by the U.S. Food and Drug Administration as the first on-demand, injectable medication to increase sexual desire.[42] Before the approval of oral flibanserin and injectable bremelanotide, treatments centred on talk therapy and the off-label use of buproprion, buspirone, phosphodiesterase inhibitors, and testosterone therapy.[21]

## SUMMARY STATEMENT 8 AND 9 AND RECOMMENDATION 4

### Arousal Disorders

The major issue for women with arousal disorders is the lack of subjective arousal from any physical or non-physical stimuli. Low arousal is manifested as decreased pelvic blood flow and lubrication during sexual stimulation.

A history and physical examination may elicit reversible causes, including medication use, menopausal changes, and/or systemic illness (e.g., diabetes). An analysis of postmenopausal women with combined HSDD and arousal disorders showed an association of these conditions with both surgical menopause and SSRI use.[43]

There are no Health Canada–approved treatments for arousal disorders in women. In women without reversible medical or psychosocial causes, phosphodiesterase inhibitors (low-dose sildenafil) can be trialed, as there is some evidence supporting their off-label use.[15] There is limited evidence for the use of mechanical devices such as sex toys or clitoral suction devices.[44] Mindfulness, as part of cognitive behavioural sex therapy, is a promising option.[45]

### Anorgasmia

There are no approved, on-label treatments for anorgasmia. Primary anorgasmia (lifelong inability to achieve an orgasm) is difficult to treat. Physical examination may reveal clitoral phimosis or lichen sclerosus, which can be treated.[21] Psycho-education, mindfulness, directed masturbation, sensate focus techniques, or vibrators may help individuals who have never achieved an orgasm.[45]

Secondary anorgasmia (anorgasmia in an individual who was previously able to achieve orgasm) may be related to psychosocial changes and may require therapy. As well, medications such as SSRIs are strongly associated with anorgasmia and can be titrated or changed to bupropion.[45] Patients with vulvar lesions and menopause-associated vulvovaginal changes may benefit from appropriate local therapies. There is some evidence that flibanserin and transdermal testosterone may improve orgasm in individuals with concomitant low desire.[45] A few studies have demonstrated the efficacy of phosphodiesterase inhibitors, specifically sildenafil, in women on SSRI therapy for depression.[45]

### Psychological Therapies

As the causes of sexual dysfunctions may be multifactorial or have ramifications for the patient's relationship, psychological well-being, work, sociocultural milieu, and quality of life, psychological counselling may be required. It may be used alone or in conjunction with directed medical therapies. Alternatives to counselling include psychotherapy, cognitive behavioural therapy, mindfulness and sexual skills training, and individual, couples, or group sexual counselling.[15, 45]

## SUMMARY STATEMENT 10

## COMMON MENOPAUSAL CLINICAL SITUATIONS

### Depression and Sexual Dysfunction

Depression is frequently associated with sexual dysfunction.[46] Secondary sexual dysfunction occurs in 35% to 70% of women on SSRIs and delayed orgasm or anorgasmia in over 40%, depending on the SSRI and dosage.[47] Forty percent of women with desire, arousal, or orgasm problems had concurrent depression.[48]

### Sexual Function of Women with Premature Ovarian Failure

Premature ovarian failure is the loss of ovarian function in women younger than 40 years; it occurs in 1% of women and is associated with psychological distress and an almost three-fold risk of sexual dysfunction.[49] Studies have shown that arousal, lubrication, orgasm, satisfaction, and pain scores were significantly different in women with primary ovarian failure compared with controls.[49]

Recommended individual therapy is any combination of counselling, antidepressant therapy, hormone replacement therapy, and androgen therapy.[50]

### Breast Cancer and Sexual Dysfunction

Women with breast cancer may be faced with induced menopause, surgical disfigurement, decreased desire, painful intercourse, and depression as result of therapies that affect sexual function.[51] Changes in sexuality are often a delayed concern, after recovery from the initial treatment. In a study of Australia women during the 12 months after a diagnosis of invasive breast cancer, 70% experienced sexual dysfunction, as did over 70% of patients who had undergone risk-reducing salpingo-oophorectomy.[52] The quality of the existing relationship is the most accurate predictor of sexual experiences following diagnosis, and the development of premature ovarian failure as the result of chemotherapy is also a major predictor. Patients on aromatase inhibitors tend to have more sexual dysfunction than those on tamoxifen, compared with controls.[53] Early recognition of sexual problems and treatment with counselling, moisturizers, lubricants, and physical therapies such as dilators are currently the recommended approach. Local estrogen therapies may be offered, after discussion with the patient's oncologist and if local non-hormonal therapies fail; this approach has been approved by the North American Menopause Society and the American College of Obstetricians and Gynecologists.[54]

## SUMMARY STATEMENT 11 AND RECOMMENDATION 5

## CONCLUSION

Sexual function declines with age but remains an important aspect of general health for menopausal and aging women. Decline in sexual desire may start 20 months before the last menstrual period but is also affected by multiple bio-psychological and relationship factors. Decreased sexual desire is the most common sexual complaint in mid-life, but painful intercourse caused by vulvovaginal changes is also very common. Maintenance of vulvovaginal health should be addressed first, employing the multiple options discussed in SOGC guideline No. 422b: Menopause and Genitourinary Health. If a menopausal woman continues to complain of distressing loss of libido after other causes have been eliminated and/or addressed, a trial of testosterone should be considered. Validation of symptoms, as well as education and counselling about physiologic changes that occur with aging is recommended. Women with breast cancer, depression, or premature ovarian insufficiency may be especially affected by changes in sexual function.

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## APPENDIX A

**Table A1. Key to Grading of Recommendations, Assessment, Development and Evaluation Quality of Evidence**

| Grade | Definition |
|---|---|
| Strength of recommendation | |
| Strong | High level of confidence that the desirable effects outweigh the undesirable effects (strong recommendation for) or the undesirable effects outweigh the desirable effects (strong recommendation against) |
| Conditional [a] | Desirable effects probably outweigh the undesirable effects (weak recommendation for) or the undesirable effects probably outweigh the desirable effects (weak recommendation against) |
| Quality of evidence | |
| High | High level of confidence that the true effect lies close to that of the estimate of the effect |
| Moderate | Moderate confidence in the effect estimate:<br>The true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different |
| Low | Limited confidence in the effect estimate:<br>The true effect may be substantially different from the estimate of the effect |
| Very low | Very little confidence in the effect estimate:<br>The true effect is likely to be substantially different from the estimate of effect |

[a] Do not interpret conditional recommendations to mean weak evidence or uncertainty of the recommendation.

Adapted from GRADE Handbook (2013), Table 5.1.

**Table A2. Implications of Strong and Conditional recommendations, by guideline user**

| Perspective | Strong Recommendation<br>• "We recommend that. . ."<br>• "We recommend to not. . ." | Conditional (Weak) Recommendation<br>• "We suggest. . ."<br>• "We suggest to not. . ." |
|---|---|---|
| Authors | The net desirable effects of a course of action outweigh the effects of the alternative course of action. | It is less clear whether the net desirable consequences of a strategy outweigh the alternative strategy. |
| Patients | Most individuals in the situation would want the recommended course of action, while only a small proportion would not. | The majority of individuals in the situation would want the suggested course of action, but many would not. |
| Clinicians | Most individuals should receive the course of action. Adherence to this recommendation according to the guideline could be used as a quality criterion or performance indicator. | Recognize that patient choices will vary by individual and that clinicians must help patients arrive at a care decision consistent with the patient's values and preferences. |
| Policymakers | The recommendation can be adapted as policy in most settings. | The recommendation can serve as a starting point for debate with the involvement of many stakeholders. |

Adapted from GRADE Handbook (2013), Table 6.1.