

NATIONAL GUIDELINE CLEARINGHOUSE™ (NGC) GUIDELINE SYNTHESIS

EVALUATION AND MANAGEMENT OF URINARY INCONTINENCE

Guidelines

1. Finnish Medical Society Duodecim (FMS). [Urinary incontinence in women](#). In: EBM Guidelines. Evidence-Based Medicine [CD-ROM]. Helsinki, Finland: Duodecim Medical Publications Ltd.; 2005 Aug 31 [Various].
2. The John A. Hartford Foundation Institute for Geriatric Nursing (JHF). [Urinary incontinence](#). In: Mezey M, Fulmer T, Abraham I, Zwicker DA, editor(s). Geriatric nursing protocols for best practice. 2nd ed. New York (NY): Springer Publishing Company, Inc.; 2003. p. 83-98. [26 references]
3. Scottish Intercollegiate Guidelines Network (SIGN). [Management of urinary incontinence in primary care. A national clinical guideline](#). Edinburgh (Scotland): Scottish Intercollegiate Guidelines Network (SIGN); 2004 Dec. 41 p. (SIGN publication; no. 79). [128 references]
4. Singapore Ministry of Health (SMOH). [Nursing management of patients with urinary incontinence](#). Singapore: Singapore Ministry of Health; 2003 Dec. 40 p. [32 references]

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INTRODUCTION

A direct comparison of guidelines developed by Finnish Medical Society Duodecim (FMS), John A. Hartford Foundation Institute for Geriatric Nursing (JHF), Scottish Intercollegiate Guidelines Network (SIGN), and Singapore Ministry of Health

(SMOH) for evaluation and management of urinary incontinence (IU) is provided in the tables, below.

While the general scope of the guidelines is similar, with all addressing the assessment and management of UI, they differ in important respects. First, the FMS guideline addresses UI in women, while the JHF, SIGN, and SMOH guidelines address UI in both men and women. Secondly, the JHF and SMOH guidelines apply to the acute care setting, while the SIGN guideline applies to the primary care setting; the FMS guideline is not specific to a particular care setting. Thirdly, the JHF and SMOH guidelines are directed towards nursing professionals, while the FMS and SIGN guidelines are directed primarily towards physicians.

It is also important to note that the scope of the guidelines with respect to the type of UI addressed varies for each of the organizations. See the table below for the types of UI addressed in each of the respective guidelines. For the purpose of this guideline comparison, recommendations pertaining to the two primary forms of UI (stress and urge UI) will be discussed. Recommendations specific to other forms of UI (mixed, overflow, transient and functional) are discussed in the respective summaries.

Type of UI	FMS (2005)	JHF (2003)	SIGN (2004)	SMOH (2003)
<i>Stress</i>	DD/RP	DD/RP	DD/RP	DD/RP
<i>Urge (including detrusor instability)</i>	DD/RP	DD/RP	DD/RP	DD/RP
<i>Mixed</i>	DD		DD/RP	DD/RP
<i>Overflow</i>	DD	DD/RP		DD
<i>Transient</i>				DD
<i>Functional</i>		DD/RP		DD
Abbreviations used in table: DD=Described and/or defined in guideline; RP=Recommendations provided for this type of UI in guideline.				

[Table 1](#) below compares the scope of each of the guidelines. [Table 2](#) compares recommendations for the assessment and management of UI. [Table 3](#) compares the potential benefits and harms associated with the implementation of each guideline.

The level of evidence supporting the major recommendations is also identified, with the definitions of the rating schemes used by SIGN and SMOH included in

[Table 4](#). References supporting selected recommendations of the FMS and SMOH guidelines are also provided in this table.

Following the content comparison tables, the areas of agreement and differences among the guidelines are identified.

Related Guideline:

Registered Nurses Association of Ontario (RNAO). Promoting continence using prompted voiding. Toronto (ON): Registered Nurses Association of Ontario (RNAO); 2005 Mar. 48 p. [42 references]

Abbreviations

- FDA, U.S. Food and Drug Administration
- FMS, Finnish Medical Society Duodecim
- JHF, The John A. Hartford Foundation Institute for Geriatric Nursing
- MOH, Ministry of Health (Singapore)
- PFME, Pelvic floor muscle exercises
- PVR, Post void residual
- RCT, randomized controlled trial
- SIGN, Scottish Intercollegiate Guidelines Network
- TVT, tension-free vaginal tape
- UI, urinary incontinence

TABLE 1: COMPARISON OF SCOPE AND CONTENT	
Objective And Scope	
FMS (2005)	Evidence-Based Medicine Guidelines collect, summarize, and update the core clinical knowledge essential in general practice. The guidelines also describe the scientific evidence underlying the given recommendations.
JHF (2003)	<ul style="list-style-type: none"> • To present a nursing standard of practice protocol for UI • To discuss the transient and established etiologies of UI • To describe the core components of a nursing assessment for UI in hospitalized elders • To identify major treatment strategies for UI • To provide indications for indwelling catheter use
SIGN (2004)	<ul style="list-style-type: none"> • To identify opportunities and effective techniques within primary care for assessing and treating UI in adults • To offer the primary care practitioner an indication of the factors that should lead to an onward referral

SMOH (2003)	To assist nurses in the management of adult patients suffering from UI in the hospital
Target Population	
FMS (2005)	<ul style="list-style-type: none"> • Finland • Women with UI
JHF (2003)	<ul style="list-style-type: none"> • United States • Older adults hospitalized for acute care
SIGN (2004)	<ul style="list-style-type: none"> • Scotland • Adults with UI
SMOH (2003)	<ul style="list-style-type: none"> • Singapore • All adult patients with UI <p>The guidelines are not applicable to children, or adults who have undergone urological or gynaecological surgeries.</p>
Intended Users	
FMS (2005)	Health Care Providers Physicians
JHF (2003)	Advanced Practice Nurses Nurses
SIGN (2004)	Advanced Practice Nurses Allied Health Personnel Nurses Patients Physical Therapists Physician Assistants Physicians
SMOH (2003)	Advanced Practice Nurses Nurses Physician Assistants
Interventions and Practices Considered	
FMS (2005)	Assessment/Diagnosis <ul style="list-style-type: none"> • Determination of the type of incontinence • Physical exam/pelvic exam

	<ul style="list-style-type: none"> • Urine culture/urinalysis • Ultrasonography/radiography <p>Treatment/Management</p> <p>Urge IC</p> <p><i>Non-pharmacologic</i></p> <ul style="list-style-type: none"> • Bladder retraining • Prompted voiding <p><i>Pharmacologic</i></p> <p>Stress IC</p> <p><i>Non-pharmacologic</i></p> <ul style="list-style-type: none"> • Weight reduction • Urethral compression • Pelvic muscle exercises <p><i>Pharmacologic</i></p> <p><i>Surgical</i></p> <ul style="list-style-type: none"> • Bladder neck suspension • Minimally invasive needle vaginal suspensions • Periurethral injection of bulking agents <p>Overflow IC</p> <p>Electric stimulation</p> <p>Containment Aids (bandages, diapers, urinals, etc)</p>
JHF (2003)	<p>Screening</p> <ul style="list-style-type: none"> • Questioning during routine visits and/or being aware of risk factors <p>Assessment/Diagnosis</p> <ul style="list-style-type: none"> • History • History of incontinence • Determination of the type of incontinence • Assessment of underlying causes • Physical exam/pelvic exam • Urine culture/urinalysis • Voiding diary

	<ul style="list-style-type: none"> • Post-void residual measurement <p>Treatment/Management</p> <p>Urge IC</p> <p><i>Non-pharmacologic</i></p> <ul style="list-style-type: none"> • Bladder retraining • Pelvic muscle training <p><i>Pharmacologic</i></p> <p>Stress IC</p> <p><i>Non-pharmacologic</i></p> <ul style="list-style-type: none"> • Pelvic muscle exercises • Bladder training <p><i>Pharmacologic</i></p> <p><i>Surgical</i></p> <p>Overflow IC</p> <p><i>Non-pharmacologic</i></p> <ul style="list-style-type: none"> • Catheterizations • Sufficient time for voiding • Double voiding <p>Functional ICM</p> <p><i>Non-pharmacologic</i></p> <p>Referral</p>
SIGN (2004)	<p>Screening</p> <ul style="list-style-type: none"> • Questioning during routine visits and/or being aware of risk factors <p>Assessment/Diagnosis</p> <ul style="list-style-type: none"> • History • History of incontinence • Determination of the type of incontinence • Physical exam/pelvic exam

	<ul style="list-style-type: none"> • Urine culture/urinalysis • Voiding diary • Post-void residual measurement • Urodynamic testing (cystometry, uroflowmetry, and ureteral pressure profile) • Digital rectal exam (DRE) • Quality of life (QOL) assessment <p>Treatment/Management</p> <p>Urge IC</p> <p><i>Non-pharmacologic</i></p> <ul style="list-style-type: none"> • Bladder retraining • Pelvic muscle training <p><i>Pharmacologic</i></p> <p>Stress IC</p> <p><i>Non-pharmacologic</i></p> <ul style="list-style-type: none"> • Pelvic muscle exercises <p><i>Pharmacologic</i></p> <p><i>Surgical</i></p> <p><i>Other</i></p> <p>Biofeedback</p> <p>Electric stimulation</p> <p>Containment Aids (bandages, diapers, urinals, etc)</p> <p>Referral</p> <p>Patient Information and Education</p>
SMOH (2003)	<p>Assessment/Diagnosis</p> <ul style="list-style-type: none"> • History • History of incontinence • Determination of the type of incontinence • Assessment of underlying causes • Physical exam/pelvic exam • Urine culture/urinalysis

	<ul style="list-style-type: none"> • Voiding diary • Post-void residual measurement <p>Treatment/Management</p> <p>Urge IC</p> <p><i>Non-pharmacologic</i></p> <ul style="list-style-type: none"> • Toileting assistance • Habit training • Bladder retraining • Prompted voiding • Pelvic muscle training <p>Stress IC</p> <p><i>Non-pharmacologic</i></p> <ul style="list-style-type: none"> • Pelvic muscle exercises • Bladder training <p>Catheterization/indwelling urinary catheter</p> <p>Containment aids (bandages, diapers, urinals, etc)</p> <p><i>Skin care</i></p> <p>Patient Information and Education</p>
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TABLE 2: COMPARISON OF RECOMMENDATIONS FOR EVALUATION AND MANAGEMENT OF URINARY INCONTINENCE	
Screening	
FMS (2005)	Screening not addressed in this guideline.
JHF (2003)	When a patient is admitted, nursing history should include questions to determine if the individual has pre-existing UI or risk factors for developing UI while hospitalized. Questions should focus on the characteristics of incontinence: time of onset, frequency, and severity of the problem.

SIGN (2004)	<p>Risk Factors for Developing Urinary Incontinence</p> <p>B - Health professional should be vigilant and adopt a proactive approach in consultations with patients who are at greatest risk of developing urinary incontinence through factors including age, the menopause, pregnancy and childbirth, high body mass index (BMI), and experience of continence problems in childhood.</p> <p>Initiating an Assessment of Urinary Incontinence</p> <p>C - Health care professionals should recognize the difficulty that some patients have in raising concerns about continence and should be proactive in questioning patients about continence during consultations.</p> <p>C - Health professional should have a positive attitude to continence problems.</p> <p>B - Assessment, treatment, and referral, as appropriate, should be offered to all patients with urinary continence problems.</p>
SMOH (2003)	Screening not addressed in this guideline.
Assessment — History and Physical Exam	
FMS (2005)	<p>Basic Rule</p> <ul style="list-style-type: none"> Differentiate between the two main types of incontinence: stress incontinence and urge incontinence <p>Aetiology</p> <ul style="list-style-type: none"> In stress incontinence the pelvic floor may be weakened because of excessive body weight (>20% overweight), pregnancy, deliveries, and heavy work. Stress incontinence may also be caused by connective tissue weakness, asthma, or muscle-relaxant drug such as prazosin. Urge incontinence is a consequence of chronic bladder irritation. It can be related to <ul style="list-style-type: none"> Sequelae of urinary tract infections Past surgery for incontinence Oestrogen deficiency after menopause Diabetes or multiple sclerosis Use of medicines, such as neuroleptics and diuretics In institutionalized patients, incontinence often is caused by cerebral ischaemia or dementia. Remember the possibility of overflow incontinence after surgery.

	<p>Investigations</p> <ul style="list-style-type: none"> • A questionnaire differentiates fairly well between stress incontinence and urge incontinence. • Exclude tumours of the pelvic region by pelvic examination (and endoscopy if required). • An anamnestic questionnaire may be helpful in differentiating between stress and urge incontinence. • The severity index, developed by Sandvik et al, is an easy and reliable way to assess the severity of the incontinence problem (Sandvik et al., 1993; Hanley, Capewell, & Hagen, 2001). <ul style="list-style-type: none"> • How often do you experience urine leakage? <ul style="list-style-type: none"> • 0 = never • 1 = less than once a month • 2 = one or several times a month • 3 = one or several times a week • 4 = every day and/or night • How much urine do you lose each time? <ul style="list-style-type: none"> • 1 = drops or little • 2 = more • The severity is described by the total score, which is the score for the first question multiplied by the score for the second question <ul style="list-style-type: none"> • 0 = no incontinence • 1-2 = slight • 3-4 = moderate • 6-8 = severe incontinence
<p>JHF (2003)</p>	<p>Assessment Parameters</p> <p>When a patient is admitted, nursing history should include questions to determine if the individual has pre-existing UI or risk factors for developing UI while hospitalized. Questions should focus on the characteristics of incontinence: time of onset, frequency, and severity of the problem. Questions also should review the past health history and address possible precipitants of UI such as coughing, functional decline, and acute illness. Nurses should inquire about lower urinary tract symptoms such as nocturia, hematuria, and hesitancy, and current management strategies for the UI. The presence and rationale for an indwelling urinary catheter should be documented.</p> <p>A bladder diary or voiding record is the gold standard for obtaining objective information about the patient's voiding pattern, incontinent episodes, and the severity of the UI. A bladder diary completed for even one day can help identify patients with bladder dysfunction or those requiring further referral.</p> <p>Comprehensive Assessment</p>

	<p>A wide variety of medications can adversely affect continence. Nurses should document all over-the-counter, herbal, and prescription medications on admission. Additionally, nurses must closely scrutinize new medications if UI suddenly develops during the patient's hospital stay. Medications that may contribute to iatrogenic (hospital caused) UI include diuretics (because these drugs increase urine volume and urinary urgency) and sedative-hypnotics (since sedation may contribute to delirium and functional UI).</p> <p>Important components of a comprehensive examination include abdominal, genital, rectal, and skin examinations. In particular, the abdominal exam should assess for suprapubic distention indicative of urine retention. Inspection of male and female genitalia can be completed during bathing or as part of the skin assessment. The nurse should observe the patient for signs of perineal irritation, lesions, or discharge. In women, a Valsalva maneuver (if not medically contraindicated) may identify pelvic prolapse (e.g., cystocele, rectocele, uterine prolapse) or stress UI as a result of increased intra-abdominal pressure with bearing down. Post-menopausal women are especially prone to atrophic vaginitis. Significant findings for atrophic vaginitis include perineal inflammation, tenderness (and on occasion, trauma as a result of touch), and thin, pale tissues. Rectal and skin examinations are essential in identifying transient causes such as constipation, fecal impaction, or fungal rashes.</p> <p>Functional, environmental, and mental status assessments are essential components of the UI evaluation in older adults. The nurse should observe the patient voiding, assess mobility, note any use of assistive devices, and identify any obstacles that interfere with appropriate use of toilets or toilet substitutes.</p>
<p>SIGN (2004)</p>	<p>Quality of Life, Patient Information, and Health Promotion</p> <p>B - Health care practitioners should consider using a validated quality of life and incontinence severity questionnaire to evaluate the impact of urinary symptoms and to audit the effectiveness of any management strategy.</p> <p>Primary Care Assessment Tools</p> <p>Clinical history taking is an essential part of the initial assessment.</p> <p>A routine clinical history of urinary incontinence should cover:</p> <ul style="list-style-type: none"> • Medication • Bowel habit • Functional status and toilet access • Sexual dysfunction • Quality of life

	<p>A clinical history may be supplemented by appropriate use of the following tools:</p> <ul style="list-style-type: none"> • Questionnaires • Pelvic floor assessment • Urinalysis • Post void residual volume • Flow rate • Digital rectal examination • Voiding diaries (frequency volume charts) • Pad tests
SMOH (2003)	<p>Assessment</p> <p>History-Taking</p> <p>Take a history from the person identified to have UI. (D/4 - Fantl et al., 1996)</p> <p>Physical Examination</p> <p>Conduct systematic physical examination to identify abnormalities that have a bearing on the incontinence. (D/4 - Fantl et al., 1996)</p> <p>Check for fluid retention. (D/4 - Fantl et al., 1996)</p> <p>Assess skin condition around the genital-perineal region and check for excoriation. (D/4 - Fantl et al., 1996)</p> <p>Assess functional state. Examine and determine patient's mobility, cognition, and manual dexterity. (D/4 - Fantl et al., 1996)</p> <p>Direct Observation of Leakage</p> <p>Instruct patient to cough forcefully when the bladder is full and observe for urine leakage. (D/4 - Fantl et al., 1996)</p> <p>Bladder Chart/Intake-and-Output Chart</p> <p>Record frequency, timing, and amount of fluid intake and voiding for a few days. (D/4 - Fantl et al., 1996)</p>
Assessment — Diagnostic and/or Specialized Testing	
FMS (2005)	<p>Investigations</p> <ul style="list-style-type: none"> • Exclude urinary tract infection by urine culture.

	<p>Indications for Specialized Investigations (Ultrasonography, Radiography, Urodynamics)</p> <ul style="list-style-type: none"> • Annoying symptoms, especially if dominated by urge incontinence • Recurrence of symptoms after surgery
JHF (2003)	<p>Diagnostic testing may provide additional information. For example, urinalysis and urine cultures are used to identify a UTI, which may contribute to new onset UI. A post-void residual urine (PVR) may reveal incomplete bladder emptying. Two ways to accurately evaluate PVR are bladder sonography or by catheter insertion after the patient has voided.</p>
SIGN (2004)	<p>Primary Care Assessment Tools</p> <p><i>Assessment Tool Recommendations</i></p> <p>D - Initial assessment of a male patient with UI should include completion of a voiding diary, urinalysis, estimation of PVR volume, and digital rectal examination.</p> <p>D - Initial assessment of a female patient with UI should include completion of a voiding diary, urinalysis, and, where symptoms of voiding dysfunction or repeated urinary tract infections are present, estimation of PVR volume.</p>
SMOH (2003)	<p>Urinalysis</p> <p>Send a sample of urine for urinalysis and culture. (D/4 - Fantl et al., 1996)</p> <p>Measurement of Residual Volume</p> <p>Measure PVR volume by in-out catheterisation or bladder scanning within a few minutes after voiding. (D/4 - Fantl et al., 1996)</p>
<p>MANAGEMENT/TREATMENT: Non-Pharmacologic Treatment</p>	
FMS (2005)	<p>Conservative Treatment</p> <ul style="list-style-type: none"> • Patients with mild stress incontinence <ul style="list-style-type: none"> • Weight reduction • Exercises for strengthening the muscles of the pelvic floor (Hay-Smith et al., 2001; Berghmans et al., 1998; DARE-981413, 2000) [A] • Patients with mild urge incontinence <ul style="list-style-type: none"> • Bladder education (normalizing the micturition interval)

	<p>(Wallace et al., 2004; Berghmans et al., 2000; DARE-20000524, 2001) [B]</p> <ul style="list-style-type: none"> Electrical stimulation is worth trying in both types of incontinence (in stress incontinence the muscles of the pelvic floor are stimulated, in urge incontinence the overactivity of bladder muscles is decreased) (Bo, 1998; DARE-981604, 2000) [D]. <p>Aids</p> <ul style="list-style-type: none"> Aids: bandages, diapers, urinals, and plastic bed sheets prevent leaking. Vaginal bullets and cones (Herbison, Plevnik, & Mantle, 2002) [A], and vaginal tampons help to find the muscles in pelvic floor muscle training and prevent incontinence in short-lasting physical strain. A specialized nurse is responsible for supplying the aids and educating the patient. <p>Related Evidence</p> <ul style="list-style-type: none"> Exercises with myofeedback may be more effective than exercises alone for stress UI, but the evidence is insufficient for reliable conclusions (De Kruif & Van Wegen, 1996; DARE-965250, 1999) [D]. There is some evidence suggesting less UI after preventive pelvic floor muscle training in childbearing women but the evidence is insufficient (Hay-Smith, Herbison, & Morkved, 2002) [C]. There was some suggestive evidence that prompted voiding reduces incontinence episodes in the short term (Eustice, Roe, & Paterson, 2000) [C]. There is not enough evidence to draw firm conclusions about the superiority of certain types of absorbent products (Brazzelli, Shirran, & Vale, 1999) [D].
JHF (2003)	<p>Nursing Care Strategies</p> <p>General principles that apply to prevention and management of all forms of UI:</p> <ul style="list-style-type: none"> Identify and treat causes of transient UI. Identify and continue successful pre-hospital management strategies for established UI. Complete bladder diary. Develop an individualized plan of care using data obtained from the history and physical examination, and in collaboration with other team members. Avoid medications that may contribute to UI. Avoid indwelling urinary catheters whenever possible. Monitor fluid intake and maintain an appropriate hydration schedule.

	<ul style="list-style-type: none"> • Modify the environment to facilitate continence. • Provide patients with usual undergarments in expectation of continence, if possible. • Prevent skin breakdown by providing immediate cleansing after an incontinent episode and utilizing barrier ointments. • Use absorbent products judiciously. <p>Strategies for specific problems:</p> <p><i>Stress UI</i></p> <ul style="list-style-type: none"> • Teach pelvic muscle exercises. • Provide toileting assistance and bladder training. • Consider referral to other team members if pharmacologic or surgical therapies are warranted. <p><i>Urge UI</i></p> <ul style="list-style-type: none"> • Implement bladder training or habit training. • Teach pelvic muscle exercises to be used in conjunction with the above strategy. • Consider referral to other team members if pharmacologic therapy is warranted. • Initiate referrals for those patients who do not respond to the above.
<p>SIGN (2004)</p>	<p>Physical Therapies</p> <p>Pelvic Floor Muscle Exercises</p> <p>A - PFME should be the first choice of treatment offered to patients suffering from stress or mixed incontinence. Exercise programmes should be tailored to be achievable by the individual patient.</p> <p>D - Pelvic floor muscle exercises should be considered as part of a treatment plan for patients with urge urinary incontinence.</p> <p>D - Digital assessment of pelvic floor muscle function should be undertaken prior to initiating any pelvic floor muscle exercise treatment.</p> <p>A - Where group physiotherapy is available patients should be offered the choice of attending or being seen individually.</p> <p>Pelvic Floor Muscle Exercises in Men Undergoing Radical Prostatectomy</p> <p>B - Pelvic floor muscle exercise treatment should be considered for</p>

	<p>patients following radical prostate surgery.</p> <p>Bladder Retraining</p> <p>C - Bladder retraining should be offered to patients with urge urinary incontinence.</p> <p>Containment</p> <p>Product Evaluation</p> <p>Containment products are an essential component in the management of incontinence, but they should only be issued after an initial assessment or when a management plan has been completed and reviewed. Offering disposable pads prematurely can lead to psychosocial dependence upon them and reluctance to accept active treatment. Patients starting physical or medical therapies may require containment products in the short term; this will depend upon their symptoms, leakage incidence, personal choice and lifestyle. Patients with intractable urinary incontinence will require products long term.</p> <p>A number of factors may influence choice of product including patient preference, level of disability, gender, skin integrity, history of allergy, incidence of infection, availability of carers and history of failure with previous products.</p> <p>D - All patients should undergo a continence assessment before product issue. Issue of products should not take the place of therapeutic interventions.</p>
<p>SMOH (2003)</p>	<p>Behavioural Interventions</p> <p>Toileting Assistance</p> <p><i>Timed Voiding/Scheduled Toileting</i></p> <p>Timed voiding/scheduled toileting is recommended throughout the whole day for patient who needs assistance in toileting. (D/4 - Fantl et al., 1996)</p> <p><i>Habit Training</i></p> <p>Habit training is recommended for patient in whom a natural voiding pattern can be determined. (D/4 - Fantl et al., 1996)</p> <p><i>Prompted Voiding</i></p> <p>Prompted voiding is recommended for patients who can learn to recognize some degree of bladder fullness or the need to void, or who</p>

can ask for assistance or respond when prompted to void. Patient is asked at regular intervals regardless whether voiding is required and is assisted to the toilet if the response is positive. (**A/1+** - Fantl et al., 1996)

When toileting is successful, reward with praise and words of encouragement. (**D/4** - Fantl et al., 1996)

Bladder Training/Bladder Re-education

Bladder training is strongly recommended for management of **urge incontinence**. (**A/1+**)

Bladder training is recommended for management of **stress incontinence**. (**D/4** - Fantl et al., 1996)

Pelvic Floor Muscle Exercise

PFME is beneficial to women with **stress incontinence**. It also enhances the benefits of other therapy. (**A++/1**)

Sustain a contraction of the perivaginal muscles or anal sphincter for at least 10 seconds followed by equal periods of relaxation. Perform this 30 to 80 times a day for at least 8 weeks or until desired muscle tone is achieved. (**D/4** - Fantl et al., 1996)

Other Measures and Supportive Care

Intermittent Urinary Catheterisation

Intermittent catheterisation is recommended as a supportive measure for patients with spinal cord injury, persistent UI, chronic urinary retention due to under-active or partially obstructed bladder. (**D/4** -- Fantl et al., 1996)

Indwelling Urinary Catheterisation

An indwelling catheter is recommended for patient with obstructive cause where other interventions are not feasible. It is also useful for the terminally ill; or patient with pressure ulcers, or for severely impaired individual in whom alternative interventions are not suitable. It may also be used when a caregiver is not available to provide other supportive measures. (**D/4** - Fantl et al., 1996)

The patient is assessed periodically for voiding trials or bladder training. (**D/4** - Fantl et al., 1996)

External Collection Systems

	<p>Uro-sheaths are recommended for incontinent men who have adequate bladder emptying and intact genital skin, and in whom other therapies have failed or are not appropriate. (D/4 - Fantl et al., 1996)</p> <p>Absorbent Products</p> <p>Absorbent products are recommended during evaluation, as an adjunct to other therapies, and for long term care of patients with chronic, intractable UI. (D/4 - Fantl et al., 1996)</p> <p>Skin Care</p> <p>Inspect genital-perineal area daily. Identify signs of contact dermatitis and skin excoriation. (D/4 - Fantl et al., 1996)</p> <p>Cleanse skin immediately after urine leakage. (D/4 - Fantl et al., 1996)</p> <p>Use appropriate skin cleansers and barrier creams. (D/4 - Fantl et al., 1996)</p> <p>Dietary and Fluid Management</p> <p>Encourage adequate fluid and fibre intake. Reduce caffeine intake (e.g., coffee, tea, colas). (D/4 - Fantl et al., 1996)</p> <p>Physical and Environmental Alterations</p> <p>Assess the environment in which the patient is in. Perform simple alterations, such as providing toileting or ambulation devices. (D/4 - Fantl et al., 1996)</p>
Drug Therapy	
FMS (2005)	<ul style="list-style-type: none"> Postmenopausal women with minimal symptoms should try local oestrogen therapy (a vaginal suppository or tablet once or twice a week) (Fantl, Cardozo, & McClish, 1994; DARE-953435, 1999; Zullo et al., 1998; DARE-983808, 2000) [B]. Local oestrogen is more effective than systemic oestrogen for either type of incontinence. Patients with mild stress incontinence <ul style="list-style-type: none"> Duloxetine* is a new pharmacological treatment option also for stress incontinence. It has been shown to reduce leakage episodes and to alleviate depression associated with leakage. Patients with mild urge incontinence <ul style="list-style-type: none"> Anticholinergic medication (Hay-Smith et al., 2002) [A] has been used. <ul style="list-style-type: none"> The starting dose of oxybutynin is small (2.5 to 3 mg); the dose should be raised individually to the maximum of 5 mg x 3/day. The new slow release

	<p>tablet (10 mg) taken once daily causes fewer side effects.</p> <ul style="list-style-type: none"> • Tolterodine is as effective as oxybutynin in urge incontinence, but may have fewer anticholinergic side effects (dryness of the mouth and visual disturbances). The dose is 2 mg x 2 from the start. A slow-releasing form for single dosage (4 mg x 1) is also available. • Trospium chloride is one of the new drugs for urge incontinence. The dose is 20 mg x 1 to 2/day. The effect is at least equal to the other drugs but it may have even fewer side effects. • Solifenacin is the newest drug for urge incontinence, with benefits and harms equivalent to other drugs for this use. <p>Related Evidence</p> <ul style="list-style-type: none"> • Adrenergic drugs appear to be more effective than placebo in reducing incontinence episodes and subjective symptoms (Alhasso et al., 2005) [B]. <p>*See Note at the end of the synthesis.</p>
JHF (2003)	<p>No recommendations are offered regarding drug therapy in this guideline.</p> <p>Stress UI</p> <p>Consider referral to other team members if pharmacologic or surgical therapies are warranted.</p> <p>Urge UI</p> <p>Consider referral to other team members if pharmacologic therapy is warranted.</p>
SIGN (2004)	<p>Stress Incontinence</p> <p><i>Combined Noradrenaline and Serotonin Reuptake Inhibitors</i></p> <p>A — Duloxetine* should be used only as part of an overall management strategy in addition to pelvic floor muscle exercises and not in isolation. A 4-week trial of duloxetine is recommended for female patients with moderate to severe stress incontinence. Patients should be reviewed again after 12 weeks of therapy to assess progress and determine whether it is appropriate to continue treatment.</p>

	<p>Detrusor Overactivity and Urge Incontinence</p> <p><i>Antimuscarinics</i></p> <p>A - A trial of oxybutynin, propiverine, tolterodine, or trospium should be given to patients with significant urgency with or without urge incontinence. The dose should be titrated to combat adverse effects.</p> <p>*See Note at the end of the synthesis.</p>
SMOH (2003)	No recommendations are offered regarding drug therapy in this guideline.
Surgery	
FMS (2005)	<ul style="list-style-type: none"> • Stress incontinence may be treated surgically according to the judgment of an urogynaecologist (Black & Downs, 1996). <ul style="list-style-type: none"> • Burch colposuspension was the "golden standard" up to the end of the 1990s (Burch, 1968). It can also be performed endoscopically quite easily either using a mesh or stitches. • The most widely used method today is a procedure where a meshlike tape is guided through a vaginal incision underneath the urethra like a sling that remains in place without tension. Originally the loose ends of the tape were lifted through the abdominal wall and cut beneath the skin (TVT) (Ulmsten, Johnson, & Rezapour, 1999). Nowadays the ends are passed through the obturator foramen (TOT, trans-obturator tape). The procedure may even be performed under local anaesthesia, and the results have been better than with Burch colposuspension (Valpas et al., 2004). • In urge incontinence, surgery usually is not effective. In extreme cases, an operation aimed at enlarging the bladder may be indicated by a specialist. • The treatment for mixed incontinence is selected according to the dominant type of incontinence. <p>Related Evidence</p> <ul style="list-style-type: none"> • Abdominal retropubic suspension appears to be better than anterior vaginal repair for subjective cure (Glazener & Cooper, 2001) [B]. • There is some evidence that laparoscopic colposuspension may have poorer results than open colposuspension. If laparoscopic colposuspension is performed, two paravaginal sutures appear to be more effective than one (Moehrer et al., 2000) [C]. • TVT procedure is at least as effective as colposuspension for the treatment of urodynamic stress incontinence and also appears to be a more cost-effective option. Long-term effects over 2 years are not reliably known (Bezerra, Bruschini, & Cody, 2005; Valpas et al., 2004; Ward & Hilton, 2004; Paraiso et al., 2005; Cody et al., 2003;

	<p>"Tension-free vaginal tape," 2004 [A].</p> <ul style="list-style-type: none"> • Bladder neck needle suspension surgery is probably not as good as open abdominal retropubic suspension for the treatment of primary genuine stress UI in terms of lower cure rates and higher morbidity (Glazener & Cooper, 2004) [C]. • Periurethral injection of established manufactured bulking agents appears to result in subjective and objective short term improvement of symptomatic female stress UI in adults (Pickard et al., 2003) [C]. • Open retropubic colposuspension appears to be a more effective treatment modality for stress UI than anterior colporrhaphy or needle suspensions, especially in the long term (Lapitan, Cody, & Grant, 2005) [B].
JHF (2003)	<p>Stress UI</p> <p>Consider referral to other team members if pharmacologic or surgical therapies are warranted.</p>
SIGN (2004)	<p>D — Patients should be referred to secondary care if previous surgical or non-surgical treatments for UI have failed or if surgical treatments are being considered.</p>
SMOH (2003)	<p>No recommendations offered.</p>

TABLE 3: BENEFITS AND HARMS	
Benefits	
FMS (2005)	<p>This guideline may help the clinician differentiate between types of incontinence in women and select appropriate interventions to reduce or eliminate symptoms of UI.</p>
JHF (2003)	<p>Patients Will Demonstrate:</p> <p>Fewer or no episodes of UI or complications associated with UI</p> <p>Health Care Providers Will Demonstrate:</p> <ul style="list-style-type: none"> • Documented continence status at admission and throughout hospital stay • Interdisciplinary expertise and interventions to assess and manage UI during hospitalization • Inclusion of UI in discharge planning needs and referral as

	<p>indicated</p> <p>Institution Will Demonstrate:</p> <ul style="list-style-type: none"> • Decreased incidence and prevalence of acute UI • Hospital policies requiring assessment and documentation of continence status • Access to the Agency for Health Care Policy and Research (AHCPR) Guidelines for Managing Acute and Chronic UI • Administrative support and ongoing education regarding assessment and management of UI for staff
SIGN (2004)	Effective treatment and management of UI resulting in reduced incontinence episode frequency, reduced urgency, increased patient satisfaction, improved quality of life, and reduced incidence of potential harms (e.g., falls and fractures).
SMOH (2003)	Appropriate assessment and management of patients with UI
Harms	
FMS (2005)	<ul style="list-style-type: none"> • Dry mouth is a common side effect of anticholinergic drug therapy. • Published studies have reported that electrical stimulation produced side effects in about half of the women treated.
JHF (2003)	Urinary catheterization can be associated with urinary tract infections. Patients requiring indwelling urinary catheters may have a higher incidence rate of infection than patients requiring sterile intermittent catheterization.
SIGN (2004)	<ul style="list-style-type: none"> • There are inherent risks of trauma and infection with catheterisation and there may be issues around patient dignity and acceptability that should be considered. • Side effects of adrenoreceptor agonists were noted to be minor, although rare and potentially serious side effects, such as cardiac arrhythmias and hypertension, were reported. • Nausea was the most commonly reported adverse event in one study of duloxetine. • The most common side effects of antimuscarinic drugs are dry mouth, blurred vision, abdominal discomfort, drowsiness, nausea, and dizziness. Urinary retention is a potentially serious but less common side effect. Oxybutynin immediate release (IR) preparation has the highest incidence of side effects. • Offering disposable pads prematurely can lead to psychological dependence upon them and reluctance to accept active treatment.

SMOH (2003)	Not stated
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TABLE 4: EVIDENCE RATING SCHEMES AND REFERENCES

FMS (2005)	<p>Levels of Evidence</p> <ul style="list-style-type: none"> • A. Strong research-based evidence. Multiple relevant, high-quality scientific studies with homogenic results • B. Moderate research-based evidence. At least one relevant, high-quality study or multiple adequate studies • C. Limited research-based evidence. At least one adequate scientific study • D. No scientific evidence. Expert panel evaluation of other information <p>References Supporting the Recommendations</p> <ul style="list-style-type: none"> • Alhasso A, Glazener CM, Pickard R, N'dow J. Adrenergic drugs for urinary incontinence in adults. Cochrane Database Syst Rev 2005 Jul 20;(3):CD001842. [49 references] PubMed • Berghmans LC, Hendriks HJ, Bo K, Hay-Smith EJ, de Bie RA, van Waalwijk van Doorn ES. Conservative treatment of stress urinary incontinence in women: a systematic review of randomized clinical trials. Br J Urol 1998 Aug;82(2):181-91. [74 references] PubMed • Berghmans LC, Hendriks HJ, De Bie RA, van Waalwijk van Doorn ES, Bo K, van Kerrebroeck PE. Conservative treatment of urge urinary incontinence in women: a systematic review of randomized clinical trials. BJU Int 2000 Feb;85(3):254-63. [64 references] PubMed • Bezerra CA, Bruschini H, Cody DJ. Traditional suburethral sling operations for urinary incontinence in women. The Cochrane Database of Systematic Reviews, Cochrane Library no. CD001754. In: Cochrane Library [database online]. Issue 3. Oxford: Update Software; 2005 • Black NA, Downs SH. The effectiveness of surgery for stress incontinence in women: a systematic review. Br J Urol 1996 Oct;78(4):497-510. PubMed • Bo K. Effect of electrical stimulation on stress and urge urinary incontinence. Clinical outcome and practical recommendations based on randomized controlled trials. Acta Obstet Gynecol Scand Suppl 1998;77(Suppl 168):3-11. [42 references] PubMed • Brazzelli M, Shirran E, Vale L. Absorbent products for the containment of urinary and/or faecal incontinence in adults. The Cochrane Database of Systematic Reviews, Cochrane Library no: CD001406. In: Cochrane Library [database online]. Issue 3. Oxford: Update Software; 1999.
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JHF (2003)	Not applicable
SIGN (2004)	<p>Levels of Evidence:</p> <p>1++: High quality meta-analyses, systematic reviews of randomized controlled trials (RCTs), or RCTs with a very low risk of bias</p> <p>1+: Well-conducted meta-analyses, systematic reviews of RCTs, or RCTs with a low risk of bias</p> <p>1-: Meta-analyses, systematic reviews of RCTs, or RCTs with a high risk of bias</p> <p>2++: High quality systematic reviews of case control or cohort studies</p> <p>High quality case control or cohort studies with a very low risk of confounding or bias and a high probability that the relationship is causal</p> <p>2+: Well conducted case control or cohort studies with a low risk of confounding or bias and a moderate probability that the relationship is causal</p> <p>2-: Case control or cohort studies with a high risk of confounding or bias and a significant risk that the relationship is not causal</p> <p>3: Non-analytic studies (e.g., case reports, case series)</p> <p>4: Expert opinion</p> <p>Grades of Recommendation</p> <p>A: At least one meta-analysis, systematic review of RCTs, or RCT rated as 1++ and directly applicable to the target population; <i>or</i></p> <p>A body of evidence consisting principally of studies rated as 1+, directly applicable to the target population, and demonstrating overall consistency of results</p> <p>B: A body of evidence including studies rated as 2++, directly applicable to the target population, and demonstrating overall consistency of results; <i>or</i></p> <p>Extrapolated evidence from studies rated as 1++ or 1+</p>

	<p>C: A body of evidence including studies rated as 2+, directly applicable to the target population and demonstrating overall consistency of results; <i>or</i></p> <p>Extrapolated evidence from studies rated as 2++</p> <p>D: Evidence level 3 or 4; <i>or</i></p> <p>Extrapolated evidence from studies rated as 2+</p>
SMOH (2003)	<p>Individual Study Validity Ratings</p> <p>++</p> <p>All or most of the criteria have been fulfilled. Where they have not been fulfilled the conclusions of the study or review are thought very unlikely to alter.</p> <p>+</p> <p>Some of the criteria have been fulfilled. Those criteria that have not been fulfilled or not adequately described are thought unlikely to alter the conclusions.</p> <p>-</p> <p>Few or no criteria fulfilled. The conclusions of the study are thought likely or very likely to alter.</p> <p>Study Design Designation</p> <p>The study design is designated by a numerical prefix:</p> <p>"1" for systematic reviews or meta-analyses or RCTs</p> <p>"2" for cohort and case-control studies</p> <p>"3" for case reports/series</p> <p>"4" for expert opinion/logical arguments/"common" sense</p> <p>Hierarchy of the Levels of Scientific Evidence</p> <p>Each study is assigned a level of evidence by combining the design designation (1, 2, 3 or 4) and its validity rating (++, + or -). The meanings of the various "levels of evidence" are given below:</p>

	<p>1++</p> <p>High quality meta-analyses, systematic reviews of RCTs, or RCTs with a very low risk of bias</p> <p>1+</p> <p>Well-conducted meta-analyses, systematic reviews, or RCTs with a low risk of bias</p> <p>1-</p> <p>Meta-analyses, systematic reviews, or RCTs with a high risk of bias</p> <p>2++</p> <p>High quality systematic reviews of case-control or cohort studies</p> <p>High quality case-control or cohort studies with a very low risk of confounding or bias and a high probability that the relationship is causal</p> <p>2+</p> <p>Well-conducted case-control or cohort studies with a low risk of confounding or bias and a moderate probability that the relationship is causal</p> <p>2-</p> <p>Case-control or cohort studies with a high risk of confounding or bias and a significant risk that the relationship is not causal</p> <p>3</p> <p>Non-analytic studies (e.g., case reports, case series)</p> <p>4</p> <p>Expert opinion</p> <p>Rating Scheme for the Strength of the Recommendations</p> <p>Categories of the Strength of Evidence Associated with the Recommendations</p> <p>A</p>
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	<p>At least one meta-analysis, systematic review, or RCT rated as 1++, and directly applicable to the target population; or</p> <p>A body of evidence, consisting principally of studies rated as 1+, directly applicable to the target population, and demonstrating overall consistency of results</p> <p>B</p> <p>A body of evidence, including studies rated as 2++, directly applicable to the target population, and demonstrating overall consistency of results; or</p> <p>Extrapolated evidence from studies rated as 1++ or 1+</p> <p>C</p> <p>A body of evidence including studies rated as 2+, directly applicable to the target population and demonstrating overall consistency of results; or</p> <p>Extrapolated evidence from studies rated as 2++</p> <p>D</p> <p>Evidence level 3 or 4; or</p> <p>Extrapolated evidence from studies rated as 2+</p> <p>Interpretation of the D/4 Grading</p> <p>The grading system emphasises the quality of the experimental support underpinning each recommendation. The grading D/4 was assigned in cases where:</p> <ul style="list-style-type: none"> • It would be unreasonable to conduct a RCT because the correct practice is logically obvious • Recommendations were derived from existing high quality evidence-based guidelines. The guideline developers alert the user to this special case by appending the initials of the source in the original guideline document. (e.g., D/4 - Fantl et al 1996). <p>References Supporting the Recommendations</p> <ul style="list-style-type: none"> • Fantl JA, Newman DK, Colling J, et al. Urinary incontinence in adults: acute and chronic management. AHCPR Publication no. 96-0682. Rockville (MD): U.S. Department of Health and Human Services, Public Health Service, Agency for Health Care Policy and
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GUIDELINE CONTENT COMPARISON

The Finnish Medical Society Duodecim (FMS), John A. Hartford Foundation Institute for Geriatric Nursing (JHF), the Scottish Intercollegiate Guidelines Network (SIGN), and the Singapore Ministry of Health (SMOH) present recommendations for the evaluation and management of urinary incontinence (UI). SIGN and SMOH provide explicit reasoning behind their judgments, ranking the level of evidence for each major recommendation; the FMS and SMOH guidelines offer literature citations to support their major recommendations; rationale for the JHF recommendations is provided in narrative form.

As noted in the introduction to this synthesis, the guidelines differ somewhat in scope, with some guidelines addressing the acute care or primary care setting and others addressing a broader range of care settings. Of note, the two guidelines that are directed at nursing professionals (JHF and SMOH) do not address pharmacologic therapy or surgery directly, but do address areas of patient care, such as skin care, not covered by the other guidelines.

Areas of Agreement

The guidelines are in general agreement concerning assessment and diagnostic procedures, behavioral management strategies, pharmacologic therapy, and surgical procedures for UI. There are also some differences between guidelines, which are discussed below.

Assessment/Diagnosis

The guidelines generally recommend similar components for the assessment and diagnosis of UI: medical and UI history; physical examination; ruling out transient or underlying causes of UI (such as infection and atrophic vaginitis); and distinguishing between stress and urge incontinence.

In addition, SIGN recommends a pelvic floor assessment, and SMOH recommends direct observation of the degree of urine leakage.

FMS and SIGN recommend that symptom severity be evaluated using a standardized questionnaire and SIGN recommends that quality of life be assessed.

With the exception of FMS, the guidelines specify that the patient's functional status and cognitive abilities also should be evaluated, since these relate to both UI etiology and management options.

There is also agreement that a voiding diary or record is useful for the initial assessment of UI. JHF notes that a voiding record is the "gold standard" for

obtaining objective information about the patient's voiding pattern, incontinent episodes, and severity of UI.

Diagnostic Tests

The FMS, SIGN, and SMOH guidelines include recommendations for diagnostic tests. SIGN recommends measuring PVR volume in men and those women who have symptoms of voiding dysfunction or repeated urinary tract infections. SMOH recommends PVR as an assessment tool as well, but does not explicitly restrict its use to particular subgroups of patients. The FMS guideline addresses urodynamic tests (cystometry, uroflowmetry, and ureteral pressure). FMS recommends that ultrasonography, radiology, and urodynamic tests be carried out when symptoms recur following surgery or when annoying symptoms are present, particularly those associated with urge incontinence.

Treatment/Management

Non-Pharmacologic Therapy

Various behavioral strategies for treating incontinence are addressed by the guidelines, including PFME, urge suppression training, bladder training, scheduled voiding, prompted voiding, double voiding, and the Valsalva and Crede maneuvers. All four guidelines agree that PFME should be used for stress incontinence and that bladder training should be used for urge incontinence. SMOH recommends prompted voiding only for those patients who can recognize the need to void. Some differences in recommendations for PFME and bladder training are discussed below.

There are no major differences between the guidelines concerning the need for environmental alterations, fluid management, and judicious use of continence aids and products (pessaries, vaginal cones, absorbent products, etc.).

Pharmacologic Therapy

Two of the four guidelines (FMS and SIGN) address drug treatment for UI. The remaining two guidelines are directed towards nursing professionals and do not address this topic.

Stress Incontinence

FMS and SIGN agree that duloxetine*, a selective serotonin and noradrenergic re-uptake inhibitor, can be useful in treating stress incontinence, although SIGN states that it should be used as part of an overall management strategy in conjunction with PFME. Areas of difference concerning drug therapy for stress incontinence are discussed below.

Urge Incontinence

Both guidelines recommend the anticholinergic agents oxybutynin and tolterodine for urge incontinence and both note that oxybutynin has a higher incidence of side effects. In addition, trospium chloride is recommended by both groups. FMS also

recommends solifenacin, but notes that it is a new drug, which likely explains why it is not considered in the SIGN guideline, which was published a year earlier than the FMS guideline (trospium chloride and solifenacin were approved for use in the United States in May 2004). Areas of differences concerning drug therapy for stress incontinence are discussed below.

Surgery

The FMS guideline addresses surgery for women with stress incontinence, and states the pros and cons of the various surgical approaches. FMS notes that Burch colposuspension was the gold standard up to the end of the 1990s, but that sling procedures are more widely used today. According to FMS, sling procedures have similar cure rates to colposuspension. FMS notes that the TVT procedure in particular is a cost-effective option. The minimally invasive needle vaginal suspension procedure is also discussed by FMS. The FMS guideline states that bladder neck needle suspension surgery is probably not as good as open abdominal retropubic suspension in terms of either cure rates or morbidity. While only FMS addresses surgery directly, both JHF and SIGN recommend referral for surgery when other therapies are unsuccessful.

Areas of Differences

Recommendations between the groups differ somewhat regarding PFME, bladder training, prompted voiding, electrical stimulation, and some aspects of drug therapy.

Non-Pharmacologic Therapy

JHF and SIGN differ from the other guidelines in recommending that PFME be used for urge incontinence. SIGN's stated rationale is that, while there is insufficient evidence concerning the efficacy of PFME in treatment of urge incontinence, expert opinion suggests it may be useful when combined with bladder training. The JHF guideline cites two references in support of its recommendation for PFME. Additionally, only JHF and SMOH recommend bladder training for stress incontinence.

Pharmacologic Therapy

Urge Incontinence

The guidelines also differ concerning the use of some drugs for treatment of urge incontinence. Estrogen is recommended for urge incontinence by FMS. The SIGN guideline states that, while a meta-analysis showed estrogen to be more effective than placebo for treating urge incontinence, there is insufficient data to determine the influence of type of estrogen, route of administration, or duration of therapy on treatment outcome; the guideline also notes that estrogens are not licensed for this purpose in the United Kingdom.

Stress Incontinence

As discussed above, the two guidelines that address pharmacologic therapy agree on the use of duloxetine* for stress incontinence, but they differ concerning the use of other drugs.

FMS recommends local estrogen (estrogen cream and intravaginal ring). SIGN, however, notes that published evidence concerning estrogen is conflicting and that estrogens are not licensed in the United Kingdom for treatment of stress incontinence.

***Note from the National Guideline Clearinghouse:** The guidelines in this synthesis reference a drug for which important revised regulatory information has been released.

On October 17, 2005, Eli Lilly and the U.S. Food and Drug Administration (FDA) notified healthcare professionals of revision to the PRECAUTIONS/Hepatotoxicity section of the prescribing information for Cymbalta (duloxetine hydrochloride), indicated for treatment of major depressive disorder and diabetic peripheral neuropathic pain. Postmarketing reports of hepatic injury (including hepatitis and cholestatic jaundice) suggest that patients with preexisting liver disease who take duloxetine may have an increased risk for further liver damage. The new labeling extends the Precaution against using Cymbalta in patients with substantial alcohol use to include those patients with chronic liver disease. It is recommended that Cymbalta not be administered to patients with any hepatic insufficiency. See the [FDA Web site](#) for more information.

This Synthesis was prepared by ECRI on June 20, 2006. The information was verified by John A. Hartford Institute of Geriatric Nursing on July 27, 2006. The information was updated most recently on October 26, 2007 to remove BWH recommendations.

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