



Clinical Sub-Group to support the delivery of
an Expanded Role for Community Pharmacy

Common Conditions Service Protocol
Uncomplicated Lower Urinary Tract Infection
(Cystitis)
(Final)

V1.5 26/09/2025

This protocol does not impede the sale and supply of medicines
'over the counter' where this legal route of supply is relevant

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1. Critical Elements

1.1 Protocol Version
Version 1.5
1.2 Protocol Authors
Clinical Sub-Group to support the delivery of an Expanded Role for Community Pharmacy (See Appendix A for membership)
- Pharmacists wishing to deliver this service must: - Complete the mandatory Common Conditions Service training. Training can be accessed on the Irish Institute of Pharmacy website. - Adhere to the information and recommendations included in the Clinical Protocol for this common condition, and always ensure that they are following the current version of the protocol. Current versions of the Clinical Protocols can be accessed on the HSE website. - Comply with legislation in place that relates to delivery of the service and any associated guidance from the PSI. - NOTE: Locum pharmacists employed on a temporary basis who have successfully completed the training may be authorised to provide the service. They must be able to produce a record of their training upon request.

2. Clinical Criteria

2.1 Clinical condition for use of the protocol and differential diagnosis

Uncomplicated Lower Urinary Tract Infections (Cystitis) in non-pregnant individuals aged 16 to 64 years of age whose sex assigned at birth is female, in the absence of current or recent fever (within past 48 hours).

Background

A urinary tract infection (UTI) is an infection of any part of the urinary system. This can include cystitis which is an infection of the bladder (lower urinary tract), and pyelonephritis, an infection of the kidneys (upper urinary tract).

An uncomplicated lower UTI (i.e. cystitis), is a typical bacterial infection in an otherwise healthy individual with no comorbidities, and with no known anatomical or functional abnormalities of the urinary tract. It is usually self-limiting. A complicated UTI is an infection in any other individual outside of those identified above e.g. males, pregnant women, those with urinary tract structural abnormalities, upper urinary tract infection, immunocompromised individuals or those with comorbidities including impaired renal function.

UTIs are usually caused by bacteria that normally live in the bowel e.g. *E. coli*. However, other bacteria, including those from the skin and environment, can also cause a UTI.

UTIs are more common in women. This may be due to:

- Shorter urethra in women.
- Pregnancy related changes in the urinary tract can increase risk of bacteriuria and of UTI.
- Post menopausal hormone changes.
- Sexual intercourse.
- Use of creams, lotions and spermicides in the genital area.

Other risk factors may include:

- Presence of a urinary catheter.
- Urological tract abnormalities (such as kidney stones, enlarged prostate, previous surgery, neurogenic bladder).
- Immunocompromise and other comorbidities such as diabetes mellitus.
- Dehydration.

Signs and Symptoms

Signs and symptoms of uncomplicated lower UTI in non-pregnant females <65 years:

- Acute dysuria – a pain or burning or stinging sensation when urinating. Pharmacists must distinguish between internal dysuria (pain which feels like burning or stinging internally when urinating) and external dysuria (stinging when urine hits external skin), as external dysuria may be indicative of an alternative diagnosis.
- New/worsening frequency – needing to urinate more frequently, can include nocturia – passing urine more often than usual at night.
- New/worsening urgency – feeling a strong sudden need to urinate.
- New onset urinary incontinence in conjunction with some of the other symptoms listed (**Note:** this rarely presents as the only symptom of uncomplicated lower UTI in an adult female. If this symptom presents on its own, it requires immediate referral to a medical practitioner as it may indicate an alternative diagnosis).
- Suprapubic pain – abdominal tenderness/pain in the suprapubic area.

- Haematuria – blood in the urine, may present as red/brown discolouration of urine (see note on “Haematuria” below).
- Absence of new onset of vaginal discharge or a significant change in vaginal discharge.

Visible Haematuria

Visible haematuria, also referred to as frank haematuria, may present as red/brown discolouration of urine. It may be indicative of more serious infection or complex diseases including bladder stones, kidney stones, interstitial cystitis or malignancy. Many of these may present with symptoms similar to uncomplicated lower UTI, including dysuria. All individuals who self-report visible haematuria should be signposted to a medical practitioner for immediate follow-up and are excluded from treatment under this protocol.

Differential Diagnoses

Pyelonephritis

Pyelonephritis is a complicated UTI of the upper urinary tract. It develops when bacteria ascend to the kidneys via the ureters. Pyelonephritis can also be caused by seeding of the kidneys from bacteraemia. Complications of pyelonephritis may include renal damage, multi-organ system dysfunction, or sepsis. Caution is required if the individual is elderly, pregnant, or has known diabetes mellitus. Pyelonephritis in a pregnant individual may cause adverse effects for the mother and increase the risk of pre-term labour and low birth weight.

Acute pyelonephritis should be considered if the individual presents with one or more of the following symptoms (with or without the typical symptoms of cystitis):

- Flank pain which radiates to the iliac fossa and suprapubic area.
- Costovertebral angle tenderness (where the ribs meet the spine).
- Sudden onset general systemic disturbance with fever ($\geq 38^{\circ}\text{C}$), rigors, vomiting.
- Tenderness and guarding over the kidney.
- New or different myalgia or flu-like symptoms.
- Nausea and/or vomiting.
- Mental confusion, more common in older adults.

Note: Patients presenting with an initial uncomplicated infection can develop acute pyelonephritis, in spite of initiating antibiotic therapy. Patient should be advised to seek medical attention should they develop signs and symptoms of acute pyelonephritis, regardless of whether they are taking antibiotics.

Vaginitis

Vaginitis is the general term for disorders of the vagina caused by infection, inflammation, or changes in the normal vaginal flora. Symptoms include abnormal vaginal discharge, odour, pruritus, and discomfort, it can also be associated with dysuria. This is generally external and in the absence of urine frequency or urgency.

Genitourinary syndrome of menopause (vulvovaginal atrophy)

Vulvovaginal atrophy is inflammation and thinning of the vaginal lining caused by lowering of oestrogen levels. It is a common symptom of the perimenopause and menopause and can also occur many years after the menopause. Symptoms may include dryness, burning, or dyspareunia. Urinary frequency, recurrent bladder infections, and sexual dysfunction may also occur.

Urethritis

Urethritis is inflammation of the urethra and is typically associated with dysuria or discomfort with urination. Symptoms which help differentiate from cystitis include pruritus,

and the presence of a urethral discharge. It may be due to infectious or non-infectious causes. Infectious urethritis is typically caused by sexually transmitted pathogens and is most commonly seen in young, sexually active males. Common infective causes of urethritis include *Chlamydia trachomatis* and *Neisseria gonorrhoeae*. Other pathogens associated with urethritis include *Mycoplasma genitalium*, *Trichomonas vaginalis*, and herpes simplex virus. Non-infectious causes of urethritis may include the use of products which are irritant such as soaps, shower gels and contraceptive gel.

Sexually Transmitted Infections (STIs)

If an individual is concerned that they may be at risk of an STI from unprotected sexual intercourse they should be signposted to their GP or HSE Sexual Health services for further information on STI screening.

It is important to advise the individual that many STIs are asymptomatic and can only be detected through testing. The HSE free home STI (sexually transmitted infection) testing service is available to anyone aged 17 or older who lives in the Republic of Ireland.

Information about STIs, availability of services and the home STI testing service is available at sexualwellbeing.ie.

Other Clinical Considerations

Cauda Equina Syndrome

Cauda Equina Syndrome (CES) is a clinical syndrome. The typical symptoms are bilateral sciatica, perianal sensory disturbance and bowel or bladder dysfunction i.e. incontinence, retention or other disturbances of normal bowel or bladder function. CES is most commonly caused by a disc herniation (which can be acute or acute on chronic) but can also be caused by compression of degenerative joints, tumours, infections or bone fragments in fractures. This is a time critical condition and delays in diagnosis and treatment can lead to permanent nerve damage and long-term disability. Individuals presenting with suspected CES require urgent medical assessment (see Section 2.4).

Asymptomatic bacteriuria:

The presence of bacteria without causing symptoms or harm is called asymptomatic bacteriuria (ASB). ASB is normal, especially in older people and is very common in people with a catheter. It may be detected through urine analysis e.g. urine dipstick tests. Persistent asymptomatic bacteriuria is not a recurrent UTI as it is not an infection. In most cases, antibiotic treatment for ASB is more likely to do harm than good. However, some people (those who are pregnant or having urological procedures) may benefit from treatment of their ASB via their medical practitioner.

Dehydration

Symptoms of dehydration include:

- Feeling thirsty
- Dark yellow, strong-smelling urine - healthy urine should look pale yellow
- Feeling dizzy or lightheaded
- Feeling tired
- A dry mouth, lips or tongue
- Sunken eyes
- Passing smaller amounts of urine than usual and fewer than 4 times a day

Recurrent UTIs

Recurrent UTIs in adults are defined as two or more UTIs in the last 6 months or 3 or more UTIs in the last 12 months. Adult women, especially older women are more likely to

experience recurrent UTIs. Recurrent UTIs in males are much less common and require specialist assessment.

Individuals are excluded from treatment under this protocol if they have had:

- one UTI within the previous six months prior to this presentation
- two UTIs within the previous twelve months prior to this presentation

As part of the pharmacy consultation process, individuals should be asked about previous UTI infections in the last 12 months.

Recurrent or persistent lower urinary tract symptoms are not always due to recurrent UTI. Many conditions can cause similar symptoms:

- Sexually transmitted infections
- Postmenopausal atrophic vaginitis
- Vulvovaginal candidiasis
- Vulval lichen sclerosis, psoriasis or other dermatological conditions
- Vulvodynia

Known resistance to previous treatment for UTI.

Individuals should be asked during the consultation process if they are aware of any known resistance with previous antimicrobial treatments.

2.2 Summary of Clinical Features

Signs and Symptoms of uncomplicated lower UTI in non-pregnant females <65 years:

- Acute dysuria.
- New/worsening urinary frequency.
- New/worsening urinary urgency.
- New onset urinary incontinence in conjunction with some of the other symptoms listed.
- Suprapubic pain.
- Haematuria (see note on “Haematuria” above).
- Absence of new onset of vaginal discharge or a significant change in vaginal discharge.

2.3 Inclusion criteria

2.3.1 CRITERIA FOR INCLUSION

- Informed consent given by the individual.
- Individuals 16 years up to and including 64 years of age whose sex assigned at birth is female.
- Individual has symptoms consistent with an Uncomplicated Lower UTI (Cystitis).

2.4 Exclusion criteria and Referral Pathways

2.4.1 CRITERIA REQUIRING EMERGENCY REFERRAL TO HOSPITAL EMERGENCY DEPARTMENT/CONTACTING EMERGENCY SERVICES

- Individual is systemically very unwell, or showing symptoms of severe/life-threatening infection, or systemic [sepsis](#): **Refer urgently to Emergency Department via ambulance.**
- Confusion, drowsiness, or slurred speech.
- Unable to pass urine all day.
- Severe symptoms getting worse quickly.
- Difficulty breathing.
- Skin changes (pain, redness, swelling, rash, discharge, mottling/blistering).
- Presence of blood clots in the urine unexplained by menstruation.

2.4.2 CRITERIA REQUIRING URGENT MEDICAL ASSESSMENT (TREATING SERVICE/GENERAL PRACTITIONER/GENERAL PRACTITIONER OUT OF HOURS/HOSPITAL EMERGENCY DEPARTMENT)

- Signs and symptoms of a more serious condition or illness including raised temperature or chills within the past 48 hours.
- Suspected complicated UTI e.g. pyelonephritis.
- Suspected Cauda Equina Syndrome.
- Individual presenting with new onset urinary incontinence only.
- Individual is immunocompromised due to underlying medical conditions or treatments.
- Known diabetes mellitus (Type 1 or 2).
- Individual is using a urinary catheter.
- Pregnancy or suspected pregnancy.
- Known Chronic Kidney Disease (CKD) or renal insufficiency or individual is on dialysis.

2.4.3 CRITERIA REQUIRING REFERRAL TO GENERAL PRACTITIONER or OTHER RELEVANT MEDICAL PRACTITIONER

Note: Pharmacist prescribing not permitted

- Males.
- Individuals under 16 years of age.
- Individuals aged 65 years of age and over.
- All individuals self-reporting visible haematuria (frank haematuria) as a symptom.
- Individuals with known urinary tract structural abnormalities.
- Recurrent UTI (one UTI within the previous six months prior to this presentation **OR** two UTIs within the previous twelve months prior to this presentation).
- Known resistance to previous treatment for UTI.
- Individuals already taking prophylactic antibiotics for UTI.
- Suspected urethritis (inflammation post sexual intercourse, irritants).
- Nursing home or residential care facility resident.
- Abnormal vaginal discharge.
- Suspected genitourinary syndrome of menopause.
- Suspected sexually transmitted infection.
- Failure to respond to treatment for this episode of UTI or there is a deterioration in symptoms.
- Contraindications as specified in the medication Summary of Product Characteristics.
- Known hypersensitivity or adverse reaction to medication treatment options as included in Section 3.1, or any of the components within the formulation (including individuals with rare hereditary problems of galactose intolerance, total lactase deficiency or glucose-galactose malabsorption).
- Individuals unable to swallow or absorb oral medications.
- Hospitalisation for greater than 7 days in last 6 months **OR** Hospitalisation in a foreign country within last 3 months.

2.5 Action to be taken where individual meets exclusion criteria, or treatment is not indicated, or if the individual/parent/legal guardian declines treatment

- If individual meets exclusion criteria, they should be referred or signposted as per the protocol (see Section 2.4).
- Advise individual/parent/legal guardian to seek medical advice if symptoms deteriorate.
- Signpost to available resources on HSE A-Z and the HSE app if appropriate.
- Follow record keeping procedures.

3. Details of medication

3.1 Name of medication, dose, and duration

Treatment Options & Formulary

Symptoms	Action
Individual is presenting with new onset of all of the following symptoms: - Dysuria - Frequency - Urgency AND - Absence of systemic symptoms or symptoms suggestive of upper urinary tract infection AND - Absence of new onset or significant change in vaginal discharge AND - Absence of visible haematuria	Uncomplicated Lower UTI likely. Consider Treatment as per protocol
Individual is presenting with new onset of one or two of the following symptoms: - Dysuria - Frequency - Urgency AND - Absence of systemic symptoms or symptoms suggestive of upper urinary tract infection AND - Absence of new onset or significant change in vaginal discharge AND - Absence of visible haematuria	May represent Uncomplicated Lower UTI. “Wait and See” approach should be adopted for 48 hours: - Self-care advice, as per Section 4.1 - Take Ibuprofen (if clinically suitable) and/or Paracetamol - Maintain adequate fluid intake - Provide safety netting advice All patients should be advised to seek medical attention if: - They become systemically unwell - They develop haematuria - They experience a deterioration in their symptoms - They develop features suggestive of Acute Pyelonephritis (See Section 2.1) Should their symptoms of possible uncomplicated lower UTI fail to resolve within 48-hours, individuals should return to the pharmacy for re-assessment for review +/- onward referral.

UNCOMPLICATED UTI IN ADULT NON-PREGNANT FEMALES (i.e. no fever / flank pain)

- Paracetamol and ibuprofen (if no contraindications) are suitable pain relief options for patients with UTI and if mild cystitis/uncomplicated lower UTI, pain

relief on its own may be sufficient to treat the UTI. A hot water bottle can also help.

- Patients should be advised to drink plenty of water to avoid dehydration and increase the flushing action through the urinary tract to eradicate bacteria.

EMPIRIC TREATMENT TABLE

The AMRIC Expert Advisory Group have recommended a course of 3 days of Nitrofurantoin or Trimethoprim for individuals symptomatic of uncomplicated lower UTI (Note: this differs from the Summary of Product Characteristics).

Drug	Dose	Duration	Notes
1st Choice Options			
Nitrofurantoin Immediate Release Capsules, hard	50 mg every 6 hours	3 days	Nitrofurantoin is contraindicated in patients with eGFR < 45 mL/min/1.73 m ² .
OR			Nitrofurantoin should not be used in breastfeeding individuals if infant is younger than one month, or if the infant is known to suspected to have any erythrocyte enzyme deficiency (including G6PD deficiency)
Nitrofurantoin Prolonged Release Capsules, hard	100 mg every 12 hours	3 days	Immediate/ Prolonged Release should be stated on the prescription (see note below on formulation difference). See medication Summary of Product Characteristics for contraindications.
Alternative 1st Choice Options (if nitrofurantoin unsuitable)			
Trimethoprim Tablets	100 mg every 12 hours	3 days	See medication Summary of Product Characteristics for contraindications. Trimethoprim is safe in breastfeeding.

Some considerations for antibiotic choice:

Nitrofurantoin is the preferred first choice if it is not contra-indicated. Nitrofurantoin resistance rates remain low in community *E. coli* UTIs throughout Ireland despite increasing resistance to other antibiotics.

Nitrofurantoin precautions

1. Tissue concentrations are too low for treatment of systemic infection, including pyelonephritis. It is only suitable for treatment of uncomplicated lower urinary tract infections in individuals who are not systemically unwell.
2. Two nitrofurantoin formulations are available: nitrofurantoin **immediate release** capsules and nitrofurantoin **prolonged release** capsules. For the treatment of infection, the **prolonged release** capsules are dosed **twice daily** whilst the **immediate release** (standard) capsules are dosed **four times daily**. The dosing

schedule should be discussed with patients to ensure acceptability and maximise adherence.
3.2 Summary of Product Characteristics including warnings, cautions, contraindications, interactions and side effects.
Visit the Health Products Regulatory Authority (HPRA) website for detailed drug information (summary of product characteristics and patient information leaflets). Dosing details, contraindications and drug interactions can also be found in the Irish Medicines Formulary (IMF) or other reference sources such as British National Formulary (BNF) / BNF for children (BNFC).
3.3 Reporting of suspected adverse reactions
Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via HPRA Pharmacovigilance, website: www.hpra.ie
3.4 Procedure for the reporting and documentation of errors and near misses involving the medication including open disclosure.
PSI Advice on Medication Error Management: https://www.psi.ie/practice-supports/practice-updates-and-learnings/advice-medication-error-management PSI Open Disclosure: Open Disclosure PSI
3.5 Resources and equipment necessary for care under the protocol to be specified. This is dependent on the assessment requirements and best practice guidelines identified for the clinical condition.
• HSE National Consent Policy • Chaperone Policy • Patient Consultation Area • Infection Prevention Control Measures • Protecting Staff – Occupational Health

4. Patient/service-user care information

4.1 General Advice for Self-Care and Safety Netting

All patients should be advised to seek urgent medical attention should they, at any point:

- become systemically unwell
- develop features suggestive of Acute Pyelonephritis (See Section 2.1)
- develop haematuria
- experience a deterioration in their symptoms

Should their symptoms fail to improve within 48-hours of commencing treatment, individuals should be advised to seek further advice from a GP or other relevant medical practitioner.

Self-care advice for the treatment/prevention of UTIs

- Paracetamol and ibuprofen (if no contraindications) are suitable pain relief options for patients with uncomplicated lower UTI, pain relief on its own may be sufficient to treat the UTI. A hot water bottle can also help.
- Patients should be advised to drink plenty of water to avoid dehydration and increase the flushing action through the urinary tract to eradicate bacteria.
- Evidence supporting the use of probiotics to prevent recurrent UTIs is currently inconclusive.
- Sexual intercourse should be avoided during cystitis as it may make symptoms worse.
- Patients should be advised on avoiding triggers and lifestyle changes if frequent cystitis is an issue. These include:
 - Not using perfumed bubble bath, bath bombs, soaps, talcs, cleansing wipes, disinfectants around the genital area.
 - Use an emollient-based product or plain warm water to wash.
 - Showering rather than bathing can reduce contact time with irritating soaps.
 - Emptying bladder fully (double-void) and as soon as feel the urge to.
 - Staying hydrated.
 - Always wiping from front to back when you go to the toilet.
 - Emptying bladder after intercourse.
 - Wearing breathable cotton underwear and not wearing jeans/ trousers too tight.
 - Note: There is limited evidence to support the use of cranberry products for managing uncomplicated lower UTI as an intervention but, anecdotally, some individuals find them effective.

4.2 Medication information to be provided to the individual/parent/legal guardian using the authorised patient information leaflet if one is available.

- Signpost to available resources on HSE A-Z and the HSE app.
- Medication Patient Information Leaflets (PILs).

Key References

- HPRa <https://www.hpra.ie/>
- HSE Antibiotic Prescribing <https://www.hse.ie/eng/services/list/2/gp/antibiotic-prescribing/>
- HSE Antimicrobial Stewardship in Primary Care Part II: An Update on Urinary Tract Infection Management for Community Pharmacists
<https://www.hse.ie/eng/services/list/2/gp/antibiotic-prescribing/antibicrobial-stewardship-audit-tools/cpd-antimicrobial-stewardship-in-primary-care-part-ii.pdf>
- HSE Staff Handbook Assessment of Urinary Tract Infection (UTI) in Older People
<https://www.hse.ie/eng/services/list/2/gp/antibiotic-prescribing/prescribing-ltcf/hse-skip-the-dip-a4-staff-booklet-digital-version-final.pdf>
- HSE Use of dipstick urinalysis to assess for evidence of urinary tract infection in adults
<https://www.hse.ie/eng/services/list/2/gp/antibiotic-prescribing/conditions-and-treatments/urinary/position%20statements%20dipstick%20urinalysis%20for%20utis%20in%20adults/position-statements-dipstick-urinalysis-for-utis.pdf>
- HSE A-Z <https://www2.hse.ie/conditions/>
- UpToDate Acute simple cystitis in female adults
<https://www.uptodate.com/contents/acute-simple-cystitis-in-female-adults>

Appendix A – Clinical Sub-Group Membership

Core Membership

- Dr. Siobhán Ní Bhriain - HSE National Clinical Director Integrated Care (Chair)
- Dr. David Hanlon - HSE National Clinical Advisor Primary Care (Vice Chair)
- Ms. Ciara Kirke - HSE Clinical Lead National Medication Safety Programme
- Ms. Linda Fitzharris - HSE PCRS Head of Pharmacy
- Dr. Diarmuid Quinlan - Medical Director ICGP & GP
- Ms. Elaine Dobell - HSE General Manager, Office of National Clinical Director Integrated Care
- Ms. Marie Philbin - AMRIC Chief Pharmacist
- Mr. Jonathon Morrissey - Community Pharmacist
- Ms. Áine McCabe - Community Pharmacist
- Dr. Clíona Murphy – National Women and Infants Health Programme
- Ms. Sarah Clarke - Medicines Management Programme

General Membership as needed

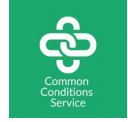
- Ms. Aoife Doyle - HSE National Clinical Lead for Ophthalmology
- Prof. Anne Marie Tobin - HSE National Clinical Lead for Dermatology
- Dr. Eavan Muldoon - HSE National Clinical Lead for Infectious Diseases
- Dr. Seán O'Dowd - HSE National Clinical Lead for National Dementia Office representing National Clinical Programme for Neurology on behalf of Prof. Sinéad Murphy
- Ms. Ruth Hoban - HSE West Assistant Director of Nursing and Midwifery for Nurse Prescribing on behalf of Dr. Geraldine Shaw
- Prof. Fiona Lyons - HSE National Clinical Lead for Sexual Health
- Ms. Caoimhe Gleeson - HSE National Office for Human Rights and Equality Policy
- Dr. Andrew Bolas - Assistant National Oral Health Lead
- Dr. Myra Herlihy - Assistant National Oral Health Lead Special Care and Training
- Prof. Basil Elnazir – Consultant in Paediatric Respiratory Medicine

Uncomplicated Lower UTI (Cystitis) CSG Working Group

- Dr. David Hanlon - HSE National Clinical Advisor Primary Care (Vice Chair)
- Prof. Fiona Lyons - HSE National Clinical Lead for Sexual Health
- Dr. Eavan Muldoon - HSE National Clinical Lead for Infectious Diseases
- Ms. Ciara Kirke - HSE Clinical Lead National Medication Safety Programme
- Ms. Marie Philbin - AMRIC Chief Pharmacist
- Ms. Áine McCabe - Community Pharmacist



Common Conditions Service Protocol -
Uncomplicated Lower Urinary Tract Infection (Cystitis)



- Dr. Ciara McCarthy – Women's Health Clinical Lead
- Prof. Eamonn Rodgers - Clinical Lead for NCP Surgery – Urology