Community Pharmacy Clinical Audit
Trimethoprim and Nitrofurantoin for Lower Urinary Tract Infection
Scope of the audit

To evaluate adherence to national guidelines of prescribing of both trimethoprim and nitrofurantoin for treatment of lower UTIs in both men and women, across London.

Background

Lower Urinary Tract Infection

- Lower urinary tract infection (UTI) in women is one of the most common bacterial infections managed in general practice - approximately 1–3% of all GP consultations;
- About one in three women will have at least one UTI by 24 years of age;
- About one in two women will be treated for a symptomatic UTI during their lifetime;
- The annual incidence of UTI in women increases with age;
- Lower UTI is less common in men, but, as with women, incidence increases with age.

Management of UTIs

- Lower UTIs are generally self-limiting:
  - Without antibiotics, symptoms can be expected to resolve in 4–9 days;
  - With antibiotics, symptoms can be expected to resolve in 3–8 days;
  - On average, antibiotics shorten the duration of symptoms by about a day;
- Relieve symptoms with paracetamol, or ibuprofen — do not recommend urine alkalinizing agents or cranberry products;
- If symptoms are moderate, or severe offer an antibiotic.

Choice of antibiotic

Female patient:

- For an uncomplicated infection prescribe either:
  - Trimethoprim 200 mg twice daily, for 3 days, or
  - Nitrofurantoin 100 mg (modified-release) twice daily, for 3 days

Male patient:

- For an uncomplicated infection prescribe either:
  - Trimethoprim 200 mg twice daily, for 7 days, or
  - Nitrofurantoin 100 mg (modified-release) twice daily, for 7 days

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1 Information taken from National Institute for Health and Care Excellence Clinical Knowledge Summaries (http://cks.nice.org.uk/#azTab), British National Formulary (latest edition), and Health Protection Agency (http://www.hpa.org.uk/webc/HPAwebFile/HPAweb_C/1279888711402)
Basis for recommendation

Antibiotic treatment
For women with lower UTI, there is evidence from a meta-analysis that antibiotics are more effective than placebo in eradicating bacteriuria and relieving UTI symptoms.

Duration of antibiotic treatment

Female patients:
A 3-day course of empirical treatment is recommended for women because there is good evidence from Cochrane systematic reviews that this achieves symptomatic cure in people with uncomplicated UTI; it is more effective than single-dose treatment and as effective as 5–10-day courses. This is also in line with recommendations from the Scottish Intercollegiate Guidelines Network (SIGN) and international guidelines.

Male patients:
There is no evidence that short courses are as effective as longer courses for men: guidelines recommend at least 7 days antibiotic treatment.

Antibiotic choice: trimethoprim and nitrofurantoin as first-line options
Trimethoprim and nitrofurantoin (both narrow spectrum antibiotics) are generally recommended as appropriate first-line antibiotics for treatment of uncomplicated lower UTI in the UK. The recommended dose of nitrofurantoin is 100mg M/R twice daily: national guidelines do not recommend use of nitrofurantoin 50 mg four times daily.

Narrow spectrum antibiotics are preferred over broad spectrum antibiotics such as co-amoxiclav, quinolones, and cephalosporins. This is in line with guidance issued by the Health Protection Agency, which recommends avoiding the use of broad spectrum antibiotics when narrow spectrum antibiotics remain effective. There are concerns that broad spectrum antibiotics increase the risk of Clostridium difficile, meticillin-resistant Staphylococcus aureus (MRSA), and resistant UTIs.

Despite their widespread use, there are few comparative trials comparing these two antibiotics. There is evidence from four trials which found trimethoprim and nitrofurantoin to be equally effective and generally well tolerated.

Renal impairment:
Nitrofurantoin should be used with caution in people with mild renal impairment, and should be avoided in people with moderate to severe renal impairment, due to insufficient urine concentrations.
A reduced dose of trimethoprim may be required in people with severe renal impairment.

**Reason for Audit**
There is a contractual requirement for community pharmacies to participate in a clinical audit programme (normally of five days), which includes at least one pharmacy-based audit, and one other audit agreed by NHS England in each financial year (DH, 2011)

The aim of this community pharmacy-based audit is to evaluate adherence to national guidelines of prescribing of both trimethoprim and nitrofurantoin for treatment of lower UTIs in both men and women. This audit will evaluate all FP10 prescriptions issued by GPs, and other providers, such as Walk-In Centres, across London, for a one month period.

**Variability in Prescribing**
There has been considerable variability, across England, in GP prescribing of 3 day courses of trimethoprim and nitrofurantoin for management of UTIs in women.

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**LONDON**

Total number of average daily quantities (ADQs) per item for trimethoprim 200mg tablets

May 2013 - July 2013

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**Antibiotic Resistance**
Antibiotic resistance is one of the most significant threats to patient safety in Europe. It is driven by overuse of antibiotics and inappropriate prescribing. Broad spectrum antibiotics (e.g. co-amoxiclav, quinolones and cephalosporins) increase
risk of *Clostridium difficile*, MRSA and resistant UTI: amoxicillin resistance is common in UTIs.

### Audit Design

<table>
<thead>
<tr>
<th>Setting</th>
<th>Community Pharmacies in London</th>
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<tbody>
<tr>
<td><strong>Cohort Characteristic</strong></td>
<td>Patients 16 to 65 years of age who present prescriptions for trimethoprim 200mg or nitrofurantoin to pharmacies in London</td>
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<tr>
<td><strong>Identification of Cases</strong></td>
<td>By pharmacy staff using prescriptions presented for dispensing, and patient medication records (PMRs)</td>
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<tr>
<td><strong>Audit Criteria</strong></td>
<td>Data to be collected for:</td>
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<tr>
<td></td>
<td>• Male and female patients;</td>
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<td></td>
<td>• 16 to 65 years of age;</td>
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<td></td>
<td>• Prescriptions for Trimethoprim 200mg tablets (Note: although trimethoprim is licensed for some chest infections it is rarely used for these indications, particularly in primary care, so assume that all prescriptions are for UTI);</td>
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<tr>
<td></td>
<td>• Prescriptions for Nitrofurantoin 50mg tablets;</td>
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<tr>
<td></td>
<td>• Prescriptions for Nitrofurantoin 100mg modified-release capsules;</td>
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<tr>
<td></td>
<td>• Prescriptions for potassium citrate;</td>
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<td></td>
<td>• Collect data for prescriptions from any source, including those issued by GPs, nurse practitioners, Walk-In centres, Accident and Emergency departments;</td>
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<td></td>
<td>• Also collect data for supplies under Patient Group Directions;</td>
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<td></td>
<td>• If known, include details as to whether the patient has a catheter;</td>
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<tr>
<td></td>
<td>• Record whether the patient is a resident of a care home.</td>
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<tr>
<td><strong>Data collection</strong></td>
<td>Collect information for 1 month (up to a maximum of 100 patients) for all prescriptions meeting the above audit criteria:</td>
</tr>
</tbody>
</table>
- Use Table 1 for data collection;
- Use Table 2 to summarise adherence to audit standards and complete discussion points and conclusions.

### Timelines

- Data collection to be undertaken for up to 1 month: data collection to commence on the 17th February 2014 and to continue for 4 weeks, finishing on the 14th March 2014, or once data have been collected for 100 patients;
- Data and action plans to be returned to NHS England (London), via Citizen Space (the URL will be circulated to contractors), by the 28th March 2014.

### Enablers and resources

NHS England Area Team contract managers will send the following to pharmacy contractors:
- Audit specification;
- Data collection forms (in electronic format);
- Summary report form.

The Clinical Adviser (Medicines) at London Region will undertake the following actions:
- Collation and analysis of data;
- Production of a report on the outcomes of the audit at London, Area Team and CCG level.

### Cost (financial or capacity)

- Dissemination of audit and tools to pharmacies across London;
- Data collection & analysis;
- Evaluation & reporting – ideally a web-based solution should be implemented for data entry and analysis;
- Administrative costs.

### Stakeholders

- Community pharmacists;
- Community pharmacy staff;
- NHS England (London Region) and Area Teams – medical directors, pharmacists, Primary Care contract managers;
- Department of Health (Chief Medical Officer and Chief Pharmaceutical Officer);
- CCGs;
- LPCs;
- Public Health England;
- Academic institution, or academics with a previous history or interest in measuring the incidence & prevalence of antimicrobial resistance.

### Outputs
- Report from each pharmacy, summarising adherence to audit standards, to be submitted to NHS England (London Region) via a web-reporting form;
- Action plan from each pharmacy, detailing how the pharmacist will act upon the results of the audit – the summary report form provides options for potential actions for the lead pharmacist, submission of the completed summary report will constitute the action plan;
- Report from the Clinical Adviser (Medicines) at NHS England (London Region), summarising the results of the audit will be sent to the stakeholders identified above.

### Risks
- Resources within NHS England (London Region);
- No designated budget;
- No designated personnel;
- Development of a new web-based reporting system;
- Lack of engagement of pharmacies;
- Lack of engagement with stakeholders.

### Benefits
- London wide approach;
- Reproducible model;
- Good return on investment;
- Building block for future development in data collection;
- Platform for developing research models;
- Increasing the profile of community pharmacy with regard to involvement in research and public health initiatives;
- Increasing the profile of NHS England (London Region);
- Increased awareness of antimicrobial resistance within the population of London;
- Better health outcomes for the population of London.
Table 1 Data Collection for Trimethoprim 200mg, Nitrofurantoin 50mg, Nitrofurantoin 100mg M/R, & Potassium Citrate

<table>
<thead>
<tr>
<th>Date</th>
<th>Patient’s age</th>
<th>Gender M or F</th>
<th>Prescriber type (ie GP, out-of-hours, WiC, PGD, etc.) &amp; post-code</th>
<th>Drug prescribed</th>
<th>Dose</th>
<th>Duration of treatment</th>
<th>Indication detailed on prescription Y or N</th>
<th>Additional drugs prescribed? (eg paracetamol, etc.)</th>
<th>Does patient have a catheter? Y or N or not known</th>
<th>Is patient resident in a care home? Y or N</th>
<th>Comments / notes</th>
</tr>
</thead>
</table>

Pharmacy.......................... Pharmacist ....................
Start Date..... End Date .......


Table 2: Adherence to Standards

<table>
<thead>
<tr>
<th>Patient criteria</th>
<th>Standard</th>
<th>Number of patients meeting standards/total number of patients audited</th>
<th>% Adherence to standard</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Women aged 16 to 65 years: Trimethoprim 200mg twice daily</td>
<td>85% of prescriptions are for 3 days</td>
<td></td>
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<tr>
<td>2. Women aged 16 to 65 years: Nitrofurantoin 100mg M/R twice daily</td>
<td>85% of prescriptions are for 3 days</td>
<td></td>
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</tr>
<tr>
<td>3. Men aged 16 to 65 years: Trimethoprim 200mg twice daily</td>
<td>85% of prescriptions are for 7 days</td>
<td></td>
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</tr>
<tr>
<td>4. Men aged 16 to 65 years: Nitrofurantoin 100mg M/R twice daily</td>
<td>100% of prescriptions are for 7 days</td>
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<tr>
<td>5. All patients: Nitrofurantoin 50mg every 6 hours</td>
<td>0% of prescriptions</td>
<td></td>
<td></td>
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<tr>
<td>6. All patients: Potassium citrate (or other alkalinising agent)</td>
<td>0% of prescriptions</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Options for Action by Lead Pharmacist (tick all that apply):

1. Present results of audit to local GPs
2. Send report to CCG
3. Present results at local Pharmacy Forum