Proposed methodology to measure the impact of GRIP toolkit materials on antibiotic prescribing for URTIs by primary care physicians

The method described here illustrates the process for assessment of one specific symptom of **upper respiratory tract infection (URTI)**, sore throat.

This has been selected as the Centor criteria may be used to predict the likelihood of a group A streptococcal bacterial infection in patients complaining of acute sore throat1 while other common URTI symptoms are likely to be due to viral infection. This protocol can be adapted for other URTI symptoms.

Using this protocol and analysing the collected data can help understand:

- The impact of GRIP toolkit materials on antibiotic prescribing in URTIs

- Thether current level of antibiotic use is indicated (e.g. in non-high risk patients)

Study arms

- **Control arm**: no access to GRIP toolkit materials (n=tbc)

- **Test arm**: full access to GRIP toolkit materials (n=tbc)

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Test arm: GRIP URTI toolkit preparation prior to assessment If you are part of the control arm and will not be using the toolkit during this assessment, you do not need to read this section. Please go straight to the patient section below.

Preparation and planning

- Review current personal and colleague management practices when dealing with URTIs, specifically acute sore throat

- Ensure each doctor within the test arm has read and understood the toolkit materials

- Identify any differences between current practice versus that advised in the GRIP toolkit

Defining use of the GRIP toolkit

There are four ways the GRIP toolkit can be used by the test arm. The doctor can choose any combination or all of these three elements:

Following the 1, 2, 3 approach for the consultation:
a continuing professional development (CPD) manual provides information on antibiotic resistance, its causes (including the inappropriate use of antibiotics in URTIs) and introduces the principles of the 1, 2, 3 approach for URTIs and sore throat consultations

Use of the patient conversation guide:
guides the doctor through communicating key messages on antibiotic use in URTIs, the problems associated with over use of antibiotics and better ways to manage the patient's sore throat symptoms

Use of the tear-off pad of patient information:
the leaflets should be personalised for patients and include suggested self-management treatment options. They include key patient information such as why antibiotics don't work for most URTIs and how to determine when signs and symptoms warrant further investigation

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Patients

- **All patients** who present complaining of a sore throat can be included in this study

- To ensure a random population, it is recommended that this study be conducted with all patients that present each day during the assessment period **(3 months at the start of the sore throat season)**

- All sore throat patients are eligible, please do not stratify based on other factors

- Set a time period over which the study will run **(3 months at the start of the sore throat season)**

- Set a suitable target number of patients **(suggested 150-200 patients)**

Data to collect

Both control and test arms are to record the following information about each patient:

Patient data
- Male/female
- Age
- Ethnicity

Number of days the patient has been experiencing the sore throat

Throat pain scale TPS (see appendix A)

Temperature
- Rank into three groups: <37°C, 37-38°C, and >38.1°C
- Patient feeling feverish

Presence of concomitant symptoms
- Tonsillar exudate
- Tender anterior cervical lymph nodes
- Accompanying cough

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High risk criteria2–4

- Elderly patients aged >65 years or young children <2 years of age or those born prematurely
- Immunocompromised patients
- Pre-existing conditions such as diabetes, cystic fibrosis, chronic lung disease and those with HIV
- Specific local populations, such as Aboriginal or Torres Strait Islander people in Australia, American Indians or Alaskan natives
- Patients who show signs of being severely unwell

Red flag symptoms1,5,6

- Coughing up blood
- Shortness of breath
- Neck swelling on one side of the neck (not related to the lymph nodes)
- Great difficulty swallowing, e.g. unable to swallow food
- Very high temperature (>39°C) or night sweats
- Drooling or muffled voice
- Wheezing sounds when breathing

Specific patient requests for antibiotic treatment

If antibiotics are prescribed, the type of antibiotic and stage at which antibiotics were prescribed (at first visit or subsequently)

Other medications prescribed and/or recommended to manage symptoms (see appendix B for a full list of symptomatic relief options)

Subsequent data recording:
Please record whether the patient required:
- a follow-up visit
- referral to another HCP
- further investigation (swab, X-ray, sinus TC)

Test arm group must also record which of the items they used from the toolkit:
- Tear-off pad
- Patient conversation guide
- Following the 1, 2, 3 approach for the consultation (detailed within the CPD manual)
- Full list of symptomatic options (appendix A)

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Analysing the data

- Total number of patients

- Average duration of sore throat symptoms at time of presenting

- Pain Severity according to the TPS (no pain, mild, moderate, severe)

- Number of antibiotic prescriptions, follow-up, referrals and further investigations in each severity group

- Number of patients that feel feverish

- Number of patients in each of the three temperature ranges

- Number of antibiotic prescriptions, follow-up, referrals and further investigations in each temperature group

- Number of patients presenting with tonsillar exudate, or with tender anterior cervical lymph nodes

- Number of antibiotic prescriptions, follow-up, referrals and further investigations in tonsillar or pharynx exudate, or with swollen lymph nodes group

- Ease of use of the toolkit materials with patients

- Usefulness of toolkit materials

- Patient satisfaction with the consultation

This data will be compared to that collected in the other test arm to determine the effect of the toolkit materials on the pattern of antibiotic use for sore throats. It is hypothesised that over a period of 3 months the number of antibiotic prescriptions will be lower in the test arm group using the GRIP toolkit.

References
1. Centor RM, Samlowski R. AAFP. 2011;83:26–28. Link: http://www.ncbi.nlm.nih.gov/pubmed/21888123 **2**. CDC. People at high risk of developing flu-related complications. 2013. Accessed 12 May 2014. Link: http://www.cdc.gov/flu/about/disease/high_risk.htm **3.** NPS. News 63: Managing expectations for antibiotics in respiratory tract infections, 2009. **4.** NICE Clinical Guideline 69. July 2008. Accessed 12 April 2014. Link: http://guidance.nice.org.uk/CG69/NICEGuidance **5.** Van Duijn HJ, et al. Br J Gen Pract. 2007;57(540):561–568. Link: http://www.ncbi.nlm.nih.gov/pubmed/?term=17727749 **6.** Merck Manual. Sore throat. 2013. Accessed 16 May 2014. Link: http://www.merckmanuals.com/professional/ear_nose_and_throat_disorders/approach_to_the_patient_with_nasal_and_pharyngeal_symptoms/sore_throat.html

Appendix A: Scoring throat pain

Ask the patient which of the following best describes their throat when they swallow?[1]

No pain	Mild pain	Moderate pain	Severe pain

1.   Schachtel BP, et al. Clin Pharmacol Ther. 1984;36(2):151-6.

Appendix B: Shared decision making around symptomatic relief

Types of symptomatic relief:

Drug class	Examples	Mode of action
Analgesics: non-steroidal anti-inflammatory drugs (NSAIDs)	**Ibuprofen Aspirin**	Inhibits prostaglandin production throughout the body and in the central nervous system (CNS),[1] to relieve pain and reduce fever[2]
Analgesics: (non-NSAID)	**Paracetamol Codeine**	**Paracetamol** thought to act on prostaglandins in the CNS to relieve pain and reduce fever[3] **Codeine** is converted to morphine, a powerful analgesic[4]
Decongestants	**Pseudoephedrine Phenylephrine**	Constricts swollen nasal blood vessels to reduce swelling and congestion[5,6]
Antihistamines	**Chlorphenamine Diphenhydramine**	Reduces histamine-related congestion and helps drain sinuses,[6] drying up a runny nose, and often used in combination with decongestants. Can also suppress cough[7] and induce drowsiness for nocturnal cough
Cough suppressants	**Dextromethorphan Codeine Pholcodine**	Suppresses the cough reflex to normal levels[7,8]

1. Burian M, Geisselinger G. Pharmacol Ther. 2005;107:139–54. 2. Rainsford KD. Int J Clin Pract. 2013;67 (Suppl.178): 9–20. 3. Graham GG, Scott KF. Am J Ther. 2005;12:46–55. 4. Derry S, et al. Cochrane Database Syst Rev. 2010;(4) CD008099. 5. Taverner D, Latte GJ. Cochrane Database Syst Rev. 2007;(1) CD001953. 6. Shaikh N, et al. Cochrane Database Syst Rev. 2012;(9) CD007909. 7. Morice AH, et al. Thorax. 2006;61(Suppl I):i1–i24. 8. Dicpinigaitis PV, et al. Cough. 2009;5:11.

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Types of local symptomatic relief:

Drug class	Examples	Mode of action
NSAIDs for sore throat	**Flurbiprofen** **Benzydamine**	Inhibits prostaglandin production[1] at the site of pain, to reduce swelling and inflammation and improve swallowing[2–4]
NSAIDs for muscle aches	**Ibuprofen** **Diclofenac**	Inhibits prostaglandin production at the site of muscle pain to relieve pain[5]
Decongestants	**Oxymetazoline** **Xylometazoline** **Saline**	**Oxymetazoline** and **xylometazoline** constrict swollen blood vessels to reduce nasal swelling and congestion;[6] **saline** irrigation clears mucus and bacteria from the nose[7]
Anticholinergics	**Ipratropium**	Reduces the amount of mucus produced in the nose to relieve a runny nose[8]
Antiseptic agents for sore throat or earache	**Amylmetacresol** **Dichlorobenzyl alcohol** **Cetylpyridinium chloride** **Acetic acid** **Boric acid**	**Amylmetacresol** and **dichlorobenzyl alcohol** are antibacterial, antiviral and have local anaesthetic properties;[9] **cetylpyridinium chloride** is antibacterial;[10] **Acetic acid** and **boric acid** have antibacterial properties[11]
Anaesthetic agents for sore throat or earache	**Benzocaine** **Hexylresorcinol** **Lidocaine**	Exerts a numbing effect achieved by blocking sensory signals locally[12–15]
Demulcents for sore throat	**Glycerin** **Honey** **Sugar**	Lubricates the throat to produce a soothing effect;[10] lozenge formulations have a demulcent action[10]

1. Sefia E, *et al.* Annual Scientific Meeting of the British Pain Society (poster) 2007. 2. Blagden M, *et al. Int J Clin Pract.* 2002;56:95−100. 3. Benrimoj SI, *et al. Clin Drug Invest* 2001;21:183−93.4. Watson N, *et al. Int J Clin Pract.* 2000;54:490−6. 5. Rainsford KD. *Int J Clin Pract Suppl.* 2013;178:9−20 6. Taverner D, Latte GJ. *Cochrane Database Syst Rev.* 2007;(1) CD001953. 7. Yeung DF, *et al. UTMJ.* 2011;88:84−87. 8. AlBalawi ZH, *et al. Cochrane Database Syst Rev.* 2011;(7). CD008231. 9. Wade AG, *et al. BMC Family Practice.* 2011;12:6. 10. Oxford JS, *et al. Int J Clin Pract.* 2011;65:524−530. 11. Osguthorpe JD, Nielsen DR. *Am Fam Physician.* 2006;74(9):1510-6. 12. McNally D, *et al. J Pharm Sci.* 2012;15:281−94. 13. Bolt P, *et al. Arch Dis Child.* 2008;93(1):40-4. 14. Buchholz V, et al. Naunyn Schmiedebergs Arch Pharmacol. 2009;380(2):161-8. 15. Priestley T. Curr Drug Targets CNS Neurol Disord. 2004;3(6):441-56.

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Tailoring sore throat treatment

Formulation	Local delivery	Relieves pain	Anti-inflammatory effect	Demulcent effect	Low dose, reduced side effect risk*	Note on formulation
Oral NSAIDs	✗	✔[1,2]	✔	✗	✗	Slower acting than local treatments[3]
Other analgesics	✗	✔[4,5]	✗	✗	✗	Slower acting than local treatments[3]
Local NSAID lozenge	✔	✔[6–9]	✔[7,8]	✔[6,7]	✔[6–9]	Faster acting than systemic treatments.[3] Can relieve pain in 2 minutes and last up to 4–6 hours[8,9]
Local NSAID spray/gargle	✔	✔[10]	✔[10]	✗	✔[10]	Faster acting than systemic treatments[1] Gargles are often swallowed and the active ingredients do not reach the throat[11]
Antiseptic/ anaesthetic lozenge	✔	✔[12]	✗	✔[12]	✔[12]	Faster acting than systemic treatments[3] Lozenges dissolve slowly to release active ingredients[3]
Antiseptic/ anaesthetic spray/gargle	✔	✔[3,14]	✗	✗	✔[3]	Faster acting than systemic treatments[3]
Anaesthetic ear drops	✔	✔[15]	✗	✗	✔[3]	Acidic agent preferred for acute early stage disease compared to topical/oral antimicrobial agents[8]
Cough syrup	✔	✗	✗	✔[3]	✔	Provides a cough suppressant (anti-tussive) effect[13]

1. Burian M, Geisslinger G. *Pharmacol Ther.* 2005;107(2):139–154. 2. Rainsford KD. *Int J Clin Pract Suppl.* 2013;178:9–20. 3. Oxford JS, *et al.* *J Clin Pract.* 2011;65(5): 524–530. 4. Graham GG, Scott KF. *Am J Ther.* 2005;12:46–55. 5. Derry S, *et al.* Cochrane Database Syst Rev. 2010;(4) CD008099. 6. Blagden M, *et al.* *Int J Clin Pract.* 2002;56:95–100. 7. Watson N, *et al.* *Int J Clin Pract.* 2000;54:490–6. 8. Benrimoj SI, *et al. Clin Drug Invest* 2001;21:183–93. 9. Schachtel B, *et al.* *Int J Clin Pharm.* 2012;34:143–258.;71:375–80. 10. Passali D, *et al.* *Clin Ther.* 2001;23:1508–1518. 11. Limb M, *et al.* *Int J Clin Pract* .2009; 63: 606–12. 12. Wade AG, *et al.* *BMC Family Practice.* 2011;12:6. 13. De Blasio F, *et al.* *Cough.* 2011;7(1):7. 14. Buchholz V, *et al.* *Naunyn Schmiedebergs Arch Pharmacol.* 2009;380(2):161–8. 15: Prasad S, Ewigman *B. J Fam Pract.* 2008 ;57(6):370–3.

*The literature available on topical OTC sore throat treatments demonstrates a good safety profile, with only very minor self-limiting adverse effects, such as headaches and coughing being reported.[3]

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