

# Educational interventions on reducing antibiotic over-prescribing among children with upper respiratory infections (URIs)

<b>Submission date</b> 17/06/2015	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
<b>Registration date</b> 23/06/2015	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 06/02/2019	<b>Condition category</b> Respiratory	<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

### Background and study aims

Over-prescribing antibiotics is a serious issue globally. It is also very common among children with acute upper respiratory tract infections. It has left many children suffering from bacterial resistance due to irrational use of antibiotics, especially in less developed rural areas. Antibiotics are widely abused in China, especially in rural areas. However, few studies have focused on this area in developing countries including China. The aim is to carry out a study in rural Guangxi, China to test an effective approach of reducing over-prescribing antibiotics for upper respiratory infections (URTIs) among children.

### Who can participate?

Parents/caregivers and doctors who have been taking care of children between 2-14 years old

### What does the study involve?

The 25 participating township hospitals in two counties of Guangxi province, China, are randomly allocated into one of two groups. The hospitals in the control group continue usual management according to the current national guidelines. The hospitals in the intervention group receive an educational intervention for both clinicians and parents. Clinicians receive antibiotic use guidelines, training on antibiotic use, and an antibiotics use appraisal in the monthly hospital staff meeting. Parents receive specific short messages and printed educational material describing rational antibiotic use during clinical consultations, and videos about rational antibiotic use play in the education area at the hospitals. A questionnaire survey is conducted to see the changes in clinicians' knowledge, attitude and practice before and after the intervention in each group. Interviews and group discussions take place to see if this study is feasible and acceptable with the intervention package. Effectiveness is assessed through the difference in the antibiotic prescription rate before and after the intervention and between the intervention and control groups.

What are the possible benefits and risks of participating?

This study may help to reduce irrational antibiotic use among clinician, increase knowledge on antibiotic use among rural caregivers/parents, improve the management of antibiotic use for policy makers, and change prescription behaviours of health providers. No risks are expected.

Where is the study run from?

China Global Health Research and Development, as the leading centre, is in collaboration with Guangxi Provincial Center for Disease Control, the University of Leeds, the Chinese University of Hong Kong and Shandong University.

When is the study starting and how long is it expected to run for?

June 2015 to March 2016

Who is funding the study?

China Programme, COMDIS Health Services Delivery Research Consortium

Who is the main contact?

Prof. Xiaolin Wei

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## Contact information

**Type(s)**

Scientific

**Contact name**

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## Additional identifiers

## Study information

**Scientific Title**

Educational interventions on reducing antibiotic over-prescribing among children with upper respiratory infections (URIs): a clustered randomized controlled trial in rural Guangxi, China

**Study objectives**

Current hypothesis as of 03/07/2017:

Educational interventions on both clinicians and parents are effective on reducing over-prescribing antibiotics for childhood upper respiratory infections (URIs).

Previous hypothesis:

Educational interventions on both clinicians and parents are effective on reducing over-prescribing antibiotics for childhood upper respiratory infections (URIs) and acute bronchitis.

### **Ethics approval required**

Old ethics approval format

### **Ethics approval(s)**

1. Ethics Committee of Guangxi Provincial Centre for Disease Control and Prevention, 13/09/2014, ref: GXIRB2014-0036
2. University of Leeds, School of Medicine, Research Ethics Committee, 11/02/2016, ref: MREC15-016

### **Study design**

Cluster randomized controlled trial

### **Primary study design**

Interventional

### **Study type(s)**

Prevention

### **Health condition(s) or problem(s) studied**

Upper respiratory infections (URIs) among children, which includes: acute URIs, common cold, acute tonsillitis and acute pharyngitis

### **Interventions**

Current interventions as of 03/07/2017:

The township hospitals randomly allocated into the intervention group will receive the educational intervention for both clinicians and parents.

For clinicians:

1. Operational guidelines (based on Chinese antibiotic use guidelines, IMCI, and the NICE guideline, we will focus on but not limit to URIs)
2. Systematic training for clinicians in township hospitals on rational antibiotic use
3. Antibiotics use appraisal in the monthly hospital staff meeting

For parents:

1. Specific short messages to be given during clinical consultations by doctors.
2. Printed educational material describing rational antibiotic use for childhood URIs
3. Videos to play in the education area at township hospitals, describing rational antibiotic use for childhood URIs

The control group will continue usual management according to the current national guidelines. Treatment is provided according to existing knowledge and antibiotics are given at the individual clinician's discretion, while no systematic health education is provided.

### Previous interventions:

The township hospitals randomly allocated into the intervention group will receive the educational intervention for both clinicians and parents.

### For clinicians:

1. Operational guidelines (based on Chinese antibiotic use guidelines, IMCI, and the NICE guideline, we will focus on but not limit to URIs)
2. Systematic training for clinicians in township hospitals on rational antibiotic use
3. Antibiotic prescription rate (APR) reminder - social media message reminders once a month by pharmacist
4. Antibiotics use appraisal in the monthly hospital staff meeting
5. Health education to patient caregivers: specific short messages to be given during clinical consultations

### For parents:

1. Printed educational material describing rational antibiotic use for childhood URIs
2. Videos to play in the education area at township hospitals, describing rational antibiotic use for childhood URIs

The control group will continue usual management according to the current national guidelines. Treatment is provided according to existing knowledge and antibiotics are given at the individual clinician's discretion, while no systematic health education is provided.

### **Intervention Type**

Behavioural

### **Primary outcome(s)**

Current primary outcome measures as of 03/07/2017:

Antibiotics prescription rate (APR) of outpatient childhood URIs between 2-14 years old, measured at baseline (3 months prior to the intervention) and endline (last 3 months during intervention period)

Previous primary outcome measures:

Antibiotics prescription rate (APR) of outpatient childhood URIs between 2-14 years old, measured at baseline (3 months prior to the intervention), 3 months after the intervention and 6 months after the intervention

### **Key secondary outcome(s)**

Current secondary outcome measures as of 03/07/2017:

Measured at baseline (3 months prior to the intervention) and endline (last 3 months during intervention period):

1. Two and more than two antibiotic combination prescription rate
2. Broad-spectrum antibiotic use rate of outpatient prescriptions
3. Injectable antibiotic prescription rate
4. Quinolones use rate
5. Average cost of a prescription

Previous secondary outcome measures:

Measured at baseline (3 months prior to the intervention), 3 months after the intervention and 6 months after the intervention:

1. Two and more than two antibiotic combination prescription rate

2. Broad-spectrum antibiotic use rate of outpatient prescriptions
3. Quinolones use rate
4. Average cost of a prescription
5. Antibiotics prescription rate of inpatient childhood URIs
6. Appropriateness of antibiotics use among inpatient childhood URIs

**Completion date**

30/12/2016

## Eligibility

**Key inclusion criteria**

Current inclusion criteria as of 03/07/2017:

All eligible township hospitals from the two selected counties of Guangxi who agree to participate in the study will be included. The two counties should have implemented the Essential Medicine List and Zero-markup policy in 2012.

Intervention:

1. Township hospitals: 25 township hospitals in two selected counties
2. Parents/caregivers: who have been taking care of children between 2 and 14 years old
3. Doctors: pedestrian or internal medicine clinician who is seeing children between 2 and 14 years old

Research:

1. Parents/caregivers: 2 parents/caregivers per township hospital in 6 township hospitals selected for process evaluation.
2. Doctors: 1 township hospital director and 3 clinicians per township hospital in 6 township hospitals selected for process evaluation.
3. Prescriptions: 200/township hospital (before and after intervention respectively)

Previous inclusion criteria:

All eligible township hospitals from the two selected counties of Guangxi who agree to participate in the study will be included. The two counties should have implemented the Essential Medicine List and Zero-markup policy in 2012.

Intervention:

1. Township hospitals: 25 township hospitals in two selected counties
2. Parents/caregivers: who have been taking care of children between 2 and 14 years old
3. Doctors: pedestrian or internal medicine clinician who is seeing children between 2 and 14 years old

Research:

1. Parents/caregivers: 6-8 parents/caregivers in each focus group discussion
2. Doctors: 1 township hospital director and 2 clinicians in each township
3. Prescriptions: outpatients: 40/township (before and after intervention), inpatients: 200 /township (before and after intervention)

**Participant type(s)**

Mixed

**Healthy volunteers allowed**

No

**Age group**

Mixed

**Sex**

All

**Key exclusion criteria**

1. Prescriptions for children diagnosed with diseases such as tuberculosis, HIV/AIDS or other immunodeficiency disease, any form of cancer, dyslipidaemia, chronic heart diseases, and pneumonia, who need long-term antibiotic treatment or prophylaxis
2. Children  $\leq 2$  years old and  $> 14$  years old will be excluded

**Date of first enrolment**

25/06/2015

**Date of final enrolment**

25/09/2015

**Locations**

**Countries of recruitment**

China

**Study participating centre**

25 township hospitals

Rong county and Liujiang

China

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**Sponsor information**

**Organisation**

China Programme, COMDIS Health Services Delivery Research Consortium

**Funder(s)**

**Funder type**

Research organisation

**Funder Name**

## Results and Publications

### Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are/will be available upon request from Prof. Xiaolin Wei (xiaolin.wei@utoronto.ca).

### IPD sharing plan summary

Available on request

### Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Results article</a>	results	01/12/2017		Yes	No
<a href="#">Results article</a>	results	05/02/2019		Yes	No
<a href="#">Protocol article</a>	protocol	27/05/2016		Yes	No