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Appendices

Appendix 1. Brief descriptions of the studies of the impact of The Campaign reviewed in Chapter 3 (Literature Review)

Table A1-1 National and regional level studies of trends in antibiotic use and impact evaluation of The Campaign

<table>
<thead>
<tr>
<th>Authors</th>
<th>Year</th>
<th>Title</th>
<th>Typology</th>
<th>Source/sampling frame</th>
<th>Level of healthcare concerned</th>
<th>Nature of data</th>
<th>Time frame</th>
<th>Comparisons (evaluative studies only)</th>
<th>Main prescribing and perioperative prescribing indicators</th>
<th>Main consumption indicators</th>
</tr>
</thead>
<tbody>
<tr>
<td>Van Boeckel et al.</td>
<td>2014</td>
<td>Global antibiotic consumption 2000 to 2010: an analysis of national pharmaceutical sales data.</td>
<td>Global and national trends</td>
<td>Commercial database IMS Health MIDAS (bar unregulated sales e.g. in supermarkets)</td>
<td>Retail and hospital pharmacies</td>
<td>Projected sales estimates based on regularly collected sales records</td>
<td>2000 - 2010</td>
<td>NA</td>
<td>Total consumption measured in standard units, and population-adjusted consumption measured in standard units per person</td>
<td></td>
</tr>
<tr>
<td>Wushouer et al.</td>
<td>2017</td>
<td>Trends and patterns of antibiotic consumption in China's tertiary hospitals: Based on a 5 year surveillance with sales records, 2011-2015.</td>
<td>National trends</td>
<td>468 out of 1000 hospitals from the China Medical Economic Information database maintained by China Pharmacy Association</td>
<td>City level tertiary hospitals</td>
<td>Sales records</td>
<td>2011 - 2015</td>
<td>NA</td>
<td>Population-adjusted consumptions measured in defined daily doses for 1000 inhabitants per day (DID)</td>
<td></td>
</tr>
<tr>
<td>Author(s)</td>
<td>Year</td>
<td>Title</td>
<td>Study Design</td>
<td>Study Period</td>
<td>Country/Region</td>
<td>Data Source</td>
<td>Measurements</td>
<td>Notes</td>
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</tr>
<tr>
<td>Li et al.</td>
<td>2013</td>
<td>Changes in antimicrobial use prevalence in China: Results from five point prevalence studies</td>
<td>National trends</td>
<td></td>
<td>National trends</td>
<td>Below 100 hospitals from before 2008, 199 hospitals from 2008 and 247 hospitals from 2010 from the National Healthcare-Associated Infection Surveillance System (NHAISS)</td>
<td>Tertiary hospitals with established healthcare-associated infection practices</td>
<td>Survey of member institutions 2001 - 2010 NA Various prescribing rates</td>
<td></td>
<td></td>
</tr>
<tr>
<td>National Health and Family Planning Commission</td>
<td>2016</td>
<td>The Administration of the Clinical Use of Antimicrobial Agents and the Status Quo of Antimicrobial Resistance in China</td>
<td>National trends</td>
<td></td>
<td>National trends</td>
<td>Center for Antibacterial Surveillance (CAS), including about 2000 hospitals by 2015</td>
<td>National surveillance data on antibiotic use 2010 - 2015 NA Various prescribing rates; timing and duration of antibiotic prophylaxis in surgical patients</td>
<td>Population-and-time-adjusted consumptions measured in defined daily doses per 100 patient-days (DDD per 100 patient-days)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Authors</td>
<td>Year</td>
<td>Title</td>
<td>Methodology</td>
<td>Setting</td>
<td>Timeframe</td>
<td>Description</td>
<td></td>
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</tr>
<tr>
<td>Zhou et al.</td>
<td>2016</td>
<td>Is there an improvement of antibiotic use in China? Evidence from the usage analysis of combination antibiotic therapy for type I incisions in 244 hospitals</td>
<td>National evaluation</td>
<td>244 specialised hospitals from 30 provinces</td>
<td>2011 - 2012</td>
<td>Survey of member institutions</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Bao et al.</td>
<td>2015</td>
<td>Significant Reduction of Antibiotic Consumption and Patients’ Costs after an Action Plan in China, 2010–2014</td>
<td>National evaluation</td>
<td>65 hospitals (35 secondary and 30 tertiary hospitals) from an informal hospital network of 300 hospitals based on common research interest</td>
<td>2010 - 2014</td>
<td>Survey of member institutions</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Lin et al.</td>
<td>2016</td>
<td>Trends and patterns of antibiotic consumption in Shanghai municipality, China: A 6 year surveillance with sales records, 2009-14</td>
<td>Regional trends</td>
<td>Database of the Shanghai Medical Procurement Administrative Agency, including about 180 secondary and tertiary hospitals, and over 400 primary care centres</td>
<td>2009 - 2014</td>
<td>Municipal level data on procurement of pharmaceutical by public hospital</td>
<td></td>
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</tbody>
</table>

**DDD** per 100 patient-days

**Population-adjusted consumptions measured in defined daily doses for 1000 inhabitants per day (DDD); unadjusted DDD**
<table>
<thead>
<tr>
<th>Authors</th>
<th>Year</th>
<th>Title</th>
<th>Study Design</th>
<th>Study Sites</th>
<th>Data Period</th>
<th>Measurement</th>
</tr>
</thead>
<tbody>
<tr>
<td>Wushouer et al.</td>
<td>2017</td>
<td>Trends and relationship between antimicrobial resistance and antibiotic use in Xinjiang Uyghur Autonomous Region, China: Based on a 3 year surveillance data, 2014-2016</td>
<td>Regional trends</td>
<td>Inpatient antibiotic use in 36 participating hospitals of the regional surveillance network for Xinjiang</td>
<td>2014-2016</td>
<td>NA</td>
</tr>
<tr>
<td>Yin et al.</td>
<td>2018</td>
<td>Antibiotic consumption in Shandong Province, China: an analysis of provincial pharmaceutical centralized bidding procurement data at public healthcare institutions, 2012–16</td>
<td>Regional trends</td>
<td>500 secondary and tertiary hospitals, 600 urban and 1600 rural primary care centres from the centralised procurement system in Shandong Province</td>
<td>2012-2016</td>
<td>NA</td>
</tr>
<tr>
<td>Wang et al.</td>
<td>2013</td>
<td>Analysis of the Effectiveness of Improvement Before and After the Special Antimicrobial Rectification of Six Chinese Cities</td>
<td>Regional evaluation</td>
<td>53 tertiary hospitals, 25 secondary hospitals and 3 primary care centres from six cities including Beijing, Tianjin, Shanghai, Guangzhou, Hangzhou and Chengdu</td>
<td>2010-2011</td>
<td>Before (2010) vs. during The Campaign (2011)</td>
</tr>
</tbody>
</table>

Population-and-time-adjusted consumptions measured in defined daily doses per 1000 patient-days (DDD per 1000 patient-days)
Population-adjusted consumptions measured in defined daily doses for 1000 inhabitants per day (DID)
Various prescribing rates
<table>
<thead>
<tr>
<th>Authors</th>
<th>Year</th>
<th>Study Title</th>
<th>Study Design</th>
<th>Study Population</th>
<th>Hospital Levels</th>
<th>Data Collection Period</th>
<th>Study Period Compared</th>
<th>Outcomes Measured</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yang et al.</td>
<td>2013</td>
<td>Analysis of the impact of special rectification activities on clinical use of antibacterials</td>
<td>Regional evaluation</td>
<td>75 hospitals (51 tertiary and 24 secondary hospitals) from 6 of the largest cities in China including Hangzhou, Guangzhou, Chengdu, Shanghai, Beijing and Tianjin</td>
<td>Secondary and tertiary hospitals</td>
<td>2010-2011</td>
<td>Before (2010) vs. during The Campaign (2011)</td>
<td>Various prescribing rates</td>
</tr>
<tr>
<td>Liu et al.</td>
<td>2014</td>
<td>Xibu Moudiqu Kangjun Yawu Linchuang Yingyong Zhanxiang Zhengzi Huodong Xiaoguo Pingjia Fenxi</td>
<td>Regional evaluation</td>
<td>28 hospitals (5 tertiary and 23 secondary hospitals) from a Western province in China</td>
<td>Secondary and tertiary hospitals</td>
<td>Unspecified</td>
<td>Before vs. during The Campaign</td>
<td>Various prescribing rates</td>
</tr>
<tr>
<td>Shi et al.</td>
<td>2014</td>
<td>Analysis on the Progression of the Special Rectification on Antibacterials Using in Tertiary Hospital of Beijing from 2011 to 2013</td>
<td>Regional evaluation</td>
<td>52 tertiary hospitals in Beijing</td>
<td>Tertiary hospitals</td>
<td>2011-2013</td>
<td>Unclear</td>
<td>Various prescribing rates; timing and duration of antibiotic prophylaxis in surgical patients</td>
</tr>
<tr>
<td>Chen et al.</td>
<td>2015</td>
<td>Use of antibiotics in outpatient department before and after special rectification of clinical use of antibiotics and influencing factors</td>
<td>Regional evaluation</td>
<td>69 tertiary hospitals from 6 of the largest cities in China including Hangzhou, Guangzhou, Chengdu, Shanghai, Beijing and Tianjin</td>
<td>Tertiary hospitals</td>
<td>2009-2013</td>
<td>Unclear</td>
<td>Various prescribing rates</td>
</tr>
<tr>
<td>Duanmu et al.</td>
<td>2015</td>
<td>Use of antibiotics in outpatient department before and after special rectification of clinical use of antibiotics and influencing factors</td>
<td>Regional evaluation</td>
<td>Hospitals in Yunnan province, composition and number of hospitals unspecified</td>
<td>Unspecified</td>
<td>2010-2012</td>
<td>Before (2010) vs. during The Campaign (2012)</td>
<td>Outpatient prescribing rates</td>
</tr>
<tr>
<td>Shu et al.</td>
<td>2015</td>
<td>2011-2013 Nian Yangzhou Shi Er, Sanji Yiyuan Kangjun Yawu Zhanxiang Zhengzi Huodong</td>
<td>Regional evaluation</td>
<td>23 hospitals (4 tertiary and 19 secondary hospitals) in Yangzhou City</td>
<td>Secondary and tertiary hospitals</td>
<td>Unspecified</td>
<td>Before (time point unspecified) vs. during The Campaign (2011-2013)</td>
<td>Outpatient and inpatient prescribing rates</td>
</tr>
</tbody>
</table>

DDD per 100 patient-days for inpatients
<table>
<thead>
<tr>
<th>Authors</th>
<th>Year</th>
<th>Study Title</th>
<th>Study Type</th>
<th>Study Design</th>
<th>Study Setting</th>
<th>Data Source</th>
<th>Time Period</th>
<th>Outcomes</th>
<th>Methods</th>
</tr>
</thead>
<tbody>
<tr>
<td>Qiu et al.</td>
<td>2016</td>
<td>Effects of antibacterials special rectification in 8 tertiary first class hospitals of Hebei Province</td>
<td>Regional evaluation</td>
<td>8 tertiary hospitals in Hebei Province</td>
<td>Tertiary hospitals</td>
<td>Aggregated prescribing data from hospitals</td>
<td>2011-2013</td>
<td>Before (2011) vs. during (2012) vs. after The Campaign (2013)</td>
<td>Outpatient and inpatient prescribing rates</td>
</tr>
<tr>
<td>Zhang et al.</td>
<td>2016</td>
<td>Impact of national antimicrobial stewardship action plan on antimicrobial administration for in-patients</td>
<td>Regional evaluation</td>
<td>Hospitals in Changsha City, number and types unspecified</td>
<td>Unspecified</td>
<td>Aggregated prescribing data from hospitals</td>
<td>2010-2014</td>
<td>No explicit comparisons made</td>
<td>Inpatient prescribing rate amongst patients covered by social health insurance</td>
</tr>
</tbody>
</table>
## Table A1-2 Single-hospital evaluations of *The Campaign*

<table>
<thead>
<tr>
<th>Authors</th>
<th>Year</th>
<th>Title</th>
<th>Hospital tier</th>
<th>Clinical setting</th>
<th>Timeframe in relation to The Campaign</th>
<th>Trends in key prescribing indicators</th>
</tr>
</thead>
<tbody>
<tr>
<td>J. Dong, X. Xiang, Y. Yin and X. Wang</td>
<td>2012</td>
<td>Analysis of the Effects of Special Management and Pharmaceutical Intervention for Antibacterials in Our Hospital</td>
<td>Tertiary</td>
<td>Hospital overall</td>
<td>2011</td>
<td>Reduction Reduction Improvement</td>
</tr>
<tr>
<td>W. Luo, L. Huang and Y. Hong</td>
<td>2012</td>
<td>Effect of special rectification activities on clinical application of antibiotics</td>
<td>Tertiary</td>
<td>Hospital overall</td>
<td>2011</td>
<td>Reduction Reduction Improvement</td>
</tr>
<tr>
<td>W. Yin, H. Shen, L. Gui and Y. Tang</td>
<td>2012</td>
<td>Effect of special rectification for clinical antibiotics application on antibiotics prophylaxis during perioperative period of inguinal hernia surgery</td>
<td>Secondary</td>
<td>Department of surgery</td>
<td></td>
<td>Improvement</td>
</tr>
<tr>
<td>R. Liu and J. Yang</td>
<td>2012</td>
<td>Effect of strict antibiotic restriction policy on use intensity and costs of antibiotics</td>
<td>Tertiary</td>
<td>Hospital overall</td>
<td>2010-2011</td>
<td>Reduction</td>
</tr>
<tr>
<td>S. Bao, Z. He, Y. Wang, X. Zhai and L. Jin</td>
<td>2012</td>
<td>Evaluation of the Effect of Antibacterial Applications in Our Hospital before and after Special Rectification</td>
<td>Tertiary</td>
<td>Hospital overall</td>
<td>2011</td>
<td>Reduction Reduction Reduction</td>
</tr>
<tr>
<td>C. Zhu</td>
<td>2012</td>
<td>Kaizhan Zuanxiang Zhengzhi Huodong Dui Woyuan Menzhen Kangjun Yaowu Yingyong De Yinxiang Diaoacha Yu Fenxi</td>
<td>Tertiary</td>
<td>Hospital overall</td>
<td>2010</td>
<td>Reduction</td>
</tr>
<tr>
<td>B. Zhang, W. Yu and X. Zhao</td>
<td>2012</td>
<td>Mouyuan Kangjun Yaowu Zhanxiang Zhengzhi Huodong Shishi Xiaoquo Fenxi</td>
<td>Tertiary specialist (oncology)</td>
<td>Hospital overall</td>
<td>2011-2012</td>
<td>Reduction Reduction</td>
</tr>
<tr>
<td>L. Li, S. Yi, Y. Li and Y. Xu</td>
<td>2012</td>
<td>The effect of administrative intervention on prophylactic antibiotic therapy during perioperative period for type I incision operations.</td>
<td>Secondary</td>
<td>Hospital overall</td>
<td>2010</td>
<td>Improvement</td>
</tr>
<tr>
<td>Authors</td>
<td>Year</td>
<td>Title</td>
<td>Setting</td>
<td>Area of Practice</td>
<td>Time Span</td>
<td>Outcome</td>
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</tr>
<tr>
<td>Y. Lin, X. Lin and L. Chen</td>
<td>2012</td>
<td>Woyuan Kaizhan Kangjun Yaowu Zhuannxiang Zhengzhi Huodong De Xiaoguo Yu Fenxi</td>
<td>Tertiary Hospital overall</td>
<td>Tertiary Department of surgery</td>
<td>2011-2012</td>
<td>Reduction</td>
</tr>
<tr>
<td>L. Bao, Y. Wang, T. Shang, X. Ren and R. Ma</td>
<td>2013</td>
<td>A Novel Clinical Pharmacy Management System in Improving the Rational Drug Use in Department of General Surgery</td>
<td>Tertiary Department of surgery</td>
<td>Department of surgery</td>
<td>2010-2011</td>
<td>Reduction</td>
</tr>
<tr>
<td>J. Guo, X. Wang and D. Sun</td>
<td>2013</td>
<td>Analysis of Intervention Measures of Antibiotics Special Rectification and Its Effects in Our Hospital</td>
<td>Secondary Hospital overall</td>
<td>Hospital overall</td>
<td>2012</td>
<td>Reduction</td>
</tr>
<tr>
<td>X. Chen and H. Xiao</td>
<td>2013</td>
<td>Analysis of Management Measures of Antibiotic Special Rectification and Its Effects in a Grade Three Hospital</td>
<td>Tertiary Hospital overall</td>
<td>Hospital overall</td>
<td>2011-2012</td>
<td>Reduction</td>
</tr>
<tr>
<td>H. Zuo, H. Li, Y. Huang, X. Liu and H. Yan</td>
<td>2013</td>
<td>Analysis of the effect of clinical application of antibacterial drugs special rectification activities</td>
<td>Tertiary Hospital overall</td>
<td>Hospital overall</td>
<td>2012</td>
<td>Reduction</td>
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<tr>
<td>X. Yang and Y. Yang</td>
<td>2013</td>
<td>Analysis of the Effects of Special Management and Pharmaceutical Intervention for Antibacterials in Our Hospital</td>
<td>Tertiary Hospital overall</td>
<td>Hospital overall</td>
<td>2010-2011</td>
<td>Reduction</td>
</tr>
<tr>
<td>F. Wang and D. Zhang</td>
<td>2013</td>
<td>Clinical use of antibiotics in a stomatology hospital before and after special rectifications</td>
<td>Tertiary Hospital overall</td>
<td>Hospital overall</td>
<td>2011-2012</td>
<td>Stable</td>
</tr>
<tr>
<td>S. Liu and P. Xiang</td>
<td>2013</td>
<td>Effect analysis of special renovation and continuous improvement of antimicrobial prophylaxis in removing internal devices operation</td>
<td>Tertiary Hospital overall</td>
<td>Hospital overall</td>
<td>2011-2012</td>
<td>Reduction</td>
</tr>
<tr>
<td>Y. Luo, J. Zhong, Y. Sun and J. Wang</td>
<td>2013</td>
<td>Effect of Special Rectification Activities on Antibacterial Application in A Hospital during 2011-2012</td>
<td>Tertiary Hospital overall</td>
<td>Hospital overall</td>
<td>2011-2012</td>
<td>Reduction</td>
</tr>
<tr>
<td>Y. Tang, L. Gui and W. Yin</td>
<td>2013</td>
<td>Effect of special rectification for clinical use of antibiotics on antibiotics prophylaxis during perioperative period of general surgery</td>
<td>Tertiary Hospital overall</td>
<td>Hospital overall</td>
<td>2010-2011</td>
<td>Reduction</td>
</tr>
<tr>
<td>Authors</td>
<td>Year</td>
<td>Title</td>
<td>Level</td>
<td>Hospital</td>
<td>Period</td>
<td>Results</td>
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<tr>
<td>N. Wu, S. Chui, J. Han, Z. Li and M. Jia</td>
<td>2013</td>
<td>Influence of special rectification activities of clinical application of antibacterials in China on antibacterial use density of inpatients in respiratory department of general hospital</td>
<td>Secondary</td>
<td>Hospital overall</td>
<td>2010-2012</td>
<td>Reduction</td>
</tr>
<tr>
<td>L. Guan</td>
<td>2013</td>
<td>Kaizhan Zhuanxiang Zhengzi Huodong Dui Woyuan Menzhen Kangjun Yaowu Yingyong De Yingxiang</td>
<td>Tertiary</td>
<td>Hospital overall</td>
<td>2011-2012</td>
<td>Reduction</td>
</tr>
<tr>
<td>Y. Xin</td>
<td>2013</td>
<td>Kangjun Yaowu Linchuang Yingyong Zhuanxiang Zhengzi Huodong Zai Woyuan De Shishi Xiaoguo Pingjia</td>
<td>Tertiary</td>
<td>Hospital overall</td>
<td>2011-2012</td>
<td>Reduction</td>
</tr>
<tr>
<td>C. Li and Y. Liang</td>
<td>2013</td>
<td>Mouyuan Kangjun Yaowu Zhuanxiang Zhengzi Huodong Xiaoguo Fenxi</td>
<td>Secondary</td>
<td>Hospital overall</td>
<td>2011-2012</td>
<td>Reduction</td>
</tr>
<tr>
<td>J. Cheng, S. Zhang and Y. Ye</td>
<td>2013</td>
<td>The Impact of Special Rectification Activity on Clinical Use of Antibacterials in Orthopedics Department</td>
<td>Tertiary</td>
<td>Department of orthopaedics</td>
<td>2011-2012</td>
<td>Reduction</td>
</tr>
<tr>
<td>L. Zhang</td>
<td>2013</td>
<td>Woyuan Kangjun Yaowu Zhuanxiang Zhengzi Guanli Cuoshi Ji Xiaoguo Fenxi</td>
<td>Tertiary</td>
<td>Hospital overall</td>
<td>2011-2012</td>
<td>Reduction</td>
</tr>
</tbody>
</table>
### Appendices

<table>
<thead>
<tr>
<th>Authors</th>
<th>Year</th>
<th>Department</th>
<th>Hospital Type</th>
<th>Year of Study</th>
<th>Reduction</th>
<th>Improvement</th>
</tr>
</thead>
<tbody>
<tr>
<td>J. Hong, D. He and X. Liu</td>
<td>2013</td>
<td>Woyuan Kangjun Yaowu Zhuanxiang Zhengzhi Xiaoguo Pingjia Yu Fenxi</td>
<td>Tertiary (traditional Chinese medicine)</td>
<td>Hospital overall</td>
<td>2012</td>
<td>Reduction</td>
</tr>
<tr>
<td>L. Li</td>
<td>2013</td>
<td>Zhuanxiang Zhengzhi Qianhou I Lei Qiekou Weishoushuqi Shiyong Kangjun Yaowu De Xiaoguo Pingjia</td>
<td>Secondary</td>
<td>Department of surgery</td>
<td>2010</td>
<td>2011-2012</td>
</tr>
<tr>
<td>A. Xue, R. Wang, H. Sun and W. Wu</td>
<td>2014</td>
<td>Analysis of clinical use of antibiotics in a maternity hospital</td>
<td>Secondary specialist (maternal)</td>
<td>Hospital overall</td>
<td>2011-2012</td>
<td>Reduction</td>
</tr>
<tr>
<td>Z. Li, P. Zhang, L. Yuan and P. Gu</td>
<td>2014</td>
<td>Analysis of lasting effects of prophylactic use antibiotics on aseptic operations after regulation in our hospital</td>
<td>Tertiary</td>
<td>Department of surgery</td>
<td>2011-2012</td>
<td>Improvement</td>
</tr>
<tr>
<td>X. Hou and J. Wang</td>
<td>2014</td>
<td>Analysis of the effects of special management and pharmaceutical intervention for antibiotics in our hospital</td>
<td>Tertiary</td>
<td>Hospital overall</td>
<td>2012-2013</td>
<td>Reduction</td>
</tr>
<tr>
<td>W. Xing, H. Mo and L. Duan</td>
<td>2014</td>
<td>Analysis on the Effects of Special Rectification of Antimicrobial Drugs and Pharmaceutical Intervention in Our Hospital in 2011-2013</td>
<td>Tertiary</td>
<td>Hospital overall</td>
<td>2011-2013</td>
<td>Reduction</td>
</tr>
<tr>
<td>Authors</td>
<td>Year</td>
<td>Description</td>
<td>Level</td>
<td>Department</td>
<td>Period</td>
<td>Outcome</td>
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### Appendices

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Appendix 2a. Ethical approval for phase 1 fieldwork in Beijing

Approval from LSHTM

LSHTM
13 June 2015

Dear

Study Title: Reducing unnecessary outpatient antibiotic prescriptions: what can be done to improve rational prescribing in China
LSHTM Ethics Ref: #31

Thank you for responding to the Observational Committee's request for further information on the above research and submitting revised documentation.
The further information has been considered on behalf of the Committee by the Chair.

Confirmation of ethical opinion

On behalf of the Committee, I am pleased to confirm a favourable ethical opinion for the above research on the basis described in the application form, protocol and supporting documentation as revised, subject to the conditions specified below.

Conditions of the favourable opinion

Approval is dependent on local ethical approval having been received, where relevant.

Approved documents

The list of documents reviewed and approved by the Committee is as follows:

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After ethical review

The Chief Investigator (CI) or delegate is responsible for informing the ethics committee of any subsequent changes to the application. These must be submitted to the Committee for review using an Amendment Form. Amendments must be received before receipt of written favourable opinion from the committee.

The CI or delegate is also required to notify the ethics committee of any protocol violations as per Suspected Unexpected Serious Adverse Reactions (SUSARs) which occur during the project by submitting a Serious Adverse Event Form.

At the end of the study, the CI or delegate must notify the committee using an End of Study form.

All amendments and forms are available on the ethics online application website and can also be submitted to the committee via the website at: http://www.lshtm.ac.uk

Additional information is available at: www.lshtm.ac.uk/ethics

Yours sincerely,

Professor John Duff
Chair
ethics@lshtm.ac.uk
http://www.lshtm.ac.uk/ethics/

Improving health worldwide
Appendices

Approval from Peking University
Appendix 2b. Information sheets for phase 1 fieldwork in Beijing

For key informants:

为了了解普通感冒治疗中的药物使用，我们将要开展一项（“改进抗生素合理用药：用定性方法理解政策影响”）研究。您符合该项研究的入选条件，因此，我们想邀请您参加该项研究。本知情同意书将向您介绍该研究的目的、步骤、获益、风险，可能给您带来的不便或不适等，请仔细阅读后慎重做出是否参加该研究的决定。当研究人员向您说明和讨论知情同意书时，您可以随时提问并让他/她向您解释您不明白的地方。

本项研究的项目负责人是杨莉博士（北京大学公共卫生学院），项目协同负责人是李立师（伦敦卫生与热带病学院），研究资金来源是个人。

1. 为什么进行这项研究？

这项研究是伦敦卫生与热带病学院公共卫生政策博士课题的一部分。该研究的目的是深入了解医疗系统和公共卫生系统对合理用药——特别是抗生素在门诊的使用——的影响。

2. 哪些人将被邀请参加这项研究？

医生，病人和与课题有关的专家。

3. 多少人将参与这项研究？

约 25 名医生，75 名病人和 30 至 40 名专家。

4. 本研究包括哪些内容？

您会参与一次 40 分钟左右的访谈；您可以选取一个可以保证隐私而又方便您的访谈地点。访谈中研究人员将记录笔记。只有获得您的允许访谈才会被录音。

5. 这项研究会持续多久？

今天的访谈有可能是唯一一次的访谈；如有需要再访谈，研究机会与您联络。

6. 参加本项研究的风险是什么？

调查问卷可能会涉及您的个人见解、想法和基本资料，如果不慎泄露，可能会给您的工作、学习和生活带来不良影响。

风险的控制措施：我们将对受访者的资料和问卷调查内容严格保密，您的问卷信息将以代码而非身份信息标识，不会将您的个人信息透露给任何的第三方。在发布研究成果是所有受访者和地点都会做匿名处理。

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7. 参加本项研究的获益是什么？

您作为专家的见解对该研究课题极为重要。有了专家的帮助，该研究才可以深刻探讨和理解围绕着合理使用抗生素的种种难题。现在随着中国加大对抗生素管理的力度，您对本课题的参与有可能会影响到将来关于合理使用抗生素的学术研究成果和后续的政策发展。

8. 是否一定要参加并完成本项研究？

如果您不愿意，可以拒绝参加。即使您同意参加以后，您也可以在任何时间改变主意，告诉研究者退出研究。原则上，在您退出之后，研究者将严守您相关信息直至最终销毁，期间不会继续使用或透露这些信息。

9. 关于研究费用和补偿

本项研究不设有参加者补偿。

10. 发生研究相关伤害的处理？

本研究为观察性研究，研究方式为访谈，无可预期的相关伤害。

11. 我的信息会保密吗？

如果您决定参加本项研究，您参加研究及在研究中的个人资料均属保密。您的个人信息将以研究编码而非您的姓名加以标识。在未获得您的许可之前，任何可以识别您身份的信息将不会披露给研究小组以外的成员。所有的研究成员和研究相关方都会按要求对您的身份保密。您的档案将妥善保存，仅供研究人员查阅。为确保研究按照规定进行，必要时，政府管理部门、学校当局或伦理委员会的成员按规范可以在研究单位查阅您的个人资料。这项研究结果发表时，将不会披露您个人的任何资料。

12. 如果我有问题或困难，该与谁联系？

如果您有与本研究相关的任何问题，请联系李立师（伦敦卫生与热带病学院 +44 7503277044 lishi.li@lshtm.ac.uk）。

如果您有与受访者自身权益相关的问题，可与北京大学生物医学伦理委员会联系，联系电话：010-82805751，电子邮件：llwyh@bjmu.edu.cn。
Appendices

For prescribers and patients:

知情同意书

为了了解普通感冒治疗中的药物使用，我们将要开展一项“对感冒药物理解的定性研究”研究，您符合该项研究的入组条件，因此，我们想邀请您参加该项研究。本知情同意书将向您介绍该研究的目的、步骤、获益、风险，可能给您带来的不便或不适等，请仔细阅读后慎重做出是否参加该研究的决定。当研究人员向您说明并讨论知情同意书时，您可以随时提问并让他/她向您解释您不明白的地方。

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这项研究是伦敦卫生与热带病学院公共卫生政策博士课题的一部分。该研究的目的是调查医生和病人对治疗普通感冒的药物的偏好、理解和选择，及普通感冒的诊断过程。

2. 哪些人将被邀请参加这项研究？

医生，病人和与该课题有关的专家。

3. 多少人将参与这项研究？

约 25 名医生，75 名病人和 30 至 40 名专家。

4. 本研究包含哪些内容？

您会参与一个简短的访谈，所需时间约为 15 分钟。研究会在其中记笔记。访问不会被录音。

5. 这项研究会持续多久？

今天的简短访谈完成后将没有后续随访。

6. 参加本项研究的风险是什么？

调查问卷可能会涉及您的个人见解、想法和基本资料，如果不慎泄露，可能会给您和您的工作、学习和生活带来不良影响。

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7. 参加本项研究的获益是什么？

您的参与会对更好的理解普通感冒的治疗及医患关系作出贡献，因此十分重要。
Appendices

8. 是否一定要参加并完成本项研究？

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本研究为观察性研究，研究方式为访谈，无预期内的相关伤害。

11. 我的信息会保密吗？

如果您决定参加本项研究，您参加研究及在研究中的个人资料属保密。您的个人信息将以研究编码而非您的姓名加以标识。在未获得您的许可之前，任何可以识别您身份的信息将不会透露给研究小组以外的成员。所有的研究成员和研究相关方都会按要求对您的信息保密。您的档案将妥善保存，仅供研究人员查阅。为确保研究按照规定进行，必要时，政府管理部门、学校当局或伦理委员会的成员按规定可以在研究单位查阅您的个人资料。这项研究结果发表时，将不会披露您个人的任何资料。

12. 如果我有问题或困难，该与谁联系？

如果您有与本研究相关的问题，请联系李立师（伦敦卫生与热带病学院 +44 (0)20 7636 8636 lishi.li@lshtm.ac.uk）。

如果您有与受访者自身权益相关的问题，可与北京大学医学伦理委员会联系，联系电话：010-82805751，电子邮件：llwyh@bjmu.edu.cn。
Appendix 2c. Consent forms for phase 1 fieldwork in Beijing

For key informants:

研究者声明

“我已告知该受访者（“改进抗生素合理用药：用定性方法理解政策影响”）的研究背景、目的、步骤、风险及获益情况，给予他/她足够的时间阅读知情同意书，与他人讨论，并解答了其有关研究的问题；我已告知该受访者当遇到与研究相关的问题时可随时与李立师联系，遇到与自身权利/权益相关问题时随时与北京大学生物医学伦理委员会联系，并提供了准确的联系方式；我已告知该受访者他/她可以退出本研究；我已告知该受访者他/她将得到这份知情同意书的副本，上面包含我和他/她的签名。”

获得知情同意的研究者签名

日期

受访者声明

“我已被告知（“改进抗生素合理用药：用定性方法理解政策影响”）的研究的背景、目的、步骤、风险及获益情况。我有足够的时间和机会进行提问，我对问题的答复很满意。我也被告知，当我有问题、想反映困难、顾虑、对研究有建议，或想进一步获得信息，或为研究提供帮助时，应当与谁联系。我已经阅读这份知情同意书，并且同意参加本研究。我知道我可以在研究期间任何时候无需任何理由退出本研究。我被告知我将得到这份知情同意书的副本，上面包含我和研究者的签名。”

受访者签名

日期
Appendix

For prescribers and patients:

研究者声明

“我已告知该受访者（“对感冒药物理解的定性研究”）的研究背景、目的、步骤、风险及获益情况，并给予他/她足够的时间阅读知情同意书，并解答了其有关研究的问题。我已告知该受访者当遇到与研究相关的问题时可随时与李立师联系，遇到与自身权利/利益相关问题时随时与北京大学生物医学伦理委员会联系，并提供了准确的联系方式。我已告知该受访者他/她可以退出本研究；我已告知该受访者他/她将得到这份知情同意书的副本，上面包含我和他/她的签名。”

获得知情同意的研究者签名

日期

受访者声明

“我已被告知（“对感冒药物理解的定性研究”）的研究的背景、目的、步骤、风险及获益情况。我有足够的时间和机会进行提问，我对问题的答复很满意。我也被告知，当我有问题、想反映困难、顾虑、对研究有建议，或想进一步获得信息，或为研究提供帮助时，应当与谁联系。我已经阅读这份知情同意书，并且同意参加本研究。我知道我可以在研究期间任何时候无需任何理由退出本研究。被告知我将得到这份知情同意书的副本，上面包含我和研究者的签名。”

受访者签名

日期
Appendix

Appendix 2d. Topic guides for phase 1 fieldwork in Beijing

For in-depth interviews with key informants (English translation):

1. General background
   PROBES: affiliation, area of expertise, role, responsibilities, years of experience

2. Experience with antibiotic stewardship policies (or other aspects of antibiotic use in hospitals as appropriate)
   PROBES: specific examples, key actors, policy background, related policies, policy intentions, policy designs, The Campaign

3. Further leads
   PROBES: other sources of information – literature, website, documents, organisations, informants

(After turning off recorder)

Recorder is off—do you have anything else you would like to add?
For semi-structured interviews with prescribers (Chinese):

介绍：调研目的，性质，研究人员机构，访谈过程，数据处理，机构与个人全匿名处理

1. 医院概况：级别，服务的地区范围，服务的人群范围，每天门诊量
2. 医生性别，年龄段，教育程度，医师职称，专科特长，从医年资
3. 您一天要看多少个病人？其中看普通感冒的多吗？
4. 平均每次的诊治大概需要多长的时间？能否大概说一下所涉及的诊疗程序？
5. 对于普通感冒的病患，您最经常开具的药物是什么？您是基于什么原因选择这些药物呢？
   - 对成分的选择（西药？中成药？感冒症状药？消炎药？抗生素？）
   - 对给药途径的选择（口服？注射？）
   - 对药品规格的选择（原研药？仿制药？）
   - 对品牌的的选择（国产？进口？大品牌？小品牌？）
   - 价格的选择（较高价？价格不敏感？较低价？）
   - 对基本药物的选择（基本药物？非基本药物？零差率？比例是否有要求？大概是多少？）
   - 对药物报销的选择（医保？非医保？）
   - 感冒病人一般希望得到什么治疗？药物？有没有病人会要求您开具某种特定的药物？这种经历多吗？能具体谈谈一些例子吗？
   - 其他考量——有没有对于感冒用药和诊疗程序的相关规定？
6. 北京其他级别/地区的医院的医生对待普通感冒会不会有不同的用药习惯？为什么？
7. 抗生素在什么情况下会被用于普通感冒？能否大概说一下所涉及的诊疗程序？
8. 有没有对于抗生素使用的相关规定或要求？如果有，这些规定由谁制定和执行，又是如何执行的呢？
9. 在您供职的这个级别的医院里，跟几年前相比，您认为：
   - 什么药物将在治疗感冒中更多的被使用？为什么？
   - 抗生素在感冒中的使用是更多，不变，还是更少？为什么？
   - 抗生素在感冒中的使用是比以前管得更严，没有变化，还是管得更松？为什么？
   - 抗生素在感冒中的使用是更敏感的话题，一个没有变得更敏感的话题，还是一个更不敏感的话题？为什么？
   - 感冒病人对抗生素的需求是更多，不变，还是更少？为什么？他们对感冒药物的需求如何变化？在他们的需求得不到满足的时候，他们会怎么做？
10. 在您供职的这个级别的医院里，对于未来几年，您认为：
    - 什么药物将在治疗感冒中更多的被使用？为什么？
    - 感冒病人对于各种感冒药物的需求将如何变化？
    - 与现在的水平相比，抗生素在感冒中的使用会更多，不变，还是更少？为什么？
11. 对于北京区域内您所供职的这一类医疗机构而言：
    - 该类医疗机构的主要资金来源是什么？
    - 该类医疗机构的病人一般如何付费？
    - 该类医疗机构是如何补偿在其中供职的医生的呢？

结语和感谢：除了我们上面谈到过的，请问您还有什么想要补充呢？
Appendix

For semi-structured interviews with prescribers (English translations):

Introduction: purpose and background of research, academic institutions involved, process of the interview, anonymity and confidentiality

1. Overview of the hospital: tier of hospital, population coverage, estimated number of patients visited per day

2. Characteristics and professional background of the prescriber: gender, age group, level of education, professional title, specialty, years of experience

3. How many patients do you see on a daily basis? How many of them are common cold cases?

4. On average how long does it take to diagnose common cold? Could you go through the diagnostic procedures?

5. What medicines do you usually prescribe for common cold patients? What are the reasons for your choices of medicines?
   Probes:
   - Types of medicines (western medicines, traditional Chinese medicines; symptom-relieving medicines, antibiotics, others)
   - Route of administration (oral, intravenous)
   - Innovator drugs vs. generics
   - Choice of brands (domestic brands, foreign brands; well-known brands, smaller brands)
   - Price (more expensive medicines, cheaper medicines)
   - Essential medicines (within the essential medicine list, outside the essential medicine list, hospital policy on prescribing essential medicines)
   - Insurance coverage (medicines covered by insurance, medicines not covered by insurance)

6. What are the expectations of common cold patients in terms of treatments and medicines?
   Probes: Do they request for specific medicines? If so, is this a common occurrence? What would you do in this circumstance? Is there any example you can talk about?

7. Would it be possible that prescribers working in other tiers of hospitals or in other areas in Beijing may have different practices or preferences of medicines in treating common cold?
   Probes: Why that may/may not be the case?

8. Is there any regulation for antibiotic use?
   Probe: Who are the enforcers of these regulations, and how are they implemented?

9. From your personal point of view and experience, what would you say about the trend in the choice of medicines used for Common cold in the next few years?
   Probes:
   - Which types of medicines would be used more often? Why?
   - What about antibiotics? Is antibiotic use in common cold likely to increase, decrease or stay at the same level? Why is that?
   - How would patient demand for different types of common cold medicines change?

10. In general, how are hospitals at this tier in Beijing financed?
    - What is the main source of funding for hospital at this tier?
    - How are patients financed?
    - What are the arrangements for the remuneration of prescribers?

Conclusion and thanks: is there anything else to add?
Appendix

For semi-structured interviews with patients (Chinese):

1. 性别：男/女
年|段：20-29/30-39/40-49/50-59/60-69
教育程度：小学/中学/中专/大专/大学/大学以上
职业：
居住地：邻近街道/附近地区/其他地区
自费/医保（医保种类：）
您今天是来看感冒吗？是/不是

2. 您认为感冒的原因是什么？
答：

3. 如果您感冒了，但症状不太严重，您最可能会（单选）：
- 到社区医院看医生/直接取药
- 到大医院看医生/直接取药
- 到药店直接买药
- 家里有药可以直接吃
- 什么都不做
为什么？答：

4. 如果您感冒了，而且症状较明显（如咳嗽多，痰多，发烧），您最可能会（单选）：
- 到社区医院看医生/直接取药
- 到大医院看医生/直接取药
- 到药店直接买药
- 家里有药可以直接吃
- 什么都不做
为什么？答：

5. 到社区医院看感冒大概要等多久：5-15分钟/16分钟-30分钟/半小时以上/没去过社区医院看感冒

6. 到大医院看感冒大概要等多久：5-15分钟/16分钟-30分钟/半小时以上/没去过大医院看感冒

7. 对于以下所列出的感冒药的各个方面，您会如何选择？

- 品牌：最好是大品牌/不一定要是大品牌（原因：）
- 价格：最好是比较贵的药/最好是比较便宜的药/价格不是主要考虑（原因：）
- 药品来源：最好是医院取的药/最好是药店买的药/两者没有区别（原因：）
- 医保：我有医保，一般只考虑用医保报销的药/我有医保，但也经常考虑用自费的药/我的药物为自费，该条不适用

8. 如果感冒症状不影响您的日常生活，您用得最多的感冒药是（可多选）：
- 对症西药：如白加黑、泰诺、百服宁
- 抗生素
- 对症中成药
- 中草药
- 其他（比如：不作特别治疗）：

9. 如果感冒症状影响了您的日常生活，您用得最多的感冒药是（可多选）：
- 对症西药：如白加黑、泰诺、百服宁
- 抗生素
- 对症中成药
Appendix

- 中草药
- 其他（比如：不作特别治疗）

10. 您认为抗生素是不是消炎药？是/不是

11. 您家里有常备一些抗生素以备不时之需吗？有/没有

12. 如果有，这些抗生素的主要来源是：去药店买的/找医生开的/以前生病用剩的

13. 您认为感冒需不需要吃抗生素（单选）？
   - 很有需要（原因：）
   - 不太需要（原因：）
   - 看情况：（写下您认为需要吃抗生素的情况：）

14. 您认为到社区医院看感冒需要做验血等检查吗（单选）？
   - 有需要（原因：）
   - 不太需要（原因：）
   - 看情况：（写下您认为需要做验血的情况：）

15. 您认为到大医院看感冒需要做验血等检查吗（单选）？
   - 有需要（原因：）
   - 不太需要（原因：）
   - 看情况：（写下您认为需要做验血的情况：）

16. 您认为感冒药最好的是通过（单选）：
   - 口服（原因：）
   - 注射或输液（原因：）
   - 很难说，看情况：（写下您认为需要注射或输液的情况：）

17. 如果您到了医院看病或取药，但医生向您解释了医学原因，不愿意开出您希望得到的药物，您会怎么办？
   - 答：

18. 现在相比起几年以前：
   - 您留意到有关于抗生素使用的宣传/您没有留意到
   - 您对抗生素的了解多了很多/您对抗生素的了解没有太大增多
   - 您感觉医生更愿意开抗生素/医生更不愿意开抗生素/没有感觉或不清楚
   - 您感觉抗生素更容易得到了/抗生素更难得到了/没有感觉或不清楚
   - 您感冒时更多的用中成药/您感冒时少的用中成药/您一直很少用中成药/您一直很经常用中成药

谢谢！

采访人：

受访者：
Appendix

For semi-structured interviews with patients (English translation):

Introduction: purpose and background of research, academic institutions involved, process of the interview, anonymity and confidentiality

1. Gender: male/female
   Age group: 20-29/30-39/40-49/50-59/60-69
   Level of education: primary school/secondary school/higher education/post-graduate education
   Occupation:
   Residence: neighbourhood/other areas in the district/other districts
   Method of finance: self-funded/health insurance (type:)
   Reason for visit: Common cold/other

2. What do you think is the cause of common cold?

3. If you have a cold, but the symptoms are mild, it is most probable that you would:
   • Visit a community hospital (to see a prescriber/to obtain medicines directly)
   • Visit a big hospital (to see a prescriber/to obtain medicines directly)
   • Buy medicines from a retail pharmacy
   • Take medicines available at home
   • Do nothing
   Why would you do that?

4. If you have a cold, but the symptoms are reasonably severe (e.g. frequent coughing, lots of phlegm, fever), it is most probable that you would:
   • Visit a community hospital (to see a prescriber/to obtain medicines directly)
   • Visit a big hospital (to see a prescriber/to obtain medicines directly)
   • Buy medicines from a retail pharmacy
   • Take medicines available at home
   • Do nothing
   Why would you do that?

5. From your experience, how long is the waiting time for a consultation for common cold in community hospitals? 5-15mins/16-30mins/more than half an hour/no experience

6. From your experience, how long is the waiting time for a consultation for common cold in community hospitals? 5-15mins/16-30mins/more than half an hour/no experience

7. Please consider the following attributes of medicines for common cold (select one option from each statement):
   a) Brand: Well-known brands preferred/Well-known brands not a must (Reason: )
   b) Price: More expensive medicines preferred/cheaper medicines preferred/price not a major consideration (Reason: )
   c) Source: Medicines from hospitals preferred/medicines from retail pharmacy preferred/no preference for either source (Reason: )
   d) Insurance coverage: I usually consider only the medicines covered by insurance/I frequently consider medicines not covered by insurance/Not applicable as I don’t have insurance

8. If your cold symptoms don’t disrupt your daily life, you’re most likely to take:
   • Western medicines that treat the symptoms (e.g. Baijiahe, Tylenol, Xinkangtaike)
   • Antibiotics
   • TCM: Chinese-patented medicines that treat the symptoms
   • TCM: Chinese herbal medicines
   • Other (e.g. take nothing at all)

9. If your cold symptoms don’t disrupt your daily life, you’re most likely to take:
   • Western medicines that treat the symptoms (e.g. Baijiahe, Tylenol, Xinkangtaike)
   • Antibiotics
   • TCM: Chinese-patented medicines that treat the symptoms
Appendix

- TCM: Chinese herbal medicines
- Other (e.g. take nothing at all)

10. Do you think antibiotics are a type of anti-inflammatories? Yes/no

11. Do you keep any antibiotics at home in case if you need it sometime? Yes/no

12. If yes to question 11, how are these antibiotics from mainly? Bought from retail pharmacies/Requested from prescribers/Leftover of previous prescriptions

13. Do you think taking antibiotics is necessary in the case of cold (select one option only)?
   - Necessary (reasons: )
   - Not so necessary (reasons: )
   - It depends (reasons: )

14. Do you think going through blood tests is necessary in the case of visiting a community hospital for cold (select one option only)?
   - Necessary (reasons: )
   - Not so necessary (reasons: )
   - It depends (reasons: )

15. Do you think going through blood tests is necessary in the case of visiting a community hospital for cold (select one option only)?
   - Necessary (reasons: )
   - Not so necessary (reasons: )
   - It depends (reasons: )

16. In your opinion, what is the best route of administration for common cold medicines (select one option only)?
   - Oral route (reasons: )
   - Injection (reasons: )
   - It depends (reasons: )

17. You go to a hospital to see a prescriber for a consultation or for requesting prescriptions, but the prescriber is unwilling to prescribe to the medicines you’re expecting to obtain, and explains the medical reasons to you. What would you do in this case? Response:

18. Reflecting on your experience of the last few years (select one option from each statement):
   a) You have noticed there’s notably more educational promotion about antibiotic use/you have not noticed an increase in such promotion
      Comments:
   b) Your knowledge of antibiotics has significantly increased/Your knowledge of antibiotics hasn’t increased
      Comments:
   c) You have found that prescribers are more willing to prescribe antibiotics/ prescribers are less willing to prescribe antibiotics/not sure
      Comments:
   d) You have found that it’s easier to purchase antibiotics in retail pharmacies/it’s more difficult to purchase antibiotics in retail pharmacies/not sure
      Comments:
   e) You have been using more Chinese-patented medicine in common cold/you have been using less Chinese-patented medicine in common cold/you have always been a keen user of Chinese-patented medicines
      Comments:

Conclusion and thanks, additional comments? Comments:
## Matching of the interviews with prescribers and patients

<table>
<thead>
<tr>
<th>Analytical categories</th>
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<td>1. Hospital context</td>
<td>10. Financing of the hospital</td>
</tr>
<tr>
<td>Professional or personal background</td>
<td>2. Experience</td>
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<td>Cold health-seeking behaviours</td>
<td>3. Cold cases</td>
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<td>5.1 Cold treatment--medicine type</td>
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<tr>
<td>Patient demand and prescriber-patient interaction</td>
<td>6. Patient demand and interaction</td>
<td>17. What to do when prescriber refuses to give antibiotics</td>
</tr>
<tr>
<td>Prescribing and health seeking in various healthcare settings</td>
<td>7. Behaviours in other health settings</td>
<td>Refer to other sections</td>
</tr>
<tr>
<td>Antibiotic stewardship measures</td>
<td>8. Antibiotic regulations</td>
<td>18c. Prescriber’s willingness to prescribe</td>
</tr>
<tr>
<td></td>
<td>18a. and 18b. Education on antibiotics</td>
<td>18d. Access to OTC antibiotics</td>
</tr>
<tr>
<td>Changes in prescribing, preferences and availability</td>
<td>9. Changes in patient demands and treatments</td>
<td>18e. Change in preferences</td>
</tr>
</tbody>
</table>


Appendices

Appendix 3a. Ethical approval for phase 2 fieldwork in Shanghai

Approval from LSHTM

London School of Hygiene & Tropical Medicine
Kapel Street, London WC1E 7HT
United Kingdom
Switchboard: +44 (0)20 7936 8636
www.lshtm.ac.uk

(Observational / Interventions) Research Ethics Committee

Mr Lulu Li
LSHTM
13 September 2017
Dear Mr Lulu Li

Study Title: Assessing the implementation of antibiotic stewardship policies in a hospital in Shanghai, China
LSHTM Ethics Ref: 14362

Thank you for responding to the Observational Committee's request for further information on the above research and submitting revised documentation.

The further information has been reviewed on behalf of the Committee by the Chair.

Confirmation of ethical opinion

On behalf of the Committee, I am pleased to confirm a favourable ethical opinion for the above research as the basic described in the application form, protocol and supporting documentation as revised, subject to the conditions specified below.

Conditions of the favourable opinion

Approval is dependent on local ethical approval having been received, where relevant.

Approved documents

The final list of documents reviewed and approved by the Committee is as follows:

<table>
<thead>
<tr>
<th>Document Type</th>
<th>File Name</th>
<th>Date</th>
<th>Version</th>
</tr>
</thead>
<tbody>
<tr>
<td>Investigator CV</td>
<td>Cover Letter + Lulu Li</td>
<td>25/09/2017</td>
<td>1</td>
</tr>
<tr>
<td>Covering Letter</td>
<td>Ethics cover letter + Lulu Li</td>
<td>14/09/2017</td>
<td>1</td>
</tr>
<tr>
<td>Protocol / Proposal</td>
<td>REVISED Protocol + Lulu Li</td>
<td>14/09/2017</td>
<td>2</td>
</tr>
<tr>
<td>Information Sheet</td>
<td>REVISED Study Information for Doctors</td>
<td>14/09/2017</td>
<td>2</td>
</tr>
<tr>
<td>Information Sheet</td>
<td>REVISED Study Information for Patients</td>
<td>14/09/2017</td>
<td>1</td>
</tr>
<tr>
<td>Information Sheet</td>
<td>REVISED Consent Form for Doctors</td>
<td>14/09/2017</td>
<td>2</td>
</tr>
<tr>
<td>Information Sheet</td>
<td>REVISED Consent Form for Patients</td>
<td>14/09/2017</td>
<td>1</td>
</tr>
</tbody>
</table>

For ethical review

The Chief investigator (CI) or delegate is responsible for informing the ethics committee of any subsequent changes to the application. These must be submitted to the Committee for review using an Amendment Form. Amendments must be initiated before receipt of written favourab le opinion from the committee.

The CI or delegate is also required to notify the ethics committee of any protocol violations and/or Suspected Unexpected Serious Adverse Reactions (SUSARs) which occur during the project by submitting a Serious Adverse Event Form.

An annual report should be submitted to the committee using an Annual Report Form on the anniversary of the approval of the study during the lifetime of the study.

At the end of the study, the CI or delegate must notify the committee using an End of Study Form.

All aforementioned forms are available on the ethics online application website and can only be submitted to the committee via the website at: http://ethics.lshtm.ac.uk

Additional information is available at: www.lshtm.ac.uk/ethics

Yours sincerely,

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Approval from Fudan University

复旦大学公共卫生学院医学研究伦理委员会于2017年8月25日批准了王伟博士有关《全国抗菌药物临床应用专项整治活动实施过程研究：上海闵行区某医院案例分析》的伦理学申请。批准号为IRB#2017-08-0631，有效期为即日起至2018年12月31日。

在项目开展期间，研究方案及其具体工作计划、调查表、知情同意书等如有任何修改和变动，必须在向本委员会报告并获得批准后方可付诸实施。由于研究项目的执行对研究对象造成的不良影响或后果必须向本委员会报告并征求调查指导。研究项目在有效期后还将继续进行的，必须向本委员会申请批准延期。

复旦大学公共卫生学院医学研究伦理委员会

国际注册号：IRB00002408 & FWA00002399

2017年8月25日
Appendix 3b. Information sheets for phase 2 fieldwork in Shanghai

For all interviewees

知情同意书

为了研究我国抗菌药物管理政策的实施状况，我们将要开展一项题为“全国抗菌药物临床应用专项整治活动实施过程研究：上海闵行区某医院案例分析”的研究。您符合该项研究的入组条件，因此，我们想邀请您参加该项研究。本知情同意书将向您介绍该研究的目的、步骤、获益、风险，可能给您带来的不便或不适等，请仔细阅读后慎重做出是否参加该研究的决定。当研究人员向您说明和讨论知情同意书时，您可以随时提问并让他向您解释您不明白的地方。

本项研究是上海医学院公共卫生课题组的研究项目。实施者是李立师，合作者为王伟博士和严非教授。

1. 研究原因
   该研究将以一个位于上海闵行区的医院作为案例，深入了解和分析我国的抗菌药物管理政策在地方医院的实施过程。

2. 参与研究人员？
   在该医院任职的管理人员和医生及就诊的门诊患者。

3. 参与研究人员数量
   约 10 名左右的管理者，10 名左右的医生和 30 名患者。

4. 研究内容
   与管理人员和医生的访谈约为 40 分钟；与患者的访谈约为 15 分钟。访谈中研究人员将记录笔记。在得到您的允许的条件下访谈才会被录音。

5. 研究持续时间
   今天的访谈有可能是唯一的一次访谈；如有需要再访谈，研究员会与您商讨联络。

6. 参加本项研究的潜在风险
   调查问卷可能会涉及您的个人见解和想法，如果不慎泄露，可能会给您的工作、学习和生活带来不良影响。

风险的控制措施：我们将对受访者的信息和问卷调查内容严格保密，您的问卷信息将以代码而非身份信息标识，不会将您的个人信息透露给任何的第三方。在发布研究成果是所有受访者的地点都会做匿名处理。
Appendices

7. 参加本项研究的获益
　细菌耐药性是目前最重要的公共卫生问题之一，加强抗菌药物的合理使用是遏制细菌耐药性的关键。作为卫生系统的重要参与者，医生和患者对于抗菌药物及其管理措施的理解和体会能直接关系到政策实施的有效性。您对本课题的参与有可能影响到将来关于我国抗菌药物管理政策的学术研究成果和后续发展。

8. 参加本项研究以自愿为原则
　如果您不愿意，可以拒绝参加，这对您目前或未来的医疗不会有任何负面影响。即使您同意参加以后，您也可以在任何时间改变主意，告诉研究者退出研究，您的退出不会影响您获得正常的医疗服务。原则上，在您退出之后，研究者将严格保存您的相关信息直至最终销毁，期间不会继续使用或透露这些信息，但在以下极少数情况下，研究者将继续使用或透露您的相关信息，即使您已经退出研究或研究已经结束。这些情况包括：

- 除去您的信息将影响研究结果的科学性或对数据安全的评价
- 为研究、教学或其他活动提供一些有限的信息（这些信息不会包括您的姓名、身份证号码，或者其他能识别您身份的个人信息）；

一旦出现任何可能会影响您决定是否继续参加该项研究的信息，我们会及时告知您。

9. 关于研究费用和补偿
　本项目对参与者的劳务设一定程度的补偿，除此之外不设有参加者补偿。

10. 发生研究相关伤害的处理
　本研究为观察性研究，研究方式为访谈，无预期的相关伤害。

11. 研究参与者的信息保密
　如果您决定参加本项研究，您参与研究及在研究中的个人资料均属保密。您的个人信息将以研究编码而非您的姓名加以标识。在获得您的许可之前，任何可以识别您身份的信息将不会透露给研究小组以外的成员。所有研究成员和研究相关方都会按要求对您的身份保密。您的档案将妥善保存，仅供研究人员查阅。这项研究结果发表时，将不会披露您个人的任何资料。

12. 关于论文和学术文章的撰写和发表
　在论文中，所有机构和人员皆会做匿名处理。在学术文章中，原则上所有机构和人员皆会做匿名处理。如具体的机构乃至于人员信息有可能因文章内容被推测出来，作者将在写作前和投稿前与相关机构沟通。

13. 如果我有问题或困难，该与谁联系?
　如果您有与本研究相关的任何问题，请联系王伟老师（电话 18918979476）或李立师（电话 13929966755，电邮 l_h_li@sina.com）。
Appendices

Appendix 3c. Consent forms for phase 2 fieldwork in Shanghai

For all interviewees

研究者声明

“我已告知该受访者（“全国抗菌药物临床应用专项整治活动实施过程分析：上海闵行区某医院案例研究”）的研究背景、目的、步骤、风险及获益情况，给予他/她足够的时间阅读知情同意书、与他讨论，并解答了其有关研究的问题；我已告知该受访者若遇到与研究相关的问题时可随时与李老师联系，遇到与自身权利/利益相关问题时随时与复旦大学上海医学院伦理委员会联系，并提供了准确的联系方式；我已告知该受访者他/她可以退出本研究；我已告知该受访者他/她将得到这份知情同意书的副本，上面包含我和他/她的签名。”

获得知情同意的研究者签名

日期

受访者声明

“我已被告知（“全国抗菌药物临床应用专项整治活动实施过程研究：上海闵行区某医院案例分析”）的研究的背景、目的、步骤、风险及获益情况。我有足够的时间和机会进行提问，我对问题的答复很满意，也被告知，当我有问题，想反映困难、顾虑、对研究有建议，或想进一步获得信息，或为研究提供帮助时，应当与谁联系。我已经阅读这份知情同意书，并且同意参加本研究。我知道我可以在研究期间任何时候无需任何理由退出本研究。我被告知我将得到这份知情同意书的副本，上面包含我和研究者的签名。”

受访者签名

日期
Appendices

Appendix 3d. Topic guides for phase 2 fieldwork in Shanghai

Overview of matching themes in instruments for non-clinical managers, manager-prescribers, prescribers and patients (English)

<table>
<thead>
<tr>
<th>Main themes</th>
<th>Policy actors concerned</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Non-clinical managers</td>
</tr>
<tr>
<td>1. Overview of the hospital</td>
<td>Tier, location, population coverage, services provided, estimated patient visits per day, How is this hospital financed?, How do patients here pay for their healthcare?, How are doctors paid by the hospital?, How are the hospital’s and its doctors’ performances measured?, Can you describe the organisational structure of the hospital?</td>
</tr>
<tr>
<td>2. Background of the interviewee</td>
<td>Role, department, clinical specialty, professional title, role in the hospital, years of experience</td>
</tr>
<tr>
<td>3. Policy actors’ perception of The Campaign</td>
<td>What do you understand about antibiotic stewardship?, What do you understand about The Campaign?, To what extent is The Campaign a distinct policy phase?</td>
</tr>
<tr>
<td>4. Key actors for antibiotic stewardship</td>
<td>Who are the key actors for antibiotic stewardship in this hospital, including the relevant departments, committees and personnel?, What is everyone’s role in antibiotic stewardship respectively?</td>
</tr>
<tr>
<td>5. Implementation process of The Campaign</td>
<td>(Pick up any relevant comments during the interview and probe where necessary)</td>
</tr>
<tr>
<td>Question</td>
<td>Answer</td>
</tr>
<tr>
<td>------------------------------------------------------------------------</td>
<td>----------------------------------------------------------------------</td>
</tr>
<tr>
<td><strong>Appendices</strong></td>
<td>(Revisit these questions about clinical settings at any point during inquiry about implementation process with heads of department and doctors, especially during the last question about barriers to implementation)</td>
</tr>
</tbody>
</table>
| (Be conscious about the temporal element here and make explicit distinction between past and present) | - How did the organisation of the key actors for antibiotic stewardship translate into a line of command?  
  o Was there a line of command?  
  o How did non-clinical managers communicated and collaborated with manager-prescribers?  
  o How did manager-prescribers work and communicate with doctors specifically?  
  o How did national and local government communicated and collaborated with the hospital to ensure Campaign implementation?  
- How was the necessary information on antibiotic use and resistance monitored and gathered at the hospital?  
  o What information was collected?  
  o How was the information used?  
  o Was the information uploaded to government databases?  
- Did the government or the hospital set any target for antibiotic prescription?  
  o What were the targets and indicators for the hospital and the individual departments?  
  o Which targets were most difficult to hit?  
  o Did The Campaign intensify the existing target system?  
  o Were the targets aligned with clinical needs?  
  o How were the targets reviewed?  
  o Was any punishment involved at any stage, for example if targets were not met, or doctors didn’t perform?  
  o Were these targets included in other policies, such as hospital accreditation and social health insurance?  
- How did you regulate your antibiotic formulary?  
  o How many antibiotics were available at the hospital?  
  o Why were these antibiotics selected for procurement?  
  o Were these antibiotics sufficient to meet patients’ clinical needs?  
  o What were the requirements of professional authority for different kinds of antibiotics?  
- What kinds of resources were necessary for the implementation of The Campaign?  
  o To what extent was information technology system important to implementation?  
  o How did the hospital come to adopt IT system?  
  
- How were the medical professionals trained for implementing antibiotic stewardship?  
  o How were doctors, clinical pharmacists and microbiologists supported, respectively?  
  o Were there new requirements in qualifications regarding antibiotic prescribing?  
- Were there any activities to educate patients?  
- What do you think are the barriers to implementing antibiotic stewardship in this hospital?  
  o Were there specific challenges to implementation faced by different clinical settings?  
  o How did different actors (senior management, heads of department and doctors) work together to address these challenges?  
  o Did The Campaign help addressed these barriers in any way, and how?  
- What do you understand about antibiotics?  
  o What do you think they are for?  
  o Are they necessary for treating common cold?  
- Where do you obtain antibiotics?  
  o Do you obtain them from hospitals?  
  o Do you expect doctors to prescribe antibiotics when you visit them for common cold?  
  o Do you obtain them from elsewhere?  
- Tell me about your experience with getting antibiotic prescriptions for common cold in recent years.  
  o Have you noticed any changes in access to antibiotics in general?  
  o Have you noticed any changes in the doctor’s readiness to prescribe antibiotics?  
  o Have you ever been denied to antibiotics by a doctor, and what did you do?  
- Have you been aware of any message regarding rational antibiotic use in recent years?  
  o Where have you noticed these messages?  
  o Have hospitals promoted these messages to patients?  
  o Are you aware of The Campaign? If so could you tell me about it?  |
<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>6. Perceived influence of <em>The Campaign</em></td>
<td>(Further probe the temporal element here if not explicit from previous answers)</td>
</tr>
<tr>
<td>-</td>
<td>In what way do you think the implementation of <em>The Campaign</em> have any lasting impacts on antibiotic stewardship in the hospital? Or have things reversed in anyway?</td>
</tr>
<tr>
<td>-</td>
<td>Do you think patients have taken onboard the messages as well as the medical professionals did? Why or why not?</td>
</tr>
<tr>
<td>7. Impact of health system factors</td>
<td>(Pick up any relevant comments during the interview and probe where necessary)</td>
</tr>
<tr>
<td>-</td>
<td>How do changes in general healthcare policies, such as healthcare financing and essential medicine policy, influence antibiotic prescribing in general?</td>
</tr>
<tr>
<td></td>
<td>NA</td>
</tr>
</tbody>
</table>
Appendices

For semi-structured interviews with non-clinical managers, manager-prescribers and prescribers (Chinese)

主题 1：医院基本情况概览
- 医院级别，覆盖的地区和人群，提供的服务种类，每天服务的病人人次
- 该医院主要的财政收入来源有哪些？
- 该院的医生一般通过何种途径支付费用？
- 该院的医生的收入由哪些部分组成？
- 该医院和该院的医生的服务表现是通过什么方式测量和评价的？
- 请您简单介绍医院的管理架构。

主题 2：被访读者的基本资料
- 部门，行政职务，临床专科，职称，年资

主题 3：对”三年整治”的理解
- 您是如何理解和看待抗菌药物管理政策的呢？
- 是否留意过三年整治？三年整治是否被看作一个特殊的阶段？
- 比较三年整治前与后医院在抗生素管理上的变化

主题 4：实施抗菌药物管理政策的人员组成
- 该院实施抗菌药物管理政策的部门、委员会和人员有哪些？
- 他们各自的职责是什么？

主题 5：”三年整治”的实施过程【注意区分”三年整治”启动之前（2011 年前）和之后（2011-2013 年）的实施过程】
- 科室的用药需求
  ○ 科室的临床功能和病人构成
  ○ 科室的临床抗生素用药需求和习惯及其背后的原因
  ○ 科室的临床用药受到一些什么因素的限制（如可用品种，科室管理，医院指标等）？
  ○ 这些限制是否影响到医生的临床发挥？

- 实施抗菌药物管理政策的指挥链和汇报机制
  ○ 是否存在政策所提到的指挥链和汇报机制？
  ○ 科室主任和医生在抗生素管理实施上的互动；科室长的管理职责；非管理层的临床医生对各项领导下达的要求的了解和理解，两者之间的沟通（如科主任对指标的把控和对临床诊治的要求）
  ○ 管理的指挥链之间的互动；医院管理层和科主任和医生之间，国家或地方政府机构与医院之间

- 该院是如何收集和监测关于抗菌药物使用和细菌耐药性的数据的呢？
  ○ 具体收集的有哪些数据？
  ○ 医院如何使用这些数据以达到政策实施的目标？
  ○ 这些数据是否会向上上传到政府机构的有关数据库？

- 政府和医院分别对抗菌药物的使用设定了什么管理指标和相应的目标水平？
  ○ 各科室的具体用药指标
  ○ 哪些指标最难实现？
  ○ 比较整治前后指标的变化；是否更严？
Appendices

- 这些指标管理是否合适临床需要？
- 政府和医院分别如何看待使用这些指标？
- 如果没有达到指标要求的目标水平，医院和医生分别会面临什么后果？
- 这些指标是否也存在于并用于其他方面的管理，例如医院评审和社保支付？

- 该院如何对抗微生物数据和处方进行管理？
  - 该院一共有多少种抗生素可使用？
  - 为什么选择进货这些抗生素？
  - 从临床角度和医生经验来说这些抗生素是否足够应对临床的需求？
  - 不同级别的抗菌药物的使用对于医生的资历和级别是否有一定要求？

- 实施抗生素管理对于医院的资源配置有什么要求？
  - 信息系统对于抗菌药物管理的实施是否重要？
  - 医院如何实现这些资源配置上的要求？

- 在实施抗菌药物管理的过程中，该院的医护人员接受了什么样的培训和考核？
  - 对于医生，临床药师和微生物研究的培训措施有哪些？
  - 是否有考核要求？

- 在教育病人的方面该院是否有系统性的措施？

- 该院实施抗菌药物管理的过程中遇到了哪些明显的困难和障碍？
  - 不同科室的临床需要给抗菌药物管理的实施带来了什么样的挑战？各科室具体遇到的有哪些难点？
  - 医生和管理层如何沟通和解决这些难点？
  - 整治活动对于解决这些难点是否起到作用？

主题 6: “三年整治”带来的影响

- 您认为 “三年整治” 的实施对是否对本院的抗菌药物管理起到了深远的影响？还是说，在 “三年整治” 结束之后抗菌药物管理遇到了反弹？
- 您认为医务人员和病人对于抗菌药物合理使用的理解分别有何变化？哪一方的变化更为明显？

主题 7：其他卫生体系因素对抗生素使用的影响

- 您认为我国的其他卫生政策—如医保政策和基本药物政策—对抗菌药物的使用有什么影响？

For semi-structured interviews with patients (Chinese)

主题 2：被访谈者的基本资料

- 性别，年龄段，教育程度，支付方式，求诊原因

主题 5： “三年整治”的实施过程【注意区分“三年整治”启动之前（2011 年前）和之后（2011–2013 年）的实施过程】

- 您对于抗菌药物有何了解？
- 您认为它们的作用是什么？
- 您一般通过什么途径获取抗菌药物？
- 如果您感冒去看医生，您会期望医生给您开处方抗菌药物吗？
- 请您讲述一下您最近几年感冒看病和获取抗菌药物的经历。
- 您在最近几年是否有留心到关于抗菌药物合理使用的信息？

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