

## 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*

Authors	Year	Title	Typology	Source/sampling frame	Level of healthcare concerned	Nature of data	Time frame	Comparisons (evaluative studies only)	Main prescribing and perioperative prescribing indicators	Main consumption indicators
Van Boeckel et al.	2014	Global antibiotic consumption 2000 to 2010: an analysis of national pharmaceutical sales data.	Global and national trends	Commercial database IMS Health MIDAS (bar unregulated sales e.g. in supermarkets)	Retail and hospital pharmacies	Projected sales estimates based on regularly collected sales records	2000 - 2010	NA		Total consumption measured in standard units, and population-adjusted consumption measured in standard units per person
Wushouer et al.	2017	Trends and patterns of antibiotic consumption in China's tertiary hospitals: Based on a 5 year surveillance with sales records, 2011-2015.	National trends	468 out of 1000 hospitals from the China Medical Economic Information database maintained by China Pharmacy Association	City level tertiary hospitals	Sales records	2011 - 2015	NA		Population-adjusted consumptions measured in defined daily doses for 1000 inhabitants per day (DID)

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Li et al.	2013	Changes in antimicrobial use prevalence in China: Results from five point prevalence studies	National trends	Below 100 hospitals from before 2008, 139 hospitals from 2008 and 247 hospitals from 2010 from the National Healthcare-Associated Infection Surveillance System (NHAISS)	Tertiary hospitals with established healthcare-associated infection practices	Survey of member institutions	2001 - 2010	NA	Various prescribing rates	
Ren et al.	2015	Point prevalence survey of antimicrobial use in Chinese hospitals in 2012.	National trends	1313 hospitals from 2012 from the National Healthcare-Associated Infection Surveillance System (NHAISS)			2012	NA	Various prescribing rates	
National Health and Family Planning Commission	2016	The Administration of the Clinical Use of Antimicrobial Agents and the Status Quo of Antimicrobial Resistance in China	National trends	Center for Antibacterial Surveillance (CAS), including about 2000 hospitals by 2015	Secondary and mainly tertiary hospitals	National surveillance data on antibiotic use	2010 - 2015	NA	Various prescribing rates; timing and duration of antibiotic prophylaxis in surgical patients	Population- and time-adjusted consumptions measured in defined daily doses per 100 patient-days (DDD per 100 patient-days)
Sun et al.	2015	Changes in patterns of antibiotic use in Chinese public hospitals (2005-2012) and a benchmark comparison with Sweden in 2012	National evaluation	15 hospitals from six geographic regions across China from Center for Antibacterial Surveillance (CAS)		Survey of member institutions	2005 - 2012	Before (2005-2011) vs. during The Campaign (2011-2012)	Various prescribing rates; timing and duration of antibiotic prophylaxis in surgical patients	Population- and time-adjusted consumptions measured in defined daily doses per 1000 patient-days (DDD per 1000 patient-days)

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Zhou et al.	2016	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	National evaluation	244 specialised hospitals from 30 provinces	Specialised hospitals, including maternity, children's, stomatological and oncological hospitals	Survey of member institutions	2011 - 2012	Preparation (2010-2011) vs. intervention (2011-2012) vs. assessment (2012-2014)	Prescribing rates associated with surgery and combination therapy; timing and duration of antibiotic prophylaxis in surgical patients	
Zou et al.	2014	Is nationwide special campaign on antibiotic stewardship program effective on ameliorating irrational antibiotic use in China? Study on the antibiotic use of specialized hospitals in China in 2011-2012	National evaluation	226 specialised hospitals from 30 provinces in total (105 in 2011, 121 in 2012)	Specialised hospitals, including maternity, children's, stomatological and oncological hospitals	Survey of member institutions	2011 - 2012	Before (2011) vs. during The Campaign (2012)		DDD per 100 patient-days
Bao et al.	2015	Significant Reduction of Antibiotic Consumption and Patients' Costs after an Action Plan in China, 2010–2014	National evaluation	65 hospitals (35 secondary and 30 tertiary hospitals) from an informal hospital network of 300 hospitals based on common research interest	Secondary and tertiary hospitals	Survey of member institutions	2010 - 2014	Before (2011) vs. during The Campaign (2012)	Various prescribing rates; duration of peri-operative antibiotic treatment	DDD per 100 patient-days for inpatients and DDD per 1000 patient-days for outpatients
Lin et al.	2016	Trends and patterns of antibiotic consumption in Shanghai municipality, China: A 6 year surveillance with sales records, 2009-14	Regional trends	Database of the Shanghai Medical Procurement Administrative Agency, including about 180 secondary and tertiary hospitals, and over 400 primary care centres	Secondary and tertiary hospitals, and primary care centres	Municipal level data on procurement of pharmaceutical by public hospital	2009 - 2014	NA		Population-adjusted consumptions measured in defined daily doses for 1000 inhabitants per day (DID); unadjusted DDD

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Wushouer et al.	2017	Trends and relationship between antimicrobial resistance and antibiotic use in Xinjiang Uyghur Autonomous Region, China: Based on a 3 year surveillance data, 2014-2016	Regional trends	Inpatient antibiotic use in 36 participating hospitals of the regional surveillance network for Xinjiang	Mostly tertiary hospitals	Regional surveillance data on antibiotic use	2014-2016	NA		Population- and-time-adjusted consumptions measured in defined daily doses per 1000 patient-days (DDD per 1000 patient-days)
Yin et al.	2018	Antibiotic consumption in Shandong Province, China: an analysis of provincial pharmaceutical centralized bidding procurement data at public healthcare institutions, 2012–16	Regional trends	500 secondary and tertiary hospitals, 600 urban and 1600 rural primary care centres from the centralised procurement system in Shandong Province	Secondary and tertiary hospitals, and primary care centres	Provincial level data on procurement of pharmaceutical by public hospital	2012-2016	NA		Population-adjusted consumptions measured in defined daily doses for 1000 inhabitants per day (DID)
Zhang et al.	2017	Trends in Antimicrobial Prescription for Inpatients in Changsha, China, 2003 to 2014	Regional trends	Inpatient records from the medical insurance for urban workers in Changsha City, Hunan Province	Secondary and tertiary hospitals, and primary care centres	Aggregated prescribing data from hospitals	2003-2014	NA	Various prescribing rates	
Ma et al.	2013	Jiceng Yiliao Jigou Kangjun Yaowu Zhuanxiang Zhengzhi Huodong Xiaoguo Pingjia He Fenxi	Regional evaluation	6 primary care centres from an industrial park in Suzhou City	Primary care centres	Aggregated prescribing data from hospitals	2010-2012	Before (2010) vs. during The Campaign (2011, 2012)	Various prescribing rates	
Wang et al.	2013	Analysis of the Effectiveness of Improvement Before and After the Special Antimicrobial Rectification of Six Chinese Cities	Regional evaluation	53 tertiary hospitals, 25 secondary hospitals and 3 primary care centres from six cities including Beijing, Tianjin, Shanghai, Guangzhou, Hangzhou and Chengdu	Secondary and tertiary hospitals, and primary care centres	Aggregated prescribing data from hospitals	2010-2011	Before (2010) vs. during The Campaign (2011)	Various prescribing rates	

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Yang et al.	2013	Analysis of the impact of special rectification activities on clinical use of antibacterials	Regional evaluation	75 hospitals (51 tertiary and 24 secondary hospitals) from 6 of the largest cities in China including Hangzhou, Guangzhou, Chengdu, Shanghai, Beijing and Tianjin	Secondary and tertiary hospitals	Aggregated prescribing data from hospitals	2010-2011	Before (2010) vs. during The Campaign (2011)	Various prescribing rates	
Liu et al.	2014	Xibu Moudiqu Kangjun Yaowu Linchuang Yingyong Zhuanxiang Zhengzhi Huodong Xiaoguo Pingjia Fenxi	Regional evaluation	28 hospitals (5 tertiary and 23 secondary hospitals) from a Western province in China	Secondary and tertiary hospitals	Aggregated prescribing data from hospitals	Unspecified	Before vs. during The Campaign	Various prescribing rates	DDD per 100 patient-days for inpatients
Shi et al.	2014	Analysis on the Progression of the Special Rectification on Antibacterials Using in Tertiary Hospital of Beijing from 2011 to 2013	Regional evaluation	52 tertiary hospitals in Beijing	Tertiary hospitals	Aggregated prescribing data from hospitals	2011-2013	Unclear	Various prescribing rates; timing and duration of antibiotic prophylaxis in surgical patients	DDD per 100 patient-days for inpatients
Chen et al.	2015	Beijing Deng Liu Diqu Sanji Yiyuan Kangjun Yaowu Linchuang Yingyong Zhuanxiang Zhengzhi Huodong Xiaoguo Fenxi	Regional evaluation	69 tertiary hospitals from 6 of the largest cities in China including Hangzhou, Guangzhou, Chengdu, Shanghai, Beijing and Tianjin	Tertiary hospitals	Aggregated prescribing data from hospitals	2009-2013	Unclear	Various prescribing rates	
Duanmu et al.	2015	Use of antibiotics in outpatient department before and after special rectification of clinical use of antibiotics and influencing factors	Regional evaluation	Hospitals in Yunnan province, composition and number of hospitals unspecified	Unspecified	Aggregated prescribing data from hospitals	2010-2012	Before (2010) vs. during The Campaign (2012)	Outpatient prescribing rates	
Shu et al.	2015	2011-2013 Nian Yangzhou Shi Er, Sanji Yiyuan Kangjun Yaowu Zhuanxiang Zhengzhi Huodong	Regional evaluation	23 hospitals (4 tertiary and 19 secondary hospitals) in Yangzhou City	Secondary and tertiary hospitals	Aggregated prescribing data from hospitals	Unspecified-2013	Before (time point unspecified) vs. during The Campaign (2011-2013)	Outpatient and inpatient prescribing rates	DDD per 100 patient-days for inpatients

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		Shishi Xiaoguo Pingjia								
Qiu et al.	2016	Effects of antibacterials special rectification in 8 tertiary first class hospitals of Hebei Province	Regional evaluation	8 tertiary hospitals in Hebei Province	Tertiary hospitals	Aggregated prescribing data from hospitals	2011-2013	Before (2011) vs. during (2012) vs. after The Campaign (2013)	Outpatient and inpatient prescribing rates	DDD per 100 patient-days for inpatients
Zhang et al.	2016	Impact of national antimicrobial stewardship action plan on antimicrobial administration for in-patients	Regional evaluation	Hospitals in Changsha City, number and types unspecified	Unspecified	Aggregated prescribing data from hospitals	2010-2014	No explicit comparisons made	Inpatient prescribing rate amongst patients covered by social health insurance	
Zhang et al.	2017	Effectiveness of antibiotic use management in Tianjin (2011-2013): A quasi-experimental study	Regional evaluation	41 hospitals (19 tertiary and 22 secondary hospitals) in Tianjin City	Secondary and tertiary hospitals	Aggregated prescribing data from hospitals	2011-2013	Before (2011) vs. during (2012) vs. after The Campaign (2013)	Inpatient prescribing rate	DDD per 100 patient-days for inpatients
Tang et al.	2018	Effects of prescription restrictive interventions on antibiotic procurement in primary care settings: A controlled interrupted time series study in China	Regional evaluation	1235 community health centres from the centralised procurement system in Hubei Province	Primary care	Aggregated prescribing data from hospitals	2011-2013	Before (2011-2012) vs. after The Campaign (2012-2013)		Unadjusted DDD

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Table A1-2 Single-hospital evaluations of *The Campaign*

Authors	Year	Title	Hospital tier	Clinical setting	Timeframe in relation to The Campaign			Trends in key prescribing indicators		
					Before	During	After	Overall prescribing rates	Inpatient consumption	Perioperative prescribing
J. Dong, X. Xiang, Y. Yin and X. Wang	2012	Analysis of the Effects of Special Management and Pharmaceutical Intervention for Antibacterials in Our Hospital	Tertiary	Hospital overall		2011		Reduction	Reduction	Improvement
W. Luo, L. Huang and Y. Hong	2012	Effect of special rectification activities on clinical application of antibiotics	Tertiary	Hospital overall		2011		Reduction	Reduction	Improvement
W. Yin, H. Shen, L. Gui and Y. Tang	2012	Effect of special rectification for clinical antibiotics application on antibiotics prophylaxis during perioperative period of inguinal hernia surgery	Secondary	Department of surgery						Improvement
R. Liu and J. Yang	2012	Effect of strict antibiotic restriction policy on use intensity and costs of antibiotics	Tertiary	Hospital overall	2010	2011		Reduction		
S. Bao, Z. He, Y. Wang, X. Zhai and L. Jin	2012	Evaluation of the Effect of Antibacterial Applications in Our Hospital before and after Special Rectification	Tertiary	Hospital overall		2011		Reduction	Reduction	Reduction
C. Zhu	2012	Kaizhan Zhuanxiang Zhengzhi Huodong Dui Woyuan Menzhen Kangjun Yaowu Yingyong De Yingxiang Diaocha Yu Fenxi	Tertiary	Hospital overall	2010	2011		Reduction		
B. Zhang, W. Yu and X. Zhao	2012	Mouyuan Kangjun Yaowu Zhuanxiang Zhengzhi Huodong Shishi Xiaoguo Fenxi	Tertiary specialist (oncology)	Hospital overall		2011-2012		Reduction	Reduction	
L. Li, S. Yi, Y. Li and Y. Xu	2012	The effect of administrative intervention on prophylactic antibiotic therapy during perioperative period for type I incision operations.	Secondary	Hospital overall	2010	2011				Improvement

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Y. Lin, X. Lin and L. Chen	2012	Woyuan Kaizhan Kangjun Yaowu Zhuanxiang Zhengzhi Huodong De Xiaoguo Yu Fenxi	Tertiary	Hospital overall		2011-2012		Reduction		Improvement
L. Bao, Y. Wang, T. Shang, X. Ren and R. Ma	2013	A Novel Clinical Pharmacy Management System in Improving the Rational Drug Use in Department of General Surgery	Tertiary	Department of surgery		2010-2011		Reduction	Reduction	Improvement
J. Guo, X. Wang and D. Sun	2013	Analysis of Intervention Measures of Antibiotics Special Rectification and Its Effects in Our Hospital	Secondary	Hospital overall		2012		Reduction	Reduction	
X. Chen and H. Xiao	2013	Analysis of Management Measures of Antibiotic Special Rectification and Its Effects in a Grade Three Hospital	Tertiary	Hospital overall		2011-2012		Reduction	Reduction	
H. Zuo, H. Li, Y. Huang, X. Liu and H. Yan	2013	Analysis of the effect of clinical application of antibacterial drugs special rectification activities	Tertiary	Hospital overall		2012				Improvement
X. Yang and Y. Yang	2013	Analysis of the Effects of Special Management and Pharmaceutical Intervention for Antibacterials in Our Hospital	Tertiary	Hospital overall	2010	2011		Reduction		
F. Wang and D. Zhang	2013	Clinical use of antibiotics in a stomatology hospital before and after special rectifications	Tertiary specialist (stomatology)	Hospital overall		2011-2012		Stable	Reduction	Improvement
S. Liu and P. Xiang	2013	Effect analysis of special renovation and continuous improvement of antimicrobial prophylaxis in removing internal devices operation	Tertiary	Department of surgery		2011-2012				Improvement
Y. Luo, J. Zhong, Y. Sun and J. Wang	2013	Effect of Special Rectification Activities on Antibacterial Application in A Hospital during 2011-2012	Tertiary	Hospital overall		2011-2012		Reduction	Reduction	
Y. Tang, L. Gui and W. Yin	2013	Effect of special rectification for clinical use of antibiotics on antibiotics prophylaxis during perioperative period of general surgery	Tertiary	Department of surgery	2010	2011				Improvement



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J. Chen, Z. Wang, G. Li and J. Xu	2013	Impact and analysis of the utilization of antibacterial drugs for special use in a first-class hospital with special rectification activities of antibacterials	Tertiary	Hospital overall		2011-2013		Reduction	Reduction	
N. Wu, S. Chui, J. Han, Z. Li and M. Jia	2013	Influence of special rectification activities of clinical application of antibacterials in China on antibacterial use density of inpatients in respiratory department of general hospital	Secondary	Hospital overall	2010	2012			Reduction	
L. Guan	2013	Kaizhan Zhuanxiang Zhengzhi Huodong Dui Woyuan Menzhen Kangjun Yaowu Yingyong De Yingxiang	Tertiary	Hospital overall	2010	2011-2012		Reduction		
J. Pan, M. Fu, W. Lei and X. Jin	2013	Kangjun Yaowu Linchuang Yingyong Zhuanxiang Zhengzhi Huodong Zai Mou Sanji Yiyuan De Shishi Xiaoguo Pingjia	Tertiary	Hospital overall		2011-2012		Reduction	Reduction	Improvement
Y. Xin	2013	Kangjun Yaowu Linchuang Yingyong Zhuanxiang Zhengzhi Huodong Zai Woyuan De Shishi Xiaoguo Pingjia	Tertiary	Hospital overall		2011-2012		Reduction	Reduction	Improvement
S. Wang and L. Wang	2013	Kangjun Yaowu Zhuanxiang Zhengzhi Huodong Dui Mouyuan Kangjun Yaowu Heli Shiyong De Xiaoguo Fenxi	Tertiary	Hospital overall		2011-2013		Reduction	Reduction	Improvement
N. Wang, L. Jia, W. Zhang, L. Wang, Q. Guo, L. Liu and Q. Wei	2013	Lasting Effect of a Special Antibiotic Restriction Program on Antibiotic Usage in the Hospital	Tertiary	Hospital overall	2010	2011-2012		Reduction	Reduction	Improvement
C. Li and Y. Liang	2013	Mouyuan Kangjun Yaowu Zhuanxiang Zhengzhi Huodong Xiaoguo Fenxi	Secondary	Hospital overall		2011-2012		Reduction	Reduction	Improvement
J. Cheng, S. Zhang and Y. Ye	2013	The Impact of Special Rectification Activity on Clinical Use of Antibacterials in Orthopedics Department	Tertiary	Department of orthopaedics		2011-2012			Reduction	
L. Zhang	2013	Woyuan Kangjun Yaowu Zhuanxiang Zhengzhi Guanli Cuoshi Ji Xiaoguo Fenxi	Tertiary	Hospital overall		2011-2012		Reduction	Reduction	Improvement

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J. Hong, D. He and X. Liu	2013	Woyuan Kangjun Yaowu Zhuanxiang Zhengzhi Xiaoguo Pingjia Yu Fenxi	Tertiary (traditional Chinese medicine)	Hospital overall		2012		Reduction	Reduction	Improvement
L. Li	2013	Zhuanxiang Zhengzhi Qianhou I Lei Qiekou Weishoushuqi Shiyong Kangjun Yaowu De Xiaoguo Fenxi	Secondary	Department of surgery	2010	2011- 2012				Improvement
H. Zhang, P. Liang, J. Zhang, X. Yang and W. Ge	2014	2011 ~ 2013 Nian Mouyuan Kangjun Yaowu Zhuanxiang Zhengzhi Xiaoguo Pingjia	Tertiary	Hospital overall		2011- 2013		Reduction	Reduction	Improvement
C. Wang, T. Shi, D. Su, M. Deng and L. Jiang	2014	Analysis of antibacterial use in the department of orthopedics after the antibacterial special rectification activity	Tertiary	Department of orthopaedics		2011- 2013		Reduction	Reduction	Improvement
A. Xue, R. Wang, H. Sun and W. Wu	2014	Analysis of clinical use of antibiotics in a maternity hospital	Secondary specialist (maternal)	Hospital overall		2011- 2012			Reduction	Improvement
Z. Li, P. Zhang, L. Yuan and P. Gu	2014	Analysis of lasting effects of prophylactic use antibiotics on aseptic operations after regulation in our hospital	Tertiary	Department of surgery		2011- 2012				Improvement
X. Hou and J. Wang	2014	Analysis of the effects of special management and pharmaceutical intervention for antibiotics in our hospital	Tertiary	Hospital overall		2012- 2013		Reduction	Reduction	Improvement
N. Wu, L. Zhang, Y. Lan, Z. Zhang, L. Ran, L. Fang, Z. Hu, F. Zhao and L. Lu	2014	Analysis on Implementing Effect of Special Rectification of Antimicrobial Drugs in Stomatological Hospitals	Tertiary specialist (stomatology)	Hospital overall		2011- 2013		Reduction	Reduction	Improvement
W. Xing, H. Mo and L. Duan	2014	Analysis on the Effects of Special Rectification of Antimicrobial Drugs and Pharmaceutical Intervention in Our Hospital in 2011-2013	Tertiary	Hospital overall		2011- 2013		Reduction	Reduction	Improvement

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W. Zeng	2014	Effect of clinical application of antibacterial drugs special rectification activities on a community hospital	Primary	Hospital overall		2011-2013		Reduction		
Y. Liu, M. Yang, Y. Zhou and L. Yang	2014	Effect of special rectification for antibacterial agents	Tertiary	Hospital overall		2013		Reduction		Improvement
X. Wu, Y. Chen and J. Xu	2014	Effect of special rectification of antibiotics	Secondary	Hospital overall		2011-2013		Reduction		Improvement
G. Lin, Y. Liu, G. Li and G. Zhang	2014	Effect of special rectification of perioperative antimicrobial prophylaxis in inguinal hernia repair	Tertiary	Department of surgery		2011-2012				Improvement
C. Luo, X. Zhu and L. Li	2014	Effectiveness Evaluation of Special Rectification Activities of Clinical Antibacterials Use in our Hospital	Tertiary	Hospital overall		2011-2013		Reduction	Reduction	Improvement
L. Guo and X. Wu	2014	Effects of Antibiotics Special Rectification Activities on the Perioperative Prophylactic Use of Antibiotics in Stomach and Colorectal Operations in Our Hospital	Tertiary	Department of surgery		2011-2012				Improvement
D. Hou, Q. Wang, C. Jiang, C. Tian, H. Li, B. Ji, H. D., W. Q., J. C., T. C., L. H., J. B., D. Hou, Q. Wang, C. Jiang, C. Tian, H. Li and B. Ji	2014	Evaluation of the short-term effects of antimicrobial stewardship in the intensive care unit at a tertiary hospital in China	Tertiary	Intensive care unit	2010	2011-2012			Reduction	
F. Yang, W. Li and P. Wang	2014	Implementation of Special Campaigns Hospital Antimicrobial Effect Analysis	Secondary	Hospital overall		2011-2013		Reduction	Reduction	Improvement
W. Zhao, H. Shu, L. Zhang and J. Guo	2014	Jinan Junqu Zongyiyuan Kangjun Yaowu Linchuang Yingyong Zhuaxiang Zhengzhi Xiaoguo Fenxi	Tertiary	Hospital overall		2011-2012		Reduction	Reduction	Improvement
E. Wu	2014	Kangjun Yaowu Heli Yingyong Zhuaxiang Zhengzhi Cuoshi Ji Xiaoguo Fenxi	Secondary	Hospital overall		2012-2013		Reduction	Reduction	

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H. Fan, L. Yuan and Z. Song	2014	Kangjun Yaowu Linchuang Yingyong Zhuanxiang Zhengzhi Huodong Shishi Xiaoguo Pingjia	Tertiary	Hospital overall		2011-2013		Stable	Reduction	Improvement
H. Cao, X. Wang, M. He, X. Du, H. Yang and H. Zha	2014	Kangjun Yaowu Zhuanxiang Zhengzhi Dui Mou Zonghexing Yiyuan Guke Kangjun Yaowu Linchuang Yingyong Yingxiang De Yanjiu	Tertiary	Department of orthopaedics		2012		Reduction	Reduction	Improvement
X. Fan and H. Liu	2014	Mouyuan Kangjun Yaowu Zhuanxiang Zhengzhi Huodong Shishi Xiaoguo Fenxi	Tertiary	Hospital overall		2012-2013		Reduction		Improvement
M. Luo and M. Peng	2014	Mouyuan Sannian Kangjun Yaowu Zhuanxiang Zhengzhi Xiaoguo Duibi Fenxi	Tertiary	Hospital overall		2011-2013		Reduction	Reduction	Improvement
G. Wang	2014	Shishi Kangjun Yaowu Linchuang Yingyong Zhuanxiang Zhengzhi Huodong Fang'an Dui Woyuan Kangjun Yaowu Yingyong De Yingxiang Diaocha	Primary	Hospital overall		2011-2012		Reduction		
B. Yao and W. Lin	2014	Special Rectification Activities on Antibiotic Use in 2011 vs 2012 in a Hospital: A Comparative Analysis	Tertiary	Hospital overall		2012-2013		Reduction		Improvement
F. Dai	2014	Special rectification activities on clinical application of antimicrobial agents in an occupational diseases prevention and treatment hospital	Secondary specialist (occupational)	Hospital overall	2010	2011-2012		Reduction	Reduction	
J. Wang	2014	Woyuan Kangjun Yaowu Zhuanxiang Zhengzhi Huodong Xiaoguo Fenxi	Tertiary	Hospital overall		2012-2013		Reduction	Reduction	Improvement
G. Qiu and P. Wang	2014	Woyuan Kangjun Yaowu Zhuanxiang Zhengzhi Xiaoguo Ji Yiyuan Ganran Qingkuang De Duibi Fenxi	Tertiary	Hospital overall		2011-2012		Reduction	Reduction	
B. Luo	2014	Woyuan Kangshengsu Zhuanxiang Zhengzhi Cuoshi Yingyong Xiaoguo Fenxi	Tertiary	Hospital overall		2011-2012		Reduction	Reduction	
L. Zou, D. Hu and S. Li	2014	Zhuanxiang Zhengzhi Dui Woyuan Guke Zhuyuan Huanzhe Kangjun Yaowu Shiyong De Yingxiang	Secondary	Department of orthopaedics		2011, 2013		Reduction	Reduction	Improvement

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W. Tao, K. Zhang, C. Xi and M. Li	2014	Zhuanxiang Zhengzhi Dui Woyuan Pogongchan Weishoushuqi Kangjun Yaowu Shiyong Qingkuang De Yingxiang	Tertiary specialist (maternal)	Cesarian section cases		2011-2013	2014			Improvement
S. Zhu, R. Xie, Q. Ou, W. Yu and L. Yang	2014	Zhuanxiang Zhengzhi Dui Yiyuan Kangjun Yaowu Linchuang Yingyong De Yingxiang	Tertiary specialist (oncology)	Hospital overall		2011-2013		Reduction	Reduction	Improvement
L. Gui and S. Zhou	2014	Zhuanxiang Zhengzhi Huodong Dui Woyuan Kangjun Yaowu Linchuang Heli Shiyong De Yingxiang	Tertiary	Hospital overall		2011-2013		Reduction	Reduction	
J. Zhang, K. Gu and Y. Zhao	2015	2011-2013 Nian Woyuan Kangjun Yaowu Linchuang Yingyong Zhuanxiang Zhengzhi Huodong Xiaoguo Fenxi	Tertiary	Hospital overall		2011-2013		Reduction	Reduction	Improvement
Q. Meng, S. Li and L. Li	2015	Analysis of antibiotic use in Harbin No. 242 hospital after the rectification.	Tertiary	Hospital overall		2011-2013	2014	Reduction	Reduction	Improvement
H. Li and K. Zhang	2015	Analysis of antibiotic use in our hospital from 2009 to the first half of 2013.	Tertiary	Breakdowns of clinical departments		2012-2013		Mixed results		
F. Xu, P. Xiao, G. He and L. Song	2015	Analysis of perioperative antibiotic use in Peking University Shenzhen Hospital before and after the special rectification.	Tertiary	Hospital overall		2011-2013	2014	Reduction	Reduction	Improvement
L. Su	2015	Antibiotic Use in Pediatric Outpatients before and after Special Rectification	Tertiary	Paediatric outpatient		2011	2014	Reduction		
J. Wang, Y. Chen, Y. Feng and J. Wang	2015	Effect of Special Rectification Activities of Antibiotics on The Antibiotic Use among The Inpatients	Secondary	Hospital overall	2010	2011-2013	2014	Reduction	Reduction	Improvement
J. Zhang, Z. Wu, R. Wang, X. Ying and X. Wang	2015	Effect of special rectification activity on antibiotic prophylaxis of patients undergoing type I incision surgery	Secondary	Department of surgery		2011	2014			Improvement
J. Li	2015	Effect of Special Treatment of Antimicrobial Drugs on Surgical	Tertiary	Department of surgery		2013	2014			Improvement

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		Incision in the Prevention of Drug Use								
X. Gao, Y. Huang, M. Zhou and H. Liu	2015	Effectiveness evaluation and summary of experience on antibacterials special rectification in a hospital of Three Grade A	Tertiary	Hospital overall		2011, 2013		Reduction	Reduction	Improvement
Z. Zhou, X. Chen, M. Guan, N. Li, F. Liu, L. Yu, Y. Huang and M. Chen	2015	Effectiveness of special rectification activity on clinical antimicrobial use in a tertiary first-class hospital	Tertiary	Hospital overall		2011-2013		Reduction	Reduction	Improvement
H. Liu, R. Liu, W. Gu and H. Huang	2015	Effects Analysis of Application of Antibiotics in Patients with Type I Incision Operation during Perioperation after Special Rectification in Huizhou Hospital of Traditional Chinese Medicine	Tertiary (traditional Chinese medicine)	Department of surgery		2012-2013	2014			Improvement
S. Deng, X. Wen, J. Yu and W. Feng	2015	Efficacy of Rectification Activity on Antibiotic Use in Pediatric Department of a Hospital	Tertiary	Department of paediatrics	2010		2014			Improvement
M. Wang and Y. Wang	2015	Fenxi Kangjun Yaowu Zhuanxiang Zhengzhi Dui Yiyuan Kangjun Yaowu Shiyong De Yingxiang	Secondary	Hospital overall		2013	2014		Reduction	
Y. Zhou, L. Y. Ma, X. Zhao, S. H. Tian, L. Y. Sun and Y. M. Cui	2015	Impact of pharmacist intervention on antibiotic use and prophylactic antibiotic use in urology clean operations	Tertiary	Department of urology	2010		2013		Reduction	Improvement
X. Zhang, Z. Jiang and M. Yang	2015	Kangjun Yaowu Zhuanxiang Zhengzhi Dui Menzhen Chufang Zhibiao De Yingxiang Fenxi	Tertiary	Hospital overall		2011-2013	2014	Reduction		
Y. Zheng, S. Jiang and J. Liu	2015	Kangjun Yaowu Zhuanxiang Zhengzhi Huodong Dui Kangjun Yaowu Qiangdu De Yingxiang	Tertiary	Hospital overall		2011-2013		Reduction		
T. Jing	2015	Mou Sanjia Yiyuan Kangjun Yaowu Zhuanxiang Zhengzhi Huodong Shishi Xiaoguo Fenxi	Tertiary	Hospital overall		2011	2014	Reduction	Reduction	Improvement
X. Lei, Y. Wang, Y. Jin, Y. Chai, X. Jiang, J. Feng, Y. Xu and C. Fan	2015	Mou Zhongliu Yiyuan Kangjun Yaowu Zhuanxiang Zhengzhi Xiaoguo Fenxi	Tertiary specialist (oncology)	Hospital overall		2012-2013		Reduction	Reduction	Improvement

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Q. Cheng	2015	Mouyuan 2011 ~ 2014 Nian Kangjun Yaowu Linchuang Yingyong Zhuanxiang Zhengzhi Guanli Xiaoguo Diaocha	Secondary	Hospital overall		2011-2013	2014	Reduction	Reduction	Improvement
X. Ren, P. Yu, G. Zheng, X. He and Y. Liu	2015	The Effectiveness Evaluation of Antibiotics Management by Applying PDCA Cycle Model	Tertiary	Hospital overall		2011-2013		Reduction	Reduction	Improvement
Y. M. Zou, Y. Ma, J. H. Liu, J. Shi, T. Fan, Y. Y. Shan, H. P. Yao and Y. L. Dong	2015	Trends and correlation of antibacterial usage and bacterial resistance: time series analysis for antibacterial stewardship in a Chinese teaching hospital (2009–2013)	Tertiary	Hospital overall	2009-2010	2011-2013		Reduction	Reduction	
Y. Liu	2015	Woyuan Kangjun Yaowu Zhuanxiang Zhengzhi Huodong Xiaoguo Diaocha Fenxi	Secondary	Hospital overall		2011-2013		Reduction	Reduction	Improvement
C. Jiang	2015	Zhuanxiang Zhengzhi Guanli Dui Yiyuan Kangjun Yaowu Heli Shiyong Qingkuang De Yingxiang	Secondary	Hospital overall		2012-2013	2014	Reduction		Improvement
Z. Ma, Y. Zhou, Y. Ma and K. Li	2015	Zhuanxiang Zhengzhi Huodong Dui Woyuan Kangjun Yaowu Heli Yingyong He Jianhuan Xijun Naiyaoxing De Xiaoguo Pingjia	Tertiary	Hospital overall	2009-2010	2011-2013	2014	Reduction	Reduction	Improvement
D. Liang, J. Chen and Q. Chen	2016	Effect Evaluation of Prophylactic Antibacterials of General Surgery Class I Incision During Perioperative Period Before and After Special Rectification in Our Hospital	Tertiary	Department of surgery		2011	2015		Reduction	Improvement
X. Zhang, J. Chen, S. Chen, M. Yang and Guangdong Pharmacy Association	2016	Effects Analysis of Special Rectification of Antibiotics for Prophylactic Use in Perioperative Period of Per-manent Cardiac Pacemaker Implantation in Our Hospital	Tertiary	Department of cardiology	2010	2012	2014			Improvement
X. Wang, J. Ding and X. Huang	2016	Influence study of pharmaceutical intervention on clinical use of antibacterials in outpatient prescriptions during special rectification	Tertiary	Outpatient	2010	2012	2014	Reduction		

## Appendices

L. Liu	2016	Influences on perioperative prophylactic use of antimicrobial drugs of the antibiotics rectification activities during cesar-ean section in our hospital	Secondary	Department of obstetrics and gynaecology		2011, 2013	2015			Improvement
Z. Tu	2016	Kangshengsu Zhuanxiang Zhengzhi Dui Woyuan Linchuang Yongyao De Yingxiang	Secondary	Hospital overall		2013	2015	Reduction	Reduction	Improvement
H. Wu, J. Chen and X. Chen	2017	Effects of Antimicrobial Special Rectification Activities on the Perioperative Use of Antimicrobials in Colorectal Cancer Operations in A Tertiary Hospital	Tertiary	Department of oncology	2010	2012	2015		Increase	Improvement
Z. Zhang, F. Chen and Y. Ou	2017	Impact of an antimicrobial stewardship programme on antibiotic usage and resistance in a tertiary hospital in China	Tertiary	Hospital overall		2011	2014		Reduction	
D. Ma	2017	Kangjun Yaowu Zhuanxiang Zhengzhi Huodong Dui Weishoushuqi Yufang Yingyong Kangjun Yaowu De Yingxiang	Secondary specialist (maternal)	Hospital overall		2010-2013	2013-2016			Improvement
Y. Wang	2018	Kangjun Yaowu Shiyong Zhuanxiang Zhengzhi Dui Guke Kangjun Yaowu Shiyong De Yingxiang Xiaoguo Fenxi	Tertiary	Department of orthopaedics	Not stated	2011-2013		Reduction	Reduction	Improvement
S. Yang	2018	Kangjun Yaowu Zhuanxiang Zhengzhi Dui Weishuqi Kangjun Yaowu Yufangxing Shiyong De Ganyu Xiaoguo	Tertiary	Department of surgery		2013	2015			Improvement



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

### Approval from LSHTM

**Observational / Interventions Research Ethics Committee**

LSHTM

12 June 2015

Dear

**Study Title:** Reducing unnecessary outpatient antibiotic prescriptions: what can be done to improve rational prescription in China

**LSHTM Ethics Ref:** 8931

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

Document Type	File Name	Date	Version
Covering Letter	Cover letter--response to comments	09/06/2015	1

**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 not be initiated before receipt of written favourable opinion from the committee.

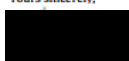
The CI or delegate is also required to notify the ethics committee of any protocol violations and/or Suspected Unexpected Serious Adverse Reactions (SUSARs) which occur during the project by submitting a Serious Adverse Event form.

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

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

Additional information is available at: [www.lshtm.ac.uk/ethics](http://www.lshtm.ac.uk/ethics)

Yours sincerely,



**Professor John DH Porter**  
Chair

[ethics@lshtm.ac.uk](mailto:ethics@lshtm.ac.uk)  
<http://www.lshtm.ac.uk/ethics/>

Approval from Peking University


D009 伦理审查批件

PU IRB\_OF 15\_v2 (2013-8-1)

北京大学生物医学伦理委员会 (PU IRB)

伦理审查批件

伦理审查批件号: IRB00001052-15022

受理号	2015029 (公卫)		
项目全称	改进抗生素合理用药: 用定性方法理解政策影响		
经费来源	自筹经费		
项目负责人	杨莉		
项目负责人所在单位	北京大学公共卫生学院		
审查类别	初始审查	审查方式	非会议审查
审查文件	详见附件“审查文件清单”		
<p>审查意见:</p> <p>依据世界医学会《赫尔辛基宣言》、国际医学科学组织委员会《涉及人的生物医学研究国际伦理准则》、《药物临床试验质量管理规范》、《涉及人的生物医学研究伦理审查办法(试行)》、《药物临床试验伦理审查工作指导原则》、等法律、法规、规章、规范性文件和国际准则, 以及北京大学受试者保护体系相关政策, 经本伦理委员会审查, 同意按研究方案开展本项研究。</p> <p>请遵循伦理委员会批准的方案开展研究, 保护受试者的健康与权益。</p> <ol style="list-style-type: none"> <li>1. 研究过程中若变更项目负责人, 对研究方案、知情同意书、病例报告表、调查问卷、招募材料等的任何修改, 请提交修正案审查申请;</li> <li>2. 请按照相关法律法规规定以及研究方案中对于安全性事件报告计划, 及时向北京大学生物医学伦理委员会提交书面不良事件报告;</li> <li>3. 研究者没有遵从方案开展研究, 可能对受试者的权益/健康、以及研究的科学性造成不良影响, 请提交违规事件报告;</li> <li>4. 申请人暂停或提前终止临床研究, 请及时提交暂停/中止研究报告;</li> <li>5. 研究结束时, 请提交结题报告。</li> <li>6. 本批件自批准之日起一年内有效, 请至少在失效日期前 1 个月提交持续审查申请。</li> </ol>			
批准日期	2015-6-2	批件失效日期	2016-6-1
主任委员签字		签署日期	2015.6.2

## 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/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卫系统对合理用药——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？

您将参与一次 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，研究员会与您联络。

#### 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和地点都会做匿名处理。

## Appendices

### 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，研究者将严密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。

### 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](mailto: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](mailto:llwyh@bjmu.edu.cn)。

### 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（北京大学公共卫生学院），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，及普通感冒的诊询过程。

#### 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. 本研究包括哪些内容？

您将参与一个简短的访问，所需时间约为 15 分钟。研究员会在其中记笔记。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之后将没有后续随访。

#### 6. 参加本项研究的危险是什么？

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和地点都会做匿名处理。

#### 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？

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，您的退出不会对您有任何影响。原则上，在您退出之后，研究者将严密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。

### 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任何问题，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](mailto: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](mailto: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

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，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（“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。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 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. 平均每次的诊询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？）
  - 对药品品规的选择（原研药？仿制药？）
  - 对品牌的选择（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一个更敏感的话题，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. 对于北京市区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？

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?

For semi-structured interviews with patients (Chinese):

1. 性别: 男/女  
年龄段: 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, 而且症状影比较明显 (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/不一定需要是大品牌 (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

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- 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：
- 您留意到有更多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特别增多
  - 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/您感冒时更少的用中成药/您一直很少用中成药/您一直很经常用中成药

谢谢！

采访人：

受访人：

## 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 nothingWhy 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 nothingWhy 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. Baijiahei, 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. Baijiahei, Tylenol, Xinkangtaike)
  - Antibiotics
  - TCM: Chinese-patented medicines that treat the symptoms

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- 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:

## Appendix

### Matching of the interviews with prescribers and patients

Analytical categories	Prescribers (question number in the topic guide)	Patients (question number in the questionnaire)
Researched healthcare setting	1. Hospital context	
	10. Financing of the hospital	
Professional or personal background	2. Experience	1. Demographics
Cold health-seeking behaviours	3. Cold cases	3. and 4. Cold behaviours
		5. and 6. Waiting time
Cold diagnosis	4. Cold diagnosis	14. and 15. Blood tests
Cold knowledge and treatment	5.1 Cold treatment--medicine type	2. Cold knowledge
		8. and 9. Medicine type
		10., 11., 12. and 13. Antibiotics
	5.2 Cold treatment--route of administration	16. Routes
	5.3 Cold treatment--patent	N/A – not a familiar concept to patients
	5.4 Cold treatment--brand	7a. Brand
	5.5 Cold treatment--price	7b. Price
	5.6 Cold treatment--EM	N/A – not a familiar concept to patients
	5.7 Cold treatment--insurance	7d. Insurance
	Refer to other sections	7c. Source
Patient demand and prescriber-patient interaction	6. Patient demand and interaction	17. What to do when prescriber refuses to give antibiotics
Prescribing and health seeking in various healthcare settings	7. Behaviours in other health settings	Refer to other sections
Antibiotic stewardship measures	8. Antibiotic regulations	18c. Prescriber's willingness to prescribe
		18a. and 18b. Education on antibiotics
		18d. Access to OTC antibiotics
Changes in prescribing, preferences and availability	9. Changes in patient demands and treatments	18e. Change in preferences



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

### Approval from LSHTM

**London School of Hygiene & Tropical Medicine**  
 Keppel Street, London WC1E 7HT  
 United Kingdom  
 Switchboard: +44 (0)20 7636 8636  
**www.lshtm.ac.uk**



Observational / Interventions Research Ethics Committee

Mr Lishi Li  
 LSHTM

13 September 2017

Dear Mr Lishi Li

**Study Title:** Analysing 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 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 final list of documents reviewed and approved by the Committee is as follows:

Document Type	File Name	Date	Version
Investigator CV	Cover Letter - Henry Lishi Li	28/06/2017	1
Covering Letter	Ethics cover letter - Lishi Li	14/08/2017	1
Protocol / Proposal	[REVISED] Protocol - Lishi Li	14/08/2017	2
Information Sheet	[REVISED] Study Information for Doctors	14/08/2017	2
Information Sheet	[REVISED] Study Information for Patients	14/08/2017	1
Information Sheet	[REVISED] Consent Form for Doctors	14/08/2017	2
Information Sheet	[REVISED] Consent Form for Patients	14/08/2017	1

#### 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 not be initiated 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 and/or Suspected Unexplained 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 applications website and can only be submitted to the committee via the website at: <http://leo.lshtm.ac.uk>

Additional information is available at: [www.lshtm.ac.uk/ethics](http://www.lshtm.ac.uk/ethics)

Yours sincerely,



Approval from Fudan University



復旦大學 公共衛生學院

School of Public Health Fudan University

上海市東安路130號 郵政 200032 130 Dong An Road, Shanghai 200032, P.R.China <http://sph.fudan.edu.cn> Email: [fdsp@fudan.edu.cn](mailto:fdsp@fudan.edu.cn)

研究課題： 全國抗菌藥物臨床應用專項整治活動實施過程研究：  
上海閔行區某醫院案例分析

課題負責人： 王偉 博士， 復旦大學公共衛生學院

復旦大學公共衛生學院醫學研究倫理委員會於2017年8月25日批准了王偉博士有關《全國抗菌藥物臨床應用專項整治活動實施過程研究：上海閔行區某醫院案例分析》的倫理學申請。批准號為IRB#2017-08-0631，有效期為即日起至2018年12月31日。

在項目開展期間，研究方案及具體工作計劃、調查表、知情同意書等如有任何修改和變動，必須在向本委員會報告並獲得批准後方可付諸實施；由於研究項目的執行對研究對象造成的不良影響或後果必須向本委員會報告並徵求調查指導。研究項目在有效期後還將繼續進行的，必須向本委員會申請批准延期。



復旦大學公共衛生學院醫學研究倫理委員會

國際註冊號：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和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。作为卫生系统的最重要参与者，医生和患者对于抗菌药物和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，研究者将严密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

本项研究对组织与协调人员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，无可预期的相关伤害。

### 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？

如果您有与本项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）。

## 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、与他人讨论，并解答了其有关研究的问题；我已告知该受试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；我已告知该受试者他/她可以退出本研究；我已告知该受试者他/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

#### 受试者声明

“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。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 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)

Main themes	Policy actors concerned		
	Non-clinical managers	Manager-prescribers and prescribers	Patients
1. Overview of the hospital	<ul style="list-style-type: none"> <li>- Tier, location, population coverage, services provided, estimated patient visits per day</li> <li>- How is this hospital financed?</li> <li>- How do patients here pay for their healthcare?</li> <li>- How are doctors paid by the hospital?</li> <li>- How are the hospital's and its doctors' performances measured?</li> <li>- Can you describe the organisational structure of the hospital?</li> </ul>	(Pick up any relevant comments during the interview and probe where necessary)	NA
2. Background of the interviewee	- Role, department, clinical specialty, professional title, role in the hospital, years of experience		- Sex, occupation, age group, educational background, reason for visit
3. Policy actors' perception of <i>The Campaign</i>	<ul style="list-style-type: none"> <li>- What do you understand about antibiotic stewardship?</li> <li>- What do you understand about <i>The Campaign</i>?</li> <li>- To what extent is <i>The Campaign</i> a distinct policy phase?</li> </ul>		NA
4. Key actors for antibiotic stewardship	<ul style="list-style-type: none"> <li>- Who are the key actors for antibiotic stewardship in this hospital, including the relevant departments, committees and personnel?</li> <li>- What is everyone's role in antibiotic stewardship respectively?</li> </ul>		NA
5. Implementation process of <i>The Campaign</i>	(Pick up any relevant comments during the interview and probe where necessary)	<ul style="list-style-type: none"> <li>- What role does antibiotics play in the clinical setting at your department?                             <ul style="list-style-type: none"> <li>o What are the typical cases at this department?</li> <li>o For what conditions antibiotics are used?</li> <li>o Are there any specific challenges to antibiotic use and antibiotic stewardship at this department?</li> <li>o To what extent are these challenges affecting your clinical decision-making and practices?</li> </ul> </li> </ul>	NA

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		<p>(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)</p>	
	<p>(Be conscious about the temporal element here and make explicit distinction between past and present)</p> <ul style="list-style-type: none"> <li>- How did the organisation of the key actors for antibiotic stewardship translate into a line of command? <ul style="list-style-type: none"> <li>o Was there a line of command?</li> <li>o How did non-clinical managers communicated and collaborated with manager-prescribers?</li> <li>o How did manager-prescribers work and communicate with doctors specifically?</li> <li>o How did national and local government communicated and collaborated with the hospital to ensure <i>Campaign</i> implementation?</li> </ul> </li> <li>- How was the necessary information on antibiotic use and resistance monitored and gathered at the hospital? <ul style="list-style-type: none"> <li>o What information was collected?</li> <li>o How was the information used?</li> <li>o Was the information uploaded to government databases?</li> </ul> </li> <li>- Did the government or the hospital set any target for antibiotic prescription? <ul style="list-style-type: none"> <li>o What were the targets and indicators for the hospital and the individual departments?</li> <li>o Which targets were most difficult to hit?</li> <li>o Did <i>The Campaign</i> intensify the existing target system?</li> <li>o Were the targets aligned with clinical needs?</li> <li>o How were the targets reviewed?</li> <li>o Was any punishment involved at any stage, for example if targets were not met, or doctors didn't perform?</li> <li>o Were these targets included in other policies, such as hospital accreditation and social health insurance?</li> </ul> </li> <li>- How did you regulate your antibiotic formulary? <ul style="list-style-type: none"> <li>o How many antibiotics were available at the hospital?</li> <li>o Why were these antibiotics selected for procurement?</li> <li>o Were these antibiotics sufficient to meet patients' clinical needs?</li> <li>o What were the requirements of professional authority for different kinds of antibiotics?</li> </ul> </li> <li>- What kinds of resources were necessary for the implementation of <i>The Campaign</i>? <ul style="list-style-type: none"> <li>o To what extent was information technology system important to implementation?</li> <li>o How did the hospital come to adopt IT system?</li> </ul> </li> <li>- How were the medical professionals trained for implementing antibiotic stewardship? <ul style="list-style-type: none"> <li>o How were doctors, clinical pharmacists and microbiologists supported, respectively?</li> <li>o Were there new requirements in qualifications regarding antibiotic prescribing?</li> </ul> </li> <li>- Were there any activities to educate patients?</li> <li>- What do you think are the barriers to implementing antibiotic stewardship in this hospital? <ul style="list-style-type: none"> <li>o Were there specific challenges to implementation faced by different clinical settings?</li> <li>o How did different actors (senior management, heads of department and doctors) work together to address these challenges?</li> <li>o Did <i>The Campaign</i> help addressed these barriers in any way, and how?</li> </ul> </li> </ul>		<ul style="list-style-type: none"> <li>- What do you understand about antibiotics? <ul style="list-style-type: none"> <li>o What do you think they are for?</li> <li>o Are they necessary for treating common cold?</li> </ul> </li> <li>- Where do you obtain antibiotics? <ul style="list-style-type: none"> <li>o Do you obtain them from hospitals?</li> <li>o Do you expect doctors to prescribe antibiotics when you visit them for common cold?</li> <li>o Do you obtain them from elsewhere?</li> </ul> </li> <li>- Tell me about your experience with getting antibiotic prescriptions for common cold in recent years. <ul style="list-style-type: none"> <li>o Have you noticed any changes in access to antibiotics in general?</li> <li>o Have you noticed any changes in the doctor's readiness to prescribe antibiotics?</li> <li>o Have you ever been denied to antibiotics by a doctor, and what did you do?</li> </ul> </li> <li>- Have you been aware of any message regarding rational antibiotic use in recent years? <ul style="list-style-type: none"> <li>o Where have you noticed these messages?</li> <li>o Have hospitals promoted these messages to patients?</li> <li>o Are you aware of <i>The Campaign</i>? If so could you tell me about it?</li> </ul> </li> </ul>

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<p>6. Perceived influence of <i>The Campaign</i></p>	<p>(Further probe the temporal element here if not explicit from previous answers)</p> <ul style="list-style-type: none"> <li>- In what way do you think the implementation of <i>The Campaign</i> have any lasting impacts on antibiotic stewardship in the hospital? Or have things reversed in anyway?</li> <li>- Do you think patients have taken onboard the messages as well as the medical professionals did? Why or why not?</li> </ul>	
<p>7. Impact of health system factors</p>	<p>(Pick up any relevant comments during the interview and probe where necessary)</p> <ul style="list-style-type: none"> <li>- How do changes in general healthcare policies, such as healthcare financing and essential medicine policy, influence antibiotic prescribing in general?</li> </ul>	<p>NA</p>



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?
- 该院的病人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: 被访谈者的基本资料

- 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
  - o 科室的临床功能和病人构成
  - o 科室的临床抗生素用药需求和习惯及其背后的原因
  - o 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)?
  - o 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
  - o 是否存在政策所提到的指挥链和汇报机制?
  - o 科室主任和医生在抗生素管理实施上的互动: 科主任的管理职责, 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)
  - o 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?
  - o 具体收集的有哪些数据?
  - o 医院如何使用这些数据以达到政策实施的目标?
  - o 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?
  - o 各科室的具体用药指标
  - o 哪些指标最难实现?
  - o 比较整治前后指标的变化: 是否更严?

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- 这些指标管理是否合乎临床需要？
- 政府和医院分别如何回顾和使用这些指标？
- 如果没有能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？
  
- 该院如何对抗菌药物目录和处方进行管理？
  - 该院一共有多少种抗生素可供使用？
  - 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上的需求？
  - 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的要求？
  
- 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员的培训措施有哪些？
  - 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？
  - 不同专科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”的实施对是否对该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一如医保政策和基本药物政策一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？
- 如果您感冒时去看医生，您会期望医生给您开处抗菌药物吗？
- 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意到关于抗菌药物合理使用的信息？