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Developing a model to address antimicrobial stewardship in primary care facilities in Zhejiang Province, China

Submission date 08/10/2020	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol
Registration date 13/10/2020	**Overall study status** Completed	[_] Statistical analysis plan [_] Results
Last Edited 12/10/2020	**Condition category** Other	[_] Individual participant data [_] Record updated in last year

Plain English summary of protocol

Background and study aims
China makes a major contribution to the global burden of antimicrobial resistance. The major underlying cause is misuse of antibiotics. In many areas of China there has been recent progress in reducing antibiotic misuse at secondary and tertiary levels in healthcare, but there has been very little progress in primary care or in the pharmacy sector. The overall goal of the project therefore is to develop replicable models to improve antimicrobial stewardship in primary care facilities and pharmacies in urban and rural settings in China.

Who can participate?
Doctors at primary care facilities in urban and rural Zhejiang Province (China)

What does the study involve?
The intervention will be multi-faceted using quality improvement and educational approaches. All primary care doctors will be trained in rational prescribing, antimicrobial stewardship and infection control measure, using an innovative mobile application combined with local on-site training. Through social media, a system of transparency will be introduced to share prescribing behaviours within and between primary care facilities. This will be combined with a knowledge sharing and mutual support system. Patients will be educated at the time of consultation and through an entertaining mobile application. The primary outcome measures will be percentage reduction in antibiotic prescribing by doctors, and in sales by pharmacists, compared both with baseline measures and with control facilities in the same areas.

What are the possible benefits and risks of participating?
Primary doctors can learn and consolidate their knowledge of antibiotics and their ability to diagnose and treat infectious diseases. For primary hospitals, it can solve the problem of the implementation of training on the right to prescribe antibacterial drugs. For society, the researchers propose a scientific management practice and overall solution for antimicrobial drugs.

Where is the study run from?
Primary health care hospitals in Hangzhou city and Kaihua County, Zhejiang Province (China)

When is the study starting and how long is it expected to run for?
January 2019 to October 2022

Who is funding the study?
Pfizer Pharmaceutical Co. Ltd

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
ZGL201901-3

Study information

Scientific Title
Regulating the rational use of antibiotics by grassroots doctors through mobile apps: a randomized controlled trial

Acronym
ZJAMR

Study objectives
Mobile application training can enhance the infection diagnosis and treatment skills of grass-roots doctors, help them understand antibiotic stewardship, and reduce the antibiotic prescription rate in primary care facilities.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 29/01/2019, Medical Ethics Committee, School of Public Health, Zhejiang University (866 Yuhangtang Road, Hangzhou 310058, China; +86 (0)571 88981368; zjusph@zju.edu.cn), ref: ZGL201901-3

Study design
Multi-center randomized controlled trial

Primary study design
Interventional

Study type(s)
Other

Health condition(s) or problem(s) studied
Antimicrobial stewardship in primary care facilities

Interventions
A computer program is used to randomly select more than 20 hospitals in Quzhou City Kailua county and Hangzhou city, Zhejiang province and allocate them to the intervention group and control group in a 1:1 ratio.

Interventions will be multifaceted, using quality improvement and educational approaches. In this study, questionnaire surveys, individual interviews and behavioral interventions are combined to collect data from the perspective of health service providers through an electronic medical record system plug-in, to study the types, degree and influencing factors of antibiotic use in primary medical institutions, and to summarize the actual obstacles and shortcomings in the management of primary antibiotics. All primary care physicians will be trained in rational prescribing, antimicrobial management and infection control measures, using an innovative mobile application, combined with local on-site training. Through social media, a transparent system will be introduced to share prescribing behaviour within and between primary health-care institutions. At the same time, the mobile application ("Antimicrobial drug treatment right Training System") is used to evaluate and strengthen the knowledge level of antibacterial drugs and the ability of infection diagnosis and treatment of grassroots doctors, so as to reduce the unreasonable use of antibiotics to the greatest extent. Pharmacists will be trained in the same way and their sales records will be spot-checked. Patients will be educated through a fun mobile app at the time of consultation. In order to promote rational drug use, improve health level, explore the establishment of primary medical institutions antibiotic use monitoring and evaluation system to provide ideas and scientific evidence.

The researchers do not conduct any intervention for the control group, and will invite the control group for relevant training free of charge after the completion of the project.

Intervention Type
Behavioural

Primary outcome(s)
Antibiotic prescription rate measured from electronic medical records using the proportion of prescriptions for upper respiratory infections and gastrointestinal infection containing at least one antibiotic (prescribers and physicians) at baseline and 12 months

Key secondary outcome(s))
1. Attitudes and behaviours of doctors and the general public in relation to antibiotic use, AMS and infection control at all levels, measured using a repeat questionnaire survey at baseline and 12 months
2. Multi-antibiotic prescription rate measured from electronic medical records using the proportion of antibiotic prescriptions containing two or more antibiotics at baseline and 12 months
3. Broad-spectrum antibiotic prescription rate measured from electronic medical records using the proportion of antibiotic prescriptions containing at least one broad-spectrum antibiotic at baseline and 12 months
4. Intravenous antibiotic prescription rate is measured from electronic medical records using the proportion of antibiotic prescriptions containing at least one intravenous antibiotic at baseline and 12 months

Completion date
01/10/2022

Eligibility

Key inclusion criteria
Primary care doctors from primary care facilities who have an antibiotic prescription qualification

Participant type(s)
Health professional

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Key exclusion criteria
1. Primary care doctors not from primary care facilities
2. Primary care doctors who do not have an antibiotic prescription qualification

Date of first enrolment
01/10/2020

Date of final enrolment
01/04/2021

Locations

Countries of recruitment
China

Study participating centre
Health Committee of Kaihua County
5 Fenghuang South Road
Kailua County
Quzhou
China
324304

Study participating centre
Hangzhou Municipal Health Commission
Block D, Civic Center
18 Jiefang East Road
Hangzhou
China
310016

Sponsor information

Organisation
Joint Commission

ROR
https://ror.org/03skrcz21

Funder(s)

Funder type
Industry

Funder Name
Pfizer

Alternative Name(s)
Pfizer Inc., Pfizer Consumer Healthcare, Davis, Charles Pfizer & Company, Warner-Lambert, King Pharmaceuticals, Wyeth Pharmaceuticals, Seagen, Pfizer Inc

Funding Body Type
Government organisation

Funding Body Subtype
For-profit companies (industry)

Location
United States of America

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Jie Chen (med_chenjie@zju.edu.cn). Data will be available after the paper is published for one year (Attribution (BY) - Noncommercial (NC)).

IPD sharing plan summary
Available on request