Can providing real-time warnings and feedback to doctors within a hospital information system reduce inappropriate antibiotic prescribing?

| Submission date | Recruitment status | [X] Prospectively registered | | |
|-------------------|-----------------------------|------------------------------|--|--|
| 29/12/2019 | No longer recruiting | [X] Protocol | | |
| Registration date | Overall study status | Statistical analysis plan | | |
| 09/01/2020 | Completed | [X] Results | | |
| Last Edited | Condition category | Individual participant data | | |
| 12/03/2025 | Infections and Infestations | | | |

Plain English summary of protocol

Background and study aims

Antibiotic overuse is a problem for the whole world. When antibiotics are used unnecessarily, bacteria can become resistant to them and infections become harder to control. Approximately 900 million people in farming communities in China are currently using primary care services, which are provided by rural doctors. Chinese healthcare in general is advancing rapidly, but rural doctors' knowledge and training can be out of date and inadequate. Previous research has shown that rural doctors in China are prescribing antibiotics inappropriately. Although guidelines and refresher courses are regularly provided, the rate of antibiotic prescriptions among rural primary doctors has not dropped. Rural doctors themselves agree that effective and continuous practical training with feedback on their antibiotic prescriptions would help to reduce their rate of antibiotic prescriptions.

Rural doctors in China use a medical computing network. A small study providing individual feedback to doctors on their antibiotic prescribing through this system. Those who received the feedback prescribed fewer antibiotics than those who did not. This study aims to provide real-time warnings of potentially inappropriate antibiotic use as well as feedback to doctors within 100 rural hospitals and examine the effects on a larger scale than in the first study.

Who can participate?

Doctors who have been working for at least 6 months in a participating township hospital.

What does the study involve?

The hospitals will be randomly divided into two groups. One group will have the real-time warnings and feedback available within its hospital information system for 3 months and will then have it removed, while the other group will have a 3-month period without the real-time warnings and feedback and will then have 3 months with these features. The antibiotic prescribing within these hospitals will be analysed to examine the effect of the warnings and feedback.

What are the possible benefits and risks of participating?

Where is the study run from?
Guizhou Medical University (China)

When is the study starting and how long is it expected to run for? January 2020 to December 2023

Who is funding the study?

Who is the main contact? Mrs Yue Chang, 4567401@qq.com

Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

Clinical Trials Information System (CTIS)

Nil known

ClinicalTrials.gov (NCT)

Nil known

Protocol serial number

71964009

Study information

Scientific Title

Research on feedback as a method to alter antibiotic prescription control in primary medical institutions based on graph neural network technology

Acronym

Study objectives

This intervention aims to increase rational usage of antibiotics based on collaboration among local health management authorities, practicing rural physicians, medical experts and IT experts.

Approximately 900 million farmers in China are currently using primary care services, which are provided by rural physicians. While Chinese medical services are advancing rapidly, inadequate professional competence of the rural physicians has always been the 'Achilles heel' of the current Chinese healthcare system.

Antibiotics overuse is one of the major global prescription problems. A previous investigation showed that the rate of antibiotic prescriptions among physicians in primary medical institutions in southwest China was as high as 50%. Although guidelines and refresher courses are regularly provided, the rate of antibiotic prescriptions among rural primary physicians has not declined. Rural physicians themselves agree that effective and continuous practical training with appropriate feedback on their antibiotic prescriptions would help to reduce their rate of antibiotic prescriptions.

In recent years, 'Paperless medical practice' has been expanded to rural China through a medical computing network. From March to August 2018, with the support of the local health authority, using a feedback system based on information technology (IT), a previous randomized controlled trial tested whether providing individual and confidential periodic feedback to practising physicians on their antibiotic prescription rate could reduce their prescription rate. The initial results are promising. The antibiotic prescription rate among 82 physicians in the intervention group significantly reduced from 32.6% to 19.4% (p <0.01) whereas among 81 physicians in the control group, the reduction was not so impressive (36.7% to 33.6%, p = 0.20).

This study aims to recruit more primary care institutions in Guizhou Province, and analyze the rationality of antibiotic prescriptions based on data stored in the health information system (HIS) of the primary hospitals. A clinical guideline of antibiotics for primary care setting will be recommended through the Delphi method. In this process, an idealized treatment plan will gradually evolve and improve the use of antibiotics through continuous learning and feedback of an artificial intelligence (AI) model based on graph neural networks (GNN). Then this study will integrate an early warning intervention into the HIS. Thus, the primary care physicians will receive real-time feedback and suggestions on the rationality of their antibiotics prescriptions, and will self-evaluate whether antibiotics are prescribed correctly. It is expected that the proportion of antibiotics used in primary medical institutions will be reduced through this automated early warning intervention system, as well as providing a viable reference for addressing antibiotic abuse problems. In the long term, the hope is that this intervention will be disseminated to other rural areas of China.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approved 27/12/2019, Institutional Review Board of Guizhou Medical University (Guian new area, Guizhou province, China; +86-851-88416078; 393043101@qq.com), ref: 2019(18)

Study design

Non-blinded cluster-randomized crossover controlled trial

Primary study design

Interventional

Study type(s)

Other

Health condition(s) or problem(s) studied

Antibiotic prescription for infectious diseases common in primary care institutions

Interventions

This is a non-blind cluster randomized crossover open controlled trial (multicentre) conducted in 100 hospitals randomly selected from the Health Information Center Database of Guizhou Provincial Health Commission. These hospitals were randomly allocated to two groups to receive the intervention for 3 months followed by no intervention for 3 months in a random sequence. This study will be conducted in primary medical institutions of Guizhou province, which is located in southwest China. Guizhou province has 1,399 primary hospitals, which are responsible for the healthcare of 35.8 million people.

The prescription information of outpatient physicians for 6 months will be classified with the International Classification of Diseases, 10th revision (ICD-10), and an analysis of the rationality of antibiotic prescriptions will be conducted. In this session, pharmacy and clinical experts will be invited to judge the reasonable use of antibiotics (unnecessary use, incorrect spectrum. escalated use of extend spectrum and combined use) for given diseases. Furthermore, the generalized estimation equation (GEE) method will be used to determine potential influencing factors of unreasonable use from the characteristics of physicians and patients. Secondly, based on the current guidelines for the clinical use of antibiotics in China and antibiotic prescription patterns in primary care setting, a more simplified expert consultation questionnaire for clinical use of antibiotics will be designed, applying the Delphi method for multiple rounds of argumentation to form the "Guidelines for the use of antibiotics in primary care settings". Thirdly, a deep graph neural network (GNN) model, which takes into account directed and edged information, will be constructed based on expert consensus of antibiotic prescription rationality results and influencing factors. The GNN model will output causal reasoning with result interpretation to form an intelligent antibiotic rationality evaluation and treatment suggestion. Fourthly, in the 100 primary hospitals, a random crossover feedback intervention will be used to implement an early warning intervention trial of unreasonable use of antibiotics. After 1-2 weeks of pilot study and commissioning, the randomized crossover trial (crossover cycle of 3 months) will be performed to test the effect of a feedback intervention on antibiotic prescriptions. Early warning feedback methods include:

- 1. Unreasonable use of antibiotics real-time warning. The alert reminder plugin will automatically retrieve the doctor's prescription data in the background and refer to the result of optimized depth map neural network learning model to provide real-time automatic warning reminders for unreasonable antibiotic prescriptions, and to give correct diagnosis and treatment advice.
- 2. Early warning of excessive antibiotic prescription. The module will contain an information popup window used in the hospital's HIS system to implant antibiotic prescriptions. After a 10-day cycle, the physicians will be confidentially informed of their ranking of antibiotic use rates, inappropriate use rates and related conditions in the form of automatic pop-up windows in the same outpatient department.

The intervention is based on existing health information systems (HIS). The feedback information will be developed and pretested under consultation with the information technology staff of by Guizhou Lianke Weixin Technology Co., Ltd. (LWTC) and the frontline physicians. The feedback intervention is updated every 10 days. The physicians can enter the HIS and click on a link to see the feedback information any time. Additionally, a pop-up window is

designed to automatically prompt them to check for the feedback information in every 10-day. Physicians assigned to the control group will not be given any such feedback. The feedback information includes two parts: The first is real-time warning on the unreasonable use of antibiotics. The second is warning of high antibiotic prescriptions rate. This part includes the top five diseases of patients seen by the physician over the previous 10 days, the start and stop time for the previous 10 days, as well as the number of prescriptions given during this period and department ranking, the antibiotic frequency and prescription rate of each antibiotic prescription, precautions and contraindications for antibiotics. The feedback information would disappear after the physician presses the escape button on the keyboard. Thus, the intervention maintains confidentiality for physicians who are also free to read the information or ignore it totally.

Intervention Type

Behavioural

Primary outcome(s)

The 10-day antibiotic prescription rate of the physicians, defined as the number of antibiotic prescriptions divided by the total number of prescriptions in each 10-day time period. A 'prescription' refers to each antibiotic drug. The antibiotic prescription rate is assessed using hospital pharmacy stock records during the 3-month intervention period.

Key secondary outcome(s))

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Completion date

31/12/2023

Eligibility

Key inclusion criteria

- 1. Primary care physicians who have worked at the township public hospital for at least 6 months
- 2. Prescribe an average of 100 prescriptions or more in 10 days
- 3. Have given their consent before being enrolled in the study

Participant type(s)

Health professional

Healthy volunteers allowed

No

Age group

Adult

Sex

Αll

Key exclusion criteria

- 1. Do not meet inclusion criteria
- 2. Do not have the right to prescribe
- 3. Refuse to accept intervention

Date of first enrolment 01/10/2020

Date of final enrolment 31/12/2021

Locations

Countries of recruitment China

Study participating centre Guizhou Medical University Guiyang China 550025

Sponsor information

Organisation

Guizhou Medical University

ROR

https://ror.org/01h0zpd94

Funder(s)

Funder type

Government

Funder Name

National Natural Science Foundation of China

Alternative Name(s)

Chinese National Science Foundation, Natural Science Foundation of China, National Science Foundation of China, NNSF of China, NSF of China, National Nature Science Foundation of China, Guójiā Zìrán Kēxué Jījīn Wěiyuánhuì, , NSFC, NNSF, NNSFC

Funding Body Type

Government organisation

Funding Body Subtype

National government

Location

China

Results and Publications

Individual participant data (IPD) sharing plan

The data sharing plans for the current study are unknown and will be made available at a later date.

IPD sharing plan summary

Data sharing statement to be made available at a later date

Study outputs

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|-------------------------------|-------------------------------|--------------|------------|----------------|-----------------|
| Results article | | 22/02/2023 | 27/02/2023 | Yes | No |
| Results article | | 06/01/2025 | 12/03/2025 | Yes | No |
| <u>Protocol article</u> | | 07/01/2022 | 10/01/2022 | Yes | No |
| Participant information sheet | Participant information sheet | 11/11/2025 | 11/11/2025 | No | Yes |