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Changing antibiotic prescribing practices in outpatient primary care settings in China: study protocol for a health information system-based cluster-randomised crossover controlled trial

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ABSTRACT

Background The overuse and abuse of antibiotics is a major risk factor for antibiotic resistance in primary care settings of China. In this study, the effectiveness of an automatically-presented, privacy-protecting, computer information technology (IT)-based antibiotic feedback intervention will be evaluated to determine whether it can reduce antibiotic prescribing rates and unreasonable prescribing behaviours.

Methods We will pilot and develop a cluster-randomised, open controlled, crossover, superiority trial. A total of 320 outpatient physicians in 6 counties of Guizhou province who met the standard will be randomly divided into intervention group and control group with a primary care hospital being the unit of cluster allocation. In the intervention group, the three components of the feedback intervention included: 1. Artificial intelligence (AI)-based real-time warnings of improper antibiotic use; 2. Pop-up windows of antibiotic prescription rate ranking; 3. Distribution of educational manuals. In the control group, no form of intervention will be provided. The trial will last for 6 months and will be divided into two phases of three months each. The two groups will crossover after 3 months. The primary outcome is the 10-day antibiotic prescription rate of physicians. The secondary outcome is the rational use of antibiotic prescriptions. The acceptability and feasibility of this feedback intervention study will be evaluated using both qualitative and quantitative assessment methods.

Discussion This study will overcome limitations of our previous study, which only focused on reducing antibiotic prescription rates. AI techniques and an educational intervention will be used in this study to effectively reduce antibiotic prescription rates and antibiotic irregularities. This study will also provide new ideas and approaches for further research in this area.

Trial registration: ISRCTN, ID: ISRCTN13817256. Registered on 11 January 2020

Keywords: antibiotic prescription rates; crossover trial; feedback intervention; primary care physicians; health information system; artificial intelligence

ATTACHMENTS

Figure 1 Overview of enrollment, intervention, and assessments of the cross-over design trial.png

Figure 2 Cross-over trial diagram.png

Figure 3 Example of unreasonable use of antibiotic warning pop-ups.png

Figure 4 Flow chart of the crossover trial.png

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KEYWORDS

antibiotic prescription rates, feedback intervention; primary care physicians, ;health information system, artificial intelligence

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IMAGE ATTRIBUTION

Figure 1 Overview of enrollment, intervention, and assessments of the cross-over design trial

Figure 2 Cross-over trial diagram

Figure 3 Example of unreasonable use of antibiotic warning pop-ups

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AI-based real-time warning pop-up windows of improper antibiotic use

- 1 Based on the HIS system of primary care institutions, the warning plug-in uses graph neural network technology to automatically access the prescription data in the background. It will compare each prescription with the big data and DMNN modeling results, determine whether the antibiotic prescription (including type, dosage, and course of treatment) is reasonable to be used in the consultation service and will provide a real-time automatic warning alert for unreasonable antibiotic prescription. Once a physician prescribes an unreasonable antibiotic, a pop-up window will automatically appear in the lower right corner of the screen to alert the physician that the prescription is unreasonable and indicate the type of unreasonable use of antibiotics. The form of pop-up window is shown in **Figure 3**. The pop-up window will disappear if the physician clicks on it. It will also automatically disappear after 5 minutes. The duration of the pop-up window will be recorded automatically by system. Extreme durations will be noticed (i.e., 1 second or 5 minutes). According to previous research, we define unreasonable prescription of antibiotics with the following indicators: 1. Incorrect or unnecessary use: for example, a physician gives antibiotics for which there is no clear indication; 2. Incorrect antibacterial spectrum: for example, prescribing aminoglycoside drugs for gram-positive bacteria; 3. Combined antibiotic use: administration of more than one injectable or oral system antibiotic at a time without any indication, for example, amoxicillin capsule and ceftazidime injection in combination.

Pop-up windows of antibiotic prescription rate ranking

- 2 This reminder system is a plug-in developed in a previous study. [We will](#) implement pop-up windows of antibiotic prescription use in the HIS system. The system will appear on the physician's screen in the form of an automatic pop-up window every 10 days, informing them of their ranking in terms of their antibiotics prescription rate within the same outpatient department, actual antibiotic prescription rate and related information. The information seen by each physician will be confidential. The physicians have the freedom to read this feedback message or not. When the

physician logs into the HIS, a pop-up window or link will appear on the computer screen, prompting him or her to view the message. If a physician presses the ESC button, it will disappear. All the on-screen procedures, including click rate and the time of the message, will be recorded automatically.

Based on a previous study involving 16 hospitals in the early stage [13], we will invite 48 medical experts to conduct two rounds of demonstration using the Delphi method. Two guidance proposals with expert consensus will be formed as detailed in the section below.

Distribution of educational manuals

- 3 The educational manuals include 2 parts: "**Instruction and Recommendations for Outpatient Clinical Use of Antibiotics in Primary Care Institutions**" and "**Instruction and Recommendations for Diagnosis of Common Infectious Diseases in Outpatients of Primary Care Institutions**". We have consolidated them into a manual for distribution to outpatient physicians in primary care institutions.

The first part is the recommendation for the rational use of antibiotics, and the second part is the diagnostic guidance of the symptoms, signs and auxiliary examinations for common infectious diseases such as digestive system, respiratory system, and urinary system.

In the first part, we divided the criteria for rationality of antibiotics into four categories: 1. **Suitable**: preferred antibiotic; 2. **Optional**: the antibiotic can be used or substituted; 3. **Wrong-spectrum**: the antibacterial spectrum is not used correctly; 4. **No use**: In the second part, based on the proportion of different diagnostic criteria and the weight, we set the most valuable diagnostic criteria as "4", and the standard for low diagnostic value was set to "1".

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