

# Effect of a knowledge-based and skills-based programme for physicians on risk of sexually transmitted reinfections among high-risk patients in China: a cluster randomised trial



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## Summary

**Background** China is experiencing growing epidemics of HIV and sexually transmitted infections (STIs). Programmes to train physicians in China on HIV and STI knowledge, diagnosis, treatment, and risk reduction counselling can potentially reduce HIV and STI risk among high-risk patients. We aimed to assess a knowledge-based and skills-based programme for physicians in China to reduce patients' STI risk.

**Methods** In this cluster randomised trial, we block randomised counties in two provinces in eastern China to intervention or control groups. In the intervention group, physicians from county general hospitals participated in a structured HIV and STI training programme and received opportunities to enhance their clinical and counselling skills, whereas in the control group, physicians from county hospitals received the training after the intervention group completed final assessments. We recruited STI patients from physicians in both groups, treated baseline gonorrhoea and chlamydia infections, and assessed 9-month gonorrhoea and chlamydia reinfection as the primary outcome. Statistical comparisons between intervention and delayed-control patients used multilevel analyses to account for cluster effects at county and physician levels. Analysis was by intention to treat. This study is registered with ClinicalTrials.gov, NCT00644150.

**Findings** Between April 1, 2007, and Sept 1, 2008, 51 counties were randomly assigned; 27 to receive immediate intervention and 24 to receive delayed intervention. 249 physicians from the 51 county-level hospitals were enrolled, 121 physicians in the intervention group and 128 in the control group. From these physicians, we enrolled 633 and 491 patients, respectively, of whom 508 (80%) and 402 (82%) were available for reassessment at 9 months. Intervention patients at follow-up had significantly lower odds of combined gonorrhoea or chlamydia reinfection than did control patients (58/508 [11%] vs 123/402 [31%]; adjusted odds ratio 0.62 [95% CI 0.46–0.84]).

**Interpretation** Integrating HIV and STI training into medical education in China could be an effective strategy to reduce the country's growing HIV risk and STI epidemics.

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## Introduction

HIV in China has evolved from an epidemic mainly associated with contaminated red-cell infusion after blood donation and injection drug use to an epidemic increasingly characterised by sexual transmission.<sup>1–4</sup> Although early HIV cases in China were geographically concentrated, during the previous decade the epidemic has spread throughout all of China's 31 provinces, autonomous regions, and municipalities (excluding Hong Kong, Macau, and Taiwan). The Chinese Government has responded to the growing epidemic with assertive public health policies, such as the 2006 AIDS Prevention and Control Regulations, which include initiatives to provide free antiretroviral treatment and HIV testing, support syringe distribution and drug treatment programmes, promote condom use, and reduce AIDS stigma.<sup>5–8</sup>

Implementation of China's national AIDS policies relies on physicians to deliver prevention and treatment

of HIV and sexually transmitted infections (STIs) in routine practice, including HIV testing, symptom diagnosis, treatment recommendations, and risk reduction counselling.<sup>9–11</sup> However, there are serious gaps in physicians' knowledge and skills in diagnosing and treating HIV and STIs.<sup>12–17</sup> Interventions to increase the ability of Chinese physicians to counsel and to treat patients at risk of HIV and STIs have shown improvements in physicians' HIV/STI knowledge and clinical skills at follow-up.<sup>18–20</sup> These studies have not, however, been tested using controlled designs or corroborated with patient-level outcomes. A recent randomised trial done in China showed the efficacy of an intervention to reduce physicians' stigmatising attitudes and behaviours towards people living with HIV,<sup>21</sup> suggesting that HIV/AIDS interventions targeting physicians can improve interactions with patients.

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We assessed a knowledge and skills-based programme for physicians in China to reduce patients' HIV and STI risk. Physicians were trained in HIV and STI transmission, diagnosis, treatment, and patient-centred risk reduction counselling. The programme, entitled *Ai Shi Zi* (meaning "AIDS Plus" in Mandarin) views physicians as important agents of change to reduce HIV and STI transmission and risk behaviours among high-risk patients in China. The training curriculum is based on social learning theory, which emphasises interactive learning, modelling of behavioural skills, self-efficacy, goal setting, and knowledge as determinants of behaviour change.<sup>22</sup> We conducted the intervention in Anhui and Jiangsu, geographically contiguous provinces in eastern China. Both provinces have expanding HIV and STI epidemics, with unprotected sexual behaviour as a primary risk factor of transmission.<sup>23–25</sup> Our primary hypothesis was a reduction in STI reinfection (gonorrhoea and chlamydia) among patients of physicians who received the intervention compared with patients of physicians in a control group who received the intervention after a delay. We also hypothesised improvements in knowledge about HIV and STI transmission, attitudes, satisfaction with physicians, and condom use among patients in the intervention group compared with those in the control group.

## Methods

### Study design and participants

In this cluster-randomised trial, counties were assigned to intervention or control groups. Cluster randomisation was used to account for interaction, and potential contamination, among physicians within hospital settings. We contacted administrators of county-level general hospitals in Anhui and Jiangsu provinces to inform them about the study and to solicit their interest in allowing hospital physicians to participate. There was one general hospital per county. We randomly assigned counties to either the intervention group, in which groups of county-level general hospital physicians received the training immediately, or to the control group in which physicians received the training after physicians in the intervention counties completed the study; a delayed control group was deemed appropriate to ensure that all physicians enrolled in the study had access to the information provided in the training. The Ethical Review Boards of Anhui Medical University and UCLA approved the study, and we obtained written informed consent from all participants.

To recruit physicians, we enlisted the provincial health bureaus to issue a formal invitation to participating county general hospitals. The announcement specified the purposes of the project, physician eligibility criteria, the fact that participation was entirely voluntary, and that some counties would receive training immediately and that training for other counties would be delayed. Hospitals were not paid to participate. County-level physicians were eligible if they were employed at a

county-level general hospital; specialised in STIs, obstetrics, gynaecology, or HIV care; had a minimum 3 years of clinical experience; had ever treated patients with HIV or STIs; and were willing to complete the intervention training programme. All costs associated with transportation and lodging were paid for, but participating physicians were not given financial compensation for taking part in the intervention.

Research assistants recruited patients from waiting rooms of participating physicians. Between three and ten patients were recruited from each physician. Patients were informed about the study and those who expressed interest were asked to provide a urine sample to test for gonorrhoea and chlamydia and to return to the county hospital in 2 weeks for test results. All patients who tested positive received treatment free of charge regardless of enrolment, and those expressing continued interest were referred to a study intake coordinator. Patients were eligible if they tested baseline-positive for gonorrhoea or chlamydia, received treatment, were at least 18 years old, received patient services from a physician who participated in the training programme, and were not planning to relocate in the next 9 months.

Patients in the intervention group were recruited after their physicians had completed the final 9-month training assessment. Patients in the control group were recruited and completed their 9-month follow-up before their physicians started the training. Based on this design, patient group differences at 9-months' follow-up would reflect comparative effects between patients of physicians who received the training immediately (intervention group) versus patients of physicians who had not yet received the training (control group).

### Randomisation and masking

To minimise uneven distribution of STI prevalence between study groups, counties were rank-ordered within province by HIV and STI cases and stratified into four blocks, and we randomised counties within each block to immediate intervention or control. Randomisation was conducted by the project data coordinator based in Hefei, the capital of Anhui province, with a computer-generated randomisation sequence. Allocation of county to treatment group remained concealed until site investigators were ready to implement the training.

### Procedures

The *Ai Shi Zi* curriculum was developed by Chinese and international collaborators based on comprehensive literature reviews and consultation activities with local and national experts, in both the USA and China. The consultation meetings included discussions about Chinese national guidelines for HIV and STI treatment and infectious disease control, behavioural risk reduction strategies, and Chinese cultural issues that can affect communication with patients. The curriculum took into consideration the Chinese medical system by

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