

FEATURE ARTICLE

Unified-Planning, Graded-Administration, and Centralized-Controlling: A Management Modality for Treating Acquired Immune Deficiency Syndrome with Chinese Medicine in Henan Province of China*

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ABSTRACT Henan Province in China has a major epidemic of human immunodeficiency virus/acquired immune deficiency syndrome (HIV/AIDS). Chinese medicine (CM) has been used throughout the last decade, and a management modality was developed, which can be described by unified-planning, graded-administration, and centralized-controlling (UGC). The UGC modality has one primary concept (patient-centered medicine from CM theory), four basic foundations (classifying administrative region, characteristics of CM on disease treatment, health resource conditions, and distribution of patients living with HIV), six important relationships (the "three uniformities and three combinations," and the six relationships therein guide the treatment of AIDS with CM), and four key sections (management, operation, records, and evaluation). In this article, the authors introduce the UGC modality, which could be beneficial to developing countries or resource-limited areas for the management of chronic infectious disease.

KEYWORDS acquired immune deficiency syndrome, Chinese medicine, complementary and alternative medicine, antiretroviral therapy

Acquired immune deficiency syndrome (AIDS) is a communicable disease which was recognized in the early 1980s to be caused by infection with the human immunodeficiency virus (HIV).⁽¹⁾ HIV has a strong infectivity and has spread worldwide in the last 30 years. There were more than 35 million people living with HIV (PLWH) worldwide by the end of 2012.⁽²⁾ Millions of people have died from AIDS, mostly in developing countries, and this epidemic will continue into the foreseeable future. While the therapy, prevention, and control of AIDS has made progress, there are still issues such as adverse effects from antiviral drugs, drug resistance, longevity of patients, and shortage of healthcare access.

Before 2000 year, most PLWH lived in rural areas where access to medicine was limited or poor in China. Some people mistakenly regarded AIDS disease as a "dirty disease" or "love sick". Therefore, the prevention, control, and therapy of AIDS was difficult. Under these circumstances, the Chinese government placed great importance on

AIDS prevention and treatment work. For example, the "Four Free and One Care" policy was initiated in December 2003, which included free antiretroviral drugs, free prevention of mother-to-child transmission,

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free voluntary counseling and testing, free schooling for children orphaned by AIDS, and care to PLWH.

In 2004 year, the State Administration of Traditional Chinese Medicine of China carried out a trial program for HIV/AIDS treatment with CM. From October 1, 2004 to October 31, 2005, 9 counties in Henan Province were enrolled by the Health Authority of Henan Province and the local governments. A total of 1,732 volunteers living with clustered distributions joined in the project. From study initiation, managers and Chinese medicine practitioners (CMPs) explored and optimized a comprehensive management modality for the treatment of AIDS with CM. In this article, we will introduce this management method and its efficiency on the treatment of AIDS with CM, which was used successfully for almost 10 years in Henan Province, China.

Reasons for the Use of CM to Treat HIV/AIDS in Henan

At the beginning of the 21st century, research on HIV/AIDS with CM was still preliminary, and the role of CM in HIV/AIDS treatment was not widely recognized or accepted. Therefore, initiating the use of CM to treat AIDS was uncertain. However, CM was used to treat HIV/AIDS in Henan for a few important reasons.

The features of the HIV epidemic in Henan Province of China prompted the usage of CM for treatment because of the disease distribution. Henan is the most populous province and is a major agricultural producer in the middle of China. In many rural areas of Henan Province during the 1990s, particularly the east, south, and central regions of Henan like Kaifeng, Shangqiu, Zhumadian, Zhoukou and Nanyang, some poor peasants were infected with HIV through participation in paid blood donation and illegal blood or plasma collection.^(3,4) Moreover, PLWH were found in focally concentrated distributions, especially in health resources limited rural areas, and some of them with lower education level. Therefore, AIDS significantly impacts local economies and social stability, and causes adverse effects on the marriages, incomes, and social relationships of patients.

CM is also used because it is necessary to offer other therapies aside from combination of antiretroviral therapy (cART). Henan is one of the main origins of

CM culture and has a long history of CM culture and famous CMPs. In addition to the cultural aspects, CM is useful in a populous area with limited health care resources. In some of areas of Henan, doctors had used CM to treat some AIDS related complications before the HIV epidemic was recognized, especially in the mid to late 20th century. Since 2000 year, more and more PLWH need to initiate free cART, but the treatment strategies were limited. And at the same time, some patients could not endure the side effects from cART, some were not suitable to initiate cART due to underlying conditions, some questioned the effectiveness of cART, and some refused to initiate cART. Therefore, it was necessary to offer some alternative therapies other than cART.

Government support was an important guarantee for the use of CM in HIV/AIDS treatment. In August 2004, a trial program in five provinces, including Henan Province, was initiated by the State Administration of Traditional Chinese Medicine as a part of national AIDS relief.⁽⁵⁾ The trial program provided patients with CM free of charge after the patient voluntarily chose to participate in the project and signed the informed consent. The project helped health practitioners understand effective management methods of HIV/AIDS using CM in rural regions.

In China, CM clinical effectiveness is often used to indicate effectiveness of treatments. In fact, CM may be able to cure and successfully control some infections, such as severe acute respiratory syndromes (SARS),⁽⁶⁾ influenza A virus subtype H1N1,⁽⁷⁾ epidemic encephalitis B,⁽⁸⁾ and hepatitis.⁽⁹⁾ According to CM theory, AIDS is an infectious disease caused by the invasion of pathogens, which leads to imbalanced of yin and yang, and disharmony of internal pathophysiological function and the external environment. Therefore, although no empirical evidences had shown that CM was effective in the treatment of HIV/AIDS before 2014 year, the initiation of CM for AIDS treatment had a theoretical basis and was supported by the use of CM for other infectious diseases.

Overall, the initiation of treating AIDS with CM was necessary for PLWH in Henan. The trial established management modalities for HIV/AIDS using CM, which are described as unified-planning, graded-

administration, and centralized-controlling (UGC).

Contents of UGC

UGC is a system that includes: one primary concept, four basic foundations, six important relationships, and four key sections.

One Primary Concept

CM is clinical medicine, with a theory system that is rooted in clinical application. CMPs focus on the clinical demands of the patients, and they regard AIDS as the aggregate of abnormal symptoms, signs, pulse, and tongue. The abnormal symptoms and signs are the reasons or manifestations of lower quality of life (QOL), complications, opportunistic infections, side-effects of cART, lower CD4⁺ T cell counts, or higher levels of plasma HIV loads. CM emphasizes the comprehensive affections and subjective experiences from the disorder of the pathological factors. Therefore, when CMPs give treatments to their patients, they often focus on not only adjusting the balance of yin and yang, but also harmonizing internal pathophysiological function and the external environment.

In order to offer the best CM treatments for PLWH, the concept of patient centered-medicine was introduced into the UGC. This concept largely reflects that the purpose of management is to provide quality services and systemic and individual treatment to the patients, which is one of the guiding principles and features of CM, but also to evaluate the effects of AIDS treatment with CM based on patient-reported outcomes (e.g. symptoms and signs and QOL) and laboratory indices (e.g. CD4⁺ T counts, and plasma HIV loads) so as to get comprehensive results.

Four Basic Foundations

AIDS is a complex infectious disease in which the immune system is gradually destroyed after HIV infection. The immunosuppression makes the body vulnerable to a variety of life-threatening cancers and opportunistic infections. Although mortality and morbidity have been reduced by cART and advanced treatments, some non-AIDS complications become issues for patients, which add additional cost to treatment. The allocation of additional medical resources is the responsibility of the government, especially in developing or resource limited regions. Further, only the government can

effectively allocate resources.

In China, CM is a mainstream medical system, and plays an important role in people's health. During the different stages of HIV infection, various clinical diseases and uncomfortable signs and symptoms that are related to the weakened immune system inevitably occur, even with patients who initiate cART. Therefore, it is necessary to offer frequent medical inventions. Patients might get more benefits from CM when CMPs offer them assistance under guidance of CM theory and treatment based on syndrome differentiation.

It was apt to centralize CM management based on the classification of administrative region, CM characters in disease treatment, health resource conditions, and focal distribution of PLWH, which are considered the four basic foundations.

Six Important Relationships

In 2004 year, the guiding principle "three uniformities and three combinations" was created and distributed by the Administration of Traditional Chinese Medicine of Henan Province, China. The "three uniformities" represent unified organization, unified treatment strategy, and unified observation indices; "three combinations" represent clinical treatment combined with scientific research, fixed prescriptions combined with Chinese herbal treatment based on syndrome differentiation, and CM therapy combined with cART. The "three uniformities and three combinations," and the six relationships therein, guided CMP treatment of AIDS with CM.

Four Key Sections

The performance of UGC consists of four key sections, including management, operation, records, and evaluation. Management is made up of different grades of management institutions and personnel, and its duty is to draft rules and regulations, organize project implementations, and contact the other three sections. In the operation section, there are two parts: the working mode of CMPs, manufacture and distribution of the fixed prescription, [i.e. Yiaikang Capsule (益艾康胶囊), the main ingredients include *Radix Astragalus*, *Ginseng*, *Tuckahoe*, *Ligusticum wallichii*, *Radix Paeoniae Alba*, and *Scutellariae*, etc.]. The record section is composed of all related documents including meeting records, prescriptions,

and case reports. The evaluation section includes evaluation instruments, process recordings, and outcomes.

UGC has patient-centered medicine as its primary concept. The modality includes five foundations: administrative region management, CM characteristics on disease treatment, health resource conditions, and distribution of PLWH. The "three uniformities and three combinations" are the guiding principles for treatment, and the four key sections include the four parts important to the management and treatment of AIDS with CM (management, operation, records, and evaluation).

Operation of the UGC

In the operation of the UGC, there are three important sections: manage and control, guarantee, and implement.

Section 1: Manage and Control

The Provincial Project Core Leadership Committee (PPCLC), the Expert Consultative Committee (ECC), and the Quality Control Inquiry Committee (QCIC) were established to manage and control the UGC. The ECC consults and suggests improvements for the performance of the project. The QCIC was founded to monitor and evaluate the project. The three organizations often work together to discuss and resolve relative issues that have

happened, or will happen, in the project.

Section 2: Guarantee

To conquer the difficulties of limited health resources and coordinate the project, the Henan Provincial Administration Office of HIV/AIDS Treatment with Traditional Chinese Medicine and Provincial Expert Committee of Traditional Chinese Medicine (PECTCM) and Information Center were established. Further, a drug manufacturer and laboratory center were selected. All units were given major duties by the PPCLC. The Henan Provincial Administration Office of HIV/AIDS Treatment with Traditional Chinese Medicine was meant to establish relationships with the other centers and offices. The major duties for different units are showed in Figure 1.

Section 3: Implement

In Henan, most PLWH live in poorer regions with a clustered distribution. The government aims to offer patients graded treatment and manage them residentially. In other words, the government should provide services for the patients to satisfy their medical needs as much as possible in their residential districts. Therefore, section 3 is regarded as the implementation. In this section, the health bureau of the city (county) level has the responsibility of implementing and harmonizing the relationship between patients and CMPs, and interpatient relationships. The other responsibility is for CMPs from

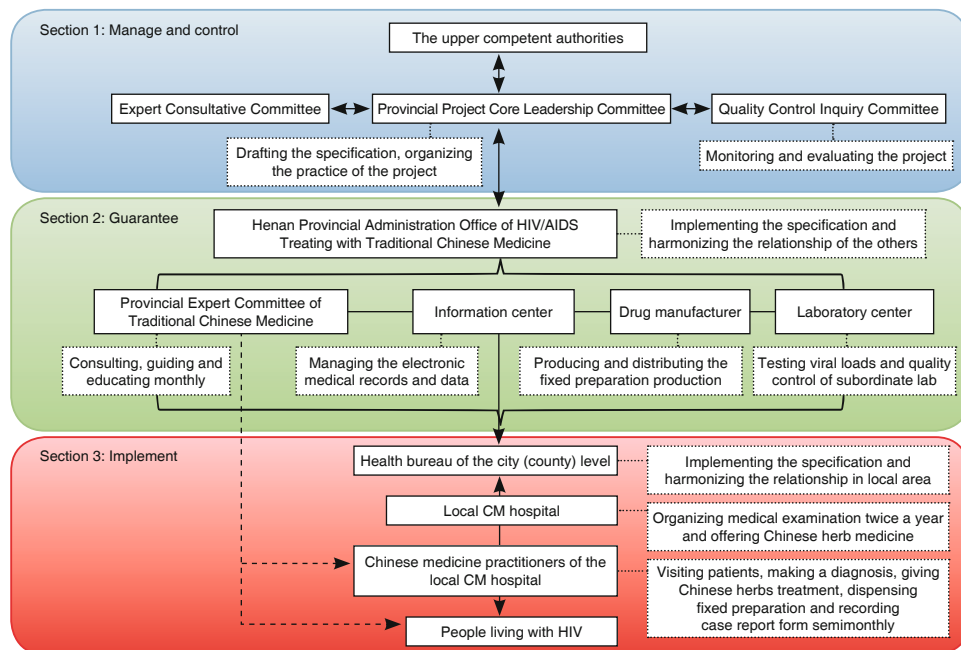


Figure 1. UGC Management Operation Pattern

local CM hospitals to visit patients, make a diagnosis, give patient additional Chinese herbal treatment according to his or her current complaint or symptoms and signs based on syndrome differentiation, dispense fixed preparations, and record case report forms semimonthly, under the guidance of the PECTCM. In the UGC, the service object is the PLWH, and all volunteers must agree to receive CM treatment, share their experiences, and sign a consent form. Moreover, anyone has a right to give up treatment and remove consent at any time.

Accomplishments of the UGC

The UGC has been in operation for almost 10 years in Henan and has several accomplishments. The scale of HIV/AIDS treatment with CM is constantly expanding. Since 2004, 1,732 AIDS patients were enrolled in the CM project, and there are more than 4,500 patients in the control projects by the end of 2014 year. Presently, Henan has the most AIDS patients that are treated with CM among 19 provinces, which suggests that the management is efficient.

Some of the important roles of CM in the treatment of AIDS have been shown by CMPs in the project, such as reducing or stabilizing plasma HIV viral loads,⁽¹⁰⁾ increasing CD4⁺ T cell counts,⁽¹¹⁾ ameliorating symptoms and reducing opportunistic infections,⁽¹²⁾ improving QOL,⁽¹³⁾ counteracting the effects of cART,⁽¹⁴⁾ and benefiting the long-term survival of PLWH.⁽¹⁵⁾

In the last decade, some state key projects including discipline, lab, and clinical research bases have organized in the First Affiliated Hospital of Henan University of Traditional Chinese Medicine in addition to the HIV/AIDS pilot projects. More importantly, some new scientific results have been attained with the help of those key projects, such as developing the guidelines and routine for treatment of AIDS with CM, the creation of four hospital preparations, the publication of influential research articles, and the establishment of a network of AIDS researchers.⁽¹⁶⁾

CM treatment on AIDS in Henan has been widely publicized. Some experts were invited to attend and talk at international conferences, and many international AIDS specialists joined and collaborated with the projects in Henan. Some research articles were cited by Science Citation Index (SCI),^(17,18) or

Engineering Index (EI).⁽¹⁹⁾ The domestic mainstream media also extensively reported Henan CM work on AIDS. Moreover, Henan CM projects were awarded by the State Administration of Traditional Chinese Medicine and recognized by other provinces.

In brief, the UGC modality has been operating for almost 10 years in Henan. The UGC has several accomplishments including: many HIV/AIDS patients have been treated with CM, effective roles of CM in AIDS treatment have been found in practice, CM development has been promoted, scientific research has been performed, and a number of research articles have been published.

Prospects of the UGC

In the past decade, some of clinical researches had showed that CM have the positive roles on treating AIDS, as it had been reported that CM can be used to alleviate HIV related symptoms and signs, improve QOL, benefit for long-term survival, counteract against adverse side effects of antiviral drugs, and promote immune reconstitution, etc. Meanwhile, a management modality of HIV/AIDS with CM was formed in Henan, and is summarized as UGC. The modality includes: one primary concept, four basic foundations, six important relationships, and four key sections. The primary concept is patient-centered medicine, which is derived from CM theory. The four foundations include classifying administrative region management, the characteristics of CM on disease treatment, health resource conditions, and the distribution of PLWH. The "three uniformities and three combinations" are the guiding principles of CM treatment, and the four key segments include: management, operation, records, and evaluation. The UGC is an effective management modality for AIDS treatment with CM in China, which might be useful as a reference for other developing countries or resource-limited areas.

Looking forward, we believe this kind of management modality will continue to play a key role for HIV/AIDS treatment with CM in Henan, and at the same time, more researches will be carried out to evaluate this management modality such as with health economic method.

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Conflict of Interest

No competing financial interests exist.

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