

Expert consensus on the positioning of the “Three-in-One” Registration and Evaluation Evidence System and the value of orientation of the “personal experience”

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Received: March 10, 2025; Revised: March 18, 2025; Accepted: April 25, 2025

ABSTRACT

Traditional Chinese Medicine (TCM), as a treasure of the Chinese nation, plays a significant role in maintaining public health. In 2019, the Central Committee of the Communist Party of China and the State Council proposed for the first time the establishment of a TCM registration and evaluation evidence system that integrates TCM theory, personal experience and clinical trials (referred to as the “Three-in-One” System) to promote the inheritance and innovation of TCM. Subsequently, the National Medical Products Administration issued several guiding principles to advance the improvement and implementation of this system. Owing to the complexity of its implementation, there are still differing understandings within the TCM industry regarding the positioning of the “Three-in-One” Registration and Evaluation Evidence System, as well as the connotation and value orientation of the “personal experience.” To address this, Academician Qi Wang, President of the TCM Association, China International Exchange and Promotion Association for Medical and Healthcare and TCM master, led a group of academicians, TCM masters, TCM pharmacology experts and clinical TCM experts to convene a “Seminar on Promoting the Implementation of the ‘Three-in-One’ Registration and Evaluation Evidence System for Chinese Medicinals.” Through extensive discussions, an expert consensus was formed, clarifying the different roles of the TCM theory, “personal experience” and clinical trials within the system. It was further emphasized that the “personal experience” is the core of this system, and its data should be derived from clinical practice scenarios. In the future, the improvement of this system will require collaborative efforts across multiple fields to promote the high-quality development of the Chinese medicinal industry.

KEYWORDS

“Three-in-One”, personal experience, clinical trials, expert consensus

CITE THIS ARTICLE

Wang Q, Wang YY, Xiao W, et al. Expert consensus on the positioning of the “Three-in-One” Registration and Evaluation Evidence System and the value of orientation of the “personal experience”. Evidence-Based Chinese Medicine and Technology Assessment, 2025, 1: 9570006. <https://doi.org/10.26599/eCMTA.2025.9570006>

1. Introduction

Traditional Chinese medicine (TCM) is a great treasure of the Chinese

nation, which has been playing a crucial role in maintaining public health and preventing and treating serious diseases. Over the years, TCM has been highly valued by the Central Committee of the Communist Party of China, the State Council, and the inheritance, innovation and development of TCM has become a national strategy. General Secretary Xi Jinping emphasizes the need to “research and produce more ‘Chinese medicinals’ that are more suitable for the genetic inheritance and physical characteristics of the Chinese people.” His instructions endow TCM inheritance and innovation with a more clear and specific new mission.

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To further promote the development of TCM and maintain public health, in October 2019, the “Central Committee of the Communist Party of China and State Council’s Opinions on Promoting the Inheritance and Innovation of Traditional Chinese Medicine” first proposed to “accelerate the establishment of a Chinese medicinal registration and evaluation evidence system that integrates the TCM theory, personal experience and clinical trials for the registration and evaluation of Chinese medicinals on the basis of combination of the TCM theory, personal experience and clinical trials.”¹ In December 2020, the National Medical Products Administration once again emphasized in its “Implementation Opinions on Promoting the Inheritance and Innovation of Traditional Chinese Medicinals,” according to the characteristics of Chinese medicinal research and development laws and practice, to construct an evaluation evidence system based on combination of the TCM theory, personal experience and clinical trials.² In February 2023, the National Medical Products Administration released the “Special Provisions on the Registration Management of Chinese Medicinals” and its Center for Drug Evaluation released a series of guidance principles for the research and development of new Chinese medicinals (including the “Technical Guidelines for Pharmaceutical Research of New Chinese Medicinal Compound Preparations Based on Personal Experience (Trial),” the “Clinical Research and Development Guidelines for New Chinese Medicinal Preparations Based on the Personal Experience (Trial),” the “Guidelines for Communication Based on the Three-in-One Registration and Evaluation Evidence System (Trial),” the “Technical Guidelines for Information Collection and Compilation of Personal Experience in the Research and Development of New Chinese Medicinal Preparations” (Draft for Solicitation of Comments).” Actively promoting the construction of the “Three-in-One” system will bring about a major historical change in the research and development of Chinese medicinals.

The publication of these guidelines has primarily established the “Three-in-One” Registration and Evaluation Evidence System for Chinese medicinals, which fully takes into account the unique clinical practice characteristics of TCM and its research and development law, and it clarifies the value and position of the personal experience in the research of new Chinese medicinals. It also reflects the basic characteristics and the research and development path of Chinese medicinals that “originates from clinical practice and returns to clinical practice.” The evaluation research mode of new Chinese medicinals has shifted from the chemical drug mode of “mice nodding” back to respecting clinical efficacy, i.e., the clinical research paradigm of “human nodding”. It conforms to the TCM characteristics.³ Under the guidance of the “Three-in-One” system, as of February 24, 2025, 14 classical formula preparations of Category 3.1 and 6 new Chinese medicinals of Category 3.2 have been approved for marketing, further stimulating the vitality of the TCM industry.⁴ The China Association of Chinese Medicine fully affirmed the important role of the “Three-in-One” Registration and Evaluation Evidence System in the TCM cause, especially in the field of new Chinese medicinals, stated in the “Top 10 Academic Progress in Traditional Chinese Medicine in 2022”.⁵

Since this is a pioneering work, the current “Three-in-One” Registration and Evaluation Evidence System is still in the process of further improvement. Owing to the complexity of the review work for Chinese medicinals, there are still some controversies in the practical operation of the Chinese medicine industry. In particular, there is still great confusion about the positioning of the system, as well as the connotation and value orientation of the “personal experience”. To address this, Academician Qi Wang, President of the China Association of Traditional Chinese Medicine, China International Exchange & Promotion Association for Healthcare, led a group of academicians, TCM masters, TCM pharmacology experts and clinical TCM experts to conduct a full discussion on the positioning of the “Three-in-One” Registration and Evaluation Evidence System and the value orientation of the “personal experience”. The finally reached consensus emphasizes that the “personal experience” is the core of the system, and the acquisition of the “personal experience” data should be positioned in clinical practice scenarios.

2. The formation and positioning of the “Three-in-One” Registration and Evaluation Evidence System

The “Three-in-One” Registration and Evaluation Evidence System is a review mode that combines TCM theory, “personal experience” and clinical trials. Compared with the former registration and evaluation system, both focus on ensuring the safety, effectiveness, and controllability of the new Chinese medicinals with the important goal of ensuring the safety of public medication. They both emphasize the pivotal role of clinical trials in verifying the effectiveness of medicinals. However, the “Three-in-One” Registration and Evaluation Evidence System, while retaining clinical trials, adds TCM theory and “personal experience” as the important review bases, emphasizing and respecting the rules of TCM clinical practice, that breaks the pattern of long-term use of chemical drug review standards saddled on Chinese medicinals.

TCM theory is the theoretical basis of the “Three-in-One” Registration and Evaluation Evidence System, and is an important basis for the review of new Chinese medicinals. The acquisition of the “personal experience” data and the implementation of clinical trials cannot be separated from the guidance of TCM theory. Specifically, the “personal experience” is based on TCM “theory, strategies, formulas and medicinal substances”, which is on the basis of understanding of the mechanism of disease, treatment principles and the selection of safe and effective medicinals according to TCM theory. Clinical trials can be randomized, double-blind, controlled trials, or cohort studies, case-control studies, etc., but they need to be rationally designed under the guidance of TCM theory, incorporating relevant disease patterns, symptoms and efficacy indicators. They are placed in a prominent position to avoid unilaterally adopting efficacy indicators from the perspective of Western medicine to replace TCM-related indicators.

Adoption of the “personal experience” is the result of practicing TCM theory. Its data include important factors such as the new medicinal composition, clinical positioning, targeted population, dosage, treatment course and safety of them, providing a research basis for the design of subsequent clinical trials and playing a connecting role in the “Three-in-One” Registration and Evaluation evidence System. Therefore, “the use of the “personal experience” is the core link of the system, and it is the characteristic and advantage of the new Chinese medicinal research and development work.

The “Three-in-One” Registration and Evaluation Evidence System is an important embodiment of the new Chinese medicinal development concept marked by “patient-centered and oriented by clinical value” in the research of new Chinese medicinals.^{6,7} The “Three-in-One” system fully taps into the potential of TCM clinical practice, promotes the conversion of significantly effective “personal experience” into new Chinese medicinals, and meets unmet clinical needs. The establishment of this system is in line with the clinical characteristics of TCM, greatly improves the efficiency of the new Chinese medicinal development cause and promotes the inheritance and innovation of TCM. It means a new era starts for new Chinese medicinals registered and evaluated with a new feature mode.

3. The connotation and value orientation of the “personal experience” in the “Three-in-One” Registration and Evaluation Evidence System

The “personal experience” in the system refers to the experience accumulated in long-term clinical practice to satisfy clinical needs and the summary of the clinical experience which has regularity, effectiveness and repeatability. Finally the effective treatment scheme or the therapeutic medicinal is completed.⁸ As the key element of the system the “personal experience” should not only reflect the clinical value, but also has some scientific rigor to meet the requirements of authenticity, traceability of data in new medicinal evaluation, and accuracy of efficacy evaluation conclusions. It should not be simply equated with the clinical practice experience summarized for the formation of clinical diagnosis and treatment plans. On the basis of whether a fixed TCM prescription or Chinese herbal compound preparation is formulated, the per-

sonal experience can be roughly divided into two stages.

The first stage is the prescription formation stage, which refers to a practitioner using a certain medicinal (often in a decoction with modifications) to treat a certain disease or symptoms or disease pattern with good efficacy in long clinical practice. By using a retrospective study method to summarize and analyze the data of this clinical practice, a fixed prescription is formed, and the main potency, indications, targeted population, common usage and course of treatment are preliminarily clear. Retrospective studies in the prescription formation stage need to ensure the integrity and traceability of the data to avoid bias in the results due to data missing.⁹

The second stage is the preliminary validation stage, which means that on the basis of the prescription formation stage, through reasonable design, targeted screening and verification of the essential elements of the new Chinese medicinal, the potency, indications, target population, dosage and course of treatment of the therapeutic prescription (agreed prescription, fixed preparation) are verified. The data obtained at this stage are regarded as an important consideration in the process of evaluation by using the system, and the research quality and evidence level will determine the subsequent research and development path. Therefore, the acquisition of the “personal experience” at this stage needs to be designed according to the research purpose to ensure compliance and rational collection of data for scientific analysis. At this stage, it is necessary to further clarify the optimal range of indications for the new preparation, the most important therapeutic effect, the people group who are mostly benefited, the optimal dosage and course of treatment. In addition it is necessary to classify and describe in more detail the disease patterns corresponding to its indications, in order to improve the consistency of the new Chinese medicinal in clinical application.

The efficacy of the “personal experience” can be evaluated based on three dimensions: symptoms, disease patterns and diseases, and it should also meet the requirements of objectivity and repeatability of the evaluation index. According to the TCM and Western medicine diagnosis and treatment guidelines it is necessary to collect an all-round information of symptoms and disease patterns before and after treatment, and the outcome indicators are directly related to efficacy evaluation. It should include laboratory indicators, functional evaluation, imaging evaluation, endpoint outcomes, etc. The efficacy judgment criteria should conform to clinical reality and be consistent with the selected potency and indications. For example, if a prescription claims it works to relieve the disease patterns, the efficacy evaluation should be based on the corresponding disease pattern differentiation diagnostic criteria; if it aims to relieve symptoms, a quantifiable method should be used to evaluate the degree of symptom control to avoid non-quantifiable descriptive efficacy. If it aims to rectify indicators, the numerical value and relevant changes of the indicators should be clearly defined in the efficacy evaluation. If it is to rectify organic changes, an appropriate diagnostic method should be used in the efficacy evaluation to assess the degree of organic changes.

When reviewing the “personal experience” data, it is important to stay within the scope of the therapeutic potency obtained from the “personal experience” data. For example, a certain medicinal capsule works to dispel phlegm, remove blood stasis, clear the lung and lump, indicated for cough, panting, tight chest and chest pain caused by phlegm retention and blood stasis in the lung due to lung cancer. Since the capsule’s indications do not clearly indicate it works to treat pleural effusion, pleural effusion should not be added and listed as an evaluation index in the review.

In conclusion, the acquisition of the “personal experience” should strictly adhere to clinical practice. No matter what stage it is, whether at the stage of prescription formation or initial verification, it should not deviate from the clinical value, i.e. “the ultimate goal of benefiting patients” and the medical practice scenarios.

4. The relationship between the “personal experience” and clinical trials in the “Three-in-One” Registration and Evaluation Evidence System

Generally speaking, the “personal experience” mainly refers to the knowledge and skills that a practitioner gradually obtains and accumulates in his

long medical career and the unique cognition formed from it, which includes a large amount of original and valuable information. Clinical trials, on the other hand, focus more on scientific rigor and objectivity. On the background of artificial control with strict trial designs and data collection, the “personal experience” is verified allowing its outcome to get universal recognition and application.

According to the provisions of articles 23, 24 and 26 of the “Special Regulations on the Registration and Management of Chinese Medicinals”,¹⁰ and the “Guiding Principles for the Clinical Development of New Chinese Medicinal Compound Preparations Based on Personal Experience (Trial)”¹⁸ released by the Center for Drug Evaluation of the National Medical Products Administration, the requirements for clinical trials vary in the “Three-in-One” Registration and Evaluation Evidence System based on the quality of the “personal experience” data and whether the research results are positive or show a clear positive trend. For example, the development pathways of Category 1.1 of the Chinese medicinal compound preparations ② point out that the evidence obtained from past “personal experience” data in clinical studies are not satisfied, but it could provide a basis for subsequent clinical study design. The follow up study can be an exploratory study (either interventional or observational), then followed by confirmatory randomized and controlled clinical trials (RCTs). The development pathways of Category 1.1 of the Chinese medicinal compound preparations ③ point out that if the high-quality “personal experience” data with satisfactory positive overcome or evident positive overcome, RCT can be immediately followed. The development pathways of Category 3.2 Chinese medicinal compound preparations ⑤ originated from ancient classic formulas point out, if the evidence from past clinical studies based on the “personal experience” data supports registration, then it can proceed accordingly. Based on the above provisions and guidelines, in the process of clinical trials, it is necessary to adhere to the “personal experience” data, which include clinical positioning, target population, dosage and treatment course. Besides, the effectiveness and safety of the new Chinese medicinal must be confirmed. Within the scope of the system, the particular clinical trial needed is determined by the new medicinal preparation to be tested.

Currently, some scholars interpret the “personal experience” in the system as a prerequisite for clinical trials, which deviates from the original intention and positioning of the system. As mentioned earlier, the “personal experience” refers to the data accumulated over a long period of time in medical practice settings, leaning towards the observation of clinical medication, and it has observational and retrospective characteristics. In contrast, clinical trials are conducted in controlled conditions to study without various confounding factors. The clinical scenarios of the two are completely different, and the research methods are entirely different too. The collection of the “personal experience” data generally can draw on the real-world research model,¹¹ while the clinical trials often use methods such as RCT.¹⁰ The data obtained from the “personal experience” are more comprehensive, not only providing relevant support information required by clinical trials such as clinical positioning, target populations, dosage, and treatment duration, but also being able to analyze the data to obtain other important clinical information such as the risk or benefit of concomitant medicinal use in comorbid patients.

In the “Three-in-One” Registration and Evaluation Evidence System there exists a clear progressive relationship between the “personal experience” and clinical trials. The quality of the “personal experience” data determines which stage of clinical trials needs to be conducted next. In addition, the acquisition of the “personal experience” data cannot deviate from the medical practice scenarios and cannot be compared with clinical trials conducted under controlled conditions to eliminate various confounding factors. The relationship between the “personal experience” and clinical trials is shown in Figure 1.

5. Summary

In conclusion, the “Three-in-One” Registration and Evaluation Evidence System is a new Chinese medicinal review evidence system with Chinese characteristics, proposed as a breakthrough in the thinking framework of

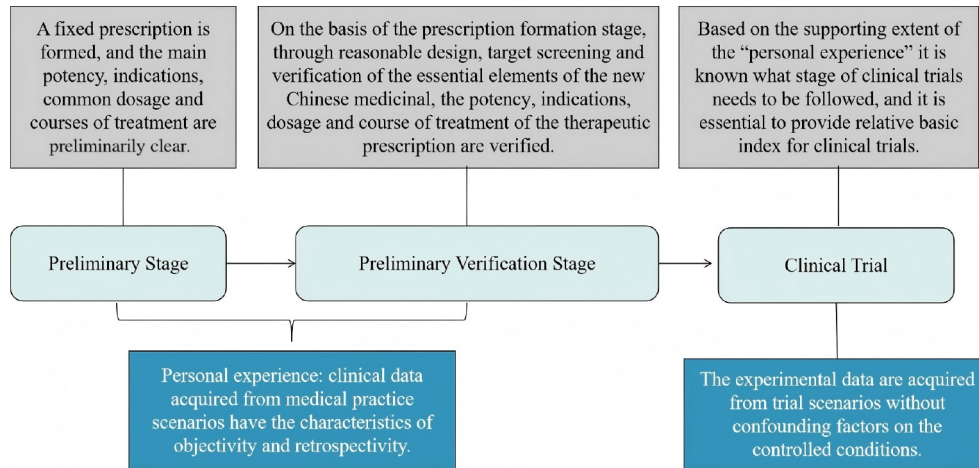


Figure 1 Relationship between the “personal experience” and clinical trials in the “Three-in-One” Registration and Evaluation Evidence System

chemical drug review. This system emphasizes the organic combination of TCM theory, “personal experience” and clinical trials, highlighting the important role of the “personal experience” in the research and development of new Chinese medicinals. It helps to better utilize the application experience, treatment characteristics and efficacy basis of Chinese medicinals, improve the efficiency in research and development of new Chinese medicinals, and promote the development of the Chinese medicinal industry. Through discussions of several academicians, TCM masters, TCM pharmacology experts and TCM clinical experts, it is believed that the “personal experience” is the core of the “Three-in-One” Registration and Evaluation Evidence System. The acquisition of the “personal experience” should not deviate from the scenarios of medical practice, and should be clearly distinguished from clinical trials. The “Three-in-One” Registration and Evaluation Evidence System is still being continuously improved and developed. It is expected with the joint efforts of the competent authorities, the academic world, the medical community and the industry the system will be perfect.

Translated by Professor Ting-yu Fang, Beijing University of Chinese Medicine.

Funding

This study was supported by the Strategic Research and Consulting Project of Chinese Academy of Engineering (grant no.: 2024-XZ-65).

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Declaration of Competing Interest

The authors declare that the research was conducted in the absence of any

commercial or financial relationships that could be construed as a potential conflict of interest. The Chinese version of this expert consensus has been officially published in the Journal of Beijing University of Traditional Chinese Medicine (2025, Volume 48, Issue 4: 445–450).

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