



Development of Holistic integrative pharmacy Based on Clinical Pharmacy

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[Abstract] With advances in modern medicine, life science technologies, economics, information technologies, and the Internet, the focus of clinical pharmacy is transitioning from drug product-oriented to patient-oriented. Current clinical pharmaceutical education curriculums cannot fulfill the requirements of preparing excellent clinical pharmacists and pharmaceutical management professionals. The professional training programs have failed to stay focused on the objective of providing scientific suggestions for clinical drug uses. Therefore, it is imperative to restructure clinical pharmaceutical education programs. This article discusses the definition, background, development, and integration approaches of holistic integrative pharmacy (HIP). The use of the schemes and methods of HIP building is proposed to prepare quality clinical pharmacy professionals who can adapt to the trends of a new era.

[Key words] Clinical pharmacy; Holistic integrative pharmacy; Preparation of professionals; Education reform

1 Background to development of holistic integrative pharmacy (HIP)

As of the 70th anniversary of the founding of new China, China has made tremendous achievements in the pharmaceutical field and has successively developed and introduced medicine policies. These policies have facilitated medicine and the health sector to be current and move ahead sustainably. However, it is difficult to make medical care more accessible and affordable in China because of a large population (1.3 billion) and a weak economic foundation. In an age where doctors and medicines are limited, the Communist

Party of China (CPC) made a decision to equally support traditional Chinese and Western medicine. It prepared a large number of educated urban youth working in the countryside or mountain areas for becoming barefoot doctors, which are medical workers with rudimentary training. They devoted themselves to providing primary care in rural villages and met the people's demand for health care in those days. Since the introduction of the Reform and the Opening-up policy, rapid progress has been achieved in China's social and economic development. However, people's demand for health care is progressively increasing. In the past, drugs would be taken regardless of their quality, but now patients want to receive safe and effective high-quality drug treatments.

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In 2016, XI Jinping, the General Secretary of the CPC proposed the Healthy China initiative at the National Hygiene and Health Conference. The report delivered at the 19th National Congress of the CPC also emphasized that the initiative would be implemented. The Party reported that they would adopt principles and policies to provide comprehensive health and medical services to the people. Holistic health is essential to the successful building of a well-off society in an all-round way. In the context of a new era, the CPC always places medicine and healthcare services at the forefront of development strategies. In this way, the development and reform of medicine and healthcare will meet the ever-growing health needs of the people. As the General Secretary Xi stated, "transformation requires not only discipline layout but also the actual integration of disciplines; besides, new trends should also be created to produce and advance emerging disciplines and inter-disciplines." In other words, integrating disciplines to achieve innovation across the world is encouraged.

Since the medicine policy of Zero Mark-up has been developed in China, the system that covered hospital expenses with profit obtained from drug sales was abandoned. Furthermore, the pharmaceutical supply that emphasizes drug sales has been upgraded to provision of clinical pharmaceutical service and care. Structure, quantity, and competence of pharmacists neither adapt to modern pharmaceutical science nor fulfill the ever-growing health needs of the people, although licensed pharmacist certification has been adopted since 1994. China still lags far behind the developed countries (e.g., USA and European nations) in the discipline of clinical pharmacy. Medicine and healthcare involve a wide range of complicated problems, which cannot be adequately addressed with pharmacy principles alone. Therefore, the effective integration of other fields is necessary. The fast development of the Internet, modern medicine, life science, and information technologies have provided new

opportunities for the growth of the pharmaceutical industry and effective tools for integration pertaining to the discipline of pharmacy. With these ideas in mind, the academician Fan Daiming, the Vice President of the Chinese Academy of Engineering, and the former President of the Air Force Medical University put forward the holistic integrative medicine approach. This new method focuses on the integration of medical treatment, medicine administration, medical-engineering integration, and more. They were committed to building a China Holistic Integrative Medicine Alliance in cooperation with Guangdong Pharmaceutical University, which is expected to lay the foundation for holistic integrative medicine for the health of the Chinese people^[1].

Guangdong Pharmaceutical University is a pioneer in this field. With the ideas of placing medicine first, combining treatment and medicine, and integrating medical treatment with engineering, it founded the School of Integrative Pharmacy and the Institute of Integrative Pharmaceutical Research based on clinical pharmacy in October 2016. In September 2017, the Holistic Integrative Pharmacy Innovation Class began to enroll students. It is a pilot program intended to devise and operate a reformed training scheme for HIP personnel^[2]. Hangzhou Normal University, Wenzhou Medical University, and other universities in China have also established HIP colleges. An effective integration of disciplines (e.g., chemistry, clinical medicine, pharmacy, and life science) important in traditional pharmacy is expected to prepare a large number of pragmatic personnel to promote rapid progress and transformation of pharmaceutical industries across nation and regions. These people should have an intimate knowledge of pharmacy, a cross-border way of thinking, and integration management capabilities.

2 Necessity of HIP

Modern clinical pharmacy has experienced

three phases. The first phase was a period of traditional pharmacy, which focused on pharmaceutical supply and dispensing of drugs. The second phase was a period of clinical pharmacy where developing new medication and promoting effective drug use was the primary focus of clinical researchers. The third phase is a period of pharmacy where patients themselves and improving their quality of life is put at the forefront^[3]. Today in China, pharmacy is shifting toward the pattern of patient-oriented pharmacy service. Swift progress has been made in modern science, technology, and clinical pharmacy. However, there are several limitations in current pharmacy education programs, such as slow updates of knowledge, a lack of diverse teaching methods, separation of pharmacy-related majors from one another (especially poor combination of TCM and Western medicine, and isolation of clinical medicine from pharmacy), uneven distribution of education resources, and failure to translate theories learned into clinical practice. Hence, it is still rather difficult to fulfill the people's expectation of rational, safe, and effective drug use.

Diagnosis, treatment, and prevention of diseases is the primary purpose of drug use. Patients are considered as the consumers of drugs. Nonetheless, an overemphasis is made on the role of theory teaching in pharmacy education, which loses touch with the clinical use of medicines. Although there are numerous academic publications about basic research, useful clinical information has been more limited. Thus, it is essential to restructure pharmacy education with the use of HIP. Medical professionals are to be developed based on an emphasis on clinical drug use. In this way, drugs can be used properly and precisely.

3 Methods of HIP

Integration is an approach used to produce a more effective and valuable combination. It properly connects separate ideas in a particular manner to share and synergize resources and information,

supporting the idea that the whole is greater than the sum of its parts. Integration requires creaming off the best and filtering out the impurities. Training pharmacy personnel suiting the requirements of the time should be considered as the main purpose. Therefore, desirable courses and resources, which are pertinent to the discipline of pharmacy, should be integrated, the knowledge that is outdated, inappropriate, repeated, and can be acquired in a more simplified way, should be removed. Ideas should be assembled to develop a novel method of disciplinary education and overcome the drawbacks of the existing education system.

3.1 Pharmacy and HIP

In the realm of science, dialectical unity exists between integration and differentiation. They contradict and supplement each other. In the field of pharmacy, traditional pharmacy majors are divided into four foundation disciplines: pharmaceutical chemistry, pharmacology, pharmaceutical preparations and pharmaceutical analysis. These are further categorized into relatively independent sub-disciplines. In addition, distinct theories, study methods, features, and limitations exist in each sub-discipline of pharmacy, such as Chinese material medical and biopharmaceutics. As the disciplines fail to work as one, it constitutes an impediment to the development of pharmacy. Integration is aimed at producing an integrated discipline by intersection, penetration, and blending of disciplines. Drug-drug integration involves a well-organized combination of the pharmacy majors, TCM and Western medicine, and noticeably, China's traditional and modern drugs. Patient-oriented pharmacy can be made available only if multiple disciplines of pharmaceutical science are integrated.

3.2 Integration of pharmacy and clinical medicine

For a long time, prescribing and dispensing always went together hand-in-hand. However,

China has now introduced a policy that involves the separation of prescribing and dispensing with the core purpose of making it so that hospitals no longer profit from drug sales. In European countries, the United States, Taiwan, and the Hong Kong Special Administrative Region of China prescribing and dispensing, just like rings in a chain, are in a relationship of interdependence. Specifically, physicians provide the diagnosis and therapy, while clinical pharmacists check prescriptions and deliver pharmaceutical service. Prescribing and dispensing are closely interwoven when developing side by side.

Clinical medicine has gone through several stages, from witnessing medicine to evidence-based medicine, individualized medicine, and precision medicine. A rapid progress in basic and clinical research of biomedicine has resulted in improved treatment options that are continuously increasing and a stream of new corrective drugs. For example, the treatment of tumors is developing. In 1942, Yale University (USA) used chemotherapy for the first time that involved the use of nitrogen mustard derived from mustard gas in patients with lymphoma. In 2003, a selective EGFR receptor tyrosine kinase inhibitor was successively administered to treat advanced non-small cell lung cancer, and since then targeted agents have become a recommended approach to treat tumors. In 2017, the FDA approved chimeric antigen receptor (CAR) T-cell immunotherapy, and cellular immunotherapy is predicted to be a promising tumor treatment in the near future. Therefore, pharmacists should keep abreast of fast-changing biomedicine, integrate up-to-date information of both clinical medicine and biomedicine, and stay current with the latest trends in the medical industry.

TCM is a remarkable treasure with a long history that has contributed substantially to the reproduction and prosperity of the Chinese nation for thousands of years. TCM is an essential mode of medical service in China. Using this method, multiple effective and widely used Chinese patent medicines have been

developed. These drugs are broadly used, not only in TCM hospitals but also in WM facilities. Patients usually respond well to the combined therapy of TCM with WM when the dosing regimen is appropriate. However, numerous doctors have limited knowledge of TCM, and therefore, may misuse TCM or Chinese patent drugs or improperly combine TCM with WM drugs. These issues provide the basis of the problems that exist in current medical education programs. TCM and WM are separately trained according to China's pharmaceutical education system. There is limited professional training that focuses on the scientific application of integrated Chinese and Western medicine. Therefore, graduates trained under the existing pharmaceutical education system are hardly eligible to provide quality clinical pharmacy services.

Clinical pharmacists should assess medical treatment protocols and provide pharmaceutical service of disease management in consultation with physicians. A clinical pharmacist should discuss medications with expertise and clinical knowledge, thereby maximizing the effectiveness of the therapy and minimizing unwanted toxicity and adverse side effects. Therefore, pharmacy and clinical medicine must be integrated into clinical pharmacy education programs. Efforts should be made to prepare versatile professionals who are clinically trained and experienced in drug use. In clinical practice, a clinical pharmacist is capable of reviewing physician advice and prescriptions in an objective manner and fixing any errors in drug use in the prescriptions. Additionally, they can correct and modify the dose regimens according to the patient's feedback of drug administration or based on the effectiveness and toxic side effects of the drugs. This system allows clinical pharmacists to improve drug efficacy and safety for their patients.

3.3 Integration of Pharmacy and Modern medical techniques

Studies show that the integration of pharmacy

and disciplines pertinent to modern medical techniques can significantly extend the academic borders and promote interdisciplinary research. It can profoundly transform the discipline of pharmacy by addressing the current problems arising in pharmacy and clinical fields^[4]. For example, in molecular pharmacy, the one gene-one protein-one drug idea is a traditional approach to screening new drugs. However, the biological activities of living beings should be considered as a complete whole. The pathogenesis of multiple diseases, especially chronic illnesses, is based on the interactions among genes and proteins. These innovative ways of thinking and novel theories have motivated the generation of new disciplines, such as systems biology and network pharmacology. These disciplines involve modern medical techniques, such as molecular biology, pharmacogenomics, transcriptomics, proteomics, metabolomics, and network pharmacology, which have impacted pharmacy dramatically and extensively in terms of advancing theories, techniques, and methods. The integration between pharmacy and advanced medical techniques can shape new approaches to prevent and control serious and refractory diseases^[5-6].

3.4 Integration of Pharmacy and other emerging techniques

In the context of rapidly developing pharmaceutical science, modern emerging techniques of other disciplines, including cloud computing, big data, artificial intelligence, and 3D/4D printing, have increasingly penetrated the pharmacy field. This suggests that revolutionary and dramatic changes are occurring in traditional pharmacy. High-level integration of pharmacy and modern emerging techniques allows pharmacy to take a "Fuxing high-speed train" and develop at an astounding rate. Cloud computing, big data, and artificial intelligence can be used to accurately predict the targets and activity of new chemical

compounds, which can provide a new approach to screen highly active candidate compounds. Living tissues and organs that are generated by 4D printing can be used as disease models in drug screening experiments, which may prevent the inconsistencies in drug efficacy/toxicity due to species-induced differences. As a result, there will be less animal testing and lower development costs^[7]. Moreover, various types of sustained-release preparation can be designed and printed with 3D technology based on specific features of drug metabolism in individual patients. This would allow for controlled release of drugs and individual drug delivery to become a reality^[8]. The integration between these emerging techniques and pharmacy unlock considerable potential for new drug development. Therefore, by combining pharmacy with up-to-date knowledge of key emerging techniques, TCM, chemical medicines, and biologic medicines, in a well-organized manner, pharmacy can quickly develop horizontally and vertically.

3.5 Integration of Pharmacy and innovative manufacturing

As a result of economic development, China lags far behind the Western countries in science, technology, and new drug development. For a nation with a large population of over 1.4 billion, a well-established health and disease control system should be prioritized to meet people's needs for a better life. To fulfill the demands for preventing and controlling clinically serious diseases, China must develop novel innovative drugs with independent proprietary intellectual property rights. We should not be over-dependent on me-too or fast-follow drugs, which are made by imitating innovative drugs developed by other nations, particularly those that have become a part of the World Trade Organization, Trade-Related Aspects of Intellectual Property Rights, and International Council for Harmonization of Technical Requirements for Pharmaceuticals for

Human Use (ICH). However, there is a large gap between international pharmaceutical giants and China's medical companies and research facilities in R&D capability, funding, and preparation of qualified new drug developers. In contrast, innovative drug development in China is still at an initial stage. From the launch of an innovative drug development project to getting new drug approval, it is an extremely lengthy, risky, and costly process. Biological medicine is one of the key sectors specified in the Made in China 2025 strategic plan, which suggests that innovative and individualized medications for serious diseases should be developed in response to clinical needs. The design, development, and manufacturing of innovative drugs should be based on the new advances made in numerous disciplines and techniques. It is also essential to integrate multiple disciplines (e.g., clinical medicine, pharmacy, and statistics) in drug clinical trials. Integration is an essential step toward increasing the efficacy and safety of new drugs during the course of their development. Thus, a combination of HIP with new drug development, leading to drug-engineering integration, can speed up the discipline of pharmacy so it can meet the people's needs of effective medication.

3.6 Integration of Pharmacy and Economics

Integration between pharmacy and economics originated in the United States in the 1970s, which lead to the development of pharmacoeconomics (PE). With new approaches to study modern economics, it combines the findings of foundation medicine, biostatistics, and other disciplines to comprehensively analyze the costs and outcomes of medical (and non-medical) treatment protocols, and assess their economic value^[9]. For the companies whose major business is drug supply, integration of pharmacy and economics may assist them in the developing, manufacturing, and selling of drugs. Not only will it help fulfill the people's

needs for prophylaxis and drug treatments, but it will also protect corporate benefits to ensure the sustained development of companies. As for patient-oriented clinical pharmaceutical services, this integration would help physicians and pharmacists prescribe cost-effective regimens to maximize health benefits.

3.7 Integration of Pharmacy and Humanities

Drug development is impossible without humans, as they are the end-user of drugs. Pharmacy's transition to patient-oriented medicine highlights the importance of caring for people. "One kind word can warm three winter months, an acute word cuts deeper than a sharp weapon." Whether in the process of drug creation or clinical use, pharmacy and humanities should be properly integrated to fill the pharmacy as natural science with humanistic spirits. This is true, especially for clinical pharmacy. A clinical pharmacist is not only responsible for checking and adjusting medical prescriptions, but also need to provide patient care psychologically. In this way, the effects of drugs can be increased.

In conclusion, pharmacy should integrate with different disciplines to achieve the effect of 1+1>2. However, HIP is not just the simple result of combining two disciplines into one, but it is an infinite addition by absorbing the essence of each discipline after filtering out the dross. With this approach, the beneficial integration of the whole process of drug development, manufacturing, distribution, and application can be finally achieved.

4 Clinical Pharmacy as the cornerstone of HIP

4.1 Clinical Pharmacy involved in integration of multiple disciplines

The focus of clinical pharmaceutical education is shifting progressively from drug-centered to patient-centered. A clinical pharmacist

should be an expert on medical treatments and an adviser who understands how to use drugs sensibly, safely, and effectively. Clinical pharmacy-based HIP education is reflected from the following two aspects: 1) integration between basic pharmacy knowledge and clinical use, which emphasizes knowledge application and 2) the integration of knowledge from pharmacy and medical science fields, with a stress on the holistic view of problems^[10].

Clinical pharmacy professionals should possess knowledge that is pertinent to medical treatment and the ability to analyze, assess, and address the problems of clinical medication using multidisciplinary theories. Clinical pharmacy in today's health facilities primarily involves ward rounds, consultations, case discussions, evaluating prescriptions/orders, monitoring and reporting adverse drug reactions, therapeutic drug monitoring, drug evaluations, instructing patients to use drugs properly, prescribing individualized drug regimens, medication consultations, composing drug messages and news, checking drug types, drug discovery studies, outpatient clinic of pharmacy, drug clinical trials, and more^[11]. The relevant disciplines are numerous and fragmented and this is why integration is warranted.

As specified in Provisions on the Administration of Pharmaceutical Affairs in Medical Institutions, "In individual health facilities, pharmacy professionals should not be less than 8% of health care professionals". A lack of clinical pharmacists is still conspicuous these days, whereas many pharmacy professionals working in health facilities are incompetent to carry out the most of aforementioned works. They have not been properly trained to acquire specialist skills and translate theories to practice.

Guangdong Pharmaceutical University (originally known as Guangdong Pharmaceutical College) was approved in 2008 to offer clinical pharmacy courses and enroll students as

clinical pharmacy majors in 2009. It is the first institution of higher education approved to offer clinical pharmacy courses. In ten-year teaching practice, a relatively well-developed training system has been shaped, which focus on theory and practice. In years of practice, we found the discipline of clinical pharmacy as a multidisciplinary science which reveals holistic integrative medicine, pharmacy, Chinese materia medica, pharmacy administration, informatics, and statistics.

4.2 Medication reconciliation in Clinical Pharmacy

Medication Reconciliation (Med-Rec), proposed by Jane Justeson, is a basic approach adopted in practice by clinical pharmacists in the developed world, such as Europe and the United States^[12]. Medication use is a rather complicated process. Patients are distinct from each other in many factors, including age, physiological and pathological states, and response to the same drugs. Moreover, clinical treatment is fraught with problems, such as combination of multiple drugs, irrational medication, poor patient compliance (patients do not completely follow medical advice), interactions between drugs and food. A clinical pharmacist should play a role in clinical medical treatment to maximize the efficacy and minimize adverse effects by customizing and implementing a drug regimen according to the patient's particular condition and medication history.

5 Development methods of HIP that is Clinical Pharmacy based

5.1 Formulation and development of HIP education theory

It is a must to adopt top-level design to promote the implementation of HIP. Top-level design is a holistic approach to manage and design the integrated content, integrating methods and the

insurance of integration mechanism. Based on the current situations of pharmacy education, teachers and students, as well as the fundamental development rules of higher education, the teaching methods and the practical theories of HIP education mode should be clearly defined. Higher education of pharmacy should be modified to prepare highly qualified graduates, who can keep abreast of developments in a new era, to embody the systematicness, integrality and synergy of the integration.

5.2 HIP training programs and teaching material reform

The focus of China's pharmaceutical industry is shifting from generic to innovative drugs. The philosophy of pharmaceutical education is also transitioning from "drugs-centered" toward "patient-centered". However, the graduates trained by outdated pharmaceutical curriculum and assessment systems cannot come up with innovations. Therefore, it is needed to reform the available pharmacy training programs by learning from developed countries, such as European nations, the United States, and Japan. Courses that are interconnected in underlying logics and core values should be integrated, and overlapped courses should be abandoned. The students should be trained to obtain awareness of integration so as to deliver solutions to problems arising in drug development, manufacturing, distribution, and application with integration in mind.

Old and repeated sections are also present in pharmacy teaching materials as those of HIP discipline have not yet been developed. In this case, the compilation of HIP teaching materials in keeping with changes in HIP and clinical pharmacy progress, can provide an important guarantee for development of HIP.

5.3 Reform and integration of approaches to teaching

Considerable and extensive knowledge is

covered in pharmacy discipline. Teachers, when conducting classes, are biased toward theory and exams, instead of practice and capability. Even with effective integration, it is impractical to instruct all sections of teaching materials in classes. Hence, the approaches to teaching and assessment should also be integrated. HIP education focuses on an integrated way of thinking. Students are trained to become independent learners and to address problems using teaching approaches, such as micro-lecture, massive open online courses, and flipped classroom on the Internet.

Research personnel can be well-trained by participating in related research and development experiments, data analysis, and pharmacy data handling. They may start from design and synthesis of compounds (or extraction, separation, and purification of active ingredients from natural drugs), instrumental analysis to identify structure, investigation into pharmacologic actions by performing molecular biology experiments using relevant cells, observation of detailed absorption, distribution, metabolism, and excretion in the body by means of pharmacokinetics. In this process, overall skills can be sharpened. In addition, in the teaching of clinical pharmacy, teachers may adopt integrative approaches to teaching, such as project-based learning. Students can collaboratively solve problems in a simulation situation of HIP by inquiring and discussing using the systematic knowledge learned in basic clinical medicine, pharmacology, and pharmaceuticals. In the period of clinical practice, students can be studied in teaching facilities of clinical pharmacy to experience the power of HIP.

5.4 Integration of research platforms

Disciplines cannot develop without scientific research. The 13th Five-Year Plan for medical industry specifies the goal of improving the capacity for independent innovation, which can only be realized by taking the prevention and treatment

of clinically serious diseases as a fundamental objective and integrating the theories, methods, and techniques of HIP, clinical medicine, and life science to build up a new HIP research system, in which multiple disciplines integrated into a whole.. This system is built for new drug development and HIP theories researches. Besides, concerted efforts should be made to integrate campus research platforms of all levels and categories. Schools should also cooperate with enterprises to make technique breakthroughs and work for collaborative innovation. Integration researches should be undertaken at multiple levels and with multiple steps. We should strive to finalize high-level integration of industry–academia–research–application by converting the focus of drug development from generic into innovative drugs and translating findings of research innovation into clinical use.

6 Conclusion

Healthy China Initiative represents the people's expectations for good drugs and safe medications, but the graduates trained by current pharmaceutical education system cannot meet this need due to the small number of qualified talents and the poor quality of personnel. In the context of "people-oriented" pharmacy education, it is a must to implement reform on the old pharmaceutical education system and to break down the barriers between medicine and pharmacy, TCM and WM, experiment and clinical practice, scientific research and industrial application, with the use of integrated concepts, way of thinking, and methods. HIP should be developed based on clinical pharmacy to prepare qualified HIP graduates with Chinese characteristics who can adapt to China's conditions and be competent in integration of industry–academia–research–application. The actions mentioned above is intended to satisfy the people's ever-growing needs for "make the best use of good drugs ", thereby contributing to Healthy China Intuitive.

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