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CLINICAL PHARMACOLOGY AND CLINICAL PHARMACY: COMPETITION OR COLLABORATION?

Svetlana Golocorbin-Kon[1], Mladena Lalic[1], Al. Raskovic[2], S. Vukmirovic[2], Z. Tomic[2], M. Mikov[3]

[1.] *Department of Pharmacy, Medical Faculty Novi Sad, Serbia*
[2.] *Department of Pharmacology Toxicology and Clinical Pharmacology, Medical Faculty Novi Sad, Serbia*
[3.] *School of Pharmacy, University of Otago, New Zealand*

Abstract. Clinical pharmacology and clinical pharmacy bring together professionals who have firm grounding in the principles of drug therapy and who aim to improve the safety and efficacy of treatments for the benefits of patients. However, there are clear differences, typically in the undergraduate and less prominent in postgraduate education. Clinical pharmacologists and clinical pharmacists are accountable for the same target groups. Clinical pharmacology and clinical pharmacy share similar and parallel development, history, the same goal and the same financial resources (they compete for the same financial sources). As an academic discipline, Clinical Pharmacology has been developed over the past 40 years, but its impact on health care services has been less conspicuous. Clinical pharmacy has had a quicker and more coordinated development in health care services dominated and synchronized by the American College of Clinical Pharmacy, but a less notable advance as academic discipline. Collaboration between clinical pharmacology and clinical pharmacy should be possible. In practice, competition and domination of one group can always be discerned depending on the country or the area of the country. Clinical pharmacology - clinical pharmacy collaboration is important for the benefit of patients, education, authorities and clinical pharmacology and clinical pharmacy associations and development.
Keywords: clinical pharmacology, clinical pharmacy, collaboration, competition

Introduction

Clinical pharmacology and clinical pharmacy have much in common. Both fields bring together professionals who have firm grounding in the principles of drug therapy and who aim to improve the safety and efficacy of treatments for the benefits of patients. However, there are clear differences. Clinical pharmacologists are generally physicians with an additional degree in clinical pharmacology, many of whom are prescribers of medicine in active practice but are usually connected to academic units responsible for research and teaching. They belong to a well recognized but small sub-specialty of medicine. On the other hand, clinical pharmacists are part of a much larger group of professionals represented in most hospitals in developed countries. While formerly subordinate and restricted to supplying the medicines requested by the medical prescribers, the pharmacists' role has progressively developed to include monitoring outcomes of drug therapy and patient safety, report management and budgetary responsibilities. Pharmacists are now proficient to take on prescribing responsibilities in certain countries and have been actively involved in collaborative prescribing practices with physicians. They also take on much of the educational

Momir Mikov
National School of Pharmacy
University of Otago
18 Frederick Street, Dunedin 9054, New Zealand
E-mail: momir.mikov@otago.ac.nz

role related to rational prescribing that was once considered the realm of the clinical pharmacologist. Given the disparity in size of the two groups there is understandably growing confusion in the minds of managers in health services as to the identity and continuing role of clinical pharmacology. This may explain, in part, the decrease in visibility and numbers of clinical pharmacologists in some countries. [1] Indeed, some might see the rise of clinical pharmacy as a direct threat to the future existence and viability of the clinical pharmacology specialty. The aim of this brief review is to chart the rise of these two disciplines, assess their current status in the clinical and academic arena, and examine prospects for the future.

Clinical Pharmacology: History and definitions

The discipline of clinical pharmacology was started in the 1960s by a group of eminent physicians who formulated a concept of a new branch of pharmacology that dealt with the effectiveness and safety of drugs in man. A contemporary definition of this discipline is "The study of pharmacology in relation to clinical science. It is a science which deals with the effects of drugs in healthy volunteers and in patients. In the evaluation process the action and adverse effects of drugs can be measured and compared. " [2]

One of the problems in defining clinical pharmacology was well depicted in 1995 by Waud who said: "Clinical pharmacology is another area of grey. Part of the problem is that there were individuals who used the clinical pharmacology label as a political tool. They would claim to be clinical pharmacologists with joint appointments in departments of Medicine and Pharmacology. When the people in Medicine thought the person was rather low grade they rationalized it by assuming the weakness was counterbalanced by strength in Pharmacology, while the pharmacologists were assuming this was compensated by being in the department of Medicine." [3]

The American College of Clinical Pharmacology put out a „white paper" in 1990 to better define the topic and to identify core curricular elements for the training of clinical pharmacologists.[4] It discerned features that distinguished the branch of learning and sought to promote harmony within the discipline, providing a background for the definition of a clinical pharmacologist, delineating the responsibilities associated with the discipline and providing the basis for further discussion and augmentation of clinical pharmacology.

In 2000, Heath and Colburn described the evolution of drug development and clinical pharmacology during the 20th century. [5] They suggested that clinical pharmacologists would play a critical role in drug development and that clinical pharmacology concepts must be brought to bear on the practice of medicine. Further, they suggested that the clinical pharmacologists of the future will need to communicate their knowledge and understanding to the management and marketing teams of pharmaceutical companies as well as to the medical community thus playing an important role as communicators and educators and bringing the various stakeholders together for the improvement of medical practice.

Clinical Pharmacology: Associations and Journals

Clinical pharmacology associations have been crucial for the development of this discipline and there are varieties with generally similar aims. The number of journals focusing at least somewhat on the field of clinical pharmacology also provides some indication of the value of the field.

Clinical Pharmacology: Purpose

The mission of clinical pharmacology as a specialty was very well presented by a working party of the UK Royal College of Physicians, which stated that "The mission of the specialty is to improve the care of patients by promoting safe and effective use of medicines and to evaluate and introduce new therapies." [6] Clinical pharmacologists often make extensive contributions to clinical service as well. At local level this may involve leading the drug and therapeutics committee, developing and maintaining a drug sheet creating prescribing guidelines, reviewing medication incidents and promoting evidence based therapeutics. Some clinical pharmacologists may play leading roles in medicines information service for local prescribers, as well as in drug regulation and health technology assessment, often with the support of clinical pharmacists.

Clinical Pharmacology: Current Status as a Specialty

Clinical pharmacology is one of the few specialties with currently decreasing numbers. [1, 7] This raises serious concerns about whether clinical pharmacology can fulfill its mission, either in a clinical or an academic environment, and indeed about the perceived necessity for clinical pharmacology. In the UK, the projected optimal staffing

is one clinical pharmacologist per district general hospital serving a population of 250,000 or one clinical pharmacologist per 180 medical students in training, or about three clinical pharmacologists per medical school (assuming that half of these have academic contracts.[8] These figures would require an expansion in UK numbers of at least 10% per annum over the next decade. A study examining this branch of learning in East European countries showed highly unbalanced numbers of clinical pharmacologists in different countries: from 1 clinical pharmacologist per 35,000 inhabitants to 1 per 10 million inhabitants, with an average of 1 clinical pharmacologist per 250,000 inhabitants. Most of them were within national health services (more than 40%) and research institutes (30%).[9]

The strengths and weaknesses of clinical pharmacology as a discipline have previously been reviewed. [6] Aronson suggested that: "clinical pharmacology is a wide angle lens because it covers so many different diseases and an X-ray because it covers them in depth from individual molecules to individual people and even whole populations. This is both a valuable asset and a weakness. Its influence touches most areas of medicine and spans from molecules to man and populations. Its weakness lies in diffusing the impact of the subject when individual specialists, experts in the usage of drugs relevant to their own field, do not always appreciate what extra value a clinical pharmacologist can offer them." [10]

Clinical Pharmacy: History and Definitions

How has clinical pharmacy advance commenced? It started based on medication errors.

In 1971 articles such as: "The physician's contribution to hospital medication errors" [11] and "Medication errors in the seventies" were published. [12] Since 1971 a lot of other articles can be mentioned on the topic of medication errors with significant titles in 2006. [13]

The Encyclopedia of Clinical Pharmacy is a highly comprehensive source on different aspects of clinical pharmacy history and development: "Clinical pharmacy has come to describe a wide range of pharmacy practices that occur in a variety of settings, including health-systems, community pharmacies, clinics, pharmaceutical industry, and governmental agencies. Clinical pharmacy incorporates the patient-oriented practices of pharmaceutical care as well as drug policy management, research, education and many other aspects within the field. As the scope of clinical pharmacy has extended, it has become less easy to capture in a simple definition. The range of topics included in the Encyclopedia of Clinical Pharmacy attests to the complexity and expansion of clinical pharmacy practice. One approach has been that of identifying areas by functional activity (e.g. nuclear pharmacy, drug information) and/or therapeutic focus (e.g. psychopharmacy, clinical pharmacokinetics). A second approach was defining clinical pharmacy as a specialty practice that would, at least initially, coalesce clinical practitioners with the common denominator of an active role in the therapeutic decision-making process." [14]

There have been several attempts to define clinical pharmacy but the best known is probably that of the ACCP in 2005.[15] This document states that clinical pharmacy is "the area of pharmacy concerned with the science and practice of rational medication use." This abridged version summarizes three main areas - the discipline of clinical pharmacy, the clinical pharmacist and the roles of the clinical pharmacist in the health care system which were outlined as follows:

- "Clinical Pharmacy is a health science discipline in which pharmacists provide patient care that optimizes medication therapy and promotes health, wellness, and disease prevention. The practice of clinical pharmacy embraces the philosophy of pharmaceutical care; it blends a caring orientation with specialized therapeutic knowledge, experience, and judgment for the purpose of ensuring optimal patient outcomes. As a discipline, clinical pharmacy also has an obligation to contribute to the generation of new knowledge that advances health and quality of life."
- "Clinical pharmacists care for patients in all health care settings. They possess in-depth knowledge of medications that is integrated with a foundational understanding of the biomedical, pharmaceutical, sociobehavioral, and clinical sciences. To achieve desired therapeutic goals, the clinical pharmacist applies evidence-based therapeutic guidelines, evolving sciences, emerging technologies, and relevant legal, ethical, social, cultural, economic and professional principles. Accordingly, clinical pharmacists assume responsibility and accountability for managing medication therapy in direct patient care settings, whether practicing independently or in consultation/collaboration with other health care professionals. Clinical pharmacist researchers generate, disseminate, and apply

new knowledge that contributes to improved health and quality of life."

- "Within the health care system, clinical pharmacists are experts in the therapeutic use of medications. They routinely provide medication therapy evaluations and recommendations to patients and health care professionals. Clinical pharmacists are a primary source of scientifically valid information and advice regarding the safe, appropriate, and cost-effective use of medications."

The role of clinical pharmacists was also defined by the Society of Hospital Pharmacists of Australia in 1996 as: "clinical pharmacists work to ensure that the correct patient receives the optimum dose of the most appropriate medication for a specific condition via a rational dosage form and regimen, over an appropriate time period." [16]. The American College of Clinical Pharmacy's 20- to 30-year vision for the profession is that: „pharmacists will be recognized and valued as the preeminent health care professionals responsible for the use of medicines in the prevention and treatment of disease." [17]

The definition of the European Society of Clinical Pharmacy is less descriptive - "Clinical pharmacy is a health specialty, which describes the activities and services of the clinical pharmacist to develop and promote the rational and appropriate use of medicinal products and devices." [18]

Steps in clinical pharmacy development

Composing a complementary white paper by task force on clinical pharmacist which will articulate the professional pathways necessary to develop and maintain the core competencies of both a clinical pharmacy generalist and clinical pharmacy specialist.

A session at the international clinical pharmacy congress in 2004 raised concerns about workforce in clinical pharmacy by 2020. The US is likely to be short of 157,000 pharmacists by that time. In UK it was a failing of the system that pharmacists are trained as scientists rather than as clinicians at undergraduate level. They suggested the necessity of the fundamental change that needs to occur in order to facilitate pharmaceutical care is to train people to be clinicians and then if they choose to become pharmaceutical scientists. In US almost all of the growth from 1989-1998 in total number of pharmacist was due to increased numbers of clinical pharmacists, a five times increase. Not only is clinical pharmacy the fastest growing pharmacy element in organized health care settings, but it has also reached critical mass as a discipline. [19]

The position and necessity of clinical pharmacy is further confirmed [20]:

"Pharmacists in community and ambulatory care settings are in a unique position to reduce drug-related morbidity and to optimize patient outcomes by identifying, resolving, and preventing drug therapy problems.

This particular approach to pharmacy practice expands traditional pharmacist responsibilities of dispensing pharmaceuticals and providing drug information to optimizing patients' drug therapy outcomes. However, pharmacists in general, and community pharmacists in particular, have yet to incorporate this expanded professional role into daily practice."

The role of clinical pharmacy in therapy was upgraded and elaborated. [21] "Pharmacists can improve the quality of drug therapy by improving the organizational structures through which drug therapy is provided, specifically by creating medications use systems and by regularly evaluating their performance and it must be patient centered, cooperative, and interprofessional. To maximize pharmacists' participation in such systems, pharmaceutical education should include courses in medication use systems as necessary counterparts to courses in pharmacotherapeutics. Clinical functions must be organized around patient need and directed at outcomes. Clinical practice should constitute the mainstream practice of pharmacy rather than an 'optional' specialty."

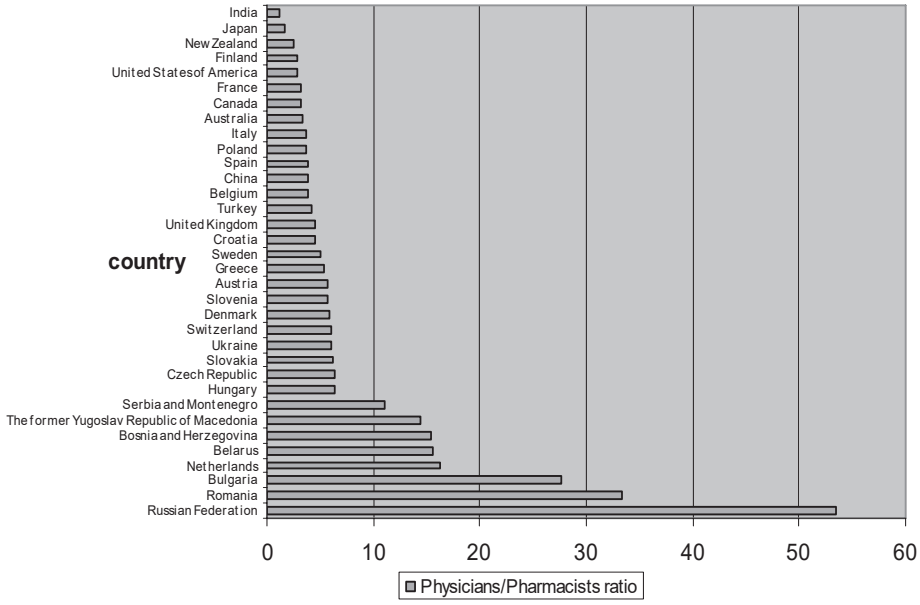
There are plenty of articles with documenting value, yet not all pharmacists provide such services. It is hampered by lack of payment for these services – there is a substantial urge to change this in the US.

Clinical Pharmacology and Clinical Pharmacy: Overlap, Competition and Collaboration

The reality is that fees and other expenses for pharmacy students (60.000US$) are lower than for medical student fees (150.000US$) (average based on data for US residents). Pharmacy studies in most countries are shorter than medical studies. The most difficult part for clinical pharmacology and clinical pharmacy development is the supply of human resources. China, India, USA, Russia and Japan gather 72% of the total number of physicians and 80% of the total number of pharmacists in the world. You can see from Fig. 1 based on World Health Organization data from 2003 that there are huge differences between the ratio of physicians to

pharmacists in different countries. The best chances for more intensive development of clinical pharmacology based on these data, are in the countries where the physicians to pharmacists ratio is equal to or higher than 4, such as the Russian Federation, Romania, Bulgaria, Netherlands, Belarus, Bosnia and Herzegovina, The former Yugoslav Republic of Macedonia, Serbia and Montenegro, Hungary, Czech Republic, Slovakia, Ukraine, Switzerland, Denmark, Slovenia, Austria, Greece, Sweden, Croatia, United Kingdom, Turkey. The best chances for clinical pharmacy intensive development due to available human resources are in Canada, France (trained as scientists), United States of America, Finland, New Zealand, Japan, and India.

Figure 1. Physicians/ pharmacists ratio in selected countries in the World in 2003



There are several articles on the interaction between clinical pharmacology and clinical pharmacy. In earlier stages, in an article dating back in 1973, Csaky wrote that: "the trends in declining emphasis on basic sciences resulted in a generation of physicians inadequately trained in the knowledge of drugs and drug-effects. The emphasis on pharmacology, therapeutics and clinical pharmacy in colleges of pharmacy resulted in a generation of pharmacists with the new professional image of a well qualified pharmacotherapist ready to claim a decisive professional position on the health delivery team. Pharmacologists may be able to bridge the emotional gap which may eventually develop between physician and the pharmacists through the adequately designed program in clinical pharmacology".

He suggested that "a pharmacist well trained in pharmacology with additional training and an MD degree will be the ideal candidate to develop the science of clinical pharmacology to its highest standard".[22]

In 1981, Miller wrote "Clinical pharmacy is a professional discipline that arose out of dissatisfaction with old practice norms and the pressing need for a health professional with a comprehensive knowledge of the therapeutic use of drugs, clinical pharmacology is a professional discipline that combines basic pharmacology and clinical medicine which is 10 years older but has had slower growth than clinical pharmacy but it has made many important contributions to our knowledge of human pharmacology and the rational use of drugs".[23]

Clinical pharmacology and clinical pharmacy collaboration was proposed in 1986 by Park who suggested: "The clinical pharmacists and clinical pharmacologists share a common goal, but approach that goal from generally differing perspectives and educational backgrounds. In the practice setting where clinical pharmacists and clinical pharmacologists are attempting to carry out their assumed respective responsibilities, conflict can occur. In the setting where clinical pharmacy and clinical pharmacology coexist, the primary responsibility for the quality of drug prescribing should rest on clinical pharmacology."[24]

A shift of pharmacy profession from a product-centered profession to a patient-centered, outcome-oriented profession is well underway and is already firmly established in institutional practice. Recently, several studies have demonstrated that pharmacists practicing in direct patient care roles reduce health care costs as well as morbidity and mortality.

In response to the "pharmacy movement" the American College of Physicians-American Society of Internal Medicine (ACP-ASIM) published a position paper in January 2002 describing their perceptions of the pharmacist's scope of practice. The ACP-ASIM supports „physician-directed, pharmacist-physician collaborative practice agreements limited to pharmacists' involvement in patient education and hospital rounds under the following conditions:

(i) expanded roles of pharmacists should not be solely based on cost-savings;

(ii) the responsible physician and pharmacist should be compensated for their time spent on collaborative services;

(iii) the physician should solely determine if a relationship will be formed with the pharmacist;

(iv) the physician should solely and individually refer a patient to a pharmacist; and

(v) only the physician can and will diagnose the patient's condition prior to any referral." [25]

This induced an editorial which stressed the crucial role of pharmacists and that the profession of pharmacy, like medicine, has evolved to include a wide array of professionals with diverse and varied levels of training, skill and experience and reinterpreting the (ACP-ASIM) paper as that the ACP-ASIM appears to desire a return to a time when pharmacists dutifully told patients in response to their drug therapy questions, "I shouldn't answer that, you'll have to discuss that with your doctor." [26]

The idea asserted by the ACP-ASIM that a patient shall not form a relationship with a pharmacist unless authorized to do so by a physician is reduced to absurdity when one considers the following:

„1.The sheer number and accessibility of pharmacists far exceeds that of physicians.

2. The very act of writing a prescription invokes the formation of a professional relationship between pharmacist and patient and all of the legislated, mandated, ethical and professional responsibilities inherent therein.

3. In most institutions, the pharmacist's duty of independently assessing and striving to ensure appropriate drug therapy on a patient-specific basis is a Medical Advisory Committee decreed policy.

4. Experience dictates that physicians lacking appropriate drug therapy skills are frequently unaware thereof.

5. Though pharmacists are not specifically trained as diagnosticians, the reality is that pharmacists interpret the complaints of scores of patients every day, form correct diagnoses and initiate and monitor appropriate drug therapy".

Pharmaceutical Medicine

Pharmaceutical medicine is a medical scientific specialty concerned with the discovery, development, evaluation, registration, monitoring and medical aspects of marketing of medicines for the benefit of patients and the public health.

Careers in pharmaceutical medicine encompass three main groups of physicians: those working in the pharmaceutical industry, those with appointments within medicines regulatory bodies, and those working in independent research organizations dedicated to the development of new medicines.

A pharmaceutical physician may be responsible, together with his or her team, of the entire clinical development for one or more compounds. The development programme must effectively evaluate the risk/benefit ratio for a product, which can be a major challenge in a discipline which is by definition always working on the frontiers of science. It is essential that good communication be maintained across the world so that effective and efficient drug development can be conducted and safety surveillance can be maintained within companies and regulatory authorities. [27]

Clinical Pharmacology and Clinical Pharmacy: Looking to the future

Textbooks in clinical pharmacology and clinical pharmacy are almost identical in their coverage like *A Textbook of Clinical Pharmacology* [28] and *Clinical Pharmacy and Therapeutics textbook.* [29]

Areas of further development of clinical pharmacology proposed by American College of Clinical Pharmacology [4] are:

- Pharmacokinetic/pharmacodynamic modeling
- The translation of pharmacogenomics into clinical practice
- Drug development strategies for designing modern pharmacogenomics clinical trials
- Novel, early clinical development strategies for improved pharmacologic therapies

- Increasing biomarker and surrogate endpoint use
- Modern drug safety monitoring: The need for genomic pharmacosurveillance
- Understudied populations: Pregnant women, neonates and pediatric populations

What should clinical pharmacology learn from clinical pharmacy development? There is a very active and extensive leadership education of pharmacists and a very well developed strategic plan, set up at American Health System Pharmacist Association. [30] In the latest article, Honig stressed that clinical pharmacology needs enhanced attention and indicates the responsibility of leadership for its status. [31]

A very good manner of promoting Clinical pharmacy has been provided by The European Fellowship for Pharmacists as a 'not-for-profit' association formed in 2004. It promoted clinical pharmacy throughout Europe by helping clinical practitioners to attend conferences of the European Society for Clinical Pharmacy (E.S.C.P.) and other similar conferences. [32] Clinical pharmacy, using a carefully selected terminology like pharmaceutical care (which is not identical to clinical pharmacy) was very skilful in its own marketing and presentation of its necessity using already very well developed existing marketing methods in pharmaceutical industry.

The skill display in their own marketing and presentation of pharmaceutical care [33] demonstrates the value of pharmaceutical care to all potential stake-holders (patients, health care providers, employers, third party payers etc.).:

- An informational partnership between patients and pharmacists
- A collaborative process with physicians and other health care providers that ensures the patient achieves the desired health care outcome
- A service that helps consumers better understand their health status and drug therapy so they can make more informed health care decisions.

Benefits of Pharmaceutical care:

- it may save lives
- it helps people become and stay healthier
- it saves people money
- it helps patients learn more about their healthcare
- it makes patients better informed
- it equips patients to make better decisions
- it helps patients take charge of their health
- it builds a trusting relationship between the patient, physician and pharmacist
- patients may experience less loss of time from work
- it reduces emergency room visits and unnecessary physician appointments due to preventable drug therapy problems

Reality is that there is insufficient coverage by either group throughout the World. Many errors continue, drug related problems continue etc. The purpose of each is similar. They need to work together in order to improve care.

Concluding remarks

In developed countries, especially during the last 20 years, there is no further need for the huge number of formulation pharmacists as before due to restructured World trade. Physicians' education in the field of pharmacology and pharmacy has decreased. The pathway from pharmacy student to clinical pharmacist is usually shorter and cheaper than that from medical student to clinical pharmacologist. Clinical pharmacologists and clinical pharmacists are accountable for the same target groups. Clinical pharmacology and clinical pharmacy share similar and parallel development, history, the same goal and the same financial resources (they compete for the same financial sources). As an academic discipline, Clinical Pharmacology has been developed over the past 40 years, but its impact on health care services has been less conspicuous. Clinical pharmacy has had a quicker and more synchronized development in health care services dominated and synchronized by the American College of Clinical Pharmacy, but a less notable advance as academic discipline. Collaboration between clinical pharmacology and clinical pharmacy should be possible. In practice, competition and domination of one group can always be discerned depending on the country or the area of the country.

In short: clinical pharmacology clinical pharmacy interaction is the repetition of the historical relations between physicians and pharmacists: *déjà vu* phenomenon: from Paracelsus Doctor (Physician) to Paracelsus Pharmacist and back to Paracelsus Pharmacy Doctor

Clinical pharmacology – clinical pharmacy collaboration? It is important for the benefit of patients, education, authorities and clinical pharmacology and clinical pharmacy associations and development.

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