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Analysis of 2022 Chinese Clinical Engineering Body of Knowledge and Body of Practice Survey

By Jing Tong[1], Kun Zheng[2], Bin Li[3]

[1] Shanghai Ocean University, China

[2] Children's hospital Zhejiang University School of Medicine, China

[3] Shanghai Sixth People's Hospital affiliated to Shanghai Jiaotong University School of Medicine, China

ABSTRACT

Background and purpose: Clinical engineers (CEs) face greater demands for their professional knowledge as healthcare technology, especially life support equipment, including ventilators and artificial heart-lung machines, becomes increasingly important and complex. However, there are significant differences in clinical engineering majors around the world, and independent research on the body of knowledge and practice in clinical engineering is lacking in China.

Materials and methods: This study is an initial investigation into the body of knowledge and body of practice in the field of clinical engineering in China, conducted through a questionnaire-based survey. The aim of the survey is to collect important data from Chinese CEs.

Results: The investigators' background highlights that Chinese CEs are predominantly young, highly educated, and have limited work experience. Ongoing education and training will be needed to keep up with technological advancements. However, the future of clinical engineering in China looks positive. The survey of knowledge and work activities in the clinical engineering industry in China indicates that the main focus is maintaining the normal operation of hospitals. After that, according to the future development trend of the hospital, new knowledge and practical activities are continuously expanded.

Conclusions: Although the survey provides insight into the knowledge and activities that are most relevant to clinical engineering in China, further research is necessary to establish a reliable body of knowledge and practice.

Keywords – *Chinese Clinical Engineering, Body of Knowledge, Body of Practice, Clinical Engineering Survey.*

INTRODUCTION

Clinical engineering is a multidisciplinary field that combines knowledge from several disciplines such as engineering, medicine, and computer science. The work of CEs involves the application of technology to improve patient care, safety, and outcomes in a healthcare setting. Their work is highly practical and requires continuous learning and experience to keep up with the rapidly evolving technology and medical practices. As a result, the body of knowledge and practice in clinical engineering has quickly grown over the years.

However, this growth in knowledge has led to challenges in education and personnel training. On the one hand, the content taught in schools may not meet the knowledge needs of actual work, and different colleges and universities have different majors and curriculum settings, resulting in differences in knowledge structure and stock.[1] Conversely, due to differences in working environments, medical treatment focus, and existing hospital technology, CEs' knowledge and experience may gradually differ. These differences and deficiencies in knowledge and practical experience are common in the industry and pose a bottleneck for industry development and personnel training. Therefore, it is necessary to establish a correct knowledge framework in clinical engineering.

Recently, the Global Clinical Engineering Alliance (GCEA) and IFMBE-CED jointly conducted a clinical engineering survey. This time, it is important to understand the type of knowledge that CEs need to develop their work (Body of Knowledge) and identify the activities that CEs carry out globally (Body of Practice). The ultimate goal is to define a set of disciplines to help any teaching unit revise and develop its academic program to train CEs. In the past, similar studies have been conducted from a global perspective.[2] However, this article only focuses on China, and aims to gain a preliminary understanding of the knowledge and practice system in clinical engineering through large-scale surveys.

The remainder of this paper is organized as follows. The research materials and methods are described in Section II. The third section is the research results, and then the fourth section analyzes according to the research results. The fifth section is the conclusion.

MATERIALS AND METHODS

The purpose of this questionnaire is to collect different relevant types of information from respondents to better understand the current knowledge system and practice system in the field of clinical engineering. The questionnaire is divided into four parts, each focusing on a specific aspect of the respondent's background and work experience.

The first part, titled "Basic Information," requests the respondent's name, gender, location, age, and contact information. This section is important for establishing basic demographic information about the respondents and their location.

The second part, titled "Occupational Background," is designed to gather information about the educational and work backgrounds of the respondents. In this section, respondents are asked to provide information on their degrees, professional fields, working years, nature of work, and whether there is a clinical engineering (CE) registration and certification process in China. This section will help to provide a clearer picture of the educational and professional backgrounds of CEs in China.

The third part, titled "Knowledge," is focused on identifying the importance of 40 different knowledge areas in the respondents' work. Respondents are asked to evaluate the level of importance of each area according to their own situation, rating them as minor, moderate, high, or not important. This section will provide insight into the specific areas of knowledge that CEs find most relevant to their work.

The fourth part, titled "Work Activities," lists 8 categories of work activities that CEs commonly engage in, such as health technology management, service delivery management, and information technology/digital health. Respondents are asked to evaluate the percentage of time they spend on each category and provide choices for supplementary descriptions of other categories. This section will help to identify the specific work activities that CEs in China engage in and the relative amounts of time they devote to each one.

It is worth mentioning that this questionnaire utilizes an online questionnaire to collect data, benefiting from various advantages. The online format facilitates quick and easy questionnaire distribution to many potential respondents, increasing response rates. The online format eliminates the need for manual data entry, thereby reducing the potential for errors and enabling more efficient data analysis. Additionally, the online questionnaire allows for the inclusion of skip patterns and branching logic to ensure that each respondent only answers questions relevant to their specific background and experience. Therefore, the online questionnaire is a practical and effective method to collect knowledge and work activity data of CEs in this study.

RESULTS

Basic Information

The survey received strong support from CEs in 21 provinces across China, with 178 valid responses received. Among them, 67 were from Zhejiang, 21 from Shanghai, 17 from Sichuan, and none of the other provinces reached 10 (Figure 1).

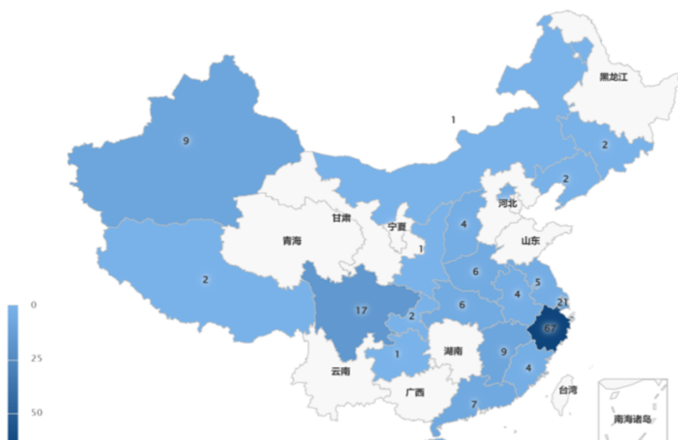

FIGURE 1. Geographical distribution of respondents.

The age structure of the respondents is an important factor in assessing the long-term development potential of CEs. As shown in Figure 2, 32.58% of the respondents are aged 20 to 30, 28.65% are aged 31 to 40, 23.03% are aged 41 to 50, and 15.73% are aged 51 to 60. Of the respondents, 60% are under 40, indicating that young and middle-aged people have become the backbone of China's clinical engineering talent pool.

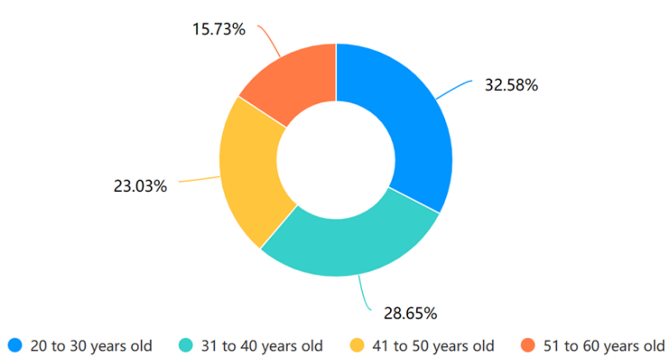

FIGURE 2. Age distribution of respondents.

Among the 178 respondents, it is worth noting that women accounted for only 27% (Figure 3). Encouraging more women to join the clinical engineering talent team is a long way to go.

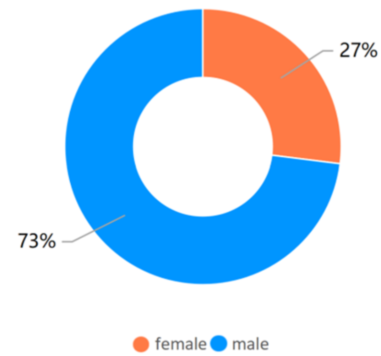

FIGURE 3. Gender distribution of respondents.

Occupational Background

The working years of CEs are an important factor in determining their level of professionalism, knowledge, and experience. In this survey, the distribution of respondents based on their working years is quite diverse. More specifically, 23.03% of the respondents have 1 to 3 years of work experience, indicating many early-career CEs in the workforce. 10.11% have 3 to 5 years of work experience, while 14.61% have 5 to 10 years of work experience. These respondents can be considered to be in the mid-career stage and are likely to have more experience and expertise in the field.

Moreover, the survey results reveal that there are also many CEs with extensive work experience. Specifically, 17.42% have 10 to 15 years of work experience, 10.11% have 15 to 20 years of work experience, and 24.72% have more than 20 years of work experience. This indicates that a significant number of senior CEs have accumulated a wealth of experience and knowledge throughout their careers. Overall, the diverse distribution of working years among respondents in this survey suggests that the clinical engineering field has both experienced and novice professionals.

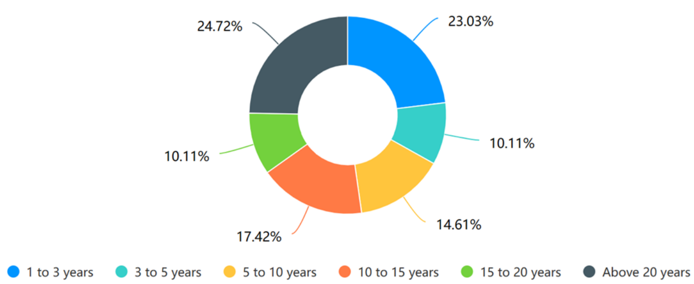

FIGURE 4. Working years distribution of respondents.

Older age is associated with more work experience (Figure 5), which seems to align with the objective law, but the trend of older practitioners with more work experience means that opportunities for professional development in clinical engineering are limited.

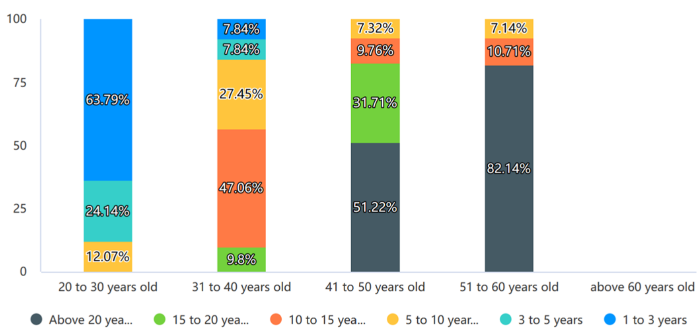

FIGURE 5. Working years of respondents in different age groups.

With the continuous and rapid progress of medical technology and the increasing integration of modern medical equipment into hospitals, the responsibilities of medical engineering departments in China have evolved from focusing on the maintenance of a single piece of medical equipment in the 20th century to covering a series of tasks such as preventive maintenance of medical equipment, regular repair and maintenance, quality control, metrological testing, technical evaluation, clinical evaluation, innovation, and improvement. This has led to an increase in the number of practitioners, and the level of education of personnel is gradually increasing to meet the needs of the role.[3]

The survey also included questions about the educational backgrounds of the respondents. The results showed that the majority of the respondents had an undergraduate degree in an engineering area (46.07%), and a significant number of them had a Master's degree in engineering area (28.65%). However, there were also respondents with educational backgrounds in non-engineering areas, such as undergraduate degrees in other areas (9.55%), Master's degrees in other areas (6.74%), and PhDs in both engineering and non-engineering areas (3.93% and 2.25%, respectively). There was also one respondent who had a degree in another area not covered by the survey options.

Figure 6 compares the educational background of respondents from the China Clinical Engineering Survey in 2021 and 2022. The results show a clear trend towards higher levels of education among CEs.

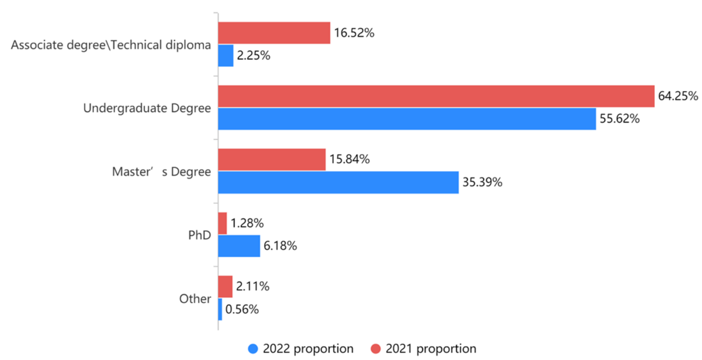

FIGURE 6. Educational background distribution of respondents in 2021 and 2022.

When asked about the main nature of their current position, above-average respondents chose Clinical/Biomedical Engineer (58.99%), followed by Healthcare Technology Managers (12.36%), Medical Equipment Planners (6.74%), Technologists (5.06%), Technicians (10.67%), Professors/Educators/Researchers (1.12%), Consultants (1.12%), and Others (3.93%). However, this question reveals an interesting finding: Chinese CEs focus more on healthcare technology planning, assessment, management, analysis, education, and support (Table 1).

Finally, the survey led to a consensus among CEs in China that there is a registration and certification process in place for CEs in the country.

TABLE 1. Occupational Nature of Respondents

Options	Count	Percentage
Clinical/Biomedical Engineer	105	58.99%
Healthcare Technology Manager	22	12.36%
Medical equipment planner	12	6.74%
Technologist	9	5.06%
Technician	19	10.67%
Professor/Educator/Researcher	2	1.12%
Consultant	2	1.12%
Other	7	3.93%

Knowledge

The knowledge domains were classified based on clinical engineering background knowledge. Respondents were asked to rate the importance of 40 items related to their daily duties and responsibilities, using a 4-point scale: 1 for not important, 2 for minor important, 3 for moderate important, and 4 for high important. The average score for each item was calculated, and the detailed results of the investigation are presented in Table 2.

TABLE 2. The Importance of Each Background Knowledge

Category\Options	Not Importance	Minor Importance	Moderate Importance	High Importance	Average
Medical Device Regulation	3	4	42	129	3.67
Maintenance Management	2	6	53	117	3.6
Quality Management	1	7	63	107	3.55
Computers, Networking, Information Technology	1	12	61	104	3.51
Data Management	2	10	66	100	3.48
Risk Management	2	16	56	104	3.47
Electronics (theory, design, analysis, etc.)	5	17	59	97	3.39
Facilities Management	1	22	64	91	3.38
Surgical Instruments & Devices	4	23	59	92	3.34
Medical Device Innovation	4	17	74	83	3.33
Interoperability of Devices and/or Systems	5	17	72	84	3.32
Procurement Strategies	5	18	72	83	3.31
Engineering Asset Management	2	24	74	78	3.28
Project Management	5	20	77	76	3.26
Respiratory Equipment	4	33	54	87	3.26
Hospital Engineering	7	23	67	81	3.25
Digital Health	4	23	81	70	3.22
Medical Imaging	0	35	73	70	3.2
Health Technology Assessment	7	25	73	73	3.19
Leadership or Executive Skills Coaching	9	25	74	70	3.15
Systems Engineering	5	32	76	65	3.13

Category\Options	Not Importance	Minor Importance	Moderate Importance	High Importance	Average
Patient Safety User/Patient Training	14	33	56	75	3.08
Health Facility Planning and Design	9	37	65	67	3.07
Statistics	3	43	71	61	3.07
Consumables	9	39	72	58	3.01
Management (area/s other than those listed)	13	27	83	55	3.01
Sterilization	10	42	65	61	2.99
Physiological Monitoring	17	40	57	64	2.94
Telemedicine / Telehealth	13	40	72	53	2.93
Hemodialysis	19	43	54	62	2.89
Presentation Skills	10	48	75	45	2.87
Airborne Infection Control	16	47	61	54	2.86
Clinical Laboratory	14	53	57	54	2.85
Human Factors Engineering	19	47	56	56	2.84
Simulation and Modelling	21	51	60	46	2.74
Home care/Virtual care (remote patient monitoring)	23	46	67	42	2.72
Accounting and Finance	15	61	65	37	2.7
Radiation Oncology	28	58	45	47	2.62
Neonatal and/or Pediatric Care	33	52	45	48	2.61
Anesthesia	35	62	35	46	2.52

TABLE 3. Overall Time Spent in Each Group of Activities

Activity\Percentage	0	1~25	26~50	51~90	91~100
Health Technology Management	2.81%	23.03%	29.78%	30.34%	14.04%
Service Delivery Management	5.62%	16.85%	22.47%	32.58%	22.47%
Development,Testing,Evaluation and Modification of Products	16.29%	38.76%	26.4%	12.36%	6.18%
Information Technology / Digital Health	9.55%	39.33%	24.16%	18.54%	8.43%
Education of Others	8.99%	39.89%	29.21%	16.85%	5.06%
Facilities Management / Infrastructure	8.99%	25.28%	29.21%	27.53%	8.99%
Risk Management / Security	0.56%	27.53%	28.09%	29.78%	14.04%
General Management	0.56%	17.98%	29.21%	37.08%	15.17%

Work Activities

Table 3 displays respondents' estimated percentage of time in eight job categories. These categories include health technology management, service delivery management, development, testing, evaluation and modification of products, information technology/digital health, education of others, facilities management/infrastructure, risk management/security, and general management. Besides these predefined categories, respondents were also allowed to provide information about other job categories they worked in. Table 3 data is a valuable resource for gaining insight into the work activities of CEs. This information can inform workforce development and training programs in the field, ultimately leading to better-prepared clinical engineering professionals.

DISCUSSION

Although the survey had a broad geographic scope, with respondents from multiple provinces in China, the fact that a large proportion of the responses (67 out of 178) came from a single province, Zhejiang, could potentially introduce bias to the data. Given that Zhejiang is a relatively affluent province and is home to many well-known medical device manufacturers, the experiences and knowledge of CEs in this region may not fully represent the wider population of CEs in China. Therefore, it is important to interpret the survey results with caution and avoid overgeneralizing based on the experiences of CEs in Zhejiang alone.

The survey results indicate that the clinical engineering community in China is relatively young, with limited work experience. However, it is encouraging to note that practitioners with more than 20 years of experience are still active in similar numbers as young practitioners. This balance between new and experienced professionals bodes well for the future of clinical engineering in China, with promising human resource reserves and team-building prospects for the younger generation.

The survey results also indicate that the vast majority of respondents, 97.75%, held at least an undergraduate degree, with many pursuing engineering-related studies. This finding highlights Chinese clinical engineering practitioners' solid professional knowledge base. It is worth noting that this trend of increasing education among domestic CEs in China is not unique, as global survey results suggest that China is among the countries with the highest percentage of highly educated CEs. In fact, while 80% of CEs worldwide have a bachelor's degree or higher, the figure for China is 97%. However, the low representation of women in the field, accounting for only 27% of the total, is a cause for concern. Efforts to encourage more women to pursue careers in clinical engineering must be made.

In addition to the issue of job diversity, there is also a concern about limited opportunities for professional development within clinical engineering, especially for older practitioners with more experience. China has a well-established registration and certification process for CEs, indicating the profession's maturity. However, in situations with limited avenues for professional development or lateral transitions, experienced practitioners may face the challenge of stagnation, potentially hindering their ability to bring novel ideas and unique perspectives to their work. To address this issue, it is crucial to promote continuing education and training opportunities for CEs. Establishing a body of knowledge (BoK) and a body of practice (BoP) in Clinical Engineering can also facilitate their continuing professional development, allowing them to expand their knowledge and expertise and stay up-to-date with the latest developments in the field. Providing opportunities for continuing education and interdisciplinary collaboration can help experienced practitioners maintain their effectiveness and innovation, ultimately leading to a more dynamic and effective clinical engineering profession.

The issue of the main nature of work in clinical engineering sheds light on the various roles that practitioners play in the healthcare industry. In China, most CEs identify as clinical/biomedical engineers, focusing on planning, evaluation, management, analysis, education, and medical technology support. The position also includes functions such as healthcare technology managers, medical equipment planners, clinical engineering technologist, clinical engineering/biomedical equipment technician and others. Practitioners must possess diverse skills and knowledge to effectively carry out their responsibilities. Additionally, many respondents were identified as healthcare technology managers and medical equipment planners. As time progresses, the work of CEs is no longer limited to the maintenance and repair of medical equipment. By combining their understanding of clinical needs, they can effectively provide hospitals with beneficial and appropriate configurations, management, and medical equipment planning.[4] The diversity of reported positions also reflects the wide range of expertise required in clinical engineering, from technical proficiency to leadership and management skills.

Regarding the importance of knowledge, three parts can be roughly divided. Medical device regulation, maintenance management, quality management, data management, risk management, facilities management, and implementation methods such as computers, networking, and information technology rank highly in the clinical engineering industry. Among them, medical device regulations are considered to be the most important as a factual basis. This highlights the significance of regulatory compliance and the proper management of medical devices in clinical engineering. Clinical engineering work in China is mainly focused on managing and maintaining hospital operations, which is also reflected in the main nature of the work of CEs. Today's medical activities development in China greatly depends on medical devices' safety, reliability, and stability. CEs effectively ensure the normal operation of medical devices through evaluation, maintenance, quality control, measurement, etc., to ensure the normal development of medical activities.[5] China promulgated the "Regulations on the Supervision and Administration of Medical Devices" on January 4, 2000.[6] After two revisions, the latest version was implemented on June 1, 2021. It shows that medical devices must follow risk management principles, whole process control, scientific supervision, and social governance. This is a guide for all CEs in China.

The important knowledge areas that follow are some of the more specialized and precise subdivisions of day-to-day management work, such as surgical instruments & devices, procurement strategies, engineering asset management, project management, hospital engineering, statistics and health technology assessment, etc. Mastery of these areas can help bridge the knowledge gap for Chinese CEs, allowing them to ensure high-quality, safe, and efficient healthcare operations. Knowledge of surgical instruments and equipment is crucial for ensuring the safety and success of medical procedures, while a procurement strategy is necessary to obtain the necessary resources while maximizing the budget. Engineering asset management involves the management of complex systems, requiring expertise in monitoring, maintaining, and optimizing equipment. Project management is critical to coordinating resources, managing timelines, and communicating effectively with stakeholders. Moreover, hospital engineering encompasses various technical disciplines, including electrical, mechanical, and structural engineering. Effective CEs must be able to design, maintain, and optimize complex systems to ensure healthcare facilities' safe and efficient operation is another essential knowledge area for CEs. A solid understanding of statistical analysis is crucial for evaluating the performance of healthcare systems, identifying areas for improvement, and measuring the impact of interventions. Health technology assessment (HTA) is an emerging field that is becoming increasingly important in healthcare. It systematically evaluates health technologies' safety, efficacy, cost-effectiveness, and social impact, including medical devices and equipment. HTA provides valuable information for healthcare decision-makers, helping them make informed decisions about which technologies to invest in and how to allocate resources effectively.

Finally, the knowledge categories in the lower part share a common feature: they overlap with the expertise of other occupations in the hospital. For example, sterilization is generally responsible for nurses, anesthesia is generally for anesthesiologists, and accounting and finance are generally responsible for professional accountants.

This rule also continues in the survey results of time spent on practical activities. Activities related to the clinical engineer's primary task—ensuring clinical applications for the medical device business (e.g., service delivery management, general management)—are more time-consuming and therefore ranked high.[7] Conversely, less relevant activities (such as education of others, development, testing, evaluation and modification of products) take up less time and therefore ranked lower. This shows that Chinese CEs may be more inclined to the direction of traditional clinical engineer functions. However, CEs play a bridge role in developing medical device products. They are integrators of medical technology, guardians of equipment safety, evaluators of instrument applications, and communicators between hospital construction and industrial development. To promote the further development of China's clinical engineering field, it is necessary to attach importance to industry-university-research-medical cooperation and knowledge sharing, and incorporate it into the strategic career development plan.

CONCLUSION

Under the new requirements of hospital-refined management and modern medical technology, the development of clinical engineering in China is facing new challenges. Strengthening the construction of the BoK and the BoP is an important measure for adapting to environmental changes and improving comprehensive strength. This survey may not cover the scope of all clinical engineering personnel and may not fully reflect the knowledge needed for clinical engineering in China, but the research results have predicted a set of knowledge required for clinical engineering in China.

The BoK and BoP in clinical engineering still require in-depth research, and determining key knowledge requires the consensus of numerous authoritative experts and stakeholders. Unless the BoK defined, relevant practices, research, and scholarly teaching information are collected, and consensus is reached, the clinical engineering knowledge system framework will be incomplete. It should be noted that the systemic nature of the knowledge system must be established based on verified evidence.

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