

论坛

我国临床研究人才队伍建设现状与改进策略研究

李冬凉^{1*}, 王甦平^{1*}, 何豪², 王炳顺², 周良³

1. 上海交通大学医学院学科规划处, 上海 200025; 2. 上海交通大学医学院临床研究中心生物统计教研室, 上海 200025; 3. 上海交通大学公共卫生学院, 上海 200025

[摘要] **目的**· 调研我国临床研究人才队伍建设现状与问题, 并提出针对性改进策略。**方法**· 通过文献查阅、专家访谈和2轮德尔菲法自制调查问卷, 对来自27个省、市、自治区的医院、生物医药企业、医学院校、政府部门中熟悉临床研究的相关人员(583人)开展网络问卷调查, 并对调研结果进行统计分析。**结果**· 共计回收问卷583份, 其中有效问卷579份, 有效率为99.3%。调研结果显示: ① 临床研究人才缺乏和人才发展环境不佳是制约我国高水平临床研究的关键因素。② 在被调查对象中, 对当前临床研究人才培养不尽如人意(很不满意、不满意和一般)者占比72.7%。主要问题包括: 高水平研究型人才的缺乏, 同时缺乏一支专业支撑队伍; 目前的绩效评价体系过于单一且薪酬、激励未向临床研究工作倾斜, 从事临床研究的医务人员、临床研究支撑服务人才缺乏晋升渠道等。③ 改进策略包括: 系统性提升医务人员临床研究能力, 完善临床研究能力培训课程体系, 在学校教育阶段和在职教育阶段采取不同的培养方式, 在临床研究人才队伍的扩充上要注重临床研究型医师和临床研究方法学专门人才两支队伍的培养。**结论**· 提升我国临床研究水平, 急需扩大优秀医学学生的培养数量, 完善临床研究方法学、相关法规等课程; 鼓励高水平研究型医师指导新人, 在研究项目中做好传帮带; 系统化提高在职医务人员的科研能力, 做好临床研究项目的规范实施、选题设计等培训; 凝聚一支高水平复合型临床研究医务人员队伍, 加大临床研究方法学的专业人才培养力度; 进一步重视临床研究, 从职称晋升、薪酬待遇、科研评价等方面完善临床研究人才的发展环境。

[关键词] 临床研究; 人才队伍建设; 现存问题; 改进策略**[DOI]** 10.3969/j.issn.1674-8115.2023.09.016 **[中图分类号]** R197.322 **[文献标志码]** A

Analysis on the existing problems and improving approaches to the clinical research talents team cultivation in China

LI Dongliang^{1*}, WANG Suping^{1*}, HE Hao², WANG Bingshun², ZHOU Liang³

1. Discipline Planning Department, Shanghai Jiao Tong University School of Medicine, Shanghai 200025, China; 2. Department of Biostatistics, Clinical Research Institute, Shanghai Jiao Tong University School of Medicine, Shanghai 200025, China; 3. Shanghai Jiao Tong University School of Public Health, Shanghai 200025, China

[Abstract] **Objective**· To investigate the current situation and problems of the construction of clinical research talents team in China, and propose targeted improvement strategies. **Methods**· Self-designed questionnaires were made after literature review, expert interviews and two rounds of Delphi. An online questionnaire survey was conducted on 583 clinical research-related personnel from hospitals, biomedical enterprises, medical colleges and government departments in 27 provinces, cities and autonomous regions, and the survey results were analyzed. **Results**· A total of 583 questionnaires were collected, 579 of which were valid, with an effective rate of 99.3%. The research results showed that: ① The lack of clinical research talents and the poor development environment of talents were the key factors restricting the high-level clinical research in China. ② Among the respondents, 72.7% of them were dissatisfied (very dissatisfied, dissatisfied and average) with the current training of clinical research talents. The main problems included lack of high-level research talents and a professional support team; the current performance evaluation system was monotonous, the salary and incentive were not profitable for clinical research, and medical

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personnel engaged in clinical research and support staff lacked promotion channels, etc. ③ The improvement strategies included systematically improving the clinical research ability of medical personnel, improving the clinical research training curriculum system, adopting different training methods in the school education stage and in-service education stage, and attaching more importance to the two teams' training, clinical research physicians and clinical research methodology professionals. **Conclusion**· Currently, it is urgent to expand the number of excellent medical students and improve the courses of clinical research methodology and relevant laws and regulations, encourage experienced research-oriented doctors to guide new staff in research projects, systematically improve the scientific research ability of current medical personnel, pay more attention to training of standardized implementation of clinical research projects, topic selection design and others, gather a high-level team of composite clinical research medical personnel, increase the amount of professionals in clinical research methodology, further attach importance to clinical research, and improve the development environment of clinical research talents from the aspects of professional title promotion, salary, scientific research evaluation, etc, so as to improve the level of clinical research in China.

[Key words] clinical research; talent team construction; existing problem; improvement strategy

临床研究不仅是临床诊治方法及医学学科发展的重要保证, 验证科学假设、提供循证医学证据、推动医学进步的必由之路, 也是人民健康生活的重要保障^[1]。伴随着临床研究理念和方法的日新月异, 复合型医务人员以及方法学专业人才显得尤为重要。经过几十年的发展, 西方发达国家在临床研究方面已形成了相对完善的人才培养体系, 以及由临床医师、护士、专职科研人员、项目管理、协调人员和临床研究方法学专业人员等组成的分类发展体系^[2], 给医学水平、医药产业的发展带来了快速提升。与发达国家相比, 我国的临床研究起步较晚且尚处于较低水平^[3-4], 创新程度较高的 I 期临床试验数量及国际多中心临床试验数量较少^[5], 多数研究设计缺乏严谨性和科学性, 统计分析方法错误率较高, 被引入高质量国内外临床实践指南的研究结果较少^[6-7]。在临床医学证据方面我国仍处在“进口国”位置, 超 90% 的临床诊疗技术源于西方发达国家的相关研究, 多数常见疾病的诊断、治疗和预防等均基于西方国家人群的研究证据^[8]。

目前, 在我国临床研究越来越受到重视。2013 年, 由科技部、国家卫生计生委、总后卫生部正式启动了 13 个国家临床医学研究中心建设, 带领全国各地的医院加强临床研究能力。此后相关文件陆续发布以鼓励医疗机构、医学研究机构、医药高等学校等开展临床试验。截至 2022 年, 我国国家临床医学研究中心已达 50 家, 各类临床研究机构陆续兴起, 这使得高水平、专业化的人才队伍建设成为了亟待解决的问题, 需要深入调研与思考。故而本研究通过问卷调研, 分析我国临床研究人才队伍建设的现状与存在的问题, 并提出有针对性的改进策略。

1 对象与方法

1.1 调查对象及其资料收集

本研究以来自全国 27 个省、市、自治区的医院、生物医药企业、医学院校、政府部门中熟悉临床研究的相关人员 (共计 583 人) 为调查对象。收集上述对象的相关资料, 包括性别、学历、职称、工作单位、职业等。

1.2 研究方法

本研究采用问卷调查法, 对我国临床研究人才建设情况进行分析。

1.2.1 问卷制作及其内容 本研究通过文献查阅、专家访谈和 2 轮德尔菲法进行问卷制作。首先, 基于中国知网、万方、维普等文献数据库, 系统检索 2010 年 9 月—2021 年 9 月间与“临床研究人才发展现状与改进路径”主题相关的文献。通过文献归纳分析, 初步形成针对该主题的调研问题清单。其次, 邀请 21 位政府相关部门、高校科研管理部门、医院临床研究、生物医药企业的相关专家进行半结构化访谈, 对调研问题进行补充和修改。再次, 开展 2 轮德尔菲论证对调研问题及选项进行完善。在该论证中专家权威系数为 0.837, 问题总体变异系数为 6.8%, 肯德尔系数 (Kendall) 为 0.474 ($P < 0.001$), 总体意见一致性较强。最后, 根据专家意见优化问题及选项, 形成调查问卷。

调查问卷主要包括: 当前制约我国高水平临床研究的主要因素界定、我国临床研究人才队伍建设的现状、问题以及改进策略, 共 8 个问题, 详见表 1。

表1 调查问卷的问题清单

Tab 1 Question list in questionnaire

Number	Main question
1	What do you think are the main factors restricting high-level clinical research in China?
2	Are you satisfied with the current situation of clinical research talent training in China?
3	What types of talents are the most lacking in the clinical research team at present?
4	What are the factors restricting the development of clinical research talents in China?
5	What are the clinical research capabilities that need to be improved for medical personnel?
6	What specialized courses are most needed to improve the clinical research ability of medical personnel?
7	To improve the clinical research ability of medical personnel, which training methods are more helpful?
8	What are the most necessary measures to fill the gap of clinical research methodology talents, clinical research project management specialists, clinical research coordinators and other professionals?

1.2.2 问卷发放 待问卷制作完毕后,本研究通过“问卷星”的形式向调查对象进行网络问卷调研。

1.3 统计学方法

所有回收的调查问卷经审核后,使用SPSS 22.0软件进行统计学分析。定性资料以例数和百分率表示,采用 χ^2 检验进行组间比较。调查问卷中的某问题选项被选中的结果采用帕累托图(亦称主次因素排列图)进行分析和展示,累积频率超过80%的前N个选项为该问题的主因。 $P<0.05$ 表示差异具有统计学意义。

2 结果

2.1 问卷有效率及调查对象的基本情况

本研究共发放调查问卷583份,回收问卷583份;其中有效问卷579份,有效率为99.3%。在有效问卷对应的人群中,男性333人、女性246人,研究生学历276人(占比47.7%),高级职称136人(23.5%),主要来自上海(224人)、河南(63人)、北京(49人)等地(分别占比38.7%、10.9%、8.5%)。具体情况见表2。

2.2 我国临床研究人才发展的现存问题与改进策略

2.2.1 影响我国高水平临床研究的主要因素分析 首先,本研究对影响我国高水平临床研究的相关因素进行调查,结果(图1)发现制约高水平临床研究的主要因素包括“临床研究一般周期过长,临床研究者迫于职称、评奖等要求,尽可能选择短、平、快的研究课题”(29.7%)、“目前科研评价体系导致‘轻临床、重基础’研究立项状况”(20.8%)、“临床研究牵涉

表2 调查对象的基本情况[n(%)]

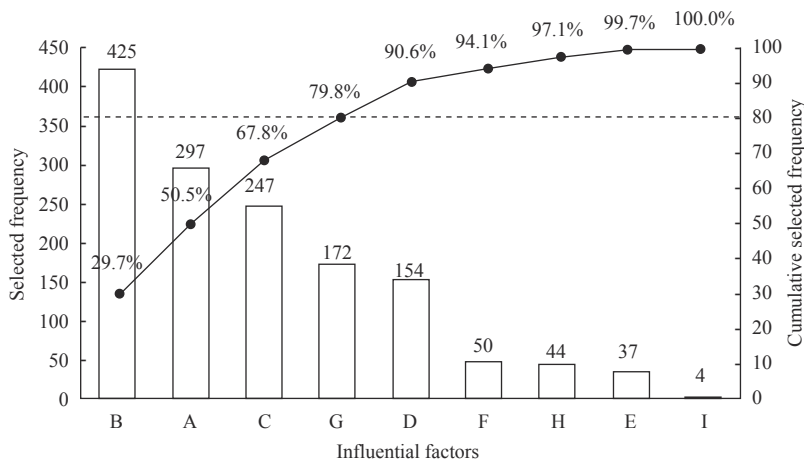
Tab 2 Basic information of the respondents [n(%)]

Item	Respondent (n=579)
Gender	
Male	333 (57.5)
Female	246 (42.5)
Education ground	
Doctor degree	114 (19.7)
Master degree	162 (28.0)
Bachelor degree	227 (39.2)
Undergraduate	76 (13.1)
Professional title	
Senior	60 (10.4)
Deputy senior	76 (13.1)
Medium	165 (28.5)
Primary	220 (38.0)
Under primary	58 (10.0)
Work place	
Hospital	246 (42.5)
Grade-A tertiary	187 (32.3)
Non grade-A tertiary	59 (10.2)
Enterprise	134 (23.1)
College and university	111 (19.2)
Government	47 (8.1)
Others	41 (7.1)
Occupation	
Physician	183 (31.6)
Nurse	60 (10.4)
Teacher	86 (14.9)
Researcher	30 (5.2)
Administrator	37 (6.4)
Corporation personnel	137 (23.7)
Others	46 (7.9)

面广,缺乏鼓励协作成果共享的举措以及建设协作共享的科研文化”(17.3%)、“医务人员日常诊疗工作

忙, 很难兼顾研究周期长的临床研究项目, 如研究者发起的项目”(12.0%)、“高水平研究人才的缺乏, 同时缺乏一支专业支撑队伍”(10.8%)等。而这些

因素均与临床研究人才队伍建设的现况和发展环境密切相关, 因此我们聚焦临床研究人才发展的现存问题进行后续分析。



Note: A. At present, the scientific research evaluation system has led to the establishment of research projects that focus on “less clinical than basic”. B. Generally, the clinical research cycle is too long, and clinical researchers are forced to choose short, easy and fast research topics as far as possible due to the requirements of professional titles, awards, etc. C. Clinical research involves a wide range of areas, lacking initiatives to share collaborative achievements, and build a collaborative research culture. D. Lack of high-level research talents and a professional support team. E. The number of clinical research wards is limited. F. Insufficient investment in clinical research and poor funding channel. G. Medical personnel are busy with their daily diagnosis and treatment, while some types of clinical researches, such as those initiated by researchers, take too much time and they cannot take care of both. H. Lack of channels to understand research frontiers and obtain other internal and external research experience, and limited research ideas. I. Others.

图1 制约我国高水平临床研究的影响因素的帕累托图

Fig 1 Pareto diagram of influential factors restricting high-level clinical research in China

2.2.2 临床研究人才培养现状的满意度评价 调研结果显示, 在所有调研对象中对临床研究人才培养现状表示很满意的仅16人(占比2.8%), 而表示很不满

意、不满意和一般的共421人(72.7%); 有关三甲医院、非三甲医院、非医疗机构这3类人员的满意度评价的具体数据见表3。

表3 调查对象对我国临床研究人才培养现状的满意度评价

Tab 3 Satisfaction evaluation of respondents on the current clinical research talent cultivation in China

Satisfaction	Respondents (n=579)/n (%)	Hospital staff (n=246)/n (%)		Non-hospital staff (n=333)/n (%)
		Grade-A tertiary hospital (n=187)	Non grade-A tertiary hospital (n=59)	
Very dissatisfied	77 (13.2)	14 (7.5)	4 (6.8)	59 (17.7)
Dissatisfied	137 (23.7)	27 (14.4)	17 (28.8)	93 (27.9)
Average	207 (35.8)	69 (36.9)	18 (30.5)	120 (36.0)
Satisfactory	142 (24.5)	69 (36.9)	19 (32.2)	54 (16.2)
Very satisfied	16 (2.8)	8 (4.3)	1 (1.7)	7 (2.1)

2.2.3 临床研究人才队伍建设现存问题的评价 从临床研究人才队伍的结构来看, 调研结果(表4)显示,

依据人才类型的缺乏程度排序, 研究型医师的缺乏度第一, 临床研究方法学人才(如统计师)位列第二。

表4 调查对象对临床研究人才类型的缺乏程度的评价统计

Tab 4 Statistics of respondents' evaluation on the lack of clinical research talent type

Lack of talent type	No.1/n	No.2/n	No.3/n	No.4/n	No.5/n	No.6/n	Ranking average score/score	Final ranking
Research physician	277	50	40	28	21	1	5.3	1
Clinical research methodology talent (such as statistician)	115	151	75	31	17	0	4.8	2
Full time scientific researcher	99	93	53	41	70	1	4.3	3

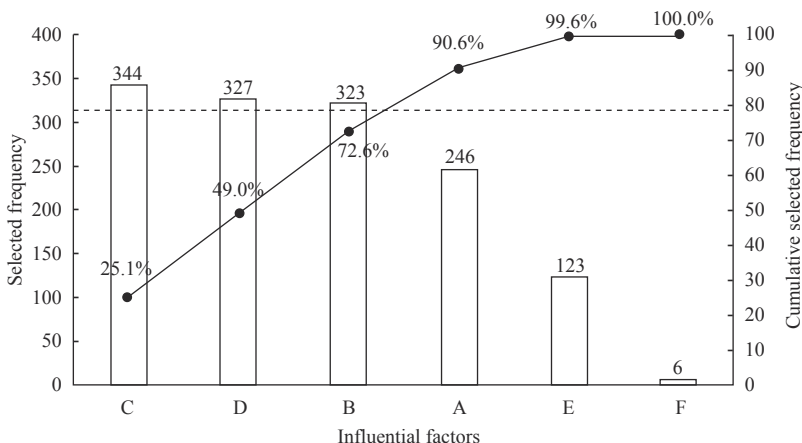
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Lack of talent type	No.1/n	No.2/n	No.3/n	No.4/n	No.5/n	No.6/n	Ranking average score/score	Final ranking
Research nurse	1	2	3	4	5	0	3.3	4
Project management coordinator	1	2	3	4	5	6	2.7	5
Others	1	2	0	4	5	6	2.4	6

Note: In this statistics, 6 points are scored for No.1 (the most lacking), 5 points are scored for No.2, and 1 point is scored for No.6 (the least lacking). Total score (one talent type) = Frequency of ranking No.1×6 + Frequency of Ranking No.2×5 + ... + Frequency of Ranking No.6×1. Ranking average score (one talent type) = total score/total frequency selected.

从临床研究人才队伍建设的制约因素来看, 调研结果显示“目前的绩效评价体系过于单一, 薪酬、激励未向临床研究工作倾斜”(25.1%)、“在现有评聘体系中, 无临床研究系列职称, 从事临床研究的医务人

员、临床研究支撑服务型人才缺乏晋升渠道”(23.9%)、“临床研究人才匮乏, 现有人员的临床研究能力不足”(23.6%)、“管理者对临床研究重要性认识不足”(18.0%)是主要因素, 具体数据见图2。



Note: A. Managers have insufficient understanding of the importance of clinical research. B. There is a shortage of clinical research talents, and the current personnel are lack of clinical research ability. C. The current performance evaluation system is monotonous, meanwhile the salary and incentive are not profit able for clinical research. D. In the existing evaluation and employment system, there is no clinical research professional title, and medical personnel engaged in clinical research and support staff lack promotion channels. E. The lack of research culture of collaboration and sharing makes it difficult to form a strong clinical research cooperation team. F. Others.

图2 制约临床研究人才建设的影响因素的帕累托图

Fig 2 Pareto diagram of influential factors restricting the construction of clinical research talents

2.3 我国临床研究人才队伍建设的改进策略

本研究从提升在职临床研究人员的科研能力、扩充临床研究人才队伍这2个维度, 对临床研究人才队伍建设行进一步的细化分析。首先, 科研能力提升方面, “规范化实施临床研究, 包括质量控制与数据采集”(27.4%)、“发现临床问题、凝练研究方向”(23.8%)、“临床研究设计”(21.2%)、“统计分析等临床研究方法”(14.0%)应是能力培训的重点, 具体数据见图3。

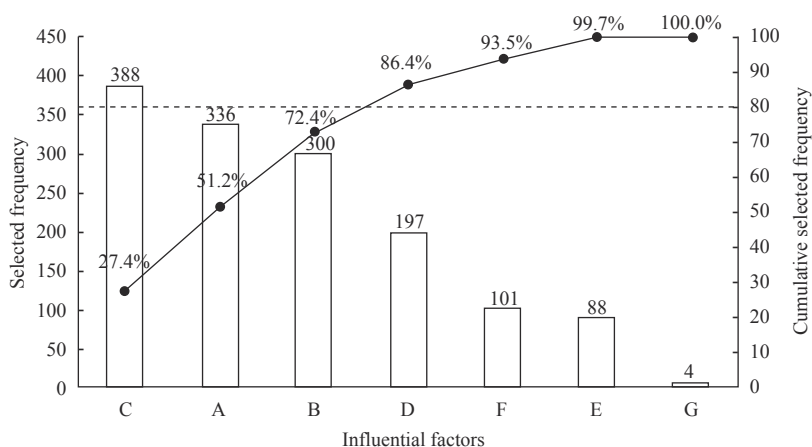
其次, 从理论课程体系建设的角度, 应重点加强“临床研究方法学课程(包括研究设计、流行病学与统计学等方法学内容)”(30.8%)、“临床研究相关法规(如伦理规范、监管政策等)”(24.5%)、“临

床本专业核心知识及新进展(包括理论与操作)”(23.4%)、“医学前沿理论与技术”(11.3%)等课程体系建设, 具体数据见图4。

再次, 从临床研究人才的培养方式来看, “在医师和护士的学校培养阶段, 增加设置临床研究相关课程”是首选方式(占比55.8%), “有临床研究经验的导师指导新人, 团队传帮带”“开展短期在职培训, 结合案例进行教学”分别位列第二、第三, 具体数据见表5。

在队伍扩充方面, 调研结果(图5)显示临床研究人才队伍的扩大主要可从如下4个方面着手, 即“在医学统计、预防医学、临床护理、医学检验等相关专业培养中, 增加临床研究课程”(31.0%)、“加大临床研究方法学专业招生, 培养临床研究专业人

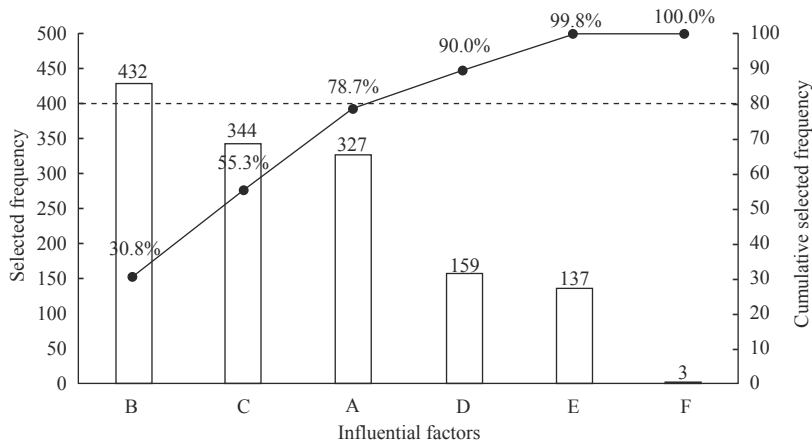




Note: A. Finding clinical problems and refining research direction. B. Clinical study design. C. Standardizing clinical research, including quality control and data collection. D. Statistical analysis and other clinical research methods. E. Knowing relevant laws and regulations. F. Communication, coordination, organization and management during project implementation. G. Others.

图3 临床研究人员亟需提升的核心能力的帕累托图

Fig 3 Pareto diagram of core competences that clinical researchers need to improve



Note: A. Core knowledge and new progress of clinical specialty (including theory and operation). B. Clinical research methodology course (including research design, epidemiology and statistics). C. Laws and regulations related to clinical research (such as ethical norms, regulatory policies, etc.). D. Advanced medical theories and technologies. E. Interpretation of actual cases in clinical research. F. Others.

图4 临床研究人员能力培训的课程体系建设的帕累托图

Fig 4 Pareto diagram of curriculum system construction for competence training of clinical researchers

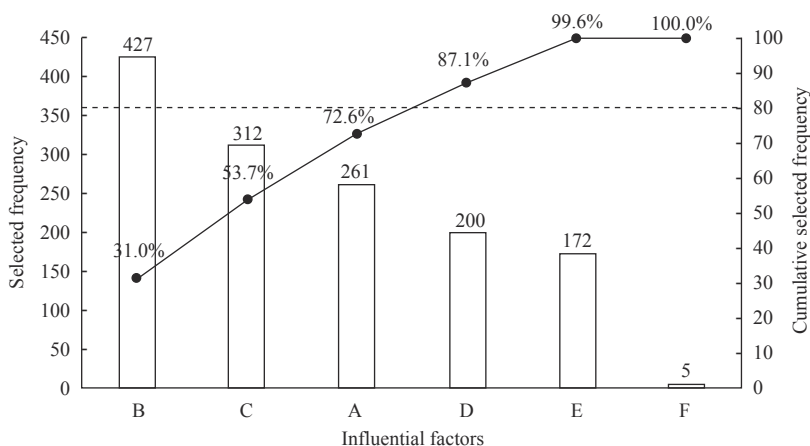
表5 临床研究人才培养方式的选择及统计

Tab 5 Selection and statistics of the training methods for clinical research talents

Item	Respondents (n=579)/n (%)	Ranking
Adding clinical research-related courses in the school training stage of doctors and nurses	323 (55.8)	1
Guiding new people and helping them in teams by tutors with clinical research experience	287 (49.6)	2
Carrying out short-term on-the-job training and teaching with cases	279 (48.2)	3
Participating in high-level and standardized clinical research projects	208 (35.9)	4
Conducting expert forums to promote peer exchanges	180 (31.1)	5
Joint training with enterprises with clinical research experience, and short-term exchange of talents	148 (25.6)	6
Others	2 (0.3)	7

才” (22.7%)、“向社会招聘具有相关资质的临床研究从业人员, 开展短期培训” (18.9%)、“设置临床

研究学位点, 吸引并培养研究生层次的临床研究方法学人才” (14.5%)。



Note: A. Recruiting clinical research practitioners with relevant qualifications from the society, and carrying short-term training. B. Increasing clinical research courses in the training of medical statistics, preventive medicine, clinical nursing, medical laboratory and other related majors. C. Increasing the enrollment of clinical research methodology, and cultivating clinical research professionals. D. Setting clinical research degree points to attract and cultivate graduate level clinical research methodology talents. E. Setting special clinical research posts, improving the professional title evaluation and employment scheme, and improving the career stability of clinical researchers. F. Others.

图5 临床研究人才队伍扩充关键途径的帕累托图

Fig 5 Pareto diagram of key approaches to expand clinical research talents

3 讨论

从调研结果可以看出,高层次研究型医师和临床研究方法学专业人才缺乏,以及临床研究人才队伍的发展环境不佳,是制约我国临床研究发展的瓶颈问题。基于此,本研究提出如下思考。

首先,扩大优秀复合型医学生的培养数量与质量。当前我国临床研究人才不足,尤其是高层次研究型医师缺乏,使得能够领衔研究者发起的、全球多中心临床研究项目的人才凤毛麟角。作为医学高层次人才培养的摇篮,高水平医学院校一方面应扩大医学生的招生数量,在临床研究方法学课程、相关法规等专业课程的设置及其教材的编写、教学方案的完善等方面进行探索,以提高临床研究课程质量,完善医学生在校期间的系统化临床研究课程教学^[9-10];另一方面应医教研协同,与附属医院、生物医药产业携手,形成医学生“全链条”的人才培养体系,发挥多学科、产学研协同育才优势,为社会输送高质量复合型医学人才。

其次,做好医师临床研究能力提升的在职培训。加大在职培养力度,对临床研究型医师进行系统性的科研能力提升,在临床研究项目规范实施、选题设计等方面开展短期在职培训并结合案例进行教学,开展科研论坛、讲座等,帮助医师掌握最新的临床专业知识及研究进展;鼓励青年医师参与高水平、规范的临床研究项目,在实践中锻炼成长,并发挥高水平研究

型医师的传帮带作用,为我国临床研究的发展培养人才^[11]。

第三,加大临床研究方法学的专业人才培养力度。在我国,临床研究服务机构的整体从业人员的专业化素质偏低,专业人才缺乏成为了行业发展的一大瓶颈^[12-13]。医学院校、医院和科研机构的薪酬待遇在市场上的竞争力较弱,使得临床研究方法学专业人才在上述机构更为稀缺。目前,部分医学院校已开设相关专业课程以进行职业教育;而在高层次的学历教育方面,国内仅北京大学设立了“临床研究(方法学)二级学科硕士及博士学位点(从2015年起招收研究生)。因此,在我国建立临床研究方法学专业人才培养体系不仅是医学教育界面临的较大挑战,也是该领域学者们的使命和责任^[14]。医学院校一方面应顺应需求,增加临床研究方法学人才的培养数量,另一方面需加快产出优秀方法学研究成果、编制专业教材,在临床研究方法学的创新、应用中进行探索,以建设临床研究方法学学科,培育高水平的临床研究方法学专业人才。

第四,重视临床研究,进一步优化临床研究人才队伍发展环境。在医学科研领域仍然存在重基础研究、轻临床研究的现象,同时临床医师忙于应对繁重的医疗事务、职称评聘量化要求,参与临床研究的积极性不够。当前,临床研究方法学专业人才在国内的待遇并不高,使得该类人才外流、转行的现象比较严重。这就要求政府、高校、医院的相关

管理部门进一步重视临床研究, 优化临床研究人才队伍的发展环境, 提高临床研究人才待遇, 完善临床研究人才职称晋升、绩效评估及资源分配体系, 倡导鼓励协同合作、成果共享的科研文化, 引导、激励各类临床研究人才释放创新活力、发挥合力, 从而促进临床研究水平的快速提升。

目前, 高层次临床研究人才的匮乏已严重影响了我国医学领域的发展。在借鉴发达国家的经验的同时, 我们还应当扩大招生规模, 完善学校教育和在职培训体系, 加大研究型医师、临床研究方法学专业人才等的培养力度, 扩充我国临床研究的人才队伍, 从而从根本上推动临床研究的发展, 促进我国真正地成为世界医学科研领域的前沿阵地。

利益冲突声明/Conflict of Interests

所有作者声明不存在利益冲突。

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作者贡献/Authors' Contributions

李冬凉、王炳顺参与了研究设计; 李冬凉、王炳顺、王甦平、何豪参与了问卷设计和数据收集; 李冬凉、周良、王甦平参与了数据分析、论文的写作和修改。所有作者均阅读并同意了最终稿件的提交。LI Dongliang and WANG Bingshun participated in the research and design. LI Dongliang, WANG Bingshun, WANG Suping and HE Hao participated in the questionnaire design and data collection. LI Dongliang, ZHOU Liang and WANG Suping participated in data analysis, paper writing and revision. All the authors have read the last version of paper and consented for submission.

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