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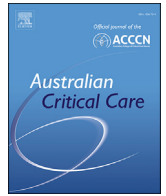


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Research paper

Organisation of clinical research in intensive care units: A scoping review

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A B S T R A C T

Background: Clinical research is essential for the development and progress of therapies and procedures. Intensive care units (ICUs) manage the sickest patients. Numerous clinical trials are organised in ICUs to evaluate new treatments or support techniques. Concomitantly, new professions involved in clinical research set-ups are emerging.

Aim: The aim of this scoping review was to identify the nature and extent of research evidence on the organisation of clinical research in ICUs.

Methods: This review focusses on observational and qualitative narrative studies dealing with clinical research organisation in ICUs, with a special interest in structures coordinating research, the roles of clinical research professionals, and the training required. Medline and Embase were analysed between January 2000 and June 2024. Assessment of the study quality was based on the Let Evidence Guide Every New Decision evaluation system and the Newcastle–Ottawa quality assessment scale.

Results: Of the 14 studies reviewed, four were narrative and 10 observational descriptive. All were based on cross-sectional surveys. Most studies were carried out in North America, the United Kingdom, and Australia/New Zealand. ICU clinical research professionals were mostly female nurses aged between 31 and 50 years who had a wide diversity of training profiles and performed greatly varied tasks from data collection to publication of the article. Reported job satisfaction depended on the degree of autonomy, the workload, the extent of professional recognition, and opportunities for professional promotion.

Conclusions: The organisation of ICU clinical research reflects considerable diversity in training, tasks, job organisation, and responsibilities.

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1. Background

Clinical research is essential for the development and progress of therapies and procedures. It also helps to improve practices. Thus, research informs care and enables us to adopt best practices.¹ There is much evidence that the more a hospital is involved in research, the better the patient care.² To conduct research in ICUs, there needs to be a skilled workforce and supporting organisation.

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Clinical trials require not only a precise methodology but also ethical rules and good practices. As a result of experiments carried out on humans during the Second World War, an international initiative arose to define ethical principles. These were set out in the Nuremberg Code of 1947, which forms the basis of the laws that now regulate human experimentation. These laws have since been supplemented by the declarations of Helsinki in 1964, Tokyo in 1975, and Manila in 1981. Based on these declarations, the first Good Clinical Practice (GCP) guidelines were drawn up in 1987. Since 1995, the International Conference on Harmonisation (ICH) has enabled the USA, Japan, and Europe to harmonise their practices.³ In 2001 and 2014, European directives were established to regulate research on drugs. In France, for example, the main current laws are the 2004 laws that established the Committees for the Protection of Individuals, in accordance with the 2001

European Union directive, and the Jardé law in 2016 that applies to all research involving human persons as stipulated in the European Union regulation of 2014. In Australia, national legislation covers all research involving humans.⁴

Against this background, clinical research has become more professional, with the emergence of new positions for clinical research professionals such as clinical research coordinators, and new institutions dedicated to the organisation of research, from the design of the project to its implementation and the dissemination of the results. Practices vary widely, however, from one country to another. Data in the literature concerning the organisation of clinical research are scattered. For example, in the USA, Abebe et al.⁵ made an overview of guidelines concerning the organisation of clinical research centres. Again, in the USA, Bevans et al.⁶ described the roles of clinical research nurses at the National Institute of Health clinical centre in a study that clearly involves two different categories of the clinical research workforce.

The intensive care unit (ICU) is the hospital department that provides care to the most seriously ill patients and to those who are very badly injured or require postoperative monitoring. Numerous clinical trials are performed in ICUs to assess new treatments, organ supports, and the organisation of care. This research is all the more specific, particularly regarding ethical considerations, since most of the time it is performed in an emergency situation on extremely vulnerable and critically ill patients often unable to give their direct consent. Before the implementation of GCP guidelines in the area of research, and because of its specificity and technicality, clinical research in ICUs was conducted by physicians and nurses, and only recently have clinical research professionals been involved, as described in several studies on the organisation of clinical research in the special field of ICUs.^{1,7–18} The organisation of research in ICUs can be highly structured, with the Australian and New Zealand Intensive Care Society Clinical Trials Group (ANZICS CTG) being one of the most representative examples.¹⁹

The aim of the present work was to perform a scoping review of published studies on the organisation of academic clinical research in the ICU setting.

2. Methods

2.1. Data sources and searches

This scoping review focusses on studies and reviews on the organisation of clinical research in ICUs in terms of (i) the structures coordinating hospital clinical research; (ii) the role and status of the different clinical research professionals; and (iii) the mandatory and actually delivered training for the professionals concerned. All studies that did not address these topics were excluded from our analysis, in particular those relating to national laws that deal with the organisation of clinical research. We only included articles written in English and published between 1 January 2000 and 3 June 2024.

A literature search was performed with Medline and Embase. The search terms used were “research coordinator”, “clinical nursing research”, “clinical research professional”, “clinical research practitioners”, “clinical trial management”, “clinical research organisation”, AND “critical care” OR “intensive care” (see Boolean algorithms in Supplementary Data).

2.2. Study selection

The studies were selected by an independent review process. Two independent reviewers (MA and CD) reviewed the abstracts for eligibility. If disagreement arose related to the content of an abstract, the full article was obtained to determine the eligibility of

the study. Excluded from the analysis were studies not dealing with the ICU setting and that did not address at least one of the following three themes: organisation, structuring, and management of clinical research; roles of clinical research personnel; and training and career development of clinical research professionals.

2.3. Data extraction and quality assessment

A data extraction form was devised before the articles were reviewed to record the name(s) of the author(s), journal, year of publication, country, type of study, study population, type of intervention performed, and the topic(s) addressed from the three selection criteria. To assess the quality of the included studies, we used the Newcastle–Ottawa quality assessment scale for cohort studies, a tool for limitation of selection bias that assesses three major items: selection, comparability, and outcome.²⁰ The quality of the studies and their risks of bias were also assessed according to credibility, confirmability, meaning, transferability, and reproducibility as set out in the Let Evidence Guide Every New Decision (LEGEND) evaluation system.^{21,22} This tool is more specific for qualitative studies based on surveys and stipulates that a study is of good quality if the following were done: the study design was reported, a questionnaire was sent to research staff in the ICUs, and a full analysis with accompanying discussion was included in the article (Supplemented file). We performed no meta-analyses but to improve the review, took into account the Preferred Reporting Items for Systematic Reviews and Meta-Analyses Extension for Scoping Reviews checklist.²³

3. Results

The review involved 14 studies published between 2005 and 2024 (Fig. 1), of which four were narrative and 10 were observational descriptive studies.

3.1. Study validity

According to the Newcastle–Ottawa quality assessment scale, none of the cohort studies were of good quality as they were only observational studies, based on surveys (Table S1). However, the LEGEND tool classified 10 cross-sectional surveys as being of good-quality qualitative studies, whereas the other four studies, which were more narrative in nature, were classified as poor-quality qualitative studies (Table S2).

3.2. Main characteristics of the studies

The narrative studies reported a single experience of clinical research organisation, whereas the observational descriptive studies were qualitative observational studies based on surveys in which questionnaires were sent to ICU research staff.^{1,7–18} All the studies described the organisation of clinical research in ICUs and the demographic characteristics, role, responsibilities, and job satisfaction of clinical research professionals (Table 1).

3.3. Main characteristics of the respondents

The respondents were mainly research nurses, clinical research coordinators, and, less frequently, principal investigators (PIs). They worked in either public or privately funded hospitals and in university and nonuniversity hospitals. Most of the respondents included in the studies were from North America, the United Kingdom (UK), and Australia/New Zealand (Table 1).

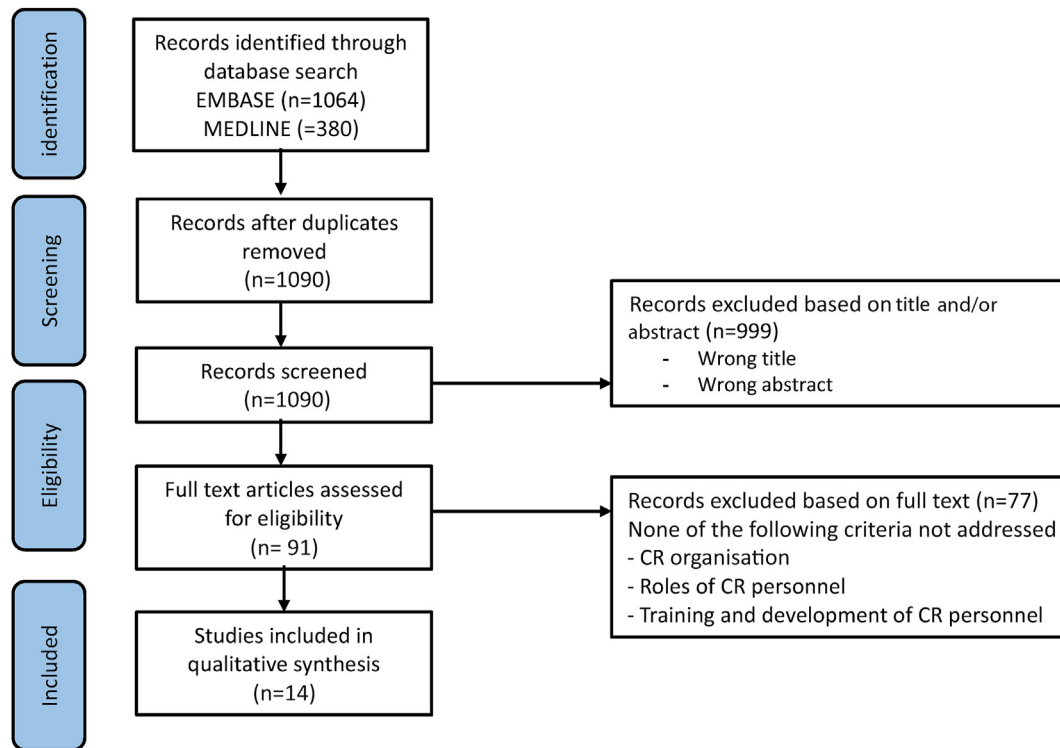


Fig. 1. Flowchart describing the selection of articles.

3.4. Demographic characteristics of clinical research professionals

Eleven studies described the demographic characteristics of the clinical research professionals, who were mostly nurses (80–100%), female (91–100%), and aged between 31 and 50 years (Table 1).

3.5. Organisation

Six studies dealt with the organisation of clinical research.^{1,7,9,11,12,14} In terms of the organisation of research at both institutional^{1,9} and ICU^{1,7,9} levels, Thompson et al. stressed how important it was to have a

department dedicated to clinical research activity and a specific team assigned to the ICU.⁹ Camsooksai et al. emphasised the importance of the presence of a research team specially dedicated to research activity.¹ Menzies et al. reported that 70% of research staff responsible for carrying out clinical research tasks in a paediatric ICU were clinical research nurses, 29% of whom had less than full-time employment. Only 52% of the ICUs had a permanent research staff.

Different aspects of the individual daily organisation of the work of clinical research professionals were detailed. Camsooksai et al. reported that the clinical research professionals' daily tasks are governed by the work of the entire research team,¹ and Menzies

Table 1
Characteristics of the 14 selected articles.

Authors, year	Country	Design	Clinical Research Professional	Participants n (%)	FTE (ratio of time work)	ICU type	ICU level	ICU beds	Organisation	Roles and Responsibilities	Training Job Satisfaction
Thompson 2005	USA	N	CC	NA	0.4	Neonatal	Level III	38	X	X	
Rickard 2006	AUS/NZ	D	RC	49/69 (71)	0.5, 0.75, 1	Adult/Paediatric Mixed	I, II, III	NA	X	X	X
Roberts 2006	AUS/NZ	D	RC	49/69 (71)	NA	NA	NA	NA			X
Rickard 2007	AUS/NZ	D	RC	49/69 (71)	0.6 to 1	Mixed	I II III	NA	X		X
Chatfield 2008	UK	N	CRN	NA	NA	Neurological	NA	NA		X	
Roberts 2011	AUS/NZ	D	RC	56/104 (54)	NA	NA	NA	NA			X
Eastwood 2012	Worldwide ^a	D	RC	NA	0.2, 0.4, 0.6, 1	Adult/Paediatric Mixed	NA	NA		X	X
Camsooksai 2013	UK	N	RN	NA	1	General medical/ surgical	II, III	12	X		
Mackle 2018	NZ	D	ResN PI NM	11/11 (100)	0.4 to 1	Mixed	III	NA		X	
O'Hearn, 2018	CA	D	CCRCRG	NA	NA	NA	NA	NA	X		
Menzies 2022	UK	D	NM	21/44 (48)	0.21 to 1	Paediatric	NA	NA	X		
Yarad 2022	AUS/NZ	D	RC	98/128 (77)	0.6 to 2.5	Mixed	II, III	NA			X
Torres, 2022	USA	D	PI RC	NA	NA	NA	NA	NA		X	
ADDA, 2024	FR	D	CRA CRT CRPM	97/151	0.2 to 1	Medical	NA	NA	X	X	X

Abbreviations: AUS, Australia; CA, Canada; CCRCRG, Canadian Critical Care Research Coordinators Group; CRA, Clinical Research Assistant; CRPM, Clinical Research Project Manager; CRT, Clinical Research Technician; D, Descriptive; FTE, Full Time Equivalent; N, Narrative; NA, not available; NM, Nurse Manager; NZ, New Zealand; PI, Principal Investigator; RC, Research Coordinator; ResN, Research Nurse; UK, United Kingdom; USA, United States of America.

ICU level: a level-1 ICU is defined as an ICU with a minimum of six beds. A level-2 ICU is defined as an ICU with a minimum of 12 beds. A level-3 ICU is defined as an ICU with a minimum of 12 beds (supplementary data).

^a Africa, Asia, Europe, Latin America, North America, and Oceania excluding Australia and New Zealand.

Table 2
Tasks of clinical research professionals broken down by frequency of execution.

	Regular or major activity (>75%)	Middle activity (75–50%)	Minor activity (<50%)
Adda (2024) ^a	Checking feasibility of the study's logistical circuits, Establishing/updating, and implementing processes, procedures, protocols, and instructions, Managing (browsing, collecting, analysing, prioritising, sharing, filing, tracking) data and information, Informing/advising the caring staff, patients, families, etc, Previsit, PrepBiol, Gathering data or information, Completing documents and files (activity or traceability sheets, etc.), Reporting/tracking adverse events, Checking application of rules, procedures, norms, and standards, Checking conformity/validity of documents, Checking logistical feasibility of the study, Monitoring adverse events	Reprography, anonymising results, and transmitting data to the coordinating centre, Dispatching study documents (recording, sorting, processing, distribution, archiving), Informing/ advising the caring staff, patients, families, etc, Checking logistical feasibility of the study, Designing and building tools or methods, Drafting reports on observations/interventions, Organising events such as meetings, visits, and specialised committees;	Pre-analytical treatment of samples, Assessing and presenting the clinical activity of the unit.
Camsooksai (2013)	NA	NA	NA
Chatfield (2008)	Identify and screen potential participants, ensure that informed consent is an ongoing process, organise and manage required procedures, assist with interventional treatment	NA	NA
Eastwood (2012)	Collect data and obtain consent	Patient assessment, screen potential trial participants, attend to regulatory and ethical submission, teach protocols and study-specific procedures to clinical staff	Writing articles for publication, performing statistical analysis of data, completing laboratory research
Mackle (2018)	Identify, screen, and recruit suitable patients, enrol patients, ensure all trial-related activities were carried out, obtaining patient consent	NA	NA
Menzies (2022)	NA	NA	NA
Rickard (2006)	Prepare ethics submissions, liaise with healthcare team, collect data, database entry, assess patient's condition, provide research advice/teaching, provide patient/relative education and support	Design data collection tools, prepare, minutes/agenda for research meetings, develop protocols, prepare grant submissions	Chair research meetings, design databases, manage research budgets, present results at conferences, write journal articles, statistical analysis, laboratory research, member of hospital nursing research committee, animal research, member of ethics committee
Rickard (2007)	NA	NA	NA
Roberts (2011)	NA	NA	NA
Roberts (2006)	NA	NA	NA
Thompson (2005)	Recruit and enrol participants, oversee data collection	NA	NA
Yarad (2022)	NA	NA	NA
O'Hearn (2018)	NA	NA	NA
Torres (2022)	Informed consent	NA	NA

^a Only the tasks of the clinical research technician and clinical research assistant have been reported in the table.

et al. that clinical research professionals took part in the regular ICU staff meetings to optimise patient inclusion in studies.⁷

3.6. Roles and responsibilities

Seven studies looked at the role and responsibilities of clinical research professionals and gave details of their multiple tasks, of which more than 20 were identified.^{8–11,15,18,24} Eastwood et al. classified the tasks depending on whether their frequency was regular, medium, or minor.⁸ The clinical research professional tasks referenced in the studies are summarised in Table 2. Thompson et al. reported that clinical research professionals coordinated all aspects of trials,⁹ whereas other authors underlined that not all clinical research professionals performed all the tasks involved. In most cases, a distinction was made between research nurses and research coordinators. In one study, for instance, research nurses, also called clinical research nurses, were solely responsible for the day-to-day management of the trials in ICUs.¹⁵ In contrast, research coordinators, also called clinical research coordinators or clinical coordinators, coordinated all aspects of the studies from study conception to study publication to ensure that they ran smoothly and oversaw the collection of high-quality data.

Some authors looked at just one of the clinical research professionals' tasks. For instance, Torres et al. focussed their

questionnaire survey on how consent to participate in clinical research was obtained from critically ill patients by 90 PIs and 105 research coordinators in an ICU network.¹⁰ They noted that the surrogate consent process involved both the PIs and research coordinators working together in 53% of cases, research coordinators alone in 38%, and PIs alone in only 8%.

3.7. Training and skills

This topic was dealt with in five studies,^{8,11,12,17,24} in which the respondents' background and the training specific to clinical research were identified. In these studies, $\geq 80\%$ of the respondents were nurses, and the rest had a scientific or other healthcare background.

The most frequent qualification required to perform the duties of CRP was a certificate attesting to full knowledge of GCP. Some respondents had postgraduate training including a master's course in project management, a doctoral level qualification, or more specific clinical courses in data management, regulations, and statistics. The level of training varied between ICUs.^{8,11,12,24}

Clinical research professionals had to combine several skills. For instance, in one study, the top four self-reported skills needed to satisfactorily perform clinical research coordinator cited by over 90% of respondents were (i) possession of clinical research

knowledge; (ii) creative problem-solving skills; (iii) ability to identify ethical questions or concerns; and (iv) objectivity (i.e., the ability to be neutral and avoid professional bias)¹⁸

3.8. Job satisfaction

Five studies^{8,13,16,17,24} addressed the quality of work life of clinical research professionals. The theme was explored in terms of the best and worst aspects of work^{8,16,17,24} and was divided into the three categories of performance of work, working conditions, and working environment. Most clinical research professionals cited autonomy as the most appreciated aspect of their work conditions. Flexibility, polyvalence, teamwork, intellectual stimulation, and knowledge acquisition were also cited as positive aspects. However, several negative aspects of life at work were identified such as lack of time, insufficient payment, job insecurity, isolation, stress, and lack of career prospects. Yarad et al. showed that during the COVID-19 pandemic, research coordinators reported signs of depression, anxiety, and stress.¹³

4. Discussion

To the best of our knowledge, this is the first scoping review of the results of reports describing the organisation of clinical research in ICUs. We identified just 14 studies on this topic, of which only 10 were cross-sectional surveys fulfilling good-quality criteria. The main results of the review to emerge were that the clinical research professionals were predominantly nurses, that there was a worldwide diversity in the organisation of clinical research in ICUs, and that differences existed between ICUs at the national level regarding the organisation of both institutional research structures and individuals.

These results warrant several comments. First, the current review shows that in most cases, ICU clinical research professionals had previously worked as ICU nurses. This raises the question of the importance of clinical knowledge in becoming a clinical research professional in an ICU. Owing to their prior training and experience, nurses develop management and organisational skills that make them effective in coordinating concurrent complex research projects.¹⁸ While this may be a major advantage for ICU clinical research because of the clinical research professionals' familiarity with ICU workflow, patient acuity, and treatment modalities, clinical research nurses in ICUs are primarily clinical research professionals and therefore, as all clinical research professionals, must also have adequate knowledge and experience of GCP, computer training, trial methodology, and basic biostatistics. Other competences in addition to clinical knowledge should now be required therefore to become clinical research professionals. In France, for example, as in other European countries, most clinical research professionals are Bachelor or Master graduates.²⁴

Three studies also included clinical research professionals with scientific backgrounds who possessed diplomas ranging from a Bachelor's degree to a doctorate.^{7,8,11} Some clinical research professionals attend complementary training courses and obtain academic qualifications to further their career.^{7,8} Ongoing training through conferences and seminars are also necessary for clinical research professionals to update their knowledge. The Joint Task Force on Clinical Trial Competence is an international team of researchers, educators, and clinical research professionals committed to providing researchers with the management skills and tools necessary to ensure the professional competence of all members of clinical research teams. The team developed a "wheel" diagram representing a framework composed of eight competency domains (Supplemental).²⁵

Four salient findings emerged from our review. First, among the specific skills that clinical research professionals must possess are knowledge of clinical research and of ethics, autonomy, and objectivity. The additional skill necessary to become a clinical research professional in the ICU setting is communication since clinical research professionals must be good negotiators and mediators in their relations with critically ill patients, their surrogates and close relations, and with healthcare teams and institutional research structures. All these skills can be acquired through initial training or professional experience.

Second, although clinical research is highly standardised worldwide in terms of laws, regulations, and GCP³, the studies we retrieved testify to the considerable heterogeneity in the organisation of clinical research at the structure level. Our review also underlines the importance of having a clinical research organisation at the institutional level to perform quality clinical research. One of the best examples is given by the ANZICS CTG, which is a collective dedicated to the coordination of research in the ICUs located in Australia and New Zealand,¹⁹ where it provides a network for investigators, research coordinators, and nurses.²⁶ Abebe et al. give examples of the role of research structures and list the different areas of expertise within these structures.⁵ Studies comparing clinical research organisations at the ICU and individual levels are mandatory.

Third, our review defines the various roles of clinical research professionals, including patient selection and recruitment, which are important stages in the conduct of a clinical research study. The involvement of clinical research professionals optimises the rate of inclusions. The provision of information and the collection of consent are highly regulated by GCP rules and research ethics committees. In most cases, GCP guidelines stipulate that only an investigator, or a person designated by the investigator, can obtain the patient's consent to take part in a study. In our review, we observed that in the ICU setting, this task is frequently carried out by clinical research professionals.^{8,15,18} Quality research with quality data requires precise procedures, knowledge, and skills, as strictly defined in GCP and regulated by ethics committees. In addition to these three main roles of clinical research professionals, there are others that, while regularly performed, are less often acknowledged. They include preparation of patients, families, and investigators to take part in the study; draughting procedures to facilitate patient inclusion; creating databases; submitting and requesting opinions from competent authorities; and draughting protocols, case report forms, and articles.^{15,18,24} Chatfield et al. defined the role of clinical research coordinators as coordinating all stages of a clinical research study. However, their role is often reduced to recruiting patients, providing information, obtaining consent, and collecting data.

Fourth, concerning job satisfaction, certain possible tasks entrusted to clinical research professionals such as draughting of study documents, seeking funding, organising/supervising the study, analysing data, or draughting the publication, can amount to a substantial workload and be stressful, especially if they are not clearly specified in the job description. Clearly clarifying issues could be one contribution to clinical research professional job satisfaction.⁸ Although clinical research professionals enjoy their work, they feel they are poorly rewarded financially, lack professional recognition, and have a limited career path.^{8,13,16,24} These factors are likely to diminish job satisfaction over time and need to be addressed. In France, in October 2008, the department for patient hospitalisation and care supply carried out a prospective study on sensitive jobs at risk of change and development in the public hospital service.²⁷ The survey focussed on the various clinical research professions and identified factors for the evolution of these professions, whose creation is relatively recent.²⁷ clinical research professional job

dissatisfaction could be partly explained by the absence of clear professional prerequisites and because research structures are self-organised.

4.1. Limitations

Our study has several limitations. First, we used only Medline and Embase for the literature search and may therefore have missed certain publications. Second, most of the included articles are from the USA, Australia, and New Zealand, which limits the external validity of our findings. Third, we did not discuss the ethical laws of the individual countries, which most of the time dictate the organisation of clinical research. Fourth, we focussed solely on clinical research performed in public-funded hospital ICUs and not in ICUs in other institutions.

5. Conclusion

This review shows not only that in ICUs, clinical research professionals are mostly nurses, but also that ICU research nurses, in addition to their nursing training, require specific clinical research courses. The studies discussed in the review vary widely in the organisation, roles, and responsibilities of ICU clinical research professionals. In low- and middle-income countries, data on this topic are scarce. In developed countries, most data reported in English-language publications come from the UK, USA, and Australia. Worldwide complementary studies are required to define guidelines on the training and roles of clinical research professionals and the management of clinical research in the ICU setting.

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CRedit authorship contribution statement

MA and CDup undertook the study design, literature review, data collection, data analysis. MA, CDup and BS undertook writing. BS, CDua, CDub, and LL reviewed and provided comments. All authors read and approved the final manuscript.

Conflict of interest

The authors declare that they have no competing interests. The views expressed are those of the author(s) and not necessarily those of the institution.

Ethics approval and consent to participate

Not applicable.

Consent for publication

Not applicable.

Availability of data and materials

The data will be made available on request.

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Appendix A. Supplementary data

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