Journal of Hospital Infection xxx (xxxx) xxx

Available online at www.sciencedirect.com

Journal of Hospital Infection

journal homepage: www.elsevier.com/locate/jhin

Review

Global randomised controlled trials in infection prevention and control: a bibliographic review from the past two decades

B.G. Mitchell [a,b,c,*], **G. Matterson** [a], **M.R. Carroll** [e], **H. Donnelly** [d,f], **K. Marimuthu** [g,h,i], **P.E. Tehan** [a,d,f]

[a] *School of Nursing and Health, Avondale University, Lake Macquarie Campus, NSW, Australia*
[b] *Central Coast Local Health District, Gosford Hospital, Gosford, NSW Australia*
[c] *Nursing and Midwifery, Monash University, Victoria, Australia*
[d] *School of Health Sciences, University of Newcastle, Newcastle, New South Wales, Australia*
[e] *School of Allied Health, Faculty of Health & Environmental Sciences, Auckland University of Technology, Auckland, New Zealand*
[f] *School of Clinical Sciences, Monash University, Victoria, Australia*
[g] *Department of Infectious Diseases, National Centre for Infectious Diseases and Tan Tock Seng Hospital, Singapore*
[h] *Department of Infection Prevention and Control, Tan Tock Seng Hospital, Singapore*
[i] *Yong Loo Lin School of Medicine, National University of Singapore, Singapore*

ARTICLE INFO

Article history:
Received 12 March 2026
Accepted 26 March 2026
Available online xxx

Keywords:
Cross-infection
Healthcare-associated infection (HAI)
Randomised controlled trial

SUMMARY

Background: Infection prevention and control (IPC) evidence is imperative to reduce healthcare-associated infections, yet IPC guidelines often rely on low-level evidence due to challenges in conducting rigorous randomised controlled trials (RCTs). Understanding long-term research trends can clarify strengths, gaps, and priorities. Therefore, this bibliometric review aimed to identify trends and patterns in IPC RCTs over the past 20 years.

Methods: A systematic search was conducted in the Scopus database between January 2002 and September 2025. RCTs in IPC were included. Identified studies were exported into Covidence software for screening. Metadata were imported into Biblioshiny® software, which analysed annual scientific production, citation data, authorship, and collaboration. Manual coding of data was also conducted to assign themes to the included research. This bibliometric review was reported in accordance with the BIBLIO reporting checklist.

Results: The search yielded 2312 studies, of which 239 were included. The findings show intermittent periods of growth in annual publication output, particularly in the past two years. Research activity is concentrated in the USA, Australia, and the UK. Over half of all publications fall within four key IPC themes — medical devices, skin antisepsis, wound therapy, and hand hygiene — while remaining studies reflect considerable topic heterogeneity.

Conclusion: RCTs in IPC has grown substantially over the past decade. Although existing international collaborations were identified, substantial scope remains to further

* Corresponding author. Address: School of Nursing and Health, Avondale University, New South Wales 2258, Australia. Tel.: +61 2 4349 4536.
E-mail address: brett.mitchell@avondale.edu.au (B.G. Mitchell).

https://doi.org/10.1016/j.jhin.2026.03.037

strengthen these networks. This presents an opportunity to strengthen the evidence base. Given the growth of RCTs, there is a case for living guidelines in key IPC areas.

Introduction

Effective infection prevention and control (IPC) practices are fundamental to reducing and mitigating the risk of healthcare-associated infection (HAI). Research plays a critical role in shaping evidence-informed IPC policies and practice. It has been recognised that IPC recommendations in national guidelines globally are often underpinned by low-quality evidence in the context of the hierarchy of evidence [1]. In recent years, there has been a global call for more robust and methodologically rigorous IPC research [2]. There are, of course, many challenges in conducting randomised controlled trials (RCTs) in the field of IPC, including but not limited to ethical considerations, difficulty blinding, challenges with governance and oversight, administrative burden for multi-site or multi-country trials, contamination of interventions, confounders such as human behaviour, the need for large sample sizes, and funding to support research [3–5].

Understanding long-term trends in IPC RCT research maybe helpful for identifying where the evidence base is strong or fragmented and where critical gaps may exist. In addition, mapping patterns in trial activity can reveal whether research efforts align with areas of greatest clinical need, emerging threats, and health-service priorities. A review of RCTs in IPC may also be valuable in highlighting domains where RCTs remain scarce, signalling opportunities for targeted investment and methodological innovation. Findings may also be helpful to ensure future research agendas are strategically directed, resources are allocated efficiently, and IPC practice continues to be grounded in rigorous, high-quality evidence.

This bibliometric review seeks to explore some of these issues. Bibliometric reviews are increasingly used to explore and analyse large volumes of research metadata, such as citations, authors, and keywords [6]. They can be used to identify influential work, emerging topics, and research gaps. To date, this method is rarely used in the field of IPC. Therefore, the aim of this bibliometric review was to identify trends and patterns in IPC RCTs in the past 20 years.

Methods

Design

A bibliometric review of the literature was undertaken to answer the following research questions:

1. What is the quantity of published RCTs in IPC globally?
2. In what fields of IPC are RCTs being published?

Reporting of this bibliometric review is consistent with the Equator Network guidelines for the reporting bibliometric reviews of the biomedical literature, namely the BIBLIO checklist [7].

Information sources

Bibliographic data for this study were sourced from Scopus. It is accepted practice when using metadata for bibliometric analysis to use either Scopus® or Web of Science® [6]. It is recommended to select one appropriate database to mitigate the need for consolidation of data, minimising unnecessary action items can help to mitigate potential human errors [6]. The Scopus® database (Elsevier, Amsterdam, Netherlands) was selected as it has the largest abstract and citation database of research literature [8]. As of January 2020, Scopus® had in excess of 25,100 active titles and over 550 articles in press [9]. Additionally, Scopus® includes a more expanded spectrum of journals than PubMed and Web of Science® [10].

Search strategy

The electronic database Scopus was searched for studies published between 1st January 2002 and 30th September 2025. The keywords included the terms 'infection control', 'infection prevention', 'nosocomial infections', or 'cross infection', and 'randomized controlled trial', 'randomised controlled trial', or 'RCT' was searched. The coding for the search was as follows:

((ABS(randomised controlled trial*) OR ABS(randomized controlled trial*) OR TITLE-ABS-KEY(RCT)) AND PUBYEAR > 2002) AND ((KEY(infection control) OR KEY(infection prevention) OR KEY(nosocomial infections) OR KEY(cross infection)) AND PUBYEAR > 2002) AND (LIMIT-TO (EXACTKEYWORD,"Randomized Controlled Trial")) AND (LIMIT-TO (DOCTYPE,"ar")).

Study selection

The inclusion criteria were as follows:

- Original articles that used an RCT design
- Articles in which the primary focus was related to the field of IPC (i.e. the prevention of HAIs)
- Research that was conducted in hospital or healthcare settings, in aged care settings, or with healthcare workers (or healthcare students)
- Outcomes that are concerned with infection or colonisation or measures from infection control processes such as hand hygiene.

Papers were excluded if they were not peer reviewed; non-original research publications; non-randomised studies, including reviews, research letters, editorials, commentaries, and studies that do not present results from an RCT; studies that were not strongly aligned with the IPC discipline, including studies evaluating or involving antimicrobial therapy and drug trials (excluding topical decolonisation approaches), vaccination efficacy, antimicrobial stewardship, and public health

Please cite this article as: Mitchell BG et al., Global randomised controlled trials in infection prevention and control: a bibliographic review from the past two decades, Journal of Hospital Infection, https://doi.org/10.1016/j.jhin.2026.03.037

initiatives; research that was not conducted in hospital, healthcare, or aged care settings; or not concerned with prevention of HAIs.

Once articles were downloaded from the Scopus database, they were exported into the online review tool Covidence® (Veritas Health Innovation, Melbourne, Australia). The titles and abstracts of all identified articles were initially screened for their relevance by one researcher (G.M.). A random selection (10%) was screened by a second researcher (B.M.). No discrepancies were identified.

A full-text review was subsequently conducted independently by two researchers (G.M. and H.R.). Researchers were experienced in the field of healthcare or IPC. When agreement was not met between authors, a third independent reviewer (B.M.) determined conflicts. Any discrepancies among the authors concerning definitions were addressed and resolved through collective discussion with the full review team.

Data refinement, extraction, and analysis

Metadata from all included studies were extracted into a custom Microsoft Excel (Version 2016, Microsoft Corp., Redmond, Washington, USA) spreadsheet. For eligible studies, the following data were extracted: name of the publishing journal, publication title, year published, authors (number per publication), affiliations of authors (authorship network), international collaboration (Y/N), institutional affiliation (relationship between authors), national or international study setting, number of countries the study was undertaken in (number), countries the study was undertaken in, type of RCT (cluster, parallel, stepped wedge, cross-over, factorial, or adaptive), blinding (nil, single, or double), citations (number of citations per article), impact factor (IF of the journal during the year prior to publication sourced from Web of Science™ Journal Citation Reports [Clarivate Analytics, Philadelphia, Pennsylvania, USA]), funding sources (funding and funding body), key words (from study), and type/theme of IPC research.

To determine the primary IPC themes of each paper, a manual review of the paper was undertaken. As there is no established system by which infection control research can be categorised, a pragmatic approach based on previous work was adopted [1]. Articles included in the final analysis were categorised into the following subject areas: hand hygiene, cleaning, sterilisation, education, devices, screening, implementation, surveillance, skin antisepsis, antimicrobial prophylaxis, transmission-based precautions, patient-focused strategies, personnel, IPC program, vaccination, sharps, and ventilation. A full description of these categories is provided in supplementary material (Table S1). A validation process was undertaken to check the allocation of the IPC theme. Ten percent of included papers were chosen at random, with a second review of these undertaken and reliability assessed ($\kappa = 0.95$, standard error $= 0.05$, $P < 0.01$).

Extraction of general characteristics of included articles, annual scientific production, average citations per year, most relevant authors, and collaboration world map analysis were undertaken using Biblioshiny software (based on R version 3.6.1, Bibliometrix package version 2.2.1; University of Naples Federico II, Naples, Italy, 2016). The analysis, including citation data, was conducted on 16th December 2025. Data extracted were cross-checked by an independent research assistant. Results were presented descriptively through figures and tables.

Results

Selection of sources of evidence

Our search identified 2312 studies, with 352 articles included following abstract and title screening. This was reduced to 239 following the full-text review (Table S2). The selection process and reasons for exclusion are demonstrated in the Preferred Reporting Items for Systematic Reviews and Meta-Analyses flowchart (Figure 1).

Study characteristics

The analysis included 239 documents obtained from 126 sources from the period 2003 to 2025 (Table I and Figure 2). The average number of citations per document was recorded as 34.6, and the average age of each document (at final search date) was 7.9 years. The top 10 most globally cited publications are presented in Table S3. Citation counts were highest from publications from the USA ($N = 2750$), followed by Australia ($N = 1101$) and the UK ($N = 662$) (Table S4). In terms of author information, 2991 different authors contributed to these documents. The number of average authors per document is 13.5, with an international co-authorship rate of 19.7%, with only one single authored document. There was strong collaboration between certain countries, including Australia, the UK, Canada, and the USA (Figure 3 and supplementary material). There appear to be six research groups that have a strong collaboration and have led several RCTs (Figure S1). Three of the six research groups were led by Australian researchers. The hospital setting was the most common study location ($N = 161$, 67.4%), followed by intensive care units specifically ($N = 51$, 21.3%), then nursing homes ($N = 15$, 6.3%).

Trends

Annual publication output increased during certain periods, particularly 2013–2017, before reducing (Figure 2 and Table S5). In 2024 and 2025, the greatest number of RCTs was published. Cumulative analysis of articles, which started with only three publications in 2003, reached its highest level of increase in 2024, increasing by 37 new publications. There were small decreases in publications throughout, with the largest decrease in new articles seen between 2017 and 2018. The top nine most relevant authors publishing IPC RCTs are presented in Table S6, with the most relevant research affiliations outlined in Table S7. Table S8 displays the most impactful (local impact) researchers in IPC RCTs. The majority of RCTs were published in the *American Journal of Infection Control* ($N = 17$), *Infection Control and Hospital Epidemiology* ($N = 15$), and the *Journal of Hospital Infection* ($N = 10$) (see Table S10).

Research themes

From the 239 papers, the most frequent IPC primary theme explored in RCTs were medical devices ($N = 42$, 17.5%), followed by skin antisepsis ($N = 37$, 15.5%), wound therapy ($N =$

Please cite this article as: Mitchell BG et al., Global randomised controlled trials in infection prevention and control: a bibliographic review from the past two decades, Journal of Hospital Infection, https://doi.org/10.1016/j.jhin.2026.03.037

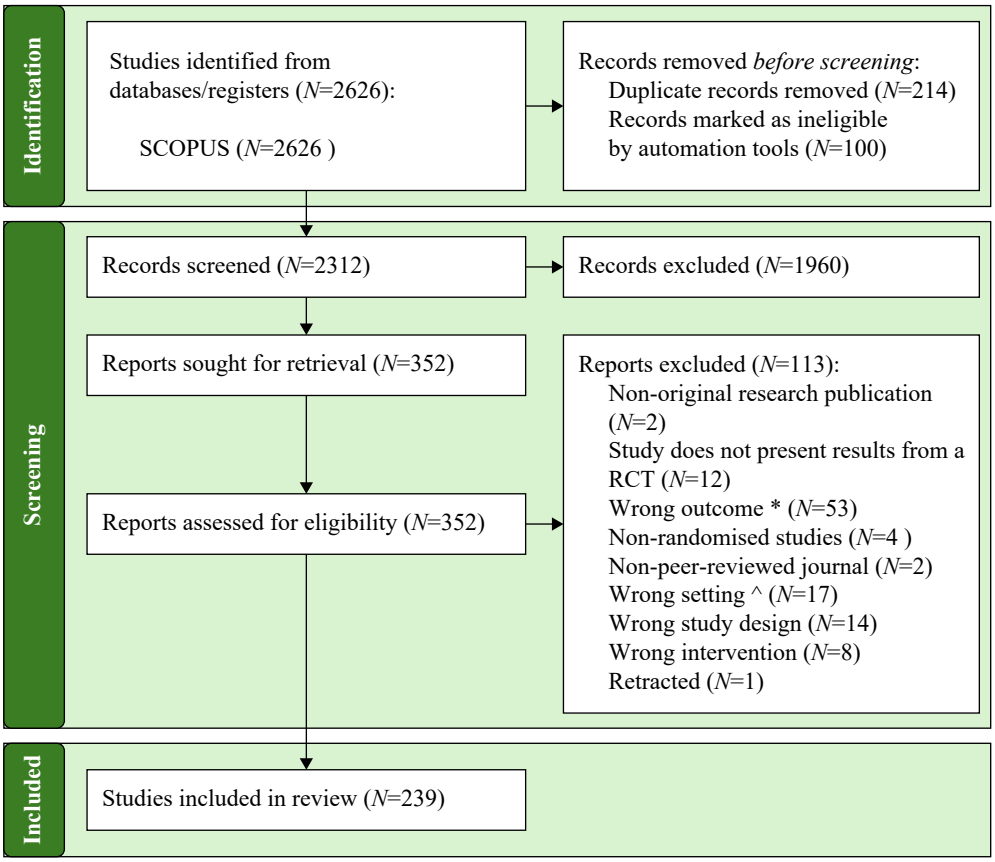

Figure 1. PRISMA flow diagram. *Wrong outcome includes studies that do not report infection/colonisation outcomes or outcomes on infection control measures or processes or studies not strongly aligned with the infection prevention and control. ^Wrong setting includes studies not conducted in a hospital, healthcare, or aged-care setting or on clinical student (nurse, dental, and medical) population. PRISMA, Preferred Reporting Items for Systematic Reviews and Meta-Analyses; RCT, randomised controlled trials.

Table I
Publication analysis: key indicators (2003–2025)

Description	Result
Sources	126
Documents	239
Annual growth rate, %	10.69
Document average age	7.89
Average citations per doc	34.6
Authors	
Authors	2991
Authors of single-authored docs	1
Author collaboration	
Single-authored docs	1
Co-authors per doc	13.5
International co-authorships, %	19.67

Sources refer to the source of publication, e.g. a journal.

30, 12.6%), and hand hygiene ($N = 21$, 8.7%). Further details are provided in supplementary material. One-third of publications related to medical devices were published in the last two years (2024–2025). Themes that were least explored included sterilisation, patient focussed strategies, self-medicated therapy, screening, and artificial intelligence (Table S11). Given the relatively low counts of individual research themes, no definitive trends over time were observed (Table S12).

Discussion

This comprehensive bibliometric review represents the first mapping of RCTs conducted in the field of IPC. The findings identify sporadic periods of growth in the yearly number of publications. However, in the past two years, there were 65 RCTs published, representing 27.2% of all RCTs in the past two decades. There is a concentration of papers produced by research teams in the USA, Australia, and the UK. International collaboration appears to be strongest between researchers from Australia, the UK, Canada, and the USA. Publications from five IPC themes (medical devices, skin antisepsis, wound therapy, hand hygiene, and antimicrobial/antiseptic prophylaxis) account for over 50% of the publications, with heterogeneity in topics for the remainder of publications.

It is important to recognise that fluctuations in publication numbers can be attributed to a variety of factors including delays in trials or publication processes. Despite this in the last 5 years, RCT IPC publication output has almost doubled. Potential reasons for this increase may include increased collaborations, availability of research funding, or efficiencies in being able undertake trials as a result of improved data integration, such as automation. These potential reasons are

Please cite this article as: Mitchell BG et al., Global randomised controlled trials in infection prevention and control: a bibliographic review from the past two decades, Journal of Hospital Infection, https://doi.org/10.1016/j.jhin.2026.03.037

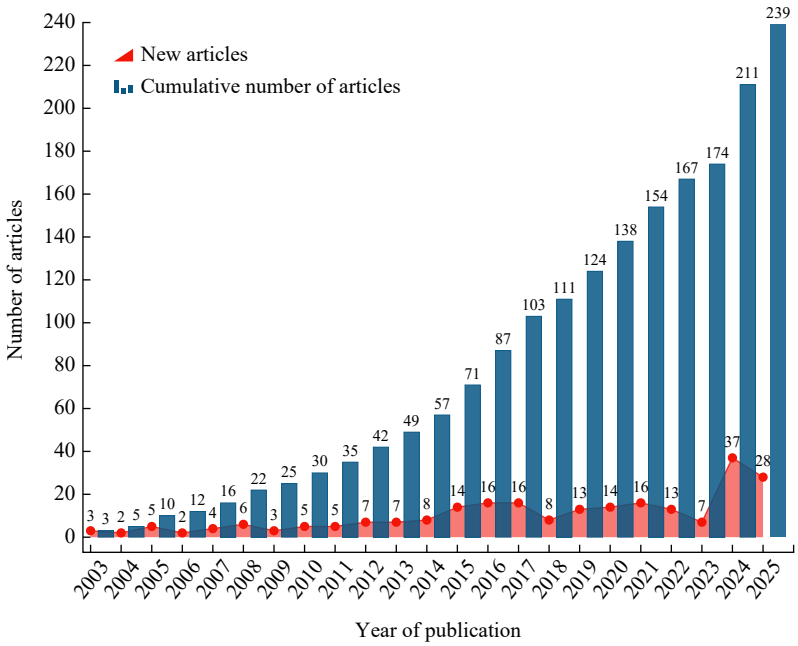

Figure 2. Annual production/publication of randomised control trials in infection prevention and control. *Wrong outcome includes studies that do not report infection/colonisation outcomes or outcomes on infection control measures or processes or studies not strongly aligned with the infection prevention and control. ^Wrong setting includes studies not conducted in a hospital, healthcare, or aged-care setting or on clinical student (nurse, dental, and medical) population.

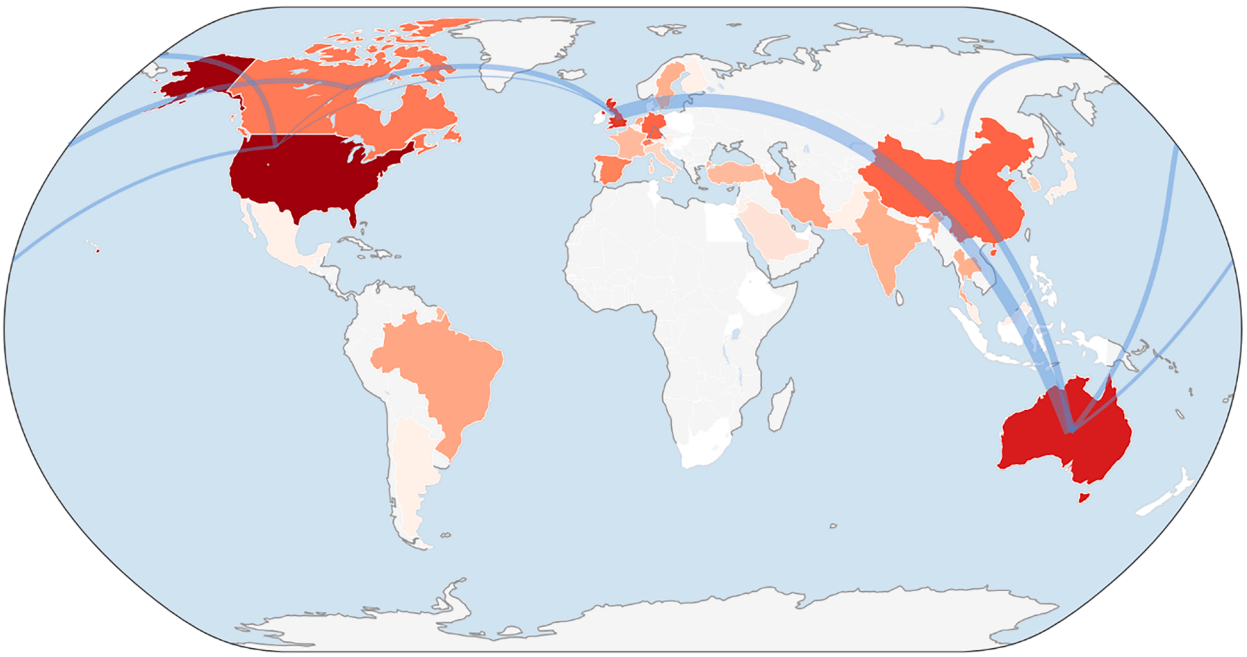

Figure 3. World map of collaboration between countries undertaking randomised control trials in infection prevention and control. Lines are weighted to indicate volume of publications.

speculative and cannot be evidenced from the data in our review. There were dips in publication in 2022 and 2023. One reason for this could be the effect that during 2020–2021, IPC teams were occupied with the coronavirus disease 2019 (COVID-19) pandemic. The research groups that have produced the most RCTs and with the strongest collaborations appear to have conducted research on different topics and themes. While findings from our review identify existing IPC international collaborations, there is an opportunity to strengthen these further. This could be facilitated by enhancing collaborations between existing hubs, expanding networking and capacity building sessions at international IPC conferences, and

Please cite this article as: Mitchell BG et al., Global randomised controlled trials in infection prevention and control: a bibliographic review from the past two decades, Journal of Hospital Infection, https://doi.org/10.1016/j.jhin.2026.03.037

government funding bodies encouraging and directly supporting international collaborations in IPC research. It is noted that existing infectious disease research groups and collaborations exist, with international collaborations [11]. However, the needs and discipline of IPC are slightly different, particularly emphasised by the strength of evidence underpinning IPC guidelines.

By examining how RCT output has evolved, this bibliometric review provides insights into the maturity of the IPC evidence base and its capacity to support guideline development and policy decisions. A previous review explored the breadth and strength of IPC recommendations from guidelines produced by government and professional organisations [1]. From 31 guidelines, there were 1885 recommendations. Two-thirds of these recommendations were underpinned by evidence from descriptive studies, expert opinions, and non-randomised control trials. Only 28 recommendations (1.5%) were derived from systematic reviews of RCTs, with 311 recommendations (16.8%) supported by evidence from RCTs [1]. There have been very limited updates to national and leading IPC guidelines globally in recent years. The positive growth in RCTs identified in our review, particularly in the past decade, offers major opportunities to update IPC guidelines. Should growth continue as it has down in recent years, there may be some value in exploring the concept of 'living' guidelines for certain IPC topics. Living guidelines are a relatively new method for developing evidence-based recommendations that remain current by rapidly integrating new research [12,13]. This approach ensures guidance is consistently updated to reflect the latest scientific findings and has been used during the COVID-19 pandemic [14,15].

The findings of this bibliometric review should be considered in the light of the following limitations. First, the review is limited to the use of the Scopus database because of its compatibility with data analysis programs, including citation data. All metrics were extracted based on our predefined search terms and data only from the Scopus® database, which may not include all publications that meet our inclusion criteria. Some peer-reviewed journals are not indexed in Scopus®. Citation data are dynamic and will change constantly. We caution against using citation data in this paper for other purposes. Citation metrics are influenced by publication date, and hence, caution should be taken when comparing citation data between papers. Due to limitations with citation data, we chose not to present citation data at the individual paper level and limited the amount of citation data presented in the main paper. Second, we used a manual coding process to determine the IPC themes for each article. Despite the process used, it is possible for papers to be misclassified. Third, our search strategy included the use of limits and keywords to identify RCTs. If keywords were not used or metadata did not contain this keyword, it is possible that an RCT would be excluded.

In conclusion, this bibliometric review demonstrates that RCT output in IPC research has grown substantially over the past decade, with recent years showing the greatest period of productivity to date. This presents a significant opportunity for the field to strengthen the evidence base which underpins guidelines and policy worldwide. Given the continued growth of RCT output, there is a compelling case for living guidelines in key IPC areas to ensure clinical recommendations are current, evidence-informed, and responsive to emerging research.

CRediT authorship contribution statement

B.G. Mitchell: Writing — review & editing, Writing — original draft, Methodology, Funding acquisition, Conceptualization. **G. Matterson:** Writing — review & editing, Writing — original draft, Methodology, Investigation. **M.R. Carroll:** Writing — review & editing, Visualization, Formal analysis, Data curation. **H. Donnelly:** Writing — review & editing, Writing — original draft, Investigation. **K. Marimuthu:** Writing — review & editing, Methodology. **P.E. Tehan:** Writing — review & editing, Writing — original draft, Visualization, Methodology, Formal analysis, Data curation, Conceptualization.

Ethics statement

Ethics approval was not required as this paper is a review.

Funding sources

This work was supported by an NHMRC Emerging Leadership Investigator grant (to B.M.; GNT2008392), administered by Avondale University.

Conflict of interest statement

The authors have no conflicts of interest to declare.

Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.jhin.2026.03.037.

References

[1] Mitchell BG, Fasugba O, Russo PL. Where is the strength of evidence? A review of infection prevention and control guidelines. J Hosp Infect 2020;105:242—51. Epub 2020/01/25. PubMed PMID: 31978417.

[2] Reilly J, Hooker EL, Mitchell BG. Under the HAI lens: pandemic learning for research priorities for IPC: a call to action. J Hosp Infect 2022;127:135—7.

[3] Bonell C, Fletcher A, Morton M, Lorenc T, Moore L. Realist randomised controlled trials: A new approach to evaluating complex public health interventions. Soc Sci Med 2012;75:2299—306.

[4] Jamrozik E, Selgelid MJ. Ethical issues surrounding controlled human infection challenge studies in endemic low-and middle-income countries. Bioethics 2020;34:797—808.

[5] Fretheim A, Elstrøm P, Julin CH, Gopinathan U, Elgersma IH, Solberg RB, et al. Why were so few randomized trials of public health and social measures conducted during the COVID-19 pandemic? The Norwegian experience. Trials 2024;25:673. Epub 20241012. PubMed PMID: 39396052; PubMed Central PMCID: PMC11470701.

[6] Donthu N, Kumar S, Mukherjee D, Pandey N, Lim WM. How to conduct a bibliometric analysis: An overview and guidelines. J Bus Res 2021;133:285—96.

[7] Montazeri A, Mohammadi S, P MH, Ghaemi M, Riazi H, Sheikhi-Mobarakeh Z. Preliminary guideline for reporting bibliometric reviews of the biomedical literature (BIBLIO): a minimum requirements. Syst Rev 2023;12:239. Epub 20231215. PubMed PMID: 38102710; PubMed Central PMCID: PMC10722750.

[8] Guz AN, Rushchitsky JJ. Scopus: A system for the evaluation of scientific journals. International Applied Mechanics 2009;45:351—62.

[9] Elsevier. Scopus content coverage guide. Elsevier; 2020. 2026 [cited 2026 10 January]. Available from: https://wwwelsevier.com/__data/assets/pdf_file/0007/69451/Scopus_ContentCoverage_Guide_WEB.pdf.

[10] Falagas ME, Pitsouni EI, Malietzis GA, Pappas G. Comparison of PubMed, Scopus, Web of Science, and Google Scholar: strengths and weaknesses. The FASEB Journal 2008;22:338—42.

[11] Fanning JP, Murthy S, Obonyo NG, Baillie JK, Webb S, Dalton HJ, et al. Global infectious disease research collaborations in crises: building capacity and inclusivity through cooperation. Global Health 2021;17:84. Epub 20210726. PubMed PMID: 34311748; PubMed Central PMCID: PMC8313114.

[12] Living Systematic Review N, Akl EA, Meerpohl JJ, Elliott J, Kahale LA, Schünemann HJ, et al. Living systematic reviews: 4. Living guideline recommendations. J Clin Epidemiol 2017;91:47—53.

[13] El Mikati IK, Khabsa J, Harb T, Khamis M, Agarwal A, Pardo-Hernandez H, et al. A framework for the development of living practice guidelines in health care. Ann Intern Med 2022;175:1154—60.

[14] Turner T, Elliott J, Tendal B, Vogel JP, Norris S, Tate R, et al. The Australian living guidelines for the clinical care of people with COVID-19: what worked, what didn't and why, a mixed methods process evaluation. PLoS One 2022;17:e0261479.

[15] Millard T, Elliott JH, Green S, Tendal B, Vogel JP, Norris S, et al. Awareness, value and use of the Australian living guidelines for the clinical care of people with COVID-19: an impact evaluation. J Clin Epidemiol 2022;143:11—21.

Please cite this article as: Mitchell BG et al., Global randomised controlled trials in infection prevention and control: a bibliographic review from the past two decades, Journal of Hospital Infection, https://doi.org/10.1016/j.jhin.2026.03.037