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Corresponding author:

Haiyang Yu

yuheroyoung@hotmail.com

Author Affiliation:

Administration of infection
nosocomial, Henan Provincial
People's Hospital: Zhengzhou,
Henan.

Intestinal colonization with carbapenem-resistant Enterobacterales in China: prevalence, dominant species, carbapenemase genes and screening methods – a protocol for a systematic review and meta-analysis

Yu, H; Han, X; Zhang, J; Zhang, Y; Li, P.

ADMINISTRATIVE INFORMATION

Support - This review received no specific grant from any funding agency commercial or not-for-profit sectors.

Review Stage at time of this submission - Preliminary searches.

Conflicts of interest - None declared.

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Amendments - This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 22 October 2026 and was last updated on 22 October 2026.

INTRODUCTION

Review question / Objective Aim. The aim of this systematic review and meta-analysis is to describe the epidemiology of intestinal colonization with carbapenem resistant Enterobacterales-carbapenemase producing (CRE-CP) in China, in order to inform active screening and infection prevention and control (IPC) policy at national, regional and hospital level.

Primary objective. To estimate the pooled prevalence of intestinal colonization with CRE (and, where separately reported, CPE) among people who underwent intestinal screening in mainland China, overall and by region (Eastern, Central, Western and Northeastern China).

Secondary objectives.

1. To describe the distribution of the dominant colonizing Enterobacterales species among intestinal CRE isolates.
2. To describe the distribution of carbapenemase-encoding genes (e.g. blaKPC, blaNDM, blaIMP, blaVIM, blaOXA-48-like) among these isolates.
3. To describe the screening and detection methods currently used (specimen type, selective/chromogenic medium, use of enrichment, identification method, carbapenemase confirmation method) and to explore whether the reported prevalence differs according to these methodological features.

Review questions.

Q1. What is the pooled prevalence of intestinal colonization with CRE among screened populations in mainland China, overall and by region?

Q2. Which Enterobacterales species predominate among intestinal CRE colonizing isolates in China?

Q3. Which carbapenemase-encoding genes predominate among these isolates?

Q4. Which screening and detection methods are used, and how is the reported prevalence related to them?

Structured question (PECO). A PECO framework is used because no intervention is evaluated; there is no comparator intervention, and the comparison is

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a single-arm pooled proportion with method- and region-based subgroup contrasts.

P — People of any age and either sex in mainland China who underwent intestinal (rectal, perianal or perirectal swab, or stool) screening for CRE/CPE colonization, in any setting.

E (exposure / index test) — Microbiological screening of an intestinal specimen for CRE/CPE, by culture-based and/or molecular methods.

C — Not applicable; screening and detection methods are contrasted only indirectly, in subgroup analyses.

O — Prevalence of intestinal CRE colonization (primary); distribution of colonizing species, distribution of carbapenemase genes, and screening/detection methods used (secondary).

Rationale CRE are among the pathogens for which new antibiotics are most urgently needed and are a leading cause of difficult-to-treat healthcare-associated infection. Intestinal colonization is the principal reservoir for CRE in hospitals and in the community: colonized individuals are usually asymptomatic, are rarely detected without active screening, and are at substantially increased risk of subsequent CRE infection, while also serving as a source of cross-transmission. Because colonization precedes infection, region-specific colonization prevalence is the key parameter for deciding whether, whom and how to screen, and for allocating IPC resources.

China is a high-burden setting with marked internal heterogeneity. Reported intestinal CRE colonization prevalences vary widely between studies, and the epidemiology differs across the country — for example, KPC-type carbapenemases have predominated in many eastern and central provinces, while NDM-type enzymes have been increasingly reported, including in western and southern provinces, and OXA-48-like and IMP-type enzymes occur regionally. Screening practice is equally heterogeneous: rectal/perianal swab versus stool; direct plating on MacConkey agar with a carbapenem disk versus chromogenic media versus selective broth enrichment; and culture alone versus culture combined with PCR or whole-genome sequencing. Because these methodological choices strongly affect sensitivity, apparent differences between regions may partly reflect differences in how people were screened rather than true differences in colonization pressure.

What is already known and what is missing. Existing syntheses have mostly addressed CRE infection, clinical isolates, or global/other-country epidemiology, with China contributing only a subset of studies; they rarely provide region-

stratified estimates of intestinal colonization, and they seldom quantify how prevalence estimates depend on the screening method. A synthesis that is restricted to mainland China, stratified by the four national regions, and accompanied by method-stratified estimates and a description of dominant species and carbapenemase genes is therefore needed to support the implementation of China's national action plan on antimicrobial resistance and hospital infection surveillance programmes.

Check for pre-existing and ongoing reviews. The review team has searched INPLASY, PROSPERO and the Cochrane Database of Systematic Reviews for registered, ongoing or completed reviews addressing intestinal CRE colonization prevalence in China [date of check:

【5/10/2026】. No review was found that reports region-stratified intestinal CRE colonization prevalence in China together with the distribution of colonizing species, carbapenemase genes and screening methods; this review does not duplicate an existing or planned synthesis.

Condition being studied Intestinal colonization (asymptomatic carriage) with CRE-CP.

Enterobacterales (the order that replaced Enterobacteriaceae) includes *Escherichia coli*, *Klebsiella pneumoniae*, *Enterobacter* spp., *Citrobacter* spp., *Serratia* spp., *Proteus* spp. and related genera. CRE-CP are Enterobacterales that are not susceptible to at least one carbapenem (imipenem, meropenem or ertapenem) according to the interpretive criteria applied by the reporting laboratory (CLSI and/or EUCAST), that produce a carbapenemase (most commonly KPC, NDM, IMP, VIM, OXA-48-like enzymes), confirmed phenotypically or by molecular methods.

Colonization means that CRE-CP are present in the intestinal tract without clinical signs or symptoms of infection attributable to them. It is detected by microbiological screening of an intestinal specimen — most often a rectal, perianal or perirectal swab, or a stool sample — using selective culture with or without broth enrichment, chromogenic or conventional media, and confirmation by identification, susceptibility testing and, frequently, carbapenemase detection.

Colonization is not a disease: it is an exposure state that matters because the colonized gut is the reservoir from which CRE-CP are transmitted between patients and from which invasive infection (bacteraemia, pneumonia, urinary tract infection, surgical site infection) may later arise. The condition being studied therefore has no formal diagnostic coding; the review will use each primary study's own operational definition of "CRE-CP isolated from an intestinal screening specimen"

and will record that definition for every included study.

METHODS

Search strategy Searches are run in four databases: PubMed (MEDLINE), Embase (Elsevier), the Cochrane Library (CENTRAL) and China National Knowledge Infrastructure (CNKI). The publication window is 1 January 2021 to 30 September 2026 in every database. A search strategy combining MeSH terms and free words was adopted. The English search formula: screening AND colonization OR carriage AND carbapenem resistant OR carbapenemase producing AND enterobacterales; the Chinese search formula: (定植 + 携带) AND 耐碳青霉烯肠杆菌 AND (筛查 + 主动监测), to identify potentially eligible studies. The strategies will be re-run and updated immediately before the final analysis, and the date of the last search will be reported.

The reference lists of all included studies and of relevant reviews identified during screening will be checked (backward citation searching) to identify additional eligible studies. No forward citation searching or grey-literature database searching is planned, because conference abstracts, theses without full data and unpublished reports cannot supply the person-level numerators and denominators required for the primary outcome; this decision will be reported as a limitation. Studies found through supplementary searching will be screened and appraised by exactly the same process as database records.

Participant or population Eligible population. People of any age, of either sex, and of any ethnicity, who were living in mainland China at the time of screening and who underwent intestinal screening for CRE/CPE colonization. Study settings may include, but are not limited to: general hospital wards; intensive care units (adult, paediatric, neonatal); haematology and oncology units; solid organ transplant and haematopoietic stem cell transplant units; surgical units; long-term care facilities and nursing homes; and community or household-contact screening programmes and healthy-volunteer screening.

Region assignment (for the primary regional objective). Each study is assigned to one of four regions according to the province, autonomous region or municipality in which it was conducted: Eastern (Beijing, Tianjin, Hebei, Shanghai, Jiangsu, Zhejiang, Fujian, Shandong, Guangdong, Hainan); Central (Shanxi, Anhui, Jiangxi, Henan, Hubei, Hunan); Western (Inner Mongolia, Guangxi, Chongqing, Sichuan, Guizhou, Yunnan, Tibet,

Shaanxi, Gansu, Qinghai, Ningxia, Xinjiang); Northeastern (Liaoning, Jilin, Heilongjiang).

Multi-province or national surveillance studies are assigned to the region containing the majority of contributing centres; if no majority exists, the study is labelled "multiregional" and is included in the overall estimate but handled separately in the regional analysis (as a prespecified additional subgroup level) and in a sensitivity analysis excluding multiregional studies.

Ineligible participants. People screened only at non-intestinal sites (blood, urine, respiratory secretions, wound, cerebrospinal fluid, catheter tips) without any intestinal screening data; studies reporting only clinical CRE isolates from diagnostic specimens; environmental sampling (sinks, surfaces, equipment); animal studies; and food-chain studies.

Handling of mixed or partially eligible populations. Where a study screened only a subset of its participants intestinally, it will be included only if the number screened and the number positive can be extracted for that subset. Where a study reports both an eligible population and clearly ineligible participants without separable data, the study will be excluded and the reason recorded. Where a study reports several distinct, non-overlapping populations separately (for example adults and neonates in separate wards with separate denominators), each population may be entered as a separate data row and assigned to the appropriate prespecified subgroup; overlapping or non-separable populations are entered once, using the largest complete denominator.

Intervention As this is a prevalence review, there is no intervention in the sense of a treatment. The index procedure whose yield is being summarised is intestinal screening for CRE-CP colonization, defined as any protocol in which an intestinal specimen — a rectal, perianal, perirectal or anal swab, or a stool/faecal sample — is cultured and/or tested molecularly for CRE-CP in a person without a clinical suspicion of CRE infection at the time of sampling.

Variations that are all eligible and will be recorded and analysed as prespecified subgroups (Item 23):

1. Specimen type — rectal/perianal/perirectal swab versus stool (or a combination, or combined swab-and-stool sampling).
2. Selective medium — conventional MacConkey agar with a carbapenem disk or a carbapenem-containing plate; chromogenic CRE/CPE media (e.g. CHROMagar, chromID CARBA/CRE, mSuperCARBA, Brilliance CRE) versus non-chromogenic selective media; other or unspecified media.

3. Enrichment — direct plating only versus selective broth enrichment (e.g. tryptic soy broth, brain–heart infusion broth, MacConkey broth, or dedicated carbapenem-containing enrichment broths such as those used in the modified CDC protocol) followed by subculture.

4. Carbapenemase confirmation and molecular characterisation —phenotypic carbapenemase confirmation (modified carbapenem inactivation method, carbapenem inactivation method, Carba NP test, or inhibitor-based assays); or molecular detection (PCR for blaKPC/blaNDM/blaIMP/blaVIM/blaOXA-48-like, or whole-genome sequencing).

Comparator Not applicable. This is a single-arm prevalence systematic review: the quantity synthesised is a pooled proportion (with its 95% confidence interval), not a between-group effect. No control group, placebo or competing intervention is required for eligibility, and studies are not excluded for lacking a comparator. Screening and detection methods are compared only in the sense of subgroup contrasts in prevalence — that is, whether the pooled prevalence differs between methods — with the subgroup-difference test. Any such difference will be interpreted as an association with the testing strategy, not as evidence that one strategy causes a higher or lower true colonization prevalence.

Study designs to be included Observational studies that report a prevalence (proportion) of intestinal CRE/CPE colonization with a defined denominator:1. Analytical cross-sectional studies, including prevalence surveys, point-prevalence surveys, admission screening surveys and multi-centre cross-sectional surveillance reports that provide person-level numerators and denominators.2. Cohort studies, including prospective and retrospective cohorts in which intestinal CRE/CPE colonization was measured at a defined time point (for example, on admission or at a defined surveillance interval). Where a cohort reports repeated.

Eligibility criteria Inclusion criteria

A study is included if all of the following apply.

1. Population — participants were in mainland China at the time of screening.
2. Exposure/index test — participants underwent intestinal screening for CRE/CPE colonization, i.e. culture and/or molecular testing of a rectal, perianal, perirectal or anal swab, or of stool/faecal material.
3. Outcome data — the study reports the number of participants screened and the number with a positive intestinal CRE/CPE screening result, or

provides data from which this proportion can be calculated or reliably derived (for example a percentage with its denominator, or separate numerators and denominators for relevant strata).

4. Publication window — published between 1 January 2021 and 30 September 2026 inclusive.

5. Availability — the full text is retrievable and the study is a peer-reviewed original research report.

Exclusion criteria

1. Narrative or systematic reviews, meta-analyses, guidelines, expert consensus statements, editorials, commentaries and letters that contain no original person-level data.

2. Case reports, and case series in which no screening denominator is reported.

3. Conference abstracts and other non-peer-reviewed material without a full report.

4. Studies in which the original data are insufficiently reported and the intestinal colonization rate cannot be calculated or reliably derived from the information given, including after attempts to obtain additional data from the authors.

5. Studies whose stated primary purpose is to develop or validate an artificial-intelligence or prediction model for CRE colonization (such studies are excluded by design, because the derivation/validation sampling frame does not yield an interpretable prevalence estimate).

6. Duplicate publications of the same dataset, and publications from the same centre with overlapping study periods. When overlap is detected, the report with the largest or most complete dataset is retained and the other(s) are excluded; the decision and its rationale are recorded.

7. Low-quality studies, operationally defined as a JBI critical appraisal score below 60% (grade C) under the scheme in Item 21. Because this is a pre-specified exclusion, a sensitivity analysis restricted to grade A studies will also be reported (Item 24).

8. Studies reporting only clinical CRE isolates from diagnostic specimens, with no intestinal screening data.

9. Studies conducted wholly outside mainland China, or conducted exclusively in Hong Kong, Macao or Taiwan.

10. Non-human studies, environmental or food-chain surveillance, and in vitro studies.

11. Studies published in languages other than English or Chinese, because the review team cannot perform reliable data extraction and risk-of-bias appraisal from those texts.

If, after registration, an eligibility criterion has to change, the change will be submitted as an INPLASY amendment with a clear rationale, and the effect of the post hoc modification will be examined in a sensitivity analysis. Eligibility criteria

will not be modified on the basis of the findings of the included studies.

Information sources Bibliographic databases. Literature published between January 2021 and September 2026 was retrieved from PubMed, Cochrane Library, Embase and China National Knowledge Infrastructure (CNKI).

Additional sources. Reference lists of included studies and of relevant reviews identified during screening (backward citation searching). No trial registries, dissertations databases, preprint servers or grey-literature databases will be searched, because conference abstracts and unpublished reports are ineligible and cannot supply the person-level data required.

Main outcome(s) Primary outcome: prevalence of intestinal colonization with CRE-CP among people who underwent intestinal screening.

1. Definition. The proportion of screened participants with a positive intestinal screening result for CRE-CP, that is $n(\text{positive}) / N(\text{screened})$, expressed as a percentage. The numerator and denominator are extracted exactly as reported; the study's own case definition (phenotypic CRE and/or genotypic CPE), the specimen type, the medium, the use of enrichment and the confirmation method are recorded for every estimate.

2. Measurement. Microbiological detection of CRE-CP from a rectal, perianal, perirectal or anal swab, or from stool. If a study reports both swab and stool results separately, each is extracted as a separate row and the combination is used only if the study reports a combined, non-overlapping denominator.

3. Instrument/analysis hierarchy (prespecified, to avoid double counting). Where a study reports several candidate estimates for the same population, the following hierarchy is applied in order: (1) the estimate based on the whole eligible screened population rather than a subgroup; (2) the estimate for which the numerator and denominator are explicitly reported rather than derived; (3) the estimate based on culture confirmed with carbapenemase information; (4) the estimate from the largest denominator. A single estimate per population is entered into the primary analysis.

The primary outcome is reported as: pooled prevalence with 95% confidence interval, overall and for each of the four regions; a forest plot of all contributing estimates; the range of study-level estimates; and the number of studies and participants contributing to each pooled estimate.

Additional outcome(s) 1. Distribution of dominant colonizing species. For each included study, the number and proportion of intestinal CRE-CP isolates belonging to each species, principally *Klebsiella pneumoniae*, *Escherichia coli*, *Enterobacter* spp., *Citrobacter* spp., *Serratia* spp. and *Proteus* spp., with a combined "other Enterobacterales" category. Reported as pooled proportions of isolates (denominator = isolates with species identified), with the number of studies contributing to each species.

2. Distribution of carbapenemase-encoding genes. The number and proportion of isolates in which each carbapenemase gene or gene family was detected — blaKPC (including KPC-2), blaNDM (including NDM-1, NDM-5), blaIMP (including IMP-4, IMP-8), blaVIM, blaOXA-48-like, and co-carriage of two or more carbapenemase genes. Denominator = isolates tested molecularly or by a validated phenotypic carbapenemase assay; the denominator and method are recorded for each study. Reported overall and by region.

3. Screening and detection methods in use. Descriptive tabulation of specimen type, selective/chromogenic medium, use of broth enrichment, identification method, susceptibility method, carbapenemase confirmation method and breakpoint system used, with the number and proportion of studies using each approach. This outcome is descriptive by design; no pooled proportion is computed for method use.

4. Prevalence by screening and detection method. Pooled prevalence within prespecified method strata (Item 23) together with subgroup-difference tests. Presented as an association with the testing strategy, not as a causal effect of the method.

5. Characteristics of screened populations. Setting (ward type), age group, sex distribution where reported, study period, sample size, city and province, screening indication (admission screening, outbreak investigation, routine surveillance, point-prevalence survey) and study design, tabulated for all included studies.

Additional outcomes are prespecified and are not limited to those that support a particular interpretation of the primary finding. Where a study reports an outcome that was not prespecified, it will be labelled exploratory in the final report.

Data management Deduplication. All retrieved records are exported to EndNote X9, where automatic duplicate detection is applied and then checked manually. The number of records before and after deduplication is recorded for the PRISMA 2020 flow diagram.

Screening. Two reviewers independently screen titles and abstracts against the eligibility criteria, then independently screen the full texts of all

potentially eligible records. Screening decisions are made independently; disagreements are resolved by discussion, and if agreement is not reached, a third reviewer adjudicates.

Full-text exclusions. Every full text excluded after full-text assessment is recorded with its reason, using the exclusion categories in Item 16; reasons are reported in the PRISMA 2020 flow diagram and in a supplementary table.

Data extraction. A standardised electronic extraction that is developed in Microsoft Excel. Extraction is performed independently by the same two reviewers. Extracted data comprise: study identifiers and full citation; first author; publication year; study design; city, province and assigned region; setting and ward type; study period; population characteristics (age group, sample size); screening indication; specimen type; medium; enrichment; number screened and number positive (overall and for every reported subgroup); species distribution; carbapenemase gene distribution; and any data needed for the risk-of-bias appraisal.

Linking multiple reports to one study. Reports sharing a centre, a population and overlapping study periods are treated as one study; the most complete report is used as the primary source. Overlapping studies from the same centre with overlapping periods, retaining the largest dataset.

Software. EndNote X9 for reference management; Excel for extraction and the study database; R version 4.3.3 with the meta package version 8.2.1 for analysis; PRISMA 2020 flow diagram generated with manually.

Quality assessment / Risk of bias analysis

Distinction between the two levels of assessment. Study-level risk of bias (whether the prevalence estimate from an individual study is trustworthy) is assessed separately from the certainty of the body of evidence for the primary outcome. The former uses the JBI critical appraisal checklists; the latter uses GRADE.

Study-level appraisal (JBI). The methodological quality of each included study is assessed independently by two reviewers using the appropriate checklist from the Joanna Briggs Institute (JBI) critical appraisal tools, matched to the study design.

Judgment and scoring scheme (prespecified). Each item is judged Y = yes, N = no, U = unclear, or NA = not applicable. Items judged NA are excluded from the denominator (they are not counted as failures). The quality score ($Y \div (Y + N + U)$) and is graded as: A (high quality) — score $\geq 80\%$; B (moderate quality) — score 60–79%; C (low quality) — score $< 60\%$

How the judgments affect the synthesis. Studies graded C are excluded from the primary synthesis, as prespecified in the eligibility criteria; this exclusion is applied after appraisal and is recorded for every excluded study. Studies graded A and B form the primary analysis set.

Disagreements between the two reviewers in appraisal are resolved by discussion; if unresolved, the third reviewer adjudicates. Inter-reviewer agreement on the overall grade is reported.

Assessment of publication and reporting bias. Funnel-plot asymmetry will be examined visually and with the Egger test when at least 10 studies contribute to a pooled estimate. For the descriptive secondary outcomes (species and gene distributions), no formal detection of reporting bias is planned, because these outcomes are derived from convenience samples of isolates; this is stated as a limitation. Reporting bias arising from selective outcomes and from missing results is considered when interpreting the primary estimate, and the protocol for this assessment is specified here rather than after the results are known.

Strategy of data synthesis Software. All quantitative synthesis is performed in R version 4.3.3 using the `meta` package version 8.2.1; single-arm proportions are pooled with the `metaprop` function.

When studies are combined. Pooled estimates are computed for the primary outcome when at least 2 studies contribute interpretable numerators and denominators to a given analysis. Estimates are pooled overall, then separately for each of the four regions, and separately for the prespecified subgroup levels. Study-level estimates and the range of values are always presented alongside the pooled estimate so that readers can see the underlying distribution even where pooling is judged inappropriate.

Effect measure. The effect measure is a proportion (%) of screened participants with intestinal CRE colonization. Proportions are transformed before pooling; the logit transformation is used as the primary approach. Pooled proportions are back-transformed to the percentage scale for reporting.

Statistical model, and how between-study differences are assessed. The primary analysis uses the random-effects model when between-study heterogeneity is present. The prespecified rule is: $I^2 > 50\% \rightarrow$ random-effects model; $I^2 \leq 50\% \rightarrow$ fixed-effect (common-effect) model. The model is not chosen solely on the basis of the significance of a heterogeneity test: the magnitude of τ^2 , the clinical and methodological diversity of the contributing studies (population, definition of CRE/CPE, specimen type, medium, enrichment, breakpoint system) and the width of the prediction

interval are all considered, and if these indicate that the studies are not estimating a single common prevalence, the random-effects model is used regardless of I^2 . When a fixed-effect model is used, this is stated explicitly and the random-effects estimate is reported alongside it.

Confidence intervals. The random-effects pooled estimate is reported with the Hartung–Knapp–Sidik–Jonkman (HKSJ) adjustment to the confidence interval, which is appropriate when the number of studies is small or heterogeneity is substantial. Because the HKSJ adjustment applies to random-effects models, estimates produced with the fixed-effect model are reported with the conventional confidence interval; wherever both models are fitted, both intervals are shown so the reader can see the effect of the choice.

Heterogeneity. Reported statistics are τ^2 (with its estimator specified DerSimonian–Laird), I^2 , the Cochran Q test (reported with its P value but not used as the sole basis for model choice), and a 95% prediction interval for the primary outcome, which indicates the range of prevalence expected in a new, comparable setting.

Reporting of the primary synthesis. Forest plots of study-level and pooled estimates (overall, by region, and by subgroup), with study-level numerators and denominators; a table of study characteristics; Subgroup forest plots are presented with the subgroup-difference test results.

When meta-analysis is inappropriate. If fewer than two studies contribute, or if the studies are so heterogeneous in population, definition or method that a pooled proportion would be misleading, results are presented as a narrative synthesis with a structured tabulation of study-level estimates, a forest plot without a pooled estimate, and an explicit statement of why pooling was not performed.

Subgroup analysis Subgroups are prespecified and limited to a small number of plausible effect modifiers, each with a rationale. Subgroup analyses are performed for the primary outcome (intestinal CRE/CPE colonization prevalence) and, where data permit, for the species and carbapenemase-gene outcomes (as proportions of isolates).

Subgroup variable: Region (Eastern, Central, Western, Northeastern, "multiregional" as an additional level); Age group (children and adolescents (<18 years); adults (18–64 years); older adults (≥65 years)); Population source (ICU; haematology–oncology; solid organ or haematopoietic stem cell transplant; surgical wards; general inpatient wards; long-term care; community, etc.); Detection method —

medium (Chromogenic CRE/CPE media; conventional MacConkey agar with a carbapenem disk; other selective media; unspecified); Detection method — enrichment (Direct plating only; with selective broth enrichment; unspecified).

Comparison method. Subgroup estimates are compared with the Cochran Q test for subgroup differences (Q_{between}); the P value reported is the one obtained under random-effects weights. Subgroup-specific pooled estimates, their confidence intervals, τ^2 and I^2 within each level, and the Q_{between} statistic are reported. For continuous effect modifiers, meta-regression is used where at least 2 studies contribute: study-level mean or median age, publication year, study period midpoint, and sample size (as a marker of screening-programme scale). Meta-regression results are reported with the number of studies and the residual heterogeneity.

Feasibility and interpretation rules. Each subgroup analysis is performed only if at least two studies and 100 participants contribute to each level being compared; otherwise the results are reported descriptively (tabulated study-level estimates without a pooled subgroup estimate) and the analysis is labelled as not feasible. All subgroup analyses are prespecified; any subgroup analysis introduced after the protocol is registered will be explicitly labelled exploratory and reported as such. Following current methodological guidance, a difference between a statistically significant and a non-significant subgroup result will not be interpreted as proof of an interaction between the subgroup variable and prevalence; only the formal subgroup-difference test is used, and even then the result is treated as hypothesis-generating because these analyses are observational, between-study comparisons that are susceptible to confounding by study-level characteristics.

Sensitivity analysis Sensitivity analyses test the effect of key decisions and assumptions, sensitivity analyses ask whether the pooled estimate is robust to analytical choices.

1. **Leave-one-out** — the pooled estimate is recomputed with each study removed in turn: Identifies single studies that dominate the pooled estimate or drive heterogeneity.

2. **Quality restriction** — analysis restricted to studies appraised as grade A (JBI score ≥ 80%): Tests whether including grade B studies changes the estimate, given that grade C studies are excluded a priori.

3. **Small-study effect** — analysis excluding the smallest studies (for example the lowest quartile of sample size): Tests whether small studies with extreme estimates drive the pooled value; complements the funnel-plot assessment.

Each sensitivity analysis is reported as a table or forest plot showing the pooled estimate with its confidence interval alongside the primary estimate, and, where relevant, the number of studies and participants included. Sensitivities 1–3 were prespecified, where a sensitivity analysis changes the interpretation of the primary estimate, this is stated explicitly in the results and in the abstract of the final report.

Language restriction Search stage, no language filter is applied to any of the four database searches. But for inclusion stage, full texts written in English or Chinese are eligible.

Country(ies) involved China. All members of the review team are based at institutions in China, the restriction of eligible evidence to mainland China is stated in the eligibility criteria.

Other relevant information Related registrations and earlier protocols. This is the first registration of this project. There is no earlier protocol, and no related registration for the same question by this team. The protocol is registered prospectively; no delayed or retrospective registration is involved, and no explanation of late registration is therefore required.

Checks performed before registration. INPLASY, PROSPERO and the Cochrane Database of Systematic Reviews were searched for completed and ongoing reviews on intestinal CRE colonization in China.

Reporting guidance followed. The protocol is reported in accordance with the PRISMA-P 2015 statement (Appendix A maps each PRISMA-P item to the relevant section of this protocol); the completed review will be reported in accordance with PRISMA 2020 and, for the search reporting, PRISMA-S. Protocol deviations will be reported as "differences between the protocol and the review", with the rationale and any resulting sensitivity analysis.

Methodological notes and limitations acknowledged at the protocol stage.

1. restricting the publication window to 2021–2026 and the review to English- and Chinese-language full texts may exclude some relevant data.

2. The regional stratification follows the four national regions (Item 12); within-region heterogeneity (for example between provinces with very different CRE epidemiology) is acknowledged and will be described descriptively in the results, with provincial-level results provided in a supplementary table where the data permit.

Keywords carbapenem-resistant Enterobacterales; carbapenemase-producing

Enterobacterales; intestinal colonization; carriage; prevalence; screening methods; China; systematic review and meta-analysis.

Dissemination plans Primary publication. The completed review will be submitted to a peer-reviewed, indexed journal, reported in accordance with PRISMA 2020 and PRISMA-S. The INPLASY registration number, the registration date and the DOI of this protocol record will be stated in the manuscript, so that the final publication is explicitly linked to the registered protocol. If the review is first posted as a preprint, it will be clearly identified as a preprint and the later journal article will be linked to the INPLASY record once available.

Other dissemination. Findings will be presented at national or regional conferences on clinical microbiology, infectious diseases or infection control; a plain-language Chinese summary of the findings will be prepared for hospital infection-control committees and for the clinical microbiology laboratories that provided the primary data; and a Chinese-language manuscript may be prepared for a domestic journal to reach the practitioners who implement screening policy, if this is compatible with the target journal's policies. Authorship, funding and any competing interests will be declared in all outputs, and the responsibility for all content remains with the human authors.

Contributions of each author

Author 1 - Haiyang Yu - Conception and design of the review; development of the search strategy; Supervision; methodological advice; interpretation;; drafting of the protocol and of the manuscript.

Email: yuheroyoung@hotmail.com

Author 2 - Xu Han - Design of the review; screening; data extraction; risk-of-bias appraisal; JBI appraisal; interpretation of results; critical revision of the protocol.

Email: aselahan@hotmail.com

Author 3 - Jie Zhang - Search strategy design and execution; database searches; deduplication and record management; supplementary citation searching; critical revision of the protocol.

Email: 728996862@qq.com

Author 4 - Youjian Zhang - Data extraction; data management and database construction; quality appraisal; preparation of tables and figures; critical revision of the protocol.

Email: 940678631@qq.com

Author 5 - Peng Li - Third reviewer for unresolved screening, extraction and appraisal disagreements; methodological advice on synthesis, subgroup and sensitivity analyses; critical revision of the protocol.

Email: lpsxjlp@whu.edu.cn