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High-concern Gram-negative organisms recovered from reprocessed gastrointestinal endoscopes and clean-zone handling sites in two Mongolian national referral hospitals: a cross-sectional complete-fleet study

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Additional Declarations: Competing interest reported. OT is employed by Medclean LLC as Senior Manager and Microbiologist. GT is the Managing Director and majority shareholder of Medclean LLC. Medclean LLC is a commercial distributor of infection-prevention products, including endoscope-reprocessing products, and provided financial and material support for this study. The remaining authors declare that they have no competing interests.

Abstract

Background

Microbiological surveillance provides direct quality-assurance evidence for flexible-endoscope reprocessing, yet data from resource-constrained national referral systems are scarce. Mongolia has had a national endoscope-reprocessing instruction since 2019, but published implementation data are unavailable.

Methods

We conducted cross-sectional surveillance from 17 to 30 June 2025 in two public national referral hospitals in Ulaanbaatar. The complete operational fleet comprised 15 flexible gastrointestinal endoscopes. Sixty samples were collected: 15 after procedures but before manual cleaning, 15 after routine reprocessing and before reuse, and 30 from associated equipment, surfaces, transport/support items, sinks, gloves and hands. Nineteen morphologically selected Gram-negative isolates were identified by MALDI-TOF mass spectrometry. Practice observations and available records were compared descriptively with selected requirements of the national instruction.

Results

The selected isolates comprised Pseudomonas aeruginosa (n = 10), Klebsiella pneumoniae (n = 5), Acinetobacter baumannii (n = 2), Klebsiella oxytoca (n = 1) and Serratia marcescens (n = 1). P. aeruginosa and K. oxytoca were recovered directly from two reprocessed endoscopes. Two further P. aeruginosa isolates and one phenotypically extended-spectrum beta-lactamase-positive K. pneumoniae isolate were recovered from three clean-labeled support or transport sites. All five recoveries at or after the clean stage occurred at one hospital. Quarterly microbiological monitoring had not been implemented before this study; implementation of several other observed or record-based requirements was incomplete or could not be verified.

Conclusions

Recovery of high-concern organisms from reprocessed endoscopes constitutes microbiological non-conformity and identifies clean-zone handling as a priority for root-cause investigation. The findings do not establish a contamination route or patient transmission. Implementing the surveillance and documentation already required nationally is an immediate, feasible corrective action.

Background

Flexible gastrointestinal endoscopes are semicritical devices whose long, narrow, multichannel construction complicates cleaning, high-level disinfection (HLD), rinsing, drying and storage. Residual organic material, biofilm, contaminated rinse water, incomplete drying, or contact with contaminated accessories, transport items, surfaces or hands can leave or reintroduce microorganisms despite completion of a reprocessing cycle [1–3]. Outbreaks and pseudo-outbreaks associated with reprocessed endoscopes have frequently involved Gram-negative organisms, including antimicrobial-resistant strains [1, 4, 5].

Microbiological surveillance complements process records by providing direct evidence of the microbiological state of a reprocessed device and can trigger root-cause investigation and corrective action [4, 6]. Published surveillance, however, comes predominantly from high-income settings with established reprocessing infrastructure [4, 5]. Evidence from national referral systems with constrained consumable and engineering resources remains sparse. Surveillance also tends to prioritize the device itself, although post-disinfection handling, transfer, transport and support surfaces can recontaminate an endoscope before reuse.

Mongolia has had a detailed national instruction for cleaning, disinfection and sterilization of diagnostic and therapeutic endoscopes since 2019 [6]. It specifies the reprocessing sequence, protected transport and storage, concentration monitoring for reusable disinfectants, process documentation, and quarterly microbiological monitoring. No endoscope-surveillance data from Mongolia have been published. We therefore assessed the complete operational gastrointestinal-endoscope fleets of two national referral hospitals, together with associated sites. Our objectives were to identify high-concern Gram-negative organisms recovered at defined operational stages, describe their source distribution and selected antimicrobial-susceptibility findings, and compare observed or documented practice with selected requirements of the national instruction.

Methods

Study design, setting and sampling frame

This cross-sectional microbiological surveillance study was conducted from 17 to 30 June 2025 in the endoscopy units of two public tertiary hospitals in Ulaanbaatar, coded Hospital 1 and Hospital 2 to preserve institutional confidentiality. Both have national referral functions and receive patients from across Mongolia. All sampled devices were flexible gastrointestinal endoscopes. The sampling frame was the complete operational fleet: eight devices at Hospital 1 and seven at Hospital 2. No patient-level clinical or identifying data were collected. Laboratory work was performed at the Microbial Ecology and Biotechnology Laboratory, Department of Biology, School of Science, National University of Mongolia.

National regulatory framework and contextual assessment

The study framework was informed by the endoscope-reprocessing annex of Minister of Health Order A/537 [6]. Provisions relevant to this study include HLD of flexible endoscopes; cleaning of all working channels; dedicated transport; clean handling after disinfection; rinsing, forced-air drying and protected storage; product-specific concentration and contact-time control for reusable disinfectants; stage-specific records; quarterly microbiological monitoring; and a channel-sampling method using 20–30 mL sterile physiological saline. Surface sampling followed MNS ISO 18593:2020 [7].

Practice was compared descriptively with selected clauses using an external assessment of one participating institution conducted in March 2024, observations by the sampling team during the 2025 study period, unit reports, and records available for review. This was not a scored compliance audit. Table 3 distinguishes observed discrepancies from requirements that were not verified and from a requirement reported as not implemented. Lack of verification was not treated as proof of noncompliance.

Reprocessing pathway as operated

Both units reported immediate manual pre-cleaning, semi-automated washing with an Endo 1000 washer, HLD according to local protocols, rinsing and drying before reuse. Hospital 1 reported using an ortho-phthalaldehyde-based product and Hospital 2 an active-oxygen/peracetic-acid-based product; both reported reuse for up to 14 days. Exact formulations, manufacturers' instructions for use (IFUs), in-use concentrations, minimum-effective-concentration records, channel-connection performance, final-rinse-water quality and drying duration were not independently verified, and in-use solutions were not sampled. Reuse duration alone was therefore not classified as compliant or noncompliant; interpretation requires the product-specific IFU, concentration monitoring, exposure conditions and solution-use history.

Sample collection

Sixty samples were collected (Table 1): 15 from endoscopes after a clinical procedure and before manual pre-cleaning, 15 after routine reprocessing and before reuse, and 30 from associated environmental surfaces, equipment, accessories, transport/support items, sinks, gloves and healthcare workers' hands. Hospital 1 contributed 31 samples and Hospital 2 contributed 29. Records documented 15 endoscope samples at each operational stage but did not permit one-to-one pairing of devices. Pre-reprocessing samples characterized incoming bioburden and were not used to assess reprocessing performance.

Biopsy, water and air channels were each flushed with 20 mL sterile 0.9% sodium chloride using a single-use syringe, and effluent was collected aseptically. No disinfectant neutralizer was added. Accessible endoscope sites, including air/water and suction valves, the biopsy port, channel openings and insertion-tube surface, were sampled using saline-moistened Amies swabs. Channels were not brushed. Flat surfaces were swabbed over approximately 50 cm² in an S/Z pattern; small or inaccessible items were

swabbed for approximately 20 seconds. Hand contamination was assessed by four-finger imprint onto nutrient agar for 5 seconds after a procedure and before hand hygiene. Swabs were transported at 1–4 °C and processed within 3–4 hours; imprint plates were processed within 2 hours.

Culture, identification and antimicrobial susceptibility testing

Channel effluent was filtered through a 0.45-µm membrane, placed on MacConkey agar and incubated aerobically at 37 °C for 18–24 hours. This workflow was selective for Gram-negative organisms. Colonies on membranes could not be enumerated; colony-forming-unit values are not reported. Swab and imprint samples were enriched aerobically in nutrient broth for 18–24 hours and subcultured onto 5% sheep blood, nutrient, MacConkey and Endo agars at 37 °C for 18–24 hours.

Morphologically distinct colonies suspected to be Gram-negative underwent Gram staining and biochemical screening using standard clinical microbiology procedures [8]. Nineteen selected isolates were identified by matrix-assisted laser desorption/ionization time-of-flight mass spectrometry. Kirby–Bauer disk diffusion on Mueller–Hinton agar used inocula adjusted to 0.5 McFarland; zone diameters for ciprofloxacin, amikacin, gentamicin and cefepime were recorded after incubation at 37 °C for 18–24 hours. The raw isolate-level zone diameters are provided in Additional file 1. They are not pooled into resistance proportions because the morphotype-selected collection was small and non-random, and CLSI breakpoints and reporting recommendations differ by organism and clinical context [9]. One K. pneumoniae isolate (XC475) underwent bioMérieux VITEK 2 AST-N438 testing with phenotypic extended-spectrum beta-lactamase (ESBL) detection.

Interpretation and descriptive analysis

Organism-based interpretation followed the FDA/CDC/ASM surveillance framework and its application in national endoscope surveillance [10, 11]. Pseudomonas aeruginosa, Enterobacterales and Acinetobacter spp. are high-concern organisms; recovery from a reprocessed endoscope is actionable irrespective of quantity. Counts and proportions describe the distribution of the 19 selected isolates, not contamination prevalence among the 60 samples. Complete sample-level culture-positivity records and paired device identifiers were unavailable; therefore, no sample positivity rate, confidence interval, between-hospital comparison or inferential model was calculated. Original source labels were reconciled conservatively against the final isolate-source record. A clean-labeled support or transport site was not treated as a direct endoscope sample.

OpenAI ChatGPT was used to support English-language editing and manuscript organization of author-prepared material. All scientific content, analyses, interpretations and conclusions were reviewed and verified by the authors.

Results

Samples and selected isolates

The 60 samples comprised 30 endoscope samples and 30 associated-site samples (Table 1). Nineteen morphologically selected Gram-negative isolates were identified: seven from Hospital 1 and 12 from Hospital 2. P. aeruginosa predominated (10/19; 52.6%), followed by K. pneumoniae (5/19; 26.3%), A. baumannii (2/19; 10.5%), S. marcescens (1/19; 5.3%) and K. oxytoca (1/19; 5.3%). All met high-concern criteria. These figures describe selected isolates and cannot be converted to sample-level prevalence.

Distribution by operational stage and site

Two high-concern organisms were recovered directly from endoscopes documented as reprocessed and awaiting reuse: P. aeruginosa and K. oxytoca (Table 2). Three additional high-concern organisms were recovered from clean-labeled support or transport padding: two P. aeruginosa and one K. pneumoniae. All five recoveries at or after the clean stage occurred at Hospital 2.

The remaining selected isolates comprised five from directly sampled post-procedure endoscopes, two from associated post-procedure pads or drapes, four from hands or gloves, two from sink/water-associated sites, and one from an environmental source originally recorded as “air”; the collection method for that source could not be reconstructed. Twelve of 19 selected isolates were recovered from associated sites rather than direct endoscope samples, but the different culture workflows and morphotype selection preclude comparison of contamination frequency.

ESBL-producing Klebsiella pneumoniae

K. pneumoniae XC475, recovered from clean-endoscope transport padding rather than directly from an endoscope, was phenotypically ESBL positive by VITEK 2. It was resistant to cefazolin, cefotaxime, ceftriaxone, ceftazidime, ciprofloxacin, levofloxacin and trimethoprim–sulfamethoxazole, and susceptible to amoxicillin–clavulanate, tobramycin, imipenem and meropenem. No patient isolate, clinical infection or transmission event was linked to this isolate.

Observed and documented practice

Table 3 presents the status of 10 selected requirements. Gloves or protective clothing were observed or previously documented as unchanged between dirty and clean handling, and reusable transport boxes were reported without documented wipe disinfection or fresh liners. Several other requirements, including channel-brushing records, product-specific indicator and minimum-effective-concentration records, final-rinse water specifications, alcohol channel flush and stage-specific cycle documentation, could not be verified from available observation or records. Both units reported that quarterly

microbiological monitoring had not been implemented before this study. “Not verified” does not establish noncompliance and was not linked causally to the culture findings.

Discussion

Complete-fleet surveillance at two Mongolian national referral hospitals recovered high-concern Gram-negative organisms directly from two reprocessed gastrointestinal endoscopes and from three clean-labeled handling sites. Recovery of a high-concern organism from a reprocessed endoscope constitutes microbiological non-conformity under organism-based surveillance criteria [10, 11]. The findings are actionable for root-cause investigation, but the study cannot identify the stage at which contamination persisted or was introduced.

The clean-site findings identify post-disinfection handling as a potential vulnerability in addition to the device pathway. An endoscope that has completed HLD can be recontaminated through hands, gloves, support materials, transport containers, rinse water or storage [2, 12–15]. The ESBL-positive K. pneumoniae recovered from clean transport padding is especially relevant to an antimicrobial-resistance and infection-prevention audience because a surface designated for reprocessed devices carried a phenotype associated with limited cephalosporin options. However, it was an environmental isolate without patient linkage or molecular typing; transmission and clinical impact were not assessed.

The regulatory comparison suggests that the immediate policy need is implementation verification rather than creation of another guideline. The national instruction already addresses separation of dirty and clean handling, transport, process chemistry, drying, storage, documentation and quarterly microbiological monitoring [6]. In the study units, microbiological monitoring had not previously been operationalized, and records needed to verify several process requirements were unavailable. Regular surveillance is not a substitute for validated reprocessing, but it creates a feedback mechanism through which undocumented or ineffective steps can be detected and corrected.

The reported 14-day reuse periods cannot be interpreted without product-level information. OPA and PAA-containing formulations differ in stability, intended concentration and allowable reuse. A calendar interval may be acceptable for one formulation and inappropriate for another; continued efficacy also depends on organic load, temperature, contact time, concentration testing and adherence to the IFU [2, 3, 6]. Because the exact formulations, IFUs and minimum-effective-concentration records were not verified and the solutions were not sampled, the culture findings cannot be attributed to disinfectant depletion or to a named product.

The national channel-sampling method was operationally relevant but less sensitive than current reference approaches. No neutralizer was added, sterile saline rather than buffered surfactant was used as eluent, channels were not brushed, the channel membrane was cultured only on a Gram-negative-selective medium, and incubation was limited to 18–24 hours [2, 13, 14]. These features may cause under-recovery; negative cultures must not be interpreted as absence of contamination. Conversely,

associated-site swabs underwent enrichment, so isolate yields from channel and associated-site workflows are not directly comparable.

Other limitations are substantial. Sample-level culture-positivity denominators and CFU counts were unavailable, preventing prevalence estimates or quantitative action levels. Devices could not be paired before and after reprocessing, and associated sites were not linked to individual devices. Morphotype selection was not exhaustive. No molecular typing, rinse-water testing, in-use disinfectant testing, procedure-volume denominator or patient linkage was available. The disk-diffusion panel was limited; raw zone diameters were not pooled across species because the collection was small, non-random and microbiologically heterogeneous. Sampling covered two hospitals during a two-week period, and the contextual comparison with the national instruction was not a scored audit. The findings are not nationally representative and establish neither causality nor patient transmission.

A strength is that every operational gastrointestinal endoscope in both units was included rather than a convenience subset. Immediate actions are to separate dirty and clean gloves and handling materials; disinfect and dry transport containers and support padding between uses; use fresh clean liners where indicated; verify each disinfectant against its IFU with documented concentration testing; and implement the quarterly microbiological monitoring already required. Repeat surveillance should prospectively pair each device and cycle, record device type and model, combine flushing with brushing and neutralization, include quantitative nonselective and selective cultures, test final rinse water and in-use chemistry, and repeat sampling after corrective action.

Conclusions

High-concern Gram-negative organisms were recovered from two reprocessed gastrointestinal endoscopes and three clean-labeled support or transport sites in one of two Mongolian national referral hospitals. The findings identify microbiological non-conformity and make clean-zone handling, transport and process verification priorities for corrective surveillance. They do not establish failure of a specific disinfectant, a contamination route or patient transmission. Operationalizing the monitoring and documentation already required nationally offers an immediate and feasible starting point.

Abbreviations

CLSI: Clinical and Laboratory Standards Institute; ESBL: extended-spectrum beta-lactamase; FDA: U.S. Food and Drug Administration; HLD: high-level disinfection; IFU: instructions for use; MALDI-TOF: matrix-assisted laser desorption/ionization time-of-flight; MEC: minimum effective concentration; OPA: ortho-phthalaldehyde; PAA: peracetic acid.

Declarations

Ethics approval and consent to participate

The cross-sectional study was approved by the Research Department of the Second State Central Hospital (approval no. 2025/06/05/01; 5 June 2025). Endoscope and associated-site sampling involved no patient-level data or direct patient contact, and individual patient consent was not required. Participating healthcare workers provided written informed consent for anonymized hand-imprint sampling. All data were deidentified and reported in aggregate.

Consent for publication

Not applicable. No individual person's data are reported.

Availability of data and materials

The dataset supporting the conclusions of this article is included within the article and its Additional file 1. Additional source records are available from the corresponding author on reasonable request, subject to institutional approval.

Competing interests

OT and GT are affiliated with Medclean LLC, which funded the study. The remaining authors declare that they have no competing interests.

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Medclean LLC provided financial and material support for the study. OT and GT, who are affiliated with Medclean LLC, contributed as investigators as described below. Beyond those investigator contributions, the funding organization had no additional role in data analysis, interpretation, manuscript preparation, or the decision to submit the manuscript.

Authors' contributions

OT contributed to conceptualization, methodology, formal analysis, data curation, visualization, writing the original draft, review and editing, and project administration. TD contributed to conceptualization, methodology, investigation, formal analysis, data curation, and review and editing. GT contributed to conceptualization, resources, supervision, project administration, and review and editing. UT, OM, KB, TT, SEA, ABa (Aminaa Bayaraa), and ABd (Anudari Badral) contributed to investigation, resources, data curation, and review and editing. All authors read and approved the final manuscript.

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Tables

Table 1. Distribution of the 60 samples by category and hospital.

Sample category	Hospital 1	Hospital 2	Total
Endoscope after procedure, before manual pre-cleaning	8	7	15
Endoscope after routine reprocessing, before reuse	8	7	15
Associated environment, equipment, transport/support items, sinks, gloves and hands	15	15	30
Total	31	29	60

The complete operational fleet comprised eight gastrointestinal endoscopes at Hospital 1 and seven at Hospital 2. Records did not permit one-to-one matching between operational stages.

Table 2. Conservative source distribution of 19 selected Gram-negative isolates identified by MALDI-TOF mass spectrometry.

Source group	P. aeruginosa	K. pneumoniae	Other species	Total
Direct endoscope, before reprocessing	4	1	—	5
Associated pre-reprocessing pad/drape	1	0	S. marcescens, 1	2
Direct reprocessed endoscope	1	0	K. oxytoca, 1	2
Clean-labeled support or transport padding	2	1	—	3
Hand or glove	0	2	A. baumannii, 2	4
Sink/water-associated site	1	1	—	2
Unclassified environmental source recorded as “air”	1	0	—	1
Total	10	5	4	19

All species met high-concern criteria [10, 11]. Counts describe morphologically selected isolates, not sample-level prevalence. Clean-labeled supports or padding are not direct endoscope samples. The ESBL-positive K. pneumoniae was recovered from this category.

Table 3. Selected requirements of the national endoscope-reprocessing instruction and evidence available during the study.

Requirement and clause [6]	Evidence available to the study team	Assessment
Clean gloves for handling after disinfection (§4.2)	Gloves/protective clothing were not changed between dirty and clean handling in the external assessment; similar practice was observed in 2025.	Observed discrepancy
Dedicated transport with clean contact surface (§4.2)	Reusable transport boxes were used without documented wipe disinfection or fresh liners.	Observed discrepancy
Padded basin accommodating the uncoiled device (§4.2)	Cleaning under running water was documented; the specified padded basin was not evidenced.	Observed discrepancy / not evidenced
Every working channel brushed at least three times (§4.2)	No process record was available for review.	Not verified
Product-specific concentration/contact-time monitoring by indicator (§4.2)	Reuse up to 14 days was reported; exact IFUs and indicator records were unavailable.	Not verified
Minimum effective concentration verified and recorded (§8.1 item 11)	No minimum-effective-concentration records were available for review.	Not verified
Second rinse with filtered or sterile water, then discard (§4.2)	Water specification and discard documentation were unavailable.	Not verified
Forced-air drying followed by 70% alcohol channel flush (§4.2)	Air drying was reported; an alcohol channel flush was not verified.	Partly verified
Stage-specific process control records (§6.2; §7.2)	No complete cycle documentation was available for review.	Not verified
Quarterly microbiological monitoring with records (§6.1)	Both units reported that monitoring had not been implemented before this study.	Not implemented

Evidence derived from an unpublished external 2024 assessment of one participating institution, 2025 investigator observation, unit reports and records available for review. This was not a scored audit. "Not verified" means that implementation could neither be confirmed nor excluded and does not establish noncompliance or causality.

Supplementary Files

This is a list of supplementary files associated with this preprint. Click to download.

- Additionalfile1.xlsx