

عنوان البحث

Analyzing the Causes of Sample Rejection in Emergency Department
Specimens: A Descriptive Cross-Sectional Study

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Title

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Introduction

Clinical laboratories are central to modern healthcare, supporting diagnosis, monitoring, and treatment decisions across nearly all specialties. A large percentage of medical decisions depend on the availability of accurate and timely laboratory results, especially in time-sensitive environments such as the emergency department (ED). In this high-pressure setting, clinicians often rely on rapid laboratory testing to guide triage, stabilization, and definitive management. Any disruption in the pre-analytical, analytical, or post-analytical phases of testing can compromise care.

One of the most critical pre-analytical quality indicators in laboratory medicine is the **specimen rejection rate**. A rejected sample is one that is deemed unsuitable for analysis because it does not meet predefined quality criteria. Common reasons include clotted samples, hemolysis, insufficient volume, wrong container, mislabeling, contamination, or dilution with intravenous (IV) fluids. [ica+2Europe PMC+2](#) When a sample is rejected, the patient must often undergo repeat collection, which leads to delays in diagnosis, extended ED length of stay, potential crowding, increased workload for nurses and laboratory staff, and patient dissatisfaction.

Evidence from multiple studies shows that the **emergency department consistently exhibits higher specimen rejection rates** compared with inpatient and outpatient areas. [Europe PMC+1](#) The ED environment is characterized by high patient acuity, unpredictable workload surges, rapid staff turnover, and frequent use of temporary or newly-hired nursing staff. These contextual features make the ED particularly vulnerable to pre-analytical errors.

Among the most problematic specimen issues in the ED are:

- **Clotted samples**, especially for coagulation and hematology testing;
- **Contaminated blood cultures**, often due to inadequate skin antisepsis or poor technique;
- **Diluted samples with IV fluids**, when blood is drawn from lines infusing fluids or medications. [MDPI+2مجلة الطب الدقيق والمخبرية+2](#)

These technical problems are not random events; they usually reflect deeper systemic issues such as inadequate staff training, high turnover, time pressure, communication barriers, and variability in nursing skills.

In many hospitals, specimen rejection is monitored as part of routine quality indicators, but the underlying causes—especially in the ED context—are not always systematically analyzed. This proposal outlines a study to examine in detail the **causes of sample rejection in emergency department specimens**, with particular attention to clotted samples, contaminated blood cultures, and diluted specimens, and to explore how ED nursing workforce factors—such as high turnover, lack of training programs, language barriers, and heterogeneous skill levels—contribute to rejection rates.

Statement of the Problem

Pre-analytical errors account for the majority of mistakes in the total testing process and are a leading cause of specimen rejection. Studies across different settings report that the most frequent reasons for rejection are clotted samples, insufficient volume, hemolysis, and labeling errors.[ايديو كيميا ميد.ica+2Europe PMC+2](#) In particular, clotted samples represent a major reason for rejecting coagulation and complete blood count (CBC) specimens, while contamination is a major concern for microbiology samples such as blood cultures.[JPTCP+2PubMed+2](#)

Research has also demonstrated that **EDs tend to have higher specimen rejection ratios than other hospital units**, due to the combination of time pressure, high patient turnover, and the complexity of procedures performed.[Europe PMC+2Lippincott Journals+2](#) However, in many institutions, the problem is treated primarily as a technical issue at the laboratory level, without sufficient investigation into **upstream causes** in the clinical setting, especially nursing-related factors.

In the ED, several recurring specimen issues are commonly observed:

1. **Clotted samples** – often linked to inadequate or delayed mixing of anticoagulated tubes, incorrect order of draw, prolonged tourniquet time, or drawing from lines where blood flow is sluggish.[Acute Care Testing+2Cureus+2](#)
2. **Contaminated blood cultures** – typically related to insufficient skin antisepsis, touching the venipuncture site after disinfection, or drawing samples through existing catheters.[PLOS+1](#)
3. **Diluted samples with IV fluid** – occurring when blood is drawn from lines concurrently infusing IV fluids or not adequately flushed, leading to falsely low analyte levels or spurious results. [مجلة الطب الدقيق.1+المخبرية](#)

These sample-level problems are closely tied to **system-level ED realities**, including:

- High **turnover of ED nursing staff**, which limits continuity and institutional memory;[JAMA Network+2ScienceDirect+2](#)
- Limited or irregular **training and competency assessment** in phlebotomy and blood culture collection;[ResearchGate+2Lippincott Journals+2](#)

- **Language barriers** between nurses and patients or between multinational staff, which can impair communication during blood collection and instruction;[MDPI+3Discovery Scientific Society+3ResearchGate+3](#)
- Wide **variation in nursing skills**, experience, and familiarity with local protocols.

Despite increasing recognition of pre-analytical errors, there is still a gap in **integrated analyses that connect specific specimen rejection patterns in the ED with nursing-related factors**. Many quality reports simply list rejection reasons but do not explore whether, for example, shifts with more newly hired staff have higher rates of clotted samples, or whether units with more language diversity show more contaminated blood cultures.

Without such analysis, interventions may remain generic (e.g., reminders, memos) rather than targeted (e.g., focused training on blood culture collection, supervision of new staff, addressing communication barriers). As a result, high rejection rates may persist, exposing patients to repeated venipunctures and delaying care.

This study aims to address this problem by systematically analyzing ED specimen rejection patterns and linking them to ED nursing workforce characteristics and practices.

Significance of the Study

This study has several layers of significance:

Clinical Significance

Rejected specimens in the ED translate directly into **delayed diagnoses and treatment decisions**. When a clotted coagulation sample or a contaminated blood culture is rejected, the patient must undergo repeat sampling, which can delay antibiotic initiation, anticoagulation decisions, or surgical planning. In time-critical conditions such as sepsis, stroke, or major trauma, such delays can have serious consequences. By identifying and addressing the causes of sample rejection, this study supports safer, more timely clinical care.[PubMed+1](#)

Operational and Quality Significance

High rejection rates increase ED and laboratory workload, as staff must repeat procedures, recollect samples, and re-enter orders. This contributes to overcrowding, staff burnout, and inefficient use of resources. Reducing sample rejection is a recognized **quality improvement target** in laboratory and ED management. Understanding which factors are most strongly associated with rejection (e.g., specific shifts, experience levels, or training gaps) will allow targeted interventions rather than broad, non-specific strategies.[ResearchGate+2Lippincott Journals+2](#)

Educational and Workforce Significance

The study will shed light on how **nursing education, supervision, and audit systems** in the ED impact pre-analytical quality. If findings confirm that high turnover, lack of structured training, language barriers, and skill diversity are key contributors to errors, this will support the design of structured orientation programs, periodic skill refreshers, and tailored audits.

Policy and Accreditation Significance

Accreditation bodies and laboratory standards, such as ISO 15189 and CAP, emphasize monitoring and reducing pre-analytical errors, including specimen rejection.[Journal of Archives of Iranian Medicine+1](#) By providing data-driven insight into ED specimen quality, the study supports compliance with accreditation requirements and offers evidence for resource allocation (e.g., dedicated educators, interpreters, or specialized phlebotomy roles).

Academic Significance

From a research perspective, the study adds to the limited but growing body of literature that connects **ED nursing factors and pre-analytical laboratory quality**, integrating perspectives from laboratory medicine, emergency nursing, and healthcare quality science.

Objectives of the Study

General Objective

To analyze the causes of sample rejection in emergency department specimens, with a focus on clotted samples, contaminated blood cultures, and diluted samples, and to explore how ED nursing workforce and practice factors contribute to high rejection rates.

Specific Objectives

1. To determine the **overall specimen rejection rate** in the ED and describe its distribution by test type and rejection reason.
2. To quantify the proportion of ED specimen rejections due to:
 - Clotted samples;
 - Contaminated blood cultures;
 - Diluted samples with IV fluids.
3. To examine the association between **nursing-related factors** (turnover, experience, training, and skill mix) and ED specimen rejection rates.
4. To explore the influence of **language barriers and communication issues** on specimen quality from the ED.
5. To identify **high-risk situations**, shifts, or processes in which sample rejection is more frequent.
6. To propose **evidence-based interventions** aimed at reducing ED specimen rejection rates.

Research Questions

1. What is the overall rate of specimen rejection for ED samples, and what are the most common reasons for rejection?
2. What proportion of rejected ED specimens are due to clotted samples, contaminated blood cultures, and diluted samples with IV fluids?
3. How are ED nursing staff turnover, experience level, and skill diversity associated with specimen rejection rates?
4. To what extent do training and auditing programs in the ED influence the frequency of sample rejections?
5. How do language barriers and communication issues within the ED workforce relate to pre-analytical specimen errors?
6. Which workflow points or clinical scenarios in the ED are most strongly associated with rejected specimens?
7. Which targeted strategies can be recommended to reduce ED specimen rejection based on the identified causes?

Research Hypotheses

1. **H1:** Clotted samples, contaminated blood cultures, and diluted specimens represent the majority of ED specimen rejections.
2. **H2:** Higher ED nursing staff turnover is significantly associated with increased specimen rejection rates.
3. **H3:** Lack of structured training and regular auditing programs in the ED is associated with higher rates of sample rejection.
4. **H4:** Language barriers among ED staff are positively associated with errors that lead to specimen rejection.
5. **H5:** Greater variation in ED nursing skill levels is associated with higher frequencies of clotted, contaminated, and diluted samples.

Literature Review

1. Pre-Analytical Errors and Specimen Rejection

Laboratory errors can occur in all phases of testing, but a large body of evidence indicates that **pre-analytical errors account for the majority** of laboratory mistakes and are a major cause of specimen rejection.[Lippincott Journals+3PMC+3PMC+3](#) Rejection reasons commonly reported include clotted specimens, insufficient volume, hemolysis, wrong containers, mislabeling, and transport delays. These problems compromise test validity and necessitate sample recollection.

Systematic analyses in clinical laboratories have identified **fibrin clots and clotted samples** as leading reasons for rejection in biochemistry, coagulation, and hematology testing.[PLOS+3ميدى كيميا+3Europe PMC+3](#) Insufficient sample volume, often due to underfilled tubes, is another prominent cause. More recent work continues to highlight similar patterns, confirming that pre-analytical quality remains a persistent challenge despite technological advances.[PMC+2Cureus+2](#)

2. Emergency Department as a High-Risk Environment

The ED is an especially complex environment for laboratory specimen quality. Dikmen and colleagues found that **rejection ratios were higher in ED samples** than in those from inpatient units and intensive care, with clotted samples and inadequate volume as dominant causes.[Europe PMC+1](#) Subsequent studies have echoed this finding, noting that stat or urgent laboratories serving EDs show elevated rates of hemolyzed and clotted specimens.[Lippincott Journals+2ScienceDirect+2](#)

Several contextual factors distinguish the ED from other settings:

- Rapid patient turnover and crowding;
- High acuity and frequent resuscitations;
- Competing clinical priorities for nurses and physicians;
- Frequent involvement of newly hired or temporary staff;
- High reliance on venous access lines and multiple blood draws.

These conditions increase the risk of shortcuts, inconsistent adherence to protocols, and communication breakdowns, all of which can manifest as pre-analytical errors.

3. Specific ED Sample Issues

3.1 Clotted Samples

Clotted ED samples are often linked with errors in **tube mixing, collection technique, and order of draw**. If anticoagulated tubes are not inverted gently and promptly, the anticoagulant may not mix adequately with the blood, leading to clot formation. In addition, prolonged tourniquet application and slow blood flow through small-gauge needles can predispose to clotting.[Acute Care Testing+2Cureus+2](#)

A number of hematology-focused studies report that clotted specimens account for a substantial fraction of rejected samples, sometimes exceeding 20–30% of all pre-analytical errors.[MDPI+2JPTCP+2](#) These problems are particularly prominent in high-volume areas such as EDs and pediatric units, where staff may have variable phlebotomy experience.

3.2 Contaminated Blood Cultures

Contaminated blood cultures are a unique and clinically serious category of pre-analytical error. Contamination typically occurs when skin flora enter the culture bottle during collection. Factors contributing include inadequate skin antisepsis, re-palpation of the venipuncture site after disinfection, or drawing blood through existing catheters.[PubMed+1](#)

In the ED, contaminated blood cultures can lead to:

- False-positive results suggesting bacteremia;
- Unnecessary antibiotic use;
- Extended hospital admission and additional investigations;
- Confusion in clinical decision-making.

Studies in EDs have found that specific patient categories (e.g., critically ill patients, older adults, or those with multiple lines) may be at higher risk of blood culture contamination.[PLOS](#) Quality improvement initiatives focusing on standardized skin preparation, use of dedicated phlebotomists, and regular feedback to staff have been shown to reduce contamination rates.

3.3 Diluted Samples with IV Fluids

Another important and sometimes overlooked issue is **dilution of blood samples by IV fluids** when drawn from lines currently infusing fluids or not properly flushed. This can artificially lower concentrations of analytes such as sodium, potassium, and hemoglobin, or alter coagulation and drug levels, leading to misleading results.[مجلة الطب الدقيق والمخبرية+2ScienceDirect+2](#)

Because IV access is widely used in ED patients and drawing from lines may seem more convenient than peripheral venipuncture, the risk of sampling near or through infusing lines is high. Recommendations to avoid drawing from lines with ongoing infusions or to employ rigorous flushing protocols are well described, yet adherence may be inconsistent due to workload, habit, or inadequate training.

4. Pre-Analytical Quality Indicators and Improvement Efforts

Several authors recommend the use of **quality indicators (QIs)** to monitor pre-analytical performance, such as the proportion of rejected samples, frequencies of specific error types (e.g., clotted, hemolyzed), and sample collection error rates by location or shift.[Lippincott Journals+2ResearchGate+2](#) These indicators can identify problem areas and support continuous quality improvement.

Quality improvement initiatives in the pre-analytical phase have employed strategies such as:

- Standardizing phlebotomy procedures and checklists;
- Providing targeted staff training and competency assessments;
- Implementing double-check systems for sample labeling;
- Introducing feedback dashboards showing unit-specific rejection rates;
- Using Lean and Six Sigma methods to identify and eliminate process waste.[ResearchGate+2PLOS+2](#)

In ED settings, some interventions have successfully **reduced rejection rates** by combining staff education, process redesign, and monitoring of performance over time.[ScienceDirect+1](#)

5. Nursing Factors in the Emergency Department

While laboratory literature often focuses on the technical aspects of sample handling, nursing and organizational factors in the ED are critical determinants of pre-analytical quality.

5.1 High Turnover and Staffing Challenges

EDs worldwide face high **nurse turnover**, staffing shortages, and rising workload. Studies report that emergency nurses frequently describe their workplaces as understaffed, stressful, and characterized by insufficient organizational support.[JAMA Network+2ScienceDirect+2](#) High turnover results in a constant influx of new staff who may be unfamiliar with local

phlebotomy protocols, blood culture procedures, and quality expectations. This reduces the overall level of procedural consistency and increases the risk of errors.

5.2 Training, Education, and Auditing

Education and competency in phlebotomy and blood collection techniques are foundational to pre-analytical quality. Research on triage knowledge and ED practice has shown that continuous **training, education, and simulation** are necessary to maintain staff competence in complex environments.[SAGE Journals+1](#) Inadequate or irregular training in blood collection methods, or a lack of systematic audits and feedback, can allow poor practices to persist unnoticed.

5.3 Language Barriers and Communication

In many EDs, especially in regions with multinational nursing staff and diverse patient populations, **language and communication barriers** are a significant challenge. Studies in emergency and acute care settings have documented communication obstacles arising from differences in language, culture, and education between staff and patients, and between staff from different backgrounds.[MDPI+3Discovery Scientific Society+3ResearchGate+3](#)

Communication barriers can influence specimen quality in several ways:

- Misunderstanding patient instructions (e.g., fist clenching, timing of draws);
- Miscommunication between nurses and laboratory staff about special handling requirements;
- Difficulties in providing or understanding feedback about previous errors.

5.4 Diversity of Skills and Experience

ED nursing teams often include staff with widely varying levels of experience, from novice nurses to seasoned clinicians. This **skill mix diversity** can be beneficial, but without structured supervision and mentorship, less experienced staff may perform complex tasks like blood culture collection or sampling from central lines without optimal technique. Studies on missed nursing care also point to workload, lack of resources, and variability in education as contributing to incomplete or rushed tasks.[BMJ Open+1](#)

6. Summary of Literature Gaps

Existing research clearly establishes that:

- Pre-analytical errors are the leading cause of specimen rejection;
- EDs are high-risk areas with elevated rejection ratios;
- Clotted samples, contaminated blood cultures, and diluted specimens are common issues.

However, fewer studies have **systematically linked ED sample rejection patterns to specific nursing and workforce factors** such as turnover, language barriers, and training gaps. There is a need for studies that integrate laboratory QI data with ED staff characteristics to generate targeted improvement strategies—precisely the gap this proposed study aims to address.

Theoretical Framework of the Study

This study is guided by two complementary theoretical frameworks:

1. **Donabedian's Structure–Process–Outcome (SPO) Model**
2. **Human Factors and Systems Thinking / Reason's "Swiss Cheese" Concept (adapted)**

1. Donabedian's Structure–Process–Outcome Model

Donabedian's model is widely used to conceptualize quality in healthcare. In this framework: [PMC+2Discovery Scientific Society+2](#)

- **Structure** refers to the attributes of the setting in which care occurs, including physical facilities, equipment, human resources, and organizational characteristics.
- **Process** refers to the activities involved in giving and receiving care—here, the steps in blood collection and specimen handling.
- **Outcome** refers to the effects of healthcare on the health status of patients and populations, or on quality indicators such as specimen rejection.

Applied to this study:

- **Structure:** ED nurse staffing levels, turnover rates, training programs, language composition of staff, availability of phlebotomy supplies and antiseptics, and laboratory collection policies.
- **Process:** How ED nurses collect blood samples (technique, adherence to protocols, skin antisepsis, handling of IV lines, tube mixing, and labeling), and how communication with the lab is handled.
- **Outcomes:** ED specimen rejection rates overall and by reason (clotted, contaminated, diluted), delays to diagnosis, and repeat phlebotomy.

The model supports the hypothesis that improving structural elements (e.g., stable staffing, structured training, clear protocols) and optimizing processes (consistent techniques, better communication) leads to better outcomes (fewer sample rejections).

2. Human Factors and Systems Thinking

Reason's "Swiss Cheese" concept emphasizes that errors typically result from multiple small system weaknesses aligning, rather than a single individual mistake. In the ED, sample rejection can be seen as an **endpoint of**

interacting human and system factors: busy environment, inexperienced staff, rushed procedures, poor communication, and unclear protocols. By using a systems lens, this study will not focus on blaming individuals but on identifying where system redesign, training, and support can reduce the likelihood of poor-quality specimens.

Together, these frameworks guide the selection of variables (structure and process factors), the formulation of hypotheses, and the interpretation of findings.

Methodology and Research Methods

Study Design

A **descriptive cross-sectional study** will be conducted, combining retrospective analysis of ED specimen rejection data with a cross-sectional survey of ED nursing staff and, optionally, laboratory personnel.

Study Setting

The study will take place in hospital emergency departments served by a central clinical laboratory. The laboratory performs routine hematology, coagulation, chemistry, blood culture, and other urgent tests for ED patients.

Study Population

1. Specimen-Level Data:

- All ED specimens received by the clinical laboratory during a defined period (e.g., six to twelve months).

2. Staff-Level Data:

- ED nursing staff involved in patient care and blood specimen collection.
- Optionally, laboratory staff responsible for specimen reception and rejection decisions.

Inclusion and Exclusion Criteria

• Specimens:

- Include: All ED samples logged into the LIS during the study period.
- Exclude: Samples not associated with ED patients, or those with incomplete or missing key data (e.g., no documented reason for rejection).

• Staff:

- Include: ED nurses with at least six months of experience in the department.
- Exclude: Temporary agency staff present for less than three continuous months, and nurses not involved in phlebotomy or specimen handling.

Sample Size

For the retrospective component, all ED specimens over the specified period will be included to maximize statistical power.

For the staff survey, all eligible ED nurses will be invited to participate. A response rate of at least 60–70% will be targeted to ensure representativeness.

Data Collection

1. Retrospective Laboratory Information System (LIS) Data

A structured extraction from the LIS will be performed, including:

- Patient location (ED);
- Specimen type and test category (e.g., hematology, coagulation, blood culture);
- Date and time of sample receipt;
- Rejection status (accepted vs. rejected);
- Documented **reason for rejection** (e.g., clotted, contaminated, diluted, insufficient volume, hemolyzed, mislabelled);
- If available, indicator of which shift/time period the sample was collected.

From this, the study will compute:

- Overall ED specimen rejection rate;
- Rejection rates by reason and by test category;
- Temporal patterns (e.g., by shift or day of week).

2. ED Nursing Staff Survey

A self-administered structured questionnaire will be distributed to ED nurses. Sections will include:

- Demographics (age, gender, total years of nursing experience, ED experience);
- Employment characteristics (permanent vs. temporary, full-time vs. part-time);
- Training and competency:
 - Frequency and type of training received in phlebotomy, blood culture collection, and pre-analytical quality;

- Participation in audits or feedback sessions related to sample quality.
- Perceived factors contributing to sample rejection:
 - Time pressure, workload, staffing adequacy;
 - Clarity of protocols;
- Perceived communication and language barriers:
 - Self-rated comfort communicating with colleagues and laboratory staff;
 - Challenges communicating with patients due to language or cultural differences.
- Perceived diversity of skills and supervision:
 - Availability of experienced mentors during each shift;
 - Confidence in own phlebotomy skills.

Most items will use Likert scales (e.g., strongly agree to strongly disagree), with open-ended questions for additional comments.

3. Optional Qualitative Component

If feasible, semi-structured interviews or focus groups may be conducted with a subset of ED nurses and laboratory staff to explore in more depth:

- Practical difficulties in obtaining high-quality specimens;
- Perceived impact of turnover, training, language, and skill mix;
- Suggestions for improvement.

Data Analysis

Quantitative Analysis

- **Descriptive statistics:**
 - Frequencies and percentages for overall ED specimen rejection and for each rejection reason;
 - Descriptive statistics for staff characteristics and survey responses.
- **Comparative analyses:**

- Comparison of rejection rates between shifts or days using chi-square tests or similar methods;
- Analysis of differences in self-reported training levels or perceived barriers among nurses with different lengths of ED experience.
- **Association analyses:**
 - Logistic regression or similar modeling approaches may be used to explore associations between:
 - Structural/process factors (e.g., staff experience, reported training, self-rated language barriers) and the pattern of ED specimen rejection (at the aggregate level);
 - For example, correlating shifts with higher proportions of new staff with higher rejection rates.

Because staff-level and specimen-level data may not be directly linkable at an individual level, analyses will primarily be conducted at aggregate levels (e.g., by shift, month, or unit).

Qualitative Analysis (if used)

Interview and open-ended responses will be analyzed thematically to identify:

- Recurrent explanations for clotted, contaminated, and diluted samples;
- Perceived gaps in training and supervision;
- Experience-based suggestions for system redesign.

Ethical Considerations

- **Patient Data:** No personal identifiers will be extracted from the LIS; only aggregate indicators and de-identified rejection data will be used.
- **Staff Data:** Participation in surveys or interviews will be voluntary; informed consent will be obtained. Responses will be anonymized and reported only in aggregate.
- Ethical approval will be sought from the relevant institutional review board or ethics committee prior to data collection.
- Data will be stored securely, with access limited to the research team.

Study Instruments

1. LIS Data Extraction Template

- A standardized data dictionary specifying variables (specimen ID, test type, rejection status, reason, timestamps) to ensure consistent extraction.

2. ED Nursing Staff Questionnaire

- Sections on demographics, experience, training, perceived barriers, and attitudes to sample quality.
- Mostly closed-ended questions with some open-ended items.

3. Interview / Focus Group Guide (Optional)

- Semi-structured questions about:
 - Experiences with blood sampling in the ED;
 - Observed reasons for sample rejection;
 - Influence of turnover, training, language, and skill mix;
 - Ideas for interventions (e.g., dedicated phlebotomists, bedside checklists, targeted training).

Study Limitations

1. Retrospective Nature of Specimen Data

The LIS data depend on accurate documentation of rejection reasons. Misclassification or missing data could influence findings.

2. Aggregate Linkage Between Staff and Specimen Data

Direct linkage between individual nurses and specific specimens may not be feasible; analysis may rely on aggregate associations (e.g., by shift).

3. Self-Reported Staff Data

Survey results might be affected by response bias, including social desirability and recall bias.

4. Single-Institution or Limited Setting

Findings may reflect the specific organizational culture and staff composition of the study site and may not be fully generalizable.

5. Cross-Sectional Design

The design provides a snapshot in time and cannot fully capture trends over many years or the impact of interventions introduced after the study period.

Despite these limitations, the study is expected to produce valuable insights that can inform targeted improvement efforts in the ED and laboratory.

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