



Patient Safety, Clinical Microbiology, and Collaborative Healthcare

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Abstract

“Right to health” is a universal right inclusive of a culture of safety. This review aims to highlight how clinical microbiology laboratories can contribute to patient safety. They can bring down medical errors through clinical collaboration and quality control. Timely and accurate inputs from microbiology laboratory help in clinical correlation and aid in safe patient care. Through internet search, using keywords such as “medical errors” and “quality assurance,” global burden of medical errors has been compiled. References have been taken from guidelines and documents of standard national and international agencies, systematic reviews, observational studies, retrospective analyses, meta-analyses, health bulletins and reports, and personal views. Safety in health-care should lay emphasis on prevention, reporting, analysis, and correction of medical errors. If not recorded, medical errors are regarded as occasional or chance events. Global data show adverse events are as high as 10% among hospitalized patients, and approximately two-thirds of these are reported from low- to middle-income countries (LMICs). This includes errors in laboratories as well. Clinical microbiology can impact patient safety when practiced properly with an aim to detect, control, and prevent infections at the earliest. It is a science that integrates a tripartite relationship between the patient, clinician, and a microbiology specialist. Through collaborative healthcare, all stakeholders benefit by understanding common errors and mitigate them through quality management. However, errors tend to happen despite standardization and streamlining all processes. The aim should be to minimize them, have fair documentation, and learn from mistakes to avoid repetition. Local targets should be set and then extended to meet national and global benchmarks.

Keywords

- ▶ stewardship
- ▶ medical errors
- ▶ accreditation
- ▶ quality assurance
- ▶ antimicrobial resistance

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Introduction

Healthcare is largely driven by human resources, errors are expected to happen; the aim should be to minimize them, wherever possible. The foundation of a safe healthcare system rests on a skilled and self-motivated workforce, well-designed job responsibilities; clear instructions and defined targets, guidance on performance outcomes; right equipment, and so on.¹ All processes must be patient-centric with a commitment to safety and understanding root cause of errors. Safety in healthcare means a patient is free from errors arising out of his clinical, laboratory, and other service domains. Treatment is guided by investigation reports; hence, laboratory results must be made fool-proof. Clinical microbiology is a science of infectious diseases in its entirety. It starts with prevention and control of infections in the hospital, diagnosis of infections, treatment guided by antimicrobial susceptibility, antimicrobial stewardship, and quality assurance. When the laboratory and clinical aspects collaborate, diagnosis becomes easier, treatment gets more objective and evidence-based. With minimal errors in diagnosis, targeted treatment and better interdisciplinary collaboration, patients start to benefit.

Patient Safety

Patient safety is the process of reduction, avoidance, and prevention of adverse outcomes or injuries during a healthcare process.² It has emerged as a separate discipline in the wake of complex healthcare systems that aim at risk prevention and reduction. The origin and solutions to patient safety are rooted in human behavior and culture, coupled with an inspiring vision and dedicated financial resources.³ It incorporates principles of continuous quality improvement and safety by learning from errors and adverse events.⁴

Factors Affecting Patient Safety

Factors in patient safety programs can be facilitators or barriers. The facilitating factors, include recruiting adequate human resources, medical equipment and facilities, quality assurance, improving employees' attitude, training, and communication with patients/relatives. Barriers include professional hierarchy, error reporting, feedback, a collaboration between multi-professional teams, communication with colleagues, and proper handover of patient data.⁵

Concerns in Patient Safety

The World Health Organization (WHO) has enlisted some factors as main concerns in patient safety.⁴ These include medication errors, diagnostic errors, healthcare-associated infections, unsafe surgical care and procedures, unsafe injections practices, unsafe transfusion practices, radiation errors, sepsis, and venous thromboembolism (blood clots). A third of these are concerned with microbiology services and infection control. A few more elements relevant to patient safety include fall/injuries, communication errors, patient identification errors.⁶

Key Elements in Patient Safety

A US-based firm has enlisted 10 key elements governing a patient safety culture.⁷ These include:

- i. A transparent and non-punitive approach.
- ii. Defining risk-based processes to ensure zero harm to patients.
- iii. Lead by example: Appropriate behavior of leaders can encourage the staff to report errors and share safety concerns.
- iv. Adherence to policies: Report all adverse events, near misses, and unsafe conditions.
- v. Focus on a just culture: Recognizing and encouraging all team members who report incidents, events, and near misses.
- vi. Use validated tools to measure patient safety: Measure a baseline and set targets to achieve better.
- vii. Analysis of data: Assessments should be done regularly.
- viii. Provision for necessary resources: Human resources, specialized training, or increased funding.
- ix. Training: Essential to strengthen safety systems, fill up hierarchy gaps, and encourage collaboration.
- x. Assess strengths and weaknesses: Proactive assessment of strengths and vulnerabilities of the healthcare system, not just react to an adverse event.

Adverse Events and Patient Safety

Adverse events due to unsafe care is one of the 10 leading causes of death and disability in the world.^{4,8} The Institute of Medicine, USA, released a report in 1999, "To err is human: building a safer health system"¹. Null et al,⁹ in their well-researched and referenced book "Death by Medicine" published annual data of medical errors in the USA. They inferred that the American medical system causes "more harm than good." Their report shared baseline data, upon which targeted improvement could begin. They reported 2.2 million adverse drug reactions, and an unnecessary 20 million antibiotic doses for viral infections, 7.5 million surgical and medical procedures, 8.9 million hospital admissions, and 783,936 deaths. Annual deaths due to healthcare-associated infections (HAI) and bedsores alone were estimated to be around 2 million. In the UK, an estimated 10% of all hospitalized patients are harmed, while in developing countries, 18% of hospitalized patients get adverse events.¹⁰ To reduce iatrogenic harms, the WHO presented two documents: "Patient Safety Curriculum Guide for Medical Schools" in 2011¹¹ and "Patient Safety: Making Healthcare Safer" in 2017.¹² The emphasis was on a holistic approach for patient safety and quality for the medical and nursing curriculum. The WHO has proposed that September 17 should be observed as a "patient safety day" every year in different aspects. They have endorsed the use of safety checklists during surgery¹³ and for a safe hospital environment.¹⁴

Medical Errors in Healthcare

Medical errors are preventable adverse events. They can be errors of omission (due to actions not taken) or errors of

commission (wrong action taken).² Common medical errors include adverse drug events, burns, equipment failure, failure to provide prophylactic treatment, falls, improper transfusions, misdiagnosis, delay in diagnosis, or failure to utilize the appropriate test as well as a failure to act on the laboratory result, mistaken patient identities, pressure ulcers and deep vein thrombosis, preventable suicides, restraint-related death, surgical injuries, under/overtreatment or errors in administering treatment (wrong dose or wrong site of administration), wrong-site surgery.² Globally, in outpatient care, 4 out of 10 (40%) patients are harmed and 80% of such events are preventable.¹⁰ In an estimated 421 million annual hospitalizations across the world, Jha et al¹⁵ reported 42.7 million adverse events (AEs) and 23 million disability-adjusted life years (DALY) lost every year to AEs. A study of 26 hospitals in eight LMICs showed that of all patients who developed AEs, 30% died. The common AEs were related to surgical procedures (27%), medical errors (18.3%), and HAIs (12.2%).¹⁶ In high-income countries (HICs), 1 in 10 patients is harmed, 50% are preventable.¹⁷ In contrast, in low- and middle-income countries (LMICs), 134 million AEs and 2.6 million deaths were attributed to unsafe care.¹⁸ Errors result from a multitude of factors acting simultaneously but offer an opportunity for constructive changes in healthcare. The Joint Commission has set the following patient safety goals to reduce medical errors²:

- Identification of patient safety dangers and risks.
- Correct patient identification by confirming the identity in at least two ways.
- Improve communication.
- Prevention of HIFs by following hand hygiene, antibiotics for postoperative infections, catheter changes, and invasive device-related precautions.
- Preventing mistakes in surgery by double-checking.
- Using device alarms on medical equipment and ensuring their use.
- Medication safety-double-checking labeling and correctly passing on patient medicines to the next provider.
- Labeling all medications, even those in a syringe.
- Extra care with patients on anticoagulants and chemotherapeutic agents.
- Prevention of nosocomial infections by hand washing before and after visiting each patient.

Unsafe Injection Practices: Unnecessary use of injections and unsafe injection practices are rampant and a frequent cause of errors, especially in LMICs. An unnecessary injection is defined as “one where oral alternatives are available, where the injected substance is inappropriate or harmful or where the symptoms or diagnosis do not warrant treatment by injection.”¹⁹ Unsafe injection practices are harmful practices that place the patient, healthcare workers, or the environment at risk of infection. Of an estimated 16 million injections given every year in the world, at least 50% are unsafe.²⁰ When asked about the number of “unnecessary injections” from the WHO’s member states in 2012, 113 countries (around 90%) could not answer because of a lack of data.²¹ About 160,000 HIV, 4.7 million HCV, and 16 million

HBV infections are attributable to unsafe injection practices. These account for ~9.2 million DALY lost every year worldwide.¹⁵ In India too, outbreaks of bloodborne viral infections due to contaminated needles and syringes have been reported. The healthcare burden of unsafe injections in India can be estimated by an attributable fraction of 12%, 38%, and 46% for HIV, hepatitis C, and hepatitis B, respectively.²²

Healthcare-Associated Infections

Overall estimates show that more than 1.4 million patients worldwide get HAIs at any time. The prevalence rates of HAIs in the ICUs vary: 9.7 to 31.8% in Europe and 9 to 37% in the USA, with crude mortality rates of 12% to 80%.²³ The US Centre for Disease Control and Prevention states that ~1.7 million hospitalized patients annually acquire HAIs and more than 98,000 die.²⁴ The common HAIs are urinary tract infections (UTIs), bloodstream infections (BSIs), surgical site infections (SSIs), and pneumonia. Device-associated infections continue to be the biggest burden.²⁵ Diagnosis and treatment of HAIs require the support of a clinical microbiology laboratory. With regular and prompt diagnoses, HAIs can be successfully treated and prevented.

Burden of Medical Errors in India

No national index of medical errors is available; these are often overlooked and underreported. The common errors are adverse drug events and HAIs causing the loss of 3 million years of healthy life every year. It has been observed that 5.2 million medical errors and AEs occur annually in India and these can be reduced by 50%.¹⁵ These may be attributed to a lack of clinical skills and inadequate training. India contributes to 25 to 30% of the global infection load and infectious diseases account for 14.8% of all diseases in India.²⁶ Infections get complicated in settings of already existing non-communicable diseases.²⁷ This has recently become more evident in diabetic patients on steroid medications during the COVID-19 pandemic. There has been a rapid disease progression to severe and reported co-infections with mucormycosis and other microbes.

Role of Clinical Microbiology in Patient Safety

Clinical microbiology deals with microorganisms in health and disease, pathogenesis, treatment, and follow-up until clinical and/or complete recovery.²⁸ A hospital microbiology laboratory has two main functions: diagnosis of infections and HAI prevention and control.²⁹ Effective clinical microbiology services support appropriate diagnosis and management of infectious diseases, promote antimicrobial stewardship, infection control, provide surveillance data, and aid in outbreak investigation.³⁰

India has a disproportionate burden of infectious diseases, antimicrobial consumption, and antimicrobial resistance.³¹ In many district hospitals in India, there is no position for a clinical microbiologist, and the work of a microbiologist is

handled by another laboratory physician. Moreover, there may not be any bacterial culture facility. Therefore, the treatment of infectious diseases relies solely on empiric antimicrobials, burdening healthcare with further antimicrobial resistance (AMR). Diagnostic stewardship in microbiology implies appropriate use of laboratory resources in patient management, impact clinical outcomes, and limit AMR.³² A test as simple as a Gram stain that forms the basics of bacteriology is of enormous significance. It is a science based on pattern recognition³³ that can guide empiric antibiotic therapy.³⁴ Quick identification of an organism from positive blood cultures by Gram stain can help in treatment initiation and contribute to control AMR.³⁵ Microbiology laboratories are at the forefront of detecting emerging pathogens, newer antibiotic resistance trends, identification of outbreaks, and a possible event of bioterrorism.³⁶ High-quality institutional clinical microbiology laboratories provide good patient care outcomes and are cost-effective.

Microbiology services need to be restructured, centralized, and consolidated to improve specialized diagnostics.³⁶ Building a multi-specialty microbiology laboratory is not financially viable for every institute. Basic microbiology support and a clinical microbiologist as an infection control officer can bring about quality in diagnostics and lower HAIs. There could be a multi-level approach with regard to clinical microbiology laboratories at primary, district, state, and central levels (→ **Table 1**). At a primary healthcare level, the resident medical officer and his staff can be trained in simple microscopy to identify endemic bacterial or parasitic infec-

tions. At the district level, bacterial identification to the genus level may be done with preliminary antimicrobial testing. This can serve as a common microbiology center for many smaller laboratories, clinics, or hospitals. Further at a state- or medical college-level laboratory, detailed characterization and testing of other microbes can be performed. A central reference laboratory can be designated for further guidance and research on newly found or rare infectious agents. This premier laboratory can retain a national database. India has enrolled itself in the WHO GLASS (Global Antimicrobial Resistance Surveillance System) program for AMR surveillance.³⁷ These data are also provided by the microbiologists. To enable the involvement of multiple sites to share their AMR data on a common platform and then represent country-wide data, a clinical bacteriology setup is a must in all districts in India.

Diagnostic Errors: The most common diagnostic errors include ordering inappropriate tests, wrong interpretation, failure to follow-up, and refer. Delay in treatment after diagnosis results in increased costs and prolonged treatment.² According to the Joint Commission Report, diagnostic errors result in death or injury to 40,000 to 80,000 patients per year globally.² In the US, these contribute to ~10 to 20% of patient deaths annually as observed on autopsies.³⁸ The incidence is not adequately documented in India.

These are less in institutions where a diagnosis is usually a teamwork. Diagnostic errors may be committed by clinicians, radiologists, pathologists, or microbiologists. Diagnostic errors can be classified as cognitive, system errors, and

Table 1 Multi-level approach regarding clinical microbiology laboratories

Microbiology laboratory levels	Diagnostic services	Infection control practices	Antibiotic stewardship	Staff required
Primary level	Simple microscopy for endemic bacterial or parasitic infections. Good microbiological techniques (GMT)	Standard precautions, hand hygiene, gloves, mask, low- to intermediate-level disinfection,	Follow district antibiotic policy for presumptive and empirical treatment of endemic infectious diseases	Resident medical officer, laboratory technicians. Establish linkage with district laboratory
District level (in addition to primary level services)	Bacterial culture: identification to genus level with preliminary antimicrobial testing	High-level disinfection or sterilization of equipment, transmission-based precautions, biosafety level (BSL)-1 or BSL-2	Prepare antibiograms and share AMR data with state authorities	Microbiology specialist, resident doctors, trained laboratory technicians
State level (in addition to district level services)	Molecular characterization with detailed identification of bacterial, tubercular, fungal, and other isolates; possibilities for research	Biosafety precautions for dangerous bacterial, tubercle bacilli, fungal and viral pathogens, biosafety level (BSL)-2 or BSL-3 laboratories	Prepare antibiotic policy, enroll in AMR surveillance, compile districts' data and send to central agencies	State or medical college level laboratory with microbiology specialists, resident doctors, postgraduate students, skilled technical staff
Central level (in addition to state level services)	Provide guidance and research on newly found or rare infectious agents. Quality-controlled laboratories with automation for higher throughput	Availability of BSL-3 or BSL-4 laboratories and appropriate PPE	National banks for microbial agents, antibiogram at national level, liaison with WHO/CDC, define targets, policies to decrease AMR	Microbiology and public health specialists, epidemiologists, policy makers, along with skilled laboratory staff

no-fault errors.³⁹ “Cognitive errors” result in misdiagnosis due to faulty data collection or interpretation, or incomplete knowledge. “System errors” result from an imperfect health-care system leading to a delayed or missed diagnosis. “No-fault errors” occur during the diagnosis of new or rare diseases.⁴⁰ A more comprehensive approach to laboratory work, focusing on the pre-analytic and post-analytic phases is required. Pre-analytical errors account for approximately two-thirds of total laboratory errors.⁴¹ These include poor specimen collection, wrong container, improper handling, storage and transportation, and delayed delivery of samples. “Pre-pre analytical” errors such as inappropriate choice of tests and samples, errors in test requisition, entry, and misidentification contribute to these errors.⁴² Post-analytic processes involve quality assurance and clinical correlation.

Quality Assurance in Laboratories: Quality assurance of laboratory means providing the right result at the right time on the right specimen from the right patient with the right interpretation based on correct reference data and at the right price.⁴³ India has ~1,00,000 registered laboratories but only 6,100 (6%) of these are approved by the National Accreditation Board for Laboratories (NABL).⁴⁴ In addition, there are many unregistered laboratories in the country. Indian Council of Medical Research has laid down guidelines for Good Clinical Laboratory Practices (GCLP) in 2008. Emphasis is on internal and external quality control, internal audit, safety, data management, and ethical considerations.⁴⁵ Carey et al⁴⁶ have emphasized the operationalization of ISO 15189 international standards and CLSI/Q system in healthcare.⁴⁷ Lean principles should be incorporated in laboratories to maximize output and minimize waste. These include zero breakdowns, delays, defects, inventory, accidents, and paper.⁴⁸ Balanced test utilization should be the aim—approximately one-fifth of all tests are overused and more than these are underused.⁴⁹ Quality tools such as the Japanese concept of Five S⁵⁰: Sort (Seiri), Set in Order (Seiton), Shine (Seiso), Standardize (Seiketsu), and Sustain (Sitsuke); provide a methodology that is easy to follow and sustain. Due to standardization in laboratory techniques, quality assurance, robotic analyzers, and laboratory information systems; a 10-fold reduction has been achieved in analytical errors.⁴² Quality management system (QMS) in clinical microbiology is a challenge. There are a variety of tests, subjective assessment of cultures, difficulty in automation, expert rules, and statistical tools.⁵¹ High reproducibility can be found among serological and molecular tests, while conventional microscopy, culture, and antibiotic susceptibility show discrepancies. Microscopy is highly subjective, with discrepancies approaching 39.5%. QMS in microbiology must be technique and competence-driven.⁵² Technical requirements for fastidious organisms (anaerobes, microaerophilic, selective media) should be made available. There should be prioritization of clinically relevant samples. Well-defined critical alerts should be sent out to clinicians in case a critical result is encountered. Aseptic collection of blood is critical with contamination rates less than 3%, preferably less than 1%. There are only two references in India. Tantry et al⁵³ reported 42% pseudobacteremia, while another institution in Delhi reported a contamination rate of 5.8%.⁵⁴ Clinical and laboratory criteria

should differentiate pathogens from contaminants in blood cultures. Coagulase-negative staphylococci (CONS) are invariably contaminants and often unnecessarily treated with nephrotoxic glycopeptides. Similarly, for viral infections, antibiotics are unwarranted unless supported by evidence for immunomodulatory effects. Such alerts should be highlighted in reports and reflected in the patient management data. Test quality is too precious to be compromised in patient care. Q-probe benchmarking scheme by CAP (College of American Pathologists) to evaluate laboratory specimen processing workflow,⁵⁵ NABL accreditation, and other quality assurance schemes can instill confidence in laboratory physicians and staff that they are providing a cost-effective and high-quality service.

Improving Patient Outcomes: Measuring clinical outcomes and continuous quality improvement was not considered a priority in India until recently. There have been some initiatives such as “Clinical Establishment Act 2010,”⁵⁶ and “Patient Safety and Access Initiative of India Foundation.”⁵⁷ Recently, “National Patient Safety Framework”⁵⁸ has been designed in which quality in healthcare has come to the forefront. This has been backed by initiatives such as Swachha Bharat Abhiyan, Kayakalp Hospital Awards, National Health Mission driven National Quality Assurance Standards (NQAS),⁵⁹ National action plans for containment of AMR,⁶⁰ CDC-ICMR-AIIMS HAIS network under Global Health Security.⁶¹ Comparison of rates of HAIs in India with developed countries has been shown in ►Table 2.^{23,27,62–68}

Cost Benefits of Quality Assurance: Laboratory tests account for around 4% of the total healthcare cost even in HICs⁶⁹ but the accuracy of results has a bearing on preventing unnecessary healthcare expenditure. The use of fluorescence microscopy using monoclonal antibodies, point of care tests such as immune-chromatographic test (ICT), enzyme-linked immunosorbent assays (ELISA), and biomarkers are useful. Nucleic acid amplification tests (NAAT) have a short turnaround time but are expensive, technically complex, cannot discriminate pathogens from colonizers and contaminants, and are unaffordable in many places in India. When safety is priority, there is a need for financial resources to improve the supply chain, strengthen laboratories, and integrate health

Table 2 Comparison of rates of HAI in India with developed countries^{23,27,62–68}

HAI	Europe	United States	India
Prevalence in ICU	9.7–31.8%	9–37%	9.7%
Rate of HAI per hospital visit	1 in 10	1 in 20	1 in 4
CR-BSI rate ^a	1.8–2.4	0.8	5.1
VAP rate ^a	1.2–1.4	0.9	9.4
CAUTI rate ^a	3.4	1.7	2.1

Abbreviations: CAUTI, catheter-associated urinary tract infection; CRBSI, catheter-related blood stream infection; HAI, healthcare-associated infections; ICU, intensive care unit; VAP, ventilator-associated pneumonia.

^aRate per 1000 device days.

information systems so that the concept of collaborative healthcare can be realized.⁷⁰

Building Collaborative Healthcare: A collaborative team in healthcare has been defined as a group of healthcare workers from different specialties who share patients' responsibilities, care, and safety goals. In this system, the team is interdependent with regular communication, has defined roles, and respects the job roles of each other. Safe patient care can be achieved, resulting in greater patient and staff satisfaction and institutional efficiency.⁷¹ Collaboration need not only mean interpersonal interactions but also integration with information technology for better patient outcomes. Final diagnosis relies on specific laboratory tests; hence, good clinico-laboratory coordination is the essence of patient care. Prior information about the patient can help to alleviate errors resulting from mismatched reports at the laboratory end. Unless both these disciplines interact and respect these needs, collaboration cannot be beneficial. Clinical case discussions and meetings involving the laboratory doctors are learning experiences for all. For infectious diseases, clinical microbiologists can further elaborate on the most susceptible antimicrobials, advise infection control precautions, and monitor response to therapy. There is a lack of close partnership between clinical microbiologists and clinicians, either because microbiologists are too shy to interact or clinicians do not team up with them. For critically ill patients, mutual interaction can significantly improve patient outcomes. Interpersonal interactions between clinicians and laboratory physicians should be encouraged through pre-service and continuous training to bring about a culture of collaborative healthcare.⁷²

Role of Artificial Intelligence: Artificial intelligence (AI) has a very significant role to play in bringing about collaborative healthcare. The role of AI starts right at the registration step with online appointments and information regarding available services. This is the time when patients' particulars are entered into the system and become available to all relevant sections. Clinicians can follow treatment protocols, calculate drug doses, request tests, and retain patient information in a digitalized format that can be reproduced whenever and wherever required. AI in the software can alert about prior patient visits, medications, test reports, interventions, and outcomes. AI may also replace human educators and impart training to the newly inducted staff and refresher training from time to time.⁷³ It may even be designed to collaborate laboratory findings with the clinical condition and send an alert to the treating physician. In the laboratory, AI helps in standardization by automating systems and processes; tracking outbreaks or breaches of infection control in hospitals.⁷⁴ However, errors may occur during the transition phase from a conventional to automated process or during the mature phase due to server or system-wide failures.²

Conclusion

The whole concept of healthcare is based on the establishment of a multi-specialist collaborative system that is pa-

tient-centric. Regular communication and bedside discussions of clinicians with clinical microbiologists can improve the outcomes of patients with infectious diseases. "Diagnostic stewardship" can be followed through quality reporting, training manpower, laboratory accreditation, regular audits, and tests with good sensitivity and specificity so that quality reports can be delivered in time. Healthcare is "Safety Culture Industry." A "culture of patient safety" should exist with a strong role of regulators, accreditation agencies, and administrators. There is a dire need for "Continuing Professional Development" programs for healthcare personnel to improve quality. As quoted by Sir Liam Donaldson, "To err is human, to cover up is unforgivable, and to fail to learn is inexcusable."⁷⁵ Practice-based learning, clinical discussions, and feedback reduce pre- and post-analytical errors. Medical errors and near misses must be reported, recorded, and discussed when discovered. Continuous learning, empathy, mindfulness, and accountability are critical for patient safety. We may not have technologically advanced programs nor have high manpower investment everywhere, but we can still build a culture of safety.

Conflict of Interest

None declared.

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