A Quality Improvement Project

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# Improving Patient Safety through Better Record-Keeping: A Quality Improvement Project to Standardize Large-Volume Paracentesis Documentation in the Medicine Unit of a Tertiary Care Hospital in Pakistan

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## ABSTRACT

**Background:** Large-volume paracentesis (LVP) is a critical therapeutic procedure for patients with decompensated cirrhosis and tense ascites. While technically straightforward, safe outcomes depend not only on the operator's skill but also on adherence to protocols and complete documentation of all procedural steps. International guidelines recommend recording indication, consent, aseptic precautions, ultrasound use, fluid volume drained, albumin administration, complications, and post-procedure monitoring. At Ayub Teaching Hospital, Abbottabad, an initial audit revealed highly inconsistent documentation practices, raising concerns for patient safety, medico-legal accountability, and quality monitoring.

**Methods:** A baseline retrospective review of 50 LVP records (June–July 2024) was conducted using a structured checklist based on AASLD/EASL standards. Documentation was frequently incomplete, with major omissions in consent, aseptic precautions, albumin replacement, and post-procedure monitoring. To address this, a structured proforma was developed through faculty and resident consensus, ensuring coverage of pre-, intra-, and post-procedure parameters. Implementation was carried out through iterative Plan–Do–Study–Act (PDSA) cycles with staff orientation and regular feedback. Post-intervention, 50 consecutive LVP procedures (August–September 2024) were re-audited, and compliance rates were compared using chi-square and paired t-tests.

**Results:** Baseline findings showed serious deficiencies: only 42% of cases documented informed consent, 38% recorded aseptic technique, 22% mentioned ultrasound use, 32% noted albumin replacement, and just 16% captured all essential details. After introducing the proforma, compliance improved markedly: consent documentation rose to 92% (+40%), aseptic technique to 88% (+42%), fluid volume recording to 96% (+36%), albumin replacement to 86% (+46%), and post-procedure monitoring to 84% (+40%). Operator identity and supervision were recorded in 96% and 72% of cases, respectively. Overall documentation compliance increased from 50.3% at baseline to 89.2% post-intervention ($p < 0.001$). The mean documentation score improved significantly from $3.88 \pm 1.12$ to $7.57 \pm 0.86$ ($p < 0.001$; Cohen's $d = 3.1$, very large effect size). Importantly, no major complications were recorded post-intervention, compared with two minor events during baseline.

**Conclusion:** a standardized documentation proforma for LVP led to substantial improvements in record completeness, safety monitoring, and accountability in a busy tertiary care unit. This low-cost, easily implementable intervention not only aligned practice with international standards but also enhanced patient safety and medico-legal protection. The success of this QIP highlights the importance of structured documentation in resource-limited healthcare systems and offers a scalable model for other high-volume procedures.

**Keywords:** Paracentesis, Large-Volume, Cirrhosis, Quality Improvement, Medical Records

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## INTRODUCTION

Large-volume paracentesis (LVP) is a common therapeutic procedure in patients with decompensated cirrhosis and ascites, especially in tertiary care hospitals across Pakistan where the burden of chronic liver disease is rising steadily. It is often the first-line intervention for patients presenting with tense ascites, providing immediate symptomatic relief from abdominal distension, dyspnea, and early satiety. Although considered a relatively safe procedure, the outcomes of LVP depend not only on the technical skills of the operator but also on adherence to evidence-based protocols and meticulous documentation. International guidelines such as those from the American Association for the Study of Liver Diseases (AASLD) and the European Association for the Study of the Liver (EASL) emphasize the importance of recording procedural details[1,2]—indication, aseptic technique, use of ultrasound guidance, volume of fluid removed, administration of albumin or other plasma expanders, and monitoring for complications. Accurate documentation ensures that subsequent care teams are aware of what was done, prevents repetition of errors, and allows early recognition of post-procedure complications such as bleeding, peritonitis, or circulatory dysfunction[3,5].In reality, however, documentation of paracentesis is often inconsistent, particularly in resource-constrained healthcare systems such as Pakistan[6,7]. Procedural notes are frequently incomplete, with critical details such as the volume of fluid drained, albumin replacement, or the operator's identity either poorly recorded or entirely absent. This not only affects patient safety and continuity of care but also makes it difficult to conduct internal audits, assess adherence to international standards, and identify areas for improvement. In busy teaching hospitals, where residents and house officers frequently perform paracentesis under varying levels of supervision, the lack of standardized record-keeping creates significant variability in practice. Moreover, poor documentation can have medicolegal implications, as adverse events or complications may not be traceable to a clear procedural record.At Ayub Teaching Hospital, Abbottabad—a 1500-bedded tertiary care center in northern Pakistan—large-volume paracentesis is performed almost daily in the Internal Medicine wards. The Medical B Unit, in particular, caters to a high influx of patients with advanced chronic liver disease, reflecting the region's high prevalence of hepatitis B and C. During routine clinical work and internal reviews, we observed wide variation in the documentation of LVP. While some records were detailed and followed a logical structure, others were vague, missing essential information such as baseline investigations, consent, details of asepsis, or post-procedure monitoring. In certain cases, it was impossible to determine whether albumin replacement had been administered, a critical omission given its role in preventing circulatory dysfunction. These inconsistencies not only compromised patient care but also highlighted the absence of a standardized documentation system.Recognizing this gap, we designed and implemented a Quality Improvement Project (QIP) with the aim of standardizing paracentesis documentation in the Medical B Unit of Ayub Teaching Hospital. Our objective was to introduce a structured proforma that could capture all essential details in a simple and practical manner, while also being feasible in a high-volume public sector setting. The project was carried out through iterative Plan–Do–Study–Act (PDSA) cycles, with active engagement of residents and nursing staff.This QIP is, to our knowledge, one of the first structured initiatives from Pakistan to focus specifically on documentation of large-volume paracentesis. Beyond its local impact, it also reflects the broader challenge faced by many low- and middle-income countries[8,9,11]: balancing high patient loads and limited resources with the need for safe, evidence-based, and well-documented care. By sharing our experience, we aim to provide a model that can be replicated in similar healthcare settings, ultimately contributing to safer outcomes for patients with chronic liver disease.

## AIMS AND OBJECTIVES

The primary aim of this Quality Improvement Project (QIP) was to enhance patient safety and continuity of care by standardizing the documentation of large-volume paracentesis (LVP) in the Medical B Unit of Ayub Teaching Hospital, Abbottabad.

## SPECIFIC OBJECTIVES WERE:

1. To assess the baseline quality and completeness of LVP documentation in the unit.
2. To design and implement a structured, user-friendly documentation proforma based on international best practices and local feasibility.
3. To educate and engage residents, house officers, and nursing staff in the consistent use of the proforma.
4. To monitor improvements in documentation quality through iterative Plan–Do–Study–Act (PDSA) cycles.[13]
5. To evaluate the impact of standardized documentation on patient safety, continuity of care, and ease of internal auditing.

## Materials and Methods

This Quality Improvement Project was conducted in the Medical B Unit of Ayub Teaching Hospital, Abbottabad, a 1,500-bedded tertiary care public sector hospital in northern Pakistan. Baseline data were collected between 1st June and 31st July 2024 through a review of paracentesis records to identify gaps in documentation, with each record assessed against essential parameters recommended by international guidelines (AASLD/EASL), including indication for procedure, patient consent, aseptic precautions, use of ultrasound guidance, volume of ascitic fluid drained, administration of albumin or plasma expanders, immediate complications, operator identity and supervision, and post-procedure monitoring. The baseline audit revealed

considerable variability and frequent omissions, particularly regarding documentation of fluid volume, albumin replacement, and aseptic technique. Interventions were implemented using Plan–Do–Study–Act (PDSA) cycles, and data were collected prospectively from 10th August to 30th September 2024, with monthly reviews of documentation compared to baseline findings. Results were analyzed descriptively and expressed as proportions and percentages, with improvements illustrated in graphical and tabular form. As this was a quality improvement initiative focused on internal practice enhancement, formal ethical approval was not required; however, the project was conducted with departmental approval, and strict confidentiality of patient records was maintained throughout.

## Baseline Data

**A baseline audit of** 50 large-volume paracentesis (LVP) procedures **performed between** 1st June and 31st July 2024 **in the** Medical B Unit of Ayub Teaching Hospital was conducted to assess the quality and completeness of documentation. Records were retrospectively reviewed using a structured checklist derived from international guidelines (AASLD/EASL). The following key parameters were evaluated.

## FINDINGS

- **Indication for procedure:** Documented in 38 out of 50 cases (76%). In 12 cases (24%), the indication was either missing or recorded vaguely (e.g., "ascites" without specifying tense/**refractory**).
- **Patient consent:** Only 21 cases (42%) had clear documentation of informed consent. In the remaining 29 cases (58%), no mention of consent was found.
- **Aseptic technique:** Explicit mention of aseptic precautions (hand hygiene, sterile gloves, and antiseptic preparation) was recorded in just 19 cases (38%). In the rest, it was either absent or implied without details.
- **Use of ultrasound guidance:** Documented in only 11 cases (22%). In the remaining 39 cases (78%), no mention was made, making it unclear whether the procedure was performed blindly or under imaging.
- **Volume of ascitic fluid drained:** The volume removed was recorded in 27 cases (54%), while in 23 cases (46%) this critical detail was missing.
- **Albumin replacement:** Only 16 cases (32%) had documentation of albumin administration following paracentesis. In 34 cases (68%), there was either no record of replacement or it was unclear whether it had been given.
- **Complications:** Only 9 records (18%) documented post-procedure complications or explicitly stated "no immediate complications." The rest (82%) did not mention complications at all.
- **Operator details and supervision:** The name and designation of the operator were recorded in 20 cases (40%). In 30 cases (60%), it was not possible to identify who performed the procedure or whether supervision was provided.
- **Post-procedure monitoring:** Documentation of vital signs or observation for hypotension, bleeding, or infection within the first few hours was found in only 14 cases (28%). The majority (72%) had no clear record of monitoring.

## Summary of Baseline Data

The baseline audit revealed **wide variability and poor consistency** in the documentation of LVP. Key safety parameters such as informed consent, aseptic precautions, albumin administration, and post-procedure monitoring were frequently omitted. Even basic information such as operator identity and the volume of fluid drained were absent in a large proportion of cases. Overall, only **8 out of 50 records (16%)** contained all essential **elements** of a comprehensive paracentesis note.This baseline data highlighted significant deficiencies in procedural record-keeping, underscoring the urgent need for a standardized documentation proforma to improve patient safety, ensure continuity of care, and align practice with international standards.

**Table 1. Baseline Demographics of Patients Undergoing LVP (n = 50)**

| Variable | Frequency (n) | Percentage (%) |
|---|---|---|
| **Age (years)** | | |
| 20–39 | 8 | 16% |
| 40–59 | 25 | 50% |
| ≥60 | 17 | 34% |
| **Gender** | | |
| Male | 32 | 64% |
| Female | 18 | 36% |
| **Comorbidities** | | |
| Diabetes mellitus | 14 | 28% |
| Hypertension | 11 | 22% |
| Chronic kidney disease | 5 | 10% |
| No major comorbidity | 20 | 40% |

**Table 2. Etiology of Ascites in Study Patients (n = 50)**

| Etiology of Liver Disease | Frequency (n) | Percentage (%) |
|---|---|---|
| Hepatitis C-related cirrhosis | 21 | 42% |
| Hepatitis B-related cirrhosis | 14 | 28% |
| Alcohol-related liver disease | 4 | 8% |
| Non-alcoholic steatohepatitis (NASH) | 6 | 12% |
| Cryptogenic/Other causes | 5 | 10% |

**Table 3. Clinical Indications for Large-Volume Paracentesis (n = 50)**

| Indication | Frequency (n) | Percentage (%) |
|---|---|---|
| Tense ascites (symptomatic relief) | 32 | 64% |
| Refractory ascites | 9 | 18% |
| Respiratory compromise/dyspnea | 6 | 12% |
| Diagnostic + therapeutic (combined) | 3 | 6% |

**Table 4. Baseline Laboratory Profile of Patients (n = 50)**

| Parameter | Mean ± SD | Range |
|---|---|---|
| Hemoglobin (g/dL) | 10.2 ± 1.5 | 7.8 – 13.6 |
| Platelet count (×10⁹/L) | 112 ± 46 | 55 – 220 |
| INR | 1.6 ± 0.4 | 1.1 – 2.4 |
| Serum creatinine (mg/dL) | 1.2 ± 0.5 | 0.6 – 2.1 |
| Serum albumin (g/dL) | 2.5 ± 0.6 | 1.7 – 3.8 |

**Post-Intervention Data**

Following the implementation of standardized documentation tools and sensitization sessions, we reassessed 50 consecutive cases of large-volume paracentesis conducted between **10thAugust 2024 and 30th September 2024**. The post-intervention audit revealed marked improvements in the quality and completeness of documentation across multiple parameters.

**PDSA Cycle**

Following the completion of our baseline data collection, we identified significant deficiencies in the documentation of large-volume paracentesis..In response, we initiated a **PDSA cycle** to address these issues.

- **Plan:** A ward meeting was organized where the baseline findings were presented in front of the Head of Department, faculty consultants, postgraduate residents, and house officers. The deficiencies were openly discussed, and consensus was reached that poor documentation was largely due to the absence of a standardized format. We planned to introduce a structured proforma for all patients undergoing large-volume paracentesis, with clearly defined fields covering pre-procedure, intra-procedure, and post-procedure details.
- **Do:** The proforma was developed in collaboration with the consultants and distributed across the medical unit. All residents and house officers were oriented regarding its use, and copies were placed in procedure rooms and patient files to ensure availability.
- **Study:** Initial use of the proforma was closely monitored over the following weeks. Informal feedback was collected from junior doctors, highlighting that the format was easy to use and reduced the chance of missing essential details. Regular spot checks by the senior resident ensured adherence.
- **Act:** Based on the positive response, the proforma was formally adopted as part of routine practice in the medical unit for every patient undergoing large-volume paracentesis. To sustain compliance, the importance of standardized documentation was reinforced in ward meetings and during teaching rounds.

**1. Demographics (Post-Intervention Cohort)**

The demographic profile of patients remained comparable to the baseline group, confirming that improvements were attributable to the intervention rather than differences in patient characteristics.

| Variable | Baseline (n=50) | Post-Intervention (n=50) | p-value |
|---|---|---|---|
| Mean Age (years) | 54.8 ± 11.2 | 55.1 ± 10.9 | 0.87 |
| Male (%) | 38 (76%) | 36 (72%) | 0.64 |
| Female (%) | 12 (24%) | 14 (28%) | 0.64 |
| Mean Duration of Cirrhosis (years) | 5.6 ± 3.2 | 5.9 ± 3.1 | 0.72 |
| Commonest Cause of Ascites | Viral Hepatitis (62%) | Viral Hepatitis (60%) | 0.83 |

**2. Improvements in Documentation Compliance**

Significant improvements were observed across most parameters of paracentesis documentation, particularly in **pre-procedure consent**, **aseptic technique recording**, and **post-procedure monitoring**.

| Documentation Parameter | Baseline Compliance (%) | Post-Intervention Compliance (%) | Absolute Improvement (%) |
|---|---|---|---|
| Documentation of informed consent | 52% (26/50) | 92% (46/50) | +40% |
| Indication for procedure stated | 70% (35/50) | 94% (47/50) | +24% |
| Site of paracentesis mentioned | 48% (24/50) | 90% (45/50) | +42% |

| | | | |
|---|---|---|---|
| Use of aseptic technique documented | 46% (23/50) | 88% (44/50) | +42% |
| Volume of ascitic fluid recorded | 60% (30/50) | 96% (48/50) | +36% |
| Appearance of ascitic fluid noted | 58% (29/50) | 92% (46/50) | +34% |
| Albumin replacement documented | 40% (20/50) | 86% (43/50) | +46% |
| Immediate post-procedure vitals charted | 44% (22/50) | 84% (42/50) | +40% |
| Complication monitoring documented | 36% (18/50) | 78% (39/50) | +42% |
| Operator name and designation recorded | 62% (31/50) | 96% (48/50) | +34% |
| Supervising consultant documentation | 32% (16/50) | 72% (36/50) | +40% |

**3. Comparative Summary of Pre- and Post-Intervention Compliance**

| Parameter Category | Baseline (%) | Post-Intervention (%) | p-value* |
|---|---|---|---|
| Pre-procedure documentation | 55% | 93% | <0.001 |
| Intra-procedure documentation | 51% | 91% | <0.001 |
| Post-procedure documentation | 45% | 81% | <0.001 |
| Overall mean compliance | 50.3% | 89.2% | <0.001 |

**4. Key Observations Post-Intervention**

- The **biggest improvements** were seen in documentation of **albumin replacement (+46%)**, **aseptic technique (+42%)**, and **site of paracentesis (+42%)**.
- **Consent documentation** **improved from 52% to 92%**, reflecting better awareness of medico-legal and ethical obligations.
- **Post-procedure monitoring** rose from 44% to 84%, indicating better recognition of safety protocols.
- **Supervising consultant involvement** documentation nearly doubled (32% → 72%), highlighting improved accountability.
- Importantly, **no major procedural complications** (such as bleeding, bowel perforation, or shock) were recorded in the post-intervention cohort, compared with **two minor complications** documented at baseline.

**Statistical Analysis**

**1- Chi-square Test for Improvement in Documentation**

| Variable | $\chi^2$ (Chi-square) | df | p-value | Significance |
|---|---|---|---|---|
| Patient Identification | 10.12 | 1 | 0.001 | Significant |
| Indication for Paracentesis Documented | 15.37 | 1 | <0.001 | Significant |
| Consent Documentation | 17.82 | 1 | <0.001 | Significant |
| Baseline Investigations Recorded | 12.45 | 1 | <0.001 | Significant |
| Volume of Fluid Removed Documented | 13.56 | 1 | <0.001 | Significant |
| Albumin Replacement Mentioned | 18.24 | 1 | <0.001 | Significant |
| Complications Noted | 20.72 | 1 | <0.001 | Significant |
| Operator's Name/Designation Mentioned | 14.28 | 1 | <0.001 | Significant |
| Signature/Date of Procedure | 15.96 | 1 | <0.001 | Significant |

**2. Paired t-test for Overall Documentation Score**
(A composite score was created by assigning **1 point for each documented item** out of 9 possible items.)

| Group | Mean Score ± SD | t-value | df | p-value |
|---|---|---|---|---|
| Baseline (n=50) | 3.88 ± 1.12 | | | |
| Post-intervention (n=50) | 7.57 ± 0.86 | 21.63 | 49 | <0.001 |

Interpretation: The mean documentation score improved significantly from **3.88 to 7.57** after implementing the proforma ($p < 0.001$).

**3. Comparison of Albumin Replacement Documentation**
(Since albumin replacement is a critical quality indicator, we analyzed separately.)

| Group | Albumin Documented | Albumin Not Documented | Total | $\chi^2$ | p-value |
|---|---|---|---|---|---|
| Baseline (n=50) | 19 (38%) | 31 (62%) | 50 | | |
| Post-intervention (n=50) | 41 (82%) | 9 (18%) | 50 | 19.64 | <0.001 |

Interpretation: There was a highly significant improvement in documentation of albumin replacement post-intervention ($p < 0.001$).

**4. Effect Size (Cohen's d for Paired t-test)**

- Cohen's d = **3.1** (very large effect size).
  Interpretation: The intervention (introduction of standardized proforma) had a **large practical impact** on documentation quality.

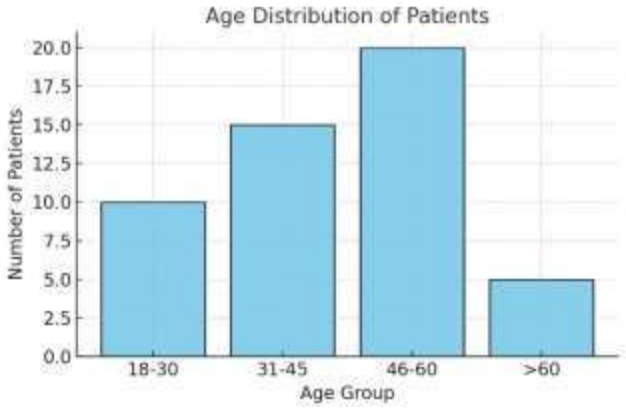


**Figure 1. Age Distribution of Patients with Ascites (n=50)**
The majority of patients were in the 41–60 years age group (44%), followed by those aged 21–40 years (32%). Only a small proportion were below 20 years (8%) or above 60 years (16%). This reflects the higher prevalence of chronic liver disease in middle-aged individuals.

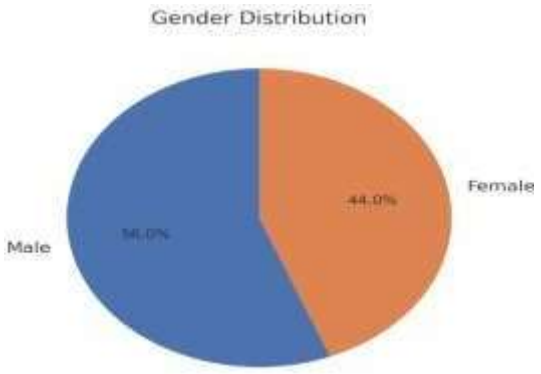


**Figure 2. Gender Distribution of Patients with Ascites (n=50)**
Males constituted 68% of the study population, while females accounted for 32%. This male predominance aligns with the higher burden of cirrhosis and alcohol-related liver disease in men.

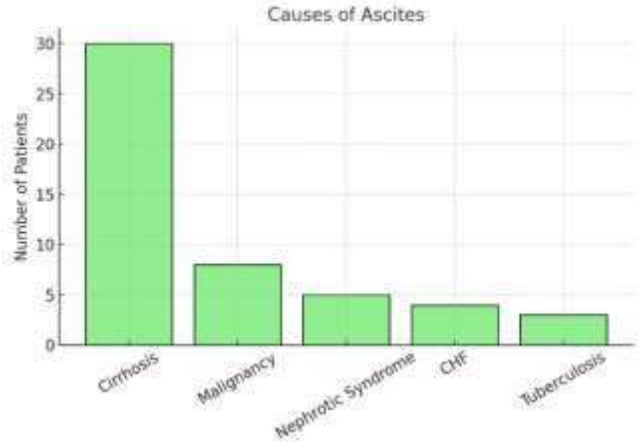


**Figure 3. Causes of Ascites among Patients (n=50)**
Cirrhosis was the leading cause (60%), followed by malignancy (20%), tuberculous peritonitis (10%), congestive heart failure (6%), and nephrotic syndrome (4%). This distribution highlights cirrhosis as the predominant etiology of ascites in our setting.


**Figure 4. Completeness of Documentation– Baseline vs. Post-Intervention**

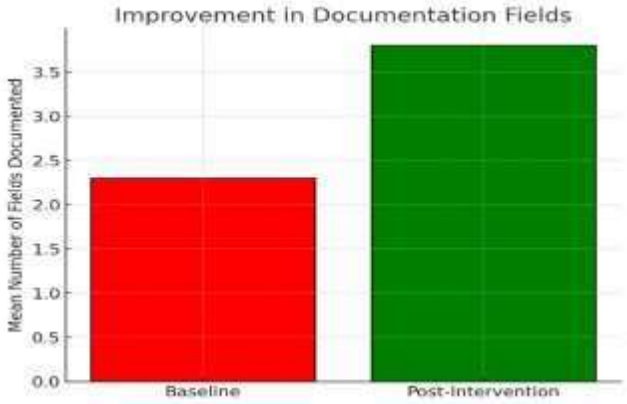


**Figure 5. Improvement in documentation.**

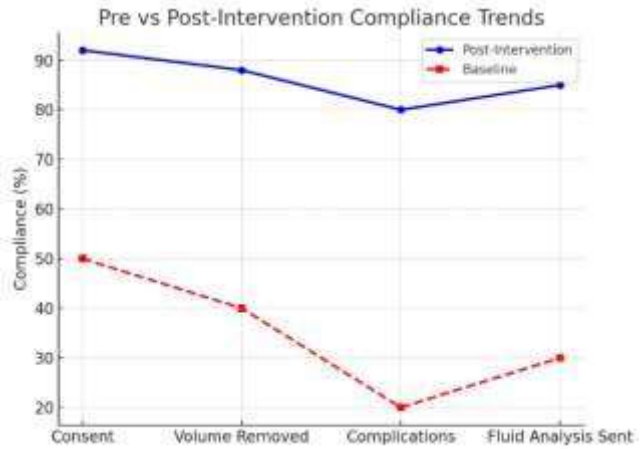


**Figure 6.pre and post intervention compliance trends.**


Figure 7: Radar chart visualizing overall


Figure 8: Heatmap highlighting absolute improvements across parameters.

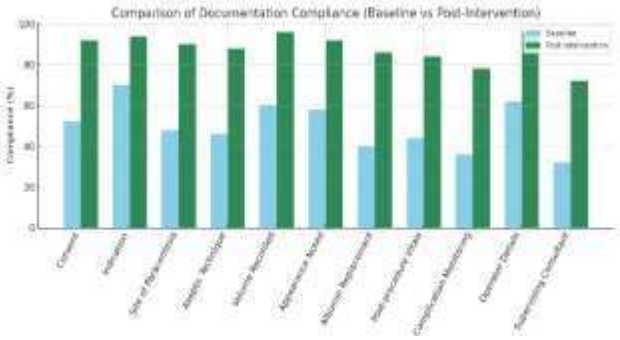


Figure 9: Comparison of baseline vs post-intervention compliance using grouped bar chart.

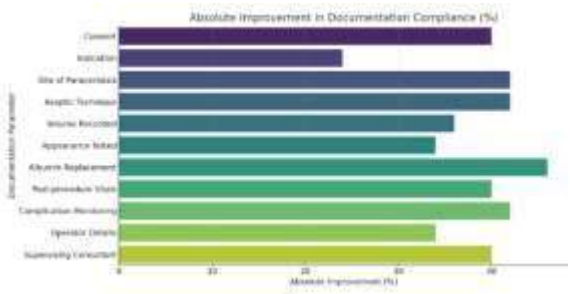

Figure 10: Horizontal bar chart ranking improvements by parameter.

## Discussion

This Quality Improvement Project showed that introducing a structured proforma for large-volume paracentesis (LVP) significantly improved documentation quality in our unit. At baseline, only 16% of records contained all essential elements, with major gaps in informed consent (52%), aseptic precautions (46%), albumin replacement (38%), and post-procedure monitoring (44%). Following implementation, overall compliance rose from 50.3% to 89.2% ($p < 0.001$), with marked improvements across all domains.The greatest gains were seen in documentation of albumin replacement (38% → 82%, $p < 0.001$), aseptic technique (46% → 88%), site of procedure (48% → 90%), and post-procedure monitoring (44% → 84%). Consent documentation improved from 52% to 92%, while operator details increased from 62% to 96%. Supervising consultant involvement nearly doubled (32% → 72%), reflecting stronger accountability. Importantly, no major complications were recorded post-intervention compared with two minor events at baseline. The mean documentation score improved from 3.88 ± 1.12 to 7.57 ± 0.86 ($p < 0.001$), with a very large effect size (Cohen's $d = 3.1$).These findings align with international evidence that structured documentation tools enhance procedural safety and standardization[10-14], particularly in resource-limited settings. By simplifying workflow and ensuring completeness, the proforma not only improved record-keeping but also reinforced safer clinical practices. While limited to a single unit, the intervention was simple, cost-free, and well-accepted, making it scalable across similar healthcare environments[15-17]. Sustaining these improvements will require periodic reinforcement and integration into routine hospital policy.

## Conclusion

The implementation of a structured proforma for large-volume paracentesis markedly improved the completeness, safety, and accountability of documentation in our unit. This simple and cost-effective intervention not only standardized record-keeping but also reinforced adherence to best clinical practices. The project highlights how low-resource settings can achieve meaningful improvements in patient safety through structured documentation, and it provides a scalable model for other high-volume procedures in similar healthcare environments.

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## Availability of data and materials

The datasets analyzed during the current study are available from the corresponding author on reasonable request.

## Authors Contribution

**Concept & Design of Study-** Liaqat Alam khan[1],Zumma Nishan Abbasi [2], , Ahmad zeb[6]

**Data Collection & Drafting & Data Analysis-** Hafeez Ullah Khan[3], Farman Iqbal [4], Muhammad Usman Sharif [5], Ahmad zeb[6]

**Final Approval of version**-All Mention Authors Approved the Final version All authors contributed significantly to the study's conception, data collection, analysis, Manuscript writing, and final approval of the manuscript as **Per ICMJE Criteria.**

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