DOI: 10.7860/JCDR/2025/75326.20954

Review Article

Pathology Section

Optimising Cervical Cancer Screening: A Critical Review of Quality Control, Assurance, and Process Improvement Strategies in Pap Smear Cytology

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ABSTRACT

Cervical cancer is a significant global health concern, with the Pap smear serving as a crucial tool for early detection. However, the effectiveness of Pap smear screening is compromised by false positives and negatives, necessitating robust Quality Control (QC) and Quality Assurance (QA) measures. This review examines the preanalytical, analytical, and post-analytical phases of Pap smear cytology, focusing on quality indicators that enhance diagnostic accuracy. The 2014 refinement of the Bethesda System for Reporting Cervical Cytology (BSRCC) provides a standardised framework for classifying cytological abnormalities. Key quality indicators, such as the ASCUS/SIL ratio and Cytology-Histology Concordance (CHC), are highlighted, along with the importance of Six Sigma metrics and Lean principles for evaluating and improving Pap smear procedures. The review emphasises the implementation of QC, QA, Six Sigma, and Lean principles in healthcare systems to ensure high diagnostic standards, operational efficiency, and patient safety.

Keywords: Cytology, Quality assurance, Quality parameters

INTRODUCTION

Cervical cancer is the fourth most common cancer in women globally, accounting for approximately 350,000 deaths in 2022, with an estimated 660,000 new cases by March 2024 [1]. In India, it is a leading cause of death among women aged 30-69, representing approximately 17% of mortality in this age group. The high prevalence—approximately 1 in 53 women testing positive compared to 1 in 100 in more developed countries—highlights its societal impact. While most cases exhibit slow progression (10-12 years from mild dysplasia to carcinoma) [2], early diagnosis and treatment are crucial for reducing mortality. The Pap smear, introduced in 1945 [3], remains an effective screening tool, encompassing pre-analytical, analytical, and post-analytical phases, and reported using the Bethesda system. This system classifies samples as low-grade or high-grade carcinomas (e.g., Atypical Squamous Cells (ASC) of Undetermined Significance (ASC-US), ASC-H, Low-grade Squamous Intraepithelial Lesion (LSIL), High-grade Squamous Intraepithelial Lesion (HSIL), Atypical Glandular Cells (AGC), squamous cell carcinoma, or adenocarcinoma). Despite its costeffectiveness and contribution to reduced mortality, discrepancies in results lead to a high number of false positives, underscoring the need for QC and QA measures [4].

QC, initially developed in industry, has expanded to healthcare laboratories, evolving from clinical chemistry to other disciplines, including QA in clinical settings [5]. Gynaecological cytology is subject to stringent regulations, with QA enforced by the Clinical Laboratory Improvement Amendments of 1988 (CLIA '88). QA in Pap smear cytology aims to improve test performance, reducing false negatives (which can lead to advanced disease and mortality) and false positives [6]. Quality indicators monitor the QA system, transforming laboratory medicine. Internal QC detects non-conformities throughout the laboratory process [7]. These indicators include positivity rate, percentage of ASC-compatible tests, ASCUS/SIL ratio, percentage of LSIL/HSIL-compatible tests, false negative rates, and unsatisfactory smear percentages [4,8,9].

Quality indicators ensure accurate detection of precancerous lesions, preventing false positives and negatives. Pap smear audits systematically review and evaluate reports and processes to assess quality, accuracy, and effectiveness, identifying deficiencies and areas for improvement [10,11]. Lean Six Sigma, a design approach with specialised tools, enhances quality and safety outcomes in healthcare [12]. In Pap smear cytology, it eliminates inefficiencies, minimises variation, and ensures consistent quality, improving patient outcomes and resource utilisation. This review emphasises the importance of QC, QA, quality indicators, internal QC, and Lean Six Sigma in Pap smear cytology.

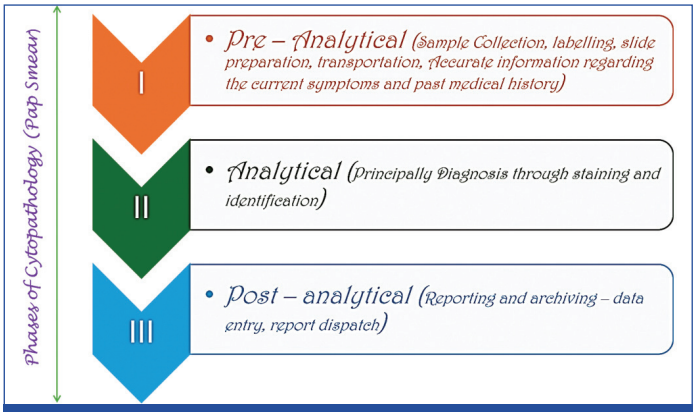
2. Critical Phases in Cytopathology for Cervical Cancer Diagnosis Using Pap Smears: Pre-Analytical, Analytical, and Post-Analytical Considerations

Pap smear processing involves three crucial phases: pre-analytical, analytical, and post-analytical [13]. The preanalytical phase, responsible for 49-68% of errors [14], involves specimen handling before it reaches the laboratory. This includes proper collection, fixation, and transport to preserve sample integrity. Stringent oversight, staff education, standardised procedures, QC measures, automation technologies (e.g., Hologic's ThinPrep Imaging System, Becton Dickinson's Focal Point GS Imaging System), and Computer-Aided Diagnosis (CAD) systems (e.g., Cytyc's AutoPap, Visioneer's Pathfinder) are crucial to reduce pre-analytical errors [14-18]. Rejecting unlabelled samples and documenting re-labelling with physician approval are also essential [14-18].

The analytical phase involves microscopic examination by cytotechnologists and pathologists to identify cellular morphology, including dysplastic cells, ASC, or cancerous lesions. Staining, identifying abnormalities, and diagnosing based on morphological criteria are key steps. Advanced techniques, such as computer-assisted screening and molecular diagnostics, enhance diagnostic accuracy [14-18].

The post-analytical phase includes reporting results to clinicians, interpreting findings within the patient's clinical history, and ensuring appropriate follow-up. Effective communication and documentation

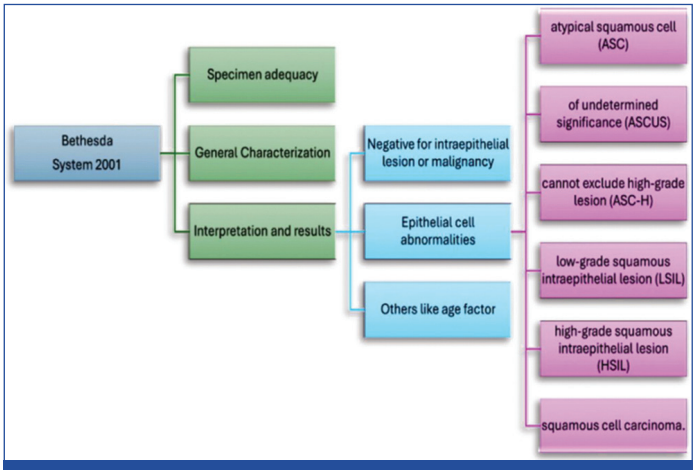
are vital for timely and appropriate patient care [19]. Reducing errors and enhancing quality requires analysis of analytical and postanalytical phases, continuous cyto-histopathological correlation, internal and external quality programs, timely turnaround with proper documentation, and continuous training [19]. Advanced Electronic Medical Record (EMR) systems (e.g., Epic EMR) facilitate electronic transmission of results, reducing transcription errors and Turnaround Time (TAT) [Table/Fig-1] [20,21]. Effective QC and QA are integral to all phases, ensuring high standards from sample collection to result reporting. The Food and Drug Administration (FDA) requires rescreening of 10% of negative Pap smears, along with smears from high-risk patients [22]. QA focuses on the outcome of the entire process, relying on comprehensive quality management, including system design, policies, and processes to prevent false results and ensure patient safety.



[Table/Fig-1]: A schematic diagram depicting the distinct phases of the laboratory testing cycle in histopathology laboratory, along with their key components.

3. Bethesda System for Reporting Cervical Cytology (BSRCC)

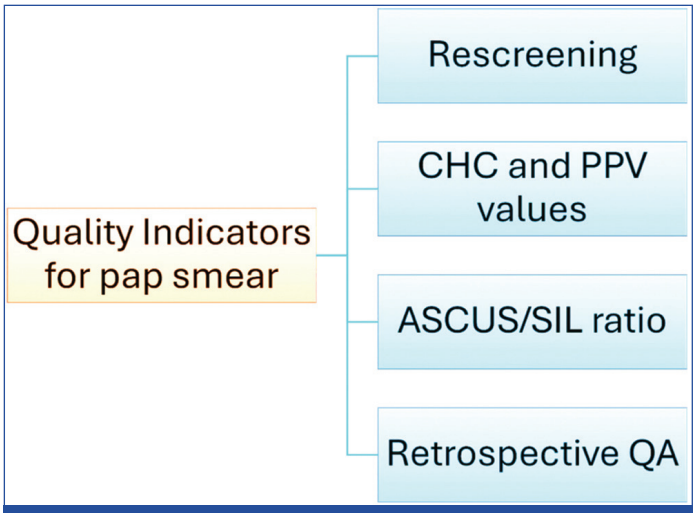
The BSRCC, developed in 1988, standardises reporting of cervical and vaginal cytology, classifying squamous cell abnormalities and providing clear criteria for specimen adequacy and cellular abnormality categorisation [4,9,23]. It supports timely identification of precancerous lesions [Table/Fig-2]. The system's primary purpose is to enhance clarity, consistency, and clinical utility of Pap smear interpretations [4,9,23]. By clearly defining categories (ASCUS, LSIL, HSIL), it enhances diagnostic precision, distinguishing between different degrees of cellular abnormalities [24]. The system also describes negative findings, including infections {*Trichomonas vaginalis*, *Candida* sp., Actinomyces, Herpes Simplex Virus (HSV)} and non-neoplastic findings (inflammation, atrophy) [24]. The BSRCC provides explicit recommendations for follow-up and treatment, aiding clinical decision-making [25]. The 2014 update incorporated new scientific insights and technological advancements, reflecting evolving understanding of cervical pathology [26]. The BSRCC enhances training and proficiency of cytopathologists and contributes to QA [27]. It distinguishes abnormalities due to HPV infection or condyloma and various grades of dysplasia, and is well-positioned to incorporate future advancements [27].



[Table/Fig-2]: Schematic representation of Bethesda System 2001.

4. The distinct phases of Pap smear cytology, guided by the standardised Bethesda System, ensure accurate diagnoses and effective communication, while quality indicators play a crucial role in maintaining procedural integrity.

Clinical laboratories must deliver precise and timely results. Cytological analysis is an essential tool for clinicians, aiding in treatment initiation and disease classification [28]. Total quality management is crucial for upholding quality standards, minimising errors, and enhancing patient safety [29]. The pre-analytical, analytical, and post-analytical processes are essential for the reliability and accuracy of Pap smears [30]. Evaluation of these phases reveals key insights into process quality and efficiency [5]. Quality indicators reflect the standards and effectiveness of patient care, serving as benchmarks for evaluating healthcare services [12,31]. They identify areas for improvement, maintain compliance, and enhance patient outcomes. Quality indicators for Pap smear cytology include rescreening, ASCUS/Squamous Intraepithelial Lesion (SIL) ratio, retrospective QA, Positive Predictive Value (PPV), and CHC [Table/Fig-3]. Rescreening requires random rescreening of at least 10% of negative Pap smears, especially for high-risk patients [22]. The ASCUS/SIL ratio (number of ASCUS diagnoses/number of SIL diagnoses) is calculated, with a low ratio suggesting a more conservative approach to categorising ambiguous cases [7,8,32]. Retrospective QA involves reviewing past test results and procedures to identify errors and areas for improvement [13]. PPV (true positives/(true positives+false positives)×100%) indicates test accuracy [33]. CHC describes the agreement between cytological and histological findings [33]. A recent study highlights the importance of incorporating CHC and PPV as key quality indicators [34].



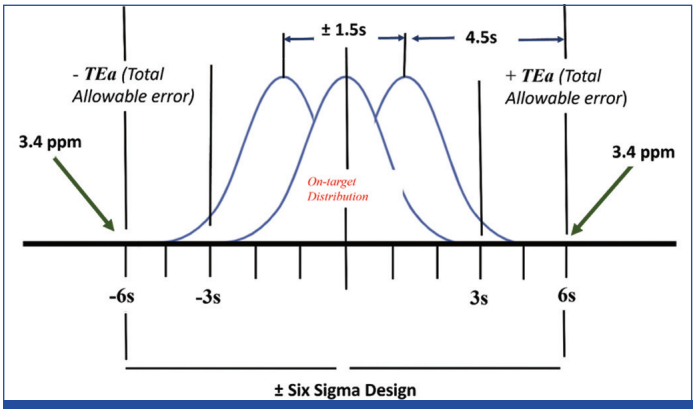
[Table/Fig-3]: Illustrates the main components of Quality Control (QC) indicators for pap smear cervical cytology.

5. Understanding Non-Conformity in Healthcare: Implications for Quality Management and Patient Safety

Non-conformity or Non-Conforming Event (NCE) refers to deviations from established standards, guidelines, or expectations. These deviations can occur at various levels, including clinical processes, protocols, administrative procedures, and documentation [35]. Non-conformities encompass medication errors, diagnostic inaccuracies, patient safety incidents, regulatory violations, and failure to adhere to best practices [35,36]. Identifying and addressing non-conformities is crucial for patient safety, quality of care, and stakeholder trust [36]. The literature emphasises proactive risk management, quality improvement initiatives, and regulatory compliance to mitigate non-conformities [35-39]. CLIA '88 mandates rescreening of at least 10% of negative cases (random and highrisk), retrospective review of HSIL or higher diagnoses over five years, and CHC [22].

6. Six Sigma metrics in clinical cytopathology enhance diagnostic accuracy by systematically reducing errors across pre-analytical, analytical, and post-analytical phases.

Six Sigma is a quality management methodology aimed at minimising defects and errors in laboratory processes. Developed in manufacturing, it has been adapted to healthcare, including clinical pathology, to enhance efficiency, accuracy, and patient safety [40-44]. Six Sigma principles provide a systematic approach for devising an effective QC strategy. Nevalainen et al., and Westgard conducted pioneering studies on evaluating laboratory performance using the Six Sigma scale [40,41]. The Six Sigma metric system (0-6) has a minimum acceptable quality level of 3 (66,807 faults per million), with 6 representing only 3.4 faults per million (99.99% success rate) [42]. A 1.5 standard deviation shift in the mean indicates a deviation from expected performance, potentially leading to increased variability and errors [Table/Fig-4] [43]. Sigma values are applicable to both qualitative and quantitative assays, providing standardised benchmarks [44]. Six Sigma uses a data-driven approach and statistical tools to identify and eliminate sources of variation, aiming for near-perfect performance. By setting rigorous quality standards and continuously monitoring and improving processes, Six Sigma helps clinical pathology laboratories deliver high-quality results, reduce turnaround times, and optimise resource utilisation, contributing to better patient outcomes and healthcare system efficiency [13]. Adherence to Six Sigma principles enables improvements in workflow, efficiency, accuracy, and the integration of technologies like telecytology and automation [13].



[Table/Fig-4]: This figure visually represents the quality of a Six Sigma assay, a standard measurement system used to assess process performance [41].

7. Integrating lean principles in hospital settings, focusing on cervical cytology to improve process efficiency, reduce errors, and ensure stringent quality

Lean principles, originating from lean manufacturing, aim to improve efficiency, quality, and patient outcomes in healthcare [45]. Lean focuses on eliminating waste, optimising processes, and enhancing value for patients. It emphasises continuous improvement and frontline staff involvement in problem-solving [46]. Lean strategies include streamlining workflows, reducing wait times, minimising unnecessary steps, and standardising procedures [47]. By eliminating inefficiencies, healthcare organisations improve patient satisfaction, reduce medical errors, and enhance quality of care [47,48]. Lean encourages innovation and collaboration [43]. Michael et al., created a Value Stream Map (VSM) of the Papanicolaou test procedure to identify areas for waste and error reduction. A redesigned VSM with Lean tools (first-in, first-out processes, minimised batch sizes) and staff engagement resulted in enhanced quality, increased patient safety, and greater operational efficiency [49]. Rabb et al., study showed that Lean workflows significantly reduced the proportion of Pap tests lacking a transformation zone component and increased the detection of cervical intraepithelial neoplasia, without significantly changing unsatisfactory Pap tests or ASC of unknown significance [50].

8. Enhancing Laboratory Performance in Pap Smear Cytology: Mitigating Non-Conformities through Rigorous Quality Control (QC) and Advanced Training Based on Comprehensive Literature Review.

A literature review on internal QC indicators for cervical smears revealed a limited number of comprehensive studies [Table/Fig-5] [7,19,51-55]. Most non-conformities occur during the pre-analytical phase, with errors such as inadequate or incorrect clinical information on test request forms having a substantial impact [7,19]. Inadequate technical training of personnel contributes to these non-conformities. Addressing these challenges requires comprehensive technical training programs focusing on proper specimen handling, accurate documentation, and effective communication. Ensuring detailed clinical information (patient demographics, medical history, reasons for testing) is critical for precise cytological interpretation. Institutions must enforce stringent protocols for thorough and complete data entry (preferably automated) before processing Pap smears [7,19]. CYTOTRAIN, a European Commission-funded program, trained doctors, cytopathologists, and cytotechnicians to maintain high-quality standards and minimise false positives and negatives. However, regular updates and training are necessary to keep professionals up-to-date [7,19].

S. No.	Pre-analytical phase	Analytical phase	Post analytical phase	Duration of study	Authors
1	57%	11%	32%	5 years	Chandra S et al., 2019 [19]
2	62.1%	NA	The study was not referenced in this phase	1 year	Muthukrishnan R et al., 2020 [51]
3	The study was not referenced in this phase	3.34%	The study was not referenced in this phase	3 months	Rajagopal P et al., 2023 [7]
4	4.5%	The study was not referenced in this phase	The study was not referenced in this phase	2 years	Belekar SV et al., 2023 [52]
5	The study was not referenced in this phase	Discrepancy in interobservation time	The study was not referenced in this phase	3 months	Siddegowda RB et al., 2016 [53]
6	Lack of pertinent clinical information on Pap test request form	The study was not referenced in this phase	The study was not referenced in this phase	Comprehensive literature synthesis	Kumar N et al., 2020 [54]
7	24.42%	The study was not referenced in this phase	The study was not referenced in this phase	1 year	Narasimha A et al., 2011 [55]

[Table/Fig-5]: Comparison of internal Quality Control (QC) indicators for cervical smears in various studies [7,19,51-55].

CONCLUSION(S)

Standardised protocols and continuous training minimise variability and enhance the quality of smear preparation, fixation, and staining. The integration of QC measures, including Six Sigma metrics and Lean principles, significantly enhances diagnostic accuracy, patient safety, and operational efficiency. Focusing on critical pre-analytical and analytical phases and utilising frameworks like the BSRCC streamlines processes and reduces non-conformity. These advancements ensure that Pap smear procedures remain reliable and precise, reinforcing their role in early detection and prevention of cervical cancer.

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PLAGIARISM CHECKING METHODS: [Jain H et al.]
- Plagiarism X-checker: Sep 12, 2024
- Manual Googling: Nov 12, 2024
- iThenticate Software: Jan 08, 2025 (10%)

ETYMOLOGY: Author Origin

EMENDATIONS: 7

AUTHOR DECLARATION:
- Financial or Other Competing Interests: None
- Was informed consent obtained from the subjects involved in the study? NA
- For any images presented appropriate consent has been obtained from the subjects. NA

Date of Submission: **Sep 09, 2024**
Date of Peer Review: **Oct 24, 2024**
Date of Acceptance: **Jan 10, 2025**
Date of Publishing: **May 01, 2025**