

Quality indicators of pathology and laboratory medicine in cancer: a narrative synthesis of published literature

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Abstract

Purpose: With the rise in global cancer incidence, inadequate access to pathology and laboratory medicine (PALM) is one of the largest gaps in the cascade of cancer care, especially in low- and lower-middle-income countries. Quality indicators (QIs) are essential to evaluate the accuracy, completeness, timeliness and cost-effectiveness of PALM services to ensure access and quality. To identify strengths and gaps, this review systematically identifies and synthesises published PALM-specific cancer QIs across cancer types and geography.

Methods: Following Preferred Reporting Items for Systematic reviews and Meta-analyses guidelines, a search of PubMed inclusive of Medline between 1990 and 2024 was conducted for studies that developed, applied or evaluated QIs for anatomical and molecular cancer pathology. Studies limited to chemopathology, immunopathology, haematopathology, haemato-oncology and paediatric oncology were excluded. Risk of bias was assessed using the Risk Of Bias In Non-randomised Studies - of Interventions tool.

Results: Of 8,685 records screened, 40 (0.5%) studies were included; 24 (61.5%) had moderate risk of bias. Nearly all the studies (97.5%) originated from high- or upper-middle-income countries, predominantly Europe and North America. Gynaecological and breast cancers were most frequently studied ($n = 12$ and 10), while prostate and lung cancers were underrepresented ($n = 4$ and 1 , respectively). Most QIs focussed on diagnostic accuracy in the analytic phase ($n = 26$). Very few QIs assessed timeliness or cost-effectiveness ($n = 2$ and 3), particularly in pre-analytic and post-analytic phases.

Conclusion: Evidence for PALM-specific cancer QIs for timeliness and cost-effectiveness, in pre- and post-analytic phases, and across resource-limited settings is deficient. To facilitate global harmonisation, stakeholders from all resource settings should review international guidance to standardise QIs that are feasible, applicable and stratified to resource level. At the national level, Delphi processes are recommended to develop context-specific QIs, which inform national diagnostic strategy and cancer control planning.

Keywords : *quality indicator, global oncology, pathology, laboratory medicine, cancer*

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Introduction

Pathology and laboratory medicine (PALM) is fundamental to cancer care, underpinning diagnosis, staging, treatment selection and prognostication. Three intertwined aspects are necessary: access to PALM services, the quality of those services and the ability to measure and monitor that quality.

First, access to PALM across the cascade of cancer care remains highly inequitable. As the global cancer incidence rises – projected to reach 30.2 million new cases and 16.3 million cancer-related deaths by 2040 – health systems are increasingly strained [1, 2]. In low-income countries (LICs), up to 62% lack access to essential cancer diagnostics [3]. Despite long-standing recognition of this gap, progress has been slow. Limited visibility and low prioritisation of diagnostics from research to advocacy, alongside constrained infrastructure and workforce capacity, continue to limit access.[4] Only one in eight pathologists reported to have routine access to immunohistochemical (IHC) tests and none to molecular testing for female genitourinary cancers in LICs, despite their inclusion in the World Health Organisation (WHO) essential diagnostic list [5]. This nosologic shortcoming calls into question the feasibility and applicability of the diagnostic essential criteria.

Access to PALM needs to be accompanied by quality. The quality of PALM services can be defined by diagnostic accuracy, completeness, timeliness and cost-effectiveness of the diagnostics. The lack of quality can lead to misdiagnosis, delayed treatment, inappropriate therapy selection and increased healthcare costs, ultimately undermining patient outcomes even where services are available. Therefore, it is critical that the quality of PALM is being measured credibly, yet this remains an underdeveloped area. Quality indicators (QIs) are defined, measurable metrics with the purpose of evaluating or benchmarking the outcome, process, or structure of care for a particular type of patient or clinical condition [6]. QIs should capture variability across the entire testing process – from pre-analytic (specimen collection and handling), through analytic (testing and interpretation), to post-analytic (result reporting) phases. As such, QIs are essential instruments for governance, benchmarking and health system strengthening.

Importantly, cancer-specific PALM QIs present unique challenges that are not fully addressed by general laboratory QIs. Cancer PALM is particularly complex, integrating morphologic evaluation, tumour staging, and increasingly molecular and genomic profiling, all of which are required urgently and all of which directly influence clinical decisions and prognosis. Despite their importance, there is a paucity of evidence on the applicability of cancer-specific PALM QIs in different resource settings. Now is an apposite time to identify and characterise existing cancer-specific PALM QIs across geography and cancer type, as innovations, such as point-of-care diagnostics which democratise diagnostics; digital pathology, which promotes telepathology and facilitates training; and artificial intelligence, especially natural language processing which helps automate and structure pathology reporting, are emerging, collectively transforming the global cancer diagnostic landscape [7–9]. This narrative synthesis aims to inform the development of a more integrated, context-sensitive approach to QI design and application in future global cancer diagnostics.

Methods

The systematic review was conducted following the Preferred Reporting Items for Systematic reviews and Meta-analyses (PRISMA) guidelines. Studies published between 01/01/1990 and 31/12/2024 were searched on PubMed, inclusive of Medline. The core search terms used to identify relevant publications were: pathology, cancer and QI, with their respective expanded search strings included in the full search strategy (Appendix A).

Inclusion criteria

Studies focusing on anatomic pathology (histopathology, cytology and immunohistochemistry) and molecular pathology, written in English and focused on human adults, were considered. Publications were included if they reported measurable QIs used for evaluating or benchmarking outcomes, process or structure of cancer-related PALM services.

Exclusion criteria

Studies were excluded if they focused on chemical pathology, immunopathology or haematopathology. Although anatomical pathology includes autopsy and forensic investigation, they are excluded in this review given non-relevance to cancer. Non-primary research publications including review articles, letters, conference proceedings, expert commentaries, non-clinical laboratory studies, protocols, case reports, editorials and pre-clinical studies were excluded. Research focused on paediatric oncology and haemato-oncology was also excluded.

Data selection

The titles and abstracts were assessed and screened by three reviewers (AR, AH and ER) to minimise reviewer errors and bias after records were identified. Full-text articles were then assessed for eligibility, and data were extracted by the three independent reviewers (AR, AH, ER). Inter-reviewer agreement was high (88%–95% across screening stages), although not formally quantified using statistical measures. Disagreements were resolved qualitatively through consensus with arbitration by senior authors (PN and RS).

Data extraction

The following variables were collected: author; reference year; country; study characteristics (including funding, research design and sample size); cancer type; domain of pathology (histopathology, cytopathology or molecular pathology); and the phase of pathology testing (pre-analytic, analytic or post-analytic). In addition, we extracted the aims and reported outcomes of the study, the purpose of the QIs (timeliness, completeness, accuracy or cost-effectiveness) and the specific QIs assessed.

Synthesis method

Given the heterogeneity of study designs, cancer types and QIs, a narrative synthesis was undertaken. Extracted data were organised thematically according to the domain of pathology, the phase of pathology testing and the stated purpose of QIs (timeliness, completeness, accuracy, cost-effectiveness). Findings were then synthesised to identify common patterns and gaps across studies.

Risk of bias assessment

Given the heterogeneity in the design of the included studies, no single validated risk-of-bias tool can be applied consistently across all the studies without losing validity or comparability [10]. The Risk Of Bias In Non-randomised Studies - of Interventions (ROBINS-I) tool was selected to assess methodological quality as it adopts a domain-based structure to enable consistent assessment of bias of all studies. The assessment focused on seven domains of bias: confounding, selection of participants, classification of intervention, deviations from intended interventions, missing data, measurement of outcomes and selection of reported results. Each domain was rated as low, moderate or not applicable (NA), with an overall judgment of risk of bias provided for each study. For studies without a defined intervention, domains relating to intervention and deviations from intended interventions (Domains 3 and 4) were NA and were therefore not assessed.

Results

Search strategy

Eight thousand six hundred and eighty-five studies were initially identified using PubMed, inclusive of Medline. Four hundred and one studies were deemed eligible after titles and abstracts were screened using the inclusion criteria. Three hundred and sixty-one studies were excluded according to the exclusion criteria, leaving 40 publications selected for inclusion, as illustrated in the PRISMA flow chart in [Figure 1](#). The summary of all included studies is attached as [Supplementary Table S1](#) (Appendix B).

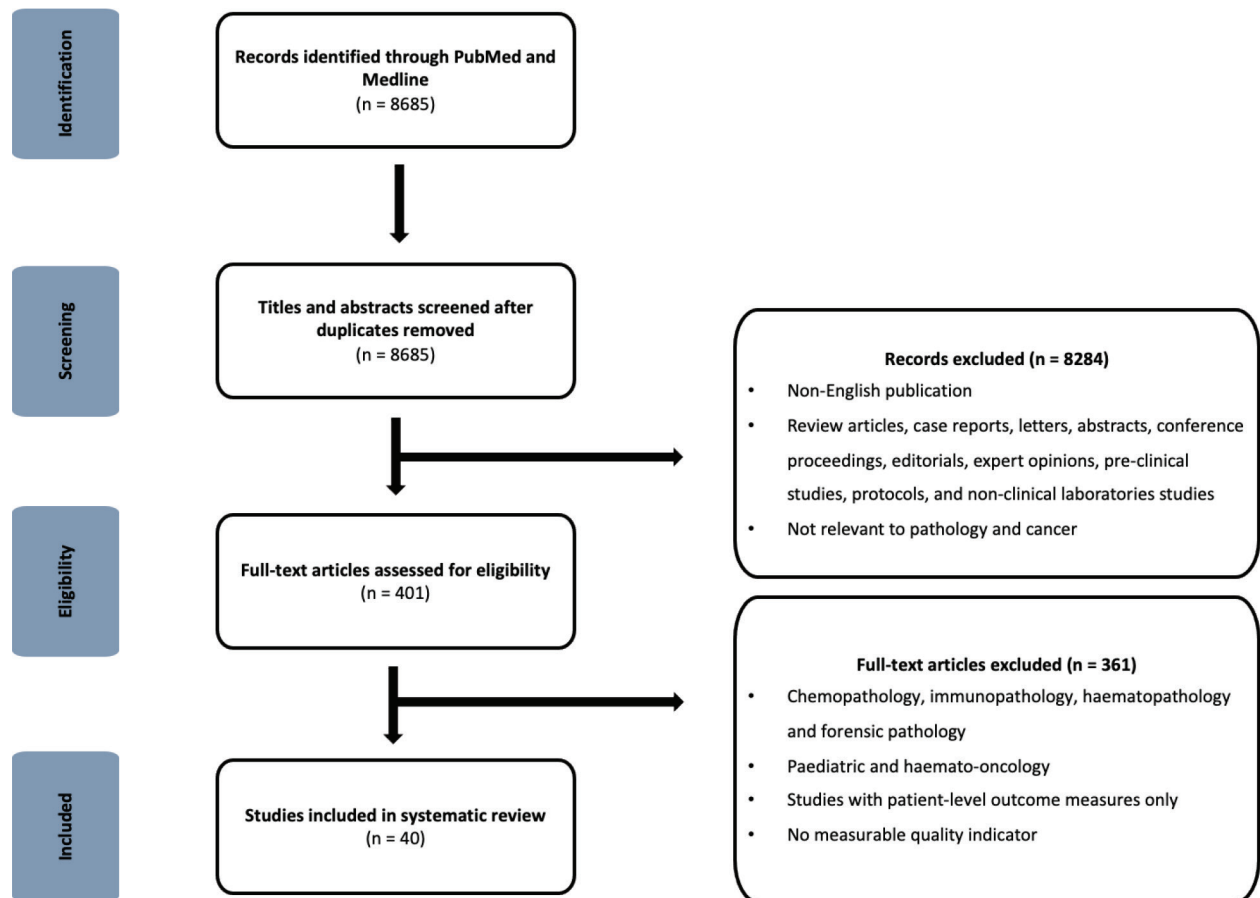


Figure 1. PRISMA flowchart of study selection.

Quality assessment of studies

Thirty-nine non-randomised studies were evaluated using the ROBINS-I tool. The breakdown and outcome of risk of bias assessment of each study was included as [Supplementary Table S2](#) (Appendix C) and a summary of each domain of bias is displayed in a bar chart, as [Supplementary Figure 1](#) (Appendix D). One study was not included in this assessment as it was a health economics study [11].

Twenty four (61.5%) studies were rated as having moderate overall risk of bias [13, 15, 18, 19, 21–23, 25–29, 34, 38–43, 45–49], primarily falling short due to confounders (n = 15, 38.5%) and/or missing data (n = 11, 28.2%). The remaining 15 (38.5%) studies were deemed to have low overall risk of bias, meaning that their risk is comparable to that of a well-conducted randomised trial [12, 14, 16, 17, 20, 24, 30–33, 35–37, 44, 50].

Location of studies

Thirty-nine of 40 (97.5%) of the studies were published in upper-middle-income countries (UMIC) or high-income countries (HIC) [11–26, 28–50]. The one study published in LMIC was from India [27]. Europe led as a continent overall, publishing 23 out of 40 (57.5%) of the

studies [11, 13, 14, 16, 18, 19, 21–25, 28–34, 37, 40, 49, 50]; followed by North America, 13 (32.5%) [12, 17, 20, 34–36, 38, 39, 42, 44–47]. There were only three studies originated from Asia [15, 27, 41]; and none from Latin America or Africa. The United Kingdom was the most prolific country with eight studies (20%), while the United States of America was second with seven studies (17.5%) published. Canada and Italy both published six studies (15%), respectively (Figure 2).

Type of studies

Thirty-four of 40 studies (85%) were retrospective observational studies [13–18, 20–33, 35, 36, 38–49]; five ($n = 12.5\%$), prospective observational studies [12, 19, 34, 37, 50]; and one ($n = 2.5\%$), health economics study [11].

Cancer type

The number of studies varied significantly by cancer type, with gynaecological cancers representing the largest proportion ($n = 12$, 30%), as illustrated in Figure 3 [11–13, 15, 16, 19, 21, 22, 25, 27, 28, 37]. This was closely followed by breast cancer ($n = 10$, 25%) [17, 20, 23, 31, 33, 41–43, 48, 51]. Four (10%) of the studies focused on prostate cancer [14, 18, 34, 47]; three (7.5%), on colorectal cancer [29, 30, 47]; and three on skin cancers [24, 26, 45]. Two (5%) studies were on upper gastrointestinal cancer [35, 38], while only one (2.5%) study examines thyroid cancer [39], kidney cancer [34], adrenal cancer [40], and lung cancer [50]. Three (7.5%) of the studies addressed broader pathology quality metrics without focusing on a particular cancer type [36, 46, 49].

Purpose of QIs

The heatmap in Figure 4 reveals the distribution of QIs across the pre-analytic, analytic and post-analytic phases of pathology testing for cancer. The purpose of the QIs was predominantly to assess the accuracy of the pathology test, particularly in the analytic phase ($n = 26$, 65%), followed by its completeness. There are notable gaps in QIs focussing on the timeliness of pathology tests, with only two studies (5%) in the analytic phase and none reported for pre- and post-analytic phases. QIs focussing on cost-effectiveness of pathology tests were uniformly sparse, with one study (2.5%) per phase. The Sankey diagram, as illustrated in Figure 5, further delineates the flow of QIs from their pathology phases to respective sub-phases.

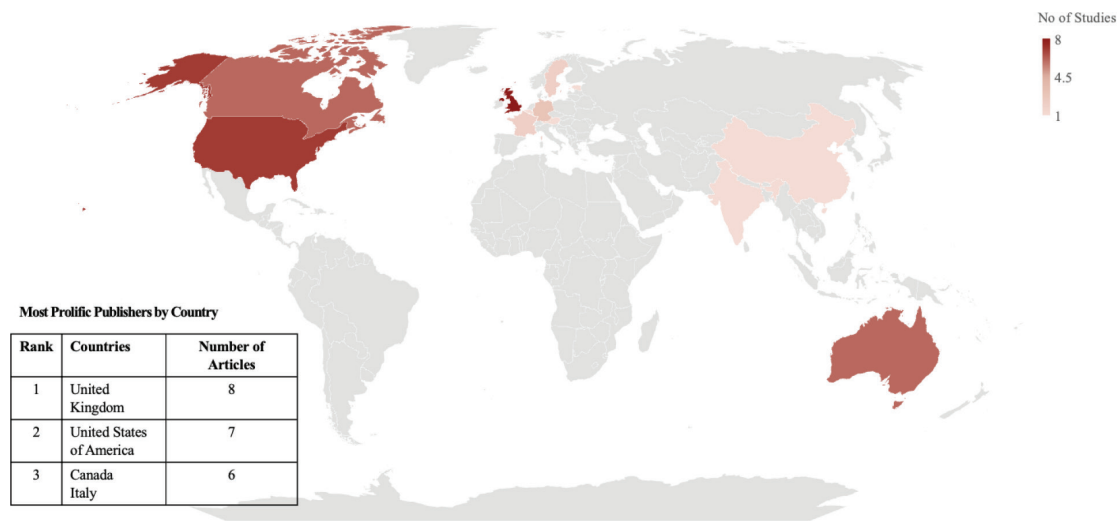


Figure 2. Global heatmap of studies related to pathology QIs in cancer.

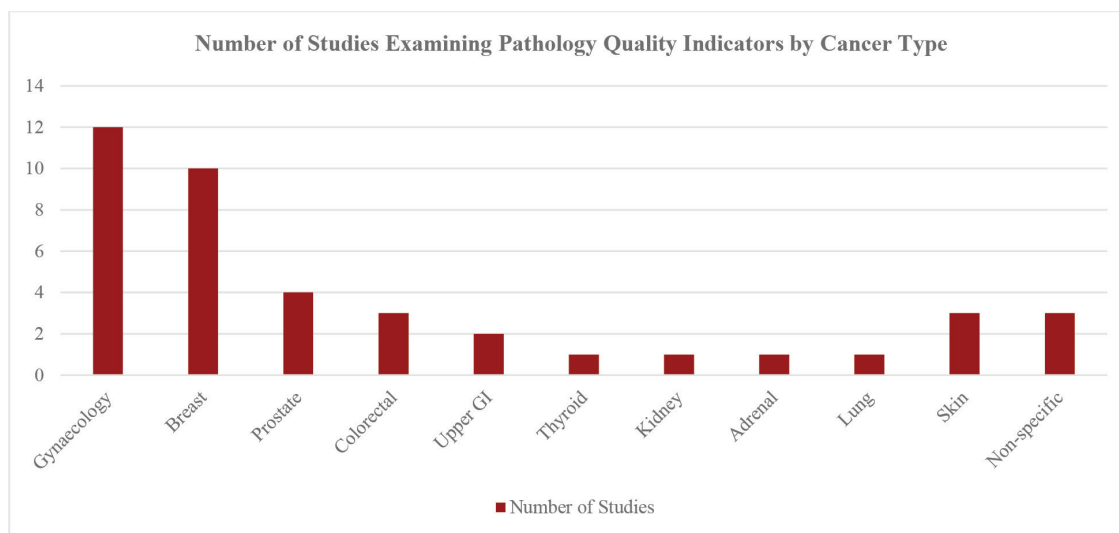


Figure 3. Barchart of studies examining pathology QIs by cancer type.

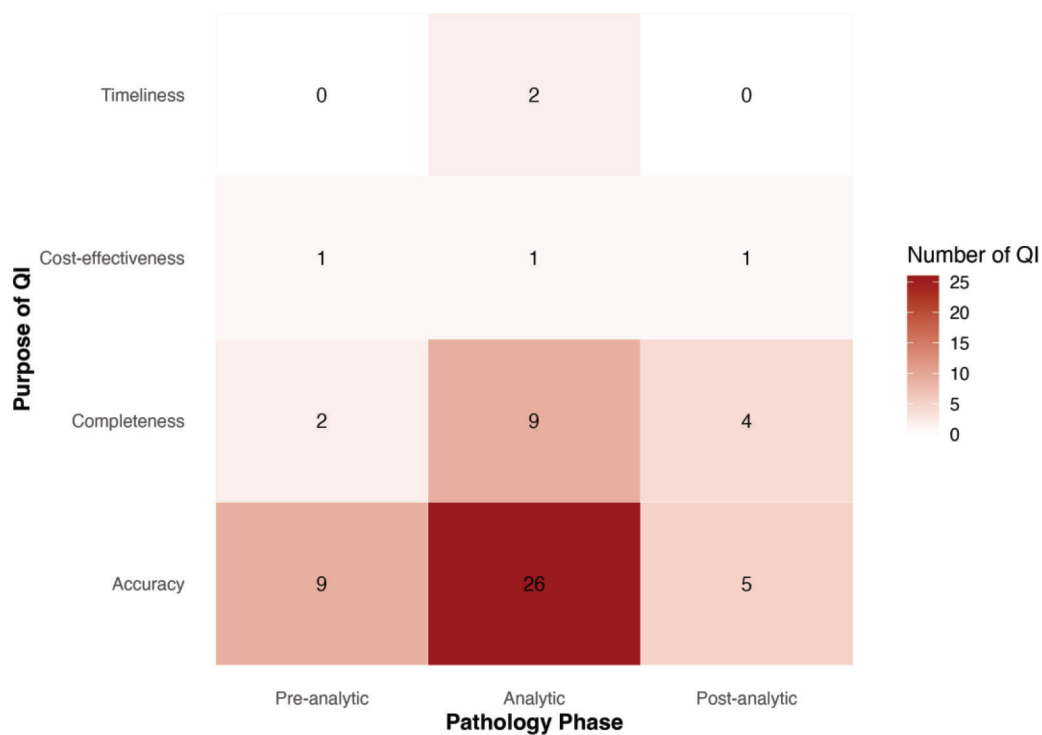


Figure 4. Heatmap of pathology QIs by purpose across phases of pathology testing.

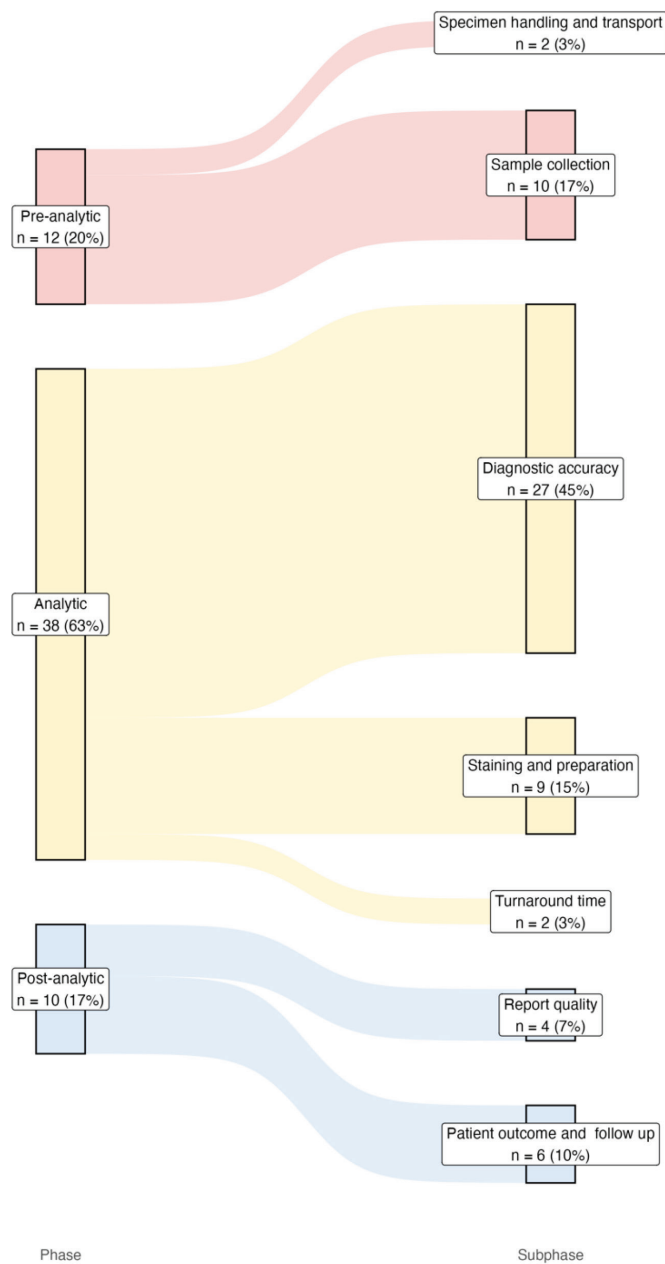


Figure 5. Sankey diagram depicting flow of QI from pathology phases to sub-phases. Line width represents QI density.

QIs by phase of testing

The array of pathology QIs was categorised based on their phase of pathology testing, as shown in Figure 6.

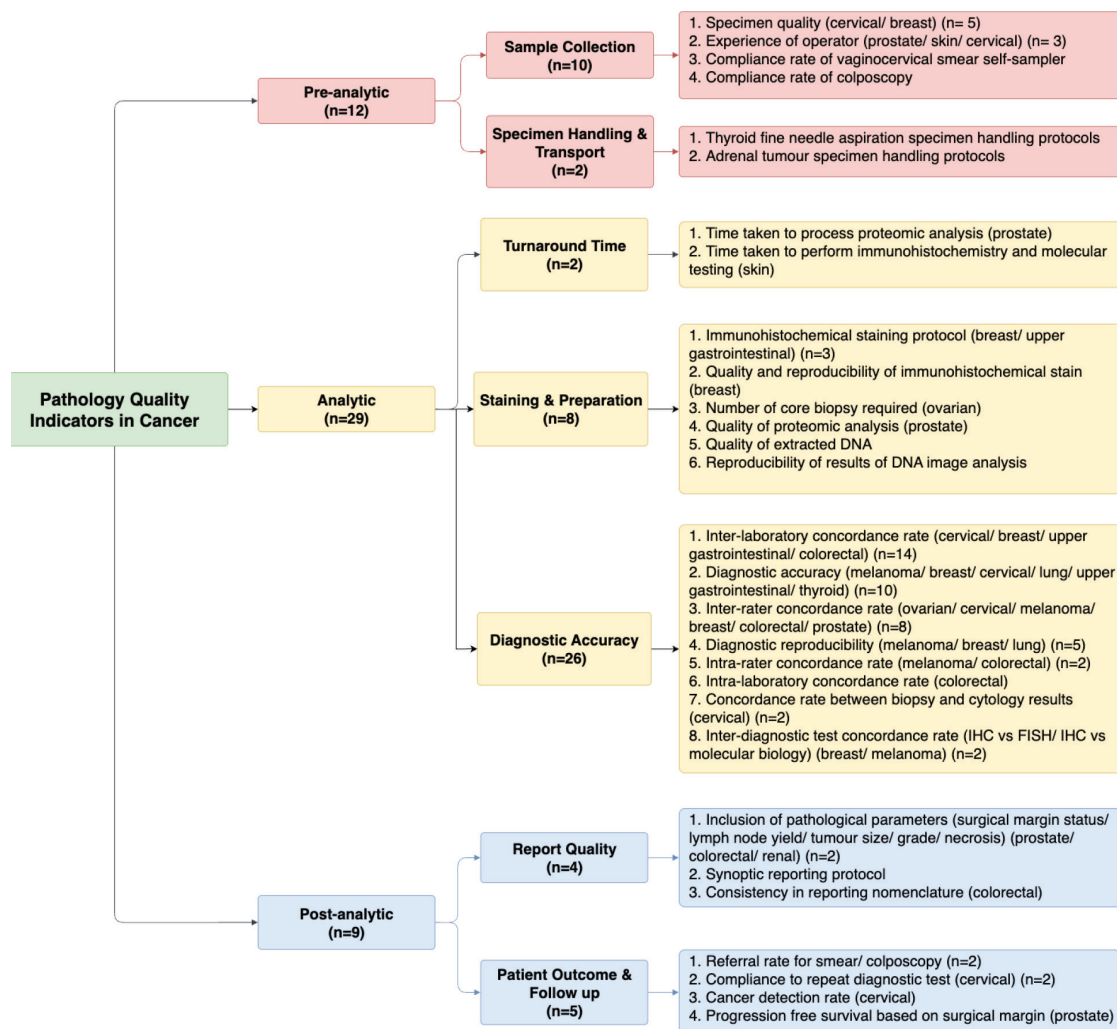


Figure 6. QIs in cancer pathology by phase of testing.

Pre-analytic

Five of the studies included QIs that ascertain the quality of specimen collected (vaginal, cervical and breast) [16, 23, 25, 28, 37]. Three focused instead on the experience of the operator who collected the specimens (prostatic, skin and cervical) [18, 26, 27]. One study measured the compliance rate of self-samplers for cervical smear [21]. Two studies employed QIs in assessing the adherence of protocol surrounding specimen handling for thyroid and adrenal lesions [39, 40].

Analytic

Only two studies assessed the turnaround time of pathology testing- one specifically on time taken to process proteomic analysis in prostatic specimens [14], while the other on time taken to perform IHC and molecular testing for skin biopsy with suspected melanoma [24]. Three of

the studies looked at adherence to IHC staining protocol for breast and upper gastrointestinal specimens [32, 33, 35]. Quality and reproducibility of IHC, proteomic analysis, DNA image analysis, as well as the number of core biopsies required for tumour representation were also identified as QIs relevant to specimen preparation [12, 14, 41, 43, 46, 49].

The diagnostic accuracy of various pathology tests was the most studied QIs ($n = 26$, 65%). Inter-laboratory concordance rate of pathology results was the most commonly used QI, applied across cervical, breast, upper gastrointestinal and colorectal cancer [15–17, 20, 29, 31, 33, 35, 36, 42, 43, 48]. This is followed by the inter-rater concordance rate [12, 17, 30, 33, 34, 37, 45, 51] and the reproducibility of cancer diagnosis based on pathology tests [45, 48–50]. Concordance rates were also measured between different types of specimen (i.e., biopsy versus cytology) [15, 28], different diagnostic tests (i.e., IHC versus molecular testing versus fluorescence *in situ* hybridisation) [17, 20, 24] and within a laboratory but across different timepoints [16, 29].

Post-analytic

Four studies zeroed in on the quality of pathology reports [29, 38, 44, 47]; two specifically on the important pathological parameters including surgical margin status, lymph node yield, tumour size, tumour grade and other prognostic factors [44, 47]. The other two studies assessed the adherence to the synoptic reporting protocol and consistency in nomenclature, respectively [29, 38]. Two studies included referral rates for a repeat diagnostic test and/or another diagnostic test, while two included the compliance rate to a repeat diagnostic test [13, 22]. Long-term cancer detection rate, number of cancers averted and progression free survival based on surgical margin of prostate specimen were used as QIs in one study each [11, 19, 34].

Discussion

This narrative synthesis identified a limited body of published evidence on QIs in cancer pathology, with only 40 studies (less than 0.5% of screened literature) directly evaluating or applying QIs. More than half (61.5%) of these studies were assessed as having low to moderate risk of bias (61.5%), reflecting variability in study design and reporting quality. The limited volume of QI-focused research reflects the historically low visibility and prioritisation of PALM within health systems [4]. PALM only accounts 3%–6% of overall healthcare expenditure and their professionals make up around 4% of the workforce in most healthcare systems [52]. This issue is critical as it may have implications for regulation for both laboratory accreditation and workforce professional standards and competencies in PALM.

In addition, there was a marked geographic disparity in research activity, with 97.5% of studies originating from high- and UMIC. This imbalance likely reflects the broader patterns of the trickle-down model in PALM, where innovations and quality frameworks are often developed in HICs before trickling down to the LMICs. The mismatch between available QIs and the needs of LMICs makes the countries vulnerable to suboptimal implementation and evaluation of PALM services. To overcome this, collaborative comparative studies on QIs between HIC and LMIC laboratories would provide insight into gaps within the country-specific context and should be encouraged.

Another observation is that QIs predominantly focused on diagnostic accuracy and completeness, with limited attention to timeliness and cost-effectiveness. While accuracy and completeness are essential, delays in diagnosis and inefficiencies in resource utilisation may significantly affect patient outcomes. The turnaround time and the cost-effectiveness of PALM are vital in assessing if the system caters to the needs of the poor, rural and marginalised communities in resource-limited settings. From a broader health systems perspective, expanding QIs to measure timeliness and cost-effectiveness of PALM would inform policymakers of bottlenecks in cancer diagnostics so resources could be allocated more transparently and efficiently between infrastructure and workforce capacity building. This might in turn strengthen accountability mechanisms and governance, the lack of which are recognised to impair delivery of PALM [53, 54].

In addition, QIs were unevenly distributed across cancer types, with greater representation in breast and gynaecological cancers compared to other high-burden cancers such as lung and prostate cancer [55]. This may be attributable to longstanding global investments in screening and early detection programmes, given that at least 15% of such investment was directly related to cervical and/or breast cancer screening programmes. This illustrates how coordinated international initiatives could drive positive downstream research and development of cancer diagnostics, fostering a cycle of innovation.

Recommendations for development of context-specific QIs in cancer pathology

A credible QI of cancer PALM should directly assess four aspects: the validity, reliability, timeliness and/or cost-effectiveness of a diagnostic service, across the three phases described above [56]. The validity of a diagnostic service should be based on clinical relevance (i.e., diagnostic accuracy, treatment selection and prognostication) and content validity, meaning measuring what it purports to measure. Its reliability should reflect operational clarity, from standardisation of procedures to synoptic reporting, to ensure completeness and to minimise subjective interpretation and discrepancy across observers, systems and time. The timeliness of a diagnostic service should be measurable and actionable, enabling prompt quality improvement action through near-real-time monitoring. Its cost-effectiveness should be modelled based on the benefit-cost ratio of the diagnostics.

On a health system level, the QIs to assess the above should be feasible, benchmarkable and sensitive so that the data collected can be utilised for public health epidemiological purposes, informing policy, regulation, financing, infrastructure and workforce planning. Last and most importantly, the benchmark set should be professionally endorsed by key stakeholders across the hierarchy of pathology services, from lab technicians and pathologists to surgeons, oncologists, industry, regulators and policymakers.

Based on the findings, we recommend a two-step approach to support the development and implementation of context-specific QIs in cancer-specific PALM. First, a multi-stakeholder international partnership is required to marshal the effort to establish a core set of global QIs for cancer pathology. The partnership should include international agencies such as the WHO, International Agency for Research on Cancer, International Organisation for Standards, professional pathology societies and Ministries of Health. To achieve global synoptic reporting and standardised cancer datasets, greater inclusion of LMIC stakeholders is essential to ensure feasibility and applicability of QIs across diverse health systems, thus facilitating regional harmonisation of cancer pathology. Stakeholders should review the existing international standards, such as the WHO Tumour Board for Cancer Staging and Classification, and the International Collaboration on Cancer Reporting [5, 57, 58].

Second, the QIs adopted should be adapted to local contexts based on country-specific health systems, including disease burden, resource availability and service delivery model. In this regard, lessons can be learnt from the recent implementation of the first national essential diagnostics list by India, which emulated the WHO diagnostic list but was adapted to meet Indian health needs through inclusion of diagnostic imaging [59]. The authors encouraged a non-hierarchical, consensus-based, participatory decision-making process involving key stakeholders across the diagnostic pathway in the co-development of the QIs. The QIs should be evidence-based, integrable and tiered to specific local, regional and national cancer networks, catering to the delivery of services grouped in specialised units or provided through a hub-and-spoke model. The final consensus could subsequently inform the External Quality Assurance Programme and be integrated into Managed Equipment Service Partnerships to on-board industry. The data would also be valuable in informing and monitoring national cancer control strategies.

Limitations

This review has several limitations. Firstly, this review is restricted to QIs reported in the literature and may under-represent QIs embedded within institutional audit systems or routine quality assurance processes. As discussed, this reflects a broader disconnect between operational quality evaluation and academic reporting. This gap limits the ability to translate operational practices into evidence, constraining the development, standardisation and scale-up of QIs across health systems. Secondly, this review did not focus on the contextual determinants that influence pathology quality, such as infrastructure, geographical access to diagnostic services, health system financing, laboratory information systems, as well as workforce capacity, which have been examined in-depth in existing literature [52, 60–62]. Thirdly, the use of a single PubMed/Medline database may have excluded relevant studies indexed in other databases, particularly those representing regional or LMIC-focused literature. Fourthly, the restriction to English-language publications may contribute to geographic bias and underrepresentation of evidence from non-English-speaking settings. Lastly, flow cytometry was not included, as its primary application lies in haematological malignancies. While it has some applications in non-haematological cancers such as DNA ploidy, cell cycle analysis and circulating tumour cells, these are not routine components of anatomic pathology practice for cancer diagnosis.

Conclusion

QIs in cancer PALM are deficient in the published literature, particularly in resource-limited settings. QIs assessing timeliness and cost-effectiveness in pre- and post-analytic phases of PALM are under-represented.

To facilitate global harmonisation of cancer pathology, international collaboration is required to standardise QIs that are feasible, applicable and stratified to resource level. Additionally, we recommend national efforts to undertake Delphi processes to develop context-specific QIs that are integrable into local workflow, address local health needs and inform national diagnostic strategy and cancer control planning.

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Conflicts of interest

Not applicable.

Author contributions

PN, RS, KF conceived, designed and supervised the study. AR, AH and SKE searched, screened and assessed the publications. GT performed risk of bias assessment. PN analysed and visualised the data. RS and KF accessed and verified the data. PN drafted the manuscript. RS, KF, LF, SS, MM, BH and LL reviewed and edited the manuscript. All authors read and approved the final version.

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Supplementary material

Supplementary material for this article can be viewed at: <https://docs.google.com/document/d/168hnPEFKM9DT4FHTxsXOV9bbF1885YLV/edit?usp=sharing&ouid=104381241870033180956&rtpof=true&sd=true>