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qPCR versus RT-PCR/PCR in a Conflict-Affected Sudanese Blood Service: Paired Agreement, Workflow, Direct Cost and Implementation Feasibility

EINASS TAJ ALKHATM ABDALLA OMAR
Medical Laboratories College, Karary University, Sudan
Prof. NADIA MADANI MOHAMED AHMAD
Dean, Medical Laboratories College, Karary University, Sudan
Dr. BABIKIR AHMAD MOHAMED
Pathologist, Faculty of Medicine, Karary University, Sudan
Dr. MUTAZ MOHAMED IBRAHIM ALI[1]
Independent Research Consultant in Medical Laboratory Sciences, Egypt.

Abstract:

Background: *Selection of a molecular platform in a resource-limited blood service requires assessment of paired analytical performance together with turnaround, manual workload, direct cost, quality assurance and resilience.*

Methods: *This prospective analytical comparison included 90 archived donor specimens initially reactive by ELISA and retrieved through functioning blood-service pathways in River Nile, Northern and Eastern Sudan. All 90 underwent paired qPCR/RT-qPCR and endpoint RT-PCR/PCR for HIV-1, HBV and HCV. Operational time, invalid rate and direct consumable cost were measured in a predefined 10-specimen subset. Discordant specimens underwent documented repeat testing/adjudication. A transparent investigator-defined decision matrix weighted turnaround and hands-on time at 35% each, direct cost at 25% and invalid rate at 5%.*

Results: *qPCR detected 66 specimens and endpoint RT-PCR/PCR detected 63; 62 were positive by both methods, four by qPCR only, one by endpoint only and 23 were negative by both. Aggregate agreement was 94.4% (κ=0.863; exact McNemar p=0.375). Virus-specific agreement was 97.8% for HBV (κ=0.938), 98.9% for HCV (κ=0.974) and 97.8% for HIV-1 (κ=0.924). qPCR detected 22 HBV, 28 HCV and 16 HIV-1 specimens; endpoint testing detected 20 HBV, 27 HCV and 16 HIV-1. In the operational subset, qPCR reduced turnaround from 3.78 to 2.72 hours and hands-on time from 36.0 to 25.9 minutes. Endpoint RT-PCR/PCR reduced direct cost from 8,248.3 to 5,056.7 SDG per sample; both methods had a 0% invalid rate. Corrected weighted scores were 84.8 for qPCR and 78.3 for endpoint RT-PCR/PCR.*

Conclusions: *qPCR showed a modest detection advantage concentrated in HBV and HCV and delivered faster, less labour-intensive workflow, whereas endpoint RT-PCR/PCR retained a substantial direct-cost advantage. A phased qPCR-led service with complementary endpoint capacity is defensible where maintenance, external quality assurance and reagent continuity can be sustained. The decision score is exploratory and not a validated cost-effectiveness result.*

Keywords: blood donor testing; qPCR; endpoint RT-PCR/PCR; virus-specific agreement; turnaround time; hands-on time; direct cost; implementation feasibility; Sudan

[1] Corresponding Author: Dr. Mutaz Mohamed Ibrahim Ali, Independent Research Consultant in Medical Laboratory Sciences, Egypt. Bank Street, Building 61, Flat 3, Wadi El-Natrun (Natrn Valley), Beheira Governorate, Egypt. Telephone: +20 45 355 2112; Email: moatasa@hotmail.com; ORCID: 0009-0000-4963-2955.

INTRODUCTION

Nucleic acid testing can reduce residual transfusion risk, but platform selection cannot be based on analytical sensitivity alone. A sustainable programme must consider turnaround time, operator workload, contamination control, quantitative traceability, reagent continuity, maintenance, external quality assurance and the cost of producing a valid result. International NAT programmes provide important benchmarks, although their automation, financing and technical support differ substantially from Sudanese conditions (Roth et al. 2012; Vermeulen et al. 2009).

Real-time qPCR and endpoint RT-PCR/PCR represent different operational models. qPCR combines amplification and detection in a closed tube, provides Ct information and supports quantitative calibration, but depends on more expensive reagents and reliable equipment support. Endpoint testing uses widely available thermal cyclers and lower-cost consumables but requires electrophoresis, manual band interpretation and stricter spatial control of amplicon contamination (Mackay, Arden, and Nitsche 2002; Candotti and Allain 2013).

The Sudan conflict introduced a systems-level requirement: specimens and records had to be retrieved from functioning facilities in River Nile, Northern and Eastern Sudan after disruption of the Khartoum-centred pathway. The present paper focuses on method agreement, workflow, direct cost and implementation. A companion analysis from the same thesis dataset addresses virus distribution, specimen-level discordance and occult-compatible HBV profiles in greater biological detail.

MATERIALS AND METHODS

Study framework and specimen retrieval

The study was a laboratory-based analytical paired method comparison governed by the protocol approved for STAK. Inclusion required initial ELISA reactivity for at least one transfusion-transmitted infection marker, traceable identification, adequate archived plasma, linked documentation and valid paired molecular outcomes. All 90 retrieved specimens completed qPCR/RT-qPCR and endpoint RT-PCR/PCR. A predefined 10-specimen subset provided operational time, invalid-rate and direct-cost measurements.

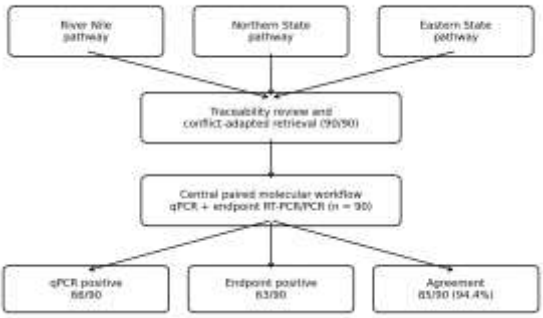

Figure 1. Conflict-adapted specimen retrieval, traceability review and central paired molecular workflow.

Molecular workflows and discordance resolution

Probe-based qPCR used closed-tube amplification and fluorescence detection. HBV was amplified directly from extracted DNA, whereas HIV-1 and HCV required reverse transcription. Endpoint testing used reverse transcription for RNA targets, direct PCR for HBV and agarose-gel electrophoresis. Both workflows used target-specific positive controls, no-template controls and internal controls where compatible. Discordant results triggered curve or gel review, repeat extraction, repeat amplification and second-target assessment where possible. The four qPCR-only results remained reproducibly positive, and the endpoint-only HIV-1 result remained positive with a band at the expected size.

Operational variables and corrected decision matrix

Turnaround time was elapsed time from molecular-laboratory registration to verified result. Hands-on time was cumulative operator-active time per sample. Invalid rate was the proportion requiring complete repetition because of extraction, control or run failure. Direct cost included reagents and consumables but excluded labour, depreciation, maintenance, transport, infrastructure, inflation and downstream clinical costs. The investigator-defined decision matrix assigned 35% to turnaround, 35% to hands-on time, 25% to direct cost and 5% to invalid rate. Correct weighted totals were calculated as the sum of domain score multiplied by domain weight.

Statistical analysis and audit verification

The complete paired outcomes were cross-tabulated overall and separately for HBV, HCV and HIV-1. Observed agreement and Cohen's kappa quantified agreement beyond chance, and exact McNemar tests assessed directional discordance. The composite result from either method was not treated as an independent reference standard; sensitivity and specificity were therefore not calculated. Operational comparisons were descriptive because run-level variance sufficient for reproducible paired hypothesis testing was unavailable. The raw dataset was retained unchanged; documented corrections were applied only in a separate working dataset, and all 90 donor identifiers were reconciled against laboratory source records before final analysis.

RESULTS

Aggregate and virus-specific agreement

Among all 90 paired specimens, qPCR detected 66 positives and endpoint RT-PCR/PCR detected 63. Sixty-two specimens were concordant-positive, four were qPCR-positive/endpoint-negative, one was qPCR-negative/endpoint-positive and 23 were concordant-negative. Aggregate observed agreement was 85/90 (94.4%), κ was 0.863 and exact McNemar p was 0.375.

Table 1. Aggregate paired agreement matrix (n = 90).

qPCR status	Endpoint positive	Endpoint negative	Total	Interpretation
qPCR positive	62	4	66	62 concordant-positive; 4 qPCR-only
qPCR negative	1	23	24	1 endpoint-only; 23 concordant-negative
Total	63	27	90	Agreement 94.4%; κ=0.863; p=0.375

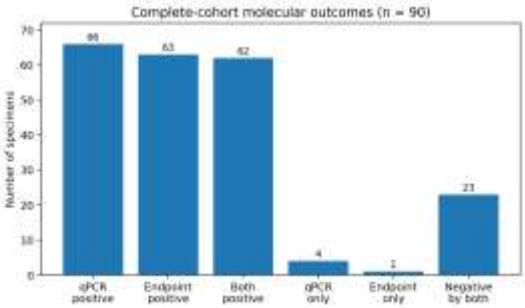

Figure 2. Complete-cohort molecular detection and paired-outcome counts.

Virus-specific analysis showed qPCR totals of 22 HBV, 28 HCV and 16 HIV-1, compared with endpoint totals of 20 HBV, 27 HCV and 16 HIV-1. The four qPCR-only results comprised two HBV, one HCV and one HIV-1 specimen; the endpoint-only result was HIV-1. The net three-specimen qPCR advantage therefore arose from HBV and HCV.

Table 2. Virus-specific paired agreement between qPCR/RT-qPCR and endpoint RT-PCR/PCR.

Virus	qPCR +	Endpoint +	Both +	qPCR only	Endpoint only	Both −	Agreement	κ	Exact p
HBV	22	20	20	2	0	68	97.8%	0.938	0.500
HCV	28	27	27	1	0	62	98.9%	0.974	1.000
HIV-1	16	16	15	1	1	73	97.8%	0.924	1.000

Operational time, invalid rate and direct cost

Detailed workflow measurements were available for 10 paired specimens. qPCR reduced mean turnaround time by 1.06 hours (28.0%), from 3.78 to 2.72 hours, and reduced mean hands-on time by 10.1 minutes (28.1%), from 36.0 to 25.9 minutes. Both workflows had a 0% invalid rate in this subset. Endpoint RT-PCR/PCR cost 5,056.7 SDG per sample compared with 8,248.3 SDG for qPCR, an absolute saving of 3,191.6 SDG and a relative saving of 38.7%. Conversely, qPCR cost 63.1% more on the direct-consumable basis used.

Table 3. Operational comparison in the measured subset (n = 10).

Metric	qPCR	Endpoint method	Absolute difference	Relative interpretation
Turnaround time	2.72 h	3.78 h	−1.06 h	qPCR 28.0% faster
Hands-on time	25.9 min	36.0 min	−10.1 min	qPCR 28.1% lower
Invalid rate	0.0%	0.0%	0	No observed difference
Direct cost/sample	8,248.3 SDG	5,056.7 SDG	+3,191.6 SDG for qPCR	Endpoint 38.7% cheaper

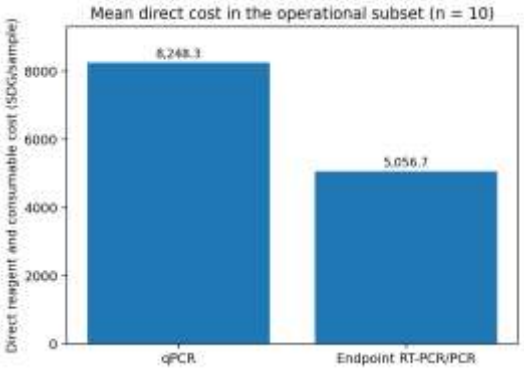

Figure 3. Mean direct reagent and consumable cost per sample; indirect programme costs were excluded.

Corrected exploratory implementation matrix

Under the investigator-defined workflow-prioritised weights, the corrected weighted total was 84.8 for qPCR and 78.3 for endpoint RT-PCR/PCR. qPCR's advantage was driven by turnaround and hands-on time, whereas endpoint RT-PCR/PCR led in direct cost. The result is conditional on the selected weights and is neither a measured clinical outcome nor a validated economic model.

Table 4. Corrected investigator-defined implementation decision matrix.

Domain	Weight	qPCR score	Endpoint score	Weighted qPCR	Weighted endpoint	Interpretation
Turnaround	35%	90	70	31.50	24.50	Favours qPCR
Hands-on time	35%	88	75	30.80	26.25	Favours qPCR
Direct cost	25%	70	90	17.50	22.50	Favours endpoint
Invalid rate	5%	100	100	5.00	5.00	No difference
Weighted total	100%			84.80	78.25 (78.3)	Conditional preference for qPCR

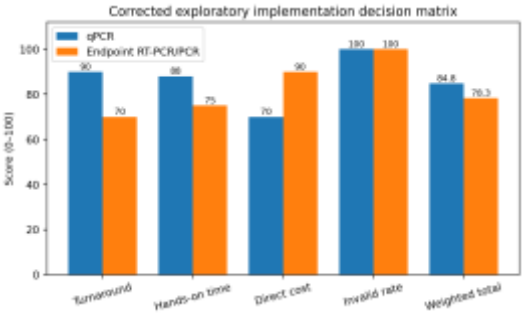

Figure 4. Corrected domain-specific and weighted implementation scores.

Quality assurance and phased implementation

All molecular runs satisfied the documented positive, negative and internal-control acceptance criteria. The five discordant specimens illustrate the need for a prespecified

adjudication algorithm rather than uncritical acceptance or rejection of a single signal. The completed comparison supports a phased implementation model focused on analytical verification, external quality assessment, traceability, supply-chain resilience and periodic total-cost review.

Table 5. Proposed phased implementation framework.

Phase	Priority action	Minimum quality requirement	Rationale
1. Verification/EQA	Verify both workflows with low-copy and variant-inclusive panels	Traceable standards, controls, proficiency testing and documented LoD	Strong agreement does not establish formal equivalence
2. qPCR primary	Use qPCR as the primary platform where sustainable	Maintenance, calibrated quantification, trained staff and reagent continuity	Modest HBV/HCV gain; faster and less manual
3. Endpoint backup	Retain endpoint PCR for confirmation and contingency use	Physical separation, contamination monitoring and gel QC	Lower direct cost and operational resilience
4. Result resolution	Apply a documented algorithm to discordant and double-negative ELISA-reactive specimens	Repeat extraction/serology, alternative targets, counselling and referral	Prevents overinterpretation
5. State network	Formalise state-to-centre links and periodic total-cost review	Cold-chain records, source denominators, electronic reconciliation and corrective action	Converts emergency retrieval into a sustainable network

DISCUSSION

The complete analytical dataset demonstrates very strong agreement between qPCR/RT-qPCR and endpoint RT-PCR/PCR, both overall and at the virus-specific level, while also showing a modest numerical detection advantage for qPCR. Across the 90 paired specimens, qPCR detected 66 positives compared with 63 by endpoint testing; 62 specimens were concordant-positive, four were qPCR-only, one was endpoint-only, and 23 were negative by both methods. This produced an overall agreement of 94.4% with $\kappa = 0.863$, indicating strong agreement beyond chance. Importantly, the virus-specific matrices show that the apparent qPCR advantage was not uniform across all targets. qPCR detected two additional HBV specimens and one additional HCV specimen, whereas HIV-1 produced one discordant result in each direction and therefore identical overall detection totals. Virus-specific agreement remained high for HBV, HCV, and HIV-1, indicating that both platforms generated largely concordant classifications.

The statistical interpretation of these findings requires caution. The exact McNemar tests were non-significant both overall and for the individual viral targets, indicating no statistically demonstrable systematic directional disagreement between the two methods. However, only five discordant pairs occurred in the entire cohort. With such few discordant observations, statistical power to identify small differences is inherently limited. Consequently, the results support high method agreement with a modest numerical qPCR advantage, but they do not establish formal superiority, non-inferiority, or analytical equivalence. Furthermore, because no independent molecular reference standard was used, the study cannot determine which method was definitively correct in

every discordant case or provide conventional estimates of comparative sensitivity and specificity.

The operational findings demonstrate an important trade-off between workflow efficiency and direct testing cost. In the measured 10-specimen operational subset, qPCR reduced mean turnaround time from 3.78 to 2.72 hours, representing approximately a 28% reduction, while mean hands-on time decreased from 36.0 to 25.9 minutes, also by approximately 28%. These differences are operationally relevant in blood-service laboratories, where rapid release of results and reduced operator workload may improve throughput and facilitate more standardized testing. The closed-tube nature of qPCR integrates amplification and fluorescence-based detection without post-amplification gel electrophoresis, thereby reducing manual manipulation and opportunities for amplicon contamination. Endpoint RT-PCR/PCR, in contrast, requires additional post-amplification handling but remains technically valuable because it uses relatively accessible equipment and generates visible amplification products that may support orthogonal assessment or subsequent sequencing (Mackay, Arden, and Nitsche 2002; Bustin et al. 2009; Candotti and Allain 2013).

The efficiency advantage of qPCR must, however, be balanced against its higher direct cost. The measured direct reagent and consumable cost was 8,248.3 SDG per sample for qPCR compared with 5,056.7 SDG for endpoint RT-PCR/PCR. Endpoint testing was therefore approximately 38.7% cheaper on the direct-cost basis used in this study. This difference is particularly relevant in Sudan and similar resource-constrained settings, where foreign-currency availability, reagent procurement, equipment maintenance, and interruptions in international supply chains can determine whether a technically superior platform remains operationally sustainable. Endpoint PCR may consequently retain an important role as a lower-cost primary, complementary, or contingency platform where real-time molecular infrastructure cannot be continuously supported.

Nevertheless, direct consumable cost should not be interpreted as total programme cost. The present calculation did not incorporate staff time, instrument acquisition and depreciation, preventive maintenance, calibration, external quality assessment, electricity and infrastructure, specimen transport, repeat testing, contamination investigations, equipment downtime, or costs associated with delayed component release. qPCR's higher reagent expenditure may therefore be partially offset by reduced hands-on time, shorter turnaround, elimination of electrophoresis, and a lower opportunity for post-amplification contamination. Conversely, qPCR instruments require dependable maintenance, calibration, technical support, and specialized consumables, which may increase long-term expenditure. Accordingly, a formal activity-based costing or cost-effectiveness analysis would be required before extrapolating the observed direct-cost difference to procurement decisions or national blood-service policy. The corrected implementation decision matrix provides a transparent framework for considering these competing priorities. Under the predefined weighting system, turnaround time and hands-on time together accounted for 70% of the total score, while direct cost contributed 25% and invalid rate 5%. This produced corrected weighted scores of 84.8 for qPCR and 78.3 for endpoint RT-PCR/PCR, giving qPCR a 6.5-point advantage. The result reflects the priorities embedded within the model rather than an intrinsic universal superiority of qPCR. A laboratory facing severe procurement or budget constraints could reasonably assign greater weight to direct cost and obtain a different

ranking. Conversely, a high-throughput blood service prioritizing rapid result release and reduced operator workload might place even greater value on qPCR. The decision matrix should therefore be regarded as an exploratory scenario-analysis tool, not as a validated cost-effectiveness index.

The conflict-adapted specimen retrieval pathway adds an important implementation dimension to the study. Despite disruption of the original Khartoum-centred blood-service environment, all 90 specimens were successfully traced, reconciled, retrieved, and subjected to paired molecular testing through functioning pathways involving River Nile, Northern, and Eastern Sudan. This demonstrates that decentralized specimen retrieval linked to centralized molecular testing can remain feasible under severe service disruption. However, successful retrieval does not itself demonstrate uniform pre-analytical quality. Differences in transport duration, temperature control, storage conditions, and freeze-thaw exposure may affect molecular testing, particularly for low-copy RNA targets. A sustainable network therefore requires standardized donor and specimen identifiers, documented cold-chain and transport records, source-facility denominators, electronic reconciliation, predefined corrective-action procedures, and participation in external proficiency testing in accordance with WHO and ISO laboratory quality-management principles.

From an implementation perspective, the findings support a phased and complementary molecular-testing strategy rather than complete replacement of one platform by the other. qPCR is attractive as the primary platform where equipment maintenance, trained personnel, external quality assurance, and reagent continuity can be sustained because it combines strong agreement with faster turnaround, reduced hands-on time, and a modest additional detection yield. Endpoint RT-PCR/PCR remains valuable as a lower-cost complementary method, a contingency platform during qPCR reagent or instrument interruptions, and a source of amplification products for selected confirmatory or sequencing applications. Such redundancy may be particularly important in conflict-affected or resource-limited laboratory systems, where resilience can be as important as analytical performance.

Several methodological strengths reinforce the reliability of these conclusions. All 90 specimens underwent paired testing by both molecular methods, minimizing differential verification. The final dataset was supported by a reconciled audit trail, virus-specific agreement matrices, and documented adjudication of all five discordant specimens. Separating the complete 90-specimen analytical cohort from the 10-specimen operational subset also prevents workflow and cost observations from being incorrectly generalized as full-cohort measurements. These features strengthen internal consistency and permit the analytical and operational findings to be interpreted separately.

Important limitations nevertheless remain. The cohort consisted of initially ELISA-reactive specimens, preventing extrapolation of the molecular-positive proportion to the general Sudanese donor population. The absence of an independent molecular reference standard precludes formal estimates of sensitivity, specificity, or comparative diagnostic accuracy. Operational measurements were obtained from only 10 specimens and lacked sufficient run-level variance for robust inferential comparisons. Direct costs are also particularly vulnerable to inflation, exchange-rate fluctuations, and changing reagent procurement conditions in Sudan. Finally, the study did not undertake full activity-based costing or evaluate long-term equipment maintenance, staffing, infrastructure, and supply-chain costs.

Overall, the findings demonstrate that qPCR/RT-qPCR and endpoint RT-PCR/PCR are highly concordant molecular approaches with different operational advantages. qPCR provided a modest additional detection yield confined to HBV and HCV and offered shorter turnaround and reduced manual workload, whereas endpoint testing maintained a substantial direct-cost advantage. The corrected implementation analysis consequently supports a qPCR-led but complementary molecular-testing model, provided that quality assurance, maintenance, reagent continuity, and financial sustainability can be maintained. In resource-constrained and conflict-affected blood services such as Sudan, platform selection should therefore be based not on analytical detection alone, but on an integrated assessment of agreement, workflow efficiency, cost, quality assurance, supply-chain resilience, and long-term operational sustainability.

CONCLUSION

In 90 completely paired ELISA-reactive donor specimens, qPCR and endpoint RT-PCR/PCR showed 94.4% aggregate agreement and strong agreement for HBV, HCV and HIV-1 individually. qPCR identified 66 positives compared with 63 by endpoint testing; its net gain arose from HBV and HCV, while HIV-1 method totals were equal. In the measured operational subset, qPCR reduced turnaround and hands-on time by approximately 28%, whereas endpoint RT-PCR/PCR reduced direct consumable cost by 38.7%. The corrected exploratory score favoured qPCR 84.8 to 78.3 under workflow-prioritised weights. The most practical Sudanese model is a phased qPCR-led service with endpoint PCR retained for complementary confirmation and contingency operation, supported by documented discordance resolution, external quality assessment and total-cost evaluation.

STATEMENTS AND DECLARATIONS

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Author contributions: Einass TajAlkhatm Abdalla Omar: investigation, laboratory work, data curation and original draft. Nadia Madani Mohamed Ahmad: conceptualisation, supervision and critical revision. Babikir Ahmad Mohamed: co-supervision, methodological review and critical revision. Mutaz Mohamed Ibrahim Ali: methodology, statistical and data-integrity verification, manuscript restructuring, visualisation and publication preparation.

Ethical approval and consent: Ethical approval was obtained from Karary University and administrative permission from STAK; informed consent was obtained under the approved protocol. Ethics approval reference: [insert official reference before submission].

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Competing interests: [All authors must confirm the final competing-interest declaration before submission].

Data availability: De-identified data supporting the complete paired analysis and operational subset may be made available by the corresponding author on reasonable request, subject to donor confidentiality and institutional authorisation.

Related-manuscript disclosure: A companion manuscript from the same thesis dataset focuses on virus-specific composite positivity, discordant-specimen adjudication and occult-compatible HBV profiles. The present paper focuses on platform agreement, workflow, direct cost and implementation; overlapping cohort counts are reported only where necessary.

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