Research Article

Adolopment of Recommendations for Standardized Reporting of Protein Electrophoresis in Pakistan

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Abstract

Introduction

The standardization of reporting in clinical laboratories, particularly regarding Serum Protein Electrophoresis (SPEP) and Urine Protein Electrophoresis (UPEP), is crucial for effective communication of findings to clinicians and optimal patient management. However, in countries like Pakistan with limited healthcare resources and a prevalent self-payment model, challenges arise in achieving standardized reporting practices. This manuscript addresses the need for standardized guidelines for protein electrophoresis reporting in Pakistan, aiming to enhance laboratory practices and patient care.

Methods

This study was conducted at the Aga Khan University Hospital (AKUH), Pakistan. A team consisting of five Consultant Chemical Pathologists and two senior technologists, led by the Section Head of Chemical Pathology at AKU, used a Modified Delphi Methodology to achieve consensus on the developed framework. Consensus was defined as agreement by at least six out of the seven experts (85.71%). The source guideline for this process was the Recommendations for Standardized Reporting of Protein Electrophoresis from Australia and New Zealand.

Results

Consultant Chemical Pathologists reviewed the original and modified recommendations, resulting in a framework of ten sub-sections and 65 recommendations. Through a series of four meetings, including a diverse team of experts, the recommendations were systematically critiqued and reviewed. After detailed deliberations, 54 recommendations were finalized by consensus. The final document was further reviewed by CCBP staff and additional consultants from different institutions in Pakistan to ensure unbiased and comprehensive expert input.

Discussion
The developed guidelines offer a framework for consistent and comprehensive reporting of PEP results, addressing variations in practices among clinical laboratories in Pakistan. Key modifications to the recommendations reflect a pragmatic approach to navigating resource constraints, ensuring that laboratory reports remain informative and actionable for clinicians. By prioritizing clinical relevance and practicality, the guidelines aim to enhance diagnostic accuracy and facilitate appropriate clinical management decisions.

Conclusion
The standardized reporting guidelines for SPEP and UPEP represent a significant milestone in optimizing laboratory practices and improving patient care in Pakistan. Moving forward, continued monitoring and adaptation of the guidelines will be essential to ensure their sustained relevance and effectiveness in meeting the evolving needs of the healthcare system. Embracing a commitment to excellence in laboratory practices holds promise for advancing healthcare quality and accessibility in low-resource settings globally.

Introduction
The fundamental purpose of conducting Serum Protein Electrophoresis (SPEP) and Urine Protein Electrophoresis (UPEP) is to identify monoclonal immunoglobulins associated with plasma cell dyscrasias and lymphoproliferative disorders. Ensuring effective communication of laboratory findings to clinicians is of utmost importance in guiding patient management. However, achieving this goal requires a thorough understanding of the requisites of a protein electrophoresis report. The standardization of reporting in Pakistan encounters challenges stemming from the absence of a national health insurance system and the prevalent self-payment model for medical care including laboratory investigations [1]. Consequently, immunofixation and electrophoresis reports are frequently issued in isolation, rather than as paired assessments, primarily due to practice of a cost-effective model by physicians for patient care [2].
The delivery of a comprehensible laboratory report is vital in aiding clinicians in patient management. Clinicians are chiefly concerned with the presence, types, and concentrations of paraproteins. Having access to a cumulative report is imperative for monitoring plasma cell dyscrasias [3].
Several notable findings emerge from Protein Electrophoresis (PEP), such as increased alpha-1 and alpha-2 globulins indicating acute phase response, decreased alpha-1 globulins suggestive of alpha-1 antitrypsin deficiency, increased beta-1 region indicative of elevated transferrin and iron deficiency, decreased gamma globulins, and a diverse gamma globulin increase reflecting inflammation, infection, autoimmune disorders, or liver diseases [4].
In Pakistan, where healthcare resources are limited and financial constraints exist, the need for standardized reporting of tests like SPEP and immunofixation electrophoresis (IFE) on which diagnoses are made becomes even more significant. Efforts towards standardization must consider the local healthcare infrastructure and availability of resources in clinical laboratories. This involves improving and following the best laboratory practices as per available guidelines and literature and aligning with available resources. This will ensure that laboratory professionals and clinicians can make well-informed decisions based on the information provided [5].
Notwithstanding the presence of established clinical guidelines pertaining to plasma cell dyscrasias, there is a notable lack of emphasis on the laboratory aspects of PEP. Notably, systematic reporting standards and recommendations are scarce in literature. A review of the literature revealed that there are currently no standardized guidelines or recommendations being followed in Pakistan aimed at analytical performance and reporting of PEP.
With the above explained problem statement in perspective, a survey was conducted to analyze the clinical laboratory practices, the method of quantification of paraprotein concentrations by PEP, and interpretation provided by Consultant Chemical Pathologists performing PEP in Pakistan. The findings highlighted variations in practices of PEP, resulting in variable and inconsistent reporting, affecting patient care.
A literature review detailed in the methods section revealed recommendations from Australia and New Zealand, Canada, and Malaysia [6-9]. Given that Australia and New Zealand, like Pakistan, are Commonwealth countries with similar clinical practices, we preferred to tailor our recommendations according to their developed guidelines. In contrast, Canada's healthcare system operates differently, primarily based on public insurance, with approximately 70% of health expenditures financed through general tax revenues [10]. On the other hand, Malaysia has adopted guidelines from Australia and New Zealand, and Canada [9].
However, it is crucial to recognize that Pakistan's healthcare system primarily relies on out-of-pocket payments [11], unlike the healthcare systems in Australia and New Zealand. Australia's health system responsibilities are broadly shared between the Australian government and state and territory governments, involving funding, operating, managing, and regulating the health system [12]. Similarly, New Zealand's healthcare system is mostly tax-funded [13].
Consequently, there is immense need for local recommendations to be developed, with appropriate context-specific modifications. The development of standardized reporting guidelines for PEP stands to offer significant advantages to pathologists nationwide, thereby facilitating substantial benefits across the spectrum of pre-analytical, analytical, and post-analytical processes. Providing relevant information about response criteria and paraprotein presence while adapting to the local healthcare dynamics can significantly contribute to improved patient management and outcomes.

Methods
Setting

This study was conducted at the Section of Chemical Pathology, Department of Pathology and Laboratory Medicine at the Aga Khan University Hospital (AKU), Pakistan in collaboration with the expertise of the Clinical and Translational Research Incubator (CITRIC) Center for Clinical Best Practices (CCBP), at AKU.

Study team

The study team was comprised of the five Chemical Pathology faculties and two senior technologists led by the Section Head of Chemical Pathology at AKU. Modified Delphi Methodology [14] was adopted to take consensus on the developed framework. Consensus was achieved when at least six out of the seven experts (85.71%) involved in the decision-making process agreed on the proposed adaptations or modifications to the guidelines.

Source guideline selection

The source guideline is the single, original, "parent" guidelines that undergoes the ADOLOPMENT process in the development of a local documents.

A literature review was conducted using the search string: ("protein s"[All Fields] OR "proteinous"[All Fields] OR "proteins"[MeSH Terms] OR "proteins"[All Fields] OR "protein"[All Fields]) AND ("electrophoresed"[All Fields] OR "electrophoresing"[All Fields] OR "electrophoresis"[MeSH Terms] OR "electrophoresis"[All Fields] OR "electrophorese"[All Fields] OR "electrophoreses"[All Fields]) AND ("reference standards"[MeSH Terms] OR ("reference"[All Fields] AND "standards"[All Fields]) OR "reference standards"[All Fields] OR "standardization"[All Fields] OR "standard"[All Fields] OR "standard s"[All Fields] OR "standardisation"[All Fields] OR "standardisations"[All Fields] OR "standardise"[All Fields] OR "standardised"[All Fields] OR "standardises"[All Fields] OR "standardising"[All Fields] OR "standardization s"[All Fields] OR "standardizations"[All Fields] OR "standardize"[All Fields] OR "standardized"[All Fields] OR "standardizes"[All Fields] OR "standardizing"[All Fields] OR "standards"[MeSH Subheading] OR "standards"[All Fields]) AND ("reportable"[All Fields] OR "reporting"[All Fields] OR "reportings"[All Fields] OR "research report"[MeSH Terms] OR ("research"[All Fields] AND "report"[All Fields]) OR "research report"[All Fields] OR "report"[All Fields] OR "reported"[All Fields] OR "reports"[All Fields]) AND ("guideline"[Publication Type] OR "guidelines as topic"[MeSH Terms] OR "guidelines"[All Fields]) on PubMed, Medscape, and Google Scholar.

Recommendations for standardized reporting of protein electrophoresis in Australia and New Zealand were selected due to its comprehensive set of recommendations, integrated approach to management, and high-quality synthesis of available evidence [6].

Results

Framework

A Consultant Chemical Pathologist thoroughly reviewed the recommendations and their following modifications by the original group published in 2012 and 2019 respectively [6, 7]. A tabulated framework consisting of ten sub sections and a total of 65 recommendations was formulated. Three options- adopt, adapt and remove- were provided with each recommendation for expert review.

Expert panel review

In the first phase, the recommendations were reviewed by two Chemical Pathology consultants (SA and IS) and their responses were recorded against each criterion and a skeleton was built for the team as shown in Figure 1.

In the second phase, three more subsequent meetings were conducted (in the presence of the above-mentioned team), in which the recommendations and responses from the first phase were critiqued and reviewed systematically.

The second meeting was convened in the subsequent week, which included a broader team consisting of SA, IS, LJ, HM, AHK, and SK. This team focused on reviewing guidelines numbered 1 to 25. Following this, another meeting took place four days later, due to time constraints of the consultant pathologists, concentrating on guidelines 26 to 45.

In the fourth meeting, two days after the third, the team expanded further with the addition of RK and SK, two senior technologists. Together, this team of experts reviewed guidelines 46 to 65. The cumulative efforts of this group of experts aimed at ensuring the guidelines were tailored to meet the specific needs and standards relevant to the Pakistani context.

The final outcome generated through modified Delphi process was in the form of a single selection from multiple response options based on consensus and reasoning from experts. Out of a total of 65, 15 recommendations underwent minor changes in the response criteria from the first phase, and 3 guidelines were merged into a single recommendation. A total of 10 were excluded because they were not suitable for the Pakistani health care setup.

Final recommendation revisions and synthesis

Following the 2 phases of detailed deliberations, a total of 54 recommendations were finalized after consensus as depicted in Table 1. The CCBP staff conducted a meeting with the expert panel's sub-team to review the final unanimous consensus and to look for the need for any revisions. The consensus document was presented to the team for final assessment, in addition to 4 consultants, M.D.K, Q.A.K, S.I, G.A, from different institutions across Pakistan to minimize bias and broaden our level of expertise.

Figure 1: Process of adolopment of recommendations.

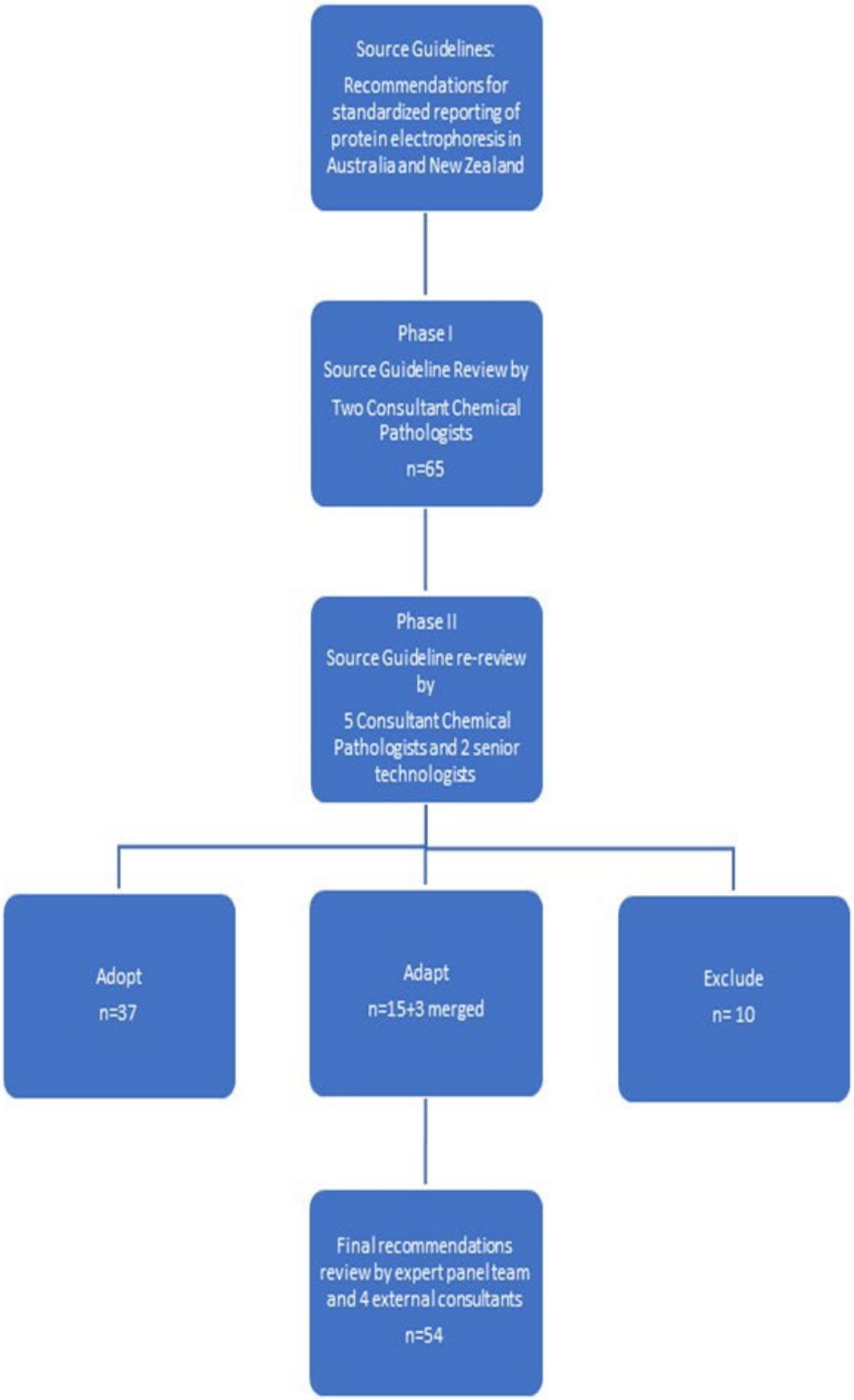

Table 1: Guidelines for the Detection, Quantification, and Reporting of Paraproteins in Serum and Urine: Standardized Nomenclature, Methodology, and Interpretative Commentary.

S No.	Recommendations
Nomenclature:	
1	The monoclonal component in serum is referred to as a Paraprotein (preferable) or Monoclonal immunoglobulin e.g. IgG kappa paraprotein or monoclonal IgG kappa.
2	The term Monoclonal free light chains is preferred to Bence Jones protein (BJP) when referring to urinary monoclonal free light chains (FLC).
3	The monoclonal component in urine is referred to generally as paraprotein or specifically as BJP or monoclonal FLCs.
Detection system for protein electrophoresis:	
4	The electrophoretic system preferably should be of high resolution and be able to detect small monoclonal bands that may co-migrate with normal proteins particularly in the beta region. However, low-resolution electrophoresis on cellulose acetate is acceptable for protein electrophoresis in case of non-availability of high-resolution system.
5	Clinicians should be encouraged to monitor the paraprotein concentration in individual patients using the same method (used by the same laboratory or laboratory network), hence ensuring analysts have access to the cumulative reports of the paraprotein delineation on the densitometric/capillary zone electrophoresis (CZE) scan
6	Isoelectric focusing (IEF) may occasionally be required in certain situations such as when examining serum samples of patients who are post-stem cell transplantation. For example, IEF may help to ascertain, if a low-concentration band detected on immunofixation electrophoresis (IFE) is the same as the paraprotein originally found in the patient's serum samples or is a new monoclonal protein, or if the band(s) on SPEP are oligoclonal. If a laboratory does not perform IEF, serum samples of patients should be referred to a reference laboratory in problematic cases.
Serum protein and albumin quantification:	
7	Total protein and albumin quantification as determined by an automated analyzer be available for assessment of the protein electrophoresis
8	Serum albumin quantification by bromocresol purple (BCP) or CZE is preferable to quantification by bromocresol green (BCG) although all are acceptable
9	Providing the same albumin result on the SPEP report as on the General Chemistry report is preferable but may not be possible depending upon the available Laboratory Information System
10	Total protein and albumin should be quantified in g/L to the nearest whole number
Quantitative reporting of SPEP fractions:	
11	The minimal quantitative fields to be reported are total protein and albumin; and, if present, the paraprotein(s)
12	The quantitative reporting of all SPEP fractions is optional
13	Protein fractions should be quantified in g/L to the nearest whole number
14	Laboratories should determine their own reference intervals or validate published reference intervals
15	Paraprotein(s) should be consistently reported in the same quantitative field to facilitate long-term cumulative review of the progress of a patient's disease and avoid misinterpretation of results
Serum para protein quantification:	
16	Paraproteins in the gamma region should be quantified by densitometric or CZE measurement in g/L rounded to the nearest whole number
17	Paraproteins of <1 g/L visible on SPEP or CZE cannot be quantified reliably especially if there is a polyclonal gamma globulin background and should be referred to as '<1 g/L' or 'trace' with comments such as 'small band cannot be quantified reliably
18	Paraproteins visible only by immunofixation should be described in the comment section (e.g., IgG kappa paraprotein only visible by immunofixation) rather than being given a quantified value
19	If a paraprotein is in the non-gamma regions, the beta region being the most common region for IgA paraproteins, report the total protein in the beta region (beta + paraprotein) quantification at presentation and during monitoring
20	The perpendicular drop method for quantification is proposed for gating of gamma-region paraproteins as opposed to tangent skimming or corrected perpendicular drop

21	The report should include a comment identifying the paraprotein as migrating in the beta-region and stating that the concentration includes normal beta proteins
22	Attempts to provide an estimate of the 'true' paraprotein concentration by subtracting a predetermined level for other beta proteins are inherently unreliable due to the non-constant levels of the co-migrating proteins and are not recommended
Urine paraprotein separation and quantification:	
23	First voided urine is suitable for screening UPEP
24	A 24-h urine specimen is preferred for staging and monitoring of the plasma cell dyscrasias, although first voided specimens are acceptable if a 24-h specimen is not available or practical
25	Laboratories should be able to detect BJP at a level of 10 mg/L with levels <10 mg/L reported as 'trace'
26	While reporting the urine total protein, any intact monoclonal immunoglobulin should also be quantified and reported
Paraprotein characterization:	
27	IFE or immunosubtraction are required to characterize all new bands and to confirm their monoclonality
28	In subsequent specimens, IFE or immunosubtraction does not need to be repeated unless there is a change in the electrophoretic mobility, there is an additional visible band or if the paraprotein is no longer visible
29	Small paraproteins in the non-gamma region or in a polyclonal background also require IFE on each presentation in order to confirm their presence
30	IFE is required to confirm the absence of a previously reported paraprotein (to enable calculation of the response criteria 'complete remission'). In general, once complete remission has been confirmed, IFE is not required on each subsequent occasion unless a new band is visible, or IFE is specifically requested
31	If the paraprotein is detected in the serum by immunofixation only, refer to this in the comment rather than in the quantification, e.g., 'IgG kappa band visible only by immunofixation'
32	If the paraprotein is detected in the urine by immunofixation only, report this as 'trace' and refer to in the comment as only visible by immunofixation, e.g. 'kappa BJP is only visible by immunofixation'
33	Preferably a final integrated report combining both the electrophoretogram and IFE should be issued
Laboratory performance of SPEP, UPEP and IFE:	
34	Preferably an assessment of laboratory performance of SPEP and UPEP requires determination of • analytical imprecision at different paraprotein concentrations to determine method repeatability and between-day and operator reproducibility. • limit of detection of protein electrophoresis and immunofixation. • the linear range of scanning densitometry.
35	A minimum competency-based standard is required for those who review and interpret protein electrophoresis patterns
36	Protein laboratories are encouraged to have an educational module suitable for continuing professional development
General Interpretive Commenting:	
37	**Normal pattern:** No significant abnormality is noted
38	**Decreased alpha-1 globulins:** Decreased alpha-1 globulins. Suggest alpha-1 antitrypsin quantitation if clinically indicated
39	**Decreased albumin and increased alpha-2 and beta globulins** is noted, advise to corroborate with serum lipid results to rule out nephrotic syndrome
40	**An increase in alpha-1 and alpha-2** fraction with a polyclonal increase in gamma globulin fraction is noted. Findings are suggestive of either chronic inflammation, chronic liver disease or autoimmune disease process.
41	**Increased beta-1 globulin (if IFE performed and paraprotein excluded):** Increased beta-1 globulin is noted, in absence of paraprotein on IFE, suggest to perform iron studies, if clinically indicated.
42	**Polyclonal hypergammaglobulinemia:** A polyclonal increase in gamma globulin fraction is noted. Findings are suggestive of either inflammatory process, liver disease or autoimmune disease process.

43	**Increased alpha-1 and alpha-2 and/or gammaglobulins:** Findings are suggestive of acute inflammatory process.
44	Beta–gamma bridging: **Hypoalbuminemia with a polyclonal increase in gamma globulin and beta fraction is noted. Beta gamma bridging is noted. Findings are suggestive of liver cirrhosis.**
45	**Hypogammaglobulinaemia (first presentation):** Hypogammaglobulinaemia is present. Suggest serum immunofixation and urine protein electrophoresis and immunofixation (or serum free light chains) together with quantitation of total serum immunoglobulins (if not already done/ordered)
46	**Hypogammaglobulinaemia (subsequent presentation):** Hypogammaglobulinemia is noted. Clinical correlation is indicated.
47	**Fibrinogen present:** Fibrinogen present. Please send repeat serum specimen. (No clinical comment is required if laboratory can run a repeat serum specimen, otherwise needs IFE to ensure small band is fibrinogen and there is no underlying paraprotein; optimally needs repeat serum specimen as a small paraprotein cannot be quantitated by agarose gel SPEP when masked by the presence of fibrinogen)
48	**Oligoclonal banding pattern with 2 or more bands on a polyclonal immunoglobulins background:** Oligoclonal bands are present. This can occur in a number of infectious or autoimmune conditions. Suggest review in 3–6 months if clinically indicated
49	**First detection of a paraprotein:** Suggest total serum immunoglobulins and urine protein electrophoresis and immunofixation (if not already done/ordered) [Typing and numerical quantitation, e.g. 'An IgG kappa paraprotein was detected in the gamma region']
50	**Follow-up of a known paraprotein which is still present:** Nil required. [A comment should be made on the original band and its current status, e.g. 'The previously reported IgG kappa paraprotein was detected']
51	**Paraprotein detected only by immunofixation electrophoresis:** The previously reported IgG kappa paraprotein is now only visible by immunofixation
52	**If paraprotein has disappeared:** A comment is required to confirm the absence of the previously detected paraprotein, e.g. 'The previously reported IgG kappa paraprotein was not detected by immunofixation'
53	**New, small abnormal band with different electrophoretic mobility from the original paraprotein in a patient with a known paraprotein:** There is a small (type: e.g., IgG kappa) band approximately (amount: e.g., 1 g/L) on a background of a polyclonal and/or oligoclonal pattern. This band is different from the original paraprotein. Its clinical significance is uncertain
54	**First presentation of small abnormal bands in polyclonal/oligoclonal background (and no known paraprotein):** A faint band is observed in the gamma region. In case of first-time occurrence (without any previous clinical history of monoclonal band), these may occur due to infectious and/or autoimmune diseases. These are often transient which may not require long-term follow-up, however serum immunofixation, urine protein electrophoresis & immunofixation is suggested to rule out any lymphoproliferative disorder. Follow up as monoclonal gammopathy of undetermined significance (MGUS) is suggested and repeat in 3-6 months' time period, if clinically advised.

Discussion

The adolopment of standardized reporting guidelines for SPEP and UPEP in Pakistan represents a significant milestone in enhancing the quality of clinical laboratory practices and ultimately improving patient care. This discussion aims to delve into the key aspects of our developed guidelines, their implications for the local healthcare landscape, and the potential benefits they offer pathologists, clinicians, and patients.

The absence of standardized guidelines for reporting protein electrophoresis in Pakistan has long been a concern, leading to variations in practices among clinical laboratories [15]. This issue has been particularly challenging given the limited resources and financial constraints prevalent in the healthcare system [16].

By synthesizing recommendations from a reputable source guideline and contextualizing them to the local healthcare dynamics, the developed guidelines address this critical gap and provide a framework for consistent and comprehensive reporting of PEP results. The process of guideline development involved meticulous review, expert consultation, and iterative refinement of recommendations to ensure relevance and applicability to the Pakistani healthcare setting [17]. The involvement of a team comprising the Consultant Chemical Pathologists and senior technologists underscores a collaborative and evidence-

based approach to guideline formulation. Senior technologists are experts with greater than 10 years of experience working at the bench with PEP, who were included in the team to provide a technical perspective when developing our recommendations. Furthermore, the adaptation and modification of recommendations based on expert consensus highlights the responsiveness of the guidelines to local healthcare infrastructure and resource constraints.

The modification made to recommendation 4 reflects a practical approach to address the resource constraints commonly encountered in low-income settings, such as Pakistan. In the initial recommendation, there was an emphasis on the necessity of a high-resolution electrophoretic system to ensure the detection of small monoclonal bands, especially in the beta region, which may co-migrate with normal proteins. However, acknowledging the reality of healthcare infrastructure in resource-limited settings, where high-resolution electrophoretic systems may not always be readily available or feasible to procure due to cost constraints, a revision was made to the recommendation to recognize the acceptability of low-resolution electrophoresis on cellulose acetate in situations where a high-resolution system is not accessible.

The initial recommendation 26 from 2012 suggested reporting the urine total protein and indicating the presence of glomerular and/or tubular proteinuria. Additionally, there was a directive to comment on the detection of Bence Jones Protein (BJP) and to quantify and report any intact monoclonal immunoglobulin found in the urine specimen. However, by focusing on reporting essential parameters according to the consensus of our local experts, the revised recommendation in the second version of the guidelines emphasizes a more streamlined approach. Hence, our modified recommendation maintains the importance of reporting urine total protein and quantifying and reporting any intact monoclonal immunoglobulin, while removing the specific indication for glomerular and/or tubular proteinuria and the comment on the detection of BJP. This revision ensures that laboratory reports remain informative and actionable for clinicians, even in contexts where comprehensive testing may be challenging to implement.

While the initial directive in recommendation 33 prioritized issuing integrated reports combining electrophoretogram and IFE for optimal patient management, the revised recommendation introduces flexibility by using "preferably." This acknowledges feasibility challenges in low-income settings and ensures diagnostic information is still provided despite constraints. It aligns with best practices while accommodating practical realities. The same rationale was implemented for recommendation 34.

The modification made to recommendation 37 reflects a shift towards a more concise and generalized interpretive commenting approach. In the initial recommendation, there was a specific mention of a "Normal pattern: Normal pattern. Paraprotein not detected," which provided a detailed interpretation of the electrophoretic pattern. However, recognizing the need for streamlined reporting practices that are both effective and efficient, the revised recommendation simplifies the interpretive comment to "Normal pattern: No significant abnormality is noted."

While the initial recommendation 39 provided detailed insights on nephrotic syndrome patterns and suggested corroborating with serum lipid results, the revised version simplifies language and removes explicit mention of syndrome consistency. By advising to corroborate with serum lipid results without specifying the pattern, the revision maintains clinical relevance while reducing the need for specialized interpretation, ensuring reports remain informative despite practical constraints.

Two recommendations were combined and refined to develop recommendation 54 in order to reduce redundancy and address potential diagnostic uncertainties. While the first recommendation addresses the presence of small abnormal bands in a polyclonal/oligoclonal background and suggests further testing to ascertain their clinical significance, the addition of the second recommendation acknowledges the possibility of faint bands observed in the gamma region without a known clinical history of monoclonal band. This addition provides additional guidance on the interpretation of such findings, suggesting considerations for infectious and/or autoimmune etiologies and emphasizing the importance of follow-up testing to rule out lymphoproliferative disorders. Hence, this guideline serves to offer a more comprehensive approach to interpreting electrophoretic patterns, thereby enhancing diagnostic accuracy, and facilitating appropriate clinical management.

10 recommendations were excluded from the final guidelines due to their infeasibility within the Pakistani healthcare system. For instance, the recommendation regarding the referral of problematic samples requiring the identification of small protein bands to a reference laboratory for isoelectric focusing (IEF) was deemed impractical due to logistical challenges and its limited commercial availability [1]. Additionally, the requirement for creatinine measurement on first voided urine specimens and the expression of BJP concentration relative to urine creatinine (BJP/creatinine) in mg/mmol was excluded as it may pose logistical and financial burdens on laboratories, especially in resource-limited settings where access to specialized equipment and reagents may be limited. These exclusions were necessary to ensure that the guidelines remained feasible and applicable within the context of the Pakistani healthcare system, while still providing valuable guidance for clinicians and laboratory professionals.

The finalized recommendations encompass a wide range of aspects related to pre-analytical, analytical, and post-analytical processes, including specimen collection and handling, instrumentation, interpretation of electrophoretic patterns, and reporting formats. Key revisions to the recommendations reflect a pragmatic approach to navigating resource constraints, such as the acceptance of low-resolution electrophoresis systems in case of unavailability of high-resolution systems. Our developed guidelines aim to ensure that laboratories in low-income

settings can still perform protein electrophoresis using available resources without compromising the integrity of diagnostic assessments.

Conclusion

The development of standardized reporting guidelines for SPEP and UPEP in Pakistan marks a significant advancement in laboratory practices, particularly within resource-limited settings. These guidelines, tailored to the local healthcare environment, ensure consistency and clinical relevance in protein electrophoresis reporting. Key revisions address practical constraints, such as the use of low-resolution systems and streamlined interpretive comments, ensuring laboratories can maintain diagnostic integrity even with limited resources. This initiative is poised to enhance diagnostic accuracy, support informed clinical decisions, and ultimately improve patient outcomes in Pakistan and similar contexts. Ongoing evaluation will be crucial to sustaining the guidelines' relevance and effectiveness.

Disclosures

None.

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Ethical Consideration

Not applicable.

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