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Synoptic reporting for protein electrophoresis and immunofixation

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1. Introduction

Synoptic reporting is defined as a clinical documentation method that uses a structured format to produce complete, consistent medical reports. Synoptic reporting has become a fundamental concept in anatomical pathology (AP). In the context of AP, synoptic reporting has been shown to improve efficiency and turnaround times, and reduce the number of errors [1–4]. Despite the apparent success and promise of synoptic reports in AP, clinical pathology has been slower to adopt standardized reporting structures [5–7]. This is particularly true for reporting in the field of clinical biochemistry, where there are few analytes for which there are interpretative reports.

The most common interpretative report encountered in clinical biochemistry is protein electrophoresis and immunofixation. While reports are provided by many laboratories, there are often substantial differences in the content and structure of interpretative comments between individuals and institutions [8,9]. This variability may stem from the fact that there are few published recommendations and guidelines for electrophoresis reporting [10–12]. While these recommendations and other publications provide a detailed discussion of technology, very few [12] propose approaches to the structure and content of text reports. This is particularly noticeable in the case of external quality assurance in the form of proficiency testing. Proficiency testing involves interpretation of blinded samples by individual laboratories. The results are then graded by the proficiency testing organization. Proficiency testing organizations, such as the College for American Pathologists (CAP) and Institute for Quality Management in Healthcare (IQMH), provide extensive feedback and goals for numeric results, but to our knowledge, none of them address the structure, similarity, or to any large extent, the content of text interpretations for protein electrophoresis and immunofixation reporting.

This lack of reporting standardization is in stark contrast to the progress that has been made in the diagnostic criteria, diagnostic workup, prognosis, and treatment of patients with multiple myeloma [13–18]. The source of this contrast is likely multi-factorial. First, treatment and prognostic guidelines are fundamental to disease management. Second, the large number of clinical trials for myeloma provides extensive high quality evidence to drive standards and practice guidelines. It is noteworthy that even the clinical trials in the field have defined standards for reporting [13], which have further helped standardization. By comparison, reporting of protein electrophoresis results in biochemistry has had little attention focused on textual comment standardization despite the relative consistency of analytical principles and clinical questions for decades. Based on our experience with Canadian consensus recommendations [19], the wide variation in current practice suggests that it will be a long road to reporting standardization. Indeed, while the working group was unanimous on the need to standardize, the field is a long way from achieving that goal.

As a step towards the goal of standardization, we considered the utility of synoptic reporting for protein electrophoresis and immunofixation. The main objective of synoptic reporting is to provide complete and consistent information in the same structured format, such that clinicians may efficiently recognize important details from disparate sources and interpreters. Further, standardized reporting structure should reduce the amount of mental energy laboratory clients (physicians) require to search for and understand important information. Given the reported benefits of synoptic reports in other specialties, and based on discussion with those who sign out protein electrophoresis

Abbreviations: SPE, serum protein electrophoresis; UPE, urine protein electrophoresis; IFE, immunofixation electrophoresis; sFLCs, serum free light chains

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Table 1
Synoptic reporting template for SPE and UPE.

Field	Content
1). Abnormal band[a]:	Yes/No/Equivocal
2). Band description: (if necessary)	Number and position of abnormal bands. Limitation of band quantitation as relevant to interpretation
3). Previous history: (if available)	History of previous analyses (SPE and IFE). Source of orders from other hospitals would be provided where relevant
4). Interpretation:	Concise summary of collective pattern and if changes are noted as relevant
5). Recommendation: (where appropriate)	Description of whether repeat testing or alternative testing is recommended (e.g. UPE, sFLC); frequency of repeat testing. Use available literature and guidelines where applicable
6). Interpreter:	Who interpreted the results, contact info

[a] Defined as an abnormality that might represent a monoclonal protein.

reports and the clinicians who receive them, it is highly probable that there would be advantages to a standardized reporting approach. Here, we propose a synoptic reporting approach for serum protein electrophoresis (SPE), urine protein electrophoresis (UPE), and immunofixation (IFE).

2. Synoptic reporting structure

Based on collaboration between the Clinical Hematologists and Clinical Biochemists at our institution, we have defined a synoptic reporting format for SPE, UPE, and IFE. Reports consist of mandatory and optional fields designed to provide essential information on each report as well as context-dependent details where appropriate. Reporting is intended to be concise, with the goal of providing information in highly user-consumable way that does not vary appreciably between interpreters.

3. SPE synoptic reporting fields

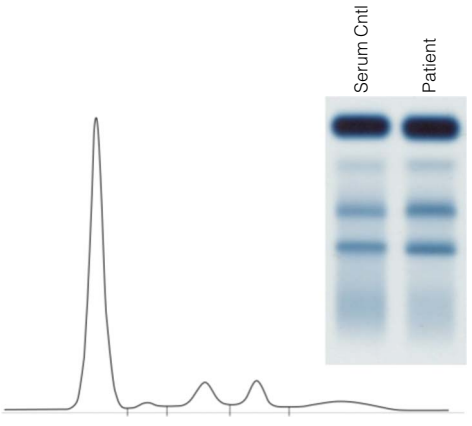
For SPE synoptic reports, we've defined three mandatory fields and three fields that are context-dependent (Table 1). Context-dependent fields are based on the presence of monoclonal proteins, previous history, and the availability of appropriate recommendations. Below is a description of each field that should be included in a synoptic report and a rationale for the content of each. Discussion of each field includes challenges, limitations, and nuances that might be encountered during routine interpretation of SPE results. Examples of SPE synoptic reporting are shown in Figs. 1–3.

3.1. Abnormal band

At the core of protein electrophoresis orders, is the question as to whether or not a patient has a monoclonal protein. Given that SPE is a screening test for monoclonal gammopathies, laboratories identify new patients with potential monoclonal gammopathies and provide the information necessary for physicians to monitor existing cases.

With this core concept in mind, synoptic reports should first answer the question of where there is or is not an apparent monoclonal protein present. In our opinion, the presence of something that either is or may represent a monoclonal gammopathy should be answered as clearly and directly as possible, ideally with a binary (yes/no or positive/negative) responsive. For the sake of brevity, we've decided to use a yes or no answer.

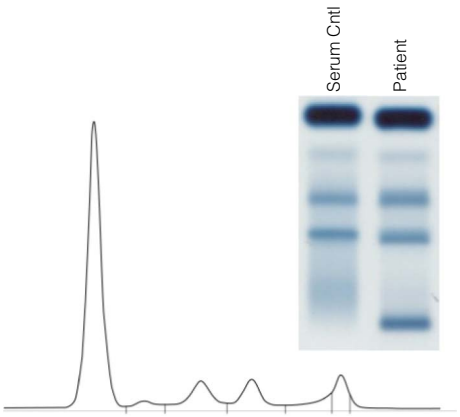
We've defined this field as “Abnormal Band”, which is intended to represent in name the question SPE testing can answer: “is there an abnormal band”. We both recognize and have debated ourselves alternate terms for this field, considering “Abnormality”, “Abnormal protein”, “Abnormal fraction”, and “Monoclonal gammopathy” in turn. We've identified limitations with each of these. For instance, “Abnormality” may refer to something other than a monoclonal gammopathy, such as in the case of alpha-1 antitrypsin deficiency, which is of clinical importance, but has nothing to do with a monoclonal gammopathy. In terms of different technologies, “Abnormal protein” may be inappropriate in screening instances using capillary electrophoresis, where non-protein compounds, such as radiocontrast dyes, may result in the appearance of an abnormal band [20]. The term “band” itself may be inappropriate when considering capillary electrophoresis, where the only “band” encountered is that created by the software in



Fraction	Concentration (g/L)	Reference Interval
Albumin	43	43-56
Alpha 1	2	1-3
Alpha 2	7	6-11
Beta	6	5-10
Gamma	9	6-14
Total protein	65	64-82

Abnormal band:	No
Interpretation:	No evidence of a monoclonal gammopathy.
Interpreter:	C. McCudden, PhD, DABCC, FACB, FCACB. Clinical Biochemist

Fig. 1. SPE synoptic reporting example of a patient with no apparent plasma cell dyscrasia. There are only three relevant fields for reporting in this example.



Fraction	Concentration (g/L)	Reference Interval
Albumin	52	43-56
Alpha 1	2	1-3
Alpha 2	8	6-11
Beta	7	5-10
Gamma	4	6-14
Fraction1	7	-
Total protein	79	64-82

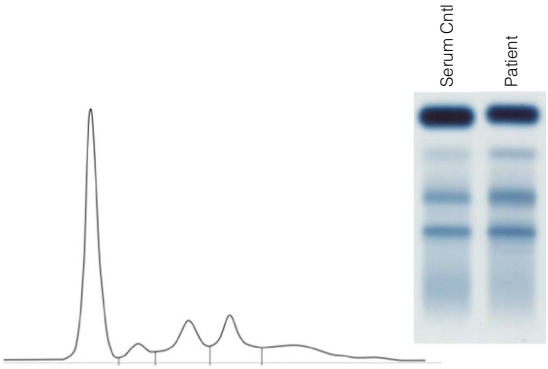
Abnormal band:	Yes
Band description:	Single, gamma region
Interpretation:	Immunofixation follows to confirm the presence of a monoclonal protein.
Interpreter:	C. McCudden, PhD, DABCC, FACB, FCACB. Clinical Biochemist

Fig. 2. SPE synoptic reporting example of a patient presenting with a plasma cell dyscrasia. Note addition of the band description field to describe the position of the abnormal band.

the form of a "virtual gel" generated from the electrophoretogram. The term "Abnormal fraction" may suggest there is an increase or decrease in the alpha, beta, or gamma fractions rather than the presence of an additional band. Finally, "Monoclonal gammopathy" requires that laboratories perform confirmation testing by IFE to be able to accurately state whether an abnormality is in fact caused by a monoclonal protein. Given the reality that some labs either can't order IFE in each case or rely on sequential/reflex testing, this term would not work universally either. With recognition of the challenges of nomenclature, particularly considering the larger goal of terminology in other languages and international consensus, we encourage the reader to focus on the content and structure of the field rather than the field name for which we are unlikely to find a perfect term. Nomenclature aside, the field name is intended to represent the presence of something that is concerning for a monoclonal gammopathy in the context of a screening test. Most importantly, our clinicians who receive the reports understand what this field name means.

While providing a yes/no answer is straightforward most of the time (Figs. 1–2), there are times where it is unclear if there is a band. In particular, it is often difficult to be definitive in cases where there are faint abnormalities, when bands are found in the alpha and beta regions (Fig. 3), and when there is a background of polyclonal immunoglobuins. Further, some laboratories are unable to provide IFE reports at the same time as SPE for regulatory or practical reasons, which again necessitates the ability to be equivocal. In addition, consideration needs to be given to asymmetric gamma regions, which may be indicative of an underlying monoclonal process even in the absence of a band. For these reasons, the "Abnormal Band" field needs to allow for some equivocation or "grey area".

There are several "Grey area" options we considered, including



Fraction	Concentration (g/L)	Reference Interval
Albumin	35	43-56
Alpha 1	3	1-3
Alpha 2	10	6-11
Beta	11	5-10
Gamma	11	6-14
Total protein	68	64-82

Abnormal band:	Equivocal
Band description:	Previous analysis showed a band in the beta region, which cannot be differentiated from normal beta globulins in this sample. Quantitation of the abnormal fraction includes normal beta globulins
Previous History:	Previous IFE (2016-12-12): monoclonal IgA kappa in the beta region Previous SPE (2017-01-10): one faint band, beta region
Interpretation:	Note pattern change: there is no evidence of a monoclonal protein, but additional testing is required to confirm.
Recommendation:	Contact the laboratory to request a repeat IFE to confirm the presence of the IgA kappa in the beta region if clinically indicated.
Interpreter:	C. McCudden, PhD, DABCC, FACB, FCACB. Clinical Biochemist.

Fig. 3. SPE synoptic reporting example with a complicated history. This patient has no apparent abnormal bands by SPE, but a known history of a monoclonal gammopathy in the beta region. The band description, history, and interpretation fields are used to convey the uncertainty of the SPE screening method.

referring to another report (e.g. “see IFE report”), hedging the call (“there is a diffuse area of restricted mobility”), or some standardized statement of ambiguity. Referring to another report or hedging with long-winded language seems unhelpful, particularly when the goal is to provide concise information in one place. Here we propose the term “equivocal”, which is by no means perfect, but does concisely convey that it is uncertain if there is a band present. Subsequent fields (e.g. band description, interpretation, and recommendation) in the synoptic report are designed to help inform the clinician as to the nature of the abnormality and whether any additional testing is recommended (Fig. 3). At the least, the use of an ambiguous term should prompt clinicians that this is not a typical monoclonal gammopathy. Ambiguity may help reduce the risk of unnecessary bone marrow biopsy or other invasive testing when the pattern is not obviously representative of a plasma cell dyscrasia.

3.2. Band description

This field is used to identify the number and position of abnormalities and convey any limitations there may be to quantitation of fractions. Describing the number of abnormal bands and their migration position is useful for several reasons including quality, disease monitoring, and commentary on quantitation.

It is useful to identify multiple bands for monitoring and diagnosis of disease. From a monitoring perspective, band position and quantity can be reviewed as part of previous history to determine if there has been a change. Changes may identify preanalytical issues (e.g. mislabeling) as part of quality assurance, and clinically significant disease progression or remission.

It is difficult to accurately quantitate bands when there is a polyclonal background or when bands migrate in the alpha and beta regions. When found in the alpha and beta regions, normal globulins account for several grams per liter of a given quantitation. Where laboratories report abnormal bands in the alpha or beta regions, a typical statement would be: “the abnormal band quantitation includes normal beta globulins” to alert the physician receiving the results that a concentration provided is inaccurate due to the migration position (Fig. 3). Similar statements would apply when there is a substantial polyclonal background. For example, a comment might indicate that the band was not quantitated at all because of the high background. Faint bands that are not quantitated should also be described in this field along with the limit of detection as applicable. Quantitation of monoclonal proteins is discussed in the Canadian consensus guidelines in this special issue [19].

Where there are multiple bands and they are quantitated, the isotype needs to be tied back to the quantitation. For this field, it is recommended that descriptions be brief, for example, “one band, gamma region” or “two bands, gamma region”. To tie this back to the quantitation, matching terms may be included, for example “one band, beta region (abnormal fraction 1)” or “one band in the gamma region (abnormal fraction 2)”. Interpreters may use additional adjectives to describe the bands, such as ‘faint’ or ‘diffuse’ to convey the nature of the bands if they are not quantitated (e.g. below the laboratory's reporting threshold). While these are subjective, they may serve to highlight relative disease burden before IFE confirmation testing is available.

3.3. Previous history

In hospital laboratories, a large portion of protein electrophoresis test requests are part of disease monitoring. Accordingly, it is highly informative to clinicians to note the history of previous analyses.

The main utilities of reviewing previous history are to identify clinically significant changes and reduce preanalytical errors. From a preanalytical aspect, patterns that change markedly over a short time period should prompt laboratories to consider sample mix-up or patient identification errors analogous to a ‘delta check’ [21]; preanalytical errors would of course not be reported. From a reporting perspective, the appearance of additional bands or a change in the location of bands may prompt additional testing that would be described in the “Recommendations” field (see below).

Where the laboratory serves as a reference testing center for many sites, it is important to indicate if the previous sample was from a workup at another hospital, where the ordering physician may not be aware of the previous analysis. This may also serve as an opportunity to mention test utilization, for example where there was a second sample from another doctor ordered the same day. Typical comments would simply state what was observed previously and when; e.g. “previous IFE (2017-05-27) showed a monoclonal IgG kappa” (Fig. 3). Where significant changes are noted, they would be described in the “Interpretation” field (see below).

3.4. Interpretation

This field is intended to facilitate communication of the overall pattern and, where relevant, a description of changes from previous history. In terms of monoclonal immunoglobulins concentration, it may also be useful to indicate if a change in concentration is significant [22]. The RCV for monoclonal immunoglobulins is reported to be ~25%. Where there is an absence of abnormalities, interpreters would indicate that the pattern does not show evidence of a monoclonal gammopathy.

Other clinically relevant patterns would also be described in the interpretation field. For example, it is reported that PiZZ deficiency phenotype for alpha-1 antitrypsin deficiency can be detected by SPE [23]. This would obviously help identify diseases that might not otherwise be detected. It is here where interpreters may provide additional details that don't fit in other fields.

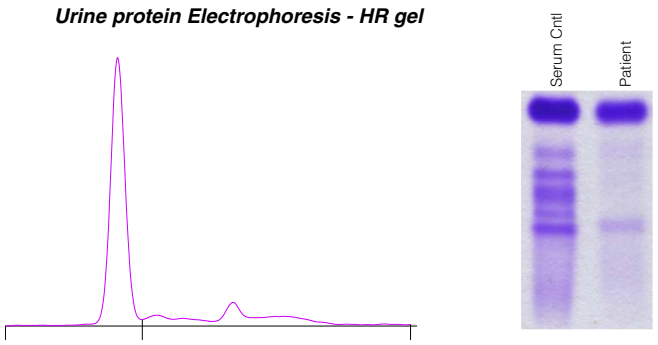
3.5. Recommendation

Where appropriate and possible, it would be of tremendous value to provide a recommended course of action (Fig. 3). This is particularly useful for clinicians who rarely order protein electrophoresis to help guide their decision making. For example, if a pattern is equivocal, it would be appropriate to indicate if additional tests may help guide the interpretation. For example, in the context of hypogammaglobulinemia, it may be useful to recommend UPE or serum free light chain analysis, which are more sensitive for free light chains [24,25].

Recommendations may also take disease progression rates into consideration. There is evidence [26,27] that trace monoclonal proteins do not progress over the course of at least 5 years. This subcategory of trace bands, referred to as IFE MGUS (band by IFE only and < 1.5 g/L), have an overall 3% progression rate, while those with IgA isotype are more likely to progress. In contrast, progression of MGUS with concentrations > 1.5 g/L is reported to be higher [27,28]. While definitive studies on progress of faint monoclonal proteins are absent, an indication of the approximate frequency of repeat testing may be useful. For example, “ $< 5\%$ of very faint IgG monoclonal bands progress within 5 years, an annual repeat sample is recommended in the absence of clinical progression”.

3.6. Interpreter

Given the goal of laboratorians as information resources, we added a field where the interpreter provides their name and credentials as they sign out results. If not immediately available on the reports, interpreters should ideally list contact information in case the ordering physician requires a consultation or has questions about a particular interpretation. This may serve a secondary benefit in terms of getting the names of laboratorians out to the ordering physicians when questions about other tests arise. This is another means towards becoming a known name and trusted resource.



Abnormal band:	No
Interpretation:	Glomerular proteinuria pattern. No evidence of a monoclonal gammopathy.
Interpreter:	C. McCudden, PhD, DABCC, FACB, FCACB. Clinical Biochemist.

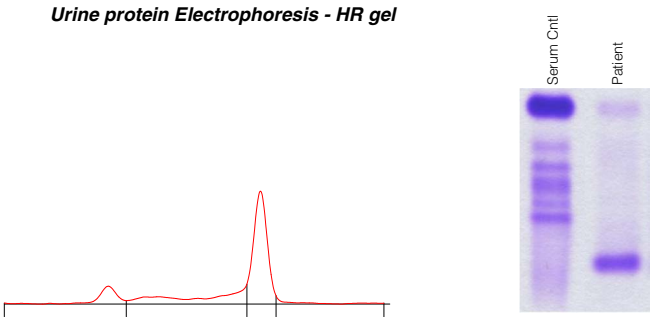
Fig. 4. UPE synoptic reporting example of a patient with glomerular proteinuria in the absence of any apparent plasma cell dyscrasia. As with Fig. 1, three fields are used.

4. UPE synoptic reporting fields

For UPE, the reporting structure is essentially the same as for SPE. The main difference between these reports is the availability of information related to the nature and extent of proteinuria, which is often a consequence of the underlying disorder [29,30]. Interpreters may readily differentiate different forms of kidney damage, such as tubular, glomerular, and mixed proteinuria (Figs. 4–6).

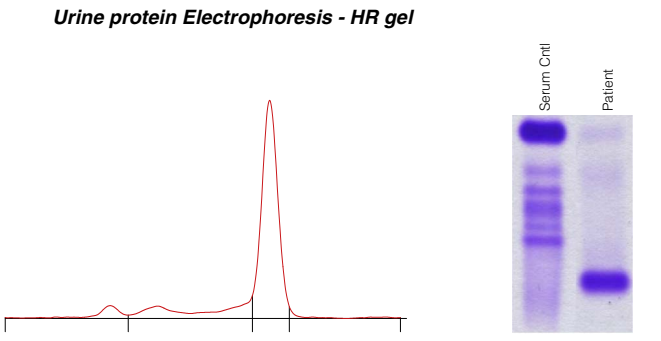
While nephrologists at our institution have indicated that the albumin to creatinine and protein to creatinine ratios have largely supplanted the need for proteinuria pattern identification by UPE, some institutions may choose to comment on particular patterns. For example, in tubular proteinuria, smaller proteins, such as alpha1-acidic glycoprotein, and β2-microglobulin are evident, reflecting proximal tubular damage [31]. In contrast, glomerular damage results in predominance of high molecular weight proteins, largely albumin, with lesser amounts of α1-globulins, and transferrin passing into urine. Severe kidney damage, as observed in nephrotic syndrome, has a characteristic pattern of very high protein concentrations.

Proteinuria aside, the goals of UPE are largely the same as SPE. The only other important exception is band quantitation details. In UPE, monoclonal proteins are usually not quantitated. Thus, while describing the number and position of abnormal bands is important, quantitation details are not usually irrelevant.



Abnormal band:	Yes
Band Description:	One, gamma region
Previous History:	None
Interpretation:	Small amounts of albumin with an abnormal band in the gamma region. Immunofixation will be performed to confirm the presence of a monoclonal gammopathy
Interpreter:	C. McCudden, PhD, DABCC, FACB, FCACB. Clinical Biochemist.

Fig. 5. UPE synoptic reporting example of a patient presenting with an apparent plasma cell dyscrasia in urine. Note the addition of the band description field to describe the position of the abnormal band.



Abnormal band:	Yes
Band Description:	One, gamma region
Previous History:	Previous IFE (2013-02-11): monoclonal free kappa light chains Previous UPE (2017-01-10): one band, gamma region
Interpretation:	Trace albumin and globulins present with an abnormal band in the gamma region. No significant change from previous specimen
Interpreter:	C. McCudden, PhD, DABCC, FACB, FCACB. Clinical Biochemist.

Fig. 6. UPE synoptic reporting example with a known history. This is a representative sample from a patient with known plasma cell dyscrasia on routine followup.

4.1. IFE synoptic reporting

Our vision of synoptic reporting for IFE is largely similar to SPE (Table 2). Here the main difference is that IFE is used to confirm if abnormal bands represent monoclonal proteins, with the added goal of identifying the isotype. IFE also enables a qualitative indication of polyclonal immunoglobulin suppression, which may not apparent from SPE; polyclonal immunoglobulin suppression is relevant to disease progression and risk for infection. Fields unique to IFE synoptic reporting are described below with examples shown in Figs. 7 and 8.

4.2. Monoclonal protein

This field is analogous to the “Abnormal Band” field used for SPE/UPE. The main difference from SPE, is that IFE definitively identifies a monoclonal protein. In this instance the term “monoclonal protein” includes intact immunoglobulins, free light chains, heavy chains, or combinations of the three. It remains a ternary field, i.e. with three options: Yes, No, and Equivocal (Figs. 7–8).

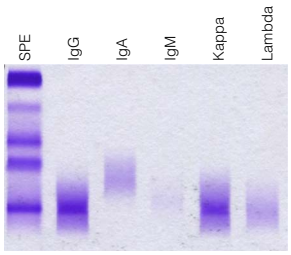
Equivocation remains because there are instances where it is unclear if there is a definitive monoclonal protein even by IFE. At times interpreters may encounter very faint bands or multiple bands, which may not be monoclonal in nature, but rather immunoreactive, artefactual, or reflective of a regenerating immune system [32–34].

4.3. Isotype

Isotyping any identified monoclonal proteins is a key component of IFE reporting. It is well recognized that different isotypes are produced by different diseases [27,28,35–37]. Classically, Waldenstrom's macroglobulinemia (lymphoplasmacytic lymphoma) is associated with IgM monoclonal immunoglobulins, whereas multiple myeloma is usually associated with non-IgM immunoglobulins; there are of course rare exceptions as in IgM myeloma, but the point is that the isotype matters and is used along with other information for making a diagnosis. In addition to diagnosis, the isotype of monoclonal proteins also is useful for prognosis. Several studies have shown that MGUS with free light chains are more likely to progress than IgG isotypes [27,36,37].

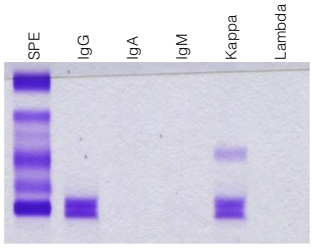
Table 2
Synoptic reporting template for IFE.

Field	Content
1). Monoclonal protein:	Yes/No/Equivocal
2) Isotype: (if present)	Isotype of intact immunoglobulin, free light chain, or heavy chain
3). Abnormal band description: (as necessary)	Number and position of abnormal bands. Align description with quantitation as relevant
4). Previous history: (if available)	History of previous analyses (IFE). Source of orders from other hospitals would be provided where relevant
5). Immunosuppression:	Yes/No
6). Interpretation: (where appropriate)	Concise summary of collective pattern and if changes are noted as relevant
7). Recommendation: (where appropriate)	Description of whether follow up and/or repeat testing; frequency of repeat testing. Use available literature and guidelines where applicable
8). Interpreter:	Who interpreted the results, contact info



Monoclonal Immunoglobulin:	Yes
Isotype	IgG kappa
Band Description (if present):	Single band in gamma region
Immunosuppression:	No
Interpretation:	IgG kappa monoclonal gammopathy
Interpreter:	C. McCudden, PhD, DABCC, FACB, FCACB. Clinical Biochemist.

Fig. 7. IFE synoptic reporting example of an IgG kappa monoclonal gammopathy. This is a representative sample from a patient presenting with a plasma cell dyscrasia. The abnormality was identified initially by SPE.



Monoclonal Immunoglobulin:	Yes
Isotype	IgG kappa, free kappa light chains
Band Description:	Single IgG kappa band in gamma region with trace amounts of monoclonal free kappa light chains in the beta region.
Immunosuppression:	Yes
Recommendation:	Urine for protein electrophoresis to confirm the presence of free kappa light chains
Interpreter:	C. McCudden, PhD, DABCC, FACB, FCACB. Clinical Biochemist.

Fig. 8. IFE synoptic reporting example of a patient with a monoclonal IgG kappa and free kappa light chains. Note the recommendation for a urine sample.

4.4. Band description

It is essential to tie the IFE interpretation to the SPE/UPE results, such that the number and nature of abnormalities identified by SPE/UPE are reported cohesively. For example, if IFE was performed because of a band in the beta region and there is something found in the gamma region, that should be discussed. The other main difference for IFE reporting is that, other than for immunosuppression, there will be no commentary on the concentration of monoclonal immunoglobulins (Fig. 7).

The field name is retained as “Band Description” rather than “Monoclonal Protein” because there will be instances where there will be bands, but they may not be associated with monoclonal gammopathies. The intent is to have a universally applicably field name. While there are, no doubt, limitations to this nomenclature, the goal is to have a defined structure to describe the number and nature of the abnormalities.

4.5. Immunosuppression

IFE may reveal other hallmarks of myeloma, such as immunosuppression [38]. In multiple myeloma, the presence of immunosuppression is indicative of advancing disease where patients are at risk of acquiring infectious diseases. Infection has been shown to be an cause of early mortality in newly diagnosed myeloma patients [39]. While it can't be determined by IFE, it is noteworthy that suppression of the uninvolved heavy chain pair has been shown to be a risk factor for MGUS progression [40].

The basis for commenting on immunosuppression based on IFE, is that quantitation of immunoglobulins fails to identify immunosuppression in the presence of monoclonal proteins. For example, a patient with a 50 g/L monoclonal may have significant immunosuppression and a high quantitative IgG. IFE provides a view of different immunoglobulin and light chain classes that neither SPE nor quantitative immunoglobulin testing can. Where immunosuppression is evident, it should be identified. We've defined this is field as binary, where immunosuppression is clearly present or not (Fig. 8). This field may also be helpful in guiding recommendations for followup testing.

4.6. Interpretation

Here we've defined a summary field for the interpretation. Interpreters may describe the overall pattern and components or provide additional details in free form. As with SPE/UPE, the provision of free text fields should alleviate any concerns over being constrained by the synoptic reporting format. While clinicians should already have everything they need in the preceding fields, there will be instances where clarification of multiple bands or other complex patterns will need to be elucidated.

5. Summary

Collectively, synoptic reporting is aimed at providing structure to what is currently a wildly variable set of comments ranging from terse to pedantic. Analogous to other areas of laboratory medicine where standardization and harmonization is being sought, this is an opportunity to provide consistency. The busier laboratory clients become the more important it becomes to provide information in consistent, rapidly digestible pieces.

In addition to providing consistent information for clinicians to rapidly assimilate, standardized reporting formats simplify data extraction for research or administrative databases. Rather than required

natural language processing and a series of key term searches, well-structured reports are highly amenable to database storage, information extraction, and data re-use. Easier data analysis may inform future re-commendations towards testing frequency and progression and serve to update synoptic reporting recommendations.

Finally, the addition of more explicit interpretative data and re-commendations is right in line with global initiatives in laboratory medicine to “add value” and engage with clinicians [41].

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