COLLEGE of AMERICAN PATHOLOGISTS

Bone Marrow Synoptic Reporting for Hematologic Neoplasms

Guideline from the College of American Pathologists (CAP) Pathology and Laboratory Quality Center

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Background

- **Agreement on the diagnosis of hematologic neoplasms generally exists among pathologists.**
- **Notwithstanding, the bone marrow is a highly complex organ and subsequently bone marrow pathology reports are also highly variable.**
- **There is ample evidence from the solid tumor literature that synoptic reporting improves accuracy and completeness of relevant data.**
- **Standardized synoptic reporting of bone marrow specimens would lead to improved consistency, accuracy, and completeness of diagnostic information.**

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Introduction

- **The College of American Pathologists through its Laboratory and Pathology Quality Center (the Center) convened an expert panel of pathologists and hematopathologists to develop recommendations to formalize the basic components of a synoptic report template for bone marrow hematopoietic neoplasms.**

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Introduction continued

- **The panel closely followed the Institute of Medicine *Clinical Practice Guidelines We Can Trust* standards for guideline development**
    1. **Establish transparency**
    2. **Manage conflicts of interest**
    3. **Establish a multi-disciplinary panel**
    4. **Perform systematic review**
    5. **Rate strength of recommendations**
    6. **Articulate the recommendations**
    7. **Include external review**

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Guideline Panel Members

- **Expert panel members**
  - **Cordelia Sever, MD, Chair**
  - **Charles Abbott, MD**
  - **Monica de Baca, MD**
  - **Joseph D. Khoury, MD**
  - **Sherrie Perkins, MD, PhD**
  - **Kaaren K. Reichard, MD**
  - **Ann Taylor, MD**
  - **Howard R. Terebelo, DO (hematologist/oncologist)**
  - **R. Bryan Rumble, MSc, Methodology Consultant**
- **Advisory panel members**
  - **Angela Dispenzieri, MD**
  - **Joan E. Etzell, MD**
  - **Kathryn Foucar, MD**
  - **M. Elizabeth Hammond, MD**
  - **John Tate, MD, PhD**
  - **Barbara Zehentner, PhD, HCLD (ABB)**
- **Staff**
  - **Nicole E. Thomas, MPH, CT(ASCP), Guideline Development Manager**
  - **Carol Colasacco, MLIS, SCT(ASCP), Medical Librarian**

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Systematic Evidence Review

- **Identify key questions**
- **Literature search**
- **Data extraction**
- **Develop proposed recommendations**
- **Open comment period**
- **Considered judgment process**
  - **Consider risks and benefits, cost, regulatory requirements, preferences, etc.**

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Key Questions

1. **Considering the possible primary bone marrow morphologic descriptors, which ones are required on a synoptic report if completeness is the outcome of interest?**
2. **Considering the possible ancillary studies that could be ordered on a bone marrow specimen, which ones are required on a synoptic report if completeness is the outcome of interest?**

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Key Questions continued

3. **What sequence of results reporting should be followed?**
   a. **Considering the options available, is there an optimum report format that should be used if ease of use, error reduction, and fewer incompletes are the outcomes of interest?**
   b. **Is there an optimal presentation for the elements of the minimum data set if the outcomes of interest are clarity and ease of use?**

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Key Questions continued

4. **Which components required for correct coding and data repositories should be included in the report?**
    a. **Coding**
    b. **Registries**
    c. **National guidelines (eg, National Comprehensive Cancer Network [NCCN])**
    d. **Physician payment incentive requirements (eg, Physician Quality Reporting System [PQRS])**
5. **What clinical or laboratory information should be included in the report?**

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Systematic Evidence Review Results

- **Literature search conduction for January 2002 - November 2012**
  - **1,731 articles included for abstract review**
  - **617 articles included for full text review**
  - **95 articles included for data extraction and quality assessment analysis**
- **Included articles/documents were comparative studies that addressed bone marrow samples for diagnosis, ancillary testing in bone marrow samples, completeness of bone marrow reports, and optimum report formats**

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Systematic Evidence Review Results continued

- **Open Comment Period**
  - **April 21 – May 19 2014**
  - **112 respondents, 178 written comments**
  - **Respondents agreed with each of the 10 draft recommendations at a level greater than 80%**

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Definition of Strength of Recommendations

Designation	Recommendation	Rationale
Strong Recommendation	Recommend For or Against a particular bone marrow synoptic reporting practice (Can include must or should)	Supported by high (convincing) or intermediate (adequate) quality of evidence and clear benefit that outweighs any harms
Recommendation	Recommend For or Against a particular bone marrow synoptic reporting practice (Can include should or may)	Some limitations in quality of evidence (intermediate [adequate] or low [inadequate]), balance of benefits and harms, values, or costs but panel concludes that there is sufficient evidence and/or benefit to inform a recommendation.
Expert Consensus Opinion	Recommend For or Against a particular bone marrow synoptic reporting practice (Can include should or may)	Serious limitations in quality of evidence (low [inadequate] or insufficient), balance of benefits and harms, values or costs, but panel consensus is that a statement is necessary.
No Recommendation	No Recommendation for or against a particular bone marrow synoptic reporting practice	Insufficient evidence or agreement of the balance of benefits, harms, value, or costs to provide a recommendation

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Guideline Statement One

- **Laboratories should adopt synoptic reporting as a component of bone marrow pathology reports for clearly defined neoplasia or widely applied classification schemes and receive appropriate institutional support.**

Strong Recommendation

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Guideline Statement One | Laboratories should adopt synoptic reporting as a component of bone marrow pathology reports for clearly defined neoplasia or widely applied classification schemes and receive appropriate institutional support.

Rationale

- **Synoptic reporting with defined data elements has significantly improved accuracy and completeness of pathology reports for numerous organs**
- **Even though bone marrow examinations are often more complex than solid tumors, there is a finite set of data elements critical for diagnosis and patient management that should be reliably included**

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Guideline Statement Two

- **When reporting on peripheral blood specimens for bone marrow synoptic reports, laboratories should report clinically and diagnostically pertinent elements, if available. These key elements may include one or more parameters from complete blood cell count, absolute cell counts, and relevant morphologic descriptors.**

Strong Recommendation

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Guideline Statement Two | When reporting on peripheral blood specimens for bone marrow synoptic reports, laboratories should report clinically and diagnostically pertinent elements, if available. These key elements may include one or more parameters from complete blood cell count, absolute cell counts, and relevant morphologic descriptors.

Rationale

- **Peripheral blood parameters are critical for complete staging and prognostic evaluation in many hematopoietic neoplasm**
- **Including the critical data elements as applicable for the disease entity will result in a more complete and integrated pathologic diagnosis**

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Guideline Statement Three

- **When reporting bone marrow aspirate results, laboratories should report clinically and diagnostically pertinent elements in the synoptic section. These key elements may include the evidence-based parameters such as blast percentage, dysplasia, myeloid to erythroid ratio, morphology of myeloid/lymphoid elements, and enumeration of lymphoid elements and plasma cells; additional elements may be included in non-synoptic sections of the report.**

Strong Recommendation for blast percentage;

Recommendation for all other parameters

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Guideline Statement Three | When reporting bone marrow aspirate results, laboratories should report clinically and diagnostically pertinent elements in the synoptic section. These key elements may include the evidence-based parameters such as blast percentage, dysplasia, myeloid to erythroid ratio, morphology of myeloid/lymphoid elements, and enumeration of lymphoid elements and plasma cells; additional elements may be included in non-synoptic sections of the report.

Rationale

- **Reporting the critical aspirate data elements in the synoptic portion of the report will assure**
  - **Reliable reporting and improve clinician comprehension and patient management**
  - **Easy tracking of data in sequential evaluations**
- **Designing several disease specific templates, tailored to the institution's patient population, should limit the number of data elements**

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Guideline Statement Four

- **When reporting bone marrow core biopsy results, laboratories should report clinically or diagnostically pertinent elements in the synoptic section. These key elements may include the evidence-based parameters such as fibrosis, cellularity, distribution pattern of hematopoietic elements, morphology of lymphoid elements, and enumeration of lymphoid elements and plasma cells; additional elements may be included in non-synoptic sections of the report.**

Strong Recommendation for fibrosis; Recommendation for all other parameters

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Guideline Statement Four | When reporting bone marrow core biopsy results, laboratories should report clinically or diagnostically pertinent elements in the synoptic section. These key elements may include the evidence-based parameters such as fibrosis, cellularity, distribution pattern of hematopoietic elements, morphology of lymphoid elements, and enumeration of lymphoid elements and plasma cells; additional elements may be included in non-synoptic sections of the report.

Rationale

- **Inclusion of critical data elements of BM biopsies in the synoptic portion will improve completeness of data elements that are difficult to find or missed entirely in narrative reports**
- **Special studies such as reticulin stain will be reliably performed and reported in applicable disease entities**

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Guideline Statement Five

- **If relevant ancillary testing studies are performed on the primary sample (blood or bone marrow), laboratories should report the results, general methodology, performance site and interpretation site or have the data be readily available. If the results are not available, pending status should be explicitly stated.**

Strong Recommendation

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Guideline Statement Five | If relevant ancillary testing studies are performed on the primary sample (blood or bone marrow), laboratories should report the results, general methodology, performance site and interpretation site or have the data be readily available. If the results are not available, pending status should be explicitly stated.

Rationale

- **Ancillary test results on the primary specimen add highly relevant data for diagnosis, therapeutic options, and risk classification of bone marrow neoplasms**
- **The inclusion of the general methodology and performing site conveys important information for diagnostic certainty and follow up**

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Guideline Statement Six

- **Laboratories should include in the synoptic section of the report data groups for diagnosis, supporting studies, and ancillary data that are critical for diagnosis. Key morphologic descriptors should be included and may be in the diagnosis line if critical or a component of the disease classification. The diagnosis (or diagnosis group) should head the synoptic section when possible. A narrative interpretative comment should immediately follow the synoptic section if required.**

Strong Recommendation for inclusion of data groups for diagnosis, supporting studies, and ancillary data; Recommendation for the layout of the data groups.

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Guideline Statement Six | Laboratories should include in the synoptic section of the report data groups for diagnosis, supporting studies, and ancillary data that are critical for diagnosis. Key morphologic descriptors should be included and may be in the diagnosis line if critical or a component of the disease classification. The diagnosis (or diagnosis group) should head the synoptic section when possible. A narrative interpretative comment should immediately follow the synoptic section if required.

Rationale

- **Data groups for diagnosis, supporting studies an ancillary studies contain evidence based data elements in a logical grouping**
- **Consistent layout enhances comprehension**
- **Narrative comments are often required to interpret inconclusive or incomplete findings and best placed after the synoptic, before additional non-synoptic elements of the report**

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Guideline Statement Seven

- **Laboratories should consider the integrity of electronic data transmission for formatting and data presentation of synoptic reports.**

Strong Recommendation

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Guideline Statement Seven | Laboratories should consider the integrity of electronic data transmission for formatting and data presentation of synoptic reports.

Rationale

- **Since data transmission is insufficiently standardized, correct reporting across interfaces must be assured to prevent potentially hazardous distortion of report content**

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Guideline Statement Eight

- **No recommendation is made regarding the inclusion of coding terms in a synoptic report because coding terms are distinct from scientific terms and vary considerably among health authorities, payers, and different countries.**

No Recommendation

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Guideline Statement Eight | No recommendation is made regarding the inclusion of coding terms in a synoptic report because coding terms are distinct from scientific terms and vary considerably among health authorities, payers, and different countries.

Rationale

- **There was no evidence that consideration of coding terms would enhance the bone marrow report**

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Guideline Statement Nine

- **Laboratories should include clinical and laboratory data required for a definitive diagnosis in the synoptic section, along with its source(s), if applicable.**

Recommendation

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Guideline Statement Nine | Laboratories should include clinical and laboratory data required for a definitive diagnosis in the synoptic section, along with its source(s), if applicable.

Rationale

- **Ancillary test results are a significant component for classification and risk determination of many bone marrow diseases**
- **Some ancillary tests are essential to avoid misclassification of benign diseases, such as Vitamin B12 deficiency**

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Limitations

- **The guideline does not include evidence-based analysis of specimen requirements.**
- **The search dates excluded more recent literature that contained genomic studies.**
- **The guideline does not include templates, but rather provides recommendations for components and elements that should be included in the synoptic report**

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Conclusions

- **Synoptic reports should be used for bone marrow examinations.**
- **A single template for all bone marrow specimens will not lend itself to succinct data presentation that is free of clutter and irrelevant information.**
- **Certain elements are more directly related to patient outcomes and should be reported in the synoptic report.**
- **The guideline is a framework and does not replace related CAP Cancer Protocols; for accreditation purposes laboratories need not create new synoptic report templates based on the guideline. The guideline will be considered for future updates of the protocols.**
- **Laboratories should adopt the guideline to improve consistency, accuracy, and completeness of diagnostic information in their synoptic reports.**

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Link to Guideline

- **http://www.archivesofpathology.org/doi/full/10.5858/arpa.2015-0450-SA**

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