Engaging Physicians on New Hematologic Parameters via Scientific Marketing

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“Take the time to pull together data based on patients actually seen in the hospital. The physicians will pay much more attention when the data involves ‘their’ patient population. It is the laboratory’s responsibility to provide the most reliable patient results efficiently, and at the same time being relevant to the needs of the physician to ensure there is sufficient Evidence-Based Medicine used in their clinical setting.”

— John F. Boyle, PhD, Director, Laboratory Respiratory, and Ancillary Services Mercy Medical Center, Rockville Centre, N.Y.

Sysmex customers are in the enviable position of being able to improve current standards of care and diagnostic efficiency by implementing two hematologic parameters that are currently available as part of the routine CBC on Sysmex analyzers: Reticulocyte Hemoglobin (RET-H) and Immature Platelet Fraction (IPF). But the challenge to the laboratory relative to the implementation of RET-H, or any other parameter, is reaching physicians with the evidence so the test becomes part of an ordering pathway.

Sysmex America’s newly-developed Scientific Marketing department, directed by Jolanta Kunicka, PhD, supported by Barbara Connell, MS, MT (ASCP) SH, provides laboratorians and pathologists with the tools they need to assess the data and to communicate the clinical value of RET-H and IPF to physicians. To this end, Sysmex follows the principles of Evidence-Based Medicine (EBM) when reviewing and discussing data from scientific, peer-reviewed studies. EBM is an organized approach to search and assess medical information and determine if a treatment or diagnostic test can benefit specific physicians and patients in a clinical setting.

According to Dr. Kunicka, “This is a significant undertaking that requires the identification of the best available scientific evidence among the over two million medical journal articles published every year. However, it is clearly a worthwhile endeavor because it underscores the importance of the parameters in a clinical setting. Adoption of the EBM approach by clinical societies can also lead to changes in recommended care pathways and quality measures.”

“As a department, Scientific Marketing works closely with Medical Affairs and Clinical Specialists groups to ensure we are providing our customers with credible solutions that help them influence clinical adoption of novel parameters, while strengthening their relationships with treating physicians. We do this by providing relevant scientific information in an unbiased format, based on peer-reviewed articles and EBM,” said Dr. Kunicka.

At times, Scientific Marketing’s efforts benefit from clinical laboratory-based pilot studies, which demonstrate the clinical utility of new assays and/or the improved diagnostic efficiency associated with the use of assays. One such pilot study is being conducted by John Boyle, PhD, Director of the Laboratory Respiratory, and Ancillary Services at Catholic Health Care’s Mercy Medical Center on Long Island, NY.

Dr. Boyle, who has spent years improving the efficiency of clinical laboratories throughout the greater New York area, recently installed two Sysmex hematology analyzers, a Sysmex® XT-Series and XE-Series Automated Hematology Analyzer. The pilot study mentioned above is designed to determine the incremental efficiency gained for the diagnosis and treatment of iron deficiency anemia when RET-H becomes part of the ordering pathway.

Dr. Boyle has looked at the CHr/RET-Hr parameter(s) for the last five years and is hoping to determine if the parameter meets LEAN Principles that look at more efficient ways in which companies and departments can apply their resources and dollars. According to Dr. Boyle, “Hospitals are becoming more aware that they need to look at changes and new procedures and not just by the sole percent of the change, because even a 1% change can be significant in terms of dollars saved if the denominator is very high.”

For example, in the case of pre-operative patients with anemia, which Dr. Boyle estimates to be around 30%, physicians may assess whether a patient needs a transfusion, understanding that transfusions themselves bear inherent risks. This is not to say that RET-H gives the answer – no single result can do that – but it could improve diagnostic efficiency for physicians by using fewer steps, thus achieving a larger savings in terms of dollars and personnel. According to Dr. Boyle, statistics show that 4,000-6,000 people die every year in the United States from anemias, and hospitalization costs are in the billions of dollars.

Dr. Boyle would challenge laboratories to “seize the moment” when it comes to introducing new parameters that can improve diagnostic efficiency, and he considers RET-Hr to be one of those. “This is a remarkably stable parameter reflecting bone marrow activity, even in the presence of inflammatory disease, and it has a key role to play in the early diagnosis of iron deficiency by physicians. Other markers, such as ferritin and Tsat, have not had sufficient time to establish baseline values, so in the early stages they are not that informative. But with RET-Hr, if a patient has (normal) values between 29 pg/mL and 32 pg/mL, the physician might move forward to consider other conditions for the anemia.”

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1 Retic, IRF, and RET-Hr are standard on the XE-5000 & XT-4000i, and optional on the XE-2100 & XT-2000i. Retic parameters are not available on the XT-3800i, XS, KX, or pceH-200i. IPF is available standard only on the XE-5000 and is optional only on the XE-2100.
Just as marketers need to determine who their customer base is, laboratories need to identify the physician populations who would be most productive in the use and clinical adoption of RET-He.

“This will vary by hospital,” says Dr. Boyle, “in that all hospitals are not the same.” In one institution it may be the hospitalists. In another it can be speakers at teaching hospitals. “I’ve seen it happen that after a speaker presents, we get requests for the test the very next day. I also believe that it is up to the laboratory to take the lead and become the presenter.”

One strategy Dr. Boyle has used to make an impact on physicians is to use data on patients that have been in-patients in the institution. “Take the time to put together a presentation based on patients’ data and benchmark it to those findings seen in other hospitals. The physicians will pay much more attention if they feel the data is relevant to their patients. It is the laboratory’s responsibility to pull the information together scientifically to ensure there is sufficient evidence-based medicine there.”

To get your project started, simply start looking at a handful of CBC’s each week, and prepare to stratify the data into diagnostic groups (i.e., CPT codes). Then compare the collected data for RET-He by CPT code. Find what the accepted normal ranges of RET-He are in the literature, and evaluate your own patient population to that range. Evaluate if it is consistent to your patient population, and whether the RET-He result correlates with the treatment (i.e., transfusion, Epogen treatment). Dr. Boyle provides the example of two patients: the first with an Hgb of 9.0 g/dl, a RET-He of 37.7 pg/mL and Hct of 27.5%. In this case, there is the possibility that the patient has a sufficiently adequate storage of iron as indicated by the relatively high reticulocyte hemoglobin concentration (RET-He) level of 37.7 pg/ml, but a potential inflammatory condition may have impacted the non-cellular values (i.e., Hgb and Hct). If the physician is basing the diagnosis and clinical decision solely on the H&H, the patient quite conceivably would be treated for iron deficiency anemia (IDA). In the second example with Hgb of 8.0 g/dl, and a RET-He of 17.9 pg/ml, “the patient is presenting a profile of IDA. The point is that the physician needs to look at these patients entirely differently because of the RET-He, and the physician needs to treat the patient not treat a single test result.” More attention has to be paid by the physician to the impact of iron overload on patients that are at risk, and RET-He is a valuable marker in that process.

Dr. Boyle also gets out of the lab. He is a member of several hospital committees, including the P & T committee, Critical Care committees and others attended by physicians. “Winning over pharmacists can be great,” he says, “but you really need to get to

Reticulocyte Hemoglobin (RET-He/CHR)

Reticulocyte hemoglobin helps physicians identify patients at risk of iron deficiency (ID) and iron deficiency anemia (IDA). Historically, a hemoglobin (Hb) level of 11.0 g/dl or less has been used by physicians to define ID/IDA, after which the clinician triages the patient to understand the cause of anemia. RET-He has been shown to provide new insights into erythropoiesis and is a more targeted assessment of the iron available for hemoglobin synthesis in reticulocytes recently released from the bone marrow. Reticulocyte hemoglobin has been shown to be more sensitive and predictive than the traditional anemia-defining guidelines based on serum iron, Tsat, Ferritin and Hemoglobin measurements (1-5). Its value in the detection of iron deficiency anemia in end stage renal dialysis patients, including those receiving EPO therapy, has seen reticulocyte hemoglobin adopted by the National Kidney Foundation in its KDOQI (Kidney Disease Outcomes Quality Initiative) clinical practice guidelines for anemia in chronic kidney disease (6) and has been adopted as an evidence-based quality measure by the Agency for Healthcare Research and Quality (AHRQ), an agency of the Department of Health and Human Services, for management of patients in End Stage Renal Disease (11).

In the pediatric population, 2.1% of infants and toddlers in the US have iron deficiency anemia and 10% have iron deficiency without anemia. Clinical value of reticulocyte hemoglobin has been recognized and is now cited in the clinical guidelines for the diagnosis by physicians of IDA in children 0-3 years of age to increase the sensitivity and specificity of the diagnosis “since screening for anemia with an Hb determination neither identifies children with ID nor specifically identifies those with IDA.” (2)

Immature Platelet Fraction (IPF)

Just as a Reticulocyte relates to erythropoiesis, IPF is an index of thrombopoiesis by assessing platelets recently released from the bone marrow. It can be used by physicians to help determine the origin of a thrombocytopenic state by being able to differentiate between bone marrow failure and peripheral blood consumption or destruction. It can further be used to predict platelet count recovery. Zucker et al. (7), in a study which followed 50 patients undergoing peripheral hematopoietic cell transplants, showed that IPF recovered on average 3.1 days prior to the recovery of the platelet count. Briggs and colleagues studied IPF in autoimmune thrombocytopenic purpura (AI TP) and in thrombotic thrombocytopenic purpura (TTP) to establish a diagnosis of thrombocytopenia due to increased peripheral destruction (8). Others have suggested the value of following IPF in lieu of a bone marrow examination to predict platelet recovery (9) or as a decision-making tool for assessing the need for platelet transfusions (9, 10).

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<tr>
<th>Parameter</th>
<th>Application</th>
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<td>RET-He (Reticulocyte hemoglobin)</td>
<td>Measured at cellular level</td>
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<td></td>
<td>Helps physicians monitor acute changes in the Hb incorporation into reticulocytes</td>
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<td></td>
<td>May be used by physicians with other standard tests in the diagnosis of iron deficiency (ID) and iron deficiency anemia (IDA)</td>
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<td>Assists physicians in diagnosis of pediatric ID/IDA</td>
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<td>Helps physicians assess and manage End Stage Renal Disease patients</td>
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<td>May have an impact on transfusion rates in surgical patients</td>
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<td>IPF (Immature Platelet Fraction)</td>
<td>Indicator of bone marrow recovery of platelet production</td>
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<td>Helps physicians differentiate decrease platelet production versus increased destruction</td>
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<td>May complement bone marrow examination to predict bone marrow recovery</td>
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<td>Assists physicians in decision-making for the need for platelet transfusions</td>
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the critical care physicians. Once they accept it, it can filter out to the rest of the world. Also, attending physicians in specialties are very aware of changes and recommendations in their specialty of practice.” Furthermore, he recommends that every laboratory have a quarterly newsletter or that information can be distributed through a simple email process.

Even if you have done your homework, you need to make sure that RET-Hr is an “orderable” test. Physicians don’t appreciate you taking-up their time talking about a test they can’t order. The test must be validated and in the LIS with the codes assigned so that it will be properly billed, and then send out a notice that the test is available for ordering.” “You really only need to get two people on the bandwagon initially,” says Dr. Boyle. “You’ll get more.”

Members of the Scientific Marketing Group benefit from working directly with Sysmex customers and the reverse is true as well. Dr. Kunicka explains, “We are happy to help our customers with study design and evidence-based articles pertinent to their area of interest. We are also ready to support them with information to help the laboratory discuss new parameters or methodologies with non-laboratory personnel throughout the hospital.”

Now manufactures and laboratories have added an additional tool, principles of Evidence-Based Medicine, the analytical, clinical evidence that will support the implementation of new parameters and can help improve the standard of care across institutions and physician practices.

Sysmex News looks forward to following up with Dr. Boyle on the results of his pilot study on diagnostic efficiencies gained through the use of RET-Hr.

References


