Complete Blood Morphology (CBM): The Biggest Breakthrough Since the CBC Analyzer?

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Hey everybody, my name is Daniel Dees. I am from Brigham and Women's Hospital up in Boston, Massachusetts. We've been partnered with Scopio on several projects, but CBM has been a really exciting project.

I'm going to talk a little bit first about what I've been able to do in my lab with just workflow changes, and how you can imagine CBM decreasing the number of manual differentials that your staff is doing could help out in your lab. Then we'll get into a little bit of the data afterwards.

The Current State

Nothing new to anybody. The US Bureau of Labor Statistics estimates approximately 2,500 jobs are going to be open per year for the next ten years, with approximately 5,000 graduates coming out of the programs. So we know that math doesn't add up.

With that, an estimated 25 to 35% of our MLS workforce is going to reach retirement age within the next 3 to 5 years. This is really the one that keeps me up at night with my lab. It's closer to probably 40% of my technologists getting closer to retirement age, which is just a huge amount of experience to lose.

Morphology is experience-based. How good you are at it directly correlates with how long you've done it.

Often, volumes are increasing at a faster rate than the standard of 3%. We're seeing sometimes seven, sometimes 9% volume increases year over year. And there's just increased training and regulatory requirements - as these people retire, as you have a lot of turnover, you're having to retrain all of these people.

But we're in the lab. What do we say? We say it is fine. We work it out. We find solutions.

About Our Lab

When I was first talking to Scopio about this, this was a really exciting solution to a lot of these problems. We're an 800-bed hospital, second largest teaching hospital at the Harvard Medical School. It's a level one trauma center, and it's a comprehensive cancer center. So not only do we do a lot of diffs, we do very complicated diffs a lot of times.

Overall I have 47 FTEs. Nine of those are in my core hematology area. Two were directly assigned to the differential bench every day, and then other technologists kind of help as needed. I also oversee several specialty areas: flow cytometry, special hematology, and special coagulation.

In our lab we perform about 500,000 CBCs annually. The manual differential rate was about 15% when I started. We did an intervention outside of Scopio that increased it - it's about around 6% on average now. That's held steady. So down to about 9% less.

The Challenge with Manual Diffs

What that means - it's not less techs. It's different allocations of those resources. They were so stretched thin.

We had a lot of challenges associated with our differential bench:

- It's very labor intensive if you know
- Limited scalability of automation - there's not a lot of availability to automate this process currently
- Lack of standardization - I can read a slide, you can read a slide, we're going to get two different answers a lot of times
- It's tedious and repetitive - we don't put our techs on the bench multiple days in a row because they're reading so many diffs in a row
- Workflow issues you're all probably familiar with: day shift left us many diffs, evening shifts left many diffs for us

What We Achieved with Just 6% Reduction

CBM is capable of decreasing that rate significantly in your lab. These are some of the things I was able to do in my lab with just that 6% decrease:

I was able to allocate more techs to my night shift. Instead of five eight-hour night shifts, I was able to do four tens. It's a better work-life balance for the techs. I brought stability to a shift that was historically very unstable. The techs have loved it, and I was able to do it without going into administration begging for more techs.

It helps to avoid last-minute coverage. My overtime costs are down significantly since we've started this, and it improves those handovers and eases tensions. When I walk in in the morning, I'm not getting yelled at anymore, which is really nice.

We're doing integrated laboratory services in groups - very specialized testing at different sites. For us, we're doing flow cytometry. I was able to actually allocate several techs to that, two to four FTEs to that group as well.

I say all of this: I did not disregard any techs. I didn't let any FTEs go. I was able to allocate my resources better. That's what I pitched to the administration when I was going through a lot of these projects.

These are just some of the things that the CBM module will allow you to do in your lab.

Dr. Chris Hergott: Clinical Data & Performance

Good afternoon everybody. My name is Chris Hergott. I'm a hematopathologist at Brigham and Women's Hospital in Boston.

In the context of some of the challenges that you just heard, I'd like to talk a little bit today about why we're excited about our collaboration with Scopio to present a solution to many of these problems.

The Inevitability of Automation

As a hematopathologist - and I think anyone in the hematology field - we sort of intrinsically understand that automation is going to become part of our lives. It's an inevitability.

The questions that remain are:

1. What is the nature of that automation?
2. Is it actually going to make my life easier?
3. Is it going to make things faster or more efficient?
4. Can I trust it?

We're in a field where the error threshold is essentially zero. There is an intrinsic trust that is required with any new system that comes into the lab. The best way to establish that trust is through "trust and verify." I think what you'll find over the next couple of minutes is that Scopio and this platform in particular provides both of those things.

Full Field Microscopy

The first thing that this provides that I think is unique - and feeds into the "trust but verify" thing - is full field microscopy.

As opposed to a small sliver of the blood smear in which you analyze 100 or 200 cells, this provides the entire blood smear from the feathered edge all the way to the end. You can navigate it, pan it, and zoom it with high resolution up to 100x.

This feeds into trust but verify because if the software calls an abnormal cell, you want to see the cells next to it for comparison. You want to see its context. You may even want to see its distribution on the slide. And Scopio provides all of these things.

Fully Automated System

But that's not to underestimate the automation involved in this. This is a fully automated system. This is not decision support or singling out cells for your manual review.

If working properly, this goes from end to end without human eyes laying on it, directly into your LIS system, to provide standardized, reproducible, quantitative data.

The layer under that is that if you want to review it manually, you have the opportunity to do that at whatever level you'd like. For someone who is used to looking at glass, I find that to be very reassuring because you get the efficiency but you also get the verification.

The Pre-Clinical Study

Where I became involved with Scopio in this collaboration is this pre-clinical study - analyzing the performance of the CBM platform on thousands of peripheral blood smears from diverse individuals from a wide range of hospitals, asking the question: how does it actually measure up to what we have now? Does it actually deliver on the promises?

Benefits of Analyzing the Entire Blood Smear

- 1,000 white blood cells analyzed over 20 morphologic categories and axes of review
- 10,000 red blood cells because you have the whole slide at your disposal
- 5x more platelets

This means more diagnostic sensitivity and more statistically rigorous results. If you're tracking a patient, you don't have that wiggle we're all used to seeing, particularly with manual differentials, that can cause problems when dealing with chronically ill patients.

The Data: Normal Blood Smears

The first test is the baseline expectation for any new platform: does this do what manual review does? How does it handle normal blood smears?

We're comparing a normal 200-cell manual differential to 1,050 cells using the Scopio platform. If you bring in 100 or 1,000 normal blood smears, does it compare favorably? Does it match what we've been doing every day? The answer irrevocably is that it does.

In this example: 75% neutrophils, 12.5% lymphocytes manually. In the automated: 69% neutrophils, 11% lymphocytes. When they differ by a couple of percentage points, you'll notice that the thousand-plus cells end up being more accurate when you count more cells manually.

The benefit of sample size - without the additional time it requires for a human being to count a thousand cells.

Low Burden & Rare Findings

The other unique advantage I'm particularly excited about is low burden or rare findings.

Imagine you have a patient with CLL that you're tracking who's on treatment, or a patient with monoclonal B-cell lymphocytosis that you're monitoring.

Then you have 200 cells, your diagnostic sensitivity is at best 0.5%. Anything that is relatively rare or low circulating burden, you're not going to be reliably detecting. And especially if you're doing multiple tests over time, it may appear and disappear and reappear - a recurring problem in hematology labs.

What happens then is everyone gets sent for flow cytometry or molecular diagnostics on the order of hundreds of dollars per patient, because we have uncertain results.

The benefit of sample size with more than a thousand cells automatically counted is that these rare events show up, and they show up reproducibly.

In this example: 0.1% smudge cells, 1.2% LGL cells, and 0.3% aberrant lymphocytes with nuclear abnormalities that may raise suspicion for a low burden of a lymphoid neoplasm.

Now with this information, you can make an informed decision about whether it's worth sending for flow cytometry - as opposed to just blindly sending everybody, which is a suboptimal use of laboratory resources.

Complicated Blood Smears & Lymphocyte Classification

The other thing this does well - because of standardization and optimization - is it can deconvolute especially complicated blood smears.

One area where reproducibility is recurrently poor is in categorizing and understanding abnormal lymphocytes. If you have a spectrum of lymphocyte morphology in your peripheral blood smear - are they reactive? What's the chance it's reactive versus some sort of subtle lymphoid neoplasm?

In this head-to-head comparison between a manual white blood cell count and the Scopio platform: 6.5% atypical lymphocytes, some LGLs, etc. And then 6% unclassified cells where reliably they can't make a definitive judgment - and we train them correctly: if there's that level of uncertainty, send it up the chain and have other eyes look on it.

That's the way to handle these cases clinically. But it obviously takes multiple people, multiple people's time, and resources.

Because of the sample size and because of the large number of blood smears used to train the model, we can more reliably and reproducibly categorize these into what might just be atypical or possibly reactive lymphocytes versus those that have a higher risk of representing a lymphoid malignancy.

Systematic Performance Analysis

So those are a couple of pinpoint pieces of data - specific examples where we feel there's a particularly good use case. But what is the meat of the data actually like? How does it perform when analyzed systematically?

This table shows the Pearson correlation for agreement between two human beings on the right - two people reviewed the same slide and we asked what is the degree of their agreement with each other. On the left is the Scopio CBM platform versus the mean counts from individuals, because that remains the gold standard.

Three key points:

1. At a constant level from 10,000 feet, the Scopio platform does as well or better in every category or nearly every category.
2. In particularly useful categories for me as a hematopathologist - mostly blast quantification, which is very important for tracking patients, particularly with low-level hematologic malignancies post-treatment - the agreement between individuals versus Scopio is better. It's great if you can segregate bands from neutrophils, but that's very rarely clinically urgent. Quantifying the number of blasts reliably can often dictate treatment decisions on the order of hours to days.

Cell Type	Correlation coefficient Scopio CBM vs. Average Manual	Correlation coefficient Inter-reviewer Manual
Lymphocytes	0.97	0.86
Neutrophils	0.97	0.98
Monocyte	0.93	0.77
Eosinophil	0.96	0.85
Basophil	0.60	0.59
Blast	**0.94**	**0.87**
NRBC	0.97	0.99
Total Immature	0.83	0.81
Aberrant Lymphocyte	0.68	0.39
Atypical Lymphocyte	**0.84**	**0.23**
Large Granular Lymphocyte	**0.84**	**0.53**
Metamyelocyte	0.55	0.48
Myelocyte	0.58	0.51
Promyelocyte	0.85	0.86
Segmented Neutrophil	0.95	0.97
Band Neutrophil	0.80	0.63

3. Returning to the lymphocytes - the trouble area for differentials. Among human beings looking at the same slide, the correlation coefficients are not great. They're in coin-flip territory. These are not bad people - these are people that have been working for ten-plus years. They're not bad at their jobs. There are just subjective borders to these decisions. But with a large number of slides used to train and statistically rigorous data from many cells, you can see improvements across the board for these discriminations.

Lymphocyte Data Deep Dive

Digging in a little bit more on the lymphocyte data: 0.23, 0.53, 0.39 Pearson correlations between humans. That's not really helpful for the patient.

We're doing the best we can. But you're seeing doubling of the Pearson correlation with the software.

So it's not just automation and it's not decision support. It is an automated, full-throughput system that provides efficiency while also improving the reproducibility of your calls.

Automation Rate

The last thing I'll emphasize is the automation with this.

We took 2,500 routine blood smears and said: let's try to put these through the fully automated pathway and see what percentage has no eyes on it - from slide gets analyzed to into your LIS. That means no manual review, and even no computerized manual review. Doesn't get flagged at all.

93% of blood smears go all the way through.

That leaves 7%. And even in that 7%, it just basically goes to what already exists - decision support, looking at snapshots of cells. Except now you can take those cells and look at them in context over the entire blood smear.

The Bottom Line

Daniel mentioned a moment ago: through a considerable amount of excellent work and effort from the lab, the manual review rate went from about 15% to about 9%. That's a huge achievement. But the floor here is 7%. And with further iterations and optimization in the lab, that will only get lower.

That leaves 7%. And even in that 7%, it just basically goes to what already exists - decision support, looking at snapshots of cells. Except now you can take those cells and look at them in context over the entire blood smear.

The idea is: not only is your data better, but it's going to come at you faster - and you can trust it.

Ready to see CBM in action?

- → Watch the full session: https://youtu.be/9AubG_YYWKk
- → Explore Complete Blood Morphology: scopiolabs.com/complete-blood-morphology-autonomous-analysis
- → Talk to our team: https://scopiolabs.com/book-a-meeting/