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Breaking the Chain: Navigating the Pitfalls of Total Laboratory Automation.

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Guest: Dr. Joe El-Khoury from Yale School of Medicine and the Clinical Chemistry Laboratory at Yale-New Haven Health.

Randye Kaye:

Hello, and welcome to this edition of *JALM* Talk from *The Journal of Applied Laboratory Medicine*, a publication of the Association for Diagnostics & Laboratory Medicine. I'm your host, Randye Kaye.

Total laboratory automation is now a common finding in mid- to high-volume clinical chemistry laboratories. Total laboratory automation integrates and physically connects the total testing process from the pre-analytical handling of clinical specimens to the analyzers that perform the tests and report results to the post-analytical storage of specimens in refrigeration units.

The benefits of total laboratory automation typically include increased efficiency, improved accuracy and precision of sample handling and results, enhanced quality assurance, and reduced hands-on labor time. However, total laboratory automation systems are a large investment, and they require laboratories to take careful consideration of the available options and configurations for their unique setting in order to maximize these benefits.

The September 2024 issue of *JALM* features a Laboratory Reflections: Professional Insights article that describes the typical process of selecting a chemistry automation system. The article highlights common pitfalls in the selection process and provides important considerations for laboratories going through this process.

Today, we are joined by the article's author, Dr. Joe El-Khoury. Dr. El-Khoury is an Associate Professor of Laboratory Medicine at Yale School of Medicine and Director of the Clinical Chemistry Laboratory and fellowship program at Yale-New Haven Health. Welcome, Dr. El-Khoury.

Joe El-Khoury

Thank you. It's a pleasure to be here.

Randye Kaye:

Let's start with this. Why should laboratories consider implementing a chemistry total lab automation system?

Joe El-Khoury:

Automation can bring a lot of benefits to the laboratory, especially if they're implementing it after being used to a

manual process for a long time. First and most obvious is improvement in efficiencies and standardizing entire workflow, so that you're creating a group of samples the same way every time and it's not dependent on every different operator handling it in a different way.

So, it can bring a lot of benefits in terms of making sure that you're creating those samples up front on the pre-analytical part, which is what we call when the sample is being centrifuged, decapped, aliquoted. All that can be handled now in automated modern analyzers, so that it's not a single person who's doing it, or different people doing it that could affect how it's being handled that could cause errors.

So, a reduction in errors is a primary reason why generally labs move towards automation. But in addition, you get improvements in workflows and efficiencies so that you no longer have samples that take longer than others for the same process. You generally have sometimes even quicker turnaround time with improved distribution of your turnaround time results, so that samples are faster, and consistently faster, versus the old manual process. It depends on the people and how they're running one sample from one end to the other. If it's lunch, it may take longer because you have less people.

So, with automation, generally, it takes care of a lot of these variabilities and improves overall. So it improves overall efficiencies of the lab at a generally lower cost and having the same full-time employees doing all of these operations, in addition to essentially making sure that there's less error that could happen due to manual intervention, or also transcribing results is another thing that could go wrong once you have that result if you're doing everything manually. So automation can bring a lot of benefits to the lab once implemented.

Randye Kaye: All right, wonderful. And we all love the personal touch but consistency is very, very important. So how would or should a clinical laboratory go about selecting an automation system?

Joe El-Khoury: So, this is the part I've tried to introduce in the letter we published. But basically, simplifying it, it's a process. So in the beginning, you're trying to gather as much information about the different solutions out there because there's more than one, and I wish I could go on Amazon and just click "laboratory automation" and look at the reviews and just choose one. But the process takes years sometimes to prepare for because simply there are too many solutions and too much information to gather to determine which one is the right one for you.

So the first step I would recommend for everyone who's looking to start the process is you need to begin with what they call an RFI or RFP, which is a Request for Information or Request for Proposal. This is a document that you can prepare your list of questions to the IVD manufacturers who make these systems, and you choose who you want to include in the process. Typically, there's what we call the big five which I won't name them, simply because we're not trying to advertise, but there could be more out there and I don't want to be missing anyone.

So choose the automation vendors, and if you're not familiar with those vendors, think about going to conferences and conventions, where typically lab medicine specialists gather, and where there are exhibitors, like ADLM typically has most of these vendors there, so you could go in and take a look, and know who would be good to invite to the process.

So, during that process, again, you send them questions, they get back to you with the responses, and then you could filter too if there are ones you prefer over others, then you move to the next stage and doing what we call the site visits.

So, the site visits are typically your opportunity as a laboratory professional to go visit labs with implemented each particular manufacturer solution so you can see how it looks like in real time in the lab, not just sitting there looking nice in an expo floor, and more importantly, how does that lab staff like their automation and the whole implementation process. So as part of that process, I recommend having alone time with the customer who's implemented the solution without the IVD manufacturer representative there to kind of get to feel a real sense of how well the system performs and how they like it.

So after you've done the site visit, gotten a sense of how it works for another lab, now you really need to make sure you customize it to your own site, so you typically can have to give data to these IVD manufacturers. So they may ask you for data about how the sample flows in your lab and how you're giving out results for all these different tests. It's something they can easily pull out themselves from your laboratory information system to get a sense of how many samples you're seeing at different times in the lab so they can custom design the solution for you. And so, they will ask you for that data and you usually, you're going to arrive in an agreement, give them the data and then they come back and present to us what they think the automation solution should look like for us.

And so, then from that part on, you basically look at these different solutions that are presented by all of the vendors, you get the costs associated with each solution, and then

you're left to making a decision, hopefully after also talking to clients of each one to get a sense of which one seems to have the pro-- what are the pros and cons and which one would work better for your lab. So that would be it in a nutshell.

Randye Kaye: Okay, that spells it out. Thank you. But what are some of the common pitfalls in the selection process?

Joe El-Khoury: So if I can focus on one major one, which was the central focus of the article I wrote, was essentially that there's a failure to plan for failure of these systems. Typically, when a vendor collects your laboratory data, as I mentioned, in terms of customizing the solution for you, they will get let's say May 7, 2022's data. They plug it in and they come back and say this is the solution, this is what your turnaround time will look like throughout the different times of the day. It looks great. But then what they fail to do in my experience is they don't really also talk about what happens when this part of the line is down.

I mean, the solution they presented is great for May 7, 2022, but May 8, May 9, May 10, I may have different things happening, including often parts of the lines going down, whether it's for maintenance, scheduled or unscheduled, which can be a problem because without that type of planning, it then becomes all hands on deck, people going back to a manual process to keep things flowing in the lab because we can't simply stop treating patients, and we have to keep putting out results.

So that's one of the major issues I find with how automation is designed today, and having a failure in terms of planning to what will happen when each different part of the line fails. So, in laboratories who are going through this exercise now or planning to, to also ask manufacturers to present you with data on having each different component of the line down, especially if you don't have redundant parts. So that could be one way that this could be addressed.

Randye Kaye: You may have already answered this, but anything else about how laboratories can avoid or mitigate these issues?

Joe El-Khoury: So you're right. I did give one part of it away, which is especially focusing on making sure that you ask those questions to vendors. But when I want to add is one way to avoid this happening all together, which is what labs who have had great experiences with automation have done is building redundancy in the process.

So, if you have a single point failure in your automation design, which it will guaranteed, because automation much like people who take vacation time, sick days, and weekends,

with automation it sounds like we don't plan for it to go down whether it's, again, scheduled or unscheduled. And one way to avoid having to need to do that is by making sure you have at least two of everything that you need including -- centrifuge is much more usually, but aliquoting modules, output buffers, refrigeration units.

So the labs that have done really well with this are typically labs who have implemented complete islands of automation that allowed them to have redundancy in the full process from beginning to end so that they could afford to have different parts of it down.

Now, I know not all labs have the money to have that kind of development, that you have two major refrigerators that are on board at your automation line.

But at least what you can do as part of your design, again, plan for what would happen if that refrigerator is down. Maybe place a small output buffer area next to a specific area where your staff can handle those specimens so you're not completely shut down when that happens.

So that would be -- one way where you can mitigate this is by either trying to get two of everything, or at least changing your workflow so that when one thing is down, you can still operate and it's not a nightmare for your staff.

Randye Kaye:

All right. Thank you. And the final question here, I guess is, what advice do you have for early career laboratory professionals who might be going through the automation system selection process for the very first time?

Joe El-Khoury:

First I'll say, I recognize this process can be daunting and you feel like there's such a big decision that's falling on your shoulders in having to do this. First, start early. That's a key part of the process. As I mentioned, when I started this for my lab, I basically spent two years going through that process. But not everybody may have that and it's understandable. So what I'll add then is at least it may be helpful for you to learn that there is no wrong decision.

So, the fact that all of these IVD manufacturers exist, they have experience doing this, whatever you choose, you will be okay. But that is a solution that may be more ideal for your lab and that's what we try to achieve as laboratory directors. We try to identify which of these solutions will work best for us. Otherwise, what ends up happening is your team is going to have to develop workflows around these inconvenient issues with the system to make it work and that's tough to deal with.

So, one advice I have for you to avoid all of this, now that you hopefully don't feel stressed about the decision, is recruit people across the spectrum in your hospital to go select and to go view and make that decision.

I've seen labs who do this, who limit the people who go on site to the leadership team, and that's a bad approach to this. You want people from your medical technologists who are doing the testing to be involved. You want people who are your front-end sample processing staff to be involved with this because they are the people running the system. They're the people who need to be comfortable with the software and how the system operates. So, get people from different parts of your lab who are involved with different aspects of the line so they can also be involved in the decision. In this case, it's not just about the expertise they bring to the selection process, but also the buy-in you get from having them involved and being fully committed to the implementation process.

So as you approach this, my key recommendations to you again, is start early and don't stress out too much because again, there is no wrong decision, and get a broad group of people involved in the process, and I wish you the best of luck. If you're ever in doubt, or need help, remember the last one is ask colleagues, reach out to a friend, that's why we're here to help.

Randye Kaye: Well, that is very realistic and excellent advice. Thank you so much for joining us today.

Joe El-Khoury: Thank you, it was a pleasure.

Randye Kaye: That was Dr. Joe El-Khoury from Yale School of Medicine describing the *JALM* article "Breaking the Chain: Navigating the Pitfalls of Total Laboratory Automation." Thanks for tuning in to this episode of *JALM* Talk. See you next time and don't forget to submit something for us to talk about.