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Rising to the Challenge: Shortages in Laboratory Medicine

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Moderator: Claire E Knezevic. Experts: Barnali Das, Joe M El-Khoury, Paul J Jannetto, Felicitas Lacbawan, and William E Winter.
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Guest: Dr. Barnali Das from the Biochemistry and Immunology Sections of Kokilaben Dhirubhai Ambani Hospital & Medical Research Institute, in Mumbai, India.

Bob Barrett: This is a podcast from *Clinical Chemistry*, sponsored by the Department of Laboratory Medicine at Boston Children's Hospital. I'm Bob Barrett. At the beginning of the SARS-CoV-2 pandemic, an immediate impact on everyone's day-to-day lives was the sudden shortage of essential consumable goods such as soap, hand sanitizer, shelf-stable foods, and of course toilet paper. With lockdowns, workplaces reduced staff density to maintain social distancing, countries employed travel restrictions, and the production and shipping of goods decreased. This caused mass shortages in the workforce, which were further compounded by existing staff becoming sick and the older workforce choosing to retire early. Healthcare, where ubiquitous disposable items provide safety and consistency to nearly every task, was far from immune to this phenomenon. Healthcare providers suffered shortages of critical items such as gloves, masks, collection kits and containers, pipette tips, reagent packs, and disinfectants at variable time intervals as successive waves of the pandemic rolled across the globe.

The ripple effects of these shortages continue to be felt by the healthcare industry and have necessitated changes in how business is conducted. Our approach to these challenges as individuals and as a community will undoubtedly impact the success of laboratory medicine for years to come. A Q&A feature appearing in the December 2022 issue of *Clinical Chemistry* examines shortages in laboratory medicine over the past few years. Five professionals from around the world and across various settings shared their experiences with labor and supply shortages to shed light on how the field can move forward in this new reality. We are pleased to have one of the Q&A participants in this podcast. Dr. Barnali Das is the lead consultant of Biochemistry and Immunology sections of Kokilaben Dhirubhai Ambani Hospital & Medical Research Institute in Mumbai, India, and she is active with the IFCC as well as AACC. So first of all, Dr. Das, can you summarize the leadership strategies that you personally adopted during this pandemic?

Barnali Das: Thanks, Bob. That's a really very important question. So as you know, I'm from India and India is diverse in terms of

ethnicity, habits, cultures, practices, location, healthcare needs and resource availability, and budget allocation, of course. So India is one of the most populous countries and dealt with mass casualties due to this COVID pandemic in a holistic and comprehensive manner. So during the pandemic, we faced disruption in the supply chain, felt the huge extra demand on the overall system as the rest of the world. Every time, a new set of challenges are faced in different waves and varied in different sectors. We faced unrealistic demands for low-end items and price hikes for commodities like gowns, masks, gloves, and hand sanitizers. So for the high-end laboratory items, we faced reagent shortages, interrupted services, and supply reduction. So during the lockdown of the first and second waves, the workforce shortages became a major issue. So we faced several roadblocks in supply chain management, workflow simplification in supply chain was a challenge. So during the pandemic with demand uncertainty, many matrices like field rate, service-level turnaround time, and safety stock were compromised and we needed to deal with these factors.

Bob Barrett: What physical supply shortages and staffing shortages have you faced since the beginning of the pandemic and how did that impact your practice?

Barnali Das: Yes, during this pandemic, labs like us or the physician -- laboratory physicians and other key stakeholders have risked -- Like you know, we faced a lot of challenges and we have responded to the challenge with initiatives to standardize and harmonize inventory management because that was the major challenge, that supply chain management resource allocation. Then, we took initiative in total cost of ownership, codification and implementation of digital technology systems to drive supply chain efficiency to maintain the healthcare ecosystem. The three key strategies we have taken like codification, standardization, and global harmonization built efficiency in the supply chain mentioned by all the other experts worldwide. So efficiency depends on commercial excellence, demand management, and compliance management system to mitigate the impact of supply chain shortages.

So therefore, we did risk-adjusted monitoring. This risk-adjusted monitoring helped us plug many leaking parts of the supply chain and helped build the trust of our patients. Supply chain shortage, price hikes, unnatural demands during the peak of pandemic forced us to rely on more than one source of supply and look to the surrounding areas. We became dependent on local vendors for low-end and high-end items instead of depending on regional, national, and international supplies. So we encouraged and promoted larger supply chains and our neighborhood distributors. So, inventory management practices such as early ordering,

cross-checking of the inventory review, implementation of contingency plans, extra buffer stock, and creation of back-up roles for laboratory staff, these were prioritized. An implementation of more Make In India incentives have ensured better local supply availability and shortages can be better handled in the future.

Bob Barrett: I have a third question here, but I think you've already answered it. The question is what successful strategies did you use to mitigate the impact of the supply chain and labor shortages? I think you pretty much answered that already, right?

Barnali Das: Yeah. Yes, I can talk about the manpower shortages. Like you know, labor shortages. So the most important shortage that was faced by every institute, I think worldwide, was that of the manpower. So due to this turnaround time increase, results were delayed. Overburden of the 50% of the staff because that was working and that increased stress. So this stress was mitigated with the help from the -- everyone, all the stakeholders. And training, re-order level, and good coordination with the purchase department, management team, administration, back-up creation was done. A lot of cross-training happened and weekly follow-up with vendors was done. So if I talk about the leadership strategies for manpower management or labor -- how we have tackled the labor shortages or how we have taken care of the mental stress during this pandemic.

So some of the leadership strategies -- like, we actually involved everyone from top to bottom in solving the challenges. If you know the Kaizen Principle -- so that helped us tremendously. Kaizen is a kind of quality circle and yeah, we talk about incremental improvement. So in that, we used to have every alternate day meetings with our staff. And we used to discuss how we can improve in our day-to-day lab practices. So as *Atomic Habits* says, 1% better every day. So we used to take each individual. Each one of us used to take one small habit change or one small implementation in our lab lives so that actually 365 days, 365% of improvements, so that's the strategy we applied.

Bob Barrett: It seems you -- since the beginning of this pandemic, you've evolved as a laboratory physician. Do you want to tell our listeners a little more about that?

Barnali Das: Absolutely. So this is kind of a story how we evolved as a lab physician, how we evolved as the clinicians, how we evolved as a -- like you know, from IVD sector. So in India, actually the private public sector partnership evolved during this pandemic. All the stakeholders have played a very crucial role to fight against this pandemic. Everyone took the onus to contribute in this difficult time. Let me give you some

example of one case history. With this, you can understand our journey and how we all lab physicians, clinicians, diagnosticians, purchase department, administration, and IVD Sector have collaborated and worked hand-in-hand for saving lives. So one fine Sunday morning of March 2020, I had a continuous buzz from my cellphone. At 6:00 a.m. in the morning, I received a call from our intensivist from ICU. Within a few minutes, our infectious disease consultant called and gave me a detailed history. She said that she wanted me to process one stat sample for Interleukin 6 as they wanted to start tocilizumab. Tocilizumab is a drug which cause Interleukin 6 receptor block it, so for one critical patient. So that time, they wanted baseline value of Interleukin 6 before starting the treatment.

So, that patient was a 69-year-old physician from some other hospital, having breathlessness and showing features of acute respiratory distress syndrome. And for this patient, all the routine lab markers were like, abnormal and cytokine storm is raging, and there is more and more requirement for the oxygen support. So at 7:00 a.m. in the morning, I was making pancakes for my child. So I was lost in thought as to how and what should I do as we were not using Interleukin 6 at that time. So I called most of the labs in the neighborhood, in the city, but none of them were doing Interleukin 6 and it's a Sunday morning. Immediately, I started calling my IVD contacts to arrange an IL-6 kit. The IVD vendor, or In-Vitro Diagnostic people, they opened their warehouse located in the outskirts of the city on a holiday with special permission and gave us the kit before 9:00 a.m. So we were having, that time, lockdown of transport system and there is only -- there was staggering of the staff in the lab. So there was only one staff in Biochemistry Department. So I called the validation technical team. So they reached the hospital. Then, our validation protocol is 5 to 20 days so I called the experts from AACC, CLSI, and College of American Pathologists for guidance for emergency stand validation during pandemic.

So around 11:00 a.m. we released our past Interleukin 6 report. So by this incident -- This incident actually taught us so many important life lessons: unifying for a patient's safety, unifying for a greater cause, integrity, responsibility, and team-building to build a healthcare ecosystem or diagnostic ecosystem. So this is kind of how we have evolved. And here I believe the philosophical lines of Albert Einstein in our lab life's journey. "Life is like riding a bicycle. To keep your balance, you must keep moving." So if you can think about this bicycle, there are two wheels. One is the wheel of healthcare ecosystem where supply chain staff or labor, or public-private partnerships, these all are important for healthcare ecosystem. The second wheel is the wheel of cause, where three magic M's: man, machine, and materials.

These three M's are very important. And all stakeholders took the onus to harmonize this to wheel of lab so that we can have a smooth ride in our lab life.

Bob Barrett: And after all that, I really want pancakes now.

Barnali Das: Thank you.

Bob Barrett: Doctor, you mentioned previously that conducting that study--clinical laboratory leadership and management during a pandemic--talk a bit more about that survey and the results that you found.

Barnali Das: Absolutely. So actually, during that time -- Actually, during the first waves and second waves, we conducted one electronic global survey on clinical laboratory leadership and management during a pandemic. So we received responses from people who have been involved in senior management, middle management, and also juniors, along with the faculty in charge, nodal officers for RT-PCR duty, and people who participated include lab directors, and then consultants, faculty in charge, and chemical pathologists, biochemists, pathologists, and heads of laboratories. So the challenges faced due to the shortage and the subsequent unavailability of reagents, the PPE kits, and other testing materials was faced by almost all the participating institutions when they responded in the survey. The shortage led to increase in the cost of PPE kits, gloves, masks for the few months, but they were resolved shortly as the production increased. So to overcome this supply shortage, there are several measures taken by the government, such as intervening by hospitals themselves, outsourcing of the testa to the other centers, prioritizing of which tests needs to be performed in urgency, suggesting alternative tests.

Inventory management needed to be done as a priority at all the places. Some of them are early-ordering, procuring more reagents for routine parameters, cross-checking of the inventory review by different people, shift supervision, implementation of contingency plan, extra buffer stock and batch practice, and most importantly, creation of a back-up role for lab staff. The supply chain management was done by different agencies at different places. The central medical supply and the regulatory authorities managed this situation.

More Make In India incentives can ensure that such a situation can be handled in a better way in the future, and then remote LIS access. I used to -- Any time, morning 5:00 a.m. or like night 10:00 p.m., I used to have remote LIS access. Cloud-based servers and more automations are the future tools that can help avoiding such shortage problems in the future. So this was the response, mainly the response from the different institutes globally.

Bob Barrett: What changes have you and your institute implemented to plan for future supply on labor shortages?

Barnali Das: Actually, we have taken a couple of strategies. The prospective strategies for better preparedness like mode-dependence and trust-building with the local suppliers, building resilience in an increasing size of the supply chain, quantifying risk measures, business continuity planning, and capacity-building, and then digital transformation for inventory management, up-scaling the scale across all specialties. This impacted the clinical outcome, so cross-training mainly, and centralized command center or system for supply chain, and identifying the right resource for the right patient for the right purpose, and cultivating and nurturing private-public partnership. So this is where -- we have taken for our institution and if you talk about Indian government -- So actually, the Indian government and healthcare and diagnostic industry have built capacities and acted promptly to ensure smooth production and supplies.

Bob Barrett: So how has the regulatory environment in India impacted your response to these shortages? And what changes in the regulatory environment are necessary to allow the field to deal with future shortages of materials?

Barnali Das: So, the Indian government treated this national emergency with utmost care within the form policy, advocacy, implementation, and enforcement. So there were centralized emergency management systems. These were created for allocation of resources like COVID beds, oxygen ventilators in Tier 1 and Tier 2 cities. I was also part of COVID task force. So I remember we used to get calls, like any hours during the day and night. So this actually -- Everyone took a responsibility to help the government to solve the problems. So however, a uniform standard of care was not available in Tier 3 cities and villages. So challenges faced across the country are gaps in infrastructure, miscommunication about demand and supply, and leaking inventory management. So to deal with the future shortages, we must better prepare for future outbreaks through integrated digital supply chain solutions, up-scaling of the workforce, and to address major disruptions of the in vitro diagnostic industry supply chain. The healthcare sector majorly reorganized this process engineering, digitized its supply chain infrastructure, and transformed these operations.

Bob Barrett: Well finally Dr. Das, you mentioned that digital health is now an integral part of this journey for you. Can you share some more on that?

Barnali Das: Absolutely. This was a very little event because we have seen the digital transformation journey. So the digital

transformation of supply chain enabled us to leverage data-driven decisions and real-time monitoring. So globally as mentioned, by all the experts, we actively adopted technologies like data analytics, artificial intelligence-based predictive models, compliance management systems, codification of rates and masters, and data standardization in decision-making. So like healthcare diagnostic and IVD sectors have effectively evolved their supply chains for breakthrough, efficiency, better productivity, and optimized operations. So the implementation of AI, or artificial intelligence, cloud-computing, machine learning or deep learning, adoption of paperless workflows, are instrumental in the transformation of laboratory, more specifically influencing clinical validation procedure efficiency, data handling, data analysis, and much more. So AI helps in computing risk stratification scores for laboratory data, and clinical data using expert system and evidence-based guidelines. Like, we also have risk-stratified mild-moderate, severe cases, and we are trying to develop some web-based tool for risk stratification of COVID cases.

So, increasing cost containment ratios make the application of this technology highly approachable. So thus, implementation of AI improves revenues, suggests patient-centric like, next-step test utilization, improves quality, standardizes treatment protocols as per local and international guidelines, improved patient satisfaction, provides patient-specific interpretation and next steps and improve standardized care by flagging the patients, apply risk algorithms, and better patient interpretation by electronic health record, EMR or electronic medical report.

Bob Barrett: This is great information. Thank you so much for taking time today.

Barnali Das: Thank you. Thank you very much. And actually, seriously, I want to mention in India there is National Digital Health mission. So, they are planning to have health ID, digital ID, personal health records, DG doctor and health facility registry. It will also include e-pharmacy and telemedicine services. If it is implemented fully, that will revolutionize healthcare.

Bob Barrett: That was Dr. Barnali Das from the Kokilaben Dhirubhai Ambani Hospital & Medical Research Institute in Mumbai, India. She participated in the Q&A feature in the December 2022 issue of *Clinical Chemistry* on shortages and laboratory medicine, and was our guest in this podcast on that topic. I'm Bob Barrett. Thanks for listening.