In Italy, lessons learned for lab testing

June 2020—*The key lesson for policymakers and hospital administrators stemming from the pandemic is that continuing to cut human and economic resources will create large organizational issues when the entire system of care, including laboratory diagnostics, is challenged by "an enormously amplified volume of tests to manage emergent situations," write Giuseppe Lippi, MD, of the University of Verona, and Mario Plebani, MD, of University Hospital of Padova, Italy, in an opinion paper published online March 19* (*Clin Chem Lab Med.* https://doi.org/10.1515/cclm-2020-0240).

They write that high-throughput instrumentation, too few employees, and reduced levels of health care funding, especially for public facilities, "all contributed to considerably reducing the flexibility to develop emergent responses" to viral outbreaks, the most recent being COVID-19.

With laboratory diagnostics central to future viral outbreak response, they are hoping what has been learned will not be forgotten.

At the University of Verona, Dr. Lippi is a professor of clinical biochemistry and clinical molecular biology; he is also director of the clinical chemistry and hematology laboratory at the university's hospital. Dr. Plebani, at University Hospital of Padova, is a professor of clinical biochemistry and clinical molecular biology and chief of the laboratory medicine department. They spoke with CAP TODAY *writer Meredith Salisbury on April 27.*

"What we should learn from this lesson," says Dr. Giuseppe Lippi (right), here with Dr. Mario Plebani, "is that working at the minimal viable standard is not enough."

How have automation, high-throughput systems, smaller clinical lab teams, and less funding changed the ability of labs to respond to an emergency like COVID-19?

Dr. Plebani: The consolidation and downsizing experiences of the last few years—starting in the U.S. but moving to Europe—have strongly decreased the power of clinical laboratories to answer some challenges, such as the COVID-19 outbreak. In Italy and in other countries, the limited capacity for molecular tests, serological tests, and other laboratory testing is due to the decrease in the power of the laboratory professional and to the view that laboratory tests are commodities.

This is a great opportunity, first of all to make visible to all citizens and communities the importance and the key role of clinical laboratories in modern health care. Second, clinical laboratories, particularly in the public sector, should have the staff and technological facilities to answer the challenge of an outbreak such as COVID-19. Third, there are many commonly requested tests such as CBC that play a great role in distinguishing severe from mild disease. In addition, some new tests such as the MDW (monocyte distribution width) and presepsin have been found very promising. This is very important in managing COVID-19 patients. This should teach us to make more

visible to the public the role of clinical laboratories and laboratory medicine in diagnosis, in prognostication, and even in surveillance of infected patients.

In the paper you suggest that a network of regional labs could help absorb spikes in testing demand, rather than leaving it to each individual lab to scale up. Does this exist anywhere?
Dr. Plebani: In Italy, until some years ago, laboratory professionals did create a network and exchanged experience and data based on voluntary willingness to increase the quality of laboratory medicine and make possible better care for patients. In the last few years there was a trend toward more autonomous organization. This is absolutely wrong. In this outbreak we did realize once again the importance of a network—of cooperation and collaboration.

Dr. Lippi: This virus caught us totally unprepared. We had some kind of reminder with SARS almost 20 years ago, but that was limited to 700 deaths. We have been saying to our hospital administrators and policymakers that cutting down the resources and working at the minimal viable standard would be trouble, not for working in our daily routine but for facing these challenges. This is a virus, but the same situation can happen with an earthquake or a tsunami. What we should learn from this lesson is that working at the minimal viable standard is not enough. This is a lesson we cannot forget.

You say in your paper that the suggested network of regional clinical laboratories in turn highlights the need for "better and wider harmonization of laboratory results and information." Can you tell me more about that?
Dr. Plebani: Harmonization is mandatory. We have to make the laboratory information comparable. That means that different labs in different parts of the world should ensure the comparability of the laboratory results and information—as well as the same preanalytical procedures and the same postanalytical reference intervals, decisions, and units. This is a great effort. Scientific societies in the U.S. and international societies should be more interested in this project.

Are there any other lessons we should learn from this pandemic to be better prepared next time?
Dr. Lippi: Everything is a good lesson. We had some troubles because we didn't have so much experience in dealing with this virus, so we had to start everything from the beginning. For instance, I had to send as many as eight of my technicians to the virology department to manage manual processing of the specimens due to the lack of automation. I had to downsize part of my laboratory to supply the personnel to virology. The lesson we have learned is that we probably should have more technology and be more prepared to face this challenge.

Dr. Plebani: I totally agree. This is a lesson that laboratory medicine should not be in silos in which there is clinical chemistry or hematology or microbiology or virology. We have to work as a department. In this case, my clinical biochemistry lab needed to work in the molecular field, and in a few days, we were able to provide more than 800 molecular tests per day. Our technicians now realize that by moving from the virology unit to the clinical biochemistry unit, they can learn and improve the way to perform tests and enable better management of the workflow and workload.

Dr. Lippi: What we have learned from this disease, paradoxically a viral disease, is that all the biochemical and immunochemistry tests are strongly driving the clinical decision-making.

Dr. Plebani: This reinforces the idea that this outbreak creates a fantastic opportunity to make much more visible the new value of clinical laboratory medicine, not only for patient monitoring but for patient management and for the clinical decision-making process. We cannot miss this opportunity.

What has the response to your article been?
Dr. Lippi: We have received a large and positive feedback, as attested to by the impressively high number of downloads and citations—nearly 20 in less than two months. This perhaps reflects the fact that the concepts we put forward in our article are actually shared by the worldwide community of laboratory professionals.