MEDTECH INSIGHT
CITELINE COMMERCIAL

11 Jan 2023 | **Interviews**

The Time Is Now: Paper Argues US Needs National Diagnostics Plan Before The Next Pandemic

Public-Private Partnerships Key

by Brian Bossetta

The US needs a comprehensive plan to meet the country's testing needs in the earliest stages of an infectious disease crisis, according to a paper posted by the John Hopkins Center for Health Security. The authors of the paper say government and industry collaboration is essential in creating such a plan and urge both sectors to act now.

A crisis is worsened when the lessons from it are not applied to tackling the next one – or better yet, preventing it entirely.

And preventing the next one – or at least keeping it at bay – is the idea behind a plan detailed in a new *paper* co-authored by Johns Hopkins Center for Health Security (CHS) and the American Clinical Laboratory Association (ACLA) calling on the US government and private sector to establish a national diagnostics plan before the next health crisis emerges, which, they say, surely will.

The authors of the preprint paper say the nation's "diagnostics testing ecosystem is a critical piece of the US public health response system" and describe that system as a complex tapestry of public and private institutions held together by the essential thread of clear communication. They further argue the COVID-19 pandemic, monkeypox, and other public health challenges have shown that without a plan, diagnostic testing "will not materialize on its own."

Two of the authors, Susan Van Meter, president of ACLA and Gigi Gronvall, senior scholar at the

CHS and associate professor in the department of environmental health and engineering at the Bloomberg School of Public Health, spoke to *Medtech Insight* about the plan and their blueprint for building it.

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In creating their national diagnostics strategy, Gronvall said she and her co-authors were inspired by the "extraordinary efforts and institutional arrangements" made to get testing up to scale during the COVID-19 pandemic and then again for monkeypox – but then to also make sure the next time around "we don't have to start from scratch."

SUSAN VAN METER

At the start of the pandemic, Van Meter was the executive director at AdvaMedDx, the trade group's diagnostic division. That experience, she said, allowed her to see firsthand the state of testing early on and what it took to get testing up to scale.

Partnerships

For the national testing plan to work, according to the report, its foundation has to be the collaboration between the public and private sectors. During the pandemic, Van Meter said those partnerships worked at breakneck speed to meet an unprecedented need.

"There were extraordinary efforts on the part of public and private sector to get the response moving," she said. But the problem was the virus got the jump on both sectors, which resulted in a scramble to catch up.

"So we want to learn from the lessons of the pandemic and make concrete and permanent institutional arrangements and policies so right when there's a new pathogen of concern identified we've got the infrastructure built, and we can flip the switch more readily to rapidly scale up to develop new tests if needed, or to take an existing test and scale it as swiftly as

possible," Van Meter said.

The value of the private sector was also demonstrated during the 2022 monkeypox outbreak, Van Meter said, when the government and commercial labs worked in tandem to expand testing capacity.

By early July 2022, the report states, five commercial laboratories were partnered with the CDC augmenting the nation's monkeypox testing capacity to 80,000 tests per week. On its own, the CDC's Laboratory Response Network (LRN) could only supply 10,000 per week. This allowed clinicians to submit more samples for testing and helped to ensure that when monkeypox was at its worst, testing volume was up to task.

But, as Van Meter pointed out, ramping up testing when a diagnostic already exists for an identified pathogen is difficult enough, but becomes exponentially more challenging when there's no test available and the virus is a novel one, as was the case in March 2020.

"With a new pathogen, it's going to take longer, in part because you actually need those patient samples to be able to develop and then validate the tests," Van Meter said, adding that in the very early stages of COVID-19 there were few samples for test developers to use to validate their tests with the FDA.

"One of the issues we hit on in our report is making sure that there is a coordinated and concerted effort when it's a new pathogen of concern to ensure that the limited set of samples is used judiciously and in collaboration with test developers," she said.

> ***"The demand from the COVID-19 Delta and Omicron surges exceeded the nation's existing testing capacity requiring the government and private-sector partners to move urgently to meet testing needs." – Susan Van Meter et al.***

One measure that the federal government can deploy to scale up testing is the Defense Production Act (DPA), a wartime measure that compels private companies to increase production.

In a September 2021 speech, President Joe Biden said he planned to use the DPA to help make up the nation's lag in testing. Even then, Van Meter was pushing for more engagement between

government and commercial manufacturers.

Before Biden's speech, Van Meter – then with AdvaMedDx – coauthored a letter urging the administration to strengthen public-private preparedness collaboration with the CDC, private sector laboratories, and diagnostics manufacturers saying it was "critical to ensure up to date diagnostics are available and rapidly deployed, and laboratory capacity is maintained." (Also see "*Biden Turns To Cold War Measure To Expand Access to COVID-19 Tests*" - Medtech Insight, 10 Sep, 2021.)

But while the DPA is a useful tool for expediting production during a crisis, the idea behind a national diagnostics plan is not getting to that point in the first place.

"The partnerships that we're talking about are really kind of baseline arrangements and collaborations that really should be contemplated in times when we don't have an emergency," Van Meter said.

One Size Fits All

Another pillar of the plan, Gronvall noted, is the predictability of a coordinated federal strategy. "Having a state-by-state strategy is generally not a successful way to have a public health response," she said.

GIGI GRONVALL

As it stands now, local, tribal, state, federal, and private health information exchange reporting requirements are "a patchwork system," the authors write, that generates inefficient and unnecessarily duplicative health data, as well as costs to reporting providers. They advocate that the federal government should establish "a uniform, single, national, accurate, actionable" public health data reporting policy that standardizes data sets and delivery mechanisms for that data.

The plan also recommends Congress, or the president through executive order, establish a "national testing coordination forum" to focus on preparedness and response for disease emergencies. This forum, housed within the Department of Health and Human Services (HHS), would meet regularly and provide recommendations to the HHS Secretary, White House, and Congress.

The authors recommend the forum include leaders from public health-sector agencies and

departments integral to diagnostic testing, as well as representatives of public-sector, commercial, and hospital laboratories, private-sector organizations that represent diagnostic manufacturers, and health care product distributors. Private-sector participants, the authors say, should be representatives of industry trade organizations whose members have the capacity "to rapidly develop, manufacture, or perform tests for a nationwide response and distributors with sophisticated supply operations."

R&D Investment

The plan also calls for greater investment in testing research and development, which the authors say will drive the next generation of screening and diagnostic tools across laboratory-based and point-of-care testing modalities, which "are needed now to prepare for the future."

> *"When your house is on fire, you're not going to negotiate the lease on the property before the fire department puts it out." – Gigi Gronvall*

The authors cite the development of at-home rapid testing for COVID-19 as an example of the potential for innovation and novel approaches to testing in a national health crisis. At the same time, however, they also highlight the current technical limits of those technologies.

Public-private sector collaborations, the authors argue, could create incentives for manufacturers and laboratories to invest in innovation and development in the pre-analytic phase of testing, including for sample collection, stabilization, and transport – all of which they say could lead to greater accuracy of tests and increased accessibility to those tests.

"There's a need to have a diagnosis," Gronvall said. "We can't just assume that you're sick and you'll get over it. We have the capacity to be able to make a diagnosis. And that's expected and will lead to better medical outcomes. So how we have to make sure that's available at scale, and as early as possible in a disease emergency so that you can use it for prevention as well as for diagnosis."

Ironing Out The Details

The authors liken the capability to deploy large-scale testing to firefighters rushing to the scene of a fire – "a quick, overwhelming, and strong response" to extinguish the blaze before it gets engulfs the building.

"When your house is on fire," Gronvall says, "you're not going to negotiate the lease on the property before the fire department puts it out." This applies to the costs of developing tests, which need to be worked out ahead of time so it's one less glitch that can slow the process during an emergency.

> *"We need to make sure that everything is set, so that it's just about the mission." – Gigi Gronvall*

Though the federal government entered into many contracts with test developers during the pandemic, there were often lags of several or more weeks between identifying the need to boost manufacturing or testing capacity and executing contracts to expand that capacity, the authors say.

"The demand from the COVID-19 Delta and Omicron surges exceeded the nation's existing testing capacity," they write, "requiring the government and private-sector partners to move urgently to meet testing needs."

The lack of a "one-stop shop" for the private sector to engage the federal government is another issue the authors claim hindered the development of tests and testing capacity, especially when there was a lack of clarity about what the government wanted and needed for testing. Further, they say the private sector also found test-reporting requirements challenging as federal, state, and municipal requirements were often inconsistent.

This is why the plan states that "the rapid establishment of medical billing codes, coverage, and national payment rates is essential."

At the outset of the COVID-19 pandemic, Congress took action to require coverage of tests by public and private insurers without cost-sharing, the authors write. However, "the process was slow, cannot be extended to other pathogens, and did not address payment rates."

As explained in the plan, Medicare initially relied upon typical processes that allowed Medicare Administrative Contractors (MACs) to establish their own payment rates. Ultimately, Medicare did enhance rates for high-throughput molecular laboratory testing in an effort to encourage the expansion of laboratory test capacity and improve the turnaround time for test results.

This approach, the authors argue, is worth replicating. Medicare, they say, should develop a

mechanism to set and communicate broad, national coverage and payment for testing of new pathogens while legislation should address the requirements for private insurers.

“We need to make sure that everything is set, so that it's just about the mission,” Gronvall says.

One And The Same

The COVID-19 and monkeypox emergencies have clearly demonstrated that diagnostics are essential to public health, the authors state in their report, and say the nation’s diagnostics infrastructure should be included as part of its critical infrastructure.

“To ensure the health of the nation’s diagnostics infrastructure, policymakers should take steps via legislation to provide for long-term sustainable and predictable reimbursement to clinical laboratories,” the report states. “Predictable and sustainable Medicare payments support patient access, innovation, and clinical laboratory infrastructure.”

The report also points to the shortage of laboratory scientists and technicians and the lack of programs to train new ones. The plan calls on policymakers to address this through proposals to expand existing training programs and loan forgiveness and repayment plans such as those available for doctors and nurses.

And while there’s no doubt there are many lessons to be learned from the COVID-19 pandemic, including the need for an effective diagnostic plan at a national scale, Gronvall and Van Meter both agree there were things that went right as well.

“There are any number of stories about the dedication of scientists and laboratorians that pulled out all the stops for their community and for the country. Same with public sector leaders who made heroic efforts to make sure that there was as robust of the response as possible,” Van Meter said. “And heroic efforts should be venerated. But we should have in place the kind of infrastructure so that when in the next pandemic we don't have to rely on heroics and individual efforts to be able to mount a robust response.”