COVID Information Commons (CIC) Research Lightning Talk

Transcript of a Presentation by Maria Jose Miguez (Florida International University), March 2022

Maria Jose Miguez CIC Database Profile

Title: *I-Corps: Lateral flow home-use diagnostic for detection of COVID-19*

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YouTube Recording with Slides

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Transcript

Maria Jose Miguez:

Slide1
Thank you for the opportunity to share the data of our COVID RAPID Test.

Slide 2
Why is it so important?

Slide 3
Well, although we all have the hope that COVID was going to finish quickly, currently, we have around 100 COVID cases every three seconds in the world, and someone dies from COVID every 12 seconds. In other words, we are still here. And we are going to continue to deal with COVID for a long time, so we need to be better prepared.

Slide 4
Why another COVID test? That was the question that always popped up. There are currently 400 tests approved by the FDA. As you see the majority are molecular tests. And mostly they are trying to simplify the process, they have 88 antibody tests and some of the 34 antigen tests.

Slide 5
What is the problem with those existing methods?

Slide 6
As you can briefly see here, the biggest problem right now, but at least has been growing with the Omicron [variant] is there is a high rate of false results. And this is with the PCR, which is the gold standard. And you can see the reference here in the Hopkins website [https://www.hopkinsmedicine.org/news/newsroom/nwes-releases/covid-19-story-tip-beware-of-false-negatives-in-diagnostic-testing-of-covid-19]. And with the rapid, the situation is worse. And with Omicron, as I told you, the situation has been getting worse and worse. And you can see on the right side that there has been calls for the FDA to recall thousands of rapid tests from the market.

Slide 7
Which will say those rapid, those false test results, that means [there are] 300 million false results in the world. So we are talking about a big problem.

Slide 8
Why? Why so many false results? Basically, because we have a big gap for diagnosis in this side of the curve. And we also have a big gap for diagnosis and for the screening in this area.

Slide 9
What is the market need? So we try to answer that question with I-Corps.

Slide 10
And we find out that we have different types of hospitals, we have small and medium hospitals that are in urban and rural areas. And then, we have the large hospital and the federally-funded for the hospitals. These hospitals on the right side, are likely to be open 24/7, and likely to have laboratories also open 24/7, have PCR, or have created their own tests to respond to the pandemic. On the other side, which is the majority, they are not running laboratories 24/7. In many cases, they refer the results to other sites. That means outbreaks, that means they need to pay more money. And every time that they have an outbreak, they have less money and, basically, they have less funds to respond to those problems.

Slide 11
What of it? If you look at the majority or a large proportion of cases that are already hospitalized, they have been diagnosed clinically - 30 to 50%. It depends on where you look at it, the numbers can go even higher in developing countries - they are diagnosed clinically because of those false results.

Slide 12
So I told you that means morbidity, mortality, losses. Which to us is a big concern. And many of the small and medium hospitals are breaking down because of that.

Slide 13
We also collect preliminary results in the laboratory and in the clinical field.

Slide 14
This is one of them. This is our high risk group, an HIV infected population. They were the smokers, so they had a dual reason to be at a high risk for COVID. And we were located in, we are located in Florida. Florida is one of the epicenters- one the biggest spots here in the United States. And if you see - we're following 400 individuals. And of those 400 individuals, we have a good distribution across socio-demographics. They were tested on average two or three times per year. During that year, they reported before that they were in close contact with other infected individuals. Ten of them, they say

that they have clear symptoms, but the test was negative. And only three individuals were told that they were infected, and they were fine.

Slide 15
So, if you see this graphic, this was Florida, at the time that we take that study, so it was 20%, 20% of the population was positive at that time. Obviously, we are talking about a high risk population, we were expecting that we will have at least 20%, or even higher. So we really have, as I told you before, the 1% with the PCR, and 4% of them were with symptoms. So we decided to go back and do antibodies - IgG antibodies - to be sure if those individuals were infected in the past year. And we find out that 50% of them, in addition to these 4% [Symptoms] and 1% [PCR] were really infected. In the - during that year - with COVID, that really was better than the 20% that was going on in Florida. With our tests, we were able to detect 60% of them.

Slide 16
So obviously, the big question was: how we were able to detect so many cases that the PCR antibodies were not detecting when they were doing it [repeatedly]? And we went back with the animal models, we used the animal model to try to track our target and do both a low doses and a high doses to be sure that we can represent those with asymptomatic and clinically symptomatic cases.

Slide 17
And we were able to demonstrate that our target for diagnosis has started being heavily produced at this level, at this day - approximately the third day post-infection. But equally important, when we check for our target, we weren't able to demonstrate it through the entire time of the infection and disease. This means we are not going to have these gaps, or these gaps.

Slide 18
So what we are trying to create right now is the 5th Generation Combo antigen / antibody test that will further increase our accuracy. A difference - so the other test needs to be done in the lab or needs to be done with swaps. This is a drop of blood. It will allow for early detection and will also give us the benefit of noticing gaps. But we're using multiple entities and that will allow us to recognize vaccine versus current infection.

Slide 19
This is the group I need to give credit to - the rest of the team that is helping me in these efforts.

Slide 20
And thank you for this presentation. I'd be happy to answer any questions.

Kenia Pujols:
Thank you, Maria.