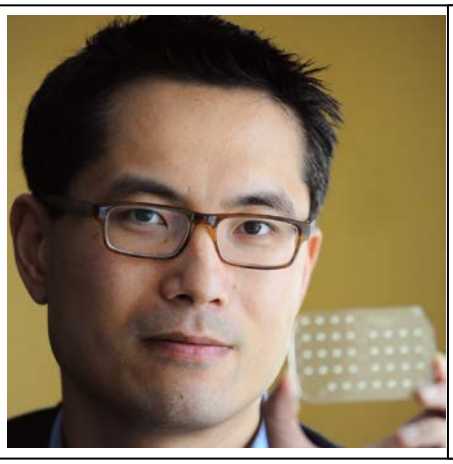
Clinical Chemistry

Mobile device for disease diagnosis and data tracking in resource-limited settings



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Guest:
Dr. Samuel Sia is an Associate Professor of Biomedical Engineering at Columbia University.

Bob Barrett: This is the podcast from *Clinical Chemistry*. I'm Bob Barrett.

In resource-limited settings, both access to laboratory diagnostics and to patients' health records can be challenging. In the April 2013 issue of *Clinical Chemistry*, Dr. Samuel Sia and his colleagues described a low-cost mobile device that combines cellphone and satellite communication technologies along with fluid miniaturization techniques for performing all of the functions of an enzyme-linked immunoassay.

They tested their new device's ability to perform HIV screening in Rwanda, and synchronized results in realtime with electronic health records. Dr. Sia is an Associate Professor of Biomedical Engineering at Columbia University. He is our guest in this podcast. Dr. Sia, you and your group described a point of care handheld analyzer that you call an mChip device. Please tell us a little about its design and its application.

Dr. Samuel Sia: Sure Bob, and thanks for having me here. Our vision was to take reference laboratory tests that tell you what you have in your blood, and provide that capability in the hands of clinicians and patients and even consumers everywhere, and we want to do it in a way that is fully automated, so that really anyone can run this device without previous training and will get performance that is comparable to a reference lab.

What we decided to do was to really take inspiration from mobile devices that a lot of us know about these days, but really try to build in the ability that reference lab diagnostics would have, so it really provides sort of a healthcare diagnostic ability. And in the way it would work is you would prick a finger just like you would do to get your glucose tested, say for a diabetic patient. This can be done anywhere. That little drop of blood would then go into a

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little tiny plastic chip, and then that chip goes into this mobile device and you press a button and you'll get the result in 15 minutes, a procedure that normally takes hours to do in one of these labs.

Not only that, the synchronization with the Cloud in terms of your results with your patient records is also automated. So, it doesn't matter where you are in the world, and in fact, we did this study in Sub-Saharan Africa. Those results will automatically be synchronized with the patient records as well.

Bob Barrett: This use of mobile device or smartphone technology appears to be a first in medical diagnostics. Can you tell us how you came to capitalize on smartphones?

Dr. Samuel Sia: Well, a lot of us really see the power and we are familiar with the power, as everyday consumers of being able to do things on the go and do it in a connected way, so that we have a two-way communication with the records that are stored on a server somewhere. We can do a lot of things now in our hands with smartphones, but one of the few things that we can't do is things that are related to health. Really, when I say that, I mean core health care services, such as diagnostics.

There are other mHealth capabilities that one is beginning to be able to do, but really not some of these core diagnostic tests, and I think a lot of people would like to monitor their diseases and their conditions and their wellness, and have that power in their own hands. We realized that to be able to not only do these tests in a mobile way, but do it in a way that makes the patient or the clinician actually connected to the record stored somewhere else, is very powerful.

That's something that we capitalized on by using these existing cellphone networks. We used the GSM out in Africa and even when the network was down, we could connect to orbiting satellites and so it doesn't really matter where you are in the world, you can stay connected.

The other way around is not just the person in the field being able to do this and stay connected. You also have the person sitting in a government office, or in a centralized location, maybe he's your doctor back home, who can actually monitor what's going on in the field, and you can actually see what the diagnostics results are in realtime and allocate your resources and conduct epidemiological studies that way, and monitor what disease outbreaks and so forth.

I think a lot of us really understand the power of being connected via smartphones, and we're trying to provide some of the core health care services along with that.

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Bob Barrett: You did your field test on this device in Rwanda. How did you come to choose that country?

Dr. Samuel Sia: We worked with a clinical collaborator. We worked with a great set of collaborators on these projects, industry collaborators, optical diagnostics, as well as a clinical collaborator, ICAP at Columbia. ICAP already has a lot of work done in Rwanda on AIDS patients, and we decided to capitalize on that. When we ended up working in Rwanda, we ended up really having to have the expertise of a lot of the Rwandan collaborators, so this study would not have been possible without them either. We worked in a Rwandan Hospital as well as two health clinics there.

I think we had -- our clinical collaborator already had studies going on in Rwanda, that's one reason, but I think another reason is also that there's a huge need in Sub-Saharan Africa for these kinds of devices because you really need to have diagnosis take place in places that are outside of hospitals, when you are in developing countries. A lot of those patients don't have access to go back to hospitals.

Another reason I think that we found out that became very interesting is there's really a huge opportunity for innovation in working in these countries. They're not encumbered by existing infrastructure and existing record-keeping systems and so forth. They are willing to innovate and go straight to the solution that is really best adapted for them and leapfrog to the solution, so cellphones is a great example of that. They didn't have to go through the landline phones and here, I think there's a similar opportunity to innovate, and so there's already a huge adoption of electronic health records in the developing world and we were hoping to capitalize on that.

Even if ultimately we want to have such a device back here at home as well, I think not only doing this in Rwanda, where we have existing collaborators with a huge clinical need, we actually found that we had a great way to explore what the possibilities were with electronic records, and these are things that we can learn to bring back home as well in the future.

Bob Barrett: You've compared your testing device to laboratory-based FDA-approved methods. Just how well do they compare?

Dr. Samuel Sia: In this study, published in *Clinical Chemistry*, we tested for just HIV. In previous work we published, we also tested a dual test HIV/syphilis. Really, we want to go into panel test for multiple diseases, which is really going to cost pretty much the same per card, but in this particular case, it was just HIV, and so we ended up getting performance that was

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really high, 99% to 100% in sensitivity and specificity. Current FDA-approved HIV Rapid Tests, such as the OraSure test, are also very accurate in their control trials.

There are some published results which suggested that some of these rapid tests perform less accurately in the field. You have to really interpret the band and that's especially a problem for so-called weak positive results. Positive results that are not clearly strongly positive, but they are positive, the patient is positive for HIV say, but they just don't have a lot of antibodies developed yet, maybe in the early stages of infection and so forth.

In a lot of these cases, the band is weak and you could mistakenly let that patient go with some of these rapid tests as they are conducted in real settings and interpreted, and run by real users in the field. I think one advantage that we have, not only in that we can match the analytical performance in a reference lab, is that we can objectively pick up some of these weakly positive results, and that was shown in this paper. I think, overall, the automation that we have in our device will just minimize the user variability and user error. There is no subjective reading of the band, everything is objectively measured and determined for you and displayed on the mobile device, and those results actually go straight to the Cloud if you wish.

There's not much of variability in the performance, once you have such an automated device. I think from straight analytical performance, we did at least as well as the rapid tests, and we did really much closer to the reference lab testing, but by even having this automation in the field under real settings, I think we may have some advantages in reducing user error and variability as well.

Bob Barrett: You mentioned that you can see this technology being used in conditions other than HIV. What other diseases or types of diseases do you see best suited for this technology?

Dr. Samuel Sia: Well, our device right now in the developing world, we really are interested in making it available to pregnant women. That is one sector of the population we're particularly interested in, for prenatal and antenatal care, and so HIV and other STDs, for example, syphilis, and other STDs as well.

In the case of syphilis, the pregnant woman could actually have stillbirths, if they're not diagnosed and treated properly. The burden of syphilis, for example, is actually just the size of malaria for a pregnant woman, so these are very serious conditions that we think we can offer in a panel test, with just one finger prick of blood, very low-cost, about

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-- right now it seems like I think two dollars per panel test that we'll be able to offer this for.

HIV, sexually transmitted diseases, and other infectious diseases for the developing world is the panel that we're looking at. Now, for the U.S., the conditions would be different that we would want to address, and that may be conditions such as chronic diseases or wellness for the average consumer, so I think there's a lot of potential for this, depending on which market we're talking about.

Bob Barrett: Can the cost restrict the use of this in some of the developing countries?

Dr. Samuel Sia: Yeah. In the developing countries, cost is a big constraint. We think based on the price points of the current rapid tests, for example the HIV Rapid Test, are used very widely in the developing world today, and they cost about a dollar. We think by having some advantages with just the HIV test plus some of these other tests we're offering, the two-dollar price point should be a reasonable price point, based on what is already going on out there with the current HIV Rapid Test. I do think that the price point is something that is important, but that has to be always assessed with respect to the benefit that you are getting. Sometimes, it's easy to just kind of throw out assumptions out there and say, "Well, things have to be absolutely dirt cheap, if you're going to be in Africa."

I think there are just a lot of cases I've shown that such an analysis would not be complete, if you are not accounting for the benefit as well. Cellphones are very popular and they're not dirt cheap, they also have to be charged, but people are willing to pay for that if they think they're getting value out of it, same thing with diagnostics and it depends on what applications you are going after because some types of diagnostics just provide much higher value as well. I think with our panel that we're looking at, around two dollars I think is the price point that the market will ultimately bear out, whether it's donors that are going to be purchasing the test or the government or the clinics.

Bob Barrett: You mentioned you could see this coming to the U.S and other countries that have more resources. Do you see a big future for these devices in the developed world?

Dr. Samuel Sia: Absolutely. I mean I just cannot be more excited about that potential. It's going to happen. Health is really one of the last bastions that has yet to be conquered in a mobile phone method. It's really just a matter of time that everyone can do everything else on their smartphones as well as do a lot of core health care services, but unfortunately, there's quite a bit of inertia to overcome, in order for that vision to

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happen, and so it will probably take a few more years for the regulatory environment to catch up, for the business models to catch up, for the consumers to understand what they can do with that information.

It's really a matter of when and not if, that a lot of these core health care services will be provided at mobile settings and up to the choosing of consumers, rather than being dictated by what the insurers would have to approve, but the price points have to be I think lower in order for mass adoption by consumers. Not to mention that the technology has to be automated and very, very friendly and simple to use because the bar has been set already, consumers are accustomed to all the other things that they can do on smartphones, but the sky is the limit here. But there are some unique challenges to getting some of these health technologies on the smartphones, challenges that are not in place for most of the existing smartphone capabilities.

Bob Barrett: Well, finally doctor, let's look ahead. What's next for you and your team?

Dr. Samuel Sia: We really want to finish what we started 10 years ago, working on this technology for the developing world. We want to take this to the finish line and really get it to a point where the device is saving patients' lives, and I think even saving one life, for me, it would really be the first real success for this technology.

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That moment hopefully will come and that's what really drives a lot of us to do this work in our collaborative team here. And myself, I think this market in the U.S. is also very interesting, where we can actually get consumers engaged and in charge of their own health care decisions, and diagnostics is really the gateway to a lot of health care services. There's a lot of potential there for us to contribute to and hopefully, we'll be able to do that.

Bob Barrett: Dr. Samuel Sia is an Associate Professor of Biomedical Engineering at Columbia University. He has been our guest in this podcast from *Clinical Chemistry*. I'm Bob Barrett, thanks for listening.

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