

Developing the Chlamydia Rapid Test

Helen Lee, Associate Professor and Reader in Medical Biotechnology at the University of Cambridge, **Penny Barber**, Chief Executive of Brook in Birmingham, and **Alison Swain**, Senior Doctor at Brook in Birmingham, talk about how a new test can transform the diagnosis of chlamydia.

HL: Chlamydia is the most common sexually transmitted bacteria infection, affecting about 10 per cent of sexually active young adults. The problem with chlamydia is that it's a silent disease so up to 70 per cent of the infected women and up to 50 per cent of infected men do not know that they're infected. So it is truly a silent disease, with devastating consequences for the babies born from infected mothers and also for women who have ectopic pregnancy and infertility.

Because chlamydia is asymptomatic, the people who are infected, particularly young people, will never go to the doctors to get diagnosed, so the only effective way to control chlamydia is actually systematic screening. So we developed this rapid test that is easy, simple to use, doesn't require skilled people and it's extremely stable and robust, so that this can be a very effective screening tool and using very easy-to-collect samples. So for instance in the women it's self-collected vaginal swabs, in men it's urine – because what is the point of having an easy test back-end if the front-end sample taking is so complicated.

There are some chlamydia rapid tests but the performance is very poor and the sensitivity is lacking. Or you can have very complicated nucleic-acid-based tests, which is highly automated and technically extremely complex and it requires centralised laboratory and highly skilled technicians. So in the end you have either a simple rapid test that is not effective or an effective test that is so complicated and expensive. So what we have really done is to develop the underlying technology, which is called the signal amplification technology, that increases the sensitivity of rapid tests. And so we improved the performance of the rapid test but retained all of the advantages that the rapid tests can provide, so the rapid test then, gives you a tool to test and treat while the patients are still onsite.

When we developed the rapid test, obviously it is for use not only in the clinics or in doctors' offices but also for young people at sexual health clinics, because this is the most vulnerable group, and so I contacted Penny Barber at the Birmingham Brook's young people's health clinic and we carried out our clinical trial at this site.

PB: The trial was brilliant, it was really interesting for us being part of such a big research exercise and such a thorough research exercise. I think we learnt a lot from working with the researchers on this. And the young people really liked being part of it.

AS: Clients were paid a small amount for agreeing to take part and basically what happened is they gave two or in fact I think they gave three samples in the end and one of them was tested with the new test, the new onsite rapid test, and then all the samples were also tested by a NATS test, which is considered to be the gold standard. We opted, although it was a test under development, we opted to treat them on the basis of the results and I think generally people liked that. So if any positive results were found people were just directed straight up to the clinic and

183 Euston Road London NW1 2BE UK
T +44 (0)20 7611 2222 F +44 (0)20 7611 8258 E info@wellcomecollection.org
www.wellcomecollection.org

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we would treat them there and then and they found that very beneficial. And also, looking at the results, there was a very high, I mean not a hundred per cent, but you never get a hundred per cent, but a very high concordance between the NATS testing and the new rapid test. So it's proven to be a very good test.

PB: We would love to start using the rapid test on the clinic. It's brilliant in a number of ways. For a start there's an awful lot of logistics and faffing around and time delays in having your samples, collecting them up, sending them to the lab, having the results come back, somebody's got to contact people with the results. There's a whole series of steps in the moving of samples about and making sure results go to people. What is absolutely brilliant with the rapid test is you can do the test there and then.

We actually have quite a good treatment rate, clients are quite good at coming back to us but we're in a city, it's easy for people to get to us, we have quite a good treatment rate, but what is marvellous is that the young person who's worried they might have a sexually transmitted infection knows straight away, so they're relieved or able to start taking action if they are infected straight away. They're not waiting a couple of weeks, worried about what is or isn't happening.

The other thing that happens if you know straight away that they're infected and you can treat straight away then you're a couple of weeks down the line of treating their partner and treating any other contacts that may exist – so the whole process moves along very quickly. So if you look at this from a public health point of view, just moving the treatment back by a couple of weeks and the contact tracing starting a couple of weeks early, must have quite an impact on the numbers of people in the population who are likely to have it.

HL: It took us something like five years to develop the base technology in order to improve the sensitivity of the rapid test. Then it took us another three years to do the skill validation and clinical trial, and now we're just beginning to commercialise the product. So it really has been a dedication I would say not just of myself, but people in the team, the scientists who were here, of really an effort of almost a decade. And we were very lucky to have been given a seed funding from the World Health Organization, but then we also obtained the tremendous amount of support both from the Wellcome Trust and the NIH. For example in the case of the Wellcome Trust, the funding was available to us from the very beginning, from research through development, through skill validation, clinical trial and now commercialisation. So really the support from the Wellcome Trust has been there every step of the way, including the formation of our company.

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