Better diagnostics for thrombosis are a matter of resources

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Cost-effectiveness is paramount for any new medical technology. If pharmaceutical companies do not see a profit, new drugs will never see the light of day. And if insurance companies think a new treatment is more expensive than the old one, they will simply not pay. Take thrombosis, or blood clotting, which affects millions of people worldwide. Blood thinners, like coumarins, are amongst the most widely used drugs to prevent blood clotting. But getting dosage right is a very

challenging problem and errors have led to hospitalisations. The need for accurate dosage testing is thus clear. But they will have to be cost-effective to enter clinical practice.

The EU funded project, EU-PACT, completed in 2013 aimed to do just that. "We've looked at the possibility of using companion diagnostics alongside the treatment of thrombosis," says project coordinator Anke-Hilse Maitland-van der Zee, associate professor of personalised medicine at the University of Utrecht, in the Netherlands. "Thrombosis is treated with coumarins, blood thinners, and getting the exact dosage right is difficult. Too much can have severe effects, like internal bleeding. Too little means blood clots can form, that's just as bad, or worse. But companion diagnostics—[that is] genotyping the patient in order to see what drug, and in what quantity, might be most beneficial—could help in this case," she tells youris.com.

The project developed a DNA test that looked for two genetic variants. Those variants can predict the correct dosage of coumarin before therapy begins. Within the test cohort of 500 patients the right dosage was found in three weeks instead of four, and over a period of three months they remained at the correct dosage 67% of the time. With previous approaches, it was 60%. Not a huge difference, but an improvement nonetheless.

But uncertainty still remains about cost-effectiveness. " Coumarins are very cheap, the patent ran out decades ago," Maitland tells youris.com. "So the DNA test should also be very cheap in order to make a real difference. Even 80 euros per test could be too much. What's more, coumarins are rather old fashioned. These days there are new anti-coagulants - noacs- which are much quicker, and at least as effective as coumarins. So I'm afraid pharmaceutical companies will not be interested in bringing our test to the market… We still need to do a proper cost-effectiveness analysis. Only then can we give a valid advice;

should the test be standard clinical practice or not."

But an independent expert is more optimistic. "Companion diagnostics have proven to be a real money saver in the development and therapeutic use of new anticancer drugs like Iressa and Herceptin. It stands to reason the same will be true of this new test to go with coumarin therapy," says Jan Tröst Jörgensen, director of the Dx-Rx Institute in Copenhagen, Denmark. "Herceptin for example only works against a very aggressive type of breast cancer that only women with a relatively rare genetic marker suffer from. Giving these women another drug is a waste of money. Giving patients too much coumarin or too little is just as wasteful," he tells youris.com.

Another expert is equally optimistic and believes in the DNA-test's commercial viability. "Noacs may be quicker. But after about a month into the therapy there is no difference with coumarins," says Colin Palmer, professor of pharmacogenomics and chair at the Ninewells Medical Research Institute, University of Dundee, Scotland. "And noacs are very expensive, so avoiding them and staying with the old and trustworthy coumarins might be financially worthwhile. That's where I believe the DNA-test developed by the project may come in handy."

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