# Cash injection for thermostable vaccines

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Research towards the first temperature-stable pentavalent vaccine has been given a boost from the UK's Department for International Development (DID), which has awarded just under US$1 million to a UK–Indian biotech consortium.

The technology they are using should render the multivalent vaccine completely stable from around –50°C to +50°C, claims Bruce Roser, Chief Scientific Advisor at UK-based Cambridge Biostability (CB; http://www.biostability.com). This means that there will be no need for refrigeration, giving the combination vaccine an effectively indefinite shelf-life, he says.

The partnership between CB and New Delhi-based Panacea Biotech (http://www.panacea-biotec.com) will coat tiny droplets of each vaccine in sugar glass, preserving them like a mosquito trapped in amber (Figure 1). These microscopic beads are then suspended in an inert fluid so they can be injected. Once the sugar-glass comes into contact with water in the body, it dissolves and the vaccines are released. Roser has high hopes for this method of vaccine delivery. 'It's within reach now to develop a single-shot vaccination that will protect children in Africa against essentially all of the fatal infectious diseases,' he says.

The World Health Organization (http://www.who.int) estimates that more than US$200 million is spent each year on keeping vaccines refrigerated from the point of manufacture to the point of delivery – the so-called 'cold chain'. Furthermore, over half the vaccines that are manufactured end up being thrown away because they are accidentally frozen or stored at too high a temperature, says Roser. 'If we can stabilize all vaccines in our form so that you can keep them in the glovebox of a landrover in the Sahara Desert rather than in a refrigerator, then you eliminate the cold chain and you will save immediately that amount,' he says.

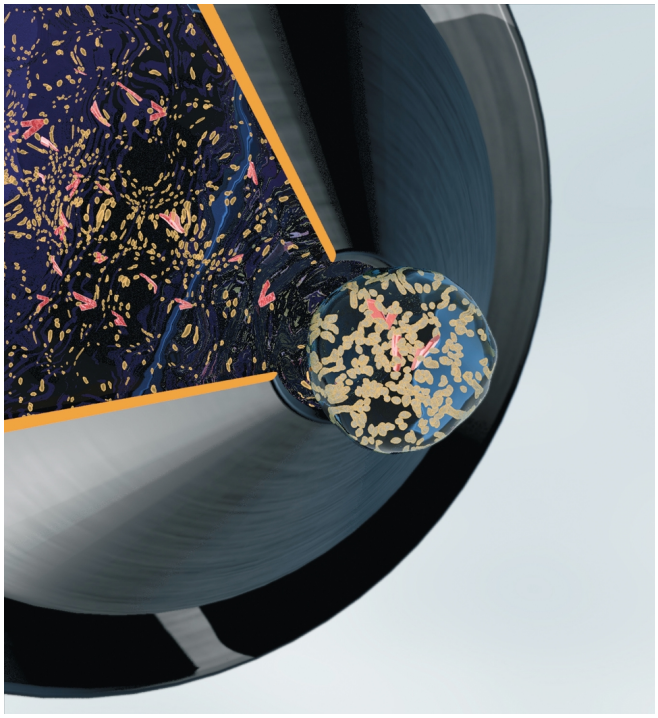

**Figure 1.** Spray-drying vaccine with sugar syrup.

Maintaining the cold chain is a significant cost, admits Martin Friede of the WHO's Initiative for Vaccine Research. But that cost cannot be eliminated until all vaccines are manufactured this way and for many established vaccines, this might not be cost-effective, he says. 'You might liberate some space in the cold chain,' says Friede. 'But just introducing one thermostable vaccine will probably have a rather negligible impact on the cost of the cold chain.' It would, however, simplify vaccine distribution, he says. 'It would probably impact on improving the availability of vaccines in really distant locations.'

It is still unclear how far CB will have to take their sugar-glass vaccines in clinical trials. Toxicology studies will be needed to demonstrate the safety of the fluorocarbon liquids in which the vaccine microspheres are suspended. However, because it is the mode of delivery that is new and not the vaccination itself, full-blown clinical trials might not be needed, says Roser.

Friede disagrees. 'This is not a minor change to the vaccine.' Preserving vaccines in stable microspheres can alter the immune response they produce, he says. 'For many vaccines, this would require quite extensive clinical trials.' So it might not be cost-effective developing this technology for long-standing vaccines that are relatively inexpensive and have an established safety profile, he suggests. In spite of this caution, such research is interesting and should be pursued, says Friede.

The DID grant should help CB do just that. The US$950,000 cash injection could mean that their thermostable pentavalent vaccine against diptheria, tetanus, pertussis, Hib and Hepatitis B will enter clinical trials by the end of 2006, says Roser.

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