AIDS vaccine group expands operations in New York

With no AIDS vaccine in sight, the International AIDS Vaccine Initiative (IAVI) is ramping up operations in a 36,000-square-foot facility in New York City.

Launched in 1996, the nonprofit, publicprivate partnership set up its AIDS Vaccine Development Laboratory in Brooklyn in 2005. The group expects to sign the lease for the new location in June and plans to move there in early 2008 from its temporary residence.

The new space will house all applied research leading up to a vaccine, from designing vectors to testing promising candidates in animal models. Staffed by researchers from the vaccine industry, the lab will also serve as a base for three of IAVI's existing research groups: the Neutralizing Antibody Consortium, which aims to design vaccines that induce broadly neutralizing antibodies against HIV strains; the Live Attenuated Consortium, which tries to understand why vaccines based on weakened viruses work in nonhuman primates; and the Vector Design Consortium, which develops candidates from genetically engineered organisms.

The lab will champion candidates that academia can't afford to develop, and that industry won't invest in because of a higher risk of failure, says Wayne Koff, IAVI's senior vice president of research and development. "We play a gap-filling role," Koff says.

Virologist Douglas Richman of the University of California San Diego applauds the move to develop neglected candidates. "[IAVI's] early projects fulfilled the intent of filling the gap, but they were not as scientifically focused or effective as they could have been," he says.

There are more than 30 AIDS vaccine candidates in the pipeline, 6 of them developed by IAVI, and at least 25 of them based on viruses and bacteria engineered to carry fragments of HIV. The new lab's goal is in part to identify the most promising of those and usher them into development.

With \$23.7 million in funding over five years from the Bill & Melinda Gates Foundation, some IAVI researchers have in the past few months begun comparing different vectors to determine which ones elicit the strongest and most durable immune response in the blood and mucosa.

"We can't take all candidates into clinical trials," says Koff. "This is an industry-like activity that is critical for vaccine design and development."

Once the lab settles into its permanent location, IAVI will have 30 scientists to carry out the research, design and product development, but will continue to partner with academics and companies.

"The lab is a good thing," says Dennis Burton, an immunologist at The Scripps Research Institute and scientific director of IAVI's Neutralizing Antibody Consortium. "The ability to have some of the immunogens that we've designed made there and to have them tested there, that can only accelerate progress towards vaccine candidates."

Alisa Opar, New York

Fertility clinics cashing in on risky immune tests, expert warns

A leading British immunologist has sounded a warning over the unnecessary-and potentially dangerous-immunological tests and drugs on offer at many fertility clinics.

Women are placing themselves at risk by taking drugs that suppress the immune system, despite little evidence that the drugs help them become pregnant, says Ashley Moffett of the University of Cambridge.

Many private clinics offer blood tests that claim to detect elevated levels of immune cells called uterine natural killer (NK) cells, which some doctors believe are involved in the immune rejection of embryos during implantation. If the test returns a positive result, patients are then offered treatment to suppress these cells, usually with steroids or intravenous immunoglobulinat a cost running to hundreds of dollars. One British clinic offering the treatment charges £173 (\$345) just for the blood test.

"This has somehow slipped through the net of any regulation," Moffett told Nature Medicine. "It is bizarre that women who may be in early pregnancy are exposed to this sort of risk."

Potential side effects of immunoglobulin treatment include kidney failure, anaphylaxis and, because the drugs are created from pooled blood products, the risk of hepatitis. "Immunoglobulin is not approved for thiswomen are signing disclaimers," Moffett says.

Although fertility patients are often desperate

to try anything that could potentially help them conceive, there is only scant evidence linking elevated blood levels of NK cells to an increased rate of miscarriage, and some evidence indicating that the cells might in fact be helpful (Nat. Med. 12, 1065-1074; 2006).

Blood levels of NK cells do not necessarily reflect levels of uterine NK cells, and a 2006 Cochrane Review concluded that immunoglobulin treatment "provides no significant beneficial effect over placebo in improving the live birth rate."

The idea that immunosuppressive therapy can avert spontaneous abortion has found favor with the media and on patient groups online



since a 1995 study reported that the treatment is effective in raising pregnancy rates (J. Reprod. Immunol. 28, 175-188; 1995). The lead author of that study, Alan Beer, went on to found a Los Gatos fertility clinic that offers the treatment.

That center's medical director, Edward Winger, declined to comment on the treatment's effectiveness in a clinical setting. Winger admits that the issue has been a source of confusion among immunologists, but says that "the number of NK cells in blood appears to increase in women with a history of recurrent pregnancy loss."

The treatment is now offered by a growing number of larger, more established fertility clinics, and is largely unregulated. The Human Fertilisation and Embryology Authority (HFEA), which oversees fertility treatments in Britain, only regulates the direct creation and handling of embryos, and not the accompanying drug regimes.

"The get-out clause is that [doctors] discuss it with their patient," says Raj Rai, a fertility consultant at Imperial College London. "But that is disingenuous, because how is a patient supposed to decide? I don't think it is reasonable to hide behind patient demand." What's more, Rai points out that immunoglobulins, used to treat a range of immune diseases, are nationally in short supply.

Michael Hopkin, London

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