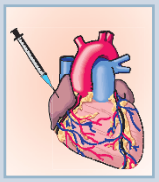
p440 Asian ambition: Is India's aim to become a clinical trial hub realistic?

p444 Braveheart: Rain or shine, Christine Seidman puts her patients first.



p445 Disheartening debate: Can hematopoietic stem cells heal the heart?

Antidepressant reputation falls to new lows

Antidepressants are seeing their popularity quickly wane as the US and UK take steps to warn consumers about their side effects.

On 22 March, the US Food and Drug Administration (FDA) issued a public health advisory on 10 antidepressant drugs, warning doctors and patients' families to watch closely for signs that patients are feeling suicidal. The agency also said it would ask manufacturers to label the drugs with stronger warnings. An FDA scientific advisory board made those recommendations at a public meeting in February. The Canadian government has also issued warnings for antidepressants, and is considering changing the drugs' labels.

The UK's Medicines and Healthcare products Regulatory Agency has told doctors there that the drugs paroxetine, venlafaxine, sertraline, citalopram, escitalopram and fluvoxamine—most of which are selective serotonin reuptake inhibitors (SSRIs)—do not work better than placebos and should not be prescribed to depressed children. In clinical trials, four of the drugs increased the risk of suicide attempts or suicidal thoughts.

SSRIs have been popular because, until recently, they have generally been considered safe. In 2002, US doctors alone wrote 157 million prescriptions for the 10 drugs named in the FDA advisory. But some doctors now say they have been given incomplete information about the drugs.

The heated debate over the drugs' safety—particularly when patients begin treatment or change their medication dose—began last year. Patient advocates have been increasingly vocal in expressing outrage that the FDA had not disclosed data on SSRIs and suicide in children, which it has been collecting over the past few years. Critics also charge that the FDA's new warning labels—which say the drugs have not been proven to cause increased risk of suicide—are confusing.

"If the drugs aren't doing it, why are they asking that a warning be put on drug labels? It's absurd," says Vera Hassner Sharav, president of the Alliance for Human Research Protection, a New York–based advocacy group. "What they need to do is issue clear warnings about the drugs' actions," Sharav says.

The FDA says data from clinical trials on the link between SSRIs and suicide are not that clear cut. For instance, the trials use different criteria for defining what sorts of events constitute suicide attempts and suicidal thoughts.

Hector Casanova/Kansas City Star

Problems also plague the published clinical studies of SSRIs, says Jane Garland, clinical head of the Mood and Anxiety Disorders Clinic at British Columbia's Children's Hospital in Vancouver. A recent review found that published studies of newer antidepressants downplay the risks of suicide and exaggerate the drugs' benefits (*BMJ* **328**, 879–883; 2004). What's more, multiple papers are written using data from a single study, giving the impression that more evidence has been collected on the drugs than is actually available, Garland notes. Negative clinical trial results are not published, and the physicians who conduct the trials are usually banned from discussing them by nondisclosure contracts. "We're trying to do evidence-based medicine on less than half the data, and that's a real problem," Garland says.

Because antidepressants do seem to help many children and adults, Garland and others say they don't want the drugs banned. But they have joined the growing movement of patients in urging caution about the drugs.

The European Union recently launched a €7.3 million, five-year effort to develop new antidepressants and some clarity may be *en route* on existing drugs: the FDA has asked Columbia University researchers to reexamine the data from 25 clinical trials of the 10 antidepressants used most often in the US. That study is expected to be complete by September.

Erika Check, Washington, DC

China launches new molecular medicine institute

China is set to launch a new Institute of Molecular Medicine (IMM) in partnership with an existing institute of the same name at the University of California in San Diego. The new institute, to be formally opened in November, will focus initially on translational research in cardiovascular science and metabolic diseases.

"China was building a lot of institutes in basic sciences, but no one was really taking it to human disease," says Kenneth Chien, director of the IMM's sister institute in San Diego.

The Chinese IMM will be housed in a new building at Beijing University and led by Rui-Ping Xiao, now a senior investigator in cardiovascular science at the US National Institute of Aging.

Cardiovascular disease is the biggest killer in China. In 2000, 3.3% of the population had coronary heart disease, but that number is expected to balloon to 12.4% by 2030. "The problem is enormous," says Xiao. "But the research is far behind international levels."

The IMM will be first national institute in China to focus on cardiovascular diseases and will combine genomics, engineering, computational biology, molecular biology and disease-oriented research. Xiao says the institute has initial funding of about $12 million, but is actively seeking new partnerships.

The institute will host about eight investigators, but Xiao expects to double that number in the next few years. It will also help train physician-scientists familiar with Western standards of science, Xiao says. Selected students would complete their medical training at the IMM in China and spend up to three years at a research institute in San Diego.

Apoorva Mandavilli, San Diego